ADOPTION OF '*RAPID ETHICAL ASSESSMENT*' AS A PRACTICAL METHOD FOR ASSESSING ETHICAL ISSUES RELATING TO BIOMEDICAL RESEARCH PROJECTS IN ETHIOPIA

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Abstract

Background: The universal principles of biomedical ethics provide overall guidance which are applicable to all settings. However, the range of ethical issues present in different communities differs subject to variations in ethno-cultural contexts. Rapid Ethical Assessment (REA) is an approach developed to improve context-tailored application of the informed consent process in low-income settings. The tool employs ethnographic and action research techniques to explore and address context specific ethical issues. However, information is lacking on its feasibility and applicability for wide-scale use. This study aimed to explore the need for REA and establish its usefulness for research in Ethiopia and similar settings. The study also aimed to assess feasibility of REA so as to provide further guidance on strategies for its future application.

Methods: Pilot REA studies were conducted in three different research projects, 'parent studies', in Ethiopia between 2012 and 2013. The studies employed a range of study designs with multi-disciplinary approach and were conducted in multi-ethnic and multi-cultural settings in Ethiopia. The study disciplines employed ranged from ethics, social science and anthropology to public health. The study designs employed ranged from qualitative, ethnographic and mixed methods to quantitative interventional studies.

Results: Qualitative and quantitative studies of research stakeholders indicated presence of gaps in the research consent process in Ethiopia. The need for the REA approach in understanding and addressing these gaps was highlighted. Based on the pilot studies, REA was found to be useful to identify important context-specific ethical issues and contextualizing consent processes for community-based medical research. The ethical issues ranged from general issues such as the cultural setting of the study, perception about research, health and health care practices to perceptions about the research subject matters, and communication dynamics and norms and their hierarchies. REA was associated with improved levels of information comprehension and quality of the informed consent process. REA also appeared to be a feasible intervention in terms of cost, time and skill. REA skills were easily transferrable to local experts and the approach was flexible and adaptable to circumstances, settings and needs.

Conclusion: Given clear strategic guidelines, REA is a highly useful approach to identify important ethical issues in research conducted in the Ethiopian context. It is feasible that the approach could be applied at wider scale in such settings. The approach is recommended for further dissemination coupled with continued documentation and validation.

Dedication

I dedicate this work to loved ones I lost during the course of my PhD.

To my young and only sister Helen Addissie, who was a crew member at the Ethiopian Airliner (ET409) which crushed in Beirut on January 25, 2010. On the very same hours of the crush I was working on the final versions of the PhD proposal. You have gone quite early but you will always live in our hearts.

To my uncle Timotewos Nuramo who left us around the beginning of my PhD journey and to my grandmother *'Achie'*, who departed towards the end.

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Introduction

The research in this volume is triggered by the awareness of gaps in the application of universal ethical principles into the informed consent processes for medical research conducted in developing countries. With advances in technology and medical knowledge, biomedical research has grown in scale and dimension. This is often accompanied with increase in ethical dilemmas and challenges both to the public and the scientific community. While these challenges hold true for both high and low resource settings, available guidance on the ethics of medical research have primarily evolved from high resource settings, based on ethical principles that primarily stem from western values and social traditions.

Universal principles of bioethics provide list of key ethical considerations for the medical practices including biomedical research which are meant to provide guidance for all settings. However, the nature of ethical issues do vary subject to ethno-cultural contexts and the universal principles do not provide guidance on how to address such context specific differences. The universal principles' lack of addressing contextual differences raises a question on the universality of their application. While universal ethical principles are important for setting common standards, they do not answer the questions related to their applications in different corners of the world. They are considered too universal and restrictive while societal and contextual realities need to be understood and judged by their context. These challenges in the application of the universal guidelines require to be further explored, understood and addressed. Having universal principles, how can we do justice to such variations and cater for contextual differences while aiming for the same universal standards?

One of the applications of the universal ethical principle of autonomy is the utmost importance of informed consent for medical research. Cognizant of the spectrum of additional determinants of autonomy in developing countries, the need to move to a broader system perspective is stressed by experts in the field. Accepting and imposing the mostly 'western' model of autonomy as an international regulatory norm for a

developing country context is questioned; with the need for critical reflection in the application of the principles in the informed consent processes for low resource settings.

A major challenge for those doing research in developing countries includes the question of how to deliver complex consent information at the right time, in an appropriate language and style. While level of information and decision making capacity of study subjects have immediate impacts on the consent process, these in turn are affected by an interplay of factors such as existing guidelines and regulations on research ethics, the legal framework operating for the implementation of the guidelines, the cultural and educational backgrounds of the study subjects, expectations of the participants and level of trust between the subjects and researchers. In addition, the contents of the consent form and the study information sheet, as well as the quality of communication between the subjects and the data collectors play important roles in determining the process. The various factors interact with each other in many possible ways in determining the dynamics of ethical issues important for different settings. All these facts have prompted investigators to seek an approach for understanding contexts better, for adapting the implementation of available guidelines to local situations. Accordingly researchers suggested use of a rapid assessment approach they named as *Rapid Ethical Assessment* (REA).

*Rapid Ethical Assessment (*REA*)* is a brief qualitative intervention designed to map the ethical terrain of the research setting prior to a research team starts recruiting participants with the purpose of connecting ethical principles to contexts and realities on the ground. REA attempts to discover, describe and respond to the ethical issues specific to a particular research setting, and as such should help researchers to address the issues that genuinely matter to proposed study participants and their community. The assessment is conducted among key stakeholders to inform the design of a particular research project. Its findings are utilised to inform and guide the research consent process; ranging from the conception and development of the consent form, to the way consent is obtained.

So far REA has been employed in few settings and recommended for further use. However information on the wide-scale application of the approach, its feasibility and guidance for researchers is lacking. The objectives of the current study are to assess the need for REA in the Ethiopian research ethics appraisal system; evaluate the usefulness and feasibility of REA documenting its outcomes by introducing the REA approach into selected research projects in Ethiopia; and provide guidelines for researchers for further application of REA. Ethiopia was considered an ideal place for the research, due to its multi-ethnic nature. It is also believed that the findings from Ethiopia could be extrapolated to other countries of similar settings.

Acknowledgement

I would like to thank all who directly and indirectly were associated with this PhD project and contributed to its accomplishments in various capacities. I am indebted to a long list of supervisors, researchers, colleagues, family and institutions. It will be impossible to mentions all of them except the few below. I hope to be forgiven if I unintentionally failed to mention names out of haste.

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All this was possible because of the Almighty God's grace and provisions. For Him be glory forever and ever, Amen !

Declaration

I declare that the research contained in this thesis, unless otherwise formally indicated within the text, is the original work of the author. The thesis has not been previously submitted to these or any other university for a degree, and does not incorporate any material already submitted for a degree.

Name: Adamu Addissie Nuramo

Signature: 

Date: March 17, 2015

List of Acronyms and Abbreviations

AAU	Addis Ababa University
AFENET	African Field Epidemiology Network
AHRI	Armauer Hansens Research Institute
BIQ	Brief Investigator Questionnaire
BICEP	Brief Informed Consent Development Protocol
BRHP	Butajira Rural Health Project
BSMS	Brighton and Sussex Medical School
CAB	Community Advisory Board
CAQDAS	Computer Assisted Qualitative Data Analysis Software
CDC	Centres for Disease Control
CHS	College of Health Sciences
CIOMS	Council of International Organizations of Medical Sciences
CS	Comprehension Score
CSA	Central Statistics Authority
DICCT	Deaconess Informed Consent Comprehension Test
DSMB	Data Safety Monitoring Board
DVM	Doctor of Veterinary Medicine
EDHS	Ethiopian Demographic Health Survey
EDTA	Ethylene Diamine Tetra Acetic Acid
EHNRI	Ethiopian Health and Nutrition Research Institute
EPHA	Ethiopian Public Health Association
ESTC	Ethiopian Science and Technology Commission
ETB	Ethiopian Birr
FDA	Food and Drugs Administration
FGD	Focused Group Discussion
FMOH	Federal Ministry of Health
GBP	Great Britain Pound
HEW	Health Extension Worker

HFIAS	Household Food Insecurity Assessment Tools
HH	House Hold
HINARI	Health Inter-Network Access to Research Initiative
HPV	Human Papilloma Virus
IC	Informed Consent
ICH	International Conference on Harmonization
ICT	Information Communication Technology
IDI	In-depth Interview
IOCC	International Orthodox Christian Charities
IRB	Institutional Review Board
IRS	In-door Residual Spray
JU	Jimma University
KAP	Knowledge Attitude and Practice
KII	Key Informant Interview
LICs	Low Income Countries
LLINs	Long Lasting Insecticide Nets
MA	Master of Arts
MCQ	Multiple Choice Questions
MICCA	Modular Informed Consent Comprehension Assessment
MD	Medical Doctor
MLU	Martin Luther University
MOH	Ministry of Health
MoST	Ministry of Science and Technology
MPH	Master of Public Health
NGO	Non-governmental Organization
NIH	National Institute of Health
NREC	National Research Ethics Committee
PGD	Post Graduate Diploma
PI	Principal Investigator
PICO	Population (Patients), Intervention, Comparison, Outcome
PLWHA	Persons Living With HIV and AIDS

P-QIC	Process and Quality of Informed Consent
QuIC	Quality of Informed Consent
RA	Rapid Assessment
RAP	Rapid Assessment Process
RDT	Rapid Diagnostic Test
REA	Rapid Ethical Assessment
REC	Research Ethics Committee
SES	Socio-economic Status
SNNPR	Southern Nations Nationalities and Peoples Region
SOP	Standard Operating Procedure
SPH	School of Public Health
SPMMC	Saint Paul's Millennium Medical College
SPSS	Statistical Package for Social Sciences
TB	Tuberculosis
UK	United Kingdom
UoB	University of Brighton
UoG	University of Gondar
UoS	University of Sussex
USD	United States Dollars
WHO	World Health Organisation
WMA	World Medical Assembly
WT	Wellcome Trust

Definitions

Acceptability: the qualitative degree of positive attitude towards REA in terms of possible future use.

Biomedical Research: research conducted in the field of medicine and health; it includes epidemiologic studies, clinical and preclinical trials.

Comprehension: degree of recall and understanding of informed consent information by potential participants recruited to a study.

Comprehension Level: the level of participant understanding and recall from memory from the information they were given from the study consent document they signed. Measured using a Comprehension Test provided after two weeks of recruitment into the study. Based on the overall scores, comprehension levels were categorized into three [high $\geq$ 75%, medium 50%-75%, low $\leq$ 50%]. This was adapted from earlier similar studies (Minnies, Hawkridge et al. 2008).

Compliance rate (Retention rate): the compliance to follow-up appointments as arranged at the previous visit. Compliance rate refers to the proportion (expressed in percentage) of participants that attend their appointment at the specified time divided by the number of participants who were given appointments and agreed to come.

Field-worker: A research team member who is attached to a university, a research institution or institutional biomedical research project, who is not an investigator but whose primary responsibility is coordinating the field aspects of the research mainly the field data collection.

Feasibility: the realistic possible applicability of REA in resource-constrained situations.

Modified consent form*:* a consent form modified based on the REA findings.

Parent Study or Parent Research Project: one of the three studies into which an REA pilot was introduced.

Parent study PI : Principal Investigator (PI) of a parent study.

Rapid Ethical Assessment (REA): a brief qualitative intervention designed to map the ethical terrain of the research setting prior to a research team recruiting participants. It serves the purpose of connecting ethical principles to contexts and realities on the ground. The model attempts to discover, describe and respond to the ethical issues specific to a particular research setting. Its methodology employs constellation of action research, rapid assessment and ethnography. The assessment is conducted among key stake holders to inform the design of the particular research project. It intends to help researchers address the issues that genuinely matter to proposed study participants.

Recruitment Rate: the efficiency of the process of selection of participants into the study. Recruitment rate is the proportion (expressed in percentage) of participants who voluntarily decide to participate in the study divided by those who were approached to take part.

Researcher: a scholar with an institutional base in a university or research centre, who has been or is currently involved in biomedical research as principal investigator or co-investigator.

Retention Rate: (see definitions for compliance rate above): the proportion (percent) of participants that attend their appointments at the specified time divided by the total number of participants who were given appointments and agreed to come.

REA Project: refers to all three phases of the PhD project which centres around REA.

REA PI: PI of the PhD research project which centres around REA and its application in other research projects.

Standard consent form*:* the consent form developed by the principal investigator of the parent study and approved by the institutional review board (IRB).

Chapter 1 : Background

This chapter provides both contextual and conceptual background to the research setting and the main thesis of the research. It describes Ethiopia and its health research review system, followed by presentations of research questions, problem statement and objectives of the thesis.

1.1. The Research Setting : Ethiopia

Ethiopia is one of the least urbanized and least developed countries with an increasingly promising economic development since the past decade. Located in the eastern part of Africa, often called the 'horn of Africa', it is the second most populous country in the continent, with more than 80% of its population living in the rural areas. Ethiopia is a home to mosaic of nations, nationalities and peoples with more than 80 different spoken languages (CSA 2012). Its ethno-cultural diversity further challenges the application of ethical principles tailored to the varieties in the different contexts. The country is known for its multi-ethnic, multi-cultural and multi-lingual diversities. This makes it an ideal place to explore the applicability and feasibility of REA tool for addressing contexts in tailoring the informed consent process.

Figure 1.1 Map of Ethiopia in the horn of Africa[1]

[1] Source: http://crisisboom.com/2011/02/25/ethiopia-protests-next

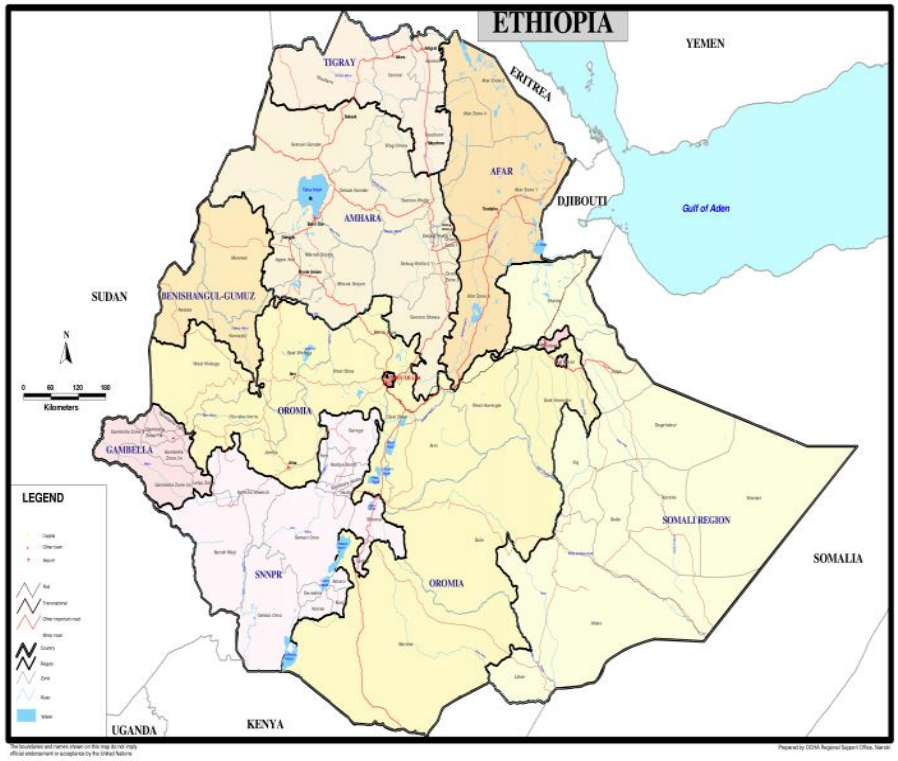

Figure 1.2. Regional Map of Ethiopia showing the different regional states which are based on 'ethnic federal system[2]

Ethiopia has ethnic based, federal state administration which is composed of nine Regional States: Tigray, Afar, Amhara, Oromia, Somali, Southern Nation Nationalities and Peoples Region (SNNPR), Benishangul-Gumuz, Gambella, and Harari (Figure 1.2); and two City Administrations council of Dire Dawa and Addis Ababa. All the regional states and city administrations in the country are subdivided into 817 administrative districts (*woredas*[3]). All the *woredas* are further divided into about 16,253 *Kebeles*[4] (FMOH 2010).

In Ethiopia, the agenda of health research ethics is relatively recent. The health department of the then Ethiopian Science and Technology Commission (ESTC) in

[2] Source: http://www.google.com.et
[3] A *Woreda* is an equivalent to a district with the basic decentralized administrative unit and has an administrative council composed of elected members
[4] *Kebele* is the smallest administrative unit in the governance

collaboration with the national health science and technology council embarked to address health research ethics issues in the country. Accordingly, in 1994, the commission officially launched a national health science and technology policy and established a broad based body at a level of a council with a function to advise the federal government on health science research and development. One of the standing committees of the council was the national research ethics committee (NREC) which is given the responsibility to review health research ethics issues, fundamental principles of health research ethics and their applications in the Ethiopian context. The first health research ethics guideline was developed by the commission in 1995 and has been revised twice, in 1997 and 2004 respectively (ESTC, 2005). Subsequently, health research ethics review committees have been established at three levels; national, regional and institutional. Accreditation and recognition of ethics committees is mainly done by NREC.

Medical research in Ethiopia is about seven decades old and lacks detailed laws and regulations (Gaym 2008). In the last century about 10,000 health research outputs have been documented about Ethiopia. With the rapid expansion of post-graduate programs in the major public universities and the increased availability of research funding, the number of research projects with human subjects is progressively increasing. These have put increasing demand on the current research governance system to be more effective and efficient (ESTC 2005). Community's awareness about research and research ethics elements in Ethiopia, are not well developed compared to communities in developed countries. There are various challenges in the research governance systems and capacity at various levels (Franzen, Chandler et al. 2013). A study on consent form standards, suggested that the standards of ethical review and informed consent need to be improved (Biluts, Mariam et al. 2009).

All the above mentioned gross facts and contextual realities were found to be convincingly enough that Ethiopia is an appropriate place for pursuing the current research project.

1.2. Problem Statement Research Questions and Objectives

1.2.1. Problem Statement

Research in the developing world is subject to an array of guidance and international declarations which primarily originated from 'western' contexts. Due to this, there is a growing concern that research undertakings in developing countries may not be adequately handled when it comes to ethically sound approaches. This specifically refers to the 'application gap' in the way universal ethics principles are applied in designing consent for research and obtaining consent for participation. Developing countries are characterized by less developed education and health systems, very complex and mainly communal ethno-cultural dynamics, with intense degrees of variability and cultural and context-specific differences across communities. Application of universal ethical principles is challenged more in this context owing to the fact that there is much less understanding about the whole notion of science and research by average citizens. Many live far from modern information technologies. There are range of languages and dialects used, some of which do not yet have the vocabulary for recent scientific phenomena. This calls for more in-depth understanding of the varied contexts of application of universal principles related to informed consent process in developing countries. The problem is not lack of regulation. However, since the international research ethics guidance and regulation is generic in form and content, this has given rise to criticism of the ‘western’ approach in identifying and addressing ethical issues related to research in developing country settings. There is growing need for research in Ethiopia and other developing countries which requires a robust ethical appraisal and implementation that sensitively assesses ethical concerns on the ground. With the increase in the number and types of research in developing countries, there is a need to develop competent ethical appraisal systems in parallel.

Research ethics approaches should be culturally appropriate and should be reconciled with the needs of the varying social conditions in developing countries. To this effect, *REA* is recommended as potentially playing a very significant role in bridging the gap between theory and practice in the consent process in developing countries. If *REA* works in the way we hypothesise, the net result of an investment of time and effort prior

to embarking on recruitment to research should be better recruitment to studies, better retention of participants, and a growth in trust between local communities and incoming researchers.

1.2.2. Research Questions

With the hypothesis that REA is a useful and feasible tool which will complement research ethics process in developing countries, and prove valuable in tailoring international principles to specific study participant and community contexts, the central theme of our research project revolves around the following questions; *Is it feasible to introduce REA as a mainstream tool to be used routinely by health researchers in Ethiopia*? *What are the evidences to demonstrable REA benefits and the levels of acceptances by the research community*? *What are the considerations in the REA tool to be addressed for wide scale use and application such as its integration in to other studies*? *What are the important system related consideration in mainstreaming REA in to the ethics review and research governance system in Ethiopia*?

Until now REA has been employed mainly in very limited settings with a clear interest in the intellectual as well as practical issues raised by the approach. In this study we would like to document evidences REA works and to explore further whether REA is conducive for widespread adoption. Once REA is identified as workable tool, question of further application comes next. *How will the system embrace this new approach? What are the levels of acceptability by its potential users*? *When shall we apply REA*? *Which projects or settings are recommended to apply REA*? *What is required*? *What general methods work best for all*? *Who should be doing the REA, the researchers or an independent team*? *How transferable are the REA tools to new researchers*?

1.2.3. Objectives

General Objective : The general objective of the study is to document the use of REA and identify feasible and acceptable ways in which it can be introduced to health research in Ethiopia.

Specific objectives :

i. To investigate the current system of ethical appraisal in developing countries including Ethiopia with particular focus on the informed consent process and explore perceived relevance of REA in the Ethiopian setting;

   Sub-objectives:-

   a. To identify gaps in the research ethics and informed consent appraisal system in the developing world
   b. To assess informed consent related practices of researchers in Ethiopia and identify gaps in consent design and implementation
   c. To assess perceptions, and attitudes of researchers towards REA, and verify need for REA in Ethiopia

ii. To evaluate the outcomes of introducing REA into selected research projects in Ethiopia so as to understand its process and document outcomes

   Sub-objectives:-

   a. To identify and document the range of ethical issues in the parent research projects through introduction of REA tools
   b. To document the effect of REA on study recruitment and retention rates of a parent research project
   c. To document the effect of REA on informed consent comprehension and quality of informed consent in a parent research project

iii. To assess and document feasibility of the REA tools, methodologies and resources so as to make REA accessible to the broader research ethics community in Ethiopia and other similar settings, and refine the tools for further use.

Sub-objectives:-

a. To disseminate REA for potential end-users for feedback and validation,
b. To assess technical and logistic feasibility of introducing REA to other research projects,
c. To refine REA tools and develop REA methodologies and guidelines for further use.

The three major objectives guided in framing of relevant methodological study designs, for the three phases of the research project. As will be further discussed in chapter III, each specific objective is addressed by the three phases of the research project.

Chapter 2 : Review of Literature

> *Despite the postmodern claim that there are no objectively right ethical standards, hardly anyone denies that ethically right standards must govern biomedical research involving human subject. Yet the international research enterprise gives rise to many of the same debates surrounding cultural and ethical relativism as we have seen in other biomedical arenas. ..."Ethical pluralism" - holds that rules governing research practices may vary according to the cultural norms accepted in the country where the research is carried out. "Respect for diversity" underlies the approach of ethical pluralism, which rejects the idea that a single set of ethical standards for research should prevail in our culturally diverse world.*
>
> Ruth Macklin[5]

This chapter provides review of key literature to the main thesis of the research. Basic principles of research ethics with a focus on informed consent and the challenges associated with its application in low income settings are introduced and the significance of addressing contexts in informed consent process, including the role of rapid techniques in addressing such gaps, is discussed. The literature review is done to explore existing gaps in the informed consent process in developing countries and the potential role of ethnographic methods, including REA, in improving informed consent processes in those settings.

2.1. The Review Process:

We conducted a desk review of documents and literature in order to map out informed consent (IC) practices and associated factors in low-income countries (LICs) including Ethiopia. Published literature on research ethics and the informed consent process, with emphasis on developing countries; guidelines, and related institutional documents were reviewed. We used the following key words for the literature search: *research*, *research ethics*, *consent*, *IRB*, *ethics committee*, *ethics*, *bioethics*, *developing countries*, *Ethiopia*, and *Africa*. The search themes were key words extracted from the problem statement of the research. Online literature search was done mainly on PubMed[6] and Google Scholar[7] search engines. The list of relevant articles was further refined by

[5] Macklin, R. (1999). Against Relativism. New York, Oxford, Oxford University Press.
[6] http://www.ncbi.nlm.nih.gov/pubmed
[7] http://scholar.google.com/

limiting the search and combining the search words in the Boolean search, where the PICO[8] approach with combinations of synonyms in the search (Sayers 2008; Yensen 2013) was used. Once in the list, most relevant full text articles were retrieved through online libraries of University of Sussex (UoS) and University of Brighton (UoB) and through HINARI[9] network. In addition we visited the libraries and document centres at Addis Ababa University (AAU) and the Ministry of Science and Technology (MoST). We also consulted IRBs at AAU, Ethiopian Health and Nutrition Institute (EHNRI) and National Research Ethic Committee (NREC) for institutional documents. Whenever required we contacted individuals known to have relevant documents. In addition to published papers, books on *bioethics*, *research ethics*, *anthropology*, *ethnography*, *qualitative methodology* and *philosophy of bioethics* were reviewed for broader understanding of the concepts in our research. All literature were uploaded to a reference managing software, Endnote Library[10], under thematic categories of sources. All documents were read by the principal investigator and important findings were thematically summarised. While the review of relevant literature continued throughout the different phases of the research, the summaries of the review in addition are used in writing the background and methods chapters of the thesis.

2.2. The Informed Consent Process and Challenges in Its Application

2.2.1. Universality of Ethical Principles and their 'application gap' in the Informed Consent Process

Guidance on the ethics of medical research have primarily evolved in the developed world, based on ethical principles that primarily stem from Western values and social traditions (ICH 1996). According to the principles approach to biomedical ethics, there are four basic principles; respect for *autonomy*, *beneficence*, *non-malfeasance* and *justice* (Beauchamp and Childress 2012). In other documents the basic principles are mentioned to be three; *respect for person*, *beneficence* and *justice*, where non-

[8] PICO stands for patients (population), intervention, comparison and outcome in medical research.
[9] HINARI an access to research in health programme, which is a WHO initiative of data base of journals with free access to subscribers in developing countries. http://www.who.int/hinari/en/
[10] Endnote. from http://endnote.com/.

malfeasance is addressed under beneficence (NCPHSBBR 1979). The principle of respect for *autonomy* is about recognizing a person as a person and making sure that individual autonomy is respected in the process of any medical intervention including medical research. The applications of this principle include the informed consent process and maintaining confidentiality and privacy of participants. *Beneficence* is about the maximization of any deserved benefits to patients or research participants, including but not limited to medical care and treatment. *Non-malfeasance*, deals with the minimization of any potential risk or harm that would result from medical interventions or other research related activities. There is a need to make adequate analysis of any risk that might arise due to research and associated intervention. These risks need to be weighed against benefits to make adequate risk-benefit analysis. Minor and acceptable risks may be tolerable for the sake of greater benefits while there are risks which cannot be afforded at any cost. Risk-benefit analysis is therefore the rule. The principle of *justice* deals with fair and justifiable application of research as well as fairness in science and service including the distribution of risk and or benefits. It also deals with fairness in selection of participants and dissemination of research findings and post trial benefits (Beauchamp and Childress 2012).

The principles approach has been criticized for its naming, notions, origins and applications (Holm 1995; Diez del Corral 2008; Stone 2008; Caballos 2010; Herissone-Kelly 2011; Karlsen and Solbakk 2011; Rauprich and Vollmann 2011). Despite these criticisms the four principles have remained key guides of medical and health ethics related dialogues, reviews and guidelines for their pragmatism and universality (Gillon 1995; Schmidt-Felzmann 2003). In all versions of the international guidelines, these basic ethical principles are considered universal. The currently available international guidelines on biomedical ethics such as the Nuremberg code, Helsinki Declarations and CIOMS Guidelines have these principles embedded into their articles, sections and codes (Nuremberg 1949; CIOMS 2002; WMA 2013). Various national ethics guidelines also adapt these universal principles for their implementation. While there are a number of international collaborative research projects with investigators and participants mainly from developing countries, these 'international' ethical guidelines have taken very little

account of the different social structures, cultural norms, legal frameworks and communication channels of the countries in the developing part of the world (Nuffield 1999).

One of the areas of utmost importance in all the available ethics guidelines is the vital need for informed consent in medical research. This has been very clearly highlighted in the Nuremberg code and other guidelines,

> *The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision. This latter element requires that, before the acceptance of an affirmative decision by the experimental subject, there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person, which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.* (Nuremberg 1949)

According to most guidelines, the informed consent process is attributed to the principle of *autonomy* (Mallardi 2005). While the decision making process in informed consent is designed to address that aspect of autonomy, the informed consent process can be considered as a constellation of all the other principles where the risks and benefits need to be analyzed and presented in a justified manner. Though the four principles appear to be distinct, in reality their application is intertwined. Informed consent is a point of convergence both conceptually and in-practice of the four principles. Decision making in the consent process is based on risk-benefit analysis and justice. The decision is made based on the provision of relevant information on risk and benefit; hence the name - ‘informed consent’. In order to fully ‘respect the autonomy of the person’, both the ‘information’ and ‘decision making’ components need to be properly

addressed (Jefford and Moore 2008). In this process there is unity-in-application between the four principles as they are all applied to a person or persons in a unitary person-time (Santillan-Doherty, Cabral-Castañeda et al. 2003).

An important consideration in the implementation of the universal ethics principles through the informed consent process is the need for a balanced provision for differences and peculiarities in human populations and their societal make-ups. Having universal principles, how do we do justice to such variations? For example, how do we apply the principle of 'respect for individual autonomy' in a society where the community's interests and decisions override those of an individual? Relativists argue that the principles are too universal while realities need to be understood and judged by their context (Spiro 1986). They consider the principles too restrictive and prescriptive against societal and contextual realities. Ruth Macklin argues that neither an absolute universalism nor an extreme relativist approach is timeless, and alludes to the fact that context specific issues are worthy of respect only if they are not in conflict with agreed basic human rights (Macklin 1999). Others have argued that one's understanding of the universal principles and their applications are dictated by context-specific interpretations (Takala 2001). Beauchamp admits to the fact that autonomy could be relative and one could see relativism working within the universal principles (Beauchamp 2003). The need for cultural and contextual sensitivity and fairness has created the need for justice as a serious consideration in the principles (Stone 2008).

While the universal ethical principles are important in setting general standards, they do not answer questions related to their application in different corners of the world. The principles deal with people and the lives of individual patients and participants. Life is never uniform and homogenous, is rather coloured with varieties and differences between people and communities as part of their peculiar identity. Accordingly, their application also has to be done in a relatively flexible and accommodative manner. This is an 'application gap[11]' which requires be further explored and understood. The

[11] Application gap refers the challenges in the application of the universal guidelines to different contexts.

question then is how do we cater for contextual differences while aiming for universally the same standards and come up with an approach.

2.2.2. Informed Consent Process Challenges in Developing Countries

Biomedical research, also known as medical research and experimental medicine, includes all research conducted in the fields of medicine and health; epidemiologic studies, clinical and preclinical trials. Biomedical science has demonstrated unprecedented growth with enormous contributions to the improvement of health status and quality of life of the human race. With advances in technology and medical knowledge, biomedical research has grown in scale and dimension. However, advancements in medical technologies and research are often associated with ethical dilemmas and challenges to the public and the scientific community (Bonair, Rosenfield et al. 1989).

While most biomedical research is conducted in the developed countries, the past couple of decades have witnessed a great number of biomedical research projects in developing countries including Africa. With this transition, scholars have stressed the need for special attention given to the way in which 'western' ethical principles are applied to research projects in the developing world. They have emphasized on the complexity of the challenges associated with research ethics in developing countries and that these cannot be addressed by regulatory processes alone. Cognizant of the spectrum of additional determinants in developing countries, the need to move to a debate beyond guidelines and mere ethical review to a broader system perspective is stressed (Bhutta 2004; Hyder 2009). Accepting and imposing the mostly 'western' model of *autonomy*, without at the same time addressing issues of application, as absolute regulatory norm in a developing country context is questioned with the need for critical reflection in the application of the principles in the informed consent process in the developing world.

Although the role of informed consent in human research is central to its ethical regulation and conduct, guidelines often recommend procedures that are difficult to implement in developing countries. Current guidelines and processes for obtaining informed consent should be reviewed with the specific aim of developing culturally appropriate methods of sharing information about the research project and obtaining and documenting consent that is truly informed. While ethics review committees can help with oversight, only an active and transparent partnership between research sponsor, investigators and the community can make this happen (Bhutta 2004).

The ability to communicate effectively with participants and community members, and sufficient understanding of cultural beliefs and values of the community are considered essential for a robust and thoughtful, cultural competence in the consent processes in research. This in turn depends on listening carefully to the concerns of individuals and communities who participate in a study. It has been argued that there is sufficient leeway for researchers to consider culturally relevant strategies for obtaining informed consent from participants. Researchers working collaboratively with local investigators and communities in developing countries should be creative in designing approaches to informed consent for particular cultural environments such as participatory approaches that would enhance informed consent based on actual experiences (Marshall 2008). Such models illustrate the significance of working with community members in the creation of a consent form that is comprehensible to potential participants and a consent process that remains active throughout the study. This has been shown to strengthen research efforts, through improved recruitment and retention of participants who better understand their roles and responsibilities (Woodsong and Karim 2005).

Other factors which are of relevance in the dynamics of IC process in LICs include vulnerability and perceptions related to research interventions. Though there are different definitions on vulnerability, in research it is mainly related power, where research participants 'have insufficient power, prowess, intelligence, resources, strength, or other needed attributes to protect their own interests through negotiations for informed consent (Levine 1988; Ballantyne and Rogers 2007) such as minority

groups, prisoners, mentally impaired patients, minors, pregnant women, elderly and those in socioeconomically disadvantages status like homeless and street youth. While having different types and causes vulnerability is context sensitive and defined by contexts. Vulnerable individuals need to be addressed with extra caution (Koffman, Morgan et al. 2009 ; Online Ethics Center for Engineering; National Academy of Engineering 2011; Koller, Raffaelli et al. 2012; WMA 2013) (CIOMS 2002).

Intervention-based research are also often associated with lots of ethical dilemmas such as clinical equipoise, placebo, adverse effects of interventions, and randomization (Friedman et al 2010) (Weijer, Grimshaw et al. 2011) (Buchanan, Miller et al. 2007). Interventions include new drugs, new treatment modalities or prevention strategies administered at individual or group levels, with the investigator's direct control over the allocation of subjects to study groups. While there are different types of interventional studies, clinical trials are special type of interventional study with highly controlled setting to investigate treatments.

Apart from interventions in the design of the research, certain procedures such as invasive procedures for data collection. Examples include the Pap test[12] and colonoscopy, lumbar puncture (LP)[13], vein punctures, vaginal specimen collection, and biopsies. Such procedures are often associated with ethical concern and dilemmas and lack of trust (Baer, Smith et al. 2010). While invasiveness has different types and degrees it is recommended that it be sensitively addressed (Queen Margaret University 2011) and looking for minimally invasive options stressed (Lindau and McDade 2008).

Sensitive issues in research are issues that 'raise concerns about disapproval or other consequences (such as legal sanctions) for reporting truthfully or if the question itself is seen as an invasion of privacy' (Torangeau and Smith 1996) or an issues with a potential threat as a result of which data collection, holding, or dissemination are

[12] Pap smear is a screening modality for cervical cancer which involves taking a cervical swab and cell study

[13] Lumbar Puncture is drawing of CSF (cerebrospinal fluid) from the cerebrospinal space through a puncture in the inter spinal space.

problematic for participants and researchers (Lee and Renzetti 1993). Such issues have impacts both on the study subjects and the researchers (Dickson-Swift, James et al. 2007). Examples of sensitive issues in research include genetic studies (Tekola, Bull et al. 2009b); studies on diseases conditions considered taboo and stigma prone in relation to sensitivity of personal information and consent around privacy and confidentiality (Singh, Abdool-Karim et al. 2006) and collecting information around personal issues associated with past-trauma (Taylor, Martin et al. 2011) (Decker, Naugle et al. 2011). Sensitive topics in research require more preparation from the researchers side in order to address them in a sensible way and win trust of participants (Dickson-Swift, James et al. 2008).

One other major challenges for those doing research in developing countries is the question of how to deliver complex information at the right time, in an appropriate language and style. Information comprehension is an important determinant for study compliance and retention (Sanchez, Salazar et al. 2001). Developing such a comprehensive document may take several reviews and assessments. To this effect, informed consent documents need be adapted to the local culture and the educational level of the population. It is only when the subjects clearly understand this information, that they make better decisions, comply with research procedures, experience less surprise later, and stay longer in the trials. Determinants of informed consent comprehension in low income settings include salience or relevance of information to the participants' lives, provision of a large quantity of information at once, appropriateness of the consent procedures for those with low education, and issues of trust between the community and the research centre (Hill, Tawiah-Agyemang et al. 2008).

Investigators must ensure that the prospective subjects have adequately understood the information. Different approaches have been implemented by researchers in developing countries to improve the consent process and subsequent comprehension (Sanchez, Salazar et al. 2001; CIOMS 2002; Ndebele, Wassenaar et al. 2012). Studies conducted in various African countries showed that there are compromised levels of

understandings among trial participants about voluntary participation. The educational status of study participants was highly associated with informed consent comprehension. Participants who had completed certain grades of formal school are were found to more likely obtain greater comprehension scores than those who did not (Minnies, Hawkridge et al. 2008). Participants in clinical trials were found to be less likely than those in observational studies to perceive that refusal to participate in the parent research project would affect their regular medical care (Kiguba, Kutyabami et al. 2012). Participant expectations including therapeutic misconceptions where the research outcomes as equivalent to therapeutic medical interventions have been documented to be important determinants influencing decision making (Lidz and Appelbaum 2002) (Tekola, Bull et al. 2009a).

Quality in the informed consent process has the following key components; adequacy of the information provided; understand-ability of the purpose, benefits and risks of the research; distinction between research and clinical care; voluntariness of participation; recall of signing a consent document; and satisfaction with the consent process (Sugarmann, Lavori et al. 2005). Quality in informed consent depends on factors such as type of consent information provided, amount of information, adequacy of comprehension by the study participants, and the voluntariness of decision making by the participants of the study. Assessment of the quality of informed consent can be done through proxies of levels of recall and understanding by the recruited participants (Minnies, Hawkridge et al. 2008; Kiguba, Kutyabami et al. 2012; Mandava, Pace et al. 2012).

Comprehension refers to the integration of previous knowledge with novel information presented in consent documents which can then be recalled from memory. In addition to informed consent comprehension levels, recruitment rates and recruitment index are considered important parameters in monitoring the quality of research implementation (Blanton, Morris et al. 2006; Galea and Tracy 2007). Studies have identified potential contributors to recruitment rates of study participant such as 'opt-out' approaches (Junghans, Feder et al. 2005); early considerations of participants' perspectives (Patel,

Doku et al. 2003); addressing ethical issues such as therapeutic misconception (Blanton, Morris et al. 2006); and established trust between researchers and potential participants (Kneipp, Lutz et al. 2009). Recruitment rate is considered to be a determinant of subsequent retention (Frank 2004; Blanton, Morris et al. 2006). In addition, other compounding factors for retention need to be taken into consideration, such as the mental state of the person (Chang, Brown et al. 2009); tracking and follow-up mechanisms (Murugesan, Anandan et al. 2011); addressing community, and specific context issues and needs in special communities (Ejiogu, Norbeck et al. 2011). There are still ongoing debates as to which interventions are effective in enhancing informed consent comprehension (Cohn and Larson 2007).

Interventions to improve consent process such as use of innovatively tailored local narratives were found to positively impact understanding of trial procedures (Ndebele, Wassenaar et al. 2012). Such interventions included local narratives (Ndebele, Wassenaar et al. 2012); extended one-to-one discussion (Flory and Emanuel 2004; Tamariz, Palacio et al. 2012; Nishimura, Carey et al. 2013); 'enhanced consent'[14] (Dunn, Lindamer et al. 2001; Nishimura, Carey et al. 2013); and a booklet of participants rights (Benatar, Mortimer et al. 2010). Cultural and linguistic modifications to the informed consent were also considered to significantly enhance understanding by study participants in low income settings (Penn and Evans 2010). On the other hand lexico-syntactic[15] readability improvement of study information sheet (Paris, Brandt et al. 2009), multimedia-enhanced informed consent (Flory and Emanuel 2004), and use of a concise version of informed consent (Enama, Hu et al. 2012) did not have effects on comprehension.

Being important, modifying the methods of obtaining informed consent or the composition and content of the consent form may not be adequate to overcome this problem. It is necessary to reflect on culturally sensitive and effective safeguards for

[14] Enhanced consent refers to the process of improving the consent forms through intervention that would serve the purpose.
[15] A lexico-syntactic pattern is a string matching pattern that is based on text tokens and syntactic structure.

protecting research subjects (Oguz 2003). It is argued that community opinions on local issues and practices should inform ethical decision-making in health research. While the notion of autonomous informed consent is supported by all, how it should be implemented in practice remains complex and unclear. It would be therefore desirable to ensure that community members are involved in its local application (Molyneux, Wassenaar et al. 2005). Culture of the people need to be taken into consideration, especially in communities where personal choice is limited and the individual is placed second to the community (Newton and Appiah-Poku 2007). Arguments are presented that community involvement can often facilitate research when this is built into the project from the beginning; both in the approval and implementation process. It is also recommended that further research be undertaken to find ways of implementing consent process in populations of differing circumstances and contexts in a variety of developing countries so as to assure genuine and voluntary informed consent (Creed-Kanashiro, Ore et al. 2005).

In summary, there are a number of factors influencing the consent process in developing countries. While level of information and decision making capacity of study subjects have immediate impacts on the consent process, these in turn are affected by an interplay of factors such as existing guidelines and regulations on research ethics, the legal framework operating for the implementation of the guidelines, the cultural and educational backgrounds of the study subjects, expectations of the participants and level of trust between the subjects and researchers. In addition, the contents of the consent form and the study information sheet, and the quality of communication between the subjects and the data collectors play important roles in determining the process.

Based on the literature review on informed consent related challenges for LICs, a conceptual framework of factors playing role in the informed consent process is created (Figure 2.1.). The framework helps to put initial thoughts on the table and was further updated as new insights arose. The thematic categories of factors emerged from the analysis of literature reviewed. The various factors interact with each other in many

possible ways. Most of the factors included in the frame fall in to socio-cultural dimensions. This raises questions on how informed consent should be approached in developing countries and the need for more research on how to improve informed consent process for participant in different educational status and other similar gaps that impede the smooth implementation of consent process. The framework also helped in framing analysis of subsequent findings. The process of coding of the qualitative data and the thematic and conceptual analysis particularly benefited from the conceptual framework.

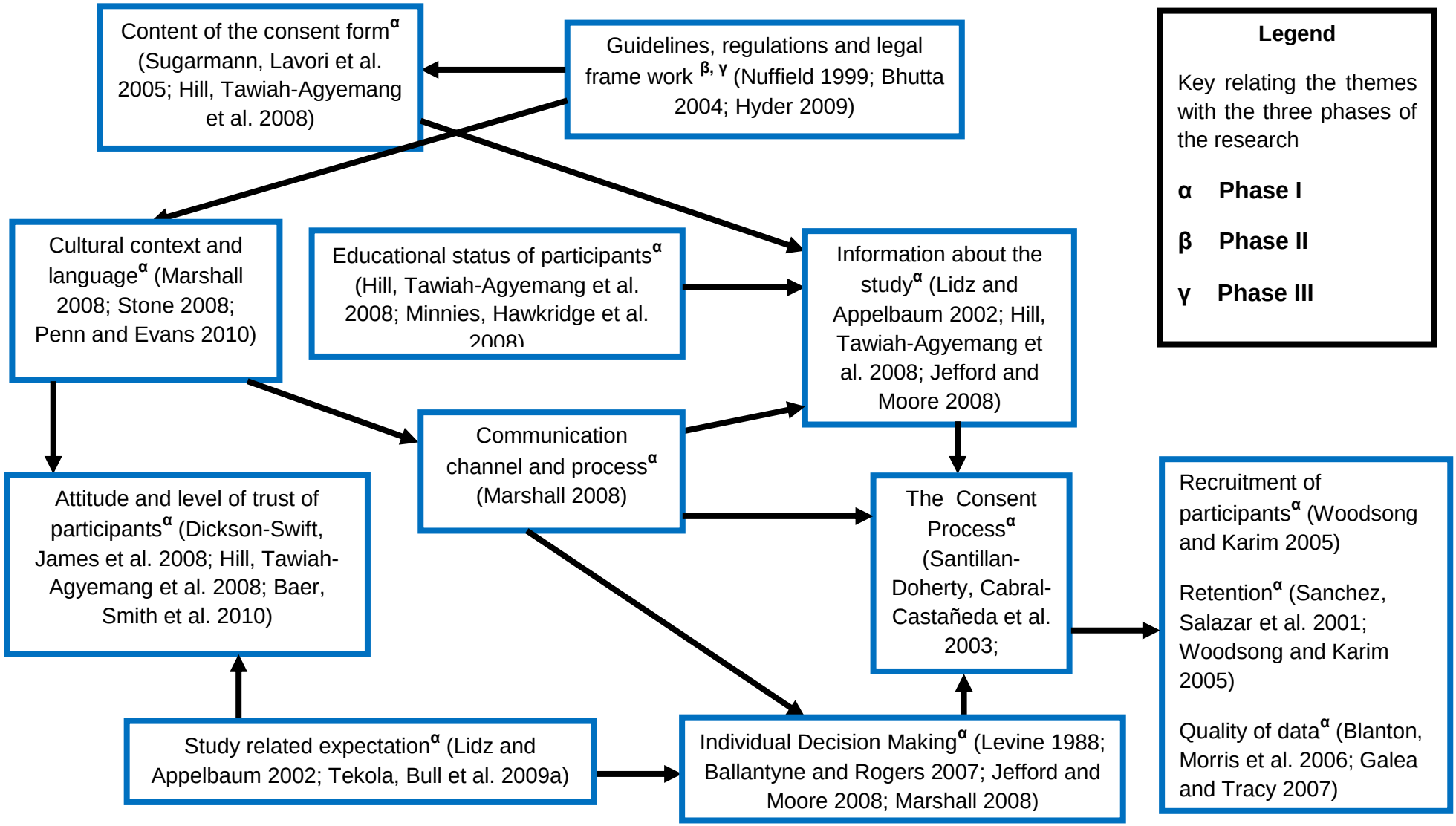

Figure 2.1 Conceptual framework of factors affecting the consent process in research in developing countries

2.3. Informed Consent and Rapid Assessment Techniques

The inflexible use of international ethical guidelines in health research have prompted investigators to seek an approach for adapting these guidelines to local situations. Studies have emphasized the importance of addressing local context, especially in the developing world where there is a disconnection between what is assumed by researchers and the practical reality (Angell 1997; Beebe 2001; Farmer 2002). Rapid assessment techniques have been documented to play important role in improving research consent process in developing countries by understanding and addressing contexts. Researchers suggested further use of the approach they named as *Rapid Ethical Assessment or Appraisal* (REA) (Bull 2007; Tekola, Bull et al. 2009a; Bull, Farsides et al. 2012; Tindana, Bull et al. 2012).

2.3.1. Rapid Ethical Assessment

*Rapid Ethical Assessment (*REA*)* is a brief qualitative intervention designed to map the ethical terrain of the research setting prior to a research team starts recruiting participants with the purpose of connecting ethical principles to contexts and realities on the ground. REA attempts to discover, describe and respond to the ethical issues specific to a particular research setting, and as such should help researchers to address the issues that genuinely matter to proposed study participants and their community. The assessment is conducted among key stakeholders to inform the design of the particular research project. Its findings are utilised to inform and guide the research consent process; ranging from the conception and development of the consent form, to the way consent is obtained.

Ethics committees in low-income countries make decisions on research protocols based on international guidance that either missed issues of importance locally or over-emphasized issues that had little ethical importance outside a western perspective. REA was believed to solve the problem of reconciling the ‘volume of sophisticated

international guidance and regulation' which are divorced from 'specific research contexts'(Bull 2007), as we move from theory to practice in applying the ethical principles for seeking consent to research. The REA first trialled in the Gambia, helped in framing a valuable tool to gain information about what aspects of research context are likely to be important for understanding the informed consent process. Bull and Farsides developed REA methodology based on rapid ethnographic assessment techniques to ensure relevant ethical issues were addressed in a culturally appropriate manner prior to the start of research (Bull 2007).

The tool was initially piloted in two studies (a TB case-contact study, and a vaccine trial) in The Gambia. Valuable information from researchers, fieldworkers and potential participants helped guide development of a consent process that took into account key issues surrounding how the research was explained, how decisions to participate were reached and how true respect for participants could be fostered. The key issues identified provided a framework for evaluating and incorporating such findings into research design.

This approach was further used prior to a genetic study in Southern Ethiopia (Tekola, Bull et al. 2009a) to inform the process of consent form development and the processes of seeking consent from the community and individual participants. The study applied in depth interviews (IDIs) and focus group discussions (FGDs) to gather data from research participants, non participant community members, field workers, researchers, and other relevant stake holders. It was found that the extent of use of everyday language, the degree to which expectations of potential participants were addressed, and the techniques of presentation of information had considerable impact on comprehension of information provided about research. Approaching study subjects via locally trusted individuals and preceding individual consent with community sensitization were considered the optimal means of communication. Prevailing poverty among participants, absence of alternative treatment facilities, and participants' trust in the local Non-Governmental Organization (NGO) were identified as potential barriers

for obtaining genuine informed consent. The findings of the rapid assessment were used to inform the consent process for the genetic research.

Based on the experiences from the studies in the two settings, the authors recommended this approach for similar settings to tailor the consent process to varying contexts. It is emphasised by the researchers that routinely implementing such studies during research projects will inform best practice in the conduct of locally appropriate consent processes (Bull, Farsides et al. 2012). Similar approach has been employed in another genetic study and was found to be useful in guiding the consent process (Tindana, Bull et al. 2012).

REA as a methodology employs constellation of action research, rapid assessment and ethnography. This makes the approach a multi-mix, multi-disciplinary approach with overlaps between various techniques.

2.3.1.1. Rapid Assessment

Rapid assessment is a type of participatory action research which is 'an intensive, team-based qualitative inquiry using triangulation, iterative data analysis and additional data collection to quickly develop a preliminary understanding of a situation from the insider's perspective. It will almost always produce results in a fraction of time and at less cost than traditional qualitative research' (Beebe 2001). *Rapid assessment* requires intensive team interaction and multiple cycles of data collection followed by data review and analysis instead of the prolonged fieldwork normally associated with traditional qualitative research. Its results can be used for planning, monitoring, and evaluating activities and for the design of additional research.

Terms such as *Rapid appraisal*, *Rapid rural assessment*, *Rapid rural appraisal*, and *Participatory rural appraisal* have been used to identify different rapid qualitative research methods. According to Beebe, *Rapid appraisal* is a tool meant for ‘a preliminary, qualitative understanding of a situation’ (Beebe 1995). While the *Rapid assessment process* (RAP) can also be referred to as *Rapid assessment*, not

everything labelled as Rapid Assessment meets the methodological rigor of RAP. Despite differences in details, all the different rapid qualitative research methods are based on small multidisciplinary teams using semi-structured interviews, direct observation, and other techniques to collect information with the entire process completed in less than six weeks. As lack of methodological rigor has been one factor in the limited use of rapid qualitative research methods, *Rapid assessment* focuses more on methodological rigor and the involvement of decision makers at different levels to ensure its credibility with decision makers (Beebe 2001).

The major advantage of rapid techniques is the fact that they are quick and focused. Its results are produced in one to six weeks. However, rapid does not mean rushed. The intensity of field work and analysis will enable the assessment team come up with rapid yet valid and meaningful results. Unlike ethnography, in *Rapid assessments* more than one researcher is always involved in data collection, with data triangulation based on teamwork; and more than one researcher is involved in an iterative approach to data analysis and additional data collection. The intensive teamwork is necessary to compensate for the shortened fieldwork period. The RAP team, needs to be multi-disciplinary and diverse, with at least one 'insider' and 'outsiders'. The insider needs to be a full team member and be involved in planning, data-collection, data analysis, and the preparation of the report. All team members are involved in data collection and data analysis, including the preparation of the report. Team-work by a multi-disciplinary team increases sensitivity to the insiders' categories and definitions. Because of the importance of team interaction, the RAP team should be together most of the time (Beebe 2001).

The main data collection method in *Rapid assessment* is a semi-structured interview, which is a directed conversation unlike an open interview. Directed group discussions involve the entire team interacting with each other as well as the respondent; not sequential interview. Relaxed, semi-structured interviewing that provides respondents with time to think helps elicit stories. Non-directive probes are culture-specific and need to be identified prior to conducting the first interview. Guidelines are used instead of a

list of questions prepared in advance of the conversation. Guidelines should be viewed as a reminder of issues that should not be missed rather than an agenda to be diligently worked through. Despite the guidelines, the direction of the study should emerge as information is collected. Individuals with whom the RAP team involves in the study are purposefully selected 'not because they are believed to be average, but because they are believed to represent the diversity found in the local situation'. Techniques of data triangulation are used for optimal results. Observations and team interaction with the respondent based on what is seen as well as heard is necessary (Beebe 2001).

Rapid assessments have been used for various purposes and its application is increasing (Trotter, Needle et al. 2001; Bowling 2002). They are used for informing programs and policy decisions for health care, humanitarian crises and other emergency situations, environmental assessment, food programs (Bergeron 1999), information technology (Wilkins, Swatman et al. 2004) and project need assessments (Bentley, Pelto et al. 1988; Bentley, Hughes et al. 1992; Bergeron 1999; Millen 2000; Trotter, Needle et al. 2001; Taplin, Scheld et al. 2002; Weir, Morroni et al. 2002; REDLAC 2006; Ash, Sittig et al. 2008; Reeves, Kuper et al. 2008; Mignone, Hiremath et al. 2009).

Rapid assessments are applied whenever results are needed within a period of 6 weeks. As discussed above, apart from its naming, experts wonder whether such a rapid technique fulfils the criteria for ethnographic research. And there is the risk of remaining superficial with less in-depth engagement with the study participants (Beebe 2001; Cole 2002). As mentioned earlier the intensity of field work and analysis coupled with structured and intensive professional engagement of the team will result in a rapid, valid and meaningful result.

2.3.1.2. Action Research

Rapid assessments done to improve interventions are considered *Action research* or *Participatory action research*. *Action research* is ‘a method used for improving practice and involving action, evaluation, and critical reflection, evidence, to guide

changes in practice' (Koshy, Koshy et al. 2011). It is an iterative approach, combining theory and practice and is applied for various purposes such as education, health and technology. *Action research* consists of two basic steps: a collaborative-analysis with the participants of the study which eventually leads to theory-formulation followed by collaborative-change with studying of results (Baskerville and Wood-Harper 1996; Avison, Lau et al. 1999; MacColl, Cooper et al. 2005). There are different versions of definitions for action research based on purpose and model.

> *Action research is strongly focused on action and change, operates over reasonably short time spans, and involves substantial collaboration and participation* (MacColl, Cooper et al. 2005).

> *Action research is about working towards practical outcomes and that it is also about 'creating new forms of understanding, since action without reflection and understanding is blind, just as theory without action is meaningless' and that the participatory nature of action research 'makes it only possible with, for and by persons and communities, ideally involving all stakeholders both in the questioning and sense making that informs the research, and in the action which is its focus'* (Koshy, Koshy et al. 2011).

The main purpose of action research is producing practical knowledge useful for day to day use. Depending on purpose and application, different models of action research may be used. Koshy et al considers action research to be 'a particular orientation and purpose of enquiry' rather than a research methodology with a 'family of approaches' that have different orientations (Koshy, Koshy et al. 2011). Waterman et al consider the following definition for action research.

> *Action research is a period of inquiry, which describes, interprets and explains social situations while executing a change of intervention aimed at improvement and involvement. It is problem-focused, context specific and future-orientated. Action research is a group activity with an explicit value basis and is founded on a partnership between action researchers and participants, all of whom are involved in the change process. The participatory process is educative and empowering, involving a dynamic approach in which problem-identification; planning, action and evaluation are interlinked. Knowledge may be advanced through reflection and research, and qualitative and quantitative research methods may be employed to collect data. Different types of knowledge may be produced by action research, including practical and propositional. Theory may be generated and refined and its general application explored through cycles of the action research process* (Waterman, Tillen et al. 2001).

Action research is about generating information based on an action so as to further understand the contextual-dynamics and improve implementation, which leads both to personal and professional development (Stringer 2007). It is also participatory in process and involves reflective cycles of planning, acting, observing and reflecting on a repetitive basis. *Action research* can be used for different types of interventions and disciplines such as education and health care, to mention few (Ferrance 2000) (Ngwerume and Themessl-Huber 2010).

2.3.1.3. Ethnography

Ethnographic studies are a subset of qualitative study techniques in anthropology. *Ethnography* is considered both a science and a method.

> *[Ethnography as a discipline is] a culture-studying culture. It consists of a body of knowledge that includes research techniques, ethnographic theory, and hundreds of cultural descriptions. It seeks to build a systematic understanding of all human cultures from the perspectives of those who have learned them* (Spradley 1980).

Ethnography as a method is used to study cultural issues and cultures which are not ours by applying anthropologic tools. It is characterized by an in-depth study of people in their own culture, based on their own word. In the ethnographic method, the ethnographer attempts to reach as close to what the insider understands as possible. Ethnographers go to the culture without major assumptions except provisionally formulated theory. Ethnographic research typically includes: field work done in natural settings, the study of the large picture to provide a more complete context of activity, an objective perspective with rich descriptions of people, environments and interactions, and a bias toward understanding activities from the informants' perspective. Participant observation is considered the hallmark of ethnography (Blomberg, Giacomi et al. 1993).

Scholars have tried to explore the role of *Ethnography* in *Action research* and vice versa (Reason 2004). Despite the fact that ethnography provides rich understanding of community, culture and contexts, it is not without questions. According to MacColl,

when *Ethnography* is applied to practical issues and applications such as system design, there are two major concerns; that it takes time, and lacks a straightforward link between understanding and practical application. *Ethnographic action research* aims to overcome these problems by combining *Ethnography* with *Action research* in an innovative community based approach (Tacchi, Slater et al. 2003; Tacchi 2004; MacColl, Cooper et al. 2005). *Ethnography* guides the research process while *Action research* links the research back to the project activity plans with the guiding principle of informed reflection based on participative approaches.

Most of the factors we discussed in the section under 'informed consent in developing countries' that are responsible for the 'application gap' in informed consent are ethno-cultural. Ethno-methodologies therefore would be useful to obtain a close-up view of the gaps and for informed action in addressing them. Traditional ethnographies take years for the researchers to learn languages and cultures, and start to integrate and assimilate with the new community (Barnard and Spencer 2002; Flemming 2011). On the other hand its rapid version is characterized by spending a few weeks or months to generate quick results concerning the culture of the community (Beebe 2001).

2.3.1.4. Rapid Ethnography

Traditionally ethnography is time-intensive. It could take several years or months on the field and same amount of time for analysis and interpretation (Bentley, Hughes et al. 1992). However, in certain cases, findings are needed for fast decision and it is impossible to spend months in the field gathering data and wait for similar amount of time for the analysis. This is a particular challenge for industries requiring quick results (Millen 2000; Isaacs 2012). One approach to meeting the ever-increasing time demands has been '*rapid'* or '*quick and dirty'* ethnography (Hughes, King et al. 1995). According to Millen, *Rapid ethnography* is, ‘a collection of field methods intended to provide a reasonable understanding of users and their activities given significant time pressures and limited time in the field’ (Millen 2000). Field-workers will be conducting short, focused field studies to rapidly gain an understanding of the setting. In addition, the field researchers refer back to previous studies of related settings in order to help provide

greater insight of the context (Millen 2000). An interdisciplinary team approach and intensive and dynamic engagement of the team while in the field are considered the key elements for successful rapid ethnographic assessment.

Rapid ethnography is gaining increased recognition as a variant of rapid assessment with many applications. The rapid ethnographic approach has been employed for various research which required rapid outputs (Millen 2000; Taplin, Scheld et al. 2002; Tedjasaputra and Sari 2005). In rapid ethnography, researchers play the role of participant observers and this is often approximated by the use of mixed methods such as interviews, discussions and non-participant observations. Like rapid assessments, rapid ethnography also does not mean rushed ethnography. The intensity of engagement from multidisciplinary and expert research team members in both data collection analysis helps in attaining a rapid and valid ethnographic findings (Beebe 1995; Beebe 2001; Trotter, Needle et al. 2001; Bowling 2002; Cole 2002 ; Tacchi, Slater et al. 2003).

2.3.2. REA and Quality of Informed Consent Comprehension

In evaluating the REA approach, it is important demonstrating with empirical evidences that REA brings about the desired changes in the informed consent processes; such as levels of comprehension, compliance and quality of the informed consent process. Earlier research on REA has documented improved informed consent processes in terms of better understanding and comprehension (Bull, Farsides et al. 2012). However, the effects of REA on study participants' level of comprehension, recruitment and retention and quality of informed consent have not been documented.

Measurement of consent comprehension and quality of consent process can be done in different ways. Currently existing tools include the Deaconess Informed Consent Comprehension Test (DICCT) (Miller, O'Donell et al. 1996); the Quality of Informed Consent (QuIC) questionnaire survey (Joffe, Cook et al. 2001a; Joffe, Cook et al. 2001b); the Brief Informed Consent development Protocol (BICEP) (Sugarmann, Lavori

et al. 2005); the Process and Quality of Informed Consent (P-QIC) (Cohn, Jia et al. 2011); the Modular Informed Consent Comprehension Assessment (MICCA) (Buccini 2009a)and the Brief Investigator Questionnaire (BIQ) (Buccini 2009a). Other variant methods and categories have been suggested by researchers depending on settings and the subjects under consideration (Wirshing, Wirshing et al. 1998; Arora, Rajagopalan et al. 2011; Chaisson, Kass et al. 2011; Mahnke, Plasek et al. 2014). DICCT, QuIC and BIECP were developed to measure clinical trial informed consent comprehension in non-cognitively impaired adults. Adequate reliability has been established for all three but validity was only conducted for the DICCT, and result showed that DICCT is moderately effective in measuring comprehension (Buccini 2009a).

2.3.3. Feasibility of REA

REA has been implemented so far into few studies mainly in generating findings for tailoring informed consent processes to the local research contexts, than documenting the feasibility of the approach. As the REA approach gains popularity, it is imperative that it is widely disseminated for use among researchers conducting research in developing countries and the research ethics community by large. Beside its usefulness, feasibility of REA then will be an important consideration in its dissemination to researchers and the research ethics community.

Feasibility studies are useful in informing decision-making regarding the continuous application, marketing and promotion of new products, tools and approaches. Such assessments usually follow principles which are used for marketing new products to customers and end-users within a given environment or market. The assessments suggest strategies of marketing products to end-users by employing decision models, and other protocols. They also are used for policy decisions related to public interventions (Michael 1995; CVHL 2008; Rawaf 2010).

Feasibility studies assess not only products but also implementation processes. *Process feasibility assessments* aim to answer whether the proposed strategy or methodology, is a) technically feasible and effective; b) economically affordable and cost-effective; including costing and cost-benefit considerations; and c) profitable. Other important process considerations include acceptability by its users, ease in application, skill-transferability, and time related factors (Soares, Dumville et al. 2013).

While there are different types and models of feasibility assessment for various disciplines, feasibility assessment models for public health interventions are limited. Available literature discusses the need for evidence in and the importance of feasibility assessment for public health interventions and suggests a mix of study approaches (Rychetnik, Frommer et al. 2005; Bowen, Kreuter et al. 2009). Feasibility assessments for community based interventions must answer questions in three important dimensions; a) the evidence that the new approach or tool is proven to be useful based on its intrinsic qualities, b) whether the approach works better under ideal or actual conditions compared to other practices and c) applicability in varied contexts, settings and cultures into which the tool is to be translated (Bowen, Kreuter et al. 2009). Major areas of focus for feasibility assessment, according to Bowen et al, include *acceptability*, *demand*, *implementation*, *practicality*, *adaptation*, *integration*, *expansion* and *limited-efficacy testing* (Bowen, Kreuter et al. 2009). The authors argue that these are important considerations for comprehensive feasibility assessments for health related and community-based interventions. Feasibility components are categorised similar by other researchers (van Haastregt, Zijlstra et al. 2007; Dingankar 2011) (van Haastregt, Zijlstra et al. 2007; CVHL 2008; Thøgersen-Ntoumani, Loughren et al. 2010).

Acceptability and *demand* are (Northway 1942) both related to end-users of REA; this includes researchers, research ethics and research governance community. Acceptability concerns attitudes, perceptions and levels of conviction of intended users. Perceptions of researchers and the research ethics community towards REA, and their reactions in terms of accepting REA for their further use in future research are important indicators for acceptability. Demand for REA implicates whether there is a justified need

for REA such as existence of gaps that can be potentially addressed by it. Demand could be directly or indirectly linked to acceptability as existence of need may dictate so. However, there is no necessarily direct relationship between the two as new approaches may be rejected despite clear need. *Implementation*, *practicality* and *adaptation* are related to the process of application of the intervention or the tool. Implementation deals with how well the tool can be implemented as originally proposed (Farley, Thompson et al. 2013) and what adjustments are necessary for its implementation in a range of settings. Practicality is whether REA is practical in terms of resources, and what the resource needs are in terms of time, finance, and expertise. This includes evaluating whether the resource needs for REA are practical to different settings; whether the required skills are easily transferable; whether the tool is applicable in the face of limited resources; and if local researchers with local funding can afford to do it. Adaptation assessment checks whether the tool is easy to adapt to varied needs and contexts, remaining true to its guiding principles. *Integration* and *expansion* assessments are system-related components. Integration relates to the system changes and modifications required to accommodate the new tool into the existing program or system and how possible is it to expand the application of REA to a wider user pool. It looks how REA might be integrated into the existing research governance and ethical review systems and guidelines (Cowley and Akkazieva 2012). Whether REA can be applied to wider settings than where it is already applied will depend on the readiness of the current research regulatory system and its capacity (GonzalezBlock and Mills 2003).

Thus in ensuring feasibility, various methods and approaches can be employed ranging from simple surveys to controlled trials (Arain, Campbell et al. 2010). Both quantitative and qualitative tools are of great value in understanding community and organizational cultures (NIH 2001; Patton 2001).

Chapter 3 : Research Methodology

Research, like diplomacy, is the art of the possible.
Michael Quinn Patton[16]

The chapter discusses research approaches and tools employed at the different phases of the research project. The research had three phases; Phase I, II and III where mix of study designs and range of data collection methods was employed to generate relevant data. We first discuss the overall study designs and data collection methodological approaches, followed by the specific methods used in each of the three project phases.

3.1. Overall Methodology

In this section we discuss the overall principles of the study designs and data collection methodological approaches employed, their advantages and limitations.

3.1.1. Study Designs

The choice of specific study designs (qualitative, quantitative or mixed) was dictated by the research objectives of each phase of the study and the variables planned for data collection.

***a) Qualitative study design*:** The study objective overall required a qualitative enquiry to explore details in real life community issues. Qualitative studies are used in exploring real life events in depth by allowing for depth of discussions. However due to the lack of numerical measures it would be difficult to compare across findings as would be done in quantitative measurements (Patton 2001). Qualitative studies have different types and approaches. In implementing REA

[16] Patton, Q. M. (2001). Qualitative Research & Evaluation Methods. Newbury park, London, New Delhi, SAGE

we mainly used *action research, rapid assessments* and *ethnographic methodologies* (Bull, Farsides et al. 2012). Principles and advantages of these study approaches have been discussed in chapter II.

b) Quantitative study design: Quantitative design was used on two occasions; a cross-sectional on-line survey to assess perceptions of research stakeholders regarding REA (Phase I) and a comparative intervention field-trial to assess the impact of REA on informed consent comprehension and quality of informed consent (as part of Phase II).

Cross-sectional surveys are descriptive observational studies conducted at a cross-section (single point) in time and they are one of the most popular methods in Epidemiology (Olsen and St. George 2004; Levin 2006; Checkoway, Pearce et al. 2007; Pearce 2012). They are also used in developmental psychology, education and other social sciences. They are preferred for the purpose of generating basic information and exploring situations in the face of limited time and resources. We applied them during Phase I, as part of a mixed approach, to generate baseline information and to guide the subsequent project phases.

Intervention studies, also termed as experimental studies, refer to trials or tests ranging from drug trials to behavioural interventions which are controlled and introduced by the researchers under controlled circumstances where the state of exposure assignment is determined by the researchers (Rothman, Greenland et al. 2008). Interventional studies are considered superior to observational designs in terms of the levels of evidence they generate. We used them to further document the evidences for effects of REA on informed consent comprehension and quality in the REA pilot studies (Phase II).

***c) Mixed methods designs*:** The use of both qualitative and quantitative methods in the same study is termed as 'mixed methods', 'multi-method' or 'multiple methods' research. There is an increasing trend towards mixing

quantitative and qualitative methods in different combinations (Stecher and Borko 2002). Mixed methods combine the strengths of both qualitative and quantitative methods (Dahlgren, Emmelin et al. 2007; Creswell, Klassen et al. 2011). A mixed method design with *sequential explanatory approach* was employed during Phase I of the research project in order to maximize understanding complexities around the informed consent process (Creswell, Klassen et al. 2011). During Phase II, mixed data gathering and analyses techniques were used for piloting REA and for documenting the outcomes of the approach on study related participant comprehension and retention rates.

3.1.2. Data Collection Methods

Mix of qualitative and quantitative data collection methods; interviews, group discussions, observations and document reviews were used for data collection.

a) Interviews: These included self-administered questionnaire interviews, interviewer-administered questionnaire interviews, in-depth individual interviews and focused group interviews.

i. Self-administered questionnaire interview: Survey questionnaires are administered either by an interviewer (interviewer administered) or by the respondents themselves (interviewer administered). Self-administered interviews are gaining in popularity and various social and behavioural studies have employed them (van Ooijen, Ivens et al. 1997; Vuillemin, Oppert et al. 2000; Kataoka, Yaju et al. 2010). They are considered appropriate when the questionnaire is on private issues or sensitive subject matter giving the respondent the freedom of anonymity. They make efficient use of time and resources as responses can be collected in a very limited periods of time. We chose to employ this method during Phase I[17] more for the second reason than the first. Drawbacks of the technique include high non-response and incomplete-

[17] As will be further discussed later in this chapter, the study is divided in to three phases; Phase I, Phase II and Phase III. Phase I was dealing with assessing perceptions of researchers in REA.

response rates and lack of opportunities for clarifying questions and probing (information bias). We tried to control for the potential limitations by a pre-test, careful design of the questions, inclusion of open-ended questions, and triangulation in the analysis stage of IDI. *On-line surveys* are version of self-administered interview in which survey questions are sent to the respondent electronically by e-mail directing a web-link to a pre-designed, web-based questionnaire which is responded to electronically. The uses of on-line survey tools are believed to maximize the advantages of self administered techniques (Chang and Krosnick 2010). As responses are given electronically, coding and data organizing are done instantly. They share same limitations with self administered questionnaires. They in addition are limited to those with internet access and skills, and specifically those who have the time and the convenience to open their e-mail invitations. We employed on-line survey among an internet literate group of researchers and we followed those not responding to initial invitation with reminder e-mail messages.

ii. Interviewer-administered questionnaire interview: We used this method for assessing levels of comprehension among potential study participants during the intervention study (Phase II) so as to assess the potential associated impact of REA on comprehension. Its advantages include possibility of prompts; improved completeness of responses; high response rate; high accuracy of responses; possibility of more exchange of information and explanations between the interviewer and the respondent; the possibility to observe at the same time; and is less burdensome to respondent in writing responses. Its potential limitations include that it is costly; time-consuming; less anonymous and difficult for very sensitive issues; and responses could be biased due to the interpersonal interaction between the interviewer and the respondent (Chang and Krosnick 2010; Kataoka, Yaju et al. 2010; MacDonald 2011; Phellas, Bloch et al. 2012). The questions used in the REA surveys were considered less sensitive. In addition, we pretested the questionnaire and trained our data collectors.

iii. In-depth individual interviews (IDIs): Semi-structured IDIs were one of the most frequently used data collection method for REA. As a conventional qualitative data collection technique, IDI intends 'to find out what is in and on someone else's mind', using open-ended techniques. Through this method we learn from others their perspectives on events which we cannot observe directly. The application of IDI as a data collection method assumes that the perspectives of others are 'meaningful, knowable and explicit'. According to Patton, there are three approaches to interviewing, each with different types of 'preparations, conceptualization and instrumentation', depending mainly on the extent to which interview questions are determined and standardized before the interview (Patton 2001). The approaches are; a) the informal conversation; b) the interview guide approach (semi-structured) and c) the standardized open-ended interview. Informal conversation is the most flexible approach and is highly responsive to individual differences and situational change, while the standardized interview is structured so all participants are asked exactly the same questions in the same way irrespective of differences. The semi-structured interview stands between these and uses a list of semi-structured outlines of issues and ideas to be included in the interviews with some degree of flexibility to cater for needs through probing techniques. The key issues in successful interviews are having the right informant with the most comprehensive information about the subject and the right interviewer with skills of asking and active listening. We made maximum efforts to achieve both.

iv. Focused group discussions (FDGs): Together with IDI, FGDs were the other key data collection method used for REA. FGD is a qualitative data collection method where 'a small group of people are interviewed on a specific topic. The approach is indeed an interview, not a problem-solving discussion or group decision-making process' (Patton 2001). It has the same purpose as an in-depth interview and same interviewer skills required. The participants are a relatively homogenous group of 6-12 people participating for one-half to two hours.

> *Participants get to hear each others' responses and to make additional comments beyond their own original responses as they hear what other people have to say. It is not necessary for the group to reach to any kind of consensus. Nor is it necessary for people to disagree. The objective is to get high-quality data in social context where people can consider their own views in the context for the views of others* (Patton 2001).

FGD is considered a highly efficient data collection method with inherent quality control mechanisms. The tool is of value in cross-cultural settings where context is important. However, the depth of discussions available in IDIs may be missed due to limited time and limited degree of participation by the group members. The group dynamics can also have positive or negative impacts on the interview process. During the REAs, we always triangulated FGD findings with IDIs.

b) Observation: While IDIs and FGDs were the main methods for REA, non-participant observations were conducted as much as possible to complement the findings. Observation is an objective qualitative data collection technique with various approaches. With focused and well-prepared observation, the method also allows open discovery where the researcher will better understand the context beyond that reported during an interview. One major distinction between observation approaches is the degree of involvement of the observer, which may be active or passive; participant or onlooker, thus participant observation or non-participant (Patton 2001). There is a range of levels of participation within this classification (Spradley 1980). Despite providing first hand information, observations are intensive in terms of time, energy and skill, which makes them less relevant for rapid methodologies.

c) Document Reviews: In qualitative inquiry document review is considered important source for content analysis in qualitative research. However this depends on availability of printed resources and their validity (Bowen 2009). We reviewed available literature on informed consent in developing countries

including Ethiopia, the universal bioethics principles and the challenges related to the informed consent process. This was not a primary method of data collection. It provided background information on the research agenda. In addition during REAs, local study site documents were accessed when ever available.

3.2. Methods Phase-by-Phase

The three phases of the research project (Table 3.1) were based upon the three major research objectives introduced towards the end of chapter I. In this section we describe details of data collection methodologies used in these three phases which is further summarised in Table 3.2.

Table 3.1 The three phases of the REA research Project 'Adoption of REA as a practical method of assessing ethical issues relating to biomedical research projects in Ethiopia', 2011-2013.

Phase	Themes	Objectives
Phase I	Consent process gaps and relevance of REA for research ethics appraisal system	To investigate the current system of ethical appraisal in Ethiopia with particular focus on the informed consent process and explore perceived relevance of REA
Phase II	Piloting REA in other studies	To evaluate the outcomes of introducing REA into selected research projects in Ethiopia
Phase III	Feasibility analyses and refinement of REA	To assess feasibility of the REA tools, methodologies and resources designed to make REA accessible to the broader research ethics community in Ethiopia and other similar settings, and refine the tool for further use

Table 3.2 A matrix of study design and data collection techniques for the three Phases of the REA Research Project, 2011 - 2013.

Phase	Themes	Design/ Methods	Target Groups	Data Collection Methods	Analysis	Major outputs
I	Investigate the current consent process and appraisal and need for REA	Literature and Document review Mixed Methods (cross sectional survey and qualitative)	Researchers Field Workers REC members	Key Informant Interview (KII) Quantitative/Online Survey	Thematic analysis Descriptive-quantitative	Analysis of the current system and its gaps (Chapter I and II) Methodology (Chapter III) Perceived relevance of REA (Chapter IVI)
II	Pilot REA into selected research projects and evaluate the outcomes of the approach	Rapid Ethnographic Field Survey Intervention study (trial)	Researchers Field Workers Community members	Rapid ethnographic assessments (Observation, individual and group discussions)	Thematic content analysis (qualitative) Descriptive analysis and test of association(quantitative data)	Ethical Issues Identified through REA (Chapter V) Potential associated Impacts of REA on Study Comprehension and on quality of Informed consent (Chapter VI)
III	REA feasibility analysis; refinement of REA tools and resources	Participant observation Desk review REA Workshops	Researchers Field Workers REC members	REA and related documents Participant observation during training-workshops Non-structured individual and group interviews	Thematic narration and discussion	Feasibility of REA (Chapter VII) Revised REA Implementation Strategy (Chapter VIII)

3.2.1. Phase I: Assessment of gaps in the current research ethics appraisal system and the need for *REA*

This first phase intended to explore existing gaps in the current consent processes in developing countries including Ethiopia and to identify potential need for REA within the existing system. Findings of this phase were important to move forward to the next phases. We initially conducted review of important literature and documents followed by an empirical study.

i) Literature and Document Review: We conducted a desk review of documents and literature in order to map out the process of informed consent practices in Ethiopian and other, similar, settings and design a conceptual framework of factors around the informed consent (IC) process in low-income countries (LICs). Published literature on research ethics and the informed consent process with emphasis on developing countries; published as well as unpublished guidelines, and documents and guidelines were reviewed. The review process is described in detail at the beginning of chapter II.

ii) Empirical Study on Consent Processes: An empirical study was conducted to further assess the current situation in the Ethiopian health research ethics review system and identify gaps with particular emphasis on informed consent process.

Study Area: The study was conducted at Addis Ababa University (AAU), the Ethiopian Health and Nutrition Institute (EHNRI), Jimma University (JU) and the University of Gondar (UoG) and Armauer Hansen Research Institute (AHRI). These institutions were identified as the main centres for health-related research within Ethiopia. AAU[18], UoG[19] and JU[20] are the three oldest teaching and research centres for public health and medicine in Ethiopia. Under their schools of public health, they run community-based research projects and each have community-based field laboratory research sites at

[18] AAU. (2014). "Addis Ababa University." Retrieved January 10, , 2014, from http://www.aau.edu.et/.
[19]UoG. (2014). "University of Gondar." Retrieved January 14, , 2014, from http://www.uog.edu.et/en/.
[20] JU. (2014). "Jimma University " Retrieved January 10, 2014, 2014, from http://www.ju.edu.et/.

Butajira (AAU), Dabat (UoG) and Gilgel Gibe (JU). AHRI[21], is a national and regional (for the African region) centre of excellence for biomedical research and clinical trials in the areas of infectious diseases. It is an international collaboration research centre and a regional training centre for researchers from Ethiopia and other African countries. EHNRI[22] is one of the oldest research centres in the country, which was established primarily for nutrition research and response in Ethiopia. Over the years it evolved as a research and development wing of the FMOH and a number of biomedical and community-based research were conducted by the researchers in the institute. Currently, due the national civil service reform, EHNRI also serves as the technical wing of the Federal Ministry of Health (FMOH) in investigating and responding to nutritional and other public health emergencies.

Study Period: The data collection period for this part of the study was July-September 2012.

Study Design: A mixed methods design with a sequential explanatory design was used (Creswell, Klassen et al. 2011), where cross-sectional, on-line survey was followed by qualitative in-depth interviews of respondent in the mentioned institutions.

Study Participants: Researchers and ethics committee members in the research institutions with the experience of independent research in the past and with a post-graduate degree were included. Exceptions to the post graduate degree were made in cases where researchers have many years of research experience and do occupy key research roles in the respective institutions.

[21] AHRI. (2014). "Armauer Hansent Research Institute, ." Retrieved January 10, , 2014, from http://eaccr.org/sites/ahri/.
[22] EHNRI. (2014). "Ethiopian Health and Nutrition Research Institute." Retrieved January 10,, 2014, from http://www.ehnri.gov.et/.

Sample Size:

a) Sample size for the cross sectional survey was computed using the sample size formula for single population proportion with finite population correction (Krejcie and Morgan 1970).

$$n = \frac{Z^2_{\alpha/2} P (1-P)}{d^2}$$

Where;

n = required sample size

$Z_{\alpha/2}$ = level of significance set at 95% (α=0.05; z=1.96)

d = degree of error (set at 10%)

P = expected proportion of outcome of interest (taken 50% since reference on level of outcome of interest (awareness and perception on ethical issues among Ethiopian research community was not available)

After adjusting for a non-response rate of 15%, the total sample size required for the cross sectional survey was 270.

b) Sample size for the in-depth interviews was guided by the degree of information saturation based on preliminary analysis during data collection. A total of 19 interview participants were purposively selected for IDI. AHRI and UoG were not included in the IDIs due to delay is obtaining institutional permission to proceed with this part of the study.

Sampling and Data Collection: For the cross sectional, on-line survey, e-mail addresses of researchers were obtained from department heads and institutional mailing lists of the institutions. Contact persons from each institution, identified e-mail lists of all eligible respondents. A total of 458 eligible participants were identified; 175 from AAU, 108 from JU, 99 from EHNRI, and 76 from UoG. Sample size (270) was proportionally distributed to the four centres (Figure 3.1) and respondents were randomly selected from e-mails list using numbers generated by the RANDBETWEEN

function in Excel (MicrosoftOffice2007®). A link to the web-based questionnaire using SurveyMonkey® (Surveymonkey® 2013) was sent via e-mail to randomly selected eligible respondents in AAU (103), JU (64), EHNRI (58) and UoG (45). Bi-weekly reminders were sent to those who did not respond to the first e-mail invitation. The on-line survey stayed open for 45 days. A total of five researchers who were not able to fill the on-line survey and or preferred paper-based interviews were offered a printed questionnaire. The assistant data collector distributed the questionnaires and collected them back.

Quantitative data were collected using a web-based (on-line) self-administered questionnaire, backed by a paper-based questionnaire, in the English language (Annex A). The questions were structured and possible responses pre-coded. One open-ended question was included at the end of the questionnaire for open text based responses. Questionnaire was pre-tested by administering 15 questionnaires to researchers and academic staff at Saint Paul's Millennium Medical College (SPMMC)[23]. Based on the pre-test, the contents and sequence of some of the questions were revised for coherence and logical flow.

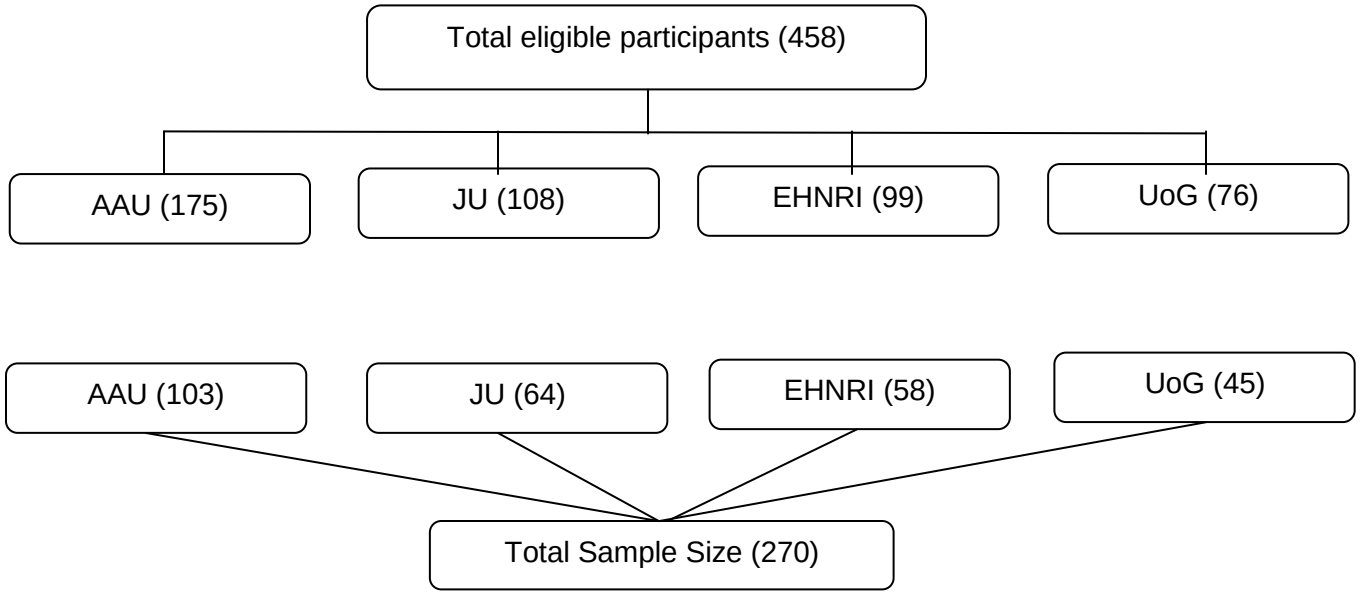

Figure 3.1 Sampling procedures for the on line survey of researchers and research stakeholders in four prominent Ethiopian health research institutions, August, 2012

[23] SPMMC - one of the new public medical schools in Ethiopia located in the capital, Addis Ababa

The 19 IDI participants were selected in a purposive manner using a snowball technique. The informants were interviewed to gather opinions and deepen information complementing quantitative findings. Researchers, research ethics committee members and administrators were interviewed. Semi structured guide questions were developed for each of the target groups mentioned above (Annex A). Interviews were conducted by the principal investigator, either in English or *Amharic*[24], based on the preference of the respondent. All interviews were digitally recorded. They were transcribed and translated to English by the research assistant. Selected transcripts were back translated by the principal investigator (PI) to monitor data quality. Some of the IDI respondents had also been included in the on-line survey. Contamination was not a concern and those who had already seen the on-line survey questionnaire were believed to have structured thoughts which nicely came out during the interviews.

Data Collectors: The on-line survey was designed and run by the PI. The IDIs were conducted by the PI and a trained field assistant who holds a post graduate degree in social anthropology and had experience in conducting interviews for public health research. The assistant was given clear interviewing guidelines and explanation by the principal investigator during a training period.

Study Variables: Study variables in the questionnaires and the interview guide included, socio demographic characteristics; research appraisal process; factors affecting research appraisal and consent process (language, communication, and culture); personal experience (training and experience in research review and consent process); attitudes towards the need and feasibility of participatory rapid ethical appraisal; and availability and use of guidelines for consent process.

Data Analysis: Quantitative data summary were downloaded from SurveyMonkey®[25] (Surveymonkey® 2013). Data cleaning and descriptive analysis was performed using Statistical package for Social Sciences (SPSS) for variables of interest. Simple

[24] *Amharic* is the official working language for Ethiopia
[25] https://www.surveymonkey.com/

frequencies and proportions (percentages) were used to present the findings. NVivo9® (NVivo® 2013) was used to organize qualitative data which were analyzed as texts and thematically summarized. Data were double coded to verify inter-coder reliability. Analytic framework by Miles and Huberman was used with the following steps as repetitive overlapping cycles; a) coding data with marginal remarks, b) displaying data and analysis; and c) drawing conclusions (Miles and Huberman 1994). Quantitative and qualitative data were triangulated and results were presented as text narrations, quotes and data tables. The results from the empirical study are presented and discussed in Chapter III.

3.2.2. Phase II: Piloting REA in three community-based research projects

After Phase I, REA tools were further refined to be piloted in three community based research projects. For the rest of the thesis we refer to these three host projects as *parent research projects* to differentiate them from the main thesis research project (REA project)[26]. The aim of this second phase was to understand the process of implementation of REA tools in a research setting and document the value-added outcomes of introducing REA. The REA tools were introduced into the three parent projects, outcomes, in terms of range of ethical issues identified and impacts on the informed consent process, were assessed and documented.

3.2.2.1. REA tool Development

Development of REA tools was a dynamic process. Earlier versions were revised and refined as we gained more insight about the REA process and its applications. Based on the documented experience of using REA in The Gambia and Ethiopia (Bull, 2007; Tekola, 2009) (Bull 2007; Tekola, Bull et al. 2009a), preliminary tools including interview guides and proformas were developed by the REA PI during the conception of the project. This version was developed based on our understanding of the issues as well as the purpose of REA. Based on Phase I, further adjustments were done to the REA

[26] We refer to their principal investigator/s (PI or PIs) as *parent project PI or PIs* to differentiate them from the *REA Project PI* who will be referred to as *the PI*.

tool formats (Annex A). They were further discussed with experts[27] in the areas of ethics and rapid-qualitative-methodology, for feedback. They were also discussed with the *REA team*[28] before the start of the various field pilots for further fine-tunes. Key issues taken into consideration in the development of REA tools were; purposes of the tools; types of research question as well as sites and subject specific issues. REA tools were readjusted to fit each project considerations. They were evaluated both for the process of their implementation and their outcomes.

3.2.2.2. REA Pilot Studies

REA were sequentially introduced to three parent research projects in five different geographic location in Ethiopia.

Study design: REA employs an ethnographic qualitative design with a blend of anthropologic ethnographic enquiry, action research and rapid assessment techniques. Detail description on REA, its principles and components are presented in chapter II.

Study Area: The study areas of the parent research projects were considered study areas for the REA pilots. As will be further discussed in the same section, we piloted REA in five different locations in Ethiopia which served as study sites for the three parent projects (Figure 3.2).

[27] This includes two of my thesis supervisors who already have been involved in earlier REA work.
[28] As will be discussed later in more detail, we employed a team of expert multidisciplinary experts for conducting the REA. This team is named as an REA team.

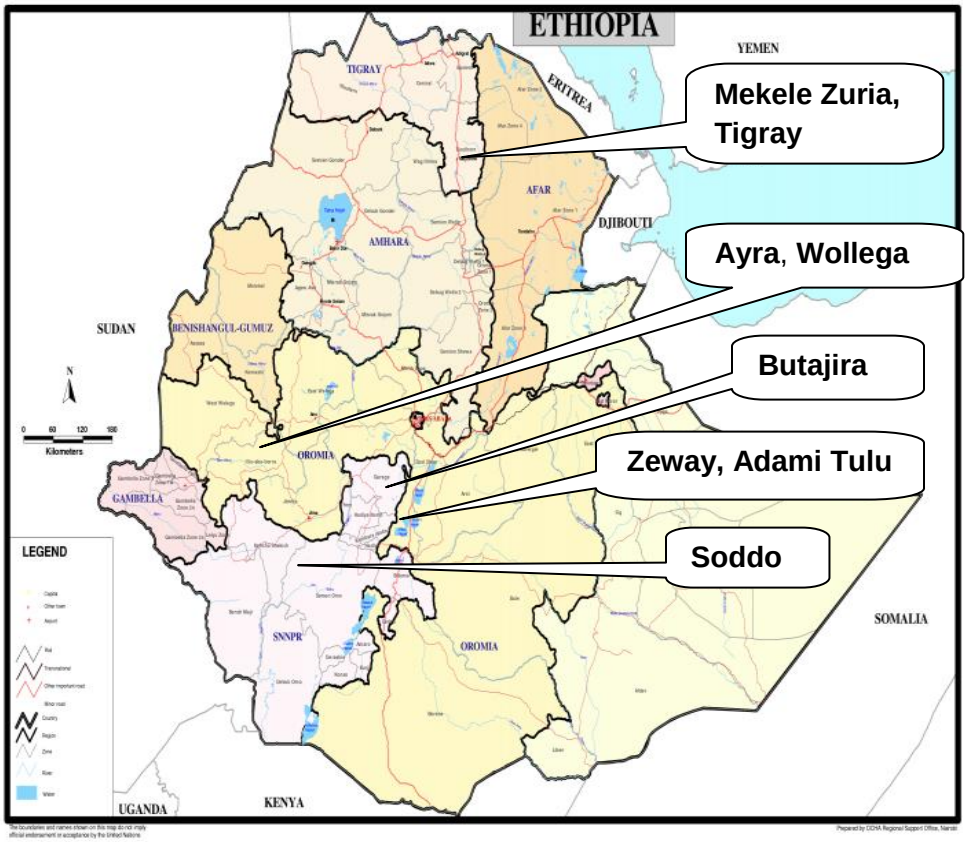

Figure 3.2 The five REA Pilot locations in Ethiopia, 2013.

The three research projects were all community-based medical research projects. Significant ethical issues such as sensitivity of the research question, availability of an intervention, inclusion of vulnerable groups and collection of biological samples were identified. Differences in geographic and ethno-cultural locations; the convenience of timing of the studies and willingness of parent project PIs to collaborate with the REA pilot were additional determinants. We contacted research institutions and researchers in our network through AAU, EHNRI, UoG, JU and AHRI for any research projects starting soon and would fall under the range of criteria we had. The selection decisions were made by the REA PI in consultation with supervisors.

The first two parent research projects for REA pilot had only one study location each, while the third pilot project had five study sites. Due to time constraints, we were able to cover only three of these five sites (Figure 3.2). The three parent projects are discussed

below in the order of their inclusion to the pilot. In the rest of the thesis we refer to each of the projects in the numbers referring to this order. Table 3.3 summarises profiles of the three parent research projects.

Parent Research Project #1*: Food Security, Climate Variability and Spatial Pattern: Modelling the Impact of Climate Variability on Food Security and Analyzing the Spatial Patterns in Ethiopia.*

The study aimed to develop conceptual models that could quantify the different dimensions of food security, nutrition and child health in Ethiopia and to validate household food insecurity assessment tools (HFIAS) developed for international use to the Ethiopian context. The project had three sub-components. While the first component was a secondary data analysis and document review, the remaining two sub-components were community-based field research in a rural setting at Butajira[29] (Hagos 2011). We employed REA for the last two components in which household food security assessments were done in the Butajira rural health programme[30] (BRHP). The study setting, BRHP, is one of the field research laboratory sites for the school of public health (SPH) at AAU which has been research-active for nearly the last three decades. The parent project employed a repeated household survey among sampled households which were surveyed twice using HFIAS tool, with a one-week interval (Annex B). Household food-intake was assessed over a 24 hr recall period (Annex B), and data on household characteristics were collected. Interviews were conducted with women in each household as they are primarily responsible for household food preparation. In the second part of the pilot project study household interviews on nutrition and household demographics and anthropometric measurements (weight, height and age) of children between 6-59 months of age and mothers were conducted. Individual study participants were able to find out their own and their children's nutritional conditions. Households with malnourished children were given nutritional advice and children with severe

[29] Butajira is located in South central part of Ethiopia, Guraghe Zone, Southern Nations and Nationalities and Peoples Region.
[30] BRHP : is the oldest demographic surveillance site in Ethiopia. A number of medical research are conducted in the area .

malnutrition were referred to the nearest health facility for treatment. All participants received information on proper infant and child feeding. Possible risks to participants included minor discomfort during the process of weighing their children and asking about food items in the household. Informed consent forms were prepared for all potential participants addressing the ethical considerations and appropriate measures to ensure voluntary participation (Annex B). Researchers were not sure about the most appropriate modes of informed consent forms appropriate for the community, use of language and effect of gender dynamics in the area on informed consent communication. In addition the study subjects (children and pregnant women) were considered vulnerable.

Parent Research Project #2*: Combining Indoor Residual Spraying and Long-lasting Insecticidal Nets for Malaria Prevention: a Cluster Randomized Controlled Trial (MalTrial)*

This prospective community based trial aimed to identify effective interventions to prevent malaria, which has been one of the major causes for morbidity and mortality in Ethiopia (Deressa 2013). Both long-lasting insecticidal nets (LLINs) and indoor residual spraying (IRS), have been consistently demonstrated to reduce malaria morbidity and mortality. These are the two main strategies currently used for malaria prevention in Ethiopia. The primary objectives of this trial were to test if IRS plus LLINs provides any added protection against clinical malaria compared to LLINs or IRS alone. It was planned to be conducted in Adami Tullu[31] district of East Shewa Zone[32] of Oromia Regional State in Ethiopia. The study is a cluster randomized controlled trial, with four "arms": (IRS+LLINs, LLINs alone, IRS alone and control (routine practice)). Clusters, with village units, were applied in the selection and randomization of interventions. Major study outcomes were measurements of malaria incidence and clinical outcomes of malaria among children and adults including pregnant women. Participants were interviewed for knowledge, behaviour and possession of LLINs during the baseline

[31] Adami Tullu is located in the Southern part of the Orimoya Regional State, about 170 Kms from Addis Ababa (the national capital)
[32] East Shewa zone is one of the Zones in Oromiya Regional state

survey, and were followed-up for malaria incidence. A Rapid Diagnostic Test (RDT) blood test was checked for all febrile patients. Pregnant women are followed for parasitaemia, anaemia and clinical malaria. All febrile cases were referred to the nearest health post for further diagnosis and treatment. RDT results were used to guide immediate treatment in the field. All persons taking part in the study are entitled to receive free malaria diagnosis and treatment. In addition, all households in the study area are provided free LLINs and IRS is freely sprayed for the study households in the intervention group. The insecticides used planned have been evaluated by the WHO pesticide evaluation scheme[33] and all the study interventions follow WHO and national recommendations. Researchers made preparations to follow the national guidelines for insecticide transport, storage and operational procedures. Informed consent forms were prepared for all study participants (Annex B). In addition a Data and Safety Monitoring Board (DSMB) was established for the study. The parent project researchers were not sure how seriously collection of blood specimens at community levels will be perceived by the community and its possible impacts. The community dynamics and the role of women in the consent to enrol to such long term study were unclear. The study subjects were poor patients including women and children which are vulnerable groups.

Parent Research Project #3: *Human Papilloma Virus (HPV) sero-survey in Ethiopian Women: an approach to cervical cancer.*

The project aimed to provide national sero-prevalence information on the various types of HPV infection sero-profiles and to measure the magnitude of HPV infection among sexually active women in Ethiopia. By determining HPV subtypes in the normal population the study serves as a foundation for national HPV vaccination efforts. It is one of the seven sub-project under the collaborative project "Gynaecologic Cancer in Ethiopia" which is a bigger project with other components (Assefa 2012), which is a research collaboration between the faculties of medicine and public health at Martin Luther University (MLU), Germany and AAU. The project focused on female cancers with the aim of providing epidemiologic information on the neglected topic of cancer in

[33] http://www.who.int/whopes/en/

Africa (Assefa 2010). The study targeted five different locations in Ethiopia from different geographic regions with urban-rural mix; Ayra[34], Harar[35], Adigdom[36], Soddo[37] and Addis Ababa. However, we piloted REA on only three of the sites due to time factor i.e. Ayra and Soddo and Adigdom (Figure 2.2). In each of the sites, about 120 pregnant women coming for antenatal care to hospitals and health centres were interviewed and underwent pelvic examinations. Vaginal and blood specimens were taken based on their consent (Annex B). The specimen collection for the pregnant women occurs while they come for routine medical Antenatal care (ANC) check up as part of the routine procedures and no harm is expected to result from the routine physical and gynaecologic examinations. While the study has no direct benefit for the study participants, it is intended to benefit all potential victims of gynaecologic cancer in Ethiopia. Informed consent was taken from every person (Annex B). The study deals with very sensitive issues of reproductive health and the not-very-well-known area of gynaecologic cancer. Researchers were not sure how to communicate study information more appropriately, how to engage the community and deal with the perceptions around biologic specimen collection without immediate medical benefits. They also were not sure what terms to use to describe about the study such as cancer and reproductive health issues. Pregnant women are considered vulnerable groups in medical research.

[34] Ayra is a very small rural town in West Wollega, Oromiyya, 362 Kms form Addis Ababa
[35] Harar is a an autonomous city administration in eastern part of Ethiopia
[36] Addigdom is in Mekele zuria which is a communal name for the woredas surrounding Mekele which is the regional capital for the Tigray Regional State in Northern Ethiopia. Mekele is located about 700 km from Addis Ababa. Adigdom is the capital town for Hintalo Woreda in Tigray regions, Mekele Zuria
[37] Soddo is located in Southern Ethiopia - Zonal Capital for Wolayta Zone which is one of the most populated zones in the Southern Region (SNNPR).

Table 3.3 Summary of the 'parent research projects' on which the REA Pilot was conducted , Ethiopia, 2013

Full Project Title	**Project Profile**	**Research Design**	**Location; Local language; Ethnic groups**	**Study subjects**	**Type of Data collected**
1. Food security climate variability and spatial pattern: Modelling the impact of climate variability on food security and analyzing the spatial patterns in Ethiopia	PhD Project (PI: Seifu Hagos) (Hagos 2011)	Repeated cross section	Butajira (rural), South Eastern Ethiopia *Amharic* and *Guragigna* *Gurage and Silte*	Women and Children	Interviews Nutritional history Clinical Examination/Anthropometry
2. Combining indoor residual spraying and long-lasting insecticidal nets for malaria prevention: a cluster randomized controlled trial in Ethiopia	Collaborative Trial (PI: Wakgari Deressa et al) (Deressa 2013)	Cluster Randomised Trial	Adami-Tulu (rural), South-Western Ethiopia *Amharic and Oromiffa* Oromo	Children, Mothers, Pregnant women and Malaria Patients (children and adults)	Interviews, Clinical Examination, Repeated blood specimen collection and testing
3. Epidemiologic survey of Ethiopian urban and rural areas on breast cancer and other gynaecologic Cancer – prevalence and clinical epidemiology; HPV in women of Ethiopia: an approach to cervical cancer	National Sero-Survey (PI: Matewos Assefa /Eva Kantelhardt) (Assefa 2012)	multisite cross sectional	Ayra (rural), Western Ethiopia; Soddo (semi-urban), Southern Ethiopia; Adigdom (rural), Northern Ethiopia Amharic, Oromiffa , Wollayitegna and Tigrigna Oromo, Woalietta, Guraghe, Silte and Tigre	Pregnant women	Interviews, Clinical Examination; Pelvic examination and vaginal swab and specimen collection; Blood/Serum specimen collection

Study Duration: The REA pilots were conducted in 2012 and 2013. While duration of individual REA pilots varied from site to site, a total 4-6 weeks per project was allotted for each pilot study. Table 2.4 presents the time periods and duration for each of the REA pilot sites.

Table 3.4 Duration and Time allocation for the various REA pilots into 'parent research projects' in Ethiopia, 2012-2013.

Project Site	Period	Duration
Butajira	November to December, (2012)	Total 6 weeks; preparation and data collection 4 weeks; preliminary analysis and feedback one week
Adami-Tulu	January to March, (2013)	Total 5 weeks; preparation and data collection 4 weeks; preliminary analysis and feedback one week
Ayra	March to April, (2013)	Total 4 weeks; preparation and data collection 3 weeks; preliminary analysis and feedback one week
Soddo	April to May, (2013)	Total 4 weeks; preparation and data collection 3 weeks; preliminary analysis and feedback one week
Adigdom	July to August, (2013)	Total 4 weeks; preparation and data collection 3 weeks; preliminary analysis and feedback one week

Study Population: Parent project PIs, community key informants, representatives of potential study participants, health professionals, health authorities, and field workers were included in the REA assessment.

Sample size and sampling: A snowball purposive sampling technique was employed in each of the study sites. We interviewed varied number of individuals both in groups and alone depending on the saturation of information as a guiding principle which in turn was based on iterative analysis of data on the field. A total of 45 IDIs and 23 FGDs (with 220 individuals participating) were conducted with a total of 265 individuals included. On average there were 8 - 10 participants in group interviews (focus group discussions). The total number of individuals sampled from each category of study population was determined by the level of information saturation during the data collection. Table 3.5 presents the total number of IDIs and FGDs conducted in each of the sites.

Table 3.5 Summary of individuals taking part in the REA pilots on three 'Parent Research Projects' in Ethiopia, 2012-2013.

Pilot sites	IDI participants			FGD participants (# of FGDs)*	Total Participants (FGD+IDI)
	Female	Male	Male + Female		
Butajira	4	6	10	57 (6)	67
Zeway	3	4	7	41 (4)	48
Wollega	4	4	8	39 (4)	47
Soddo	3	4	7	38 (4)	45
Mekele	5	8	13	45 (5)	58
Totals	19	26	45	220 (23)	265

*NB: some of the FGDs were mixed

Data Collection Techniques: Data were collected using mainly IDIs and FGDs, supplemented by non-participants observation. All data were collected in the respective local language and all individual and group interviews were either tape recorded or extensive session notes taken.

a) IDIs: Target groups for the IDIs were key-informants in the respective sites, on health research and cultural context issues, including health professionals and health extension workers. REA tools were used for data collection (Annex B) and individual interviews lasted 45 – 90 minutes. Different interview guides were used for different target study groups. The preliminary tools developed during Phase I were further developed and refined for this purpose. Data collection was done by the REA team.

b) FGDs: Target groups for the FGDs were community representatives where groups of men, groups of women and mixed groups were included in the study. Each group had 8-12 participants chosen purposively. REA tools were used for data collection (Annex B). Each FGDs on average lasted 60– 90 minutes and FGD facilitators were REA team members.

Figure 3.3 Focus group discussion, Adami-Tulu, Zeway, March 2013

c) Observations : Non participant observation was conducted on public places, such as markets, health facilities, and health research project activities. This was not a primary data collection technique and was employed only when needed or something of interest arose. For example, in Butajra we were able to observe a training session for field data collectors and we also observed selected data collectors as they pre-tested their tool in the households. In all the cases the observants were members the REA team.

Sequence of Steps in REA

The process of piloting REA into parent research projects followed several steps (Figure 3.4). The steps related to identification of the need for REA and relevant

projects as well as process of refinding REA tools have been already discussed earlier. The remaining components are discussed below.

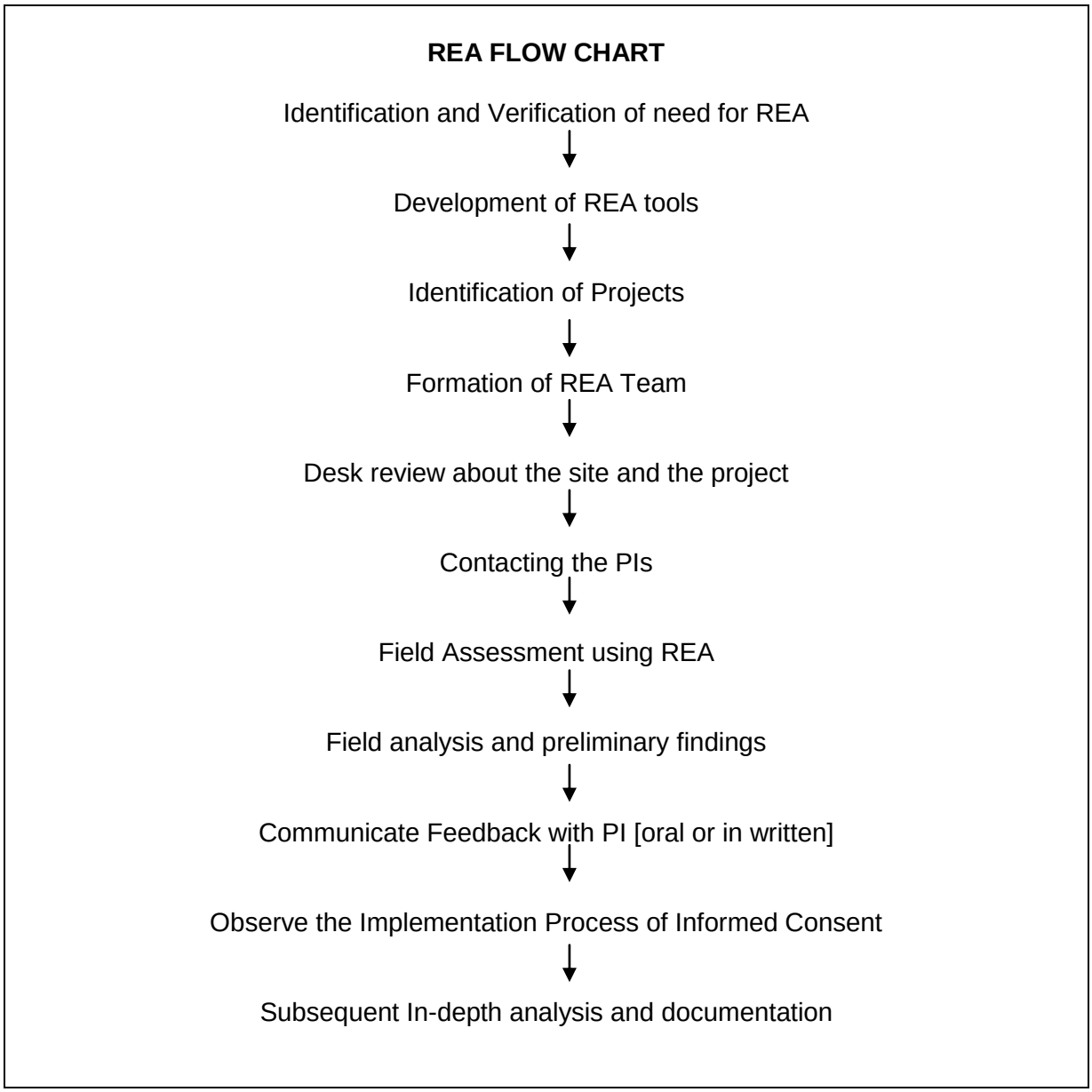

Figure 3.4 A flow-chart of steps employed in the REA Pilot to three Parent Research Project in Ethiopia, 2012-2013

i) Preparation for REA field study: Once the study project and the site for the REA pilot were decided, we made an appointment with the respective parent project PI to learn more about the project and to explain the REA process and its benefits. Concerns were discussed and clarifications given. For parent project II, we

participated in the project inception meeting where the REA PI was invited to speak about anticipated ethical issues and discussed with the parent project PI and co-investigators on the ethical issues of the project. This gave both sides of researchers very good information about the project under consideration. We also took time to review the parent research project proposals focusing more on the ethical considerations and mapping out anticipated issues. This served to further refine the REA tools tailored to the research project and the field site under consideration. The Parent Project PIs were asked if they already had a focal person identified in the field site who could serve as a point of entry to the site[38].

ii) Formation of REA team: REA team responsible for leading the REA process was formed at the beginning of the field research. The team was composed of, the PI of the REA project, parent project PI, a social scientist, a public health expert, a local area expert[39] and a local area contact person. The main functions of the REA team were to identify IDI and FGD participants, conduct field data collection (interview/FGD/observation); organize data through recording, labeling, translation and transcription; do interim analysis and provide feedback to the principal investigators. An REA team for each parent project site was organized by the REA PI in consultation with the parent project PIs. In the pilot I and III, parent project PIs were able to take part in the REA processes together with the REA team. In project II the parent project PI was not on site during REA. For projects I and II, the REA PI was leading the REA including the field investigation. In the project III the REA team was able to conduct the field part of the REA without the REA PI.

The REA team throughout the study was composed of the REA PI and three postgraduate students from Addis Ababa University, local area contacts, and translators identified for and from the specific locations. The REA PI is a medical doctor, public health specialist and ethicist by training and this is his PhD research

[38] Some of them already had a contact person in the field site which was very helpful for the REA.

[39] Identified based on language, duration of residence in the area. Usually identified from the study area during the initial introductory visits to the sites.

project. He speaks English and *Amharic*[40] very well. His roles were organizing REA teams, training the other team members on REA, developing data collection tools, doing interviews and FGD discussions, supervising the data collection and providing support as required. He was also responsible for contacting the parent project PIs, for getting official permission, and for communicating the feedbacks to the PIs of the respective research projects. The social-scientist team member was a social anthropologist by training. At the time of the data collection, he was a final year Master student in Social Anthropology at Addis Ababa University. He is well versed with qualitative data collection techniques, and ethnography. He speaks *Amharic* and English very well. He was involved in the first phase of the REA project as an assistant data collector to the REA PI. He assisted in data collection and transcription of the IDIs of the mixed methods study in Phase II. During the REA pilots, his roles were to retrieve secondary information about each of the sites, conduct interviews, and facilitate focus group discussions. He did translation and transcription[41] of interviews and focus discussions from *Amharic* recordings to English narrations. He also helped in organizing field logistics and took field pictures. During REA pilot in parent project III, he was the acting REA team leader. He led daily debriefing sessions of the REA team and was continuously communicating with and updating REA PI while on the field. The third and the fourth team members had similar profiles and roles. Both were public health officers and final year post graduate students at AAU in a Masters program in Public Health (MPH). They were given an induction about the project and the field work in this study. They both speak English, *Oromiffa*[42] and *Amharic* very well. They did interviews and ran FGDs in both *Amharic* and *Oromiffa* and did translations and transcriptions of into English transcripts.

In addition to the four constant members of the REA team, we also employed local contact persons and assistant data collectors at each site; who knew the area; who

[40] *Amharic* is the Ethiopian national and official working language. However, not everyone in Ethiopia speaks and understands Amharic as >80 languages are spoken in the country.
[41] Throughout the study no transcription was done in the languages of data collection (*Amharic*). All transcripts were written in English (the language of data analysis).
[42] *Oromiffa* is one of the most widely spoken languages in Ethiopia second to only the national language (*Amharic*). It is spoken mainly in the *Oromia* regional state which has a population of ~ 35 million

spoke the language very well, and were available throughout the study. They were 'insider'[43] members of the REA teams. In Butajira our local expert was a nurse, who speaks local language very well and has been working with BRHP for more than 25 years. In Admi-Tulu, we had a public health professional and malaria expert for the *woreda*[44] health office at Zeway[45]. He is permanent resident and speaks the local language *Orommifa* as his mother tongue. In Ayra we had a high school teacher, who taught in the area for > 20 years and is fluent in *Oromiffa*. The local expert in Soddo also was born in the area and was fluent in *Wolayitegna*[46] and is a public health professional working in Wolayitta-Soddo University.

iii) Initial site visit and communication with the field site: During the initial site visits[47] a meeting with the focal person was conducted. When there was no focal person pre-identified, the first point of contact was the health bureau of the *woreda* who facilitated the process and helped in identifying an appropriate local focal person to work with the REA team. In addition, official permission was sought based on letters written from AAU/SPH and project ethical clearance. Whenever possible, all the REA team members went for the initial preparatory visit so that they could start to get to know the place and important points of contact for the actual field study.

[43] According to the principles of Rapid Assessments, the assessment team is supposed to have an insider, who brings perspectives to the team representing the community under study.

[44] *Zones*, *Woredas* and *Kebeles* are parts of the hierarchical administrative levels in Ethiopia. The country is politically divided into 9 regional states or regions where each regional state administration is accountable to the federal state. Each region is sub-divided into sub-regions (*zones*). *Zone* is a sub-region with recognized *zonal* government structures and administrations accountable to its regional government. Each zone has its own *zonal* capital where most government offices and public services are located. Currently Ethiopia has 68 Zones and *Zonal* administrations. Each *Zonal* administration is again sub divided on to *'Woredas'*. A *woreda* is equivalent to a district with recognized district (*woreda*) government structures accountable to its *Zonal* administration. Currently there are more than 900 *woredas* (districts) in the whole country. Each *woreda* is again divided into sub-districts known as *kebeles* (equivalent to villages) with an average of 5,000 residents. Each *kebele* is considered as the lowest level of a local government administration with major public services and appointed government officials and offices.

[45] Zeway is the district town where the government offices and the major business centers such as banks etc are located. It is about 5 Kms from Adami Tulu.

[46] Wolayitegna is the main language in Soddo town and Wolayita Zone.

[47] The first site visits were done for the purpose of creating first contact with the study sites before the actual field studies.

iv) Final preparation for the field: Final preparations for the field included finalization of REA tools, logistic arrangements; and conducting meetings amongst REA members to brainstorm on expectations and arrangements. Tools were translated to local languages; data collection materials such as recorders and camera were prepared; transportation and accommodation arrangements were done.

v) Field study and data collection: Once on the field, the first meeting was on-the-site planning by including the 'insider' member of the REA team; a schedule was planned, sites to be visited were mapped including a list of individuals and groups to be interviewed. The very first interviews were usually done with a key informant knowledgeable about the area and its inhabitants. This individual was asked to recommend others to be interviewed. The following were important guiding principles for the REA team during filed studies in all the sites:-

- Working with the existing local government structure: as far as possible we always contacted the *zonal*, *woreda* and *kebele* administrations and sought permission before conducting any data collection. This is an important procedure and in addition helped facilitate our entry into the community.
- Team spirit and division of labour: the group members stayed together in the same accommodation, ate together and travelled together. This helped to maintain the group bonding. Discussions were often held over meals and in the car while travelling between study sites. Tasks were shared as needed among the group members.
- Daily debriefing: The REA team met every evening after the data collection as part of the interim analysis and for planning the next day's activity.
- Maximizing opportunities: not only the formal and planned sessions but a number of informal discussions were conducted as issues emerged. An example was frequent discussions held with locals in restaurants during meals.

vi) Data Management and Analysis: Data were constantly reviewed and data collection process regularly monitored to maintain data quality. The data analysis had

two aspects; for immediate use and for further documentation. Preliminary analysis was done on-site for immediate use. A detailed analysis was done afterwards for documentation and wider dissemination. The preliminary analysis served three purposes; it generated information on the emerging ethical issues[48] to be addressed by the parent project PIs; the REA team modified the data collection guide based on any emerging theme that needed to be explored more; and the decision to stop data collection was made based on information saturation. The preliminary analysis was done through 'debriefing' sessions among data collectors. Every day, the REA team met to de-brief and do field analyses based on the day's data. More in-depth analysis of ethical issues and the REA process to produce formal documentations began once all the field data collection was completed, as input for the formal scientific report.

vii) Field data analysis: In the daily debriefing sessions, every evening REA team members identified various emerging ethical issues. Summary notes were taken to list the emerging issues. By the end of the field work we had a list of issues identified this way. This helped in summarizing the feedback to be provided to the parent project PIs. This quick analysis helped the parent project PIs who wanted to embark on their field work not long after the REA.

viii) Communication of findings: There were three levels of communication; discussions within the group members, feedback for the parent project PI, and communication based on in-depth analysis and write-up of formal report. In the first pilot project, the REA team had a debriefing session with the parent project PI after the field visit and we provided him with the list of issues identified and discussed what would be the best consideration in the consent process for the study. The parent project PI also invited us to attend the parent project pre-test sessions and training of data collectors which helped a lot in providing feedback to the parent project data collectors as well. In the second project, a written briefing was provided to the project

[48] Ethical issues are issues identified as a result of the REA findings which needed to be addressed by modifying informed consent information, the communication mechanism or the way how consent decision is made in the informed consent process

PI. In the third project the PI was part of the REA team and took part in the debriefings and final feedback session.

ix) Detailed analysis: A detailed analysis with transcription, translation and detailed coding of the text data was done after completion of field data collection in all the sites. The analysis was done by the REA PI based on the English transcripts from IDIs, FGDs, debriefing summaries and observation notes. All transcripts were entered into computer assisted qualitative data analysis software (CAQDAS), for the qualitative data analysis. NVIVO 10[49] was used to serve this purpose. Both open (detailed and specific) codes[50] and axial (broader and overarching) codes[51] were used. Once the first cycle coding[52] was completed, a second cycle coding[53] (thematic analysis) was done based on the codes. Thematic areas were related to the pre-identified and emerging ethical issues[54] and feasibility[55] of REA. Once the analyses were completed, the findings were written in a scientific report format and incorporated in this thesis chapters V, VI and VII.

3.2.2.3. Comprehension Assessment

As part of the REA pilot, a quantitative comparative intervention study was done in one of the REA pilot sites of parent project III to assess the potential influence of REA on informed consent comprehension, study recruitment, compliance, and quality of informed consent process.

[49] NVivo - 10 is the tenth version of NVivo. This CAQDAS has several version which progressively improved in function. The principal investigator took an intensive course on NVivo prior to the data analysis. (NVivo®. (2013). from www.qsrinternational.com/.)
[50] Open codes are free codes of the transcripts that are imbedded on the text data. The coder does not have any pre-identified codes in mind. The codes at times could be based on the actual words used in the transcripts (in vivo code).
[51] Axial codes. These are broader codes based on pre-identified categories and the text are assigned to codes which belong to similar categories.
[52] Assigning codes to the transcripts.
[53] Re-code by assigning categories for the codes from the first cycle coding.
[54] The ethical issues (see ealier foot note)
[55] The variables of interest for REA implementations process assessment included cost, ease, acceptability and technology transfer etc. These were used as input for the 'feasibility assessment' conducted in Phase III.

Study Area and Period: The field study of comprehension assessment was conducted from July 8 to August 23, 2013, in the Tigray Regional State of Northern Ethiopia, in the surrounding sub-urban woredas of Mekele Town[56] namely Wukro-Keleteawlelo[57] and Hintalo-Wajirat[58]. Both are located in the eastern zone of Tigray Regional State.

Study Design: Comparative, quantitative, intervention study design was employed to compare comprehension and related outcomes between the groups with and without an intervention. Our intervention was modification of the informed consent process based on REA. For the comparison group, the consent process was not modified. The two groups were compared for comprehension, recruitment and retention (compliance) and perceived qualities of the consent process.

Source and Study Population: The study and source population of the parent project (HPV sero-survey) in the selected woredas were considered as source and study populations for the comprehension assessment. The same inclusion and exclusion criteria as set in the HPV sero-survey were used. Healthy pregnant women who were 18-45 years old attending ante natal care (ANC) follow up in the four selected health facilities during the study period were included. Those with communication challenges; with severe illness; gestational age greater than 34 weeks, and not willing to return after two weeks for the follow-up interview[59] were excluded.

[56] Regional capital for the Tigray regional state.

[57] Wukro is 47 km north of Mekelle with total area of about 988 square kilometres (Mekelle City Administration (2008). Mekelle City Administration Report). As projected by CSA the total population as of June 2005 was 107,862 (with 60,330 females and 57,532 males). The health service coverage in 2003/04 for the study area was 59% and the antenatal coverage 68.4%. The largest ethnic groups reported were the Tigray (96.2%). Tigrigna is spoken by 95.5% (CSA (2007). Ethiopian Population and Housing Census).

[58] Hintalo-Wajirat Wereda (Adigdom the woreda capital) is 37km from Mekelle. The total area of the Wereda is approximately 1393 square kilometres. The wereda comprises of 7 health centres. According to the CSA 2007/8, the total population is estimated to be 152,219 (75,262 males and 76,957 females). Of the total population, 11,928 (7.8%) of them live in town and the remaining 140,291 (92.2%) live in rural areas (CSA (2007). Ethiopian Population and Housing Census).

[59] The follow-up period was the time when the test for comprehension was to be done.

Sample Size Determination: Sample size was determined using sample size formula for double-population proportion

$$n = \frac{P_1 (1- P_{1)} + P_2 (1-P_2) X f (\alpha, \beta)}{(P_2 - P_1)^2}$$

where ;

n	:	number of participants per group
P1	:	expected levels of outcome in the control group
P2	:	expected levels of outcome in the intervention group
α	:	degree of error
β	:	power of the study

To estimate expected levels of comprehension we used a comprehension assessment findings from South Africa which showed a score of 75% informed consent understanding (Minnies, Hawkridge et al. 2008) (P1 = 0.75); we assumed an improved level for comprehension of 13% (P_2 = 0.88); 80% power (β = 0.80) ; and 95 confidence interval (α = 0.05)[60]. After adjusting for 10% non-respondent rate, the total sample size required was 300 participants (150 per group) with a 1:1 ratio between intervention and control groups .

Sampling Procedure: Two of the woredas targeted for the HPV sero-survey were selected purposively based on comparability and proximity to Mekele. The selected woredas were randomly assigned by lottery method to either intervention or control. Health centres (HC) in each woreda were short listed based on selection criteria; availability of ANC service provision, availability of lab services, and appropriate professionals to collect and handle specimen and flow of adequate number of ANC clients. Two health centres from each woreda (a total of four health centres from both woredas) were randomly selected from the short listed health centres. Sample size was proportionally allocated to the health facilities in each woreda based on reported

[60] A(α, β) = 7.85;

flow of ANC clients in the previous one year reported by respective woreda health offices (Figure 3.5).

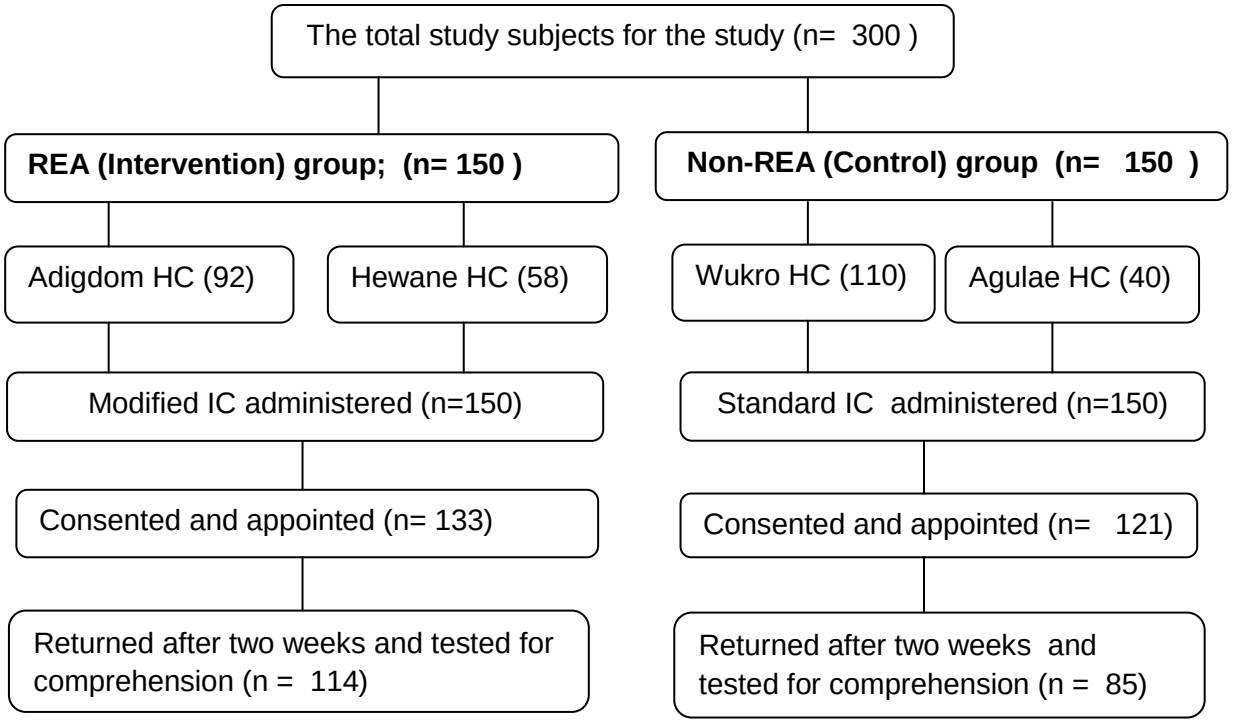

Figure 3.5 Flow-Chart showing the sampling procedures for the study, Tigray, Ethiopia, July - August, 2013

Data collection procedures, instruments and variables: Participants in the intervention group were provided with a modified information sheet and consent form, which was developed after and based on the findings of REA. Major REA findings included low awareness of the concept of research (therapeutic misconception), presence of indigenous descriptions and terminologies for technical disease-related terms; concerns about biological samples; major discomfort around signing a consent form; discomfort with male enumerators; suspicions surrounding study selection criteria; concerns with outsiders coming to the community with incentives; and concerns over test results and their implications. These findings dictated the need for further elaboration on some of the components of the research, for extended discussion on the issues identified, and for change in the consenting mechanism.

Based on the findings, the consent form and information sheet, consent process and the data collection procedures were modified by the REA team. The standard IRB-approved consent form was revised to address the issues highlighted and this revised version was employed for the intervention site (Annex B). Revisions included use of local terminologies, concrete explanations of study information with examples, and contextual clues based on the REA findings. Consent information was provided by reading the information sheet to participants in both groups. In the intervention group, this was accompanied by additional narratives which were attached to the consent document based on the issues identified by REA (Annex B).

Participants in the control site were provided with the information sheet and consent form developed by the PI of the parent project and approved by the IRB. Both the study participant and the consent providers were double blinded and did not know which consent form had been used to enrol. Neither were they aware of the comprehension assessment component of the study. Those who consented to the study were given an appointment to return after two weeks, during which assessments of the comprehension and quality of the IC process were done.

Data were collected using structured questionnaire-based interviews. We used MICCA and BIQ to measure informed consent comprehension of participants and QuIC to assess quality of the informed consent process in this project (Annex B). These two instruments were developed to address the gaps in the other comprehension assessment tools. They have the flexibility to test comprehension specific to a particular trial, yet can be utilized across a variety of trials. MICCA measures comprehension by incorporating both generic and trial-specified approaches. Results of psychometric study provide preliminary evidence that the MICCA can be utilized in various clinical trial settings and can produce reliable and valid scores (Buccini 2009a). The MICCA and BIQ instruments for our assessment were developed, by adopting the existing generic tools (Annex B).

Dependent variables for the study were informed comprehension score, quality of informed consent process, recruitment and compliance rates. Independent variables included socio-demographic variable, previous exposure to clinical trials and modifications of consent based on REA.

A total of 25 questions were used to assess informed consent comprehension of participants, of which 13 questions were to assess understanding and the rest (12) were for recall. The comprehension assessment tool included 13 questions with either a 'True' or 'False' answer; 7 multiple choice answer questions (MCQ) with a single correct answer and 5 check-box choice questions with multiple possible answers each scoring 1 point. The test items consisted of both generic and trial specific questions. Of the 25 test items, 14 were generic test items that appear on each version of MICCA, 6 were trial-specific test items which were generated based on responses to BIQ and the 5 remaining were trial-specific test items in which the response options for each of the test items are generated based on response to BIQ. Each correct response was scored as 1, while each incorrect response was scored 0. For multiple choices with more than one correct response a score value of 1 was given for each possible answer (Annex B). All the correct answers for understanding and recall were separately summed and calculated out of hundred.

The MICCA (+BIQ) and QuIC based questionnaires (Annex B) were initially prepared in English and then translated to Tigrigna. The Tigrigna version was translated back to English to check for consistency of meaning.

Data collectors and supervisors: For the initial recruitment and consent-taking procedures, the data collectors were ANC-providing nurses from the respective health centres, who had been trained to provide the information sheet and ask for consent to participate in the parent study. During the comprehension assessment, the data collectors had undergraduate degrees in nursing and all were trained on use of the assessment tools. Data collectors were supervised by public health experts who are MPH candidates with adequate orientations.

Data Quality Assurance: The following measures were taken during data collection to increase the validity and reliability of data.

a) Double blinding: The data collectors and participants were blinded regarding the intervention status of the individuals in the study.

b) Pre-test: The translated Tigrigna version questionnaires were pre-tested prior to the actual data collection in the same facilities on 15 respondents that were not included in the main survey. The result of the pre-test were discussed, and some corrections were made to the questionnaires.

c) Supervision: The REA PI and field supervisor rechecked all questionnaires daily to check for accuracy and completeness. During data collection, the supervisor checked study sites at least once a day. Anything that was unclear or ambiguous and incomplete was corrected on the next day.

Data Analysis: Data were pre-coded and entered into a data-base using Epi-Info version 3.5.1 and subsequently cleaned and edited using simple frequencies and cross tabulation before further analysis. For further analysis, data were exported to SPSS Version 16. Descriptive statistics were generated and used for describing the study population in relation to relevant variables. Regression analysis were done for comparative analysis and assessing association between dependent outcomes and independent risk actors. Risk ratios with 95% confidence intervals were used to assess associations between dependent and independent variables. Multivariate logistic regression was used to control for confounders and adjust measures of association. The results are presented in chapter VI.

3.2.2. Phase III: Assessing Feasibility of REA and Finalizing REA Guidelines for Further Application

This third and last phase addressed practical considerations related to feasibility of REA and its further use by other researchers. A workable template of REA tools was presented; a guideline on how to conduct REA (practical issues on which project, how

to form REA, training etc.) suggested and a tool kit introduced. REA tools designed for web-based dissemination were introduced as strategies to finalise REA tools and dissemination strategies.

As will be discussed below, we conducted dissemination workshops, feasibility assessment analysis and revision of REA tools.

i. Dissemination Workshops: We conducted two REA workshops. The first was a half-day workshop with Ethiopian health research stakeholders to comment on and endorse the tools developed to bring *REA* into the Ethiopian research context. The second workshop was another half day workshop with researchers from Ethiopia and other African countries. Based on the feedback obtained, REA tools were further revised.

Figure 3.6 REA Workshop II, AEFENET conference, UNCC, Addis Ababa, October, 2013

Workshop I (Addis Ababa University, October 2013): The participants of the workshop held at Addis Ababa University were faculty members and PhD students from the School of Public Health. The workshop was announced by e-mail through the PhD program coordinators at SPH. The total number of participants was 21 which were mainly SPH faculty and PhD students from the college of health sciences. The workshop was facilitated by REA project PI and his PhD supervisor[61]. The participants were motivated in the desire to learn more on the ethics of research. There was high level of participation and interest throughout the session.

Workshop II (AFENET Conference, November, 2013): The workshop was one of the pre-conference workshops for the AFENET conference[62]. The participants of the workshop were researchers, faculty members and post-graduate students from Field Epidemiology Training Programs (FETPs)[63] in Ethiopia and six other African Countries. In addition there were participants from public health schools in other Ethiopian Universities. The workshop was kindly sponsored by the Ethiopian Field Epidemiology Training Program (EFETP) through a grant from CDC. The workshop announcement was web-posted on the African Field Epidemiology Network (AFENET) website and interested participants were invited to register. There was very keen interest in participating in the workshop. The workshop was attended by 32 participants. The initial interest for the workshop was driven mainly by the desire to know more about the ethical issues of community-based research. There was active and enthusiastic participation as the attendees raised critical questions on REA and its application.

The workshop was piloted in a progressive manner; the workshop for PhD students and staff at AAU was followed by the workshop African Field Epidemiology Network (AFENET) for African field epidemiologists and faculty. Data and findings from the workshops were used as input in to feasibility assessment and development of REA

[61] My supervisor, Prof Gail Davey, was in Addis that week and helped in the facilitation of the REA and provided important feedback at the end.
[62] http://www.afenet.net
[63] Field Epidemiology Training Programs are advanced post graduate trainings on applied epidemiology following the EIS (Epidemic Intelligence Service) training model from CDC Atlanta in the US.

guidelines discussed below. As part of wider dissemination, a third workshop was also planned to be held with the objective of introducing the revised tools to a wider audience including researchers, ethics committee members, relevant NGO representatives, Ministry of Health civil servants and community members. The workshop was planned to be held over 3-5 days with practical, hands-on elements to create skills in using REA and to encourage its adoption throughout the research community. Due to time constraints, it was not possible was postponed for a later date. In addition, a database will be developed and publicised so that the findings of REA pilot are available to interested parties conducting research in Ethiopia. At the moment REA is under discussion in the Global Health Trials website[64]. We plan to further disseminate the tool and techniques for researchers with case studies and training guides.

ii. Feasibility Assessment: Based on data from the three Phases of the REA project, feasibility analysis was conducted. Feasibility in terms of time, cost and skill were assessed; how much does REA cost, what skills are needed, and are the skills transferable? Who will conduct the REA, the researcher or another expert? Is it acceptable to researchers, and do researchers trust the tool? Is it possible to integrate the tool into existing research ethics appraisal systems? Is this approach sustainable? Is it user-friendly and cost effective? Feasibility assessment study was needed to deal with all these concerns. Relevant data were extracted from Phase I, Phase II and Phase III.

From Phase I, we retrieved data on the views and opinions of Ethiopian research ethics stakeholders on the feasibility of REA. Findings from second Phase addressed process feasibility based on the documented experiences and outcomes of introducing REA into three community based research projects in Ethiopia. In the third Phase, additional feedback on REA was obtained from researchers from Ethiopia and other African countries who participated in our REA workshops.

[64] http://globalhealthtrials.tghn.org

We followed the same steps in analyzing the qualitative data for ethical issues as depicted in the methods section of Phase II. We triangulated findings from all three phases of the project to identify relevant themes related to the various components of feasibility. Transcripts, memos and summaries of interviews, discussions and observations were coded to identify patterns and emerging themes in line with the variables of interest. Following the coding of responses using themes, we categorized and synthesized the results thematically. Thematic variables used to measure the various components of feasibility included attitude and perception about REA, satisfaction with REA, suitability of REA, perceived demand and expressed intent to use REA, actual use of REA, expertise and resources needed and available for REA (such as time, financial costs, human resources), training and skills needed, efficiency of implementation in terms of adaptability and flexibility; accommodation of the tool into the system and scalability (Annex C).

Based on the findings from Phase I, we did a need and acceptability assessment among research stakeholders. Findings from Phase II provided information on practicality of REA in terms of resources, further levels of acceptability by researcher, implementation and the possibility for adaptation. Based on Phase III feasibility of adaptation, integration and expansion of REA in the existing system in Ethiopia were assessed. The results of the feasibility assessment are presented in chapter VII.

iii. Refinement of REA Tools and development of REA guidelines: REA tools were further refined and validated for use in subsequent research projects in Ethiopia. This was done to come up with detailed guidelines on how to conduct REA for consumption of by researchers for further use. Three phases have been important in the evolution of the tools.

a) *Adaption of Rapid Assessment (RA) tools*: The basis for developing the REA technique in our project has been earlier work by researchers such as Bull, Tekola, Farsides and others (Bull 2007; Tekola, Bull et al. 2009a; Bull, Farsides et al. 2012). We adapted the tools and techniques employed earlier based on further reading,

training in qualitative methods and discussion with experts in anthropology, ethnography, ethics and philosophy. From these discussions, we developed a list of methodological approaches and tools for the REA field study. We designed provisional REA field methods and tools based on the experiences of researchers who pioneered REA. We tried to build on their experiences and recommendations. In addition, we paid attention to the fundamental principles of qualitative and ethnographic enquiry and action research.

b) *REA Field Pilot*: The adapted REA tools were further tested out in the field as explained in Phase II of the methods. We employed REA in three different projects in five field sites in different parts of Ethiopia. As described in chapter VII, this field pilot enabled assessment of the feasibility and relevance of the various tools. In the process of REA implementation we were also able to make adjustments and improvements from one pilot study to the next.

c) *REA Workshops*: We were able to conduct two REA workshops based on the refined REA tools. The tools were demonstrated to workshop participants, who were given a practical case-study based on one of the research projects chosen for the pilot. Feedback from the participants was obtained at the end of each workshop regarding usability of the approach and any improvements recommended. Feedback was collected both in written through a questionnaire and discussions with participants (Annex C). The same guiding principles were maintained during the field pilots. However due to time limits our workshops were mainly for REA dissemination and getting feedback on the method from researchers than 'validation' in its strict sense. The reflections included important feedback on the application of the tools and valuable recommendations on how the tools can be improved in future implementation. The workshops gave us a sense of interest towards and perceived practicality of the tools. Our results are presented in chapter VIII.

3.3. Additional Methodological Issues

Ethical Issues, Data Management and Sharing Policy

Ethical approval for the REA research project was obtained primarily from Institutional Review Board (IRB) of the College of Health Sciences (CHS) at AAU (Annex G). Additional approval was also obtained from BSMS Research Ethics and Governance Committee in the UK. Formal permission to conduct the study was obtained from the organization managers and research project PIs of the projects selected for REA pilot. All the three parent studies in which REA was piloted obtained ethical clearance from recognised IRBs and were granted permission by the respective local administrations. Documented individual consent was sought from each participant during data collection. The purpose of the study was adequately explained and they were informed that participation was only on voluntary basis.

The data generated represent information from respondents about their beliefs and personal opinions and about societal values related to research conducted in their own environments. Any data with personal information was handled with confidentiality, and privacy of subjects respected at all stages of the project. Respondents' privacy was respected through informed consent and the right to withdraw. Personal identifiers (including name) were not recorded. Once information was collected, the primary data were handled only by the researchers, and the database was password protected. During data analysis, data were stored through a password protected system and data were analysed using codes, without personal identifiers. Data ownership is for the project and the research community at large. During report sharing and communication of results, no personal individual identifiers like name or physical address will be used. The database created will be accessible to interested research community members, potential users first applying for permission to access the data. The study was financially supported by the Wellcome Trust (WT) through Biomedical Ethics Doctoral Fellowship 089769. However WT had no part in the execution of the study and write-up.

Chapter 4 : Perceptions of Research Stakeholders' on the Relevance of REA

> *[Y]ou don't go to the field with your backpack and say I am from France, assuming these people are subjects and they will agree; this is what was done in the old days. Now, in the community, you have to try to teach them as much as possible, telling them the pros and cons of the research. [T]hey have to negotiate their benefits.*
>
> Researcher from AAU

This chapter focuses on the findings from Phase I, on opinions and perceptions of relevant research ethics stakeholders regarding challenges in the informed consent process and perceived relevance of introducing REA as a mainstream tool for addressing ethical issues for health research in Ethiopia. Phase I research was conducted to map out entry points and lay the groundwork for piloting REA tools, by exploring how REA is perceived by various research stakeholders including researchers, ethics committee members and policy makers. A mixed methods study with explanatory approach was conducted in four major Ethiopian health research centres. Quantitative and qualitative data were triangulated in drawing findings. Detailed background information and methodological issues have been provided in Chapters I and II respectively.

4.1. Results

Quantitative analysis was done for 241 complete responses, with a 89.3% response rate. Majority of the respondents were males (86.3%) and in the 26-35 year old age group (42.7%). While 82.8% were from the four target institutions AAU, EHNRI, JU and UoG; the rest were collaborators on research projects with the four main target institutions from the Armauer Hansen Research Institute (AHRI), the Federal Ministry of Health (FMOH), the Ministry of Science and Technology (MoST) and the Ethiopian Public Health Association (EPHA). More than sixty percent of respondents were either

medical or public health professionals and 87.1% had postgraduate or specialty medical education; either Master's degree, clinical residency or PhD. The rest had undergraduate training with or without post graduate diploma but with relevant research experience (Table 4.1.)

Most respondents assumed roles as principal investigators (82.2%), or co-investigators (74.3%). More than two-third (69.7%) had taken roles as data collectors or field workers and one quarter had been a member of an Ethics Committee. More than one-third (34.4%) of the researchers reported that they had never had any training on research ethics (Table 4.1). The types of training courses attended by trained respondents included orientation sessions (36.1%), certified short training courses (43.7%), academic training courses[65] (37.3%) and other training courses (such as on-line) (11.4%). Respondents of the qualitative study were 19 researchers, faculty, IRB members and policy makers from AAU, EHNRI, JU and MoST. The majority (14/19) of the IDI respondents were males. All the respondents had experience working in various places in Ethiopia. Except one IRB administrator who had a first degree and many years of experience, all had post graduate qualifications.

[65] university courses including diploma and degree level training

Table 4.1 Socio-demographic profile of respondents (research ethics stakeholders) to the online survey on REA, September, 2012 (n=241)

Variable	Frequency	%
Sex		
Male	208	86.3
Female	33	13.7
Age		
<26	19	7.9
26-35	103	42.7
36-45	71	29.5
46-55	39	16.2
>55	9	3.7
Institution (241)		
Addis Ababa University	87	36.1
Jimma University	49	20.3
EHNRI	35	14.5
University of Gondar	27	11.2
Others (MOH, MOST etc)	43	17.8
Highest qualification		
Bachelor	20	8.3
MD/DVM	14	5.8
Masters	129	53.5
Specialty	32	13.3
PhD	35	14.5
Others (e.g. PGD)	11	4.6
Major Training (multiple responses)		
Biology	28	11.6
Public Health	90	37.3
Social Science	13	5.4
Medicine	63	26.1
Laboratory	33	13.7
Nursing	19	7.9
Others*	63	26.1
Roles in research (multiple responses)		
Lead researcher/ PI	198	82.2
Co-investigators	179	74.3
Data collector	92	38.2
Field Worker	76	31.5
Ethics committee member	62	25.7
Data encoder	23	9.5
Other	19	7.9
Training on research Ethics		
Yes	158	65.6
No	83	34.4

* e.g. Environmental health, health promotion etc

4.1.1. Informed Consent Process and its Gaps

Most survey respondents believed that preparation of consent for research is performed by the principal investigator without prior assessment of potential context-specific ethical issues (58.9%). Only 14.5% thought the best interests of study participants were sufficiently considered; 15.4% claimed to be satisfied with the current process by which consent forms are developed and implemented, and 40.2% thought the consent information and the consent process were adequately understood by the study participants. The most frequently reported challenges in the consent process were; lack of clarity of information sheet (48.1%), inadequate information provided for study participants (34%), use of inappropriate language (28.2%), failure to understand cultural differences (27.4%), undue expectations (26.6%), power imbalances (20.7%) and coercion (7.9%) (Table 4.2). According to IDI respondents, research consent process is mainly dealt with by individual researchers who in most cases have very little experience and training in research ethics. At times, they may seek counsel from experts in the area. As a result, there is a tendency to perceive ethics review as another bureaucratic step rather than for the scientific and moral merits it may have. Several researchers perceived ethical review as discouraging and mere administrative matter. On the other hand, respondents agreed that there needed to be review of certain types of research but not for all research. Most were sceptical about the amount of time it takes for review of simple projects such as secondary data analysis. Coming to the review process, this is done based on what is stated in the protocol, and what happens in the field is not known. After ethical approval has been granted, there usually is no mechanism to check on comprehension of study information by study participants.

IDI respondents further alluded to the following gaps and problems in the current consent process; language challenges, lack of adequate awareness on the research subject matter by participants, undue expectation and manipulation by researchers.

Language: In Ethiopia it is mostly assumed that *Amharic*, as is the national language, will be used in all parts of the country and will serve the purposes of gaining consent.

Table 4.2 Opinions of Researchers from Various Ethiopian Institutions on the Consent Processes and gaps, September, 2012 (n=241)

Variables	Frequency	%
How is consent form developed in your experience? (multiple responses**)**	142	58.9
By the investigator	70	29.0
With prior ethical assessment	41	17.0
With stakeholder participation/consultation	17	7.1
By the sponsor	13	5.2
Others (research advisors, collaborators, students)		
Opinions on consent process		
Do you think all participants understand consent forms well?	97	40.2
Yes	144	59.8
No		
Based on your experiences, are you satisfied with the way the consent process was designed and conducted? (Y/N)	37	15.4
Yes	204	84.6
No		
Do you think that the best interest of study participants is taken in to consideration and adequately addressed through the current ethical appraisal and consent processes?	35	14.5
Yes	206	85.5
No		
Important Gaps in the Informed Consent Process		
Based on your experiences, what do you think are the most common problems in the current consent process?	116	48.1
Lack of clarity	82	34
Inadequate information	68	28.2
Language	66	27.4
Cultural difference	64	26.6
Undue expectations	50	20.7
Power imbalance	19	7.9
Coercion	11	4.6
Others		

However, Ethiopia is a diverse and multi-ethnic country, where there are many other languages and dialects[66]. Failure to understand differences may be problematic. According to the national guidelines, all consent documents in a research protocol need to be translated into the national language and the language of data collection which is often not Amharic. This is an important point in the ethics review checklists of key ethics committees. However, mechanisms of ensuring whether the right language is used in the field are lacking. In certain societies, the terms and concepts of research and most medical terminologies do not exist. In addition, concepts of health and disease may be based on local traditional understandings rather than the modern medical models used by researchers.

> *When we come to information, there is a problem of language. Ethiopia is a diverse country, so even when you translate to Amharic, it is hard to bring the understanding, it is hard to translate scientific words to Amharic.* [Researcher, AAU]

Lack of awareness about research, health and ethics: Generally there is little understanding about science and research, especially among communities with very low levels of literacy. Thus, participants might consent or decline to consent due to their lack of comprehensive understanding about the scientific research process.

> *The society might be where they have no knowledge about research*. *People might also not understand what is written if they can't read. These are (some) loop holes.* [*Researcher, EHNRI]*

> *E*ven, *the participants don't know what research is ... [T]hey don't know whether the research has benefit or harm ... [they] say yes [or no] without knowing it*. [Researcher, JU]

> *In Ethiopia, most places where research is done, the people don't know how to read and write, so how much do the researchers need to explain?* [Researcher, AAU]

Undue Expectations by participants and manipulation by researchers: There is a tendency to expect direct benefits from the research by its participants and undue promises are given by field workers just for the sake of obtaining consent. This

[66] Ethiopia is a country of over 80 ethnic groups and more than 80 different languages spoken, while *Amharic* is considered as the official working language.

especially occurs in rural communities due to misconceptions and failure to comprehend the intended purpose of research.

> *There is also this thing, ... (even with) the tone of your voice, you might emphasis mainly the benefit, there might be some persuasion. (And), they have to believe in it.* [Researcher, JU]

Undue focus on consent and recruitment [without adequate information]: There is a tendency to focus more on the consent i.e. the decision to participate than on 'informed consent' which should be based on prior information and comprehension. Participants decide to take part without adequate information or with misinformation. As long as consent is given it is considered alright.

> *There is a lot of negotiation and bargaining (around consent), which is not a proper way of getting consent or a proper consent (process) application.* [Researcher, JU]

Undue emphasis on rules and procedures: Respondents felt that there is too much emphasis on fulfilling requirements and procedures than fulfilling a genuine concern for the rights and welfare of study subjects. Researchers cannot proceed without these requirements and for most researchers 'research ethics' is about completing paperwork to get the 'ethical clearance letter'. The regulators also focus more on the of the rules without proportional levels of creating awareness among researchers and the research community. Most regulators do not explain to researchers the reasons for which a rigorous review of research proposals is needed. The undue emphasis on rules and procedures has created discouragement on the researchers' side. Researchers expressed their concern that too much emphasis on the rules and procedures may eventually discourage and hamper the progress of research and science.

> *Even the Civil law has been too protective to the extent of not allowing the conduct of trials – Ethics should not hamper Science!"* [Researcher, AAU]

Participants mentioned that ethics review in Ethiopia is a relatively new phenomenon. The system is not very uniform and relies on the experience of very few individuals. The national guidelines were thought to be old and ripe for review. Thus the need for rigorous and tailored ethics review was mentioned. Respondents emphasized the need for addressing research ethics in proportion to the expansion in health research in the country. The following are major themes of suggestions given by the survey respondents as ways of addressing the problem in research ethics and improving the consent process.

- *Training:* Ethics training courses were suggested by the respondents as important avenues for improving consent process and ethical standards in general. The training courses could be for researchers, health professionals or the general public. Suggestions on how the training courses might be delivered included integrating the course into research methodology courses and making them part of undergraduate and postgraduate degree programs.

- *Field visits*: Field visits were suggested to follow how consent and other ethical procedures stated in the protocol are actually being implemented in the field. Depending on the nature of the study, these visits might be conducted before the study or after the study, in order to monitor the implementation of consent or any emerging issues. The mandate of deciding which projects need follow-up, and coordination of the follow-up would be that of the IRB.

- *Involvement of the community/participants*: Respondents suggested that the community needed to be involved in the research process in various ways; including community representatives in ethics committees, and seeking the opinions of community leaders on potential ethical issues prior to and during research. Mechanisms suggested included approaching and involving the community through Community Advisory Boards (CAB).

- *Pre-assessment*: Doing an assessment prior to the actual field study in order to identify potential context-specific ethical issues by involving potential study participants in the assessments. Others suggested involving the community advisory board rather than study participants. (See 'involvement of community' above).

- *Differentiated approach (depending on the type of research)*: Participants emphasized the importance of acknowledging differences in contexts and designing approaches accordingly. The application of interventions to improve consent processes would depend on prior knowledge of the research design and anticipation of emerging ethical issues. Approaches would depend on the type of research design and the sensitivity of the issue to be addressed by the research. It was repeatedly mentioned that clinical trials would be ideal for such interventional approaches.

- *Balanced approach, 'not to be a hurdle for research':* Out of concern that too much emphasis on rules and regulations might discourage researchers, respondents mentioned how important it was that ethical regulations did not become a hurdle to research itself. The importance of striking the correct balance was also reflected in informal discussions with researchers.

4.1.2. Importance of REA

Regarding the importance of conducting pre-assessments to explore potential context-specific ethical issues for designing the consent form, 95.4% of the survey respondents agreed it was important to contextualize consent to the setting; 81.3% thought it was important to approach participants before the study to get input into the consent process; 71% thought it was important to involve local people in consent design in some way; 39.4% agreed to the idea of doing an additional and separate rapid assessment of the local situation such as REA before designing the consent process, with 12% reporting that they already knew of similar initiatives (Table 4.3). Conducting a prior assessment at the beginning of a study with the aim of exploring context-specific

Table 4.3 Opinions of researcher from the research institutes regarding the need for REA, September, 2012 (n=241)

Variables	Frequency	%
Do you think it is important to contextualize consent forms and consent processes to local settings?		
Yes	230	95.4
No	11	4.6
Do you agree with the idea of the study participant be approached in advance before the start of the study to get input for the development of the consent form and to find out how it should be administered?		
Yes	196	81.3
No	45	18.7
Do you think that study participants should be involved, in the development of consent forms and designing of the consent process so as to make it culture and setting sensitive?		
Yes	171	71
No	70	29
In your opinion, would REA serve adequately addressing the consent process issues and in making sure that ethical issues are very well addressed in a research process?		
Yes	95	39.4
No	146	60.6
From your experiences, is there any initiative so far; is there any initiative that involves the study participants in the development and design of consent information sheet and consent process?		
Yes	29	12
No	212	88

potential ethical issues was considered a good idea by most IDI participants, but there were concerns surrounding its practicality and feasibility. Briefed about REA, the majority appreciated the tools. However, there was confusion about the term ‘rapid’. Many thought that this was about a 'rapid' ethics approval process. The term was explained as a method of assessment used to explore the ethical issues in a relatively quick fashion at the beginning of the study and had nothing to do with speeding up the process of ethics review. Once they had understood the concept and its intended purpose, most respondents saw REA as a reassurance that would guarantee the community’s role as a stakeholder in research and would ensure the community’s concerns with regard to ethical issues. There was agreement among most that in any research, the community needed to be contacted to seek counsel from them ahead of time regarding their concerns including ethical aspects of research projects.

> *You don’t go to the field with your backpack and say I am from France, and assuming these people are subjects and they will agree; this is what was done in the old days, now in the community, you have to try to teach them as much as possible, telling them the pros and cons of the research,...they have to negotiate their benefit.* [*Researcher, AAU*]

> *Things that are important to the local people might not be important to others. To make it relevant to the local people, we need to ask questions like “do you have any concerns?”, “do you have a question?” at the piloting time.* [*Researcher, JU*]

Respondents were asked if they would recommend the REA tool for all research projects. Many indicated that the approach would depend on the type of research. As REA takes time and additional resources, it might not be feasible to apply it to all research projects. Most mentioned that use of REA needs to be dictated by the nature of the study. The existence of prior knowledge about the community was suggested as an important issue. If the ethical issues in the setting are already mapped out, there may not be a need to do REA.

> *Yes for big research studies, for example clinical trials, ... (and for) cohort studies …it might be possible. ... [A]round here ... most research projects are cross-sectional, and ... the duration of data collection might only take 10 days. If you ask them to do the consent form [based on REA] and if it takes them 3 months, it*

> *might not be practical for most people. But for bigger projects, I think it will have a place*. [*Researcher, JU*]

> *If we already know [the ethical issues in] our own community there is no use in doing an additional formative assessment*. [Researcher, JU]

4.2. Discussion

The study highlighted important considerations in the research ethics system in Ethiopia. The gaps identified call for quality monitoring and standardization of efforts. However, the views in this research were mostly responses from institutional researchers and regulators. The study also identified clues specifically related to the research consent process in Ethiopia both at information provision and decision-making stages. The findings also suggested that REA tools could be considered relevant and potentially feasible in the Ethiopian context in order to address these gaps.

In this study, we employed a mixed methods approach incorporating both quantitative and qualitative techniques with a sequential explanatory design (Creswell, Klassen et al. 2011), where in-depth interviews were performed after the conduct of the on-line survey. The contents of the interviews were modified as required, based on emerging findings. We triangulated qualitative and quantitative results which provided a deeper understanding with a more flexible, iterative process. The use of an on-line survey, which we believe to be one of the first uses of this technique in Ethiopia for health research, was found to be efficient in terms of generating information in a reasonably short period of time. However, researchers who were not accessing their e-mails during the data collection period were not included. On the other hand, a significant proportion of the intended sample size was reached, as respondents were able to answer the survey questions irrespective of their physical availability or current location as long as they have internet connectivity. The fact that the respondents themselves were researchers who understood the importance of responding to such surveys may have contributed to the high level of compliance (Davison, Li et al. 2006) (Evans and Mathur 2005). It was possible to send reminders and additional invitations on the basis of

responses. This may have resulted in selection bias as busy people and those on vacation during the survey might not have responded to the survey. However, we do not know reasons for non-participation and non-response. The survey was conducted at the beginning of the academic year, assuming most academics would have time to complete the survey questionnaires. The study has demonstrated the potential of using on-line survey tools in Ethiopia among groups such as academics and researchers. Its preliminary findings also helped shape the qualitative study which followed it.

The qualitative study did not include representatives of all academic and research institutions, which makes it difficult to generalize the findings to other settings. Yet we believe that most of the concerns are shared by similar institutions. Accordingly, the study has enabled identification of many key issues relating to research appraisal and exploration of perceptions surrounding REA. The mix of study respondents which included high level researchers and regulators of ethics review systems with considerable research experience, was representative of the group targeted for the study. Their current roles and experience in research made them ideal to identify gaps in health research ethics, and suggest possible ways of addressing them. However, since the study was limited to researchers and regulators, the perspectives of other important stakeholders in health research such as non-researcher health professionals, community members, senior officials and country level policy makers were not included in the study. Despite the fact that most respondents were involved in doing research in ethical review or in development of ethics review guidelines, a significant proportion of respondents had not had any formal training in research ethics. Possible explanations for this include the absence of structured research ethics training courses and the fact that Ethiopia is in the early stages of implementing a universal system of research ethics. One example of this is the recommendation given by the study participants about having a community representative on ethics review committees. This is already included in the national ethics guideline (ESTC 2005), but is not uniformly implemented. As is highlighted by the participants, there is lack of uniformity in application of the guidelines with undue emphasis on mere procedures. The REA PI had similar observations both as a member of an IRB for over two years and as a researcher

seeking ethics approval for his own research projects. In the IRB meetings, the focus is more on the way the proposal is written and the informed consent is designed and written than the potential applicability of it on the field. There is no mechanism to check how the consent information will be understood by the community. The only check point closer to the community is the presence of a lay person who reads all the Information Sheets during the IRB meetings, usually in English and the Amharic versions. Language being an important issue, there is no way to check other language versions of information sheet and consent forms.

Lack of standardized and structured ethics training was a critical gap. From the qualitative findings, there are suggestions that this may lead to systemic gaps in the ethical conduct of research. Other studies also documented knowledge gap among academics and researchers have suggested ways of including ethics training in mainstream curricula (Nyika, Kilama et al. 2009; El-Dessouky, Abdel-Aziz et al. 2011).

According to our findings, there is no established mechanism in place to assess the community risks, vulnerabilities and benefits beyond what is written in the application submitted for approval. Most IRB reviews are on the Risk-Benefit assessment based on the submitted proposal and whether the consent form is as per the standard and is written well. One important parameter in most IRB review formats is ‘involvement of community in the research’. However, this assessment of community involvement is based solely on what has been included in the proposal, and refers mainly to the development of the research problem. As one of the implicit principles in community health research, ‘community concern’ is an important criterion. A 'pre-assessment' which includes the community would reduce the reliance of the IRB on making a judgment based on the written proposal only. Community Engagement approaches, which aim to create awareness and a sense of ownership by the community, are becoming more popular. These approaches often work with and through community groups such as Community Advisory Boards (CABs). Community Engagement is also used as a process of influencing of change in the community through provision of information, negotiation, local capacity building and empowerment (NIH 2011; Asante,

Agyemang et al. 2013). Community Engagement might also be used to address ethical issues around research (Marsh, Kamuya et al. 2010) (Boga, Davies et al. 2011) (Rotimi, Leppert et al. 2007) (Participants in the Community Engagement and Consent Workshop Kilifi Kenya March 2011 2013). Community Engagement and REA share some overlaps, since they both address community issues and share qualitative methodological approaches. However, REA is primarily done by a REA team (a multi-disciplinary team of researchers) and employs rapid ethnographic research methods, while Community Engagement, on the other hand, employs groups of community members.

Respondents' perceptions of existing consent processes were not found to be favourable. Most respondents thought that potential participants understood little about the consent process or the information provided to them. They also thought that the participants' best interests were rarely considered, reflecting gaps in communication and decision-making process. Major gaps, in relation to communication and comprehension of study participants included usage of language including problems in use of appropriate terms to explain medical concepts, lack of health and research awareness of participants, undue expectations and manipulation by researchers. The same list of issues could influence decision making, which in turn is influenced by factors such as manipulation by researchers and the local dynamics in decision making. These factors vary from context to context. In Ethiopia ethno-cultural differences are very visible, and the use of generic consent forms and consent approaches for varied setting will be inappropriate. Traditionally, consent forms have been developed by researchers based on the requirements of an information sheet and a decision page. This approach addresses consent from the perspectives of the basic principles in ethics and the major international guidelines. The assumption is that the contents would be relevant irrespective of whom the participants are. Sometimes consent forms have been developed by international investigators and adapted purely by translation. Ethiopian communities have varied levels of awareness of public health issues. According to the Ethiopian Demographic Health Surveys (EDHS), levels of understanding on health issues vary by characteristics such as area of residence, income, region, religion,

ethnicity, and literacy status (CSA 2012). Tekola *et al*. reported that words for health, research and medical treatment either do not exist in some languages or are used interchangeably in a confused way (Tekola, Bull et al. 2009a). This may give rise to expectations of medical treatment which confound the decision making processes. Some researchers are tempted to take advantage of this vulnerability of participants to increase rates of recruitment by promising unrealistic and unavailable benefits. Gaps in the consent process are also reported elsewhere related to information and communication, and decision-making indicating the need for informed consent processes tailored to the context (Bhutta 2004) (Tekola, Bull et al. 2009a) (Tekola, Bull et al. 2009b) (Bull, Farsides et al. 2012) (Kiguba, Kutyabami et al. 2012) (Oduro, Aborigo et al. 2008) (Krosin, Klitzman et al. 2006) (Mandava, Pace et al. 2012) (Saleem and Khalid 2009; Boga, Davies et al. 2011).

Based on studies which have employed REA, consent processes have significantly improved both comprehension and decision making. The key steps were identification of issues prior to and during the conduct of studies and guiding the consent process based on those qualitative findings. REA tool has been recommended for use by researchers who have used them in their respective research (Bull 2007) (Tekola, Bull et al. 2009a) (Tekola, Bull et al. 2009b) (Bull, Farsides et al. 2012) (Tindana, Bull et al. 2012). The current findings support the need for a pre-assessment to explore potential context-specific ethical issues as is demonstrated by the responses of researchers and regulators included in this study. Pre-assessment in health research may have various objectives such as testing data collection tools and assessing study feasibility and optimizing community engagement (Faux 2010) (Chernyak and Icks 2012) (Thabane, Ma et al. 2010) (Arain, Campbell et al. 2010) (Burgess and Sulzer 2011) (Asante, Agyemang et al. 2013). However REA is distinct from these forms of pre-assessment being focused primarily on ethical issues.

Some respondents mentioned that they were aware of the role of some form of pre-assessment and stakeholder participation in exploring ethical issues. However, the extent of actual use of pre-assessment was not measured, and neither was any

assessment made of the techniques. The qualitative responses revealed that ethical pre-assessments are not widely used, and that the term 'pre-assessment' in relation to research may be used to refer to feasibility studies or piloting of tools. In the literature, genuine ethical pre-assessment is rare. Stakeholder participation usually refers to involvement of community representatives in identifying the problem to be investigated rather than the consent process *per se*, with the due importance of community involvement in research inception (Burhansstipanov and Schumacher 2005) (Horowitz, Robinson et al. 2009) (Macaulay and Robbins 1999). There are fewer experiences of pilot studies for ethical pre-assessment, and these were limited to the specific research projects under consideration and did not dictate any wider-scale use (Gillam, Poulakis et al. 2006) (Duma, Khanyile et al. 2009) (Taljaard, Weijer et al. 2009).

The study documented considerable interest in REA as a tool to improve research consent process. However, respondents were concerned about the potential burden REA would put on the researcher in terms of time and other resources. One suggestion made was to conduct REA as part of traditional pre-test during community based studies. However, the objectives and duration of such pre-tests vary considerably. Some are rapid and done in a day or two and would not permit REA, which required about 4-6 weeks in earlier studies (Tekola, Bull et al. 2009a) (Bull, Farsides et al. 2012). Others types of pilot studies such as feasibility studies for randomized trials would be ideal in terms of integrating REA. The studies so far employing the REA approach have documented its significant contribution in identifying important ethical issues in the research context. In those studies, REA has helped to come up with findings that were used for the consent process of the studies (Bull, Farsides et al. 2012) (Tindana, Bull et al. 2012). But such studies have not assessed how the usability of the tool would be considered by the research community.

According to the findings of the current study, the 'rapid' aspect of the REA tool was confused with expediting the review process. Some respondent were confused about the terminology as they tended to understand this in the sense that the 'rapid' tool was meant for accelerating the ethical appraisal and review process. According to most

researchers, the current appraisal process takes too long a time and there is a need for finding a way to improve this. They were intrigued to learn that REA entails additional time and resources.

Whether REA should be applicable to all studies depends on a number of issues such as the nature of the study, the characteristics of study participants, the nature of issues under investigation and the availability of resources. Clinical trials and studies that include vulnerable subjects or sensitive issues would require REA. In clinical trials and classical longitudinal studies, there are a number of encounters with the study subjects. This would allow plenty of room for addressing consent issues. One respondent stressed that consent in such settings should not be regarded as for one point in time. As the consent process is repeated, it can be improved. Some communities are better informed about science and research than others and they are well known to the researcher. In localities where health systems are well accessed and previous research has been conducted, the community generally has a better understanding of health research and the anticipated ethical issues will already be familiar to researchers. REA is therefore likely best reserved for communities that are not well researched and are less familiar to researchers.

There is a concern that REA may unnecessarily delay small, cross-sectional research projects into less sensitive topics. It is then very important to have adequate time within the project for REA. One suggestion forwarded to address this concern was to marry REA with the pre-test part of research projects integrating the REA into the research pre-test, so the consent form is pre-tested at the same time as the questionnaire. As REA is an additional tool which requires time and expertise, research projects need to take this into account when planning their project. It is then important to be clear about what resources are required so that researchers can take this into consideration.

Limitations:

The main objective of the current study was to assess the perceived relevance and perception of the research community towards the REA tool. In this paper we did not

intend to explore the practical feasibility beyond the perceived relevance and applicability of the tools in the views of researchers and research ethics reviewers. Perceived relevance of the tool is different from its practicality and feasibility which needs to be explored further. Expressed demand and acceptability of an approach are important components in assessing feasibility but are not sufficient. The study has clearly demonstrated the need for such a tool and its potential acceptability. Qualitative data analysis was done in English while conducting the analysis in the language of data collection would have been preferred. Community representatives were not included in the study and the assessment regarding the research ethics review system in Ethiopia was primarily based on perception of researchers and ethics committee members. A more comprehensive assessment of the research ethics governance system in Ethiopia is needed before making further remarks on the system. We used post graduate training as a proxy indicator of research experience which may not always be correct as there are variations in the profiles of post graduate programs.

4.3. Conclusions and Recommendations

Though the country has national guidelines and structures in place to regulate ethics in health-related research, research ethics and its review systems are relatively new in Ethiopia faced with several challenges. There is rapid expansion of health and medical research activities in recent years with lack of proportional development in the capacity of the ethics review systems. The current review process has demonstrated critical gaps in ensuring reliable consent processes. The problems arise from three distinct areas; those embedded in the health research review system, those related to researchers and those related to the general public. These can be potentially addressed by ethical pre-assessment to inform the consent process. REA tools and techniques were considered relevant and acceptable to the Ethiopian research community, with practical challenges anticipated in their implementation. The applicability and feasibility of REA need to be further explored.

Chapter 5 : Ethical Issues Identified through REA Pilot Studies in Ethiopia

FGD Moderator: What will happen if he (data-collector) talks to her (your wife) directly?
Male FGD Participant : [laughter] ... how can this happen while I am alive?

FGD, Butajira[67]

This chapter discusses the ethical issues identified through REA piloted in three community-based health studies in Ethiopia between 2012 and 2013, and the comparative contributions of REA in the three different contexts. Identified ethical issues are further explored and discussed for their implications on the consent process. The REA pilot was wider in scope and application than earlier studies on REA. Larger-scale, country-wide pilots on REA have not been conducted to date. Such studies demonstrate the relevance of REA in terms of identifying significant ethical issues, with a focus on the variabilities of the terrain of ethical issues which would not otherwise have been picked up. Our aim was to illustrate the range of ethical issues that REA can identify in community based research in a developing country setting, and add to the existing pool of evidence on the use of REA during the informed consent process. For this part (Phase II) of our project, preliminary REA tools were further refined based on assessments done in Phase I, to be piloted in the three community based research projects or *parent-studies*. We then documented the process of REA implementation in a real research setting, and its added value. By presenting the important findings of REA, we lay a foundation for the subsequent chapters, where we will be discussing the REA process and its application. Detailed methodologies related to study design, study area descriptions and data collection and analysis methodologies for the REA pilot (Phase II) are discussed in chapter III.

[67] Taken from FGD conducted in Butajira among group of adult men. Butajira is a rural town in South Central Ethiopia

5.1. Results

The results cover findings of REA pilot in four locations (Butajira, Adami-Tullu, Ayra and Soddo) of the three 'parent research projects'. REA findings from Mekele Zuria in Tigray are not included as the data in full transcript were not readily available during the write-up of the chapter. Ethical issues identified in these four sites are presented in categorical themes. The thematic categories include background on health-related aspects of the study areas including major health issues, health research in the past, research-related ethical issues anticipated such as benefit and risk, taboos, stigma, specimen issues, approaching community and community channels including gate-keepers, gender dynamics, signature, trust and disclosure of study results. The themes cut across all field sites with specific accounts given only when indicated.

5.1.2. Research Related Issues

The study sites had varied levels of exposure to medical research in the past ranging from being relatively naive to medical research to extensive exposure for a number of years.

The Butajira community has been actively involved in a range of community-based research and has been aware of medical research endeavours for nearly 30 years. A range of research has been undertaken on mental health, neurology, and nutrition, to mention few. The community is used to the pattern in which researchers come and go. Many researchers have come to Butajira from Addis Ababa and some from outside Ethiopia. According to the community, researchers have not very well explained their research to the community. Participants appreciated the fact that they were approached this time through REA for their opinions in relation to research.

Adami-Tulu is relatively naive to community-based health research. However, people are familiar with community-based research by health extension workers (HEWs), who are cadre of community health workers as part of the public health system. They come

to households and collect data at regular intervals. The community is appreciative of the HEWs and they are very cooperative with them.

There is not much health research conducted in Soddo, though some research on podoconiosis[68] has been conducted in the surrounding areas. Despite the fact that modern medical services have been delivered in Ayra for a long time due to missionary efforts, medical research has rarely been conducted in the area. The hospital in Ayra was one of the national HIV/AIDS sentinel surveillance sites. The surveillance study has been conducted for many years. Otherwise there are very limited health research efforts in the area.

5.1.3. Health Related Issues

This theme addresses prevalent health problems in the respective area, health care levels, health care-seeking behaviours of the community and their attitudes towards health workers including health extension workers.

In Butajira the major health problems were malaria and communicable diseases. Malnutrition has been a problem among children. The health status of the community improved over the years and especially recently due to the expansion of health services at the community levels.

The study participants at Adami Tulu in Zeway mentioned marked improvements in health service provision at the *woreda* (district*)* level, including construction of health facilities and health professionals being assigned to all *woredas*. The health care seeking behaviours of the community also have improved over the years. Even though there are changes and improvements, there still are gaps such as inadequate availability of drugs. The major health problem mentioned by the participants was

[68] Podoconiosis is a type of tropical lymphoedema clinically distinguished from lymphatic filariasis (LF) through being ascending and commonly bilateral but asymmetric. Evidence suggests that podoconiosis is the result of a genetically determined abnormal inflammatory reaction to mineral particles in irritant red clay soils derived from volcanic deposits. Korevaar, D. and B. Visser (2012). "Podoconiosis, a neglected tropical disease." Neth J Med **70**(5): 210-214.

malaria and they were happy about any intervention related to malaria at the community level. Malaria is known by the vernacular term which is different from the names given in other *Oromiffa*-speaking parts of the country. They even have names for the species and different clinical features and manifestations.

Ayra is known for malaria endemicity and this was mentioned as one of the health challenges for the community. Malignancies and cancers are seen infrequently. However there is not much done to investigate the prevalent health problem in the area and there is increasing concern about the problem of cancer. A hospital and several Health Centres are available and provide services to the community, and it is 'normal' to visit them. Their services are highly appreciated and the healthcare seeking behaviour of the community is good.

Regarding Soddo, the town is under development in terms of infrastructure and there is now a new university in the town with a health sciences college and medical school, because of which the medical activities and the health related research undertakings are expected to increase. There is an on-going community based NGO project and research on podoconiosis has taken place for many years. Health care provision and health care seeking behaviour have improved considerably over the years.

Health Extension Workers: In all the sites, HEWs were mentioned frequently as key stakeholders in the community, who have won respect and are considered important gate-keepers for community health issues. They are said to be the reason behind the improved health seeking behaviour. The community is appreciative of their services and they are important actors within the health system and in community collaborations. It was strongly recommended that any public health effort utilizes them.

> *Most of the time they (the community) hear what the kebele administration says. Next to them they (the community) trust the HEW. [Health Extension worker IDI, Soddo]*

5.1.4. Benefits and Risks in Research

Research-associated benefits and risks were important considerations in all the sites. They were considered important by both participants and researchers.

Benefits: While benefits of any kind were considered important, most importantly participants wanted to know the results of the research in their areas, especially when specimens are collected. However they expressed their concern that researchers repeatedly fail to provide them with the results of their investigations. Researchers often promise to come back with the results and to inform the community, but this does not happen. Disappointments were expressed by many about this and the absence of interventions based on study results. Researchers usually disappear with the data and do not return to do something for the community. They considered this an unfortunate trend among many researchers and asked what they benefit in participating in research if there is no visible benefit either to the participants or the community.

> *The people want to know about the results of the study, most of the time they don't get to see the results, so if this result is brought here and ... [communicated] at the kebele it would have been better. If the result was given it would be easy to convince the people to participate in future research, so giving them the result and ... some incentive is a very good thing. [Data collectors, FGD, Butajira]*

> *They (researchers) come here, they give us numbers, and then they ask us. That's all they do, nothing else, that's all they do, ... they took blood and [stool],...they took a number of times but they didn't give the results. [Mixed group of Community members[69], FGD, Butajira]*

> *There was a study that was done on TB, but after he (the researcher) did get the data he went somewhere and we haven't heard from him ever since. ... after all this, they (again) came back and did another study by taking a random sample. [Again] this time they didn't tell the results. What the people are saying now is 'why do you take another sample without giving us the results of the first study'? They have said they will give the results back. This is the thing that is not clear to the people. If the results were known the people will be motivated, then their willingness will increase. [Mixed group of Community members*, *FGD,* Butajira*]*

[69] Mixed FGDs refer to mix of m*ale and female participants*

Types of benefits: The community mentioned that they understand the existence of different types of benefits with different levels and different beneficiaries. Benefits in medical and health-related research are generally understood as they relate to diseases and their treatments. Knowing one's disease status was considered a benefit. Participants expressed that any justified benefit is welcome. They consider themselves progressive and ready to embrace any reasonable benefit.

> *We accept anything that comes. We expect new things. They give us training about how to keep ourselves clean, and we are always open to learn. [Mixed Group, FGD, Soddo]*
>
> *In a research project, I expect that the one studied will be of benefit for my area and for me. ... I do not expect you [to] give [me] money. [If] it creates awareness to me, I can get that benefit, [then] and I can take care of myself and I can promote my health. This is my benefit. [Male group, FGD, Ayra]*
>
> *I think it (research) has a benefit for the country. ....[I]t also has a benefit for the kebele. It even has a worldly benefit [for the rest of the world]. It also has political benefit. ... There was a research done here to improve the meningitis medicine, they collected blood examined it then they improved the medicine then they brought it back here. First it made the kebele famous then, it made the country known. We are happy that we contributed. [Male group, FGD, Butajira]*

Random benefits: Apart from the results of studies, other forms of benefits included benefits in the forms of incentives and compensations. On this issue, most wondered why only few community members were selected to get benefits such as free medical care, support for their children, hand-outs for hygiene, and other useful items for personal and family use. These benefits were provided only to those selected in some way unclear to them. Respondents did not understand why one household is selected and the next one is skipped. They considered this as lack of transparency and unfair. They were told that this selection was based on chance. But this was thought to be unfair, since all wanted to be considered for incentives and benefits. They recommended that such studies need to be all inclusive and not unfairly random like the monetary lottery, which is a game.

> *She (a study participant in the neighbourhood) is saying 'I got the lottery from (out of) the family'.* [*Rural inhabitants, FGD, Butajira*]

> *I feel like a foreigner. What are the criteria by which these people were selected? Is it by selecting people or is it in a row? ....If the study is for all why don't they do it for all? If it is for all the people, we will not feel suspicious. The people will accept it. If they have given us explanation we will have understood.* [*Town inhabitants, FGD, Butajira*]

Benefits to researchers: Benefits were also understood as they relate to researchers. Researchers make some kind of benefit from the research. For example, students are doing research for their educational purposes and this is their benefit. Participants considered they are doing the researchers a favour when they participate in the research.

> *The main benefit of the students [research students] coming here is, they don't know this place so they get new information. Every kebele is different from the other. They see different things. You might know things we don't know and we might know things you don't know. So it's a two-way benefit. [Mixed group, FGD, Soddo]*

*Harm***:** Perceptions of research related harm were expressed in relation to the type and amount of specimen collected for research. Blood specimens particularly are subject to suspicion. Any amount of blood taken is considered to harm one's health. Parents usually find it very hard to allow their children give blood tests. Blood specimens also raised suspicions about what exactly would be tested and many did not want this to happen. They reported incidents associated with this.

> *Last time a number of people refused to let their children because they fear that the child will be hurt. Some of them returned after they took their children to the health centre, they refused and they returned.*
> *[Rural inhabitants,* FGD, Butajira]

> *Studies were undertaken on under five children. They give blood when they turn five. Some mothers complain. They think the blood they take is more than enough,(and) these mothers were dissatisfied. They (even) tried not to go to give blood. Maybe by taking this blood, the people [researchers] might find some problem and help the children. But the*

> *mothers didn't understand this. Some mothers stayed home when they heard they (researchers) were taking blood.[Town inhabitants, FGD, Butajira]*

> *We are suspicious of different things nowadays. Recently some people came and they took blood, when they took it from my child, she fell over. I felt so sad. Last time I forced my son to give blood then he fell down after giving blood. I told them (data collectors), to never come to this village. Then they didn't return. Some children (even) run away (from data collectors). [Male group, FGD, Butajira]*

There is a high degree of sensitivity towards biological specimens in general and blood specimens in particular. There is a tendency not to give particularly blood specimens due to; a) the testing of blood being associated with certain medical problems like HIV which in turn are associated with high degree of stigma. Any unexplained blood testing might raise the suspicion that HIV is being tested; b) usually blood tests are taken in the health facility and taking the blood or other samples at home was considered odd[70]. If a blood sample is involved, they would prefer this to be taken at a health facility; and c) specimens and samples are usually associated with investigation of a sick person. It is unusual to take samples from a healthy person. Giving samples for investigation when someone is sick is considered normal but not for a healthy person.

> *The people don't give blood for research. When you take blood everyone will suspect it is for HIV test. They also think that their blood will be put in the market and sold. There are people (who) refuse to give saying, 'I am not going to let you sell my blood'. [Mixed group, FGD, Soddo]*

> *Even if they are called by (ordered by) the kebele, they don't give blood. They need a reason to give; reasons like, there is an outbreak or something. They only give blood when they are sick or if there is an outbreak . [Male group, IDI, Soddo]*

5.1.5. Cultural Taboos and Stigma

Each of the communities expressed levels of concern over certain research issues under consideration. Like many other cultures, the societies had taboos related to

[70] The author also had similar experience in a 'Acute Watery Diarrheal' study where we decided to move to health facility based study for the technical difficulties of specimen preparation at home which was not impossible but was compounded by the community discomfort.

answering certain research questions. For example, in Butajira, participants mentioned that according to their norms, it is taboo to ask about what someone has eaten and how many children one has. The question about food is often associated with socioeconomic status (SES) which is a very private matter for a family. Therefore, especially individuals and families from lower SES are not comfortable to answer such questions.

> *They might not be willing to answer the question 'what have you eaten?', ... it will be hard to answer the question, 'what have you eaten?' ... it is hard ... it will be hard for him to answer what he has eaten yesterday, he might answer the question but he will be embarrassed to answer it, this might cause a problem.* [Enumerators, FGD, Butajira]

> *Most of the time they are not happy when you ask them about food. They don't want to tell you about their house, they answer vague when you ask them about the food they eat.* [HEW, IDI, Butajira]

> *Because they are embarrassed by the food they eat, they might feel inferior, ... [lest] other people might say 'they don't eat what we eat'.* [HEW, IDI, Butajira]

Another point mentioned to be taboo was asking the number of one's children. Parents in general and mothers in particular are not comfortable with the counting of their children. They think that this will bring bad luck on the children and the family. They tend to shy away from mentioning the number of their children and they tend to be protective against anyone who knowingly or unknowingly tries to count their children. Not allowing a child to be counted is a sign of protection and concern for the welfare of the family. Parents tend to cheat by giving a wrong number assuming that the bad luck will be cheated.

> *They can hide things related to the number of people in the house. They will say 'I will not let them count my children'. So they hide this [information].* [Male group, FGD, Butajira]

Another concern in relation to stigma is disclosure of personal information and disease status. Depending on the type of disease or health problem, some level of stigma is expected to occur. There is stigma and discrimination associated with some illnesses. There especially is a high level of stigma against HIV and AIDS. Because of this, there is reluctance towards disclosing one's disease status. If people are investigated for

diseases such as HIV or cancer and are found to be positive, the information often becomes public. By having the tests, they risk becoming stigmatized by the community. They are also worried about what others would say about their children. Another issue is what is going to happen to very personal information and information very private to the household. Once the information goes beyond the individual and family, the person or family are thought to be vulnerable to the rest of the community. There is a concern of losing one's privacy and ownership over private information. This concern is at the back of the minds of those making the consent decision. Reassurance about both privacy and the exact nature of the test is suggested.

> *People do not talk about these issues. For example in a meeting there can be more than 10 people who are HIV positive. But because they don't say they are, no one knows. [They] talk about small diseases like malaria and diabetes but when we come to HIV and things related to cervix, people don't talk about it.* [Mixed group, FGD, Soddo]

> *When we were doing child vaccination,[and] when we tell them to bring their children for examination they said what are you going to do with our children, are you going to [measure and judge] my child?* [Town inhabitants, FGD, Butajira]

5.1.6. Community Channels and Gate-keepers

Creating awareness at the community level was considered important to maximize awareness and understandings on research. Important channels mentioned by the respondents included long-standing informal community structures such as 1) informal community meetings; and 2) informal community originations such as *Iddirs*[71].

> *The first thing here is creating awareness. It is a recent phenomenon to talk about these things [research on reproductive health issues and chronic diseases like cancers]. So we need to teach them all these*

[71] *Iddirs* are indigenous voluntary associations established primarily to provide mutual aid in burial matters but also to address other community concerns. Households become members of the associations and pay fixed contributions monthly. Whenever death occurs among members, the association raises an amount of money (depending on the specific bylaws) and handles the burial and related ceremonies. In addition, certain members are assigned to stay at the house of the bereaved for two to three days to assist the household." (Pankhurst, A. and D. Haile-Mariam (2000). "The Iddir in Ethiopia: Historical Development, Social Function, and Potential Role in HIV/AIDS Prevention and Control." Northeast African Studies **7**(2): 35-57.)

> *things, if you teach me I will do it if not I will never cooperate. [Mixed group, FGD, Soddo]*
>
> *What I propose is, if the researchers select some people from the community and make them aware. Then they can in turn make the rest of the people aware, ... For example, we were taking action in relation to women. We talk to them in Iddirs and they in turn talk to the people in their areas.* [Mixed group, FGD, Butajira]

The community explained the role of gate keepers at the community levels, including existing community structures such as Kebeles and clusters of House Hold (HH) arrangements; health extension workers, faith based organizations (such as churches), community elders and the traditional systems (such as the *Geda System*[72]) and *Iddirs*.

They especially considered the *kebele* structure and local administration an important channel. There is high trust and reliance on information received through this channel. They also considered the role of elders who are well known and respected by the community to be very important. The *kebele* structure is considered vital when it comes to community-level interventions and processes. The *kebele* has the trust of the people and is considered an important voice and point of contact with the government and the local administration. To this effect, they mentioned the importance of working with the *kebele* structure which has already won trust and is considered reliable. Recently introduced structures which are extensions of the *kebele* administration include the "one-to-five" village structure or *Shane and Gare*[73]. The *kebele* is also a sense of

[72] " *Gadaa* government comprised a hierarchy of triple levels of government: the national, the regional and the local. At the pan-Oromo level, the national government was led by an elected *luba* council [leaders] formed from representatives of the major Oromo moieties, clan families and clans, under the presidency of the *abbaa gadaa* and his two deputies The national leadership was responsible for such important matters as legislation and enforcement of general laws, handling issues of war and peace and coordinating the nation's defense, management of intra-Oromo clan conflicts and dealing with non-Oromo people" (Jalata, A. (2012). "Gadaa (Oromo Democracy): An Example of Classical African Civilization." The Journal of Pan African Studies **5**(1): 126-151.)

[73] *Gare* and *Shene* are *Oromiffa* terms referring to the one-to-five household structures are recently introduced in most communities where each five households forms a unit lead by a leader. The structure is used for passing information much efficiently to Household levels with accountability and responsibility. *Shene* means five in Oromiffa and refers to the one-to-five community structure which functions as a cell and is currently the basic structure for sharing information and community sensitization. This is a relatively recent national implementation. Each *Shene* has a team leader accountable to the *Gare*. *Gare* refers to the sub-kebele structure or village-like arrangement within the kebele, which constitutes several *Shenes.* Each *Shene* has a leader accountable to the kebele.

security for its inhabitants. They trust the *kebele* irrespective of political opinions and the government is considered responsible for looking after the community. They also are well known to *kebele* officials. The *kebele* is considered to be a powerful voice and there is a very high level of compliance to the suggestions provided by the community. It is important that the *kebele* administration is involved in any information-giving activities at the community level.

> *We don't accept anything if it doesn't come from (through) them (the Kebele). For example, if Melese[74] [kebele focal person] wasn't with you we wouldn't even accept you,.... How can a person we don't know be trusted? We trust kebele workers, if a person comes to us suddenly (as a surprise) how can we trust him, how can we?" [Male group, FGD,* Butajira]

> *There is structure that is followed from kebele administration through Shane. The kebele administration makes the Gares aware, and the Gares makes the Shanes aware. If you come directly to our homes, we [will not help] you .... It is not sufficient just to get permission from the kebele administration. If you come to my house, I want to see somebody from my Gare or Shane. I do not think that our people accept you, if you only get permission from the kebele administration. [Male group, FGD, Ayira]*

> *If you come with the kebele leaders no one will refuse, if you are alone the husband [household head] will say 'who are you?' But if you are with a kebele official he will not have a problem. [Mixed group, FGD, Soddo]*

The *Oromo* traditional community rule and belief system (called the *Abba-geda*), based on the *Geda* system, was an important community channel mentioned by the study participants. The system actually exists in Adami Tulu area. The traditional *Abba-Geda* rule is recognized by the public government administration and the *Abba-Geda* leaders are well recognized by the woreda council and they work in collaboration with the local government administration. REA team was able to meet two *Abba Geda* leaders through the woreda administration.

*Faith institutions***:** Faith based organizations in the community, such as the church, are considered important voices in the community. In Ayra for example the population is

[74] The real names are replaced by other names to hide the identity of individuals for the sake of maintaining anonymity.

predominantly Protestant Christian and is made up mainly of members of the Mekane-Yesus Church[75]. The district hospital in the area (Ayra Hospital) is owned by the Mekane-Yesus church and is still supported by missionaries from partner churches in countries such as Germany and Sweden. In Soddo, health care provision including the first hospital to the area dates back to the time of the missionaries. There are two major hospitals in town, an old missionary (now government-owned) hospital and there is another new mission hospital in town. In these localities, churches work in close collaboration with *kebeles.*

> *I think, it is better if [community information on health research] is announced either at churches or (government) offices. From these two the choice is yours. [Mixed group, FGD, Ayira]*
>
> *It is better if you use the church, because most people (in the area) go to the church and they will listen about it in the churches. ... It will be good if you come to kebele first, then you can go to the church or to other places. The kebele is the one who will refer you to the church or to other parties. [Mixed group, FGD, Soddo]*

5.1.7. Language

Every ethnic community in the study area has its own language. They use *Amharic* to communicate between the different ethnic groups and with outsiders. However, they have difficulty understanding some words if they are not explained in their tongue. In Butajira, there are three ethnic groups residing in the area namely *Gurage*, *Mareko*, and *Dobi* each having its own language. They share some common cultural practices and all the three communities in addition use *Amharic* as a common language medium. The BRHP data collectors use *Amharic* for their medium and their demographic data collection tools are also in *Amharic*. BRHP data collectors also know the local language and use it for approaching the community, for explanation and general communication, and consider this very important for the community. The inhabitants of Adami Tulu *woreda* are generally from the *Oromo* ethnic group and *Affan oromo* is their language. Diseases including malaria have words in the local language. Malaria is named in different ways: *Busaa*, *Bicha-Waba*, and *Shekere* due to the insect *Bookee*. Ayra also is

[75] Mekane Yesus Church (*www.eecmy.org)* is one of the largest main line evangelical protestant churches in Ethiopia.

predominantly rural and the language spoken in general is *Oromiffa*. For Soddo the language of the area is *Wolayitigna* but in the town *Amharic* is widely spoken and used for official communications. Butajira community indicated that their preference is that they are communicated in their own languages.

> *If you use Meskan (the ethnic language) they will be happy. ... They will 'be like water' [compliant and obeying] when you use their language. ... Almost all in the area speak Amharic, but if something happens you will have to talk to them in Meskan. To convince them to participate in the research you will talk to them by their language. If you don't talk to them in their language they could refuse to give information. [Mixed group, FGD,* Butajira]

Explanations **:** BRHP data collectors, based on their experiences, stressed the value of allowing questions in order to enhance communication. Sometimes participants spontaneously ask questions for clarification and this is to be encouraged. At times this does not happen and the data collectors need to encourage study participants to ask questions and provide them with explanations. This helps to enhance levels of communication and mutual understanding. Provision of appropriate explanation for the respondent is also considered a key skill for the data collectors. Explanation is given about the research to be undertaken, to all the concerns around the subject matter including risks and benefits. The community also needs clarification and assurance as to how participation in the research will positively or negatively affect them. They want to be reassured that if there is no any political activism associated with the research and the home to home visits of data collectors[76]. Concepts like randomisation and random selection of participants were found to be very difficult to understand and conceptualize by the community and need further elaboration at a conceptual level. It was stressed that the information provision needs to be accompanied by reading the information sheet. Reading alone is not considered adequate, as potential participants may not understand the information only from it being read. There needs to be an accompanying explanation until they have understood. The need for explanations given in the local languages is repeatedly mentioned by respondents. Data collectors tried to check if

[76] In the past there were incidents where home-to-home activism was used for politics and religious purposes with undesired outcomes.

study participants have questions. They also asked questions based on consent information given to check for understanding.

> *They asked lots of questions. ... When we do a research, we go to the house and tell them the purpose of the research, then I will convince them and ask them questions. It is all about explanation. [Data collectors, FGD,* Butajira]

> *We have to tell them that there is no problem in giving information (for research). And we have to tell them that it is not related to any government [political] organization, and that there is no help that will come because of it. We have to convince them that this thing is only for research and nothing more. [Data collectors, FGD,* Butajira]

> *After the reading [and explanation] is finished, then we ask them if they have questions. Then they will tell us if they have understood it [or not]... It is us who (should) make them understand....There are times when they tell us, that they agreed just for us [to make the data collector happy], ... then I tell them you should agree, not for me. But only because you wanted to be a part of it. Then I make her understand. I tell her even if you participated or not I will get my salary but, this thing will help you in the future, this means she will agree because she wanted to be [part of it]. [Data collector, IDI,* Butajira]

Reading **:** Most of the community does not have high level of literacy, and the ability to read cannot be assumed. Some have gone to school many years ago and their levels of reading and comprehension may not be comparable to the level of grade they then had. Therefore, when it comes to written information, it is difficult to expect uniform levels of understanding from reading consent information. Many participants would require someone to read them the information irrespective of their literacy status.

> *There are people who read and there are people who don't read. There should be someone who will read this for them. We can't say all are educated. There are people who sign using their fingers*[77]*. ... If there are people who will read for the family they will read it, then they will make you (them) understand. The person who collects data will read it for them and explain it. Then they will consent and sign. [Mixed-group, FGD*, Butajira]

[77] Signing with finger prints and ink. This is how those with problems of writing ability make official signatures.

*Data Collectors' Approach***:** Respondents stressed that the way they are approached by data collectors who come to their households is very important to them, even before knowing why the researchers have come and what the research is about. If they felt that they are approached inappropriately, they will not be willing to cooperate. They appreciate respect for themselves and their family members whenever approached by researchers and data collectors. This includes gestures like greetings and using their own language and showing signs of respect as per the community traditions.

> *Most things depend on the way the data collector approaches the participants. They like nice greeting, truth (honesty) and being clear [transparent].* [*Data collectors, FGD,* Butajira]

> *It depends on the approach of the person (data collector); the way he enters the household. If you enter giving them greetings, then talking to them slowly. If he enters there systematically, It will be good, [and] you can [then] talk to them.* [*Mixed group (urban), FGD,* Butajira]

5.1.8. Gender Dynamics

In all study sites, it was mentioned that gender status in the community is reflected on how decisions are made at individual and family levels. In the family set-up there is suspicion from the husband's side regarding involving the wife in health-related discussions. Male respondents expressed their stance on this as follows:

> *" [Moderator] : What will happen if he [data collector] talks to her directly?*
> *[FGD Participant] : hahaha... how can this happen while I am around (alive)?"*
> *[Male FGD Participant,* Butajira]

The reasons mentioned for this were the male-dominated patriarchal community structure; suspicion and jealousy; and the desire to control decision and information going out of the family. Regarding preferences surrounding the gender of the data collector for their wives, the male respondents generally preferred female data collectors. Some disagreed, saying what mattered was not the gender of the data collectors but their readiness, approach and communication skills. The community expressed a variety of views on whether women could make independent decisions to take part in a study or not. In Zeway and Adami Tulu, women were considered not able

to make decisions without their husbands. While many thought they could not, others disagreed and claimed the days when husbands were deciding for their wives had passed.

> *She cannot [do it] alone ... She can ... [only]... after discussing with her husband. I decide first, [then] we decide together. If we agree she can do whatever she wants because [since] we have already decided.* [*Male group, FGD, Adami Tulu*]

> *[A female participant]: Why do you say I can't decide? These days all rights are respected..... Yes, I can decide by myself. I am the one who has the right to decide on my blood. Has he?[Laugh]*
> *[Another woman] :It needs agreement with the husband. Don't say there is no, thing what you can face. It will come to face you. I tell you the truth. I can't decide on this thing myself alone, and I have to agree with my husband to do this thing.... If it is something that has benefit, deciding is impossible, of course, without him. It is impossible without the husband.*
> *[Female group, FGD, Adami Tulu]*

> *I do not think she can. Since husbands and wives discuss together to do things both should know about each other. In case she does not understand the idea, she talks to her husband to discuss. She says I discuss this with my husband. She cannot give answer by herself.* [*Male group, FGD, Ayra*]

Discrepant views: Discrepancies in views were reflected related to women's decision making autonomy. Some women mentioned that women making autonomous decisions without their men is appropriate and not a problem. While they think they can decide autonomously, husbands wanted to know what is happening and demanded to be informed of what is going on and be reassured. While some discussants said it was impossible to talk to and ask consent from a woman without the husband's involvement, others said it was not a problem and the problem is rather understanding of the issue. It is important both in relation to communications and decision-making to be sensitive to the gender related differences. In addition pre-information and the timing of home visits were considered important.

> *There was a part which was only for her, then the man didn't want me to ask her alone, I explained it to him, but he refused. He suspected that I was giving her pills. When we ask the females, there were some*

> *husbands who did cause some difficulty, some even refused, ...They want to be asked permission .[Data collectors, FGD,* Butajira]
>
> *I was a supervisor, the data collectors were females, but I was the one who went to most houses and interviewed the females. There was no problem. Even if they were females (sometimes), there was no understanding among them. So I helped. [Of course] I agree with .. the idea. Even we the people who has to ask the question might be embarrassed to ask the [sensitive] questions. [Male d*ata collectors, FGD, Butajira]
>
> *At the time when the males were superior, the husband was asked first, now there is no problem, if she is willing he will not tell her not to do it. [another respondent]: First we ask the husband for permission, to talk to the wife, this thing has been practiced for a long time. [Mixed group, FGD, Butajira]*

Trust: Apart from the issues of ownership and control, men lack trust in the responses their wives would give to the data collectors. They lack trust in both directions towards the data collectors as they suspect that they may convince their wives of information that they do not want (such as family planning) but also think the wife may not answer the questions in the way they would like them to answer.

> *Both the wife and the husband can give the information but the information can be different. The wife might give false (wrong) information. She might refuse to let the researcher count her children. If the husband is asked he will give the true information. It is better if both are present. If they are not around, the data should not be collected. [Male group, FGD,* Butajira]

*Male data collectors***:** Out of discomfort that a stranger male data collector is talking to their wives, preference for female data collectors was expressed by husbands. The reasons mentioned for preferring female data collectors included reduction of husband's discomfort and suspicion; reduction of woman's discomfort in discussing sensitive 'women' issues with another man; and creation of better understanding as women tend to understand women better. It is considered inappropriate if a woman in the area is found talking to a strange man in her homestead. Therefore it would be difficult for women in the community to communicate with a strange man coming into the house on

his own. It is preferred if data collectors come in pairs or groups and stay outside the house.

> *For example, it is not acceptable if an individual like you [a male] enters alone into somebody's home. Even she does not give answers. But they accept four or five individuals who give education or collect information for research. If you are two, [and about to] enter into my home, she is voluntary. If you are one she will not be voluntary, she asks why you entered into her house and what will my husband say if he comes?* [*Mixed group, FGD, Adami Tulu*]

> *If he [the data collector] is a male, it would have been bad. When he (the husband) returns back he will face death. But if they[respondent and data collector] are both females and if they don't take much time there will be no problem.* [*Male group, FGD,* Butajira]

> *They can decide. But, if you simply go where there is no awareness, they may refuse to give you idea on what you need, if she is alone, she may not give.* [*Mixed group, FGD, Ayira*]

5.1.9. Decision Making

Signature : Even in a situation where an environment of understanding and agreement is reached, there is a tendency to express agreement orally rather than in a written signature. Signature is not favoured for a number of reasons such as inability to read and write; uncertainty surrounding the intentions; and associating signatures with some unforeseen accountability and responsibility. It is considered enough to ask for agreement orally instead of asking for a signature. Some warned that requesting a signature might interfere with the trust-based relationship built between the data collector and the respondent. When someone is asked to sign, it may imply that his verbal agreement is not good enough. Still others argue that signature has a place, particularly among the more-educated, and is important as it further affirms the decision of the person. However, a signature is considered a mark of further confirming one's stance and agreement and a way of indicating a stronger level of agreement.

> *When they come looking for signature we might not agree, because we don't know the person. The verbal is better. because we are not educated, [so that] the person might not trick us.* [Male group, FGD, Butajira]

> *I [better] simply say I have interest to participate, orally. Interest can be expressed in different ways. For example, if I am asked of my interest in doing something I orally say I want to do. So, most of the time if you talk to somebody, you agree orally. Even if they disagree they express orally. In this area expressing interest orally and by signature differ. The signature can come next.* [Mixed group, FGD, Adami Tulu]

> *Signature is not needed. [They] prefer to explain interest orally. They think it is forcing people to do something. ... They fear signature. Signature seems enforcement. [Male group, FGD, Ayra]*

> *For example, if somebody comes to our church, if they say blood testing will be done after the end of the program and all of you can be tested, all will go and be tested. If these people are called and asked to put their signature and are told that they will give blood for the test on a specific day, they ask why they are being asked to sign. [they will say] why do they ask me to sign since it is my own will to take part. .... They say I am [already] willing why you ask me to sign.* [*Mixed group, FGD, Ayira*]

> *As I see it, when someone says he is going to do something the only way he can be held accountable is if he signs for it, this is my belief. If I sign this means I am going to do it, I can also use verbal consent. [But] to confirm it is better to sign, ...It is better to have a signature, because it really does confirm that I am going to be held responsible for my word, ... the educated people they read the paper and then they sign. Those people who don't know how to read and write might fear that the person might lie and make them sign on a different paper.* [*Mixed group, FGD, Soddo*]

Witness and Trust : Some participants indicated the importance of involving another person in the decision process to increase the level of trust. Having trust in the data collectors is important in the consent process. For this, the people want to know who the person is, whether coming through the known and trusted *kebele* structure or not. In addition, the level of trust regarding the information given and the person approaching is key for making further decisions and giving out consent.

> *If there are educated people in the house, they will also sign as a witness, or they will bring an educated person from the neighbourhood. [Mixed group, FGD, Butajira]*

> *Just as I said, giving blood itself is not necessary. Unless I go to health facility, if someone ask me to give blood, I can't do that. Even if he tells*

me everything, I do not believe him and I do not have trust to give. [Female group, FGD, Adami Tulu]

5.2. Discussion

The REA conducted in the three parent research projects were able to identify important ethical issues for improving consent processes. We were able to generate evidences indicating that REA is worth conducting for exploring context-specific ethical issues and informing the consent process. This further substantiates the findings of other studies which have employed REA and have come up with a range of ethical issues.

The current work has tried to extend the work of others on REA (Tekola, Bull et al. 2009a) (Tindana, Bull et al. 2012) (Tekola, Bull et al. 2009b) (Bull, Farsides et al. 2012). While earlier work was limited to individual research projects, the current pilot addressed three projects in one country, in four different geographic locations. This helped us to gain a bigger picture of REA in action. We were also able to make comparisons across the different sites. Ethical issues identified by the REA varied by location even for the same project, indicating that no two REAs are the same. For example, REA was performed in Soddo prior to a genetic study project in 2009 (Tekola, Bull et al. 2009a). The current REA revealed new issues in relation to the research project under consideration. When REA was performed in the same area in relation to another project, new issues were identified owing to the different timeline and research issue under consideration. REA is considered to be a function of the research issue, place and time. Any different combination of the three creates a range of issues peculiar to that context.

A number of important ethical issues were identified through the pilot REAs. Ethical issues are a range of issues with implications for ethical considerations in light of the basic principles of ethics. An ethical issue can be defined as 'a problem or a situation that requires a person or organisation to choose between alternatives that must be evaluated as right (ethical) or wrong (unethical)' (BusinessDictionary 2013). Ethical

issues are often understood in the light of ethical and moral principles (Beauchamp and Childress 2012). There is a suggestion from experts that the boundaries of ethical issues tend to be restricted to the philosophical and moral dimensions and less accommodative of societal and lay perspectives (Braunack-Mayer 2001). Others have suggested the need for a more context-driven than theory-driven approach to applied ethics (Hoffmaster 1992). In our REA based assessment of ethical issues we tried to be inclusive of theoretical frameworks, principle-based understanding of issues and the concerns of lay people, data collectors and researchers. For the same reason, we presented and discussed the ethical issues in an open frame than trying to fit them to a fixed model. The major ethical issues identified in this multisite pilot included gender dynamics, the place of signatures, randomization, stigma, community gate-keepers and channels, and language.

Gender dynamics and the household power struggle in decision making for research were important in every site. As women were target groups for the projects, this was a vital finding. Different societies have different dynamics regarding the role of women in decision making. Ruth Macklin argues that though these are justified as cultural contexts, they are violations of individual autonomic rights and are to be challenged rather than acknowledged (Macklin 1999). However the purpose of the REA was to identify issues such as this, and to understand the contextual dynamics than to fix them. Each project was able to contextualise their consent process by including the option of involving the husband if necessary.

Preferences for providing oral information and verbal consent rather than reading and signing were reported by the other REAs performed to date (Tekola, Bull et al. 2009a) (Tindana, Bull et al. 2012). The arguments put forward by these studies and others suggesting a flexible approach towards verbal consent were those of illiteracy and not being able to understand written information without additional explanation (Tindana, Kass et al. 2006) (Krogstad, Diop et al. 2010). In the current study, perceptions of taking a risk and giving a person responsibility for whatever is to come were identified as the main concerns surrounding signing. Other researchers have emphasised the

relationship between signature and consent and the importance of information and self-autonomy beyond the procedural signature (English 2002) (Sokol 2009). The Food and Drug Administration (FDA) of the United States government has suggested investigators are responsible for the consent process that requires signatures (Goldfarb 2009). In the studies that followed these REAs, the option of verbal consent accompanied by signature by the data collectors was offered.

Expecting benefits was a common theme expressed in all the research sites. Many considered the research outcomes as equivalent to therapeutic medical interventions – the 'therapeutic misconception'. The issue has been in detail explained elsewhere (Lidz and Appelbaum 2002) and was identified by the earlier REA by Tekola et al. in Soddo (Tekola, Bull et al. 2009a). However, selection for research was associated with benefits, so the community found random selection difficult to understand. The concepts of randomization and random selection were confused with the lottery which benefits the few lucky ones. This is considered unfair and many said it should have been possible to involve the whole community so all might benefit. Writers have argued that understanding the concept of randomization may not be very important especially for randomized controlled trials and this could even tamper with the study design and introduce bias (Wendler 2009). However in a situation where the misunderstanding is considerable, one has to find ways of explaining in lay terms. Additional explanations were given to participants to illustrate what random selection is and its implications.

The issue of stigma has also been documented by earlier researchers. Stigma against any condition may result in potential participants declining to take part in medical interventions including research (Easton, Entwistle et al. 2013). This was documented in earlier findings (Tekola, Bull et al. 2009b). Perceptions of stigma, especially if accompanied by lack of trust and lack of assurance of privacy and confidentiality, will be counterproductive to the consent process and recruitment of participants (Eyal 2014). To complicate matters this concern may not be overt and expressed. That is why a deliberate effort to understand the dynamics behind decision making will be important. This is addressed by proper explanation of the research issues, the intentions of the

study and all the mechanisms available to ensure confidentiality. This must be done proactively, even if the participant has not raised stigma as an issue.

The need to utilize the existing community structures and gate-keeping channels was another common theme. In developing countries, decision-making dynamics are embedded in the community structure and the gate-keepers make public opinions and can either hinder or facilitate access the community and subsequently individual consent processes (Bhutta 2004) (Tindana, Kass et al. 2006) (Gallo, Weijer et al. 2012). This has been documented by earlier researchers who employed REA (Tekola, Bull et al. 2009a; Tindana, Bull et al. 2012). In our case, REA helped map out the community structures and the important area-specific actors. The *kebele* and health extension workers were mentioned by all, while the roles of traditional systems, religious structures and community based organizations were not uniform across the various locations. This again justifies doing REA to highlight such subtle issues which may otherwise be overlooked.

Language was prominent issue, and the linguistic dynamics for each of the locations was not exactly same. Language barriers are mentioned as important challenge for the consent process for research in developing countries (Campbell) (Minnies, Hawkridge et al. 2008). Ethiopia is a multi-ethnic country with over 80 languages spoken. It appears obvious to explore language dynamics ranging from the prevalent language to the role of various languages in each society. Even when a common language is acceptable for consent and research communication, almost always the community prefers this to be accompanied by explanations and socializing using their own language. Other researchers also have reported the importance of identifying key vocabulary to be used in consent information for the specific settings (Tekola, Bull et al. 2009a).

Overall in this study we were able to demonstrate that REA is useful in exploring a wide range of ethical issues. After analyzing responses and codes of the qualitative enquiry, we have come up with set of major categories of ethical issues as they relate to the

informed consent process dynamics which fall to four classifications; a) context, b) content, c) communication (and comprehension) and d) consent (and its consequences). The categories are intertwined with each other and they are by no means mutually exclusive. They are however useful in further framing of the ethical issues.

Context includes the background, circumstance and setting in which the researcher is planning to operate in and for which the consent process will be designed for. The ethno-cultural context is of utmost interest for framing a proper research consent process. It is important to have a picture of the context in general terms in addition to the other specificities such as health seeking behaviours. What does the area in general look like; is the area naive to research or not; what is the area profile in terms of language, religion, and remoteness; what impressions are formed about the people, the area and social systems and structures? Cultural taboos and norms relating to certain issues will also be important.

In all the four geographic areas it was possible to identify background information and context-specific issues in the areas of culture, ethno-cultural, and religious prevailing issues. This helped the researchers to lay a sound background of information about each area and community beyond that gained through desk review. In addition to the general ethno-cultural and demographic issues, background information on previous research in the area and the health system and health-seeking behaviours prevalent in the different settings helped map the terrains in each area. Understanding the health problems and health system dynamics helped describe the receptiveness of the community to health-related discussions and issues. Their experiences with health professionals such as HEWs also provided many clues on how the communication with data collectors would be perceived and how they needed to be tailored to meet community expectations. Existing experiences in each area, in particular how the provision of biological specimens is perceived by the community, gave valuable information for planning specimen collection in the subsequent research. Levels of stigma associated with certain illnesses and medical interventions were also explored.

The second category, *Content,* refers to the minimum package of information to be contained in the study information sheet and conveyed to the study participants. This deals with any pre-existing knowledge in the community or any prevalent misconceptions in relation to ethical principles of autonomy, risk or benefit. It includes how benefits and risks are perceived by the community and what pertinent information should go into the information sheet and the consent communication processes, on top of the basic standard requirements. Based on REA, it was possible to modify the information sheets and provisional consent forms to reflect the communities' perceptions and misconceptions on issues such as risks and benefits.

The third category, *Communication* addresses what communication channels are prevalent in the area, and by what modality people deliver information on important issues to individuals. The dynamics between the communicators and the receiver is a key issue here. When deciding who should be the communicators and what virtues are expected from the community, the identity of the receiver is important as is the context. This needs to be evaluated from the perspectives of both the actual communicators (e.g. data collectors), the channels, and those communicated. With REA, it was possible to identify the acceptable approaches in communicating with different target groups and the value of deeper explanations in resolving unexpressed doubts. The optimal language for communication and the key points of entry to the community (*kebele*, church, *gare/shen* or health extension workers) were identified. Optimal communication needs to be accompanied by comprehension, and REA helped to identify ways of assessing this. For example, it was possible to pick difficult concepts such as research vs therapy/benefit, control arm and randomization, and explore ways of assessing comprehension of these using questions and further discussion.

As part of consent communication, *Comprehension* is a related key issue which is often overlooked due to practical challenges. Even if the right content is communicated, it will be futile if it does not result in proper comprehension. Comprehension is 'understanding' of the ethical issues, not necessarily learning new knowledge. How do we ensure

understanding; what issues deserve further attention and explanation? It is the duty of the researcher to ensure mechanisms are in place for enhancing consent comprehension. Various implementations have been suggested and utilised to improve comprehension and quality of informed consent process in medical research and medical interventions (Dunn, Lindamer et al. 2001; Flory and Emanuel 2004; Sudore, Landefeld et al. 2006; Cohn and Larson 2007; Benatar, Mortimer et al. 2010; Penn and Evans 2010; Ndebele, Wassenaar et al. 2012; Tamariz, Palacio et al. 2012; Nishimura, Carey et al. 2013). However it is only when we know the target community better that the proper intervention can be designed, and REA helps serve this purpose.

The remaining important categories have to do with *Consent* and its *Consequences*. This is about decision making and the process by which the decision to take part or not is made. This entails both 'who' and 'how'; who are the important actors in the decision making; what are the mechanisms in the community for making such important decisions; and what flexibilities and provisions are recommended. Issues accompanying decision dynamics such as gender dynamics were identified for possible adjustment in the consent process. The need for involvement of husbands when recruiting their wives, preferences for female data collectors, the care and caution male data collectors must take when interviewing a woman were all areas requiring careful negotiation. The preferred means of expressing one's decision, such as attitudes towards signatures, were explored. In many communities, signatures are not preferred, because the people cannot read and write or sign saying they have read. Even for those who can read, signing has another connotation of suspicion and trust. They think they are being accountable as signatures are associated with debts and, in hospital, consent processes are often associated with agreeing to the risks of procedures. Signing means taking full responsibility and releasing the practitioner if any problem occurs due to the procedure in a surgical operation. The availability of witnesses was mentioned as a way out and this was implemented in Parent research Project I, whereas the researchers were asked to sign in Parent research Project III. In addition, the role of local organizations like the *kebele*, in the decision making process, was evaluated, as was the value of trust and its place in the relationship between the interviewer and the

respondent. Consent consequences are the future perceived outcomes that may result from decisions made now, and are strongly linked to the issue of consent. Consequences that may be important to people considering consent to research include what other people may feel or think about the decision and anticipation of stigma relating to participation in research. Consequences may occur at individual or communal level. REA identified that participants are concerned that the results of the research may not be communicated back to them, making their role useless and without apparent consequences. On the other hand, when the issue is very sensitive, potential participants are concerned about disclosure of their personal status and possible consequences of becoming stigmatised as a result.

Limitations

Making site to site comparisons was at times difficult as the issues were not uniform across all sites. As REAs are action research whose results are intended for field use, we provided feedback to researchers during and after the pilot. The pressure to deliver results to the investigators, so they could incorporate changes into their processes and documents, may have led to over-rapid analysis on the field.

5.3. Conclusions and Recommendations

The following conclusions can be reached from the findings discussed above:-

- REA is useful in informing the consent processes in community based research. It enables identification of a range of ethical issues important to a particular community, which are unlikely to have been identified in the absence of REA.

- The ethical issues identified cover a considerable range. The flexible and iterative nature of REA was able to explore these issues in a reasonable period of time.

- Major categories of issues include those of Context, Content, Communication and Consent. As a package these categories can help in framing the future design of REAs. Though ethical issues are detailed and specific to context, it is useful to have a framework such as this in mind when developing a REA for a specific context.

- The exact nature of ethical issues identified by REA were not identical and were a function of place, time and subject-matter. The issues varied whenever the research issue, the study area or the timing of the study changed.

Based on the findings and conclusions made above, the following recommendations can be made;

- Researchers are advised to familiarize themselves by employing REA to explore the ethical issues important to their study context when indicated.

- REA is likely to generate new issues of importance given differences in time, area or research subject area.

- Researchers are advised to follow a categorical framework in the design and conduct REA. This provides a general framework while still allowing new issues to emerge.

Chapter 6 : REA and Comprehension and Quality of the Informed Consent Process

The problem with comprehension is it often comes too late.
Rasmenia Massoud[78]

This chapter presents quantitative empirical findings on the association between REA and consent comprehension, and quality of consent process, including study recruitment and retention rates. More specifically we deal with the potential impacts of REA on comprehension of consent information by study participants and subsequent compliance and retention. We measured consent-information comprehension level, recruitment rate, retention rate and quality-of-informed consent among participants enrolled into one of our parent studies; *HPV Subtype seroprevalence study* (Assefa 2012), in Northern Ethiopia, Hintalo Wujirat Woreda, Tigray Regional State. For the intervention group the consent form and process were modified based on REA findings. For the control group, consent protocol and process as was originally planned by the respective researchers were applied. The two groups were compared for IC comprehension, recruitment and retention rates as well as quality of the consent process measured by different tools such as MICCA, BIQ and QuIC (Buccini 2009a). Details of the methods are described in chapter III.

6.1. Results

6.1.1. Socio- demographic and economic characteristics of study participants

A total of 300 pregnant women (150 in the intervention and 150 in control groups) were approached for recruitment into the parent research. Of the total 254 participants who consented (133 from the intervention and 121 from the control groups), 199 showed up for the follow-up visit and participated in the comprehension assessment (114 from the intervention and 85 from the control groups). The mean age of the participants who attended the follow-up appointment and were included in the comprehension

[78] *Massoud, R. (2010). Human Detritus. NC, Lulu Press, Inc. .*

assessments was 27.3+6.3 years. Majority were married (83.4%); from the Tigre ethnic group (99.5%); Orthodox by religion (86.4%); able to read and write (70.8%); and earn a monthly family income of >1000 Birr (61.8%). For most participants (72.9%) it was their first time to participate in any medical research (Table 6.1).

The REA conducted at the study site, at the very beginning of recruitment identified a number of ethical considerations (Figure 6.1) based on which the consent form and process for the intervention group were modified so as to address the issues. The consent process revisions included use of local terminologies, provision of concrete explanations with examples, and contextual clues in the consent communication. The average time it took for reading and providing information was 9.63 and 10.00 minutes in the control and intervention groups respectively. Participants were asked whether they had any questions after reading each section of the form, and once more after the end of the entire reading. Then consent for the parent study was requested. In the control group, this was indicated by signing a form, whereas in the intervention group, consent was indicated orally with the signature of the data-collector as a witness. Sentences and paragraphs in the modified form were relatively short, and the words chosen were more familiar and local. The major characteristics of the two versions are summarized in Table 6.2.

Table 6.1 Demographic and economic characteristics of respondents of WukiroKilte-Awulaelo and Hintal-Wajirat woredas, Tigray region, July 2013

Variable (n=199)	Intervention group f (%) (n=114)	Control group f (%) (n=85)	Total f (%) (n=199)
Age in years			
18-24	34(29.8%)	38(44.7%)	72 (36.2)
25-31	45(39.5%)	30(35.3%)	75 (37.7)
32-38	30(26.3%)	14(16.5%)	44 (22.1)
39-45	5(4.4%)	3(3.5%)	8 (4)
Mean (± SD)	27.9 (±6.2)	26.4 (± 6.2)	27.3 (±6.3)
Marital status			
Married	99(86.8%)	67(78.8%)	166 (83.4)
Single	5(4.4%)	8(9.4%)	13 (6.5)
Divorced	7(6.1%)	6(7.1%)	13 (6.5)
Widowed	3(2.6%)	4(4.7%)	7 (3.5)
Educational status			
Not able to read and write	37(32.5%)	21(24.7%)	58 (29.1)
Able to read and write	11(9.6%)	6(7.1%)	17 (8.5)
Primary school	29(25.4%)	21(24.7%)	50 (25.1)
Secondary school	24(21.1%)	27(31.8%)	51 (25.6)
Diploma and above	13(11.4%)	10(11.8%)	23 (11.6)
Religion			
Orthodox Christian	100(87.7%)	72(84.7%)	172 (86.4)
Muslim	13(9.6%)	10(11.8%)	23 (11.6)
Others(catholic/protestant)	1(0.9%)	3(3.5%)	4 (2.0)
Mother tongue			
Tigrigna	114(100%)	83(97.6%)	197 (99)
Amharic	0	1(1.2%)	1 (0.5)
Others	0	1(1.2)	1 (0.5)
Occupation			
Housewife	24(21.1%)	47(55.3%)	71 (35.7)
Farmer	38(33.3%)	4(4.7%)	42 (21.1)
Merchant	28(24.6%)	6(7.1%)	34 (17.1)
Government employee	15(13.2%)	13(15.3%)	28 (14.1)
Private employee	4(3.5%)	10(11.8%)	14 (7.0)
Others (student, jobless)	5(4.4%)	5(5.9%)	10 (5.0)
Family monthly income			
Less than 500ETB*	6(5.3%)	10(11.8%)	16 (8.0)
500-1000ETB	26(22.8%)	34(40.0%)	60 (30.2)
Greater than 1000ETB	82(71.9%)	41(48.2%)	123 (61.8)
Participated in medical research previously	21(18.4%)	15(17.6%)	36 (18.1)

* 1 USD (US Dollar) ~ 19 ETB and GBP ~ 28.5 ETB

Low community awareness on biomedical research: Most did not differentiate between health related research from medical interventions and treatment. Some participants considered all individuals obliged to be involved in research.
Local Terminologies: The local language has words for describing some of the key technical terms in the consent form. For example, cancer in the local language is termed as *'Menkersa'*, *'Kintarot'* or as swelling. Breast cancer was the better-known type of cancer in women, whereas cervical cancer was less known.
Signature: During consent, asking participants to sign to might result in high non-response rate and hinder recruitment.
Sample: Giving a vaginal secretion sample for testing was associated with considerable embarrassment, and giving a blood sample was associated with fear of testing for other diseases and lack of confidentiality.
Gender issues: In the community, women had the full right to participate actively in social activities, and make decisions about their lives, except under certain circumstances like choice of family planning and HIV testing; in which husbands expected to be involved in. Female sample collectors were preferred to males so that women would voluntarily participate and freely discuss reproductive health issues.
Communication channels: The community reported that they had past experience in which some investigators came offering aid and then introduced other agendas including religious teachings. The preferred communication channels in the community were through religious leaders and health professionals, both of whom are well-known to the community. Political leaders should also be involved for legal issues.
Expectations: The community did not expect immediate benefits like incentives or money from research. Instead they are concerned about their test results and subsequent treatment. They had past experience of payment for participation in demographic surveys.
Sampling: There was poor understanding about random sampling in research. The individual selected worried that they were selected because of their health condition and on suspicion that they had the disease. On the other hand those who were not selected thought they were mistreated and were denied of some benefits for participation in the study.

Figure 6.1 Highlight of Ethical Issues identified by REA done prior HPV Sero- prevalence survey at Wukro Kilite Awulao and Hintalo Wujirat Woredas, Tigray Region, July 2013

Table 6.2 Comparison of 'standard' and 'modified' information sheet, consent forms and procedures used for comprehension study in Wukro Kilite Awulao and Hintalo Wujirat Woredas, Tigray Region, July 2013

Consent components	Modified	Standard
Font, style	12, power geez uni-code 1	12, power geez uni-code 1
Language	Tigrigna	Tigrigna
Average words per sentence	12.4	16.3
Average word per paragraph	67.1	97.8
Average sentences per paragraph	5.6	7.6
Total words	604	587
Total No of paragraphs	9	6
No of pages	Two and a half	Two
Average time taken (minutes)	Mean=10 ; Median=10	Mean=9.6 ; Median=10
Used narrative explanations?	Yes*	No
Invited questions on unclear ideas or concepts	Yes. Written and included in the consent form	Yes. Orally
Type of consent seeking	Verbal consent	Signed written document
No of days between consent taking and comprehension assessment	Mean =12 days Median =12 days	Mean=11.9 days Median=12days

***** see annex for the narratives of the explanations used (Annex B)

6.1.2. Recruitment and Retention rates

The overall study-recruitment rate among the study participants was 84.7% (88.7% in the intervention and 80.7% in the control group; p= 0.05), with refusal rates for the intervention and control groups being 11.3% and 19.3% respectively. The overall study-retention rate was 78.3 % (85.7% for the intervention group and 70.3% for the control group; p < 0.005). The loss to follow-up rates after initial consent, were 14.3% and 29.8% in the intervention and control groups respectively (Figure 6.2).

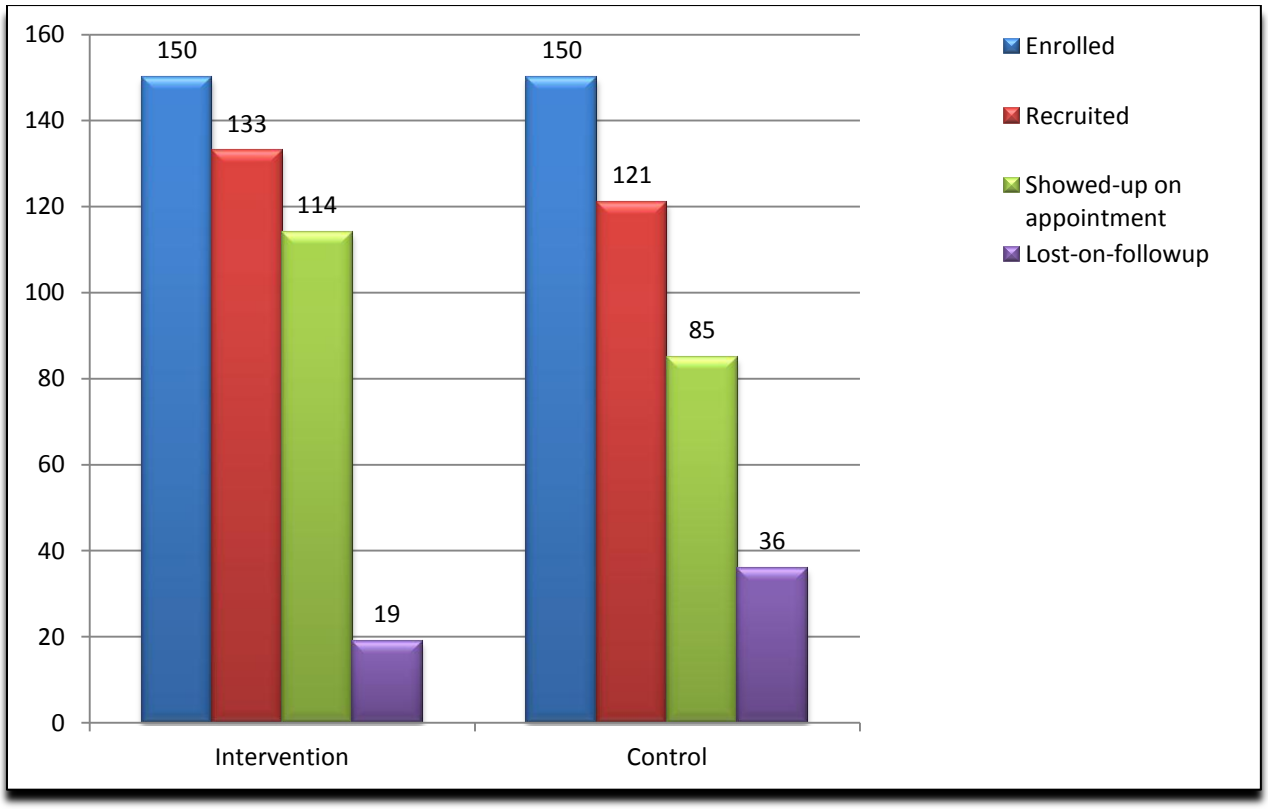

Figure 6.2 Rates of recruitment and retention among participants by type of consent form, WukiroKilte-Awulaelo and Hintal-Wajirat woredas, Tigray region, July, 2013

6.1.3. Informed-consent Comprehension Scores

In the control group, the majority (77.6%) had low comprehension score (50% or less); only 4.7% had high comprehension score (75% or greater) and the remaining 17.6 % had medium comprehension score (between 50% and 75%). In the intervention group, 43% of participants had high comprehension scores (75% or greater), only 8.8 %

obtained a low comprehension score (50% or less) and the remaining 48.2% had a medium score (between 50% and 75%) (Table 6.3).

Participants in the intervention group were 4.6 times more likely to have medium than low comprehension scores and were 14.5 times more likely to have high than low comprehension scores than participants in the control group (Table 6.3). Comparisons of comprehension levels for the various components of consent information are given in Figure 6.3.

The mean scores of the two groups (intervention and control) for all the 25 questions used in the comprehension test are presented in Table 6.4 and further summarised in Table 5.5. Participants in the intervention group obtained an average score of 73.1% in overall comprehension, 73.2% in the recall and 73.0% in the understanding sections. Participants in the control group obtained an average score of 45.2% in the overall comprehension, 44.8% in the recall and 45.6% in the understanding categories. There were statistically significant mean differences in all three categories between the intervention and control groups ($p< 0.001$).There was a significant net difference in the mean score comprehension in almost all of the components in the intervention group compared to the standard. The highest mean difference (42.7%) was observed in the understanding of participant rights. There was no statistically significant mean score difference in disease-related information between the intervention and control groups (Table 6.5).

Table 6.3 Level of informed consent comprehension in the intervention and control groups, Wukiro Kilte-Awulaelo and Hintal-wajiratworedas, Tigray region, July 2013

Comprehension Score	Intervention Group f (%) (n=114)	Control Group f (%) (n=85)	RR (95% CI)	P value
Low [<=50%]	10 (8.8)	66 (77.6)	1.00	
Medium [50%-75%]	55 (48.2)	15 (17.6)	4.6(2.9, 7.3)	<0.0001
High [>=75%]	49 (43.0)	4 (4.7)	14.5 (5.6, 37.9)	<0.0001

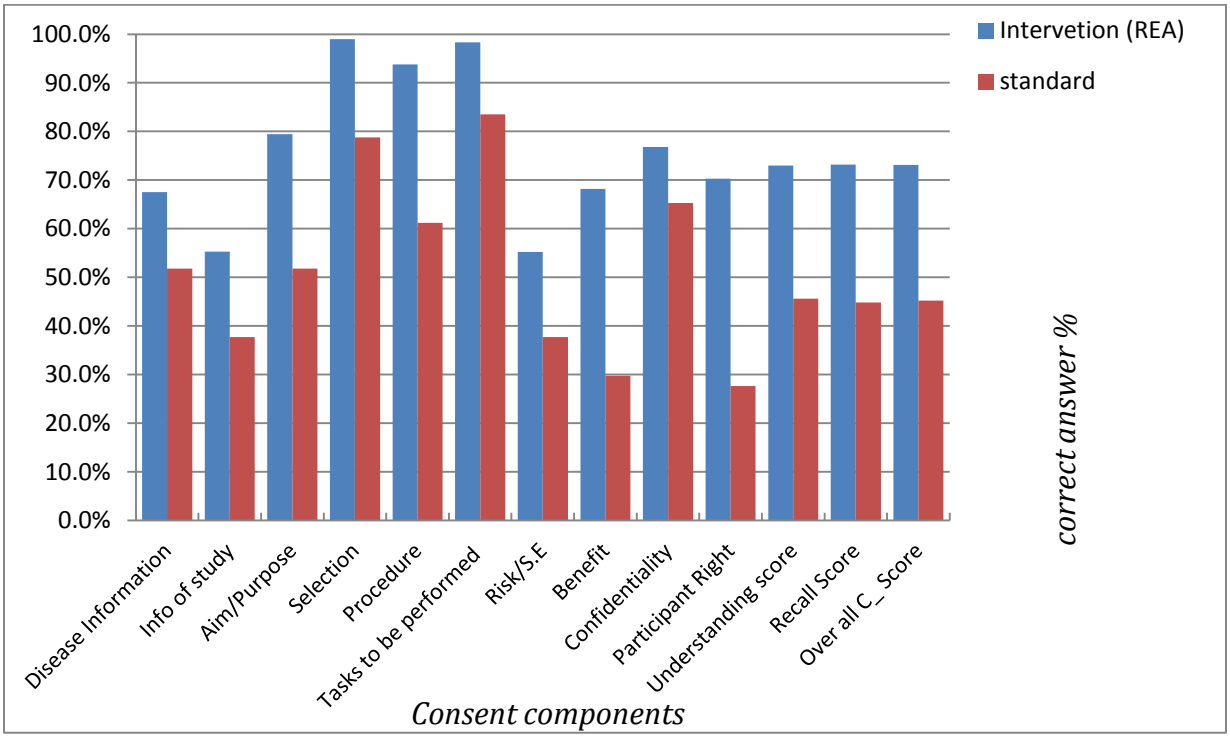

Figure 6.3 Percentage of participants (intervention and control) giving correct responses to the main consent comprehension components

Table 6.4 Mean informed consent comprehension score (CS) of participants, Tigray region, July 2013

	Consent component	Mean % CS			
		Intervention (N=114)	Control (N=85)	Mean difference (95% CI)	P value
201	This health related study is a form of a research[1]**.[True]***	44.7	30.6	14.1 (0.5 , 27.8)	0.043
202	Obligation to participate in this medical research[1]**.[False]**	19.3	8.2	11.1 (1.2 , 21.0)	0.029
203	Told who is funding this research[1]. **[True]**	46.5	34.1	12.4 (1.5 , 26.2)	0.080
204	Told the total number of people that participate in this research[1].[**False**]	57.9	44.7	13.2 (0.9, 27.3)	0.066
205	Except study team no one will be allowed to see my health information[1]**.[True]**	65.8	81.2	15.4 (27.9, 2.9)	0.016
206	I will be told test results from this research[2]. **[False]**	76.3	15.3	61.0 (49.7, 72.3)	<0.0001
207	Treated for the infection tested by this research[2].[**False**]	63.2	11.8	51.4 (39.4, 63.4)	<0.0001
208	I have been told contact person address[1]. [**True**]	71.9	41.2	30.8 (17.5, 44.0)	<0.0001
209	I will get a special care in my regular ANC follow up[2]. [**False**]	64.0	55.3	8.7 (5.1, 22.6)	0.215
210	My participation in the study can be stopped at any time[1]. [**True**]	81.6	20.0	61.6 (5.0, 72.8)	<0.0001
211	I will be asked for costs related to my participation in this study[1].[**False**]	80.7	50.6	30.1 (17.5, 42.7)	<0.0001
212	I will be paid or got any incentive for participating in this study[1].[**False**]	95.6	42.4	53.3 (43.1, 63.4)	<0.0001
213	The sample taken in this study can be used for other purpose[1].[**False**]	87.7	49.4	38.3 (26.6, 50.0)	<0.0001
301	Selection to participate in this study[1].[**A**]	99.1	78.8	20.3 (12.5, 28.1)	<0.0001
302	When to visit a doctor to avoid cervical cancer[2].[**B**]	67.5	51.8	15.8 (2.1, 29.5)	0.024
303	Who analyze and discuss test results **[2].[A]**	95.6	51.8	43.3 (33.6, 54.1)	<0.0001
304	At what time can leave the study?**[1][A]**	64.0	12.9	51.1 (39.0, 63.1)	<0.0001
305	Agreed or signed to participate in this research mean[1]**.[C]**	87.7	61.2	26.5 (15.1, 38.0)	<0.0001
306	Can stop participation after you signed to participate?**[1][A]**	73.3	21.2	52.5 (40.4, 64.6)	<0.0001
307	Any difference made to regular ante natal care if not participate?**[1][B]**	85.1	81.2	3.9 (6.6 , 14.5)	0.466
308	**The main purpose(s) of the study?[3]**				
	To know more about cancer disease in Ethiopia **[A]**	67.5	56.5	11.1 (2.6 , 24.7)	0.111
	To introduce vaccine to benefit future generation of girls **[B]**	91.2	47.1	44.2 (33.1, 55.3)	<0.0001
309	**The main benefit(s) taking part in this research?[3]**				<0.0001
	Future generation of girls but not me will benefit.**[C]**	69.3	36.5	32.8 (19.5, 46.2)	
310	**Procedure(s) asked to take part in?[3]**	96.5	65.9	30.6 (21.0, 40.3)	<0.0001
	Giving a small amount blood for test **[A]**				
	Giving vaginal secretion for test **[C]**	91.2	56.5	34.8 (23.7, 45.8)	<0.0001
311	**Task(s) asked to complete?[3]**				
	Attend appointment **[A]**	98.2	83.5	14.7 (7.3, 22.2)	<0.0001
312	**Side effect(s) that might occur during blood drawing for test?[3]**				
	Pain or bruising on the vein **[A]**	57.0	41.2	15.8 (1.8, 29.9)	0.027
	Bleeding at the site of the needle**[B]**	47.4	34.1	13.3 (0.6 , 27.1)	0.061
Over all C-Score		**73.1**	**45.2**	**27.9** (**23.96**, **31.87**)	**<0.0001**

[1]*Generic test item- These test items appear on each version of MICCA*

[2]*Trial specific test item- These test items do not appear on every version of the MICCA. They are generated based on responses to BIQ.*

[3]*Trial specific test items appear on each version of the MICCA. The response option for each of these test items are generated based on response to BIQ.*

*In the square bracket are the correct answers for the questions asked

Table 6.5 Comparison of percentage of participants giving correct responses to the main consent components in the intervention and standard group, WukiroKilte-Awulaelo and Hintal-wajiratworedas, Tigray region, July 2013

Consent component	Mean % CS Intervention N=114)	Mean % CS Control (N=85)	Mean difference (95% CI)	p value
Disease information [Q302]	67.54	51.77	15.8 (2.1, 29.5)	2.4
Information about the study[Q201, 203, 204, 208]	55.26	37.64	17.6 (9.46, 25.76)	<0.001
Aim /purpose of the study[Q308A, 308B]	79.38	51.76	27.6 (19.5, 35.7)	<0.001
Selection criteria [Q301]	99.12	78.82	20.3 (12.5, 28.1)	<0.001
Procedure of sample collection [Q310A, 310C]	93.86	61.18	32.7 (25.2, 40.9)	<0.001
Tasks to be performed by participants [Q311A]	98.25	83.53	14.7 (7.3, 22.2)	<0.001
Risk of the study/ side effect of sample collection [Q312A, 312B]	52.19	37.65	14.6 (4.1, 25.0)	0.007
Benefit of the study [Q206, 207,209, 309C]	68.20	29.71	38.5 (29.4, 47.6)	<0.001
Confidentiality [Q205, 213]	76.75	65.29	11.5 (2.2, 20.7)	0.015
Participant right [Q202, 210, 212, 304, 305, 306]	70.32	27.64	42.7 (36.4, 48.9)	<0.001
Summary comprehension score				
*Understanding	73.01	45.61	27.4 (22.6, 32.2)	<0.001
**Recall	73.16	44.78	28.4 (23.3, 33.4)	<0.001
Over all C- score	73.09	45.17	27.9 (23.9, 31.9)	<0.001

*Understanding -score of Q201, 202, 205, 209, 210, 211, 212, 213, 301, 304, 305, 306, 307
**Recall- score of Q 203, 204, 206, 207, 208, 302, 303, 308A, 308B, 309C, 310A, 310C, 311A, 312A, 312B

6.1.4. Quality of informed consent

To assess the quality of the consent process, participants were asked 13 QuIC questions regarding information adequacy and the process of decision making during the initial consent and recruitment processes. There was a statistically significant mean difference in the overall mean quality of informed consent scores between the intervention and control groups. In addition, there was a statistically significant difference in all but three components of quality assessment. The three components with non-significant mean difference between the intervention and control groups were;

'whether the consent form was read and explained carefully'; 'whether the consent from was an important source of information'; and 'whether the consent form was important for making the consent decision' (Table 6.6). More than eighty percent (81.2%) of control participants and 99.1% from the intervention group were satisfied with the overall consent process. Overall the mean informed consent quality assessment score for the control group was 78.5%, and that for the intervention group was 89.1%, with a statistically significant mean score difference Table 6.6.

Table 6.6 Comparison of mean quality of informed consent process (QuIC) _score from the participant's perspective by intervention group in WukiroKilte-Awulaelo and Hintal-wajiratworedas, Tigray region, July 2013

	Quality of IC (Mean %)			
Informed consent process components (Correct answers in bracket)	**Intervention (n=114)**	**Control (n=85)**	**Mean difference (95%CI)**	**P value**
There was sufficient time for consent discussion.[**Agree**]	93.9	82.4	11.5 (2.7, 20.3)	0.010
Agreed to participate in this study voluntary and with full understanding.[**Agree**]	100	87.1	12.9 (6.7, 19.2)	<0.001
Enrolment decision made mainly by me the respondent.[**Agree**]	99.1	92.9	6.2 (1.0, 11.3)	0.019
Discussed about the research with other patients or participants.[**Agree**]	91.2	17.6	8.9 (0.5, 18.2)	0.062
Consent form read or explained carefully.[**Agree**]	82.5	81.2	1.3 (-9.7 , 12.2)	0.818
Consent form was important source of information.[**Agree**]	92.1	88.2	3.9 (-4.5 , 12.2)	0.361
Consent form was easy to understand.[**Agree]**	97.4	90.6	6.8 (0.4, 13.2)	0.039
Consent form was important to the decision.[**Agree**]	95.6	95.3	0.3 (-5.6, 6.2)	0.915
Pressure from provider to sign/agree/ consent form.[**Disagree**]	95.6	76.5	19.1 (10.1, 28.2)	<0.001
Sufficient opportunity to ask questions.[**Agree]**	95.6	67.1	28.6 (18.8, 38.3)	<0.001
Questions answered thoroughly by the consent provider.[**Agree**]	99.1	74.1	25.0 (16.6, 33.4)	<0.001
Satisfied with informed consent process.[**Agree]**	99.1	81.2	17.9 (10.4, 25.5)	<0.001
Decision to participate was easy or very easy.[**Agree**]	99.1	87.1	12.1 (5.5, 18.6)	<0.001
Mean score of quality of IC	**89.06**	**78.53**	**10.5(6.8, 14.2)**	<0.001

6.2. Discussion

The comprehension assessment study demonstrated significant association between REA and study-retention rate, levels of comprehension and quality of the informed consent process among potential participants of the parent study. The REA revealed a number of relevant context-specific ethical issues concerning the parent study. These findings helped in adapting the study information sheet, consent form and consent procedures to the local culture and the educational level of the population**.** Effective communication with the community and identifying information contacts were also found to be important.

The study was conducted in a well-defined population group with relative homogeneity in language, ethno-cultural and geographic parameters. The parent study ("HPV study") was selected primarily based on parameters which suggested that REA might be relevant. The two study sites allocated to either intervention or control, were similar in relation to major societal parameters. They were adjacent to each other and belong to the same ethno-cultural cosmos including health system profiles. The use of two woredas had methodological benefits. If done in one woreda, this would likely have led to communication between members of the two groups and hence contamination and spill-over of information. The socio-demographic characteristics of the selected study participants also revealed similar over all profiles except that the intervention group had more farmers and merchants, and the control had more housewives than their comparison groups. The intervention group also had better family income status than the control. Otherwise the two groups had similar profile in educational status, language and previous participation in research.

We employed MICCA and BIQ for measuring comprehension and QuIC for assessment of quality of informed consent. The tools were chosen for their advantages in-terms of comprehensively addressing generic standard informed consent items as well as the flexibility to accommodate study specific test items in to the assessment tool (Buccini 2009a). However due to practical difficulties, we adjusted the tool by dropping the

observation components which required observations by the data collector. The objective of the observation component was to increase the objectivity of the measurement by the tool. The tools have been validated for use by researchers in different settings (Buccini 2009a). We assessed comprehension as a function of understanding and recall. The understanding aspect referred to the concepts explained in the consent process such as purpose, benefits and risk. Recall issues included issues that needed to be memorized such as date of appointment, and specific procedures such as signature, copy of consent given or not (Buccini, Jones et al. 2009b).

Recruitment rates and the recruitment index are considered important parameters in monitoring the quality of research implementation (Blanton, Morris et al. 2006; Galea and Tracy 2007). In this study higher rates of both recruitment and retention were documented for the intervention group. While, we documented a rather strong statistical association between study-retention rate and REA modified informed consent process, no statistically significant difference was documented in the recruitment rates of the intervention and control groups. Recruitment rate is considered to be a determinant of subsequent retention (Frank 2004; Blanton, Morris et al. 2006). Previous studies have tried to identify potential contributors to recruitment rates of study participant such as 'opt-out' approaches (Junghans, Feder et al. 2005); early considerations of participants' perspectives (Patel, Doku et al. 2003); addressing ethical issues such as therapeutic misconception (Blanton, Morris et al. 2006); and establishing trust between researchers and potential participants (Kneipp, Lutz et al. 2009). Other factors affecting retention include mental state of the person (Chang, Brown et al. 2009); tracking and follow-up mechanisms (Murugesan, Anandan et al. 2011); addressing community and context-specific issues and needs in special communities (Ejiogu, Norbeck et al. 2011). However, every study has its own peculiar features and it may be difficult to generalise these factors. The complexities of the challenges of recruitment are also determined by the complexities of the respective studies (Frank 2004; McDonald, Knight et al. 2006; Galea and Tracy 2007). The registered improvement in the study-retention-rate in our study has possibly resulted from improved understanding of the consent information by

the intervention group owing to the changes and modifications made. The recruitment rate, however, might have been possibly affected rather by other additional factors beyond the consent information. Studies have documented decisions already prior to recruitment based on information circulating in the community (Paré Toe, Ravinetto et al. 2013).

The study also documented significant differences in the comprehension levels (understanding and recall) of the intervention and control groups. Various researchers have utilized different interventions to improve the consent process and understanding, such as use of local narratives (Ndebele, Wassenaar et al. 2012); extended one-to-one discussion (Flory and Emanuel 2004; Tamariz, Palacio et al. 2012; Nishimura, Carey et al. 2013); enhanced consent (Dunn, Lindamer et al. 2001; Nishimura, Carey et al. 2013);a modified consent process (Sudore, Landefeld et al. 2006); and a booklet in participants' rights (Benatar, Mortimer et al. 2010). Cultural and linguistic modifications of the informed consent process were considered to significantly enhance understanding by study participant in low income settings (Penn and Evans 2010).On the other hand, it is shown that lexicosyntactic readability improvement of the consent form (Paris, Brandt et al. 2009), multimedia enhanced consent (Flory and Emanuel 2004), and use of a concise version of the consent form (Enama, Hu et al. 2012) do not have effects on comprehension. There are still ongoing evidence-based debates as to which interventions are effective in enhancing comprehension (Cohn and Larson 2007).

In our study the following sub-components of comprehension were documented to improve significantly: study information and objectives; selection criteria; sample collection procedures; participant tasks and responsibilities; risks and benefits of the study; participants' rights and confidentiality. REA-based adjustments to the content and delivery of consent information in the intervention group were linked to improved understanding and recall. These findings concur with studies which have reported improved consent information comprehension with appropriate interventions such as provision of more explanations and socio-culturally tailored approaches (Penn and Evans 2010). Provision of tailored terminologies and additional narrative explanations

on the pre-identified ethical issues and the allowing of more time for discussion and questions from the participants in the intervention group might have been potential determinants. There was no statistically significant difference in comprehension levels related to disease information between the intervention and control group. However, there was a 15.7% increment documented in the levels of comprehension of disease information in the intervention group compared to the control group. The reasons for non-significance could be the sensitivity and novelty of the issues of cervical cancer in the area.

One of the dilemmas faced by researchers while modifying the consent form was what level of change on an IRB-approved form would be appropriate and allowable once in the field, and what principles should guide this. According to existing guidelines, any amendments of an approved research project require further approval before implementation (Johns Hopkins Medicine 2013; University of Northern Texas Health Science Center 2013). The only exceptions to this are if the changes are immediate and urgently required for the safety of the subjects. In this case, the IRB must be informed immediately after regarding the need for the changes (University of Connecticut Health Center 2013). The other possible exception to this rule is if the study is a determined to be non-research by the IRB and does not need further IRB follow-up (Johns Hopkins Medicine 2013). We made modifications to the consent form in the field on the following basis: a) that the modification added to the approved consent and did not reduce any major component (the consent form content and structure approved by IRB was maintained with improvements); b) that the study was a simulation study and the study subjects did not actually undertake the HPV study beyond the comprehension assessment; c) that the comprehension assessment project and the possibility of modifying the consent form were already approved by IRB and d) that the changes were important for the welfare of the subjects in the study. Since getting approval from IRB for the modification might take time, unless there were expedited provisions, provision for making appropriate adjustment without tampering with the basic components of consent may be necessary in future. Another ethical dilemma we faced with no clear answer was whether it would be fair to continue to do the study using the unmodified

version of consent when it appeared that modification improved the consent content and process.

In our study we assessed the quality of the informed consent process based on the respondents' perspectives. According to Sugarman*et al*, quality in informed consent is understood as addressing the following issues from the participants perspectives; adequacy of the information provided; understandability of the purpose, benefits and risks of the research; distinction between research and clinical care; voluntariness of participation; recall of signing a consent document; and satisfaction with the consent process (Sugarmann, Lavori et al. 2005). Quality-of- informed consent depends on factors such as type of consent information provided, amount of information, adequacy of the comprehension by the study participants, and the voluntariness of decision making by the participants of the study (Mandava, Pace et al. 2012). Other have assessed consent quality by proxy of satisfactory levels of recall and understanding by the recruited participants (Minnies, Hawkridge et al. 2008; Kiguba, Kutyabami et al. 2012; Mandava, Pace et al. 2012).

The study demonstrated a significant difference in the overall levels of perceived quality of the consent process in the intervention compared to the control group. In addition, there was a statistically significant difference in all but three of the components of quality assessment; adequacy of time for consent, voluntariness of consent decision; understand ability of consent information; absence of coercion; and overall satisfaction. But not with whether consent form was read and explained carefully; whether consent from was important source of information; and whether consent form was important for consent decision. In the clinical set up participant-related factors such as age, intelligence quotient (IQ) , level of cognitive function and external locus of control were associated with poor quality and information recall. Written information provided immediately before admission was associated with better outcomes (Lavelle-Jones, Byrne et al. 1993). Possible reasons for the improved perception of the quality of the consent process in this study include the improved consent information and the modified consent procedures both of which were geared to the needs and concerns of

the potential participants. There are several possible reasons for lack of statistically significant improvements in three areas. Regarding readability, the participants in the intervention groups mainly had the form read to them rather than reading it themselves, the question was a loaded one. Another reason is that all three measures already scored highly in the control group with little room for improvements. Even though not significant, there were improvements observed in the three categories and if a larger sample had been used this might have been significant. We did not calculate a separate sample size for quality assessment and we had a significantly higher non-response rate than expected.

Strengths and Limitations of the study

Strengths

- We used improved informed consent comprehension assessment techniques which were validated for use in settings like ours (MICCA and BIC).
- Comparative study design used in the study increases the grade of evidence generated.
- We adjusted the statistical analysis for personal level confounders such as socio-demographic characteristics.

Limitations

- Comparability of the intervention and control group: efforts were made to ensure the uniformity of the two sites, apart from family income and occupation, there may have been other undocumented differences in the settings which may have confounded the study outcomes.
- Subjective quality assessment: quality of the informed consent process is based on participant perceptions unaccompanied by independent observation methods. This might reduce the objectivity and validity of the responses.
- Loss to follow-up with unknown characteristics: reasons for loss to follow-up of those who did not attend were not documented, and neither did we document the basic socio-demographic characteristics of non-attendees.

- Sample size assumptions: the sample size determination was done based on assumptions from other countries as there was no local estimate available. In addition we assumed 10% non-response rate while the non response rate for the study was about 15%. The single cluster intervention also might have reduced the study power. The relative inadequacy of sample size could have generated type 2 errors.

6.3. Conclusions and Recommendations

Based on the findings and discussions provided above, it is possible to make the following conclusions:

- Investing in understanding the local context and tailoring the consent information and process accordingly improves overall consent comprehension, study recruitment rates and retention rates in low income settings.

- The REA results in improved understanding of the study concepts, purposes and procedures. In addition, REA improved participants' perceptions of the informed consent process and the quality of IC process.

- REA can be considered a quick, cheap intervention by which recruitment, retention and Informed Consent comprehension can be improved.

We would like to make the following recommendations, based on the findings and conclusions:-

- We would like to encourage researchers and research ethics committees and policy makers to employ REA to improve research consent comprehension, recruitment and retention levels in similar low income settings.

- As this is the first study to explore the association between REA and comprehension, additional studies in other settings with more objective methods of measurement would provide greater insight on the overall effects of REA on

comprehension of consent. Such studies might even expand into consent processes for medical interventions.

- Ethicists and research policy makers are encourage to explore the consequences of utilizing REA in the light of IRB requirements and operating procedures. In future studies, if REA is planned, it should be included in the research proposal, so it and any subsequent consent form modification are approved by the IRB.

Chapter 7 : Feasibility Assessment in applying REA for Health Research in Ethiopia

[REA] ... might bring resistance among researchers..., people resist new things... so it should be done slowly,... showing its benefit. Eventually it will grow slowly as a culture (among researchers)...
IDI respondent[79]

The chapter presents findings of feasibility assessment based on data from all three phases of the REA project. When disseminating REA tools for researchers and the research ethics community, feasibility is an important consideration. The most common questions potential REA stakeholders would ask about REA include not only whether this new tool really works, but also its feasibility in terms of time, cost and skill. How much does it cost, what skills are needed, and are the skills transferable? Who will conduct the REA, the researcher or another expert? Is it acceptable to researchers, and do researchers trust the tool? Is it possible to integrate the tool into existing research ethics appraisal systems? Is this approach sustainable? Is it user-friendly? Is it cost effective? Feasibility assessment (study) is needed to deal with all these concerns.

We triangulated findings to identify relevant themes related to various components of feasibility. During Phase I, we did a needs and acceptability assessment among research stakeholders based on views and opinions of Ethiopian research ethics stakeholders. In Phase II, we documented the process using qualitative process indicators to help further decisions in mainstreaming the REA tools. This gave us information about practicality in terms of resources, levels of acceptability by researcher for further, implementation and the possibility for adaptation. During Phase III, dissemination workshops were conducted and acceptance was further assessed. Ideas related to the adaptation, integration and expansion of the tool to the existing system in Ethiopia were also sought. The thematic variables used to measure the various components of feasibility included - attitude and perception about REA, satisfaction with REA, suitability of REA, perceived demand and expressed intent to use REA, actual use of REA, expertise and resources needed for REA (time, financial costs, human

[79] The respondent is a researchers and faculty member at Addis Ababa University.

resources), training and skills needed, efficiency of implementation in terms of adaptability and flexibility; accommodation of the tool into the system and scalability. The details of methods used for REA feasibility assessment are discussed in chapter II.

7.1. Results

REA feasibility results are presented in three categories; its acceptability to intended end-users; practicality in its implementation; and dynamics of its integration into the current system and potentials for further expansion.

7.1.1. Acceptability of REA to intended users

During the first phase of the project, researchers and ethics committee members were interviewed about their perceptions and acceptance of REA, and its perceived need. Results pertaining to demand for REA in terms of the existing gaps and the potential contribution of REA to cover these gaps have already been presented in Chapter IV. Acceptability of REA to researchers and research ethics stake-holders and their attitudes, perceptions and perspectives towards REA are presented below.

Perceptions and Attitudes: Researchers interviewed during Phase I had generally positive perceptions about REA and many thought this is a useful approach. Their main concern however was the practicality of the REA approach. As conducting a rapid qualitative study to improve consent process is a new concept, many had to ask more to learn before understanding it. Many admitted that there was a gap in investigating current practices in developing consent documents for research. Most researchers had no experience in it and the issues made them critically review their current positions regarding the consent process for research. During the field pilot of REA in the three community-based research projects, the researchers of the projects were interested in and supportive of the whole REA process. They also claimed to have benefitted from it. When we initially approached them they raised issues of practicality and resources. REA was not part of their original proposal and they were unsure how it could be

incorporated into their projects. They gave time for further discussion and mentioned that they were willing to collaborate on the grounds that the ethical aspects of their research projects would be improved by employing REA.

Acceptance: In Phase I, researchers and ethic committee members interviewed appreciated the potential contribution of REA towards improving the standards of medical research. They appreciated the fact that REA creates a good opportunity for researchers to understand their research community in relation to the research process and particularly the consent process. Respondents expressed general acceptance towards REA and considered the principles governing REA and its application to be similar to the principles behind pre-test studies conducted before the actual studies. Respondents acknowledged that REA tool might be included in the ethical review system as part of the currently existing research ethics review guidelines.

> *If the (researchers) understood [the community] well, this will simplify the process of research. I think it is a very good idea. ... Especially in Ethiopia and [other] developing countries, [where] there are diverse cultures, lot of surprises will be there waiting for you [in the community], so I think it is a good idea. This can [even] be included in the guideline(s).* [Academician and Researcher, IDI, AAU]
>
> *It is applicable, it is so easy. The problem is in how much time can a person understand a new culture.* [IRB admin and researcher, IDI, EHNRI]
>
> *If he (the researcher) asks the people (the community to be studied), prior to the study, this is a very good idea.* [Academician, REC member, IDI, JU]
>
> *I think it is applicable, the aim of ... pre-tests is,.. one step before, understanding the community, to create trust in them, or making it easy the thing you prepare (tools)...This (REA) is one such an approach.* [Researcher and academician, IDI, JU]

All Parent project PIs during Phase III were very cooperative for REA pilot introduction. When we approached the PI of the first parent research Project, his first question was to learn what REA is, its benefits and what exactly it takes to implement REA. Finally he

agreed to consider the pilot, but said he could not cover the resources. We further explained about the pilot and how we wanted to collaborate by covering the costs of the REA based on which he was delighted to collaborate with us. He arranged meetings and made plans for the field study. The PI of Parent Project II immediately agreed with the proposal and REA PI was invited to the project inception meeting to which a variety of experts from the project, the University and the Ministry of Health had been invited. I was asked to reflect on the ethical aspects of the proposed project, and to make presentations on ethics and the ethical challenges of research in community based settings. For the field study, the PI shared his study protocol and field plans and linked us with contact personnel who further facilitated our entry to the field. The findings and inputs from the REA were well received. The PIs of Research Project III agreed outright to the collaboration on REA. One of the lead investigators of the project subsequently became part of the REA team and took part in the debriefing on the site, so the feedback from REA was immediately taken into consideration in the consent process and recruitment of the study participants. It was possible to share some logistic arrangements during the field part as the costs related to the investigator were covered by her own project while we covered the costs of the REA team from our side. The investigators were willing to start the discussion in Addis Ababa even before departing to the field sites and preparatory meetings were held accordingly.

During Phase III, in the two REA dissemination workshops, acceptability of REA were expressed by researchers, faculty and post graduate students in Ethiopia and six other African countries. There was great interest from those attending the REA workshops. The participants were excited about this new tool and very eager to learn more and to try it out in one of their research projects soon. Most of the participants who had a chance to give us verbal and written feedback at the end of each of the workshops said they thought REA was a very important approach to improve the quality of recruitment and consent procedures for research. The question of practicality was raised whether the tool was recommended for all research projects, and what resources and expertise it would need, as well as whether engaging with the community before data collection would introduce contamination.

Overall there was keen interest in participating in the workshops. The initial interest in the workshop was driven by a desire to know more about the ethical issues of community based research as there are few training courses and workshops available on this topic. The other important motivation for the workshops was the 'Rapid' in the term REA. Several assumed that the workshop would deal with some kind of 'fast-tracking' through the ethical approval system, as most were already frustrated by the current slow speed of ethical approval. The workshops helped in elaborating further the concept of REA and raising awareness. This gave rise to very active and enthusiastic discussion during the group work, and almost all who started finished the workshop despite the fact that we took more time than planned. They asked for more inforamation and materials, and argued that the time was short. At the end of the session, participants were able to understand and internalize and ask critical questions about the tool. During the feedback sessions much interest and appreciation was expressed. They appreciated the tool and the importance of qualitative and formative assessments in medical research for the purpose of understanding communities, including consent dynamics.

During the workshops and the group work sessions, the active discussion continued and a case-study based on one of the Pilot Project studies done in Phase II of our project[80] was conducted. About 90% of participants finished the workshop in a very active manner. Some participants asked further questions by e-mail and mentioned their interest in trying the tool in their settings. Others who were not able to attend the session wanted to hear more and asked for materials or subsequent sessions. Based on the information they received from the website, three researchers and two ethics committee members from AAU and CDC requested the REA materials for their information and use.

Resistance: REA respondents expressed their concerns that some researchers might resist REA as a mainstream tool, despite in principle agreeing to it. Possible reasons for this included that new things usually face resistance, the additional work burden that it

[80] REA on HPV Sero-survey among Ethiopian Women

might result, and not being able to understand its benefits fully. This was considered especially important in the early stages of introducing REA. Researchers have negative attitudes towards the ethical review system as a result of very lengthy procedures, and many researchers thought that REA would further lengthen this. Introducing REA as a pre-requisite for ethical appraisal and as a mandatory requirement without adequate awareness and background work might be very unpopular. Accordingly, training and awareness raising were considered vital along with continued negotiation and demonstration of the benefits of REA.

> *Putting it (REA) as a [mandatory] requirement might bring resistance among researchers...[just] because it is a new thing. People resist new things because of lack of knowledge. So it should be done slowly, showing it in other studies, showing its benefit. When they see the benefits, if one study is done properly it will be a base for another study, it will be like that. Eventually it will grow slowly as a culture (among researchers).* [Academician and researcher, IDI, AAU]

> *You have to try to teach them as much as possible, telling them the pros and cons of the research ... they have to negotiate [its] benefits.* [IRB member and researcher, IDI, AAU]

During the REA pilot implementation, researchers were introduced to REA and its application in practice. They demonstrated the acceptability of REA in their attitudes and levels of understanding about and levels of satisfaction towards REA. Apart from the three projects on which the pilot was done, we also approached four more other researchers from different institutions[81]. All these researchers were very willing to try the REA pilot. The reasons that these projects were not included in our REA pilots were related to timing rather than willingness of the investigators. Of all the researchers we approached, none declined the idea of piloting REA in their project. All asked for more information about REA and its added values and benefits.

Understanding: During discussions with researchers about REA, there was a lot of confusion regarding the term 'rapid ethical assessment'. Many thought this meant a tool

[81] In the process of identifying the parent research projects to pilot REA, we had to identify list of potential projects and approach their PIs. We approached about seven different research PIs, but REA was piloted in only three of the projects.

to speedily address the ethical approval process. It took considerable discussion with the PIs and researchers to clarify this. Phase II researchers were able to understand and internalize the REA process in due course, so the piloting process incorporated suggestions from them as well as the REA team. During both workshops, most participants initially misunderstood the term 'Rapid Ethical Assessment. As many researchers are frustrated with very protracted ethical appraisal process, they thought this tool was intended to speed up the review process and were surprised to learn that REA rather involves addition of a step or process. When they heard more and got more informed, they were not disappointed, but appreciated the importance of this new tool and considered using it despite the demands it creates on researchers.

Satisfaction and suitability: Phase II researchers were happy with the outcomes of the REA process and appreciated the invitation from the REA project. They expressed their appreciation and satisfaction with the feedback they obtained for the consent processes of their studies. Based on the feedback received from Phase III workshop participants, it was possible to demonstrate satisfaction with the case studies with a spill-over effect to the REA team facilitating the workshops. At the end of each workshop, evaluation forms were distributed for participants to rate the contents and the mode of delivery of the workshop. In addition we held open evaluation discussions to get overall feedback and any suggestions for future improvements. Most participants appreciated the relevance of REA and the descriptions and illustrations used. They were very excited to learn about this new technique and expressed interests to know more in due course. Participants also said that the tools appear to suitably address very important aspect of research in LIS.

Acceptability Considerations: Researchers in Phase I expressed concerns that REA might be an additional burden to researchers in terms of time and budget. It was emphasised that in order to win acceptance, REA must be accompanied with maintaining ethical and operational standards. Other respondents stressed the need for awareness raising and training on REA. Too much involvement with the community

before the actual data collection might bring about contamination of the instrument and measurement bias during the field research.

> *They [researchers] might say it will create a bias on our .. study [due to contamination].* [Academician and researcher, IDI, AAU]

> *I think this is a good idea and very appropriate. [However], this alone is not enough. We need standards.* [Researcher and academician, IDI, JU]

7.1.2. Practicality of REA in its Implementation Process

The findings presented in this section are mainly related to practical feasibility of REA in terms of time, cost and man-power in all the three phases of the project. During phase I, researchers and ethics committee members felt there might be practical repercussions of applying the tool in the field. Despite the generally positive acceptance to REA, they raised concerns regarding its implementation and feasibility.

Burden: It was mentioned that REA might become an additional burden both to the individual researcher and the research governance system (including ethical review) due to the additional pressure and burden on the researcher by increasing the process and steps of research and increased complexity of the review process. Some researchers felt that it would be difficult to conduct REA because of these constraints. They wondered whether it was the right time to introduce REA to the Ethiopian ethical review system which is already under-resourced. Thus they felt it may not be the right time now or that the process of introducing REA should take longer time and processes.

> *This (REA) will increase the bureaucracy and make the process long, and it complicates the ethical process .... I don't think we need another body for this. No need of additional review. It will increase the time [needed for the review]. Then you have to pass [through] all this to start working. It lengthens the steps. As you make it more organizational, it will increase the complexity specially in our environment which is already bureaucratic. It is bureaucratic in [responding]. [As] the capacity level is low, they (the review systems) need to be [first] strengthened.* [IRB member and Researcher, IDI, EHNRI]

Differentiated Approach Depending on Research Type: Phase I respondents felt that applicability would depend on the type of research under consideration. They questioned whether all research requires REA. They suggested that simple and quick surveys with no major ethical issues might not require it, while studies with anticipated ethics issues such as genetic studies would require REA. To introduce REA not in blanket fashion for all research, but only for selected type of research projects based on criteria such as risk level and anticipated ethical issues (e.g. community-based research, invasive procedures, biological specimens involved) appeared more sensible.

> *I think it can work for some kind of studies. ... based on risk-level, ... It is very hard to do this in all research (specially for minimal risk).*[Researcher and REC member, IDI, JU]

> *(Even) in research ethics there are (applications of) requirements for informed consent, depending on the type of study. The same principle can be applied (for REA). .. By the same token... this pre-assessment procedure could be applied to those which involve [invasive] procedures and human biological specimen [collection].* [Researcher and academician, IDI, JU]

> *It depends up on the research question, ... so if there was a check list .. based on the research question... like clinical trial, ... sensitive issues, like genetic studies, in remote areas, vulnerable population.* [IRB member and researcher, IDI, AAU]

> F*or clinical trial, cohort study, it can be done since the research also takes time. What I am seeing around here is that most research projects are cross-sectional, and the ... data -collection might only take 10 days. If you ask them to do the [REA for the consent] and if it takes them 3 months, it might not be practical ... [But] maybe, [for]those researches whose focus is on marginalized rural community, illiterate, disadvantaged communities, I think it will be appropriate.* [Researcher and academician, IDI, JU]

Others had opposing views and suggested that it would be difficult to introduce REA based on the research-type, risk and harm levels, as it would be difficult to foresee risks

in research. To address this dilemma, an all-inclusive approach of national REA was suggested[82].

> *It will be better if it is not like that, it is hard to classify research a priori, which one does harm. It is hard to decide in the beginning. It is hard to predict what research could do to the society, you can't say "let me do formative [REA] for this one and not for this one".* [IRB member and Researcher, IDI, JU]

Conducting Repeated REA: Whether REA should be done repeatedly in the same area, for different studies, and for similar studies which are to be done in different area, would have considerable resource implications. In addition, the cost-effectiveness of repeating REA for every research project was questioned. One suggestion was to create a system whereby REA done for one research project could be used for another similar project in a similar setting.

> *" For example if you have a KAP[83] research project and ... did a formative assessment [i.e.REA for one study], can these (the findings from an earlier REA) be applied for another person (researcher) who is doing his study on KAP, or is it doing (going to do) a formative [REA] for all new research?."* [IRB member and Researcher and academician, IDI, JU]

Resource: According to the respondents, important resource considerations included time and cost. It was stressed by participants that the approach is resource-intensive and may not be practical time-wise. Considering time as an important factor, there was a dilemma about how much time is enough to be allocated.

> *It needs a lot of resource [including] time. When we start a research, there are deadlines and time constraints. To study exhaustively we need time, so it depends on resource and time. If the area is far, it is hard to go there and do it and come. Making it as a requirement is a little hard.* [Academician and researcher, IDI, AAU]

[82] This refers to doing a 'one-off' REA at the national level to map out all possible ethical issues at the national level for subsequent use by researchers. This point is further presented in detail under the section on integration below.

[83] KAP studies stand for Knowledge, Attitude and Practice studies

> *I think it is applicable. The problem is how much time it takes for a person to understand a new culture? ...They (researchers) might say it will take time* [IRB administrators and researcher, IDI, EHNRI]

The issue of cost and the implication of additional cost needs for REA was mentioned. Most local research projects operate under meagre budgets, and REA will be another competing factor for the budget available.

> *Cost is the main thing. Asking a researcher to do additional formative assessment when he comes to do research is costly. ... If you ask me now to recommend that all research should do a formative assessment, I won't ...because it doesn't work. The researchers don't want it and they can't - while there are [already] other compromises adding this new compromise. ... It is [of course] needed and yet the budget (given for researchers) is usually very small.* [IRB member and Researcher, IDI, JU]

During the REA pilot phase (Phase II), we further documented the resource inputs required for REA implementation. Results on feasibility from the angle of financial costs, time and human resources are presented below. The REA pilot consisted of two levels, i.e. planning and the execution of the plan. We made plans (road-maps) for each REA depending on the parent research project plan and the location of the study. The planning included tool development, REA team formation, training and mentoring of REA team members. This is explained in detail in chapter III, in the methods section. The implementation steps included the field survey, data analysis and communication of the REA results as feedback to the Parent Project PI.

Costing: All operation costs for the Pilot REA in all the three parent projects were covered by the REA Project. It was possible to implement REA with a separate budget allocated for the REA needs (Annex C). The budget planning took into consideration line items such as personnel costs, transportation and field instrument as well as data management and analysis costs. Below are summaries of cost spent per site and a summary of average cost per REA (Annex C). Average costing per REA amounted to 42,812.5 Ethiopian Birr (approximately £1500 or 2250 USD)[84]. This excludes the costs

[84] 1 USD ~ 19 ETB ; 1 GBP ~ 28.5 ETB

of other items which were not directly paid for such as NVivo software, a digital camera, a laptop computer, and data storage devices. The overall minimum cost of those fixed items (excluding the per-diem) would amount to 16,530 Ethiopian Birr (£590 or 870 USD) (Annex C). In one of the sites the PI was involved in the REA but covered her costs.

Compared to the field research budgets of the individual research projects, the REA cost ranged from 1.92% in Adami-Tulu (Zeway) to 4.99 % in both Ayra and Soddo. The overall details of field costs of the three parent projects are presented in Table 7.1.

Table 7.1 Field site project costing compared to REA costs for the four REA pilot sites, 2012-2013.

Site	Parent project research cost estimates			Proportion of cost of REA* against project cost
	ETB	USD	GBP	%
Butajira	748,850	39,413	26,275	5.72
Adami Tulu	2,233,000	117,526	78,351	1.92
Ayra	856,662.5	45,087	30,058	4.99
Soddo	856,662.5	45,087	30,058	4.99

* Average cost per REA ~ 42,812.5 ETB

Time: This takes in to account the time needed per project for planning (preparation for field work) and implementation (time in the field). Each of the days spent on the field were longer than normal working days (with on average, 12 hrs/day spent on field work and analysis. In the first parent project (Butajira), it took us a total of 6 weeks to do the field survey including communicating the findings back to the researcher. Preparation and data collection took 4 weeks and preliminary analysis and feedback each took us one week. The second parent project (Adami Tulu), took us a total 5 weeks, of which 4 weeks were preparation and data collection, while feedback took one week. Parent project III had three sites (Ayra, Soddo, Adigdom). REA in each site took 4 weeks. Overall, the average time range for REA was 4 to 6 weeks (including initial analysis); 3-5 weeks for the data collection and field work, and one week to compile the summary findings and communicate back to the researcher (Table 7.2).

Table 7.2 Time taken by REA Field Work for five REA pilot sites, 2012-2013

Site	Time Period	Total Duration
Butajira	November/December, 2012	6 weeks
Adamu Tulu	January/March, 2013	5 weeks
Wollega	Mid March/April, 2013	4 weeks
Soddo	Mid April/May, 2013	4 weeks
Mekele	July/August, 2013	4 weeks

Manpower: Manpower needed for REA included the REA team and its technical expertise. The profile of the personnel involved in terms of professional expertise and other characteristics for each pilot project and field sites are presented below (Table 7.3.

For the first REA Pilot Project (Butajira), five individuals, including local personnel, made up the REA team. Team members included public health experts, a social anthropologist and local area and language experts. The REA PI is a medical doctor with Public Health specialty and MA in ethics. The other public health experts included one health officer, and a nurse. The social anthropologist had a degree in social anthropology from AAU. All the members needed to be oriented and trained on REA and field research. Training and orientation was given by the PI of the REA project. The social anthropologist continued to be a member of the REA teams in the subsequent pilots.

In the second REA Pilot (Adami Tulu), again five individuals were included in to the REA team. The team was composed of the same REA PI and social anthropologist from Parent Project I. Two additional public health experts who knew the language of the area (*Oromiffa*) were included after training. We also involved one insider health professional from the study area. For the first few interviews and group discussions, the new members were allowed to observe and learn as the REA PI conducted the

interviews and led the daily evening debriefings. Subsequently they were allowed to lead interviews and discussions in the PI's presence.

The third Pilot Project was done in three field sites. In all cases, five experts were involved as members of the REA team. The REA PI was not involved in the field work. The purpose was to explore if REA could be implemented with a new team. The PI was however involved in the final week in compiling the field findings. Instead, in the first site (Aira-Wollega), the PI of the parent project was involved and was part of the whole process before fieldwork and in the field. The insider for this team was a long-serving teacher from the area, who is a university graduate who has spent more than 20 years teaching in the same area. He had a good network with the experts and organization in the area. In addition, the three professionals from the second REA (two public health experts and a social anthropologist) were members of the team. In the second field site (Soddo), the only difference in the team composition from the first field site was the insider. In the Soddo case, a public health professional from the area who spoke the language and had lived in the area since birth was REA team member. The new member needed to be trained by the three experienced members and all the interviews and the discussions were led by the three existing experienced members. The same was applied in the REA at Mekele Zuria site.

Table 7.3 REA team composition (number and expertise) for the different REA pilot sites, 2012-2013.

Project	No of REA team members	Team Composition and Expertise
Butajira	5	Anthropologist (1); Public Health professional (2); Expert insiders (2)
Adami- Tulu	5	Health professional and PI (1); Public Health Professional (2); Anthropologist (1); Expert Insider (1):
Ayra	5	Anthropologist (1) ; Public Health professional (2); Expert Insider (1); PI of the Cervical Cancer Project (1)
Soddo	5	Anthropologist (1); Public Health professional (2) Expert Insider (1); PI of the Cervical Cancer Project (1)
Adigdom	5	Anthropologist (1); Public Health professional (2) Expert Insider (1); PI of the Cervical Cancer Project (1)

7.1.3. Feasibility of Integrating REA to Existing System

We explored how REA might be integrated into the existing research governance and ethical review system based on opinions from researchers and research ethics stakeholders, our observations and documentation of how the REA fitted into the pilot research projects, and the reflections and feedback from REA workshop participants.

Phase I respondents considered the process of REA integration to be a time-taking process. To this effect, integration was thought to happen at two levels: a) integration with the research project to be conducted[85]; and b) integration into the existing ethics system and guidelines.

Pre-test: As part of integrating REA into the research project, it was recommended to integrate REA into pre-test phases of research. REA and pre-test studies were thought to share similar principles in improving the implementation of research during field data collection. Integrating REA to the main study would simplify the issue of ethical clearance for REA component of the project as the REA would be approved together.

> *Integrating it (REA) to the pre-test phases is better than doing it alone. It will also save time. Because whatever you do, you test them on the pre-test and it will be an input when you do your main study. I think this will be good. When clinical trial is done, ... they do the background (pilot) study. I think this thing is already there. ... you need to add this in there.... carrying it out at the pre-test or pilot time is good. Because it is(it gets) already approved [together].* [Academician and researcher, IDI, AAU]

During the REA pilot phase, it was possible to observe integration issues with the parent research projects in terms of ethical review and , communication with PIs. The REA project proposal was approved separate from all the three parent research projects. The support letters for the field surveys referred to both the ethical approval for the REA and for the main project. Due to delays in ethical approval, some projects whose PIs were keen to pilot REA were not ready within the duration of the REA study. Other projects

[85] Refers to the research into which the REA is to be employed.

were delayed through waiting for funding release or purchasing, so we were forced to drop these projects. Despite the fact that the REA project was already approved at the AAU College of Health Sciences (CHS) IRB, two health institutions (UoG and AHRI) asked for another round of review and approval of the REA project. We made applications but no feedback was given from Gondar. AHRI provided feedback but we decided to drop both sites due to time pressures. We heard after 9 months that the project was approved by the University of Gondar, by which time we have already excluded the site and were concluding the REA pilots.

Communication with PIs of the respective parent research projects was done through various channels. PIs were all willing to collaborate with the REA pilot. PIs were initially communicated with face-to-face, and then by phone call, e-mail exchanges and meetings as needed. PIs shared their proposals and briefed the REA team on their projects. They were available for questions during REA and for feedback from the REA. In addition, the REA team members were able to build good team relations, were able to train project staff in REA methods and were eventually able to conduct the REA independent of the PI.

REA and Guidelines: When it comes to system integration, it was mentioned repeatedly that REA needs to be mainstreamed and should be part of the existing guidelines for research and ethical governance. The country circumstances in terms of ethno-cultural diversity to be taken in to consideration, as a justification for including it in the guideline. While it is possible to include REA in the guidelines, this would need to be accompanied by continuous capacity building and training. If the training were made a requirement, certification would be necessary. Based on existing experience of guideline development, it is possible to introduce new issues into the guideline (for example material transfer), for selected research projects. The same could be done for REA.

> *This (REA) can be included in the guideline, ... adding it (REA) to the guideline allows them [researchers] to think about it ... [and*

> *include it in their protocol] ... but ... do they see the guideline? The most important things are ... continuous trainings for investigators.* [Academician and researcher, IDI, AAU]

> *There is a topic "consent" [in the national guideline]. Then [it is possible to include] what consent look like in the Ethiopian situation, in this multinational [country], [where] there are more than 80 ethnicities, and we have different languages, different cultures. Then how do you approach when you try to get consent, it should be described there. ... if we do a formative assessment and community assessment, in all fields and I think it is better if there was a national guideline not only for health science but also for other sciences like social science. It might not be always but you will work based on this, I think this will be better.* [IRB member, , Researcher and academician, IDI, JU]

However, mainstreaming REA into the current research governance system could complicate the process. Caution in application was advised in order to keep the approach as simple as possible.

> *Research is premature in Ethiopia. What I suggest is if we simplify this (the REA introduction process) and help the researchers, and protect the society.* [Researcher and academician, IDI, JU]

The REA PI participated in workshops and meetings at which the national guidelines were being discussed. The REA team also provided awareness-raising and sensitization about REA at various opportunities. One of the REA project collaborators was invited to be a reviewer of the National Research Ethics Guidelines and was able to mention the need to understand the community to inform the consent process. While conducting the pilot REAs, we drafted the following paragraph for this purpose.

> *'Various gaps are observed regarding comprehension and informed decision making among study participants in developing countries with the issues varying for different ethno-cultural groups. As Ethiopia is a country of diverse ethnic groups and cultures, it is important that researchers address contexts when designing consent processes to address potential emerging context specific issues such as language and understandings on the issue under study. Whenever relevant, it is recommended that researchers undertake rapid assessments to understand the existing context*

> *and accordingly inform the consent process. This approach is known as 'Rapid Ethical Assessment'.*

Participants expressed the need for more workshops as a means for dissemination and expansion of REA to wider audiences. During the workshops, participants asked if there were any written guidelines available on how to conduct REA. They also asked what provisions had been made should the tool be required by ethical committees, and who would be responsible for implementation. They all stressed that these components are vital for further application. The participants said the workshops raised their awareness regarding the gaps in the consent process and opened gates for further discussions with various researchers and ethics committee members. They highlighted the need for organised and systemic follow-up on the issue of REA use at wider scale. Based on the two REA workshops invitations and requests were sent to the REA project PI from researchers at AAU for additional workshops and seminars on the ethical challenges of research in LIS and the role of REA.

National REA: Instead of doing REA for every study separately, it was suggested that REA be done at a national level to map out existing ethical considerations in the various ethnical and cultural groups. Then the issues and recommendations could be included in a national document as a guideline (catalogue). Researchers could use this information as a reference for research in a specific setting .

> *Instead of doing a formative assessment (REA) for all research which is tedious, there should be a guideline (guiding document). You can do a [national] survey (REA), and put it on the guideline, saying this is the Ethiopian community [and], if you want to get a signed consent you should do like this [depending on the site]. Otherwise if you come to [do REA in] all research, one it might be different what each researcher will bring (find), [and] there might be conflicting outcome, the formative [REA findings] that you bring (find) is (could be) different from what another person might bring, there might not be a common ground.* [IRB, Researcher and academician, JU, IDI]

7.2. Discussion

Feasibility assesses whether a new intervention or approach is appropriate for further use. Feasibility assessments are usually done for new interventions when their implementation and outcome are not well documented on a wider scale (MRC 2006). REA has been employed by a few researchers in the past. Based on earlier REA experiences, it was possible to demonstrate the usability of the tools in improving the consent and recruitment processes for the study projects under consideration (Bull, Farsides et al. 2012) (Tindana, Bull et al. 2012). The current feasibility analysis was able to indicate the practical issues and considerations in applying REA for further use in the Ethiopian setting. REA implementation appears feasible, yet some areas require caution and must be addressed in parallel.

While we primarily used qualitative methods, the most popular approaches for feasibility designs are either quantitative or mixed. The application of purely qualitative approaches for feasibility assessments including feasibility of public health related interventions, have been documented in reference to new interventions and phenomenon for the sake of providing deeper understandings. Depending on the nature of outcomes of interest it would be appropriate to employ such qualitative approaches (Patton 2001; Holland, Thomson et al. 2006; Ajayi, Falade et al. 2008; Schreiber 2008; Bowen, Kreuter et al. 2009).

According to models suggested by researchers who have conducted feasibility assessment in public health interventions, three general categories are considered important, each with its own respective thematic areas (Bowen, Kreuter et al. 2009) (Rychetnik, Frommer et al. 2005). Applying these models, we assessed feasibility related to a) REA end-users, b) REA application process and c) incorporating REA to the system. Results are discussed in light with these categories.

7.2.1. End-user related feasibility

Demand and acceptability are thematic categories which are considered to be directly and indirectly related to end-user in assessing implementation of REA. Both are closely related to each other. Demand assesses whether there is a justified need for REA. This has been already addressed in Chapter IV, where we have demonstrated gaps in the current consent process in the Ethiopian set-up. Researchers and ethics committee members acknowledged the need for REA as an approach which would address these gaps. As need is indirectly linked to acceptability, we could justify acceptance based on observed and expressed need, with the assumption that need dictates acceptance and presence of a need would indicate likelihood of acceptance. However, it is possible that a tool could be rejected, despite availability of needs and existence of gaps to be potentially addressed by REA, for a number of reasons. Thus assessment of acceptance irrespective of need is justified.

Acceptability: Acceptability is expressed through user's perspectives and perceptions; how do researchers, the REA team and the wider research ethics community accept the tool. Variables utilized for measuring acceptability of a tool by its potential users include perception, attitude, understanding, satisfaction and suitability. There are two levels of acceptance by end-users, the first one concerns perceptions and attitudes towards the REA, while the second level is more practical where end-users agree to use it. Potential end-users of REA include researchers (current and future), ethics committee members and REA team members. Even though not included in the current assessment, field workers will also be responsible for REA implementation. Even if they were not primarily included in the study, there is growing recognition of the role of field workers in the implementation of research as key stakeholders rather than simply as means to the end (Kingori 2013).

Phase I measured attitudes and intended use where respondents expressed positive attitudes towards REA. Positive attitudes arose from the identified need to improve the consent process. Since REA is a very new approach, concerns about potential resistance were also expressed. According to Rogers' theory on "diffusion and adoption

of innovation", the rate at which a new approach diffuses for use by its users depends on the nature of the end-users (Rogers 1995). While only a few will adopt the innovation immediately, the majority take time. A few will never adopt the new technology at any cost. While this model may not explain all the dynamics of change in the introduction of new approaches, and it is too early to appreciate the whole dynamics of REA acceptance by its end users, the model is worth considering (Banyte and Salickaite 2008). The other reasons for resistance include practicality, the potential cost and time burdens and researchers' perceptions about the current ethical approval system. These are practical considerations discussed under 'process related feasibility' below.

Despite that fact that REA is a novel approach, parent project researchers in Phase II were very keen to bring REA in to their research projects. This may have been partly influenced by the fact that the PI of the REA project is a colleague to the researchers of the parent projects, which enhanced communication and trust. Major concerns reflected by parent project PIs during initial communications were issues of timing and cost. They wished to know who would be covering the costs and when in the existing timeline to conduct the REA. Once they were provided with satisfactory explanation on the practical issues, REA was accepted. The pilots showed that researchers could actually engage with REA and integrate it into their research project. This was chiefly because researchers were convinced in the added value of REA in improving the consent process and increasing the quality of the research process.

During the REA dissemination workshops, acceptability of REA among the workshop participants was demonstrated more related to their perceptions and attitudes towards the tool. Their attitudes expressed were dictated by the introductory discussions on the challenges of informed consent in the developing country settings and the experiences the researchers had in their own research projects and the various challenges they faced. They also raised issues of cost and time as well as how the results of the REA would actually be used by the researchers and how problems detected in the field through REA might be solved.

In the process of disseminating REA beyond the two workshops in Ethiopia, the REA approach was presented in two seminars in the UK; at a BSMS 'Work in Progress'[86] session in June 2013, and on a 'Pharmaceuticals and Global Health'[87] conference staged by the University of Sussex in July 2013. During both sessions, great interest on REA was expressed by participant researchers and important feedback was given. Questions on the availability of quantitative evidence for the usefulness of REA were raised, as were suggestions to extend the possible use of REA in improving the consent process for clinical and medical intervention and treatment. This was another indication that REA can be taken in to a wider circle.

7.2.2. Process-related feasibility:

Process-related feasibility indicators include ease of implementation according to plan, resource feasibility, and adaptability to circumstances and needs.

Implementation: Implementation of an intervention is a continuous process which starts with planning and making sure what is planned is executed. We needed to assess whether it was possible to implement REA intervention as planned, and how well it could be implemented (Bowen, Kreuter et al. 2009). Based on Phase II of the pilot, it was possible to implement REA as per plan with only slight adjustments and relatively minor challenges.

The evidences for effectiveness of REA can be categorised into intrinsic and extrinsic evidence. The inherent value in the process of improving consent processes in medical research for low-income setting carries an inherent merit. Maintaining ethical values in research and especially in the informed consent process takes a central position in medical research. Measurable qualitative and quantitative outcomes are important 'extrinsic' justifications. Studies have documented qualitative outcomes of REA and how the findings were used for further improving consent processes (Tekola, Bull et al.

[86] Work in progress sessions are sessions where research projects are presented to the doctoral students and their supervisors at BSMS.
[87] Hosted by Centre for Global Health Policy at University of Sussex, UK. (http://www.sussex.ac.uk/globalhealthpolicy/events/forthcomingevents)

2009a) (Tindana, Bull et al. 2012). In the current study, we documented important ethical issues in our pilot studies, as discussed in chapter V. In addition, we also documented quantitative findings on the associated and potential effects of REA on comprehension and retention as is presented in chapter VI.

Practicality: In all three phases of the project, questions of practicality and cost-effectiveness were important considerations. Practicality is an important determinant of acceptability; as respondent's views on the practicality of the REA tools relates closely to whether they have favourable attitudes or the opposite.

In this project, we were not in a position to conduct cost-benefit assessment, instead we were able to document the resource needs and associated costs in terms of personnel, time, expertise, logistics and training. Such costing assessments in business are done by calculating the costs of production and the running costs of the business or function and allocating the expenditures to the various stages of the process or operations for further comparison and analysis. Costing includes expenses which are directly paid and all expenditures of some kind such as time or labour (Businessdictionary), while cost accounting is keeping account of the costs of items in production (Thefreedictionary). As processes are not fixed and keep on changing, opportunity costs and market inflation need to be taken into considerations. Cost-benefit assessments address such details using models of economics and econometrics. WHO has recommended approaches for cost benefit assessment in public health interventions of different categories (WHO 2006) and cost-effectiveness assessments in public health have been advocated for in program evaluations (Banta and de Wit 2008) (Saha, Hoerger et al. 2001) (Briss, Zaza et al. 2000). However, as mentioned earlier, our project did not take this approach and we focused only on costing analysis.

Three important resource considerations for REA included cost, time and manpower. We calculated the financial cost incurred by each of the REA pilots and compared these with total project cost to determine the proportion required for REA. We also documented time demanded of REA in comparison with that of the main research. In

terms of manpower need, we documented what expertise was required for the pilot and commented on the practicality of being able to find such expertise.

As documented during the REA pilots, it was possible to conduct REA at a reasonable cost of 42,815.5 Birr[88] per REA. Several factors might have contributed in attaining this reasonable cost. We tended to be conservative in expenditure and negotiated minimum possible pricings for items and personnel. When possible, we avoided commercial renting of cars, and used available resources such as office vehicles, and paid for the fuel and the driver instead. We also involved trainable young professionals than senior and expensive professionals. Team members were being paid for their time and expertise on a daily basis at 250 birr per day (~13.2 USD or 8.8 GBP), a rate arrived at using government allowance rates for an 8 hour day. However most of our working days were much longer than 8 hrs. But we did not pay overtime. If full overtime costs were included, the personnel cost would increase by at least by 50% (an additional overall amount of 45,625 ETB (~2401 USD or 1601 GBP) which is 11,406.25 ETB per site (~600 USD or 400 GBP). This would bring the cumulative REA cost per site to 54,218.72 ETB (~2854 USD or 1902.4 GBP)[89].

Though the REA costs were covered by a separate budget, when we compared the ratio of budget spent for each REA, this ranged between 1.92 % and 5.72 % of the overall budget allocated for the parent research projects. On the other hand, in view of the benefits one gets from the REA, the budget it consumes seems reasonable. Researchers need to plan well in advance to cater for the budget needs, by considering REA as part of the overall research proposal and accordingly budget for it part of the main research project.

Considering the fact that researchers may spend weeks or months waiting for ethical review (Ezzat, Ross et al. 2010), planning a 6 week REA does not seem unrealistic. Most researchers are already unhappy with the current ethical review processes in

[88] Equivalent to 1500 GBP or 2250 USD
[89] See annex for details

terms of the length of time it requires (Ezzat, Ross et al. 2010) (Gold and Dewa 2005). REA may create additional time burdens on the researchers. Some projects may be working against deadlines academic or donor related and the time frame may not allow them to allocate time for additional procedure. All these could trickle down to increasing the resistance of researchers for REA.

According to the REA pilots, on average it took 4-6 weeks to conduct REA. Previous researchers have conducted REA in range of 5 to 7 weeks (Bull, Farsides et al. 2012) (Tindana, Bull et al. 2012). Rapid assessments are generally considered to be conducted in an average of 6 weeks (Beebe 2001). Despite such short durations, very useful findings were generated. This may convince end-users that REA is a tool that can generate useful results in a reasonably short period of time.

Duration of the REA depended on how smoothly the data gathering process went, especially over the first few days. It was also determined by the dynamics within the REA team. As the team became more experienced, it was possible to shorten the REA process. The intensity of the daily data analysis was another factor which in turn is dictated by the REA dynamics. Many hours were spent on analysis each day out of working hours. The evenings were spent in debriefings, compiling emerging results and themes, and discussing the implications of the findings on the consent process. Accordingly, it was possible to compile the preliminary findings to be communicated back to the researchers within a week irrespective of the overall time spent in the field. Another contributing factor was the multi-disciplinary mix of REA team members; a social scientist working with health professionals, insiders working with outsiders. This helped to generate views and interpretations from different angles and perspectives. There is increasing global move towards inter-disciplinary and trans-disciplinary research for its benefits (Lasker and Weiss 2003). This has been very well documented by REA as well.

Regarding manpower, the average number of professionals needed was 5 per REA team. The number was reasonable and manageable as a group for creating a group

dynamics. In rapid assessments it is recommended that the team need not be big in number (Beebe 2001). The REA team was composed of a mix of individuals from different disciplines as well as members from the study area who were considered to be key informants and were in some senses 'gate-keepers' to the community during the field work. In rapid ethnography, it is recommended that the rapid process is augmented by involvement of a mix of professionals who have a good team dynamics. It was possible to implement this in our pilot REAs. The social scientist member had the role in making sure that the qualitative designs were properly done, and advised the whole REA process. Health professionals helped the team in exploring the health issues in the research and their public health and clinical implications. The outsiders brought new issues to the community, while insiders helped in balancing views and avoiding assumptions from outside (Beebe 2001).

It was always possible to identify local expertise in the area of social anthropology and public health. While the PI is faculty member at AAU, all the professionals involved were post graduate students from AAU. The fact that the PI is attached to AAU (an academic research centre) could have made the process of identifying the professionals easier. This could be seen as part of the available existing network. It was also always possible to have an insider. The fact that parent project PIs of the respective research projects had already had contact with individuals in the field facilitated our entry to the area.

Identifying individuals within the right networks was a rate limiting step. The Pilot I site, Butajira Rural Health Project, is administered by the School of Public Health of AAU and we were able to identify key individuals through this pre-existing link. Adami-Tulu (Zeway) is located in an area which is close to the field site for AAU medical students' rural attachments. The existing recognition of the university (AAU) by local authorities helped in creating a positive start. For Soddo and Wollega we needed to contact individuals who knew the area and would link us to someone in the ground. Accordingly we succeeded in identifying very useful and resourceful insiders of the REA team in all four research sites. We were able to demonstrate that it is possible to train other experts to do REA. Accordingly, it was possible to transfer REA skills and expertise into the pool

of personnel we identified. REA team members were able to independently conduct REA towards the end of the pilot.

Adaptation and Flexibility: The flexible and adjustable nature of REA helped meeting practical challenges in the process of implementation throughout the phases of pilots. During the field survey, some of the challenges of implementation which required adaptation included timing and duration; the community structure and gate keeping; and language. During REA analysis, challenges included producing findings rapidly. The provision for iterative analysis and daily-debriefings helped a lot in providing usable results for researchers on time. Inclusion of parent project PIs in the third pilot project increased the efficiency of the REA process, as the researcher was able to internalise the findings of the REA as they emerged.

Challenges regarding communication of feedback included, timing (when to disclose information - during, before or after the actual survey) and in what format (written or verbal). There was flexibility in both cases as there was an open invitation for the researchers to join the REA team. However, since we initiated the REA and it was not part of the original proposal we were not able to force them to join the team. The reason why REA was not included in the respective project proposal was mainly due to issues of time and uncertainty of whether time will be with us or not. We used both verbal and written feedback to communicate findings to the parent project PIs.

7.2.3. System-related Feasibility:

Based on system related feasibility indicators, we looked in to integration and potentials for REA expansion.

Integration: Looking ahead to wider-scale use of REA, system related assessments are crucial. It is only when it is possible to demonstrate that the new approach can be integrated into the existing system that the sustained use of the approach can be guaranteed. *How do we integrate REA into the ethical review system and guidelines?*

What are the critical elements and points of integration? There is a need to assess the required system changes and modifications to accommodate REA in to the existing system.

The mere fact that REA is an 'additional' piece of project with its own resource requirements which means additional work load to the researchers should not be a reason to postpone its integration in to the existing research governance system. All current research governance and ethical regulations are all additional procedures which have implications of time and resources with burden on researchers. Despite concerns and complaints on the efficiency of the current system in different setting, their presence and role cannot be compromised at any cost due to their inherent importance. Researchers are expected to make adjustments and still comply to the requirements. If ethical review takes longer than planned, researchers rather review their time-lines. The same applies to donors and academic institutions. The same applies to REA. As long as REA is shown to add value that cannot be gained otherwise, the question is how to make it as flexible and easy to apply as possible in a given timeframe.

The integration of REA into the existing system depends on a number of factors. Feasibility considerations discussed earlier such as acceptability and applicability are important considerations for integration, as it is a process rather than a one-off event. New approaches pass through a number of phases and steps before they fully integrate into routine practice (Gitlin 2013). Suggestions given as to make effective ways of charting the integration of REA included, integrating REA into the pre-test phases of studies; including REA in the National Research Ethics guidelines; and conducting a National Survey of ethical issues using REA.

Most research project have a pre-test phase to check the tools and make revisions and adjustments accordingly (Faux 2010; Chernyak and Icks 2012). REA and pre-test would share the principle of adjusting the tool and the process based on field experiences. However they have two distinct and separate objectives and would be difficult to together. Though the duration of pre-test studies may vary from project to project, they

are mostly completed in a couple of days. While REA needs an average of 6 weeks (4-6 weeks in our pilot) depending on the circumstances in the field. Pre-tests are conducted in a population other than the actual population but with some shared similarity to avoid contamination, while REA studies are conducted in the population to be included in the main study, but focus on the ethno-cultural and ethical issues in relation to the actual target population.

Integration of REA into the existing guidelines was discussed by respondents. Development of REA to the level of guidelines is a process that takes time. Issues eligible for inclusion in national guidelines require awareness raising and advocacy, a series of workshops and finally buy-in from a higher governing body at national level. In this case, the responsible body would be the Ministry of Science and Technology. The three Ethiopian national ethics guidelines had to pass though these stages (ESTC 2005). During the recent revision of the national research ethics guideline, attempts were made to introduce the concept of REA, however, this may be premature given low levels of awareness and the lack of documentation on REA. Respondents also doubted the practicality of introducing REA to all research projects and suggested a differentiated approach depending on the type of research. In addition they argued that the findings of one research REA might be applied to a similar research project, avoiding the need to repeat REA. Application of ethical checks based on checklist and criteria have been commonly practised even for a consent process. Based on those criteria and level of risk assumed IRBs can prescribe practical approaches (Belmont, ICH) (NCPHSBBR 1979) (ICH 1996).

As part of introducing REA for national usage, a ‘national REA’ was suggested as a one-off ethnographic survey in all the ethno-cultural pockets in Ethiopia with the objective of mapping out ethical issues. The results would be collected for reference for future studies. This was thought to be more feasible and cost-effective approach, than prescribing REA for every study. The suggestion was made with the assumption that the ethical issues identified for one piece of research could be reasonably applied to another. Such approaches have been suggested and discussed by other researchers

(Falzon 2009; Moore 2011). However, contexts and realities are not static and the ethical issues associated with them will also not be static, weakening arguments for this approach. In addition, assessing ethical issues in the absence of a planned research project is far from ideal. Ethical issues are a function of settings as well as the research question and design proposed. Based on experiences so far, REA discloses 'unexpected' ethical issues related to a specific project. Thus, merely studying the context will not be enough. REAs are done in the reality of the setting and the issues and not in general terms. Earlier work has also indicated drawbacks of such approaches (Falzon 2009). On the other hand conducting national REA would be a hugely expensive exercise and time-consuming, whose findings would be severely limited. Project-specific REAs will definitely be of use to the proposed project, leaving the question of which projects should be preceded by REA, which is discussed further in chapter VIII.

Limitations: The feasibility assessment had some limitations.

- Due to the nature of our subject area, we mainly used qualitative methods and data for the feasibility analysis. Quantitative data for feasibility assessment would help in creating decision models and make easier and objective comparisons.

- In documenting outcomes, we relied on outcome measurement in the absence of comparison groups. Ability to apply such designs would inarguably increase the value of our conclusion. However such studies are difficult to implement and need more rigorous planning and resource.

- Cost-feasibility and cost-effectiveness studies would employ economic models and cost-effectiveness analysis which are beyond the scope of the current project. The study did not conduct a full blown cost-effectiveness economic analysis; however, we were able to calculate simple costing and compare them with overall project costs.

- The study did not assess feasibility in relation to field workers and data collectors. Since they are important stakeholders in research, their perspective would have enriched the study. This would be a fruitful area of exploration in future.

- The REA workshops were not recorded, so the findings were based mainly on summary notes and observations. We might have missed some information due to this.

- The discussion on REA feasibility was based on selected findings. Some aspects (elements) of feasibility such as demand were already addressed in the other sections (chapters) of the thesis. In addition we did not generate much data on adaptation and expansion. The discussion is therefore limited to selected variables such as acceptability, practicality and integration.

7.3. Conclusions and Recommendations

Based on the findings, application of the REA tool and its integration into the existing research governance system appears feasible. REA has potential for further application both before individual research projects and as part of the research governance system. However some practical concerns will need to be addressed before mainstream applicability is established.

Acceptability: There is a good level of recognition and acceptability of REA by its end users; researchers and ethics community. However, concerns remain that REA might place additional burdens on researchers and the research governance system. The main issues identified were time and budget constraints, 'contamination' related to the data collection instrument, the flexibility in modifying the consent form in the field might affect the quality and standards of the IRB approved consent forms and procedures. Creating understanding about REA is not automatic and many potential stakeholders had misunderstandings and unworkable expectations.

Implementation: It was possible to implement REA as planned, with only slight adjustment and modification, and with the resources and skills available in the Ethiopian context. REA is flexible and adaptable to circumstances, settings and needs.

Resources: The resources needed for REA are not different from most research and with proper planning and trans-disciplinary collaboration it should be possible to implement REA in research projects conducted in Ethiopia. REA results were conveyed to PIs in a reasonably short period and were feasible.

Integration: There is potential to integrate REA into the current research review and governance system at two levels; 1) integration with individual research project to be conducted; and 2) integration of the approach into the existing system. Integration with research proposals has the advantages of an integrated review and efficiency in planning and resource management. Acceptability and practical feasibility of the approach, cost-effectiveness and flexibility for easy adoption, all contribute as key factors for successful integration. The successful integration of REA within the planned parent research projects was due to a number of factors such as the awareness and good understanding created among the researchers owing to the intensity of communication and relationships with the PIs. Integration with pre-tests seems unrealistic as the two have distinct and separate objectives, timings and settings. Conducting national REA to generate a national 'catalogue' of ethical issues also appears unrealistic as it would be very expensive and its findings would not reflect the unique dilemmas related to individual projects. Development of REA into national guidelines is a time-consuming process which will require training and capacity building.

Based on our conclusions, recommendations can be made in three areas:-

a) End-user related;

Continuous awareness raising through workshops for researchers, research ethics committees and regulators, with the aim to promote REA and its use. In addition to the researchers there is need to design a mechanism to involve data collectors and field workers in the conduct of REA

b) Application-related;

It is advised to follow a differentiated approach to develop criteria for projects requiring REA than a more general one as projects have their own peculiarities. There is a need to guide researchers opting to use REA in relation to the resource and skill needs and the planning considerations so as to have a practical financial and time budgeting. The costing need to be made based on the realistic market for the listed items, with an adequate time and man power allocated. As much as possible the REA plan need to be integrated into the initial research proposal development. As part of wider use the model of implementation where REA is an integral part of the research project is to be further pursued. There is a need to document resource feasibility of REA with a cost-benefit analysis

c) System-related;

For wider implementation, documented guidelines in applying REA need to be developed. In preparation for wide scale application, continue working on awareness and capacity building of various stakeholders at institutional and policy levels.

Chapter 8 : Revised REA Strategy

Problems are not stop signs, they are guidelines.

Robert H. Schuller[90]

In this chapter, we elaborate the REA process for further use, what researchers need to think about and make plans for, in order to conduct an REA. In the preceding chapters, we have shown that REA is a useful and feasible approach to tailor research consent process to context by identifying ethical issues specific to each community and research project. Even though plenty of resources are available in relation to qualitative methodology, development of a guideline for REA is still necessary. Documentation available on the REA approach in general, and its practical application techniques in particular, is very limited. The objective of this chapter is therefore to provide guidance with revised strategies on applying REA tools for researchers and stakeholders who have little idea about qualitative and ethnographic techniques. In addition, it is useful to those promoting and disseminating REA tools. Though the guideline targets mainly researchers in Ethiopia, researchers in other similar contexts could benefit from it.

The chapter provides revised strategy on, which kinds of research projects require REA; who are the right people to perform REA; what are the recommended strategies for data collection, analysis and feedback with examples and illustrations from our REA pilot projects. The chapter differs from the methodology chapter (chapter III) as it describes REA application based on reflections on the process of REA implementation; and lessons learnt from field application and feedback from the REA dissemination workshops. As discussed in Chapter III, the REA tools and guidelines evolved through three stage; a) adaption of earlier rapid assessment tools, b) REA field pilots and c) REA dissemination workshops.

[90] Crystal Cathedral Ministries : Robert H. Schuller. BrainyQuote.com, Xplore Inc, 2014. http://www.brainyquote.com/quotes/quotes/r/roberthsc107067.html, accessed January 24, 2014.

Below we present revised strategy in conducting REAs, for deciding if REA is needed for a particular research project and the steps to be followed in planning, conducting and concluding REA in an eligible research project.

8.1. Which research projects need REA?

REA may be useful for any research in providing researchers with more insight into the ethical issues for the community in which the research is to be based. For some projects, REA will bring essential new insights, while for others it may simply confirm already known existing understanding of a community, and ethical issues would have been addressed without it. The distinction between these two extremes seems clear. However, there will be many projects that fall somewhere in between, leaving researchers and the ethical appraisal system in dilemma. REA need not be made a universal requirement. The decision to employ REA should take in to consideration, important facts in relation to the community in which the study is to be sited, the research topic and methodology, and the resources available. List of possible criteria for research in which REA might be required include studies with anticipated ethical issues are presented in Figure 8.1.

- Community based studies,
- Studies in research-naïve settings,
- Studies on sensitive issues,
- Studies on vulnerable groups,
- Studies involving invasive data collection procedures,
- Intervention studies such as randomized controlled trials,
- Longitudinal studies.

Figure 8.1 List of suggested criteria for identifying research for applying REA

Community-based studies: REA is designed to assess cultural and other context-specific issues within communities. As an ethnographic assessment, REA explores

values, practices and perceptions possessed by communities. According to Merriam-Webster, *communities* are defined as "a group of people who live in the same area (such as a city, town, or neighbourhood); a group of people who have the same interests, religion, race, etc." (Merriam-Webster). Gusfield states that there are two integral components in the term community; territorial (geographic and neighbourhood based) and relational (quality and character of human relation) (Gusfield 1975). According to McMillan and Chavis-George, the sense of community is based on four elements; membership; influence; reinforcements (integration and fulfilment of needs); and shared emotional connection (McMillan and Chavis-George 1986). Community-based research refers to studies with a defined community or communities as study population. Studies focussed on a defined population group would be eligible to apply REA as a tool. The target population of some studies is defined on the basis of disease status rather than living circumstances, language or culture. For example, a health facility-based follow-up study on outcomes of radiotherapy at Black Lion Hospital[91] in Addis Ababa would have a study population defined by disease status and referral to the treatment centre rather than residence, language or social structure, whereas the study population of the cluster randomised trial on malaria done in Zeway was confined geographically to an area and shared communalities such as language and social structure. In the case of a referral centre-based study, application of REA to identify shared communal beliefs, perceptions and cultural practices would be meaningless.

Research-naïve communities: Some communities such as minority population groups could be poorly understood, and their cultures little researched. Equally, others may be 'research naive', meaning that little is known about their perceptions of medical research. Even when research has been undertaken in a community in relation to one topic of research, REA may still be needed if a very different piece of research is planned. For example, in Soddo, community-research dynamics in relation to genetic research were documented using REA about five years ago. However, using REA prior to research on a different topic, new ethical issues emerged.

[91] A specialised tertiary referral and teaching hospital in Addis Ababa

Studies on sensitive issues: Sensitive issues in research include issues that 'raise concerns about disapproval or other consequences (such as legal sanctions) for reporting truthfully or if the question itself is seen as an invasion of privacy' (Torangeau and Smith 1996) or a topic with a potential threat as a result of which data collection, holding, or dissemination are problematic for participants and researchers (Lee and Renzetti 1993). Such issues have impacts both on the study subjects and the researchers (Dickson-Swift, James et al. 2007). Sensitive topics in research require more preparation from the researchers side (Dickson-Swift, James et al. 2008). Examples of sensitive issues in research include genetic studies (Tekola, Bull et al. 2009b); studies on diseases conditions considered taboo and stigma prone in relation to sensitivity of personal information and consent around privacy and confidentiality (Singh, Abdool-Karim et al. 2006) and collecting information around personal issues associated with past-trauma (Taylor, Martin et al. 2011) (Decker, Naugle et al. 2011). Researchers have documented the importance and ethnographic value of qualitative tools such as FGDs in exploring and understanding sensitive issues within their contexts (Jordan, Lynch et al. 2007).

Studies on vulnerable groups: Vulnerability can be broadly defined as the inability to protect oneself and one's interests. Vulnerable subjects are those who 'have insufficient power, prowess, intelligence, resources, strength, or other needed attributes to protect their own interests through negotiations for informed consent (Levine 1988; Ballantyne and Rogers 2007). Examples include involvement of vulnerable study groups such as minority groups (such as indigenous communities), prisoners, psychiatric patients, minors, pregnant women, elderly and those in socioeconomically disadvantages status like homeless and street youth. While having different types and causes vulnerability is context sensitive and defined by contexts. Vulnerable individuals need to be addressed with extra caution (Koffman, Morgan et al. 2009 ; Online Ethics Center for Engineering; National Academy of Engineering 2011; Koller, Raffaelli et al. 2012; WMA 2013) (CIOMS 2002).

Studies with invasive data collection procedures: An invasive procedure in medical practice is 'a diagnostic or therapeutic technique that requires entry of a body cavity or interruption of normal body functions (The Free Medical Dictionary 2014). There are ethical issues associated with such sample collection methods such as distress, discomfort and concern over bio-specimens and their implications (Baer, Smith et al. 2010). While invasiveness has different types and degrees it is recommended that it be sensitively addressed (Queen Margaret University 2011) and looking for minimally invasive options stressed (Lindau and McDade 2008). Examples of invasive procedures include the Pap test[92] and colonoscopy, lumbar puncture (LP)[93], vein punctures, vaginal specimen collection, and biopsies.

Intervention study designs: Intervention studies (or trials) are characterised by the introduction of an intervention by the researcher with the aim of establishing its effectiveness. Interventions include new drugs, new treatment modalities or prevention strategies administered at individual or group levels, with the investigator's direct control over the allocation of subjects to study groups. While there are different types of interventional studies, clinical trials are special type of interventional study with highly controlled setting to investigate treatments. Intervention studies involve lots of ethical dilemmas such as clinical equipoise, placebo, adverse effects of interventions, and randomization (Friedman et al 2010) (Weijer, Grimshaw et al. 2011) (Buchanan, Miller et al. 2007).

Longitudinal studies: These are studies in which a long term prospective interaction between the researcher and the research target group is anticipated. There is long term interaction with the community, not just at a cross section. Researchers will be visiting the community repeatedly and study subjects will be enrolled for some years. Longitudinal studies may be on various issues and range of population groups with

[92] Pap smear is a screening modality for cervical cancer which involves taking a cervical swab and cell study

[93] Lumbar Puncture is drawing of CSF (cerebrospinal fluid) from the cerebrospinal space through a puncture in the inter spinal space.

range of ethical issues (Kotch 2000) (Scott and White 2005) (Aquino, Vasconcellos-Silva et al. 2013).

Are there studies for which REA is not necessary? There are no contraindications for REA, and any research endeavour would benefit from it. However, the scale of return is not the same for all research. In situations where there is very little benefit, REA is not recommended. In situations where the ethical issues are fully mapped out beforehand, REA would represent a duplication of effort. If the PI, the research team and the ethics review committee agree that the community is well known and there is a clear picture of the ethno-cultural landscapes in relation to the topic and methodology of the research project, then REA may be deemed unnecessary. If the community under consideration has already been assessed using REA, these findings should be reviewed before embarking on a new REA. This assumes that the earlier REA was conducted recently and is not radically different in topic or design from the previous project. When no major ethical issues or challenges are anticipated, for example where there are no recruitment or consent procedures as in secondary research, REA is clearly unnecessary.

Making decisions: The decision whether REA needs to be done or not depends on more than one. One needs to make the judgement based on the different aspects of the research project, the community under consideration and resources available listed above. Practical issues related to the project are also important. These include time, professional skills and the finances to cover REA. Clear arrangements need to be in place in terms of support from the research governance system.

Who makes the decision and how? In the current situation, the researchers of the individual project (the PI and the research team) need to decide if the project falls into the categories listed above or not. Discussion with REA experts and ethicists may be useful in arriving at this decision. Based on this, the PI must make the ultimate decision. As the tool moves to main-stream application, research ethics committee could include a standard operating procedure (SOP) about REA. Based on list of criteria, they can recommend or seek for the application and incorporation of REA in to research projects.

How far should REA be integrated into the planned study? Once it is clear that REA is required for a particular study, the next question is how far to integrate it, and into which steps. Our experience suggests that application for REA should be included in the main research proposal as submitted for approval. The ethics committee would then give provisional approval, with the condition that the information sheet and consent form are submitted following REA and that final approval would depend on these. If for some reason, REA is recommended for a project already submitted, then by requiring it, the ethics committee demonstrates approval, pending submission of a brief proposal template.

Project title: "HPV in women of Ethiopia: an approach to cervical cancer"

Description: Assessing HPV subtypes from cervical cancer patients and asymptomatic women (attending antenatal clinic) involves taking a cervical smear. These patient groups will have gynaecologic examination for other reasons (antenatal care) – during this examination a cervical smear can be taken within a minute and additional serum sample taken afterwards. The procedures do not cause any harm, and there are no side effects.

Project Objectives:

- To determine the sero-prevalence of HPV
- To characterise the serotypes (subtypes) responsible for HPV infection among women in the reproductive age group

Methods :

- **Study area**: Multi-centre study with different urban-rural locations; Addis Ababa, Wollega, Mekele, Wollayita, Harar and Bale (Ghinir).
- **Study period**: March - June 2013
- **Study design**: Cross sectional
- **Study population**: Pregnant women who are attendants of ANC follow-up clinic
- **Sample size and sampling**: 100 pregnant women, asymptomatic women attending antenatal clinics age 15-40 years. There should be a minimum of 100 persons per site. Rural and urban sites will be considered resulting in a representative cohort.
- **Data collection and analysis**: Data collection method involving interview, collection of blood sample and vaginal swab for lab testing.
    - Interview : Socio-demographic, Reproductive and Sexual history, [questionnaire]
    - Physical examination : Visual inspection of genitalia [checklist]
    - Whole blood : whole venous blood, 70µl, EDTA tube, Saver Card [syringe]
    - Vaginal swab : Delphi Screener [screener]
- **Data analysis**: Sample to be further analyzed for HPV and its subtypes in and outside the country. Assessing HPV subtypes from specimen involves analysis of tumour blocks

Illustration 1: Deciding the need for REA

One of the study projects we piloted REA on was a 'Sero-survey of HPV' among pregnant women. The need for REA was agreed after discussions were held with the PI and the sponsors of the research project and REA experts. The final decision was made by the lead PI of the project. The study was a 'community-based' study for all its sites except Addis Ababa. Addis Ababa was excluded. REA had been performed in one of the sites, Soddo, five years previously for a genetic study. We still did the REA in Soddo despite the earlier REA since five years had passed and the study concerned a very different topic The site in Wollega was relatively research-naive. The ethical issues we identified included inclusion of pregnant women (considered a vulnerable group); the research subject area (reproductive tract cancer is associated with a high level of taboo and stigma); involvement of invasive procedures for data collection (whole blood sample and vaginal swab). As the project had already been approved, the plans for REA were submitted for approval separately. Logistics for REA were provided by the REA project, while the HPV project covered costs related to the PI during the REA.

Figure 8.2 Case Study on "HPV in women of Ethiopia: an approach to cervical cancer" to illustrate REA application

8.2. Who will conduct the REA?

Based on the experiences, we recommend forming an REA team of multi-disciplinary experts, as soon as the decision is made to conduct an REA. The team needs to be small in number for coherence and manageability with an average of 5 members.

Responsibilities: REA team is responsible for the REA, including the initial inception meetings, planning for the field, data collection, analysis in the field and suggestions based on the REA findings.

Composition: the REA Team should include the following expertise:-

Research Subject Expert: This health professional will have expertise in health issues at the community level, and can be considered a 'subject matter' expert. It is recommended that the research subject expert be part of the whole REA process and analysis. In ideal situations the project PI (assuming the PI is an expert in the topic of the project) may be the right person to play this role. If the PI does not have public health or subject area expertise, he or she may recruit another expert to join the team, while the PI leads the REA team.

Social Scientist: The social scientist ensures that qualitative ethnographic methodologies are properly applied. A sociologist, social anthropologist, or researcher with ample experience in social and qualitative methodologies is an appropriate person to have in the team.

Local area (and Language) Expert: While the research subject area expert and social science expert are outsiders to the area under investigation, the local area expert is a person who is an insider, ideally with a research background. It is also preferable that this individual has a working knowledge of English[94] so he or she can take an active role in the REA discussions. In a situation where the language spoken in the area is unknown to the lead researchers or investigators in the REA team (i.e. both the research subject and social science experts), it will be important to have a local area

[94] Since most research tools are designed in English, and the write up and analysis also happens in English.

language expert and a local area expert, both of whom have lived in the area for several years and are well versed in the culture and language. In areas where there is considerable language heterogeneity, it is advisable to have more than one expert representing each major language group. Identification of these experts is usually possible during the earliest visit to the area, through district government or health office officials and then using a snowball approach if necessary. Sometime it will be appropriate for one person to take on more than one of these roles. For example the research subject expert or the social scientist might be well versed in the local language.

Guiding principles: The following are important guiding principles in the formation and functions of REA.

Team spirit and team dynamics: the PI should foster team spirit in the small group and should take time to get to know each member, to introduce them to each other and create opportunities both formal and informal to make the team dynamics smooth. In the field, the team need to stay together even through meal times and evenings to strengthen these dynamics. Such incidents are important times of discussion and reflection on observations from the fieldwork.

Training and orientation: the REA team members need to be well oriented on REA as a technique and what is expected of them, including team rules, field assignments and division of labour[95], in order to avoid confusion and duplication of effort. It is important to describe who is in charge of the team and how to deal with issues. The team members also need to be versed about the subject matter of the study and about the ethical issues expected to arise from the study. They also need to be briefed about the area of the study and it is often helpful to allow a day or two for a desk review and familiarisation with the study area, and then a time to share what everybody has found. Once in the field, the insider should give a very brief on-site orientation. It is important

[95] Various supportive task include photography, recording, refreshments for the discussion participants, etc

not to interview the insider as he or she is a team member and also needs to remain open to the findings to be revealed by the study. Formally interviewing the team member might bias the REA team.

Coordination: Even if this is a small team, the team members and the individual in charge should be very familiar with their tasks. The tasks of each team member should be given in writing and discussed before work begins. It is good to review how the team works on daily basis and reflect on the coordination of time, resources, appointments, updates, and schedules. The team leader should be informed of all the changes of plan while on field by telephone. Planning for the next day is done together the day before, and back up plans are made.

Back-up: If there occur unforeseen circumstances and one of the team members can no longer continue to be part of the team, replacement plans need to be made by the REA leader. It will be helpful to have list of people as back-ups from the original planning.

Illustration 2: REA Dynamics

The REA prior to the study "HPV in women of Ethiopia: an approach to cervical cancer", was performed by a team composed of a public health expert(the PI of the HPV project, also the research subject expert), two further public health experts from Addis Ababa University (AAU) who spoke the local language (*Orommiffaa*), and one social scientist a social anthropologist from AAU. All the experts from AAU were found through our existing research and academic. The Local Area Expert was an insider and language expert (also fluent in *Orommiffa*). The whole REA team met and were introduced to each other in Addis Ababa two weeks before the field trip. We gave the recruited members of the REA team additional training and orientation about the REA process and the research project under consideration, through brainstorming and planning meetings. The team also travelled together on public transport and stayed together in the same guest house with individual bed rooms and sharing one common-room. One of the team members with public health background and more research expertise than the rest of the team members was assigned as a team leader. The additional motivations for the REA team included the learning experience and recognition they gained. We wrote them recommendations and two of the team members were recruited for other qualitative studies based on their REA experiences.

Figure 8.3 An illustration of REA team dynamics, an example form REA pilot on HPV study

8.3. What is needed for the REA?

The most important and basic inputs are manpower, time and field logistics.

Manpower: the core manpower needed is the REA team. In addition, supporting individuals such as a focal person for field coordination may be needed. The insider REA member (local area expert) may help in this, but at times it may become too much of a distraction for him/her. It is important that there is someone responsible assigned to do these tasks, as it is likely to be inefficient for the REA team leader to take care of each of these details. This person then serves in assisting him in routines such as making arrangements for venues for discussion, taking messages to communities and convincing community leaders of the importance of meetings and group discussions. The focal person in addition helps to get permission from the district administration, arranges refreshments for the discussion participants, and purchases items like batteries. The insider (time allowing) or the field driver could be delegated to do these routine logistic tasks.

Motivation : how do we motivate the REA team members? Depending on available arrangements, the team members need to be compensated for the time they spend in the REA engagements. Payment and subsistence issues should be clarified at the beginning so they do not become points of dispute and later on have effects on the REA process and team dynamics. Apart from financial compensations, the REA team might be given recognition in the form of a letter of recommendation, or considered for subsequent REA, or acknowledged by name in any publication; or even included as authors in publications, based on their contributions. Motivation of the REA team is very important. As the REA team needs to stay in the same place - the same hotel if in a hotel. It is good to consider this as part of the plan. It would be difficult to force someone to the place without providing adequate resources.

Logistics: Important logistics for the field data include transportation, accommodation, stationery, voice recorders and camera.

Transportation: an important consideration for efficient movement of the team in the community is having a reliable means of transport. Some areas have very smooth public transport systems while others have difficult topography so hiring a vehicle and a driver is recommended.

Accommodation: As the team need to stay together, it is important to book a communal accommodation ahead of time for the duration of the study. Hostels and guest houses with communal areas for team meetings are very good arrangements for such functions.

Communication and data-collection equipment: Cell phones are necessary for communication between the team and the focal personnel in the area (the air-time refill needs to be part of the financial plan). Stationery includes paper, note books and writing materials. It is important to have enough copies of the question guide, brief summaries of the REA proposal and the summary of the original study. Consent forms for the interviews and group discussions need to be duplicated early. Recorders need to be prepared in duplicate as back up and their functionality be checked ahead of interviews. The batteries have to be checked and spares made available. Recordings should be downloaded every day so that the recorder is ready for the next day. It is wise to have a spare recorder for every interview or discussion. Chargeable recorders need to be fully charged the night before[96]. Digital cameras with still and moving picture recording functions are preferred.

Time: Adequate time for the REA preparation and field work is another important aspect of planning. Investigators need to be able to allot an average of 6 weeks ahead of the study. The REA may overlap with the pre-test phase of the study, and observations of pre-test data collection may be part of the REA fieldwork. Working hours in the field should not be limited to the conventional 8 hrs. This needs to be negotiated with the REA team ahead of time and necessary provisions made.

[96] As long as there is electricity - availability of electricity is a plus for accommodation when booking for the REA team

8.4. How do we do an REA?

The following are important steps in the actual conduct of REA in the field.This is further summarised in Table 8.1, at the end of the chapter.

Early communication with field site: Once the research project and the study site is known, the person in charge of the REA is advised to start communication with the field as early as possible. This requires letter of support and ethical clearance, assuming REA is part of the proposal. In the first visit to the area, it is advised to communicate with the area representatives and officials, and to obtain permission for the field study in the form of a letter of support from the community administrators. In addition, in this very first meeting, it is advisable to identify potential focal person/persons from the area for further communication and field planning.

Identify ethical issues: While pursuing preliminary administrative arrangements for the REA, it is important to start studying the research issues and their implications for ethical issues. Studying the research issues and methods in detail and identifying the potential ethical challenges will help in framing the research tools. For the HPV study, we identified list of potential issues for REA (Figure 8.4)

Example 3 : Pre-identified ethical issues

Some examples of pre-identified ethical issues for the Cervical Cancer (HPV) study included the following :-
Information about research (in general) and the research subject matter (reproductive tract cancer),
Channels of information and communication in the community,
Decision-making dynamics in the community,
Expectations of participants,
Perceptions of the data collection methods: vaginal examination and blood specimen collection
Attitudes and levels of trust of participants,
Educational status of the community and its impact on consent process,

Figure 8.4 List of pre-identified ethical issues based on the REA pilot on the HPV sero-prevalence study.

Development of data collection methods and tools: Data collection tool i.e. interview and discussion guides to be developed by the REA team based on ethical issues identified and basic guiding ethical principles. The data collection methods include discussions (individual and group) as well as observations. The tools may be revised during the data collection process.

- Individual interviews : Interviewing individual experts in the area on one to one basis. These individual experts are usually few in the area e.g. leaders of *woreda* health office, religious leaders, etc. The interviews are accompanied by recording and note-taking be done.

- Group Discussions (FGDs): This is usually ideal for large groups representing big groups of community group with some degree of homogeneity. A group of 8-10 individuals in one focus group. E.g. group of men or women representing the community or mixed groups of men or women adults in the community.

- Observations: While IDIs and FGDs are the primary data collection methods, observations augment the data obtained from the discussions. Examples of observations include observing public scenes like market places, participating in community gatherings like religious ceremonies, observing routines in health facilities and medical-consultations, and observing communication between data collectors and study participants.

Field Data Collection: Depending on the chosen methods of data collection, REA team members are assigned to lead individual and group discussions and make both formal and informal observations. Identification of key informants is a key-step to collecting rich and relevant information. Key-informants are individuals who possess potential appropriate information. They are identified through snowballing, a process of identifying the potential study subject through other study subjects. Snowball sampling may identify candidates for ID and FGDs (Lewis-Beck, Bryman et al. 2004; Handcock

and Gile 2011; Hennink, Hutter et al. 2011). Potential key-informants in the Ethiopian setting may include the following:-

- Community leaders: local administrators, heads of *woreda* (district) offices such as *woreda* council, *woreda* health office and tourism bureau.

- Community representatives: includes general community representatives (adult men and women or mixed groups). Depending on the research topic, different group compositions may be appropriate. For example, if the study is on disabled individuals, a group of disabled persons, or if the study is on persons living with HIV (PLHIV), a group of PLWHIV, can be contacted.

- Community workers: such as data collectors who have worked in the community. Some communities have existing community-level data collectors or enumerators for ongoing projects or community level caregivers or health workers (such as Health Extension Workers).

- Health Professionals working in the area: this refers to professionals in the local health facilities. These health care professionals have close working relationships with the community and they will tell us about their experiences, the community's reaction to medical procedures, overall awareness and attitudes about and towards medical interventions.

Sample size: *How many IDIs and FGDs will be adequate? When do we stop data collection in the REA process?* In theory, sample size for qualitative studies is based on level of information saturation of emerging themes and ideas rather than pre-meditation. This has been and is the recommended approach (Marshall 1996; Mason 2010). Based on daily reflection on the findings, the decision is made based on whether new questions need to be asked or saturation has been reached. The qualitative expert (social scientist) will be able to guide the REA team in this exercise.

Recording/Field notes and memos: During each data collection session, the discussions and interviews need to be properly recorded to generate adequate and appropriate data for the analysis. Data collectors are advised to take field notes and memos as well as back up notes for all sessions, in case the recording fails for some reason.

Filing, organising and storing the data: As important as generating the data, the REA team needs a way of organising these data in both electronic and back up formats. All recordings need to be saved, adequately labelled, in a central database, and a similar file kept on an external disk for back up. Whenever more than one recorder is used, both recordings need to be kept together and a decision made as to which is the best version. N-Vivo is a powerful tool for filing and storing multiple sources of information including multimedia (NVivo® 2013). As N-Vivo is relatively expensive, researchers can use open source software tools such as Open Code® for being an open source (University of Umea - ICT Services and System Development and Division of Epidemiology and Global Health 2013).

8.5. How to analyze and utilize REA findings?

In the conduct of REA, we do not wait until the REA data collection is over in order to start the data analysis. Analysis starts in the field. It actually starts on the first day of field work with debriefing and reflection on the findings of the day. Further analysis can be done after the fieldwork to finalise documenting the findings and for the sake of publication.

Daily debriefing sessions: Daily debriefings start once the field data collection is on. On the first day it is recommended to do 1-2 IDIs and review basic documents about the area. At the end of the day's work a debriefing led by the lead investigators is conducted in the presence of all REA members to go through the major findings of the IDIs and come up with early themes. The study question guide used by the data collectors of the

day is used to guide the discussion. Time allowing, it is advised to listen to the recordings of the interviews provided it is in language format understandable by all. This can be done for the first few interviews; as time goes on each of the data collectors will be responsible for summarising their findings if needed after reviewing the major section of the recording. During the discussion the data collectors will use their field notes and summary of findings from the day as well. It is recommended that the debriefing sessions are recorded for the in-depth analysis. Facilitators make notes of the discussions which will be used for subsequent discussions and are useful in the final analysis of the field data. The facilitator of the debriefing session will ask for contributions from each of the team members as to which areas to explore further in subsequent days. In addition, new and emerging issues will be discussed and decisions made on how to explore them further. At the end of the debriefing, the facilitator summarises major points and decision is made on required updates or revisions to the tool.

Summarising REA field findings: Once the field data collection is over, a week needs to be allotted to compile the findings and produce a preliminary summary report. This report is expected to include recommendations for the consent process and what adjustments need to be made to the information sheet and consent form. When the summary is finalised, the original consent forms and processes are tabled, and the discussion centres around them. After discussion, the REA lead investigator will compile the decisions agreed upon.

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Illustration 4: Refined Themes following REA on HPV Sero-survey

The following themes were identified after the conduct of REA and the list of issues was modified.

- Communication of findings
- Decision-Making modalities
- Status (Economic and Social)
- Language
- Gender dynamics
- Power
- Trust/ Honesty/
- Study Expectations and Benefits/
- Signature
- Field Workers
- Biological Samples
- Children

Figure 8.5 List of refined ethical issues based on REA pilot done on HPV sero survey, Tigray region, Ethiopia

Checking facts: *Where to make the finalisation*. It is very beneficial that the preliminary analysis and compiling the summary feedback is done on the study site. One important advantage of this will be validation of the findings and counter checking facts and information as required. During the final analysis, REA team members might consider counter checking or triangulating some practical information. This will be done easily if the final analysis is done on the site of the study.

Feedback: Communication of the REA findings to the parent study PI obviously depends on his or her role in relation to the REA. If the PI of the parent project was part of the REA team, no separate feedback session may be required. But if the PI of the parent project team is not part of the REA, it is advised for him / her to attend the last days of field analysis and take part in the process. This will serve as mode of feedback to the PI. If the PI cannot be part of the REA team or the on-site analysis, the mechanism of communicating the information needs to be decided. The available options are sharing the written feedback report, or an oral feedback session with the PI. A combination of both approaches is beneficial. The leader of the REA team is

responsible for communicating feedback with the PI of the parent study. Any written or verbal communication of feedback needs to include the major findings and their implications on the consent process. Again, it is best to have the consent forms on the table during the discussion. It is up to the parent study PI to make further decisions.

In-depth analysis and documentation: In-depth analysis to document the scientific process and produce scientific reports or publications may be done off-site any time after completion of the summary report, and may take considerable time. As there are limited publications in the area, researchers are advised to pursue this if they have the time and the interest. In-depth qualitative analysis follows the conventional qualitative data analysis techniques and principles.

Thematic content analysis would provide a good framework for the analysis. The major steps include

- *Transcription*: All the recordings need to be transcribed to a text.
- *Texting*: all observations and any motion pictures and clips need to be converted to text data
- *Translation*: Since the interviews are mostly done in a local language (either Amharic or another language), the transcripts need to be translated to English.
- *Transcription-Through-Translation*: In order to increase efficiency of the analysis process, the transcription and translation can be done by the same person listening in the language of the interview and transcribing into English. Again, to increase efficiency, it is advisable if the transcription is done by the person conducting the interview or group discussion.
- *Transportation*: for ease of management, the text data could be stored using qualitative data analysis software such as N Vivo. However, N Vivo is a commercial product, and licences may be expensive. There are open source options such as OpenCode (University of Umea - ICT Services and System Development and Division of Epidemiology and Global Health 2013). This provides the basic functions of analysing text data, but does not allow storing of other media formats.

- *Transformation*: this is the process of transforming the open text-based material into meaningful information with themes and categories. This process of transformation entails a series of coding cycles and synthesis of thematic and categorical clusters. First Cycle or open coding is a free coding of the entire dataset to open themes and categories. Second Cycle coding is done to categorise the themes from the first cycle in a logical and meaningful way. Based on the second cycle of coding, further thematic categories emerge and organisation is done.

Quality control: In-order to increase data quality and validity, double coding and back translation can be done on part of the text data. Double coding is when the same section of the transcript are coded separately by two independent coders. Once done, inter-coder variability is checked for any major differences and deviations. Then the two coders discuss how to resolve any major deviations. Back translation is when selected translated texts are back translated to the original language by an independent translator. The back translation is counterchecked with the original version to check for consistencies in meaning and content of concepts.

8.6. What are the end results of REA?

The ultimate objective of REA is, based on its findings, to inform and guide the informed consent process. The following steps are expected to be achieved:

a) **Revise Consent Form:** for content, language and associated explanations regarding the information to be given for study participants;

b) **Make Information Dissemination Plan:** assess the need for community-level communication and information sharing and how to disseminate information, taking area -specific communication dynamics into consideration;

c) **Make Consent Process Plan:** this will include decision-making dynamics, how consent should be obtained, and who influences decision making. The REA outputs can be further classified as those related to Content (What Information to include), those related to Communication (Language etc); and those related to Consent (How to reach a decision). Table 8.1 summarises the key steps and considerations for REA.

Table 8.1 Summary of steps in conducting REA

Step	Methodology	Required Resources	Responsible
Decide if REA is needed	Brainstorming and discussion; consensus building	Guideline, Criteria,	Researcher/Research-team/IRB/Ethics committee
Plan for conducting REA	Priority setting	Guideline/ Check-list, Time, Expertise	Researcher/Research-team
Establish REA Team	Networking, Recruitment, Training, Team-spirit,	Guideline/Human-resource/Social-scientist,/Research subject-area expert	Researcher/Research-team
Prepare for the field	Brainstorming Desk review	Field logistics/Preliminary tools, / Field guide,	Researcher, REA Team
Collect data	Desk review Discussions (Individual and group)/Observation	Manpower/ Time Field logistics Data collection guides	REA Team (+/- Researcher)
Field Analysis of data	Daily de-briefings	Field notes Interview, Discussion and Observation notes Reflections Recordings Pre-defined themes	REA Team, (+/- Researcher)
Reflect on the findings	Iterative reflection Consensus building	Debriefing notes Emerging themes	REA Team, (+/- Researcher)
Amend consent form and process	Iterative reflection Consensus building	Check list of recommendations	REA team (+/- Researcher)
Plan for and communication of feedback	Debriefings Meetings and Discussions	Check list of recommendations	REA Team
Monitors and Evaluate Consent Process	Field visit Supervision Observations	Check list of recommendations	Researcher IRB/Ethics committee
Documentation of REA findings and dissemination to the public	Detailed qualitative analysis Transcription Translation Coding Abstraction (Thematic content analysis)	Recordings Pictures Field notes and memos	REA Researcher and REA Team

8.7. Discussion

REA is a novel approach which is still under development and it is too early to prescribe every detail in its implementation. However, the guidelines provided will be useful in providing a basic framework for researchers conducting research project in Ethiopia and are opting to employ REA. However, implementation may not be as straightforward as mentioned, and the guidelines are in no way intended to be exhaustive. The use of REA methods will vary depending on need and variations in the contexts. The flexible nature of the tool allows this to happen.

The current REA technique and tools presented evolved over three phases. The phases included a) development of a provisional REA tool and methods based on others' earlier experiences; b)REA field pilot studies where the provisional tools were introduced to selected research projects; and c) critical feedback was obtained from intended potential end users of REA (researchers) during subsequent REA dissemination workshop. Other groups which have employed rapid assessments for other purposes have also followed similar steps in validating rapid assessment tools before recommending them for wider use. They conducted both field trials and validation workshops (ILO 2005; Secretariat of the Convention on Biological Diversity 2006; McMullen, Ash et al. 2011).

Based on the guidelines given in this document, researchers can take the principles of REA and apply them to their respective research projects and contexts. Further application of REA by other researchers will help in further validation of the REA tools and suggestions that will improve REA implementation. Critical elements of REA presented above include a) deciding if REA is needed; b) formation of the REA team; c) thorough technical and resource planning; d) supervised and well-coordinated field work accompanied by iterative analysis; and e) generating and providing results to the parent study researchers. McMullen et al identified six similar stages in the application of Rapid Assessment in Clinical Information System, these included '1) developing a fieldwork guide; 2) carefully selecting observation sites and participants; 3) thoroughly preparing for site visits; 4) partnering with local collaborators; 5) collecting robust data by using

multiple researchers and methods; and 6) analyzing and reporting data in a structured manner helpful to the organizations being evaluated' (McMullen, Ash et al. 2011).

The naming of 'Rapid Ethical Assessment' reflects the intended use of the tool. We believe that the terms meet expectations in the naming of methodologies in that it is a simple, clear and concise description. As the REA workshops demonstrated, the term also served to attract significant attention and interest. It is simple to remember and consistent with other technical terms. The word 'rapid' implies a quick way of generating meaningful information. Rapid and instant techniques are often associated with low quality. However in this instance, efforts are made to cater for technical rigor and competence. As there a range of rapid methods exists, the word 'ethical' will help differentiate this rapid assessment from the others. The ethnographic aspect of the method is not explicit in the naming; however rapid ethnography may be inferred by the word 'rapid'. There is a growing understanding that a rapid assessment is not a rushed assessment. It rather is done with intensity and rigor to compensate for the short time spent in the field. Rapid assessments try to balance the urgent need for the results to inform an action with the time needed for adequate data generation. This balancing act has been argued for by several researchers (Beebe 2001; McMullen, Ash et al. 2011). While the term 'Rapid Ethical Appraisal' has been used interchangeably with 'Rapid Ethical Assessment', the earlier terms appears to aggravate the confusion where readers (or hearers) confuse the method for an expedited appraisal or review process. Therefore, we believe the latter term, ‘Rapid Ethical Assessment’, to be less confusing.

REA is recommended primarily for community-based research. We described community-based research as a study with a defined community or communities as its study population. Community-based research may be defined differently as collaborative research between researchers and communities (Israel, Schulz et al. 1998; Banks and Armstrong 2012). This definition deviates from our description, which is based on defined population groups targeted irrespective of partnerships. This differentiates community-based research from, for example, facility-based research where the target research population is not necessarily a confined population but may

be a mix of several communities served by a referral centre. Our description also excludes studies done at a national level such as national surveys where multiple cultures and community groups are included. It will clearly be important to define what is meant by 'community-based' research as referred to by REA guidelines. Using other phrases such as 'community-focused' and 'confined-community-targeted' for the description might also improve understanding of the nature of the research.

Guidelines may be disseminated in many ways including through publication or development of national or institutional documents. However the efficiency of these approaches in reaching the target audiences is questionable and different strategies may be appropriate for different target audience (Grou, Zwaard et al. 1998; Grimshaw, Thomas et al. 2004). In recent years, due to information technologies, there is a move towards web-based applications which have the potent to reach many target communities (Duffy 2000). One such example is Global Health Trials[97], which has been developed through collaboration of various research institutions in the field of global health. The purposes are networking among researchers and sharing guidance, tools and resources. We are working with the network to post communications in the community group for researchers (Global Health Trials 2013), and hope to post the REA tool and methodology on the web in the future.

[97] http://globalhealthtrials.tghn.org

8.8. Conclusions and Recommendations

Based on the findings and the discussions we would like to draw the following conclusions.

- REA is a useful tool which needs methodological guidelines. Provision of these guidelines is an important step in the wider application of the tool and its further development. A basic framework for application of REA has been developed in this chapter.

- The application of REA to identify and address ethical issues in research depends on a set of principles and considerations. The principles are universal qualitative ethnographic principles coupled with flexible application of tools to various settings and needs. REA application is based on the following important criteria; nature of community, type of study, anticipated dynamics between the issues under investigation and the community as well as range of speculated ethical issues.

- The key steps in the successful application of REA include a) determining whether REA is needed for the research project under consideration; b) formation of an interdisciplinary, cohesive, dynamic and competent REA team; c) careful and thorough planning for both the technical implementation and logistic resources, based on a checklist provided; d) well-coordinated, intensively supervised fieldwork accompanied by iterative analysis; and e) timely identification of relevant findings and recommendations accompanied by creative and effective communication of findings to the parent study researchers.

- The REA team has a central role in all the steps mentioned above. The rigor of the process and effectiveness of the results depends heavily on this team. Spending time in identifying the appropriate group of professionals and investing in the group's dynamics is a determining factor for the effectiveness of the REA.

- REA is not a final product and is still under evolution. Further validation based on experience from wider implementation is required.

Based on the findings we would like to forward the following recommendations regarding the application of REA methodologies.

- We would like to encourage researchers to employ the REA methods based on the above guidelines. Thought the guideline would be more appropriate for the Ethiopian context, would also serve for other countries with similar settings.

- Once researchers opt to employ REA into their research, they are advised to document their experiences so the REA tool can be further modified.

- Researchers employing REA are encouraged to refer to qualitative enquiry, ethnography and action research guidelines in addition to the guidelines above.

- Ethics committees and research regulators are encouraged to try introducing a requirement for REA prior to certain selected research projects into the existing research review and appraisal systems.

- Finally, we would like to encourage researchers and interested parties to widely disseminate the REA tools and gain experience through actual use.

Chapter 9 : Conclusions and Recommendations

The research projects undertaken have highlighted important findings regarding REA in relation to the informed consent process for medical research in Ethiopia and similar low income settings. In the preceding chapters we have presented and discussed results on the need for REA and its effects on informed consent processes of the individual research projects. This chapter aims to synthesise the findings so far and conclude the thesis. We present major conclusions from chapter IV through chapter VIII, preceded by summaries of the strengths and limitations of the research as a whole. This is followed by the future implications of the findings.

9.1. Strengths and Limitations

9.1.1. Strengths

We conducted multi-disciplinary research which employed a mix of study designs and approaches appropriate for the subject under study. Mixed methods, qualitative enquiry and a comparative intervention study, which increases the grade of evidence versus descriptive, were all used at various stages. A mix of qualified experts from medical, public health and social science backgrounds were involved in the design of the research, the field work and analysis.

Data quality measures were instituted at all stages of the research, including pre-tests of tools, counterchecking language translation, training of data collectors, and double coding. Validation of REA tools was performed progressively by seeking consensus from potential users such as researchers.

Existing networks and links with researchers and collaborators helped in smooth communications between the various research centres and projects in the field. During the pilot phase of REA, the successful integration of REA within the parent research

projects was due to awareness and understanding of the researchers, which resulted from good communication with the PIs.

9.1.2. Limitations

Opinions of the community and data-collectors were not included in the REA perception study in Phase I. Since they are important stakeholders in research, their perspective would have given a fuller picture. In Phase II, we included data collectors and the community perspectives in feasibility assessment. However, the study did not assess feasibility in light of field workers and data collectors in terms of possibilities of including them and how this would be accepted. We do hope that future studies will improve on this.

All qualitative tools were developed and analysis of text data was conducted in the English language, while data collection happened in the respective local languages (none in English). Some findings could have been masked by this as qualitative studies analyzed in the language of data collection often yield more meaning. In addition, the REA workshops were not recorded for transcription. Analysis was based mainly on summary notes and observation summaries and we might have missed some details due to this.

Due to the nature of our subject area, we mainly used qualitative methods and data for the feasibility analysis. Quantitative feasibility assessment would help in creating decision models and make easier and objective comparisons. In addition, we did not conduct a full blown cost-effectiveness economic study and analysis. Cost-feasibility and cost-effectiveness studies would employ economic models and cost-effectiveness analysis which are beyond the scope of the current project. However, we made deductions based on costing of the REA implementation process.

In the comprehension assessment trial, maximum effort was made to ensure the uniformity of the intervention and control sites, however there may have been undocumented differences in the two settings which might have confounded the study

outcomes. In the same study, assessment of quality of the informed consent process was done based on participant perceptions unaccompanied by independent observation, which might reduce the objectivity of responses. We also were not able to document the reasons for loss-to-follow-up among those who did not attend after consenting. Sample size determination was done based on assumptions from another country due to local estimates being unavailable. We used relatively low non-response assumptions, which may have masked some potentially significant statistical tests.

Finally we were not able to run REA validation workshops, and tried our best to extract relevant findings from the REA dissemination workshops.

9.2. Summary Conclusions

Overall the various studies documented that REA is a useful approach to tailor the research consent process to context through identifying and addressing ethical issues for community-based medical research in a Ethiopia and similar Low Income Settings, with both inherent intrinsic values and measurable extrinsic evidences.

Chapter IV reported opinions and perceptions of relevant research stakeholders regarding their understanding of problems in the consent process and the perceived relevance of introducing REA as a mainstream tool for addressing ethical issues for health research in Ethiopia. The study findings clearly indicated that there are correctable perceived gaps in the consent process of medical research in Ethiopia both at information provision and decision-making stages. The problems arise from three distinct areas; those embedded in the health research review system, those related to researchers and those related to the general public. The study demonstrated the need for such a tool and its potential acceptability as REA is considered relevant, acceptable and potentially feasible approach in the Ethiopian context by researchers and stakeholders (ethics reviewers and policy makers). However, respondents were concerned about the potential burden that REA would place on the researcher in terms

of time and other resources. REA would increase the burden on the end-users (researchers) and the research governance system (including ethical review) in terms of time, budget, contamination of the data collection instrument, and maintaining ethical and operational standards. Expressed demand and acceptability of an approach are important components in assessing feasibility but are not sufficient. Practicality and feasibility needed to be explored further.

Chapter V discussed ethical issues identified through REA in three community-based health studies in Ethiopia. The ethical issues identified cover a considerable range from general issues such as cultural setting of the study locality, perceptions about research, health and health care practices, to perceptions about the research subject matter, and communication dynamics and norms and their hierarchies. Major categories of issues included that of Context, Content, Communication and Consent. These categories are intertwined with each other and are by no means mutually exclusive and are useful in conceptual framing and analysis of ethical issues in REA. The nature of identified ethical issues was very diverse and a function of place, time and research subject-matter. The findings further demonstrated the relevance of REA in terms of identifying significant ethical issues which would not have been picked-up had it not been for REA, which also laid a basis for understanding the REA process and it application for future use.

Chapter VI discussed feasibility of REA based on the lessons learnt in the process of introducing REA into the three health research projects mentioned in Chapter IV, exploring more practical end-user related questions in terms of practicality of time, cost and skills. The findings surrounding perceptions of REA, in Chapter III, were further substantiated by the findings of actual field introduction of REA. These findings illustrated that REA implementation is possible within a reasonable time frame, is affordable with reasonable cost and manageable with locally available expertise. REA skills were found to be easily transferrable to local experts. REA is flexible and adaptable to circumstances, settings and needs. The resources needed for REA are not different from most research and with proper planning and trans-disciplinary

collaboration it should be possible to implement REA in research projects to be conducted in Ethiopia and other similar settings. Even though the findings suggest that application of REA and its integration into the existing research governance system are considered feasible, practical concerns must be addressed before REA can be made mainstream.

Chapter VII, based on one REA pilot, discussed the impact of REA on recruitment and retention rates as well as informed consent comprehension and quality of informed consent process. This served to further substantiate the evidence of the benefits and outcomes of REA reported in Chapter IV. The findings demonstrated that application of REA in the informed consent process was associated with significant improvements in comprehension levels (understanding and recall), recruitment and retention (compliance) rates and overall levels of quality. The findings implied that investing in understanding the local context to tailor the informed consent process pays off through measurable outcome indicators of quality.

Chapter VIII presented revised strategy on how REA could be practically done by other researchers. Concerns about the lack of clear guidelines for REA reported in Chapter IV and V were addressed by these provisional guidelines, which resulted from lessons accumulated in the process of REA implementation. REA is not necessarily required by all research projects. Its application is rather guided based on type of study, the range of anticipated ethical issues, the nature of the community, and the anticipated dynamics between the issues under investigation and the community. The REA tool follows universal principles and uses standard qualitative methods, action research and ethnography coupled with flexibility to the settings. Key steps in REA include determining whether REA is needed; careful and thorough planning for both the technical implementation and logistics including formation of a cohesive, dynamic and competent REA team; well-coordinated, intensively supervised field work accompanied by iterative analysis for timely identification of relevant findings; and creative and effective communication with the parent study researchers. The REA team has a pivotal

role in all these steps, and the rigor and effectiveness of the process very much depends on this team.

9.3. Future Implications and Recommendations

REA skills are transferrable and it is possible to build local REA capacity. REA could be recommended for improving study quality recruitment, retention and informed consent comprehension, through improved understanding of the information sheet and consent form. In their current state, REA tools and application guidelines are fit for dissemination to the research community for further use. This can be done through awareness-raising seminars and training workshops for researchers, research ethics committee and regulators.

As part of the popularisation and dissemination of REA, there is a need to proactively encourage engagement of researchers and provide them with opportunities to use REA in their research projects. REA tools and guidelines need to be made available and accessible in web formats with interactive support and guidance.

In addition to helping the research community to gain more practical experience in its use, REA dissemination will also help refine and validate the tool. Raising awareness about REA among researchers during REA workshops is also a step towards integration of REA.

While researchers are encouraged to adapt REA tools to their research project as indicated in chapter VIII, it is also advised that researchers attend an orientation workshop to start with. In implementing REA, researchers are encouraged to integrate REA into their main research proposal rather than considering REA as a separate entity detached from the research project. Integrating REA into the planned research will mean that the main research, implementation of REA and informed consent modification are all approved by the IRB at the same time.

Once researchers opt to employ REA in their research they are advised to share their experiences of implementation so that the tool can be improved. Documenting the effects and outcomes of REA in other settings will provide further insight and may suggest wider potential applications, even in relation to other medical interventions.

Expanding the use of REA to the wider research community will depend on a number of issues including demonstration that integration is effective. In preparation for wide scale application, awareness must be raised not only among researchers, but also among regulators and policy makers. Ethics committees and research regulators are encouraged to try introducing REA methods into the existing research review and appraisal systems. Ethicists and research policy makers are encouraged to explore how best to utilize REA outputs in light of IRB requirements and operating procedures.

REA is not yet a final product. Further validation based on its wider implementation is required, and conducting validation workshops for potential stakeholders is recommended. It would also be useful to document its economic feasibility with economic studies such as cost benefit analysis; conduct follow-up studies exploring the roles of data collectors and field workers in REA implementation; and study the applicability of REA in informed consent processes beyond research such as those associated with treatment and clinical interventions.

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Annex

Annex A : Supplementary Material for Phase I of the Project

Annex A.1 Self- Administered Questionnaire for Quantitative Data Collection for Adoption of *Rapid Ethical Appraisal* as a practical method of assessing ethical issues relating to biomedical research projects in Ethiopia (Phase I)

Part I: General Questions: The questions in this section are about your general demographic, social and academic back ground as well as your research related experiences and qualifications.

No	Question	Options/Responses
1	Sex	1. Female 2. Male
2	Age	_____ (in completed years)
3	Institution	1. Addis Ababa University 2. University of Gondar 3. Jimma University 4. AHRI 5. EHNRI 6. Other _____
4	The highest Qualification attained (Tertiary)	1. Diploma 2. First degree 3. Second Degree 4. Third degree
5	Major area of specialty	1. Biology 2. Medicine 3. Public Health 4. Social science 5. Other _____
6	What is your major role in relation to research so far? (more than one response is possible: in this case please indicate in their order your major roles by writing 1 in front of your major role and continue in a decreasing order)	1. Researcher _____ 2. Field worker _____ 3. Ethics committee member _____ 4. Other _____; _____ _____; _____
7	How many years have you served in total in the role/s mentioned? (If less than 1 year,	1. Researcher _____ 2. Field worker _____ 3. Ethics committee member _____ 4. Other _____

	mention as <1) (more than one response is possible)	
8	How can your current role be best described? (more than one response is possible)	1. Researcher 2. Field Worker 3. Research ethics committee member 4. Other _____
9	How many years have you served in total in your current role? (If less than 1 year, mention as <1)(more than one response is possible)	1. Researcher _____ 2. Field Worker _____ 3. Research ethics committee member _____ 4. Other _____
10	Do you have any formal training in research ethics?	1. Yes 2. No
11	If yes, what was the level of training you attended?	1. Short orientation session 2. One week long training 3. A university training (Diploma, Degree) 4. Other (Specify) _____

Part II: Ethical Appraisal System: This section includes questions about your perception and attitudes about the current research ethical review process and the need for introducing *Rapid Ethical Assessment*

No	**Question**	**Options/Responses**
1.	How is consent form developed in your experience?	1. By researchers/investigators from abroad 2. By local researchers/investigators 3. By the sponsors of the research 4. By the researcher with participation from stake holders 5. With a prior assessment of the context before writing the consent form and study information sheet 6. Other _____
2.	Up to your knowledge, are there any particular guidelines available to be used by researchers in developing consent forms and guiding them in the consent processes	1. Yes 2. No

	by addressing the context of participants?	
3.	If yes, which guidelines do you think are addressing this aspect?	1. National guidelines from ESTC 2. Local guidelines by the local ethics committee/ IRB 3. Other _____
4.	Do you think the guidelines mentioned above address ethical issues well enough that the researchers can use them with ease?	1. Yes 2. No
5.	Based on your experiences, are you satisfied with the way how the consent process was designed and conducted?	1. Yes 2. No
6.	Do you think that the best interest of study participants is taken in to due consideration and adequately addressed through the current ethical appraisal and consent processes?	1. Yes 2. No
7.	Based on your experiences, what do you think are the most common problems in the current consent process? (Multiple responses possible)	1. Lack of clarity 2. Language barriers 3. Coercion 4. Power imbalance 5. Undue expectations 6. Others _____ _____ _____
8.	Do you think all participants understand consent forms very well?	1. Yes 2. No
9.	If no, what are the reasons for not being able to understand consent forms uniformly?	1. Lack of clarity 2. Language barriers 3. Coercion 4. Power imbalance 5. Undue expectations 6. Others _____

10.	From your experiences, is there any initiative so far that involves the study participants in the development of consent form and consent process?	1. Yes 2. No
11	Do you think it is important to contextualize consent forms and consent processes to local settings?	1. Yes 2. No
12	Do you think that study participants get involved, as much as possible, in the development of consent form and designing the consent process so that it will be culture and setting sensitive?	1. Yes 2. No
13	Do you agree with the idea of the study participant be approached in advance before the start of the study to get input for the development of the consent and how it is best administered?	1. Yes 2. No
14	Which one of the following options, in your opinion, would serve adequately addressing the consent process issues and in making sure that ethical issues are very well addressed in a research process? (more than one answer is possible)	1. Ethical review by independent body 2. Technical rigor 3. Rapid assessment of the situation in the ground before embarking on the consent process 4. Periodic field check by independent body to ensure the consent process 5. Periodic field check by the researchers themselves to monitor the consent process and undertake modifications if required 6. Other _____ _____
15	Any additional comments	

Thank you for your time.

Annex A.2 Self- Administered Questionnaire for Quantitative Data Collection for the project entitled, Adoption of *Rapid Ethical Appraisal* as a practical method of assessing ethical issues relating to biomedical research projects in Ethiopia

Study Information Sheet:

Background and objective of the research: There is a growing concern about the ethical appraisal of research in developing countries. Often, principles from the west are used during ethical appraisal and the development of consent processes. The application of these principles, though, has a different shape when it comes to developing countries. Recently there are expert recommendation in the adoption of *Rapid Ethical Appraisal* as a prerequisite for development of consent forms and guiding the acquisition of consent from research participants. The purpose of this study is to assess feasible ways of introducing *Rapid Ethical Appraisal* to the research appraisal process in Ethiopia.

In this study researchers, field workers and research ethics committee members are interviewed. It is the expectation of the study team that based on your experience and observation so far, you will provide us with the most relevant information by responding to the questions in this questionnaire.

Your name and other specific personal/private identifiers will not be asked. Its output will contribute to research participants being handled with due respect in their own context. Your honest and thoughtful responses are highly valued. Participation in the study is purely voluntary. If you do not want to respond to any of the questions you are free to make your own decisions. The interview will take about 15-20 minutes.

Contact address of the PI (for any question or communication):

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Annex A.3 Consent Form: Self- Administered Questionnaire for Quantitative Data Collection for the project entitled, Adoption of *Rapid Ethical Appraisal* as a practical method of assessing ethical issues relating to biomedical research projects in Ethiopia

I confirm that I have understood the objective of the research, and have decided to take part in answering the self administered questionnaire without any coercion. I understand that no identifying information about me will be recorded on the questionnaire/report and that confidentiality will be maintained throughout the study.

Do you agree with the statement above and agree to fill out the questionnaire? (Please Circle)

Yes: Thank you in advance, please proceed to the next page.

No: You can return the questionnaire back to the data collector.

Signature _____ Date _____

Annex A.4. Data collection guides for Quantitative Data Collection for the project entitled, Adoption of *Rapid Ethical Appraisal* as a practical method of assessing ethical issues relating to biomedical research projects in Ethiopia (Phase I)

Annex A.4.1 Guide Questions for Researches

1. Approximately how long have you been involved in medical research?
2. What kinds of research have you been involved with?
3. What roles have you played during your research involvement?
4. Have you received any training in research ethics?
5. What is the main purpose of consent form and consent process in research?
6. Can you explain the processes of consent in research? Who is involved in the design for consent for a particular research and how it gets finalized? What steps and stages does it go through?
7. Is there any guidance for researchers to be followed in the consent process?
8. How useful/influential do you think are the various forms of ethical and professional guidance are on the design of consent process?
9. How useful were they for you? What problems have you faced in gaining consent in studies you have been involved with? (Based on your own field/Research experiences)
10. How are the consent process undertaken in the field once the research has been approved?
11. What do you think is the most important information that should be provided to participants? Is there other information that you think should be as well?
12. What is the best way of providing this information?
13. How appropriate and effective do you think information sheets and informed consent forms are?
14. How well do the field workers understand the research? Training for field workers?
15. How well do you think participants understanding is?
16. What aspect of research do you think is hardest for them to understand?
17. Have you been involved in formal or informal measures to assess participants understanding?
18. What do you think are research participants' views on the consent process?
19. What do you think participants motivations are in agreeing to take part in research?
20. How clearly do you think participants understand that they can decline to participate in research or withdraw if they wish?
21. Have you been involved in any formal or informal assessment taken to assess the voluntariness of participants agreeing to take part in research,
22. Overall, how satisfied are you with the way consent processes you've been involved with are designed and conducted?
23. How compatible do you think are the interests of the various groups (ranging from funders to participants) involved in the designs and conducts of consent process?
24. Do you have any suggestions for improvements that could be made to consent processes that we haven't already covered?

Thank you very much for your time

Annex A.4.2. Guide Questions for Policy Makers

1. Could you please introduce yourself, your back ground and current role?
2. What is your involvement in the management and policy issues related to health research? Approximately how long have you been involved?
3. Have you received any training in research ethics?
4. How important is it to monitor the implementation of research activities from ethical view point?
5. What is the main purpose of consent form and consent process in research?
6. Can you explain the processes of consent in research? Who is involved in the design for consent for a particular research and how it gets finalized? What steps and stages does it go through?
7. Is there any structured guidance for researchers to be followed in the consent process?
8. How useful/influential do you think are the various forms of ethical and professional guidance on the design of consent process?
9. Who is responsible for health research ethics guideline development and implementation?
10. What does it take to develop or revise guidelines?
11. Which actors are involved in the process?
12. How are the consent process undertaken in the field once the research has been approved?
13. What do you think is the most important information that should be provided to participants? Is there other information that you think should be as well?
14. What is the best way of providing this information?
15. How appropriate and effective do you think information sheets and informed consent forms are?
16. How good do the field workers understand the research? Training for field workers?
17. How good do you think participants understanding is? Is there a means recommended by the guidelines on making sure SIS and CS are understood by the participants?
18. What do you think are research participants' views on the consent process?
19. Do you think participatory approach is important in the consent process?
20. How clearly do you think participants understand that they can decline to participate in research or withdraw if they wish?
21. Is there any formal or informal assessment recommended to be under taken to assess the voluntariness of participants agreeing to take part in research?
22. How compatible do you think the interests of the various groups (ranging from funders to participants) involved in the designs and conducts of consent process are? And development of policies and guidelines?
23. Do you have any suggestions for improvements that could be made to consent processes that we haven't already covered?

Thanks very much for your time

Annex A.4.3. Guide Questions for Research Ethics Members

1. Could you please introduce yourself, your back ground and current role in research ethics review?
2. How long have you been involved?
3. Have you received any training in research ethics?
4. How important is it to monitor the implementation of research activities from ethical view point?
5. What is the main purpose of consent form and consent process in research?
6. Can you explain the processes of consent in research, as per the expectations of REC/IRB?
7. Who is involved in the design for consent for a particular research and how it gets finalized? What steps and stages should it go through?
8. Is there any structured guidance for researchers to be followed in the consent process for researchers and REC members?
9. How useful/influential do you think are the various forms of ethical and professional guidance are on the design of consent process?
10. Who is responsible for health research ethics guideline development and implementation?
11. What does it take to develop or revise guidelines? Which actors are involved in the process?
12. How are the consent process expected to be undertaken in the field once the research has been approved?
13. Is there any formal or informal way of checking if the consent process has been undertaken as approved?
14. What do you think is the most important information that should be provided to participants? Is there other information that you think should be as well?
15. What do you think is the best way of designing consent process? What is you opening in participatory approach like REA?
16. What do you think is the best way of providing this information?
17. How appropriate and effective do you think information sheets and informed consent forms are?
18. How good do you think participants understanding is? Is there a means recommended by the REC/IRB to make sure SIS and CS are understood by the participants?
19. What do you think are research participants' views on the consent process? Do you think participatory approach is important in the consent process?
20. How clearly do you think participants understanding that they can decline to participate in research or withdraw if they wish?
21. Is there any formal or informal assessment recommended to be under taken to assess the voluntariness of participants agreeing to take part in research?
22. How compatible are the interests of the various groups (ranging from funders to participants) involved in the designs and conducts of consent process ?
23. Do you have any suggestions for improvements that could be made to consent processes that we haven't already covered?

Thanks very much for your time

Annex A.5. Study Information Sheet and Consent Forms for the Quantitative Data Collection for the project entitled, Adoption of *Rapid Ethical Appraisal* as a practical method of assessing ethical issues relating to biomedical research projects in Ethiopia (English Version)

Study Information Sheet:

Objective of the research: There is a growing concern about the ethical appraisal of research in developing countries. Often, principles from the west are used in ethical appraisal and the development of consent processes. The application of these principles, though, has a different shape when it comes to developing countries. Recent recommendation from experts is adoption Rapid Ethical Appraisal as a prerequisite for development of consent forms and guiding the acquisition of consent from research participants. The purpose of this study is to assess feasible ways of introducing REA to research appraisal in Ethiopia.

In this study, policy makers, researchers, field workers, research ethics committee members, community members and CBO/NGO representatives are interviewed. It is the expectation of the study team that based on your experience and observation so far, you will provide us with the most relevant information by responding to the questions in this questionnaire.

Your name and very personal and specific personal/private identifiers will not be used in the data analysis and report writing. The interview will take about one hour. We strongly encourage you to take part in the interview. Its output will contribute to research participants being handled with due respect in their own context. Your honest and thoughtful responses are highly valued. All your responses will be tape recorded to make sure that everything you said is captured. If you do not want to be tape-recorded let me know in advance, it is also possible to pause the recording at any point. If you also decide to take no part in the interview your decision is respected. In case of any questions here is the address for your contact person:

Contact address of the PI (for any question and communication):

Dr Adamu Addissie, Addis Ababa University School of Public Health,
P. O. Box 366 Code 1029,
Tel. 0911404954
E mail: adamuaddis@yahoo.com

Contact address of IRB (for any question or communication):

Prof Yeweyenhareg Feleke, IRB Chairperson, College of Health Sciences, AAU
Tel +251 115 538734 E mail - yeweyenharegf@yahoo.com

Annex A.6. Consent form for Key Informant Interview Guide for Quantitative Data Collection for the project entitled, Adoption of *Rapid Ethical Appraisal* as a practical method of assessing ethical issues relating to biomedical research projects in Ethiopia (English Version)

Consent form:

Do you confirm that having understood the objective of the research, have decided to take part in the in-depth interview out of voluntariness without any coercion, understanding that no personal identifier information about will be recorded on the transcript or the report and that confidentiality will be maintained throughout the study.

Are you willing to take part in the interview?

Yes – proceed with the interview No – thank the respondent and leave

Annex A.7. List of study participants contacted and Interviewed for Phase I study from AAU, EHNRI, JU, UoG and AHRI

Individual	Institution	Role	Background
Interviewee #1	Addis Ababa University	Researcher	Medicine, Ethics
Interviewee #2	Addis Ababa University	Researchers and IRB member	Biomedicine, Ethics
Interviewee #3	Addis Ababa University	IRB Administrator	Management
Interviewee #4	EHNRI	Researcher and IRB member	Biomedicine
Interviewee #5	EHNRI	IRB Administrator	Public health
Interviewee #6	NERC	IRB Secretary	Biotechnology
Interviewee #7	Addis Ababa University	Researcher IRB member	Medicine, Public Health
Interviewee #8	Addis Ababa University	IRB member Community representative	Lawyer
Interviewee #9	Addis Ababa University	Researcher	Lawyer
Interviewee #10	AHRI/ALERT	Researcher IRB member	Medicine, Public Health and Ethic
Interviewee #11	EHNRI	Researcher	Biomedicine
Interviewee #12	Addis Ababa University	Researcher	Public health
Interviewee #13	University of Gondar	Researcher	Medicine
Interviewee #14	University of Gondar	Researcher	Medicine
Interviewee #15	Jimma University	Researcher, IRB member	Biomedicine
Interviewee #16	Jimma University	Researcher, IRB member	Biomedicine
Interviewee #17	Jimma University	Researcher	Medicine
Interviewee #18	Jimma University	Researcher	Medicine
Interviewee #19	Jimma University	Researcher	Public Health

Annex B : Supplementary material for Phase II of the Project (REA Pilots)

Annex B.1. List of REA team members involved in the REA Pilot Studies

Name	Profession and Role	Sites involved in
Adamu A.	MD, MPH Project PI	All sites
Israel M.	MPH Data collection	Zeway, Aira, Sooddo
Befirdu L.	MPH Data collection	Zeway, Aira, Sooddo
Thomas A.	MPH Data collection and analysis	Butajira, Zeway, Aira, Soddo, Tigray
Serebe A.	MPH Data collection and analysis	Tigray
Isabel K.	Medical Resident Researcher	Aira, Sooddo
Seifu H.	MPH Researcher	Butajira
Tsegaye M.	MA Field Assistant	Ayra
Mulugeta	Nurse Field Assistant	Butajira
(Soddo Insider)	MPH Field Assiatnt	Soodo
(Mekele Insider)	MPH Field Assistant	Mekele
Hussen A.	Environmental health Field Assistant	Adami Tullu
Ashebir M.	Data collector	Butajira

Annex B.2. IDI and FGD Tools used for REA Pilot Studies

Annex B.2.1. Guide Questions for Field Workers

1. Please briefly tell me about yourself, your back ground, training and your research related experiences.
2. What exactly are involved in research? How long have you been doing this?
3. Have you been given any training/trainings to do this? Was consent process addressed in your trainings?
4. What do you see is the purpose of the consent process? Why do we ask participants to consent to take part in research?
5. Can you briefly tell me the consent process in the last research project you got involved with? How are participants enrolled and interred to the study, starting from the moment the participant hears about the study until is made to take part?
6. When you meet the participant how do you describe the research information? What information about research do participants seem most interested in?
7. What do you think is the most important information that should be provided to people who might enroll in research?
8. What other information you think should be given as well?
9. What is the best way of providing this information?
10. How useful do you think the information sheets and informed consent forms are?
11. How good do you think participants' understanding of the research?
12. What aspects of research do you think are easiest for participants to understand?
13. What aspects of research do you think are hardest for them to understand?
14. What do you do to help them understand?
15. Is there variation in the amount of information provided to different participants? What influences this?
16. What do you think the research participants views of the consent process are,
17. What do you thinks participants motivations for agreeing to take part in research are?
18. How clearly do you think participants understand that they do not have to do the research or can stop doing the research if they wish?
19. In practice how easy it is for a participant to decide not to take part in research?
20. What is the involvement of others in the decision-making process? What is the role of researchers, fieldworks, family members, community leaders, others?
21. Over all how satisfied are you with the way consent processes you have been involved with were done? Which went well and which parts were difficult?
22. What do you think are your responsibilities to researchers when you are enrolling participants in a trial/research and seeking their consent?
23. What are your responsibilities to participants when you are enrolling them to a study?
24. Was it any difficult to manage your responsibilities to the researchers and the participants?
25. Do you have any suggestions about improving consent processes?

Thank you very much

Annex B.2.2 Guide Questions for Research Participants

1. Would you introduce yourself?
2. Have you ever been involved in research projects as a participant? Would you like to tell us about the different projects you got involved with?
3. Can you tell us more detail about your last research experience?
4. How much did you know about the subject matter under study because you were involved in the study?
5. Can you tell me about what happened when you first met the field worker? How did you meet? Did you know each other before? Were you able to understand him/her easily? What language was used? Were you comfortable with him/her?
6. What was the situation? Who else was there when the field worker was explaining to you about the research? Busy? Quiet? Does the situation allow concentrating?
7. What did the field worker do? How did he/she behave? Did you feel comfortable to ask questions or to ask for something to be repeated?
8. If you asked any questions were you happy with the answers?
9. What did the field worker tell you about the overall research project? What specific things did he tell you about the subject matter of the study?
10. What were you told about the objectives of the study? About what will happen when you are enrolled?
11. What do you think the field workers think it is important thing to know about the research?
12. Can you tell me something about how you decided whether or not to be part of the research? Did you have to discuss with your family first? Did you discuss with some other parson? Who made the decision?
13. Why did you decide to take part, what was important to you?
14. Was it explained that you did not have to take part or could stop at any time? Would it been hard to turn the research down?
15. Can you tell me about what happened when you got enrolled to the study? Did anything unexpected happen? Did you understand all the things in the research? Did you have time to discuss things and ask questions? Did you ask all the questions you wanted answers to? Did you get good answers?
16. Do you have any suggestions on improving the consent process?

Thank you very much!!!

Annex B.2. 3. Guide Questions for CBOS/NGOS having a stake in the Research Ethics in Ethiopia

1. Could you please introduce yourself, your back ground and current role?
2. What is the role of your organization in the management and policy issues related to health research? Approximately how long have you been involved?
3. What activities are undertaken by the organization to ensure standardized check in the process of ethical research?
4. What is the policy of the organization on how important is it to monitor the implementation of research activities from ethical view point?
5. Is there any structured guidance for researchers to be followed in the development of consent process?
6. How useful/influential do you think are the various forms of ethical and professional guidance are on the design of consent process?
7. Who is responsible for health research ethics guideline development and implementation?
8. What does it take to develop or revise guidelines? Which actors are involved in the process?
9. Which actors do you think should be involved in a process?
10. Do you think participatory approach is important in the consent process?
11. Is there any formal or informal assessment recommended to be under taken to assess the voluntariness of participants agreeing to take part in research?
12. How compatible do you think the interests of the various groups (ranging from funders to participants) involved in the designs and conducts of consent process are? And development of policies and guidelines?
13. Do you have any suggestions for improvements that could be made to consent processes?

Thanks very much for your time!!!

Annex B.2.4 Guide Questions for Community members

1. Would you please tell us your age, job, educational level and duration for how long you live here? No need to mention your name.
2. What do you know about research? How the communities understand it? How you understand medical research? What about medicine or treatment mean?
3. What do you know about cancer? What about cervical cancer?
4. Would you please tell us the local name given to cancer if any!
5. As I explained you earlier there is a proposed study to find out more about cancer disease in Ethiopian women. Cervical cancer is the most prevalent and mostly associated with human papilloma virus and other co-infections of the genital or reproductive organ infection. For this study pregnant women who have ante natal follow up in health facilities will be interviewed, and small drop blood and vaginal fluid will be collected. The findings of the study will help the government to introduced vaccine against cervical cancer in the country. Future generation of girls will benefit. How could we get volunteer pregnant women participant in this study?
6. Which consent take method do you prefer? Oral or signed consent? Why?
7. Who decide in participation of a medical research in the family members? Who decide the pregnant women to participate in this proposed study?
8. In general what is the decision making power of women in this society?
9. What could be the possible barriers for pregnant women to give a small amount blood and vaginal secretion? Cultural or religious effect if any.
10. How can we help pregnant women to understand consent and participate voluntary? Who do you thing better to collect the samples? Male or female health professional?
11. During participants selection what could be the effect of including some participant in the study and others not?
12. What the participant expect in response to participation in a research?

Annex B. 3. REA Comprehension Assessment Tools (Phase II)

Annex B.3.1. Modified information sheet

Introduction: Hello /Greetings, my name is _____. I am health professional. I am member of a team from Addis Ababa University School of Public Health. We are trying to find out more about cancer (Menkersa or Menshiro) diseases in Ethiopian women. Most common is cervical cancer. Sometimes infections like "Human Papiloma Virus" and other infections can make the cervix weak and then a cervical cancer can grow. There are different options to help women to avoid cervical cancer. **Please** always see a doctor if there is too much vaginal bleeding. Vaccination for human papiloma virus (virus that cause infection of the cervix) is one possible option to prevent cervical cancer. To implement a vaccination in the future, information on HPV infections and co-infections must be collected. We want to collect information in 600 women from different parts of Ethiopia. From this study area we need 75 volunteer pregnant women. This study conducted by Addis Ababa University in coorporation with Saale University of Germany. The study is approved by respective authority at different levels and the administrative office of this district. This study has no any hidden political or religious agenda.

Procedures: The study process includes a face to face interview, drawing a small amount of blood and small vaginal fluid (secretion) from pregnant mothers. Pregnant mothers selected by chance when they come for their regular ante natal care follow up. The sample will be taken by a female health professional. The collected samples will be analysed and doctors from School of Public Health at Addis Ababa University will discuss on the results. Then the findings help the government to implement vaccine against cervical cancer in the future.

Risk and Benefits: There is no perceived harm to you or your baby. However, you may feel some pain, bruise or minimal bleeding as a result of the injection. You may also feel discomfort following disclosing your private parts.The result of the HPV-test will not be given back to you because there is no treatment for human papilloma virus. This infection is naturally acquired. The benefit will only be for future generations. The findings of the survey will inform further policy related discussions for cervical cancer in Ethiopia. Detection of prevalence of the virus will subsequently help the government to implement national programmes for immunisation against cervical cancer.

Study Consent and Decision to Participate: - Participation is purely on voluntary bases. You can decide not to take part in the study and this will not in any way interfere with your ante natal care follow-up. If you do not want to answer any of the questions you have the right not to answer. You can also stop the interview at any time. To maintain privacy and confidentiality, there will be no names on the questiannare, blood and vaginal fluid (secretion) sample. We use codes instead. Therefore information on the results will not be given back to you.No personnel data will be revealed to the public. The collected data and samples will not be used other than for the purpose of this study.

Contact Persons for any question aboutb the study:

Ethical review board Contact

Dr Yimtubezinash W/Amanuel, AAU, CHS-IRB, Addis Ababa, Tel – 01189613XX

Annex B.3.2. Modified Consent Form

Now I can continue the interview if and only if you are volunteer to participate. As I explain you before, if you agree to participate in this study you are expected to respond to a questionnaire, give asmall amout of blood and vaginal secretion. A female health professional will assist you to do that. If you believe that you have clear and enough information about the study, you are kindly invited to participate in this study. I would like to remind you again that you have the right not to take part or to withdraw from the study at any time. However, your participation has a great contribution for the success of this study.

Note that your regular antenatal clinic will be done in any case – weather you decide or not to participate in this study.

In general do you have any question or concern about the study?

1. Yes (**for data collector**: give enough explanation for questions and concerns, use Annex IV)
2. No (**for data collector**: ask for consent)

Are you willing to participate? (**For data collector**: tick in the box)

1. Yes, I am will to participate ☐
   (**For data collectors:** *Thank for participation and appoint for second part interview of this study. Use explanation in the bottom*)
2. No, I am not willing to participate ☐
   (Thank the participant and end the interview)

I _____ [the data collector] assure that I have explain all necessary information about this study to the respondent and she agree to participate voluntarily.

Signature of the data collector _____ date _____ code: _____

Appointment after two weeks: *Thank you for participation in this study. Today there will no blood or vaginal secretion taking. We ask you again if you are voluntarily to come back after **two** weeks for second part interview of this study and we will discuss about giving the sample then*. [**For data collector:** *give an appointment about **12-16 days** after first consent taking. The date should be at their convenience.]*

Annex B.3.3. Additional Accompanying Narrative Explanations used in the intervention group

1. **Research** is a work trying to find new facts. For example a farmer wants to use new method of farming like sowing in line or to use fertilizer to make his farm land more productive. So first he tries the new method or the fertilizer in a plot of land. If the product is better enough then he use this method for the Whole of his farm land. This best experience will be expanded to his neighbors.
2. **Medical research:** In a medical research is also the same. If the findings from few study subjects are important for health, then will be used for the majority of the community. As you know before many years there was no vaccine for measles (Nifyo, local language). Many children were blind and died due to this disease. Now after research has done vaccine for measles has found and many children saved from blindness and death by vaccination. Similarly this study is to introduce vaccine against “Human Papilloma Virus” and to prevent cervical cancer. Then future generation girls could be benefited.
3. **Use local words:** for cancer**: - “menkersa” (very** common**), cancer (some**) **“menshiro” (**rarely).

Annex B.3.4. English version data collection format

General information for the study participants

Hello, my name is _____; I am health professional. Now I am collecting data from the study participants in a research conducted in different parts of Ethiopia to know more about **cancer in Ethiopian women**. Thank you for your coming in your appointment. You had asked to participate in this study about two weeks before. Now I would like to ask you some questions about how you gave informed consent to participate in the study about **"cancer in Ethiopian women"** and what you understand about participating in that study. These questions are just to assess medical research participants understanding and the situation how they signed or agreed to participate. This research is conducted by Mr. Serebe Abay who is Master of public Health student in Addis Ababa University.

The aim of this research is to know the effect of based line Ethnographic Assessment before a medical research to improve participant consent understanding and quality of consent process. The result of the study is important to identifying a better way to improve informed consent understanding of participant in medical research. It is also helpful to design ethical approaches that fit to local social and cultural values. This study will be conducted only by interview which lasts about 20 minutes. So we need your voluntary participation in this study by responding the following questions concerning consent taking and your decision to participate in the study to know more about **cancer in Ethiopian women**.

When you respond to these questions feel free that the questions are just to know the situation of agreement and how do you understand about the study you agreed to participate. **Not** to measure you general knowledge. All the information you are going to give me will be kept in secrete and your name will not be written on this form.

Responding to these questions will be based on your voluntary help and without any enforcement. You can also jump questions that you don't like to answer or with drown at any time. However, your participation and honest answer to these questions will help me to know how people understand about the study they agreed to participate and their right as a participant.

So shall we continue with the interview? (**Data collector:** circle 1 or 2)
1. **Yes** (start the interview) 2. **No** (Thank participant: end interview)

Data collection questionnaire: comprehension and quality of consent process assessment

Instruction 1: please circle the numbers that best answers each statement listed below. (**You may only circle on one number for each question)**.

S.No	Question	True	False	I do not know/ I am not sure
201	This health related study is a form of a research[1].	1	2	99
202	It is my obligation to participate in this medical research[1].	1	2	99
203	I have been told who is funding this research[1].	1	2	99
204	I have been told the total number of people that participate in this research[1].	1	2	99
205	During this research other than the study team no one will be allowed to see my health information[1].	1	2	99
206	I will be told about my test results from this research[2].	1	2	99
207	I will be treated for the infection tested by this research[2].	1	2	99
208	I have been given the name and phone number of the person to contact if I have questions or concerns about the research[1].	1	2	99
209	I will get a special care in my regular ante natal care in response to my participation in this research [2].	1	2	99
210	My participation in the study can be stopped at any time without any form of prejudice[1].	1	2	99
211	I will be asked for costs related to participating in this study[1].	1	2	99
212	I will be paid or got any incentive for participating in this study[1].	1	2	99
213	The sample taken from me can be used other than the purpose of this study[1].	1	2	99

Participant promoted to choose I don't know rather to guess

---

[1]Generic test item- These test items appear on each version of MICCA
[2]Trial specific test item- These test items are not appears on every version of the MICCA. They are generated based on response to BIQ.

Instruction 2: for question **301-307**, please circle the numbers that best answers each statement listed below. (**You may only circle on one number for each question**.)

301. How do you selected to participate in this study? [2]

A. I was asked to participate in this study when I come for regular my Ante Natal Care follow up.

B. I was selected to participate in this study based on my health situation and suspecting that I might have cancer

C. I don't know how I was selected

302. When do you have to visit your doctor to avoid cervical cancer? [2]

A. Always

B. When I have too much vaginal bleeding

C. I don't know

303. Who analyze and discuss your test results? [2]

A. Doctors from Addis Ababa University

B. My routine Ante natal care providers

C. I don't know

304. At what time can you leave the study?[1]

A. I can leave at any time

B. I can only leave if the investigator is volunteer

C. I can only leave after all data has been collected

D. I don't know

305. What does it mean when you agreed or signed to participate in this research?[1]

A. I will be legally asked if not participate in this research

B. My participation will be obligatory

C. I agreed voluntarily to participate in this study

D. I don't know

306. Can you leave this study if you want to stop after you singed to participate?[1]

A. Yes

B. No

C. I don't know

307. Suppose that you had decided not to participate in this study, do you think that would have made any difference to your regular ante natal care?[1]

A. Yes

B. No

C. I don't know

Instructions3:- For questions **308-313** you may circle on **more than one** number for each question.

308. Which describes the main purpose(s) of the study?[3]

- **A.** To know more about cancer disease in Ethiopia
- **B.** To introduce vaccine which benefit future generation girls
- **C.** To improve my own medical/health condition
- **D.** I don't know

309. Which describes the main benefit(s) taking part in this research? [3]

- **A.** I will be informed of my test results
- **B.** I will be treated according to my test results
- **C.** Future generation girls but not me will be benefited
- **D.** I don't know

310. Which procedure(s) you asked to take part in? [3]

- **A.** Giving a small amount blood for test
- **B.** Having X-ray examination
- **C.** Giving vaginal secretion for test
- **D.** I don't know

311. Which task(s) will be asked to complete? [3]

- **A.** Attend on your appointment
- **B.** Coming without eating food
- **C.** I don't know

312. Which side effect(s) might occur during blood drawing for test?[3]

- **A.** Pain or bruising on the vein
- **B.** Bleeding at the site of the needle
- **C.** It cause blood deficiency
- **D.** I don't know

313. What is your concern or fear taking part in this study?[3]

- A. This study may have hidden religious or political agenda
- B. I might be diagnosed to have cancer in this study
- C. Other people may know my test result
- D. I have no any concern or fear

---

[1]Generic test item- These test items appear on each version of MICCA

[2]Trial specific test item- These test items are not appears on every version of the MICCA. They are generated based on response to BIQ.

[3]Trial specific test items appear on each version of the MICCA. The response option for each of these test items are generated based on response to BIQ.

Instruction 4: Please tell us (circle the number) how often you use the following resources to gather health information. **Please circle only one number for each item.**

S.No	**Source**	**Always**	**Sometimes**	**Never**
401	Books/Journals	**1**	**2**	**3**
402	Friends/Families	**1**	**2**	**3**
403	Health care provider (Drs, nurses, health extension professionals etc.)	**1**	**2**	**3**
404	Internet	**1**	**2**	**3**
405	Popular magazines	**1**	**2**	**3**
406	Radio	**1**	**2**	**3**
407	TV/Movies	**1**	**2**	**3**

Annex B.3.5. Quality of Informed Consent (QuIC) process assessment

Instruction: Please tell us (circle the numbers below) how the information given to you and your decision making was to involve in this study. (**Please circle only one number for each item.)** When you respond to these questions feel free that the questions are just to know the situation of agreement and how do you understand about the study you agreed to participate. **Not** to measure you general knowledge.

S.No	Questions	Agree	disagree	I don't know /I am not sure/
501	There was sufficient time for consent discussion	**1**	**2**	**99**
502	Agreed to participate in this study voluntary and with full understanding	**1**	**2**	**99**
503	Enrolment decision made mainly by me the respondent	**1**	**2**	**99**
504	Discussed about the research with other patients or participants	**1**	**2**	**99**
505	Consent form read or explained carefully	**1**	**2**	**99**
506	Consent form was important source of information	**1**	**2**	**99**
507	Consent form was easy to understand	**1**	**2**	**99**
508	Consent form was important to the decision	**1**	**2**	**99**
509	Pressure from provider to sign/agree/ consent form	**1**	**2**	**99**
510	Sufficient opportunity to ask questions	**1**	**2**	**99**
511	Questions answered thoroughly by the consent provider	**1**	**2**	**99**
512	Satisfied with informed consent process	**1**	**2**	**99**
513	Decision to participate was easy or very easy	**1**	**2**	**99**

You have now completed the survey. The sample needed for this study is now collecting for Mekelle hospital. Thank you for taking time and giving us important information for the study!!(**Data collectors: -** explain the purpose of this study and give health education on cervical cancer for participant)

Annex B.3.6. Keys used of Comprehension Assessment

Table showing the type of question (superscripts numbers) and their correct answer (given in brackets) used for comprehension and quality of consent process assessment

Part A. TRUE or FALSE: correct answer given in brackets

Consent component
This health related study is a form of a research[1]**.[True]**
Obligation to participate in this medical research[1]**.[False]**
Told who is funding this research[1]. **[True]**
Told the total number of people that participate in this research[1].[False]
Other than the study team no one will be allowed to see my health information[1]**.[True]**
I will be told test results from this research[2]. **[False]**
Treated for the infection tested by this research[2].[**False**]
I have been told contact person address[1]. [**True**]
I will get a special care in my regular ANC follow up[2]. [**False**]
My participation in the study can be stopped at any time[1]. [**True**]
I will be asked for costs related to my participation in this study[1].[**False**]
I will be paid or got any incentive for participating in this study[1].[**False**]
The sample taken in this study can be used for other purpose[1].[**False**]

[1]**Generic test item**- These test items appear on each version of MICCA

[2]**Trial specific test item**- These test items are not appears on every version of the MICCA. They are generated based on response to BIQ.

[3]**Trial specific test item-** appear on each version of the MICCA. The response option for each of these test items are generated based on response to BIQ.

Part B. MULTIPLE CHOICES with single and multiple correct answers given in brackets used for comprehension assessment

Consent component
Participate selection in this study[1].[**A**]
When to visit a doctor to avoid cervical cancer[2].[**B**]
Who analyze and discuss test results [2]**.[A]**
At what time can leave the study?[1]**[A]**
Agreed or signed to participate in this research mean[1]**.[C]**
Can stop participation after you singed to participate?[1]**[A]**
Any difference made to regular ante natal care if not participate?[1]**[B]**
The main purpose(s) of the study?[3] To know more about cancer disease in Ethiopia **[A]**
To introduce vaccine which benefit future generation girls **[B]**
The main benefit(s) taking part in this research?[3] Future generation girls but not me will be benefited.**[C]**
Procedure(s) asked to take part in?[3] Giving a small amount blood for test **[A]**
Giving vaginal secretion for test **[C]**
Task(s) asked to complete?[3] Attend appointment **[A]**
Side effect that might occur during blood drawing for test?[3] Pain or bruising on the vein **[A]**
Bleeding at the site of the needle**[B]**

[1]**Generic test item**- These test items appear on each version of MICCA

[2]**Trial specific test item**- These test items are not appears on every version of the MICCA. They are generated based on response to BIQ.

[3]**Trial specific test item-**appear on each version of the MICCA. The response option for each of these test items are generated based on response to BIQ.

Part C. Table showing the questions and their correct answer give in brackets respectively used for quality of informed consent process assessment

Informed consent process components
There was sufficient time for consent discussion.[**Agree**]
Agreed to participate in this study voluntary and with full understanding.[**Agree**]
Enrolment decision made mainly by me the respondent.[**Agree**]
Discussed about the research with other patients or participants.[**Agree**]
Consent form read or explained carefully.[Agree]
Consent form was important source of information.[**Agree**]
Consent form was easy to understand.[**Agree]**
Consent form was important to the decision.[**Agree**]
Pressure from provider to sign/agree/ consent form.[**Disagree**]
Sufficient opportunity to ask questions.[**Agree]**
Questions answered thoroughly by the consent provider.[**Agree**]
Satisfied with informed consent process.[**Agree]**
Decision to participate was easy or very easy.[**Agree**]

Annex C : Supplementary Materials for REA Training Workshop

Annex C.1. Copy of REA Workshop Announcement

5th AFENET Scientific Conference Workshop,

UNCC-ECA, Addis Ababa, Ethiopia

Research Ethics Workshop on Rapid Ethical Assessment

Nov 17, 2013, 2-6 PM,

Ethical Assessment for Community Based and Public Health Research in Developing Countries using Rapid Ethical Assessment Techniques

Workshop Resources

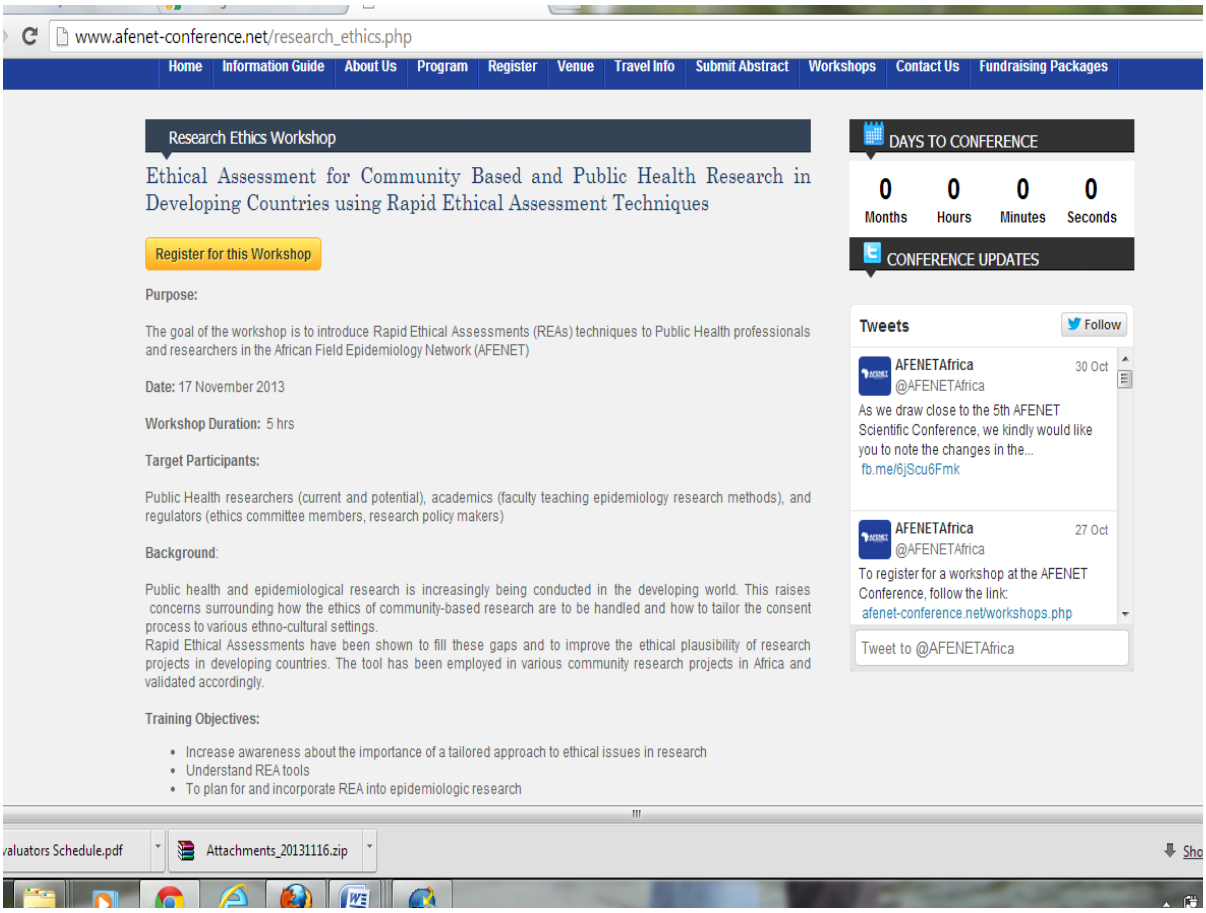
Dr Adamu Addissie, Addis Ababa University (Ethiopia) and Brighton and Sussex Medical School (UK) : adamuaddis@yahoo.com

Professor Gail Davey, Brighton and Sussex Medical School (UK) : G.Davey@bsms.ac.uk

Professor Bobbie Farsides, Brighton and Sussex Medical School (UK): B.Farsides@bsms.ac.uk

Prof Yeweyenhareg Feleke, Addis Ababa University (Ethiopia) : yeweyenharegf@yahoo.com

Annex C.2. Copy of REA Workshop Announcement (Screen Shot)



Annex C.3. Copy of REA Workshop Time Table

"Ethical Assessment for Community Based and Public Health Research in Developing Countries using Rapid Ethical Assessment Techniques"

Time	Topic	Remark
9:00 - 9:30	**Welcome and Introduction** **Introduction and Background to REA** - Challenges related to research ethics in developing countries - Gaps in the consent process for the Ethiopian research community [assessment findings] - History and background of REA - Q & A	Gail Adamu Bobbie Clip Gail and Adamu
9:30 - 10:00	**Demonstrate REA tools and techniques** - Principles of Ethnography and qualitative Assessments - REA in Action - Q & A	Adamu Gail and Adamu
10:00 - 11:00	**Practical Group Session - Exercise** - HPV Sero-prevalence survey in Ethiopia - Small group exercise on the designing of REA for the study protocol - Discussions	Gail and Adamu [Tea and Coffee]
11:00 - 11:30	**General discussion** - feedback and wrap-up	All

Annex C.4 Copy of REA Workshop Training Materials

Addis Ababa University, School of Public Health, Training Workshop on Rapid Ethical Appraisal

Case Study - "HPV Sero-survey"

Facilitator's Guide

This guide gives you the overall structure of the session for 'REA steps and tool development'

Learning objectives

By the end of the exercise, the facilitators will be able to :-

- Critically analyze context specific ethical issues in relation to consent process for community based health research

- Plan for and develop REA tools to tailor the consent process to the context

Contents

Part I - **Background and Introduction to the Research Project and Settings**
Part II - **Ethical Issues and Consent Process**
Part III - **Rapid Ethical Appraisal**

Materials needed

LCD Projector and computer
Case study PowerPoint presentations
Flip chart and markers
Enough copies (print outs) of the 'HPV Project Background'

Divide the participants into groups of 4-5. Let the groups assign a group moderator and note taker. Aware the groups that they will be making presentations on the highlights of their group discussion The groups are encouraged to record their discussion on a flip chair for a later presentation.

Part I - Background and Introduction to the Research Project and Settings

Project Title : "Epidemiologic survey of Ethiopian urban and rural areas on breast cancer and other Gynaecologic Cancer – prevalence and clinical epidemiology"

Project Objectives : To determine the sero-prevalence of HPV and to characterise the serotypes (subtypes) responsible for HPV infection among women in the reproductive age group

Project Research Methods : Multi-country, cross-sectional, in-country study involving ANC clinic clients involving interview, collection of blood sample and vaginal swab for lab testing

[Refer project summary for the details]

Question : What are the anticipated ethical challenges in this research?

Part II - Ethical Issues and Consent Process

Participants are expected to go through the ethical considerations section of the protocol and critically analyze the section for any additional considerations if appropriate. Based on this they are expected to reflect on the consent process for this study and anticipated challenges.

Ethical considerations

Autonomy of participants: All patient derived data will be made anonymous. The results will not allow any tracking of individual patients or persons. Data will be obtained by medical personnel/medical students under the supervision of the respective heads of department. All patients identification will be cleared when the data collection is finished and the collection is complete. The collection of data in the rural hospitals will accordingly take place under the supervision of the heads of the surgical departments.

Study Consent: Informed consent will be taken from every person in advance at the commencement of every interview. The structured interviews will take place after notification of local authorities. The names of the interviewees will be kept in a separate code list until all data is clarified and there is no need to come back to the interviewee. Results of the interviews will be recorded with the code. After the end of the interview-phase, all codes will be destroyed.

Beneficence and Non-malficence: The study will not have a direct benefit for the study participants but there is not any harm that will be imposed on them as a result of taking part in the study. The study is aimed to benefit all victims of gynaecologic cancer. Therefore there is no harm to the patient, the benefit is for the general public and future patients in Ethiopia since the nature of breast cancer in Ethiopia will be studied in depth. There is no component of research involving human embryonic stem cells and recombinant DNA. All participants are subject to the Convention on Biological Diversity (CBD).

Material Transfer: Sub-project 6 involves the collection of specimen from breast and cervical cancer patients. Basic clinical and pathological data will be obtained. Then the samples will be made anonymous. Only the anonymous material will be taken out of the department to Germany together with AAU staff pathologist. The pathologist will be responsible for the specimen when investigations are done in Halle/Germany. This procedure ensures full respect to personal rights of the patient. Material transfer agreement will be provided for the respective regulating authority during the sample transfer.

Conflicts of Interest with commercial activities: The study has no any involvement with commercial activities of any kind. Therefore no conflict of interest is disclosed.

.

Question : What are the specific challenges in relation to consent process; both the design of the consent form and the consent seeking process? Challenges for the researcher; for the data collectors; for ethics committee

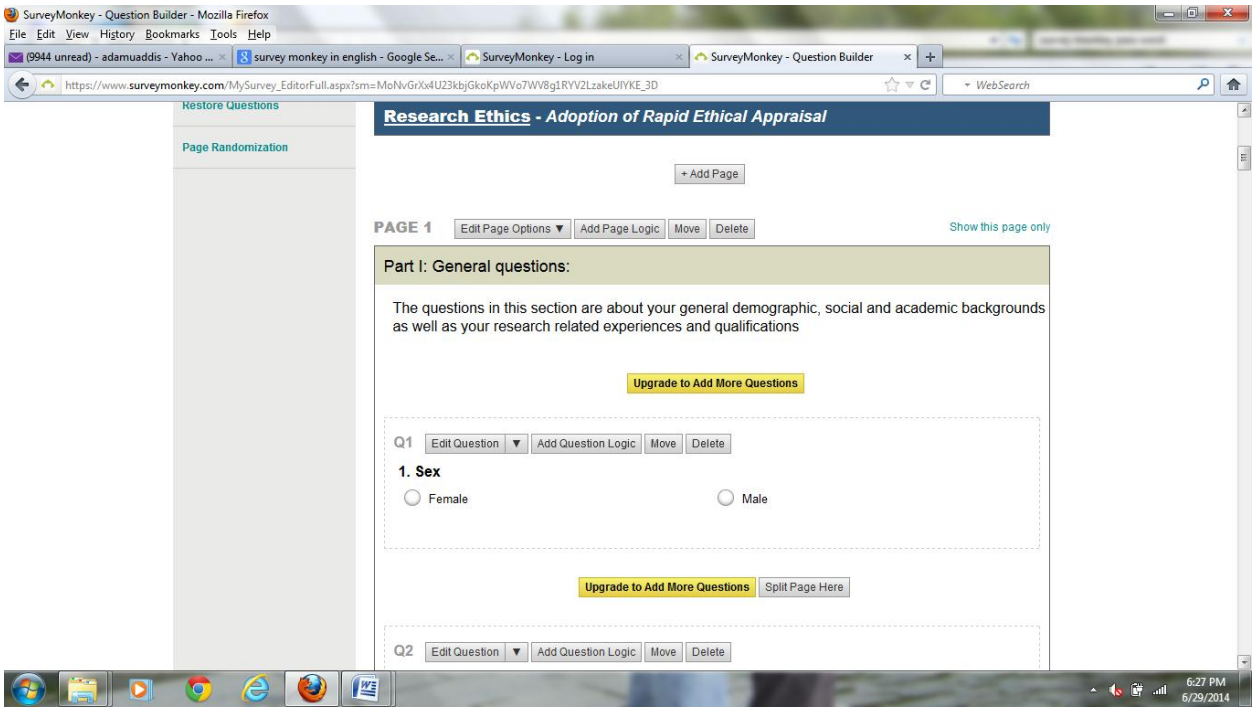
Part III - REA

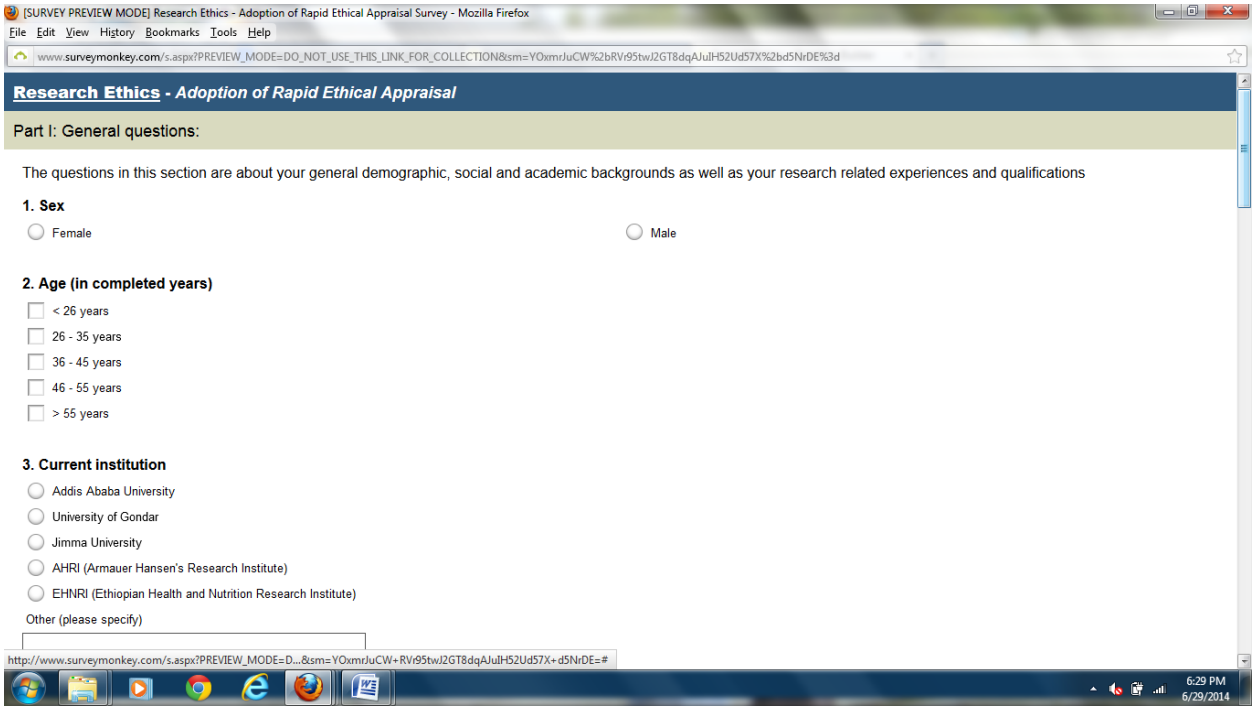
How would you design REA for this project? How would you incorporate REA to the planned project? What are the challenges in planning and implementing REA?

Participants are expected to reflect on the anticipated problems identifies in part III and see how REA will hap them in addressing those challenges.

Annex D : Supporting Documents for Chapter III

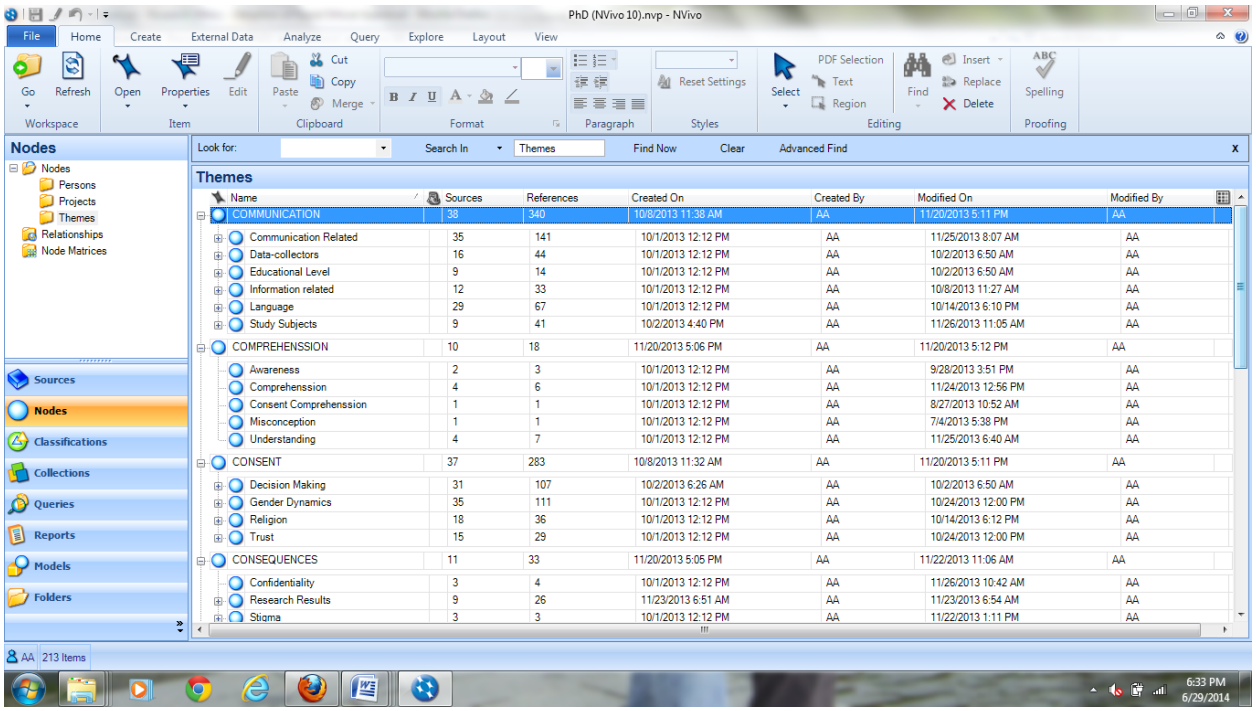
Annex D.1 Survey Monkey Results Tables (outputs) : PRTSC

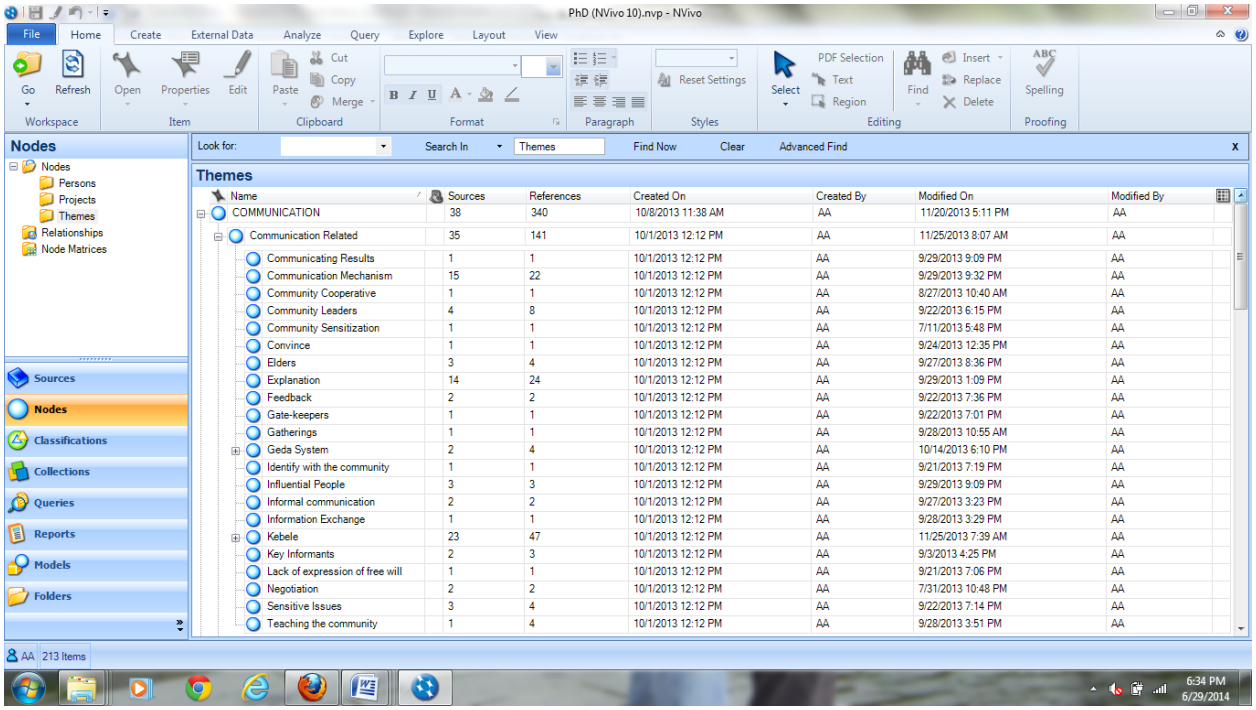




Annex E : Supporting Documents for Chapter IV

Annex E.1. Nvivo PRTSC





Annex F : Supporting Documents for Chapter VI

Annex F.1 Framework used for the Feasibility Analysis of REA [98]

Table 1

Key areas of focus for feasibility studies and possible outcomes

Area of focus	The feasibility study asks …	Sample outcomes of interest
Acceptability	To what extent is a new idea, program, process or measure judged as suitable, satisfying, or attractive to program deliverers? To program recipients?	• Satisfaction • Intent to continue use • Perceived appropriateness
Demand	To what extent is a new idea, program, process, or measure likely to be used (i.e., how much demand is likely to exist?)	• Fit within organizational culture • Perceived positive or negative effects on organization • Actual use • Expressed interest or intention to use • Perceived demand
Implementation	To what extent can a new idea, program, process, or measure be successfully delivered to intended participants in some defined, but not fully controlled, context?	• Degree of execution • Success or failure of execution • Amount, type of resources needed to implement
Practicality	To what extent can an idea, program, process, or measure be carried out with intended participants using existing means, resources, and circumstances and without outside intervention?	• Factors affecting implementation ease or difficulty • Efficiency, speed, or quality of implementation • Positive/negative effects on target participants • Ability of participants to carry out intervention activities • Cost analysis
Adaptation	To what extent does an existing idea, program, process, or measure perform when changes are made for a new format or with a different population?	• Degree to which similar outcomes are obtained in new format • Process outcomes comparison between intervention use in two populations
Integration	To what extent can a new idea, program, process, or measure be integrated within an existing system?	• Perceived fit with infrastructure • Perceived sustainability
Expansion	To what extent can a previously tested program, process, approach, or system be expanded to provide a new program or service?	• Costs to organization and policy bodies • Fit with organizational goals and culture • Positive or negative effects on organization • Disruption due to expansion component
Limited efficacy	Does the a new idea, program, process, or measure show promise of being successful with the intended population, even in a highly controlled setting?	• Intended effects of program or process on key intermediate variables • Effect-size estimation • Maintenance of changes from initial change

[98] (Source: Bowen, D. J., M. Kreuter, et al. (2009). "How We Design Feasibility Studies." Am J Prev Med. **36**(5): 452-457.)

Annex F.2. Summary of feasibility components with accompanying variables and tools

Focus area of Feasibility Assessment (contextual definition)	**Variables (indicators)**	**MOV (Means of Verification)**	**Remark**
Acceptability How do intended users and intended implementers of the tool accept it	Attitude and Perception about REA Satisfaction with REA Suitability to use Study participant's satisfaction	Interview of researchers, ethnographers REA team REC members Study participants	Phase I -researchers/REC members Phase II - researchers/REA team Phase III - Workshop participants
Demand How much likely that the methods will be used? Is there a need for the tool?	Perceived demand Expressed interest (intention to use) (Interest to use and apply) Existence of gaps to be addressed Any actual use Study participant's opinions and perceptions	Interview Researchers REC members Study participants	Phase I Phase II
Implementation Was it possible to implement the tools (the integral components) according to plan? To what extent applicable in uncontrolled setting/context?	Expertise needed and available Resources needed and available Time Finance / Cost Human resource Training Methods employed [versus outcome obtained] Successes and failures in each aspect	Post-intervention assessment (feedback) [Compare against plan]	Phase II Challenges and lessons learnt
Practicality Practical in terms of resources? Is it applicable in limited resource? Are resource needs practical to the	Cost analysis [predicted cost] Burden due to intervention Frequency of	Pilot document review financial and analysis reports and documents Key informant Interviews	Phase I (concerns and suggestions) Phase II (documents)

setting?	intervention Duration of intervention Benefits Efficiency of implementation Manpower and expertise		Phase III (feedback)
Adaptation Are the tools adaptable to varied contexts and settings? Is the tool easy to adapt to varied needs and setups as well as contexts? What will be the guiding principles for the adaptations of the tool?	Adaptability Flexibility Range of options and possibilities	Pilot document review KII	Phase II (documents) Phase III (feedback)
Integration Required system changes/modifications needed to accommodate the current intervention (new tool) in to the existing program/system? Possibility to integrate to the current ethical review system? Integration in to the research undertaking process?	Tool flexible (to the system)? or not? Perception ...	Guideline review Discussion with REC members etc Discussion with researchers ESTC chapter ESTC review process	Phase I (documents/researchers) Phase II (Observations and field notes) Phase III
Expansion Possibility to expand the tool to a wider user pool? Can REA be applied to wider settings other that where it is already applied?	Scalability	Discussion with researchers Discussion with REA team	Phase II (documents and REA team discussions) Phase III (workshop participant feedback)

Annex F.3. Costing of Project Expenses during the REA Pilot

Line Items	Butajira	Zeway	Ayra	Soddo	Average
Data collectors (number)	5	5	4	4	4.5
Person days spent	2 persons (15 days) 3 persons (20 days) 90	1 person (15 days) 4 person (25 days) 115	4 person (20 days) 80	4 person (20 days) 80	
Total Paid (250 Birr/ day)	22,500	28,750	20,000	20,000	22, 812.5
Sub-total				91,250	
Stationary	Copying and printing				
Lump sum (Birr)	500	500	500	500	500
Sub-total				2000	
Participants transportation and refreshments					
Lump sum (Birr)	1500	1500	1500	1500	1500
Sub-total				6,000	
Transportation					
	Driver : 20 days (5000 Birr)	Driver : 20 days (5000 Birr)	Public transport 1200	Public transport 1200	
	Fuel : 2000 Birr	Fuel : 2000 Birr	Local transport 300/person	Local transport 300/person	
	7000	7000	1500	1500	4250
Sub-total				17,000	
Local communication (Telephone and e-mail)					
Lump sum	250	250	-	250	250
Sub-total				750	
Transcriptions	3	3	3	3	
	5000 / person	5000 / person	5000 / person	5000 / person	

Lump sum	15000	15000	15000	15000	15,000
Sub-total				60,000	
N Vivo software	FREE				
				670 USD[99]	
Recorders	Used own				
	Digital recorders (3) Laptop Computer (1)			100 USD each 500 - 1000 USD	
Picture cameras	Used own				
	Digital camera (1)			200 - 300 USD	
Data storage					
	External disk			50-100 USD	
	Flash drives			20 -25 USD	

[99] http://www.qsrinternational.com/products_nvivo_pricing_pricelist.aspx

Annex G : Miscellaneous Supporting Documents

Annex G.1. Copy of Manuscripts on REA

Annex G.1.1. Manuscript on BMC Medical Ethics

Addissie et al. BMC Medical Ethics 2014, 15:35
http://www.biomedcentral.com/1472-6939/15/35

BMC Medical Ethics

RESEARCH ARTICLE Open Access

A mixed-methods study on perceptions towards use of Rapid Ethical Assessment to improve informed consent processes for health research in a low-income setting

Adamu Addissie[1,2*], Gail Davey[1], Melanie J Newport[1], Thomas Addissie[2], Hayley MacGregor[3], Yeweyenhareg Feleke[2] and Bobbie Farsides[1]

Abstract

Background: *Rapid Ethical Assessment (REA)* is a form of rapid ethnographic assessment conducted at the beginning of research project to guide the consent process with the objective of reconciling universal ethical guidance with specific research contexts. The current study is conducted to assess the perceived relevance of introducing *REA* as a mainstream tool in Ethiopia.

Methods: Mixed methods research using a sequential explanatory approach was conducted from July to September 2012, including 241 cross-sectional, self-administered and 19 qualitative, in-depth interviews among health researchers and regulators including ethics committee members in Ethiopian health research institutions and universities.

Results: In their evaluation of the consent process, only 40.2% thought that the consent process and information given were adequately understood by study participants; 84.6% claimed they were not satisfied with the current consent process and 85.5% thought the best interests of study participants were not adequately considered. Commonly mentioned consent-related problems included lack of clarity (48.1%), inadequate information (34%), language barriers (28.2%), cultural differences (27.4%), undue expectations (26.6%) and power imbalances (20.7%). About 95.4% believed that consent should be contextualized to the study setting and 39.4% thought REA would be an appropriate approach to improve the perceived problems. Qualitative findings helped to further explore the gaps identified in the quantitative findings and to map-out concerns related to the current research consent process in Ethiopia. Suggestions included, conducting REA during the pre-test (pilot) phase of studies when applicable. The need for clear guidance for researchers on issues such as when and how to apply the REA tools was stressed.

Conclusion: The study findings clearly indicated that there are perceived to be correctable gaps in the consent process of medical research in Ethiopia. REA is considered relevant by researchers and stakeholders to address these gaps. Exploring further the feasibility and applicability of REA is recommended.

Keywords: Rapid ethical assessment, Ethiopia, Research ethics, Consent

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Background

With research increasingly being undertaken in low-income settings, there is a need to contextualize the application of ethical standards. Informed consent is one of the cornerstones of ethics in medical care and in health research irrespective of culture and geography. However, as elsewhere, the consent process in low-income settings is subject to influence from cultural beliefs and values. Experts in the field have emphasized that the challenges associated with research ethics in these settings are complex and cannot be addressed by regulatory processes alone. There is a need to move beyond guidelines and mere procedural ethical review to a broader system which is open to addressing the various other determinants in the developing world [1,2]. It is desirable to ensure that community members are involved in the local application of universal ethical values [3]. Assessment and monitoring of the process of informed consent are essential and are the joint responsibility of the local ethics review committee and the research sponsors. While ethics review committees can give oversight, only an active and transparent partnership between the research sponsor, investigators and the community can allow for effective on-going governance [1]. Whilst the concept and application of the doctrine of informed consent should be standardized and applied in the same way in any setting, the process of seeking consent quite appropriately varies. Amongst other considerations the culture of the people approached must be understood when balancing principles of individual autonomy against community-wide decision-making [4]. It has been argued that there is leeway for researchers to consider culturally-relevant strategies for obtaining informed consent from participants. Accordingly, researchers working collaboratively with local investigators and communities should be creative in designing approaches to acquiring informed consent in particular cultural environments [5].

Participatory action research methods such as Rapid Ethnographic Assessments are often employed to understand and address context-specific issues pertaining to cultural differences. They will almost always produce results in a fraction of the time and at lower cost than traditional qualitative research [6]. Farsides and Bull, in their study in The Gambia, developed an approach in which a form of rapid ethnographic assessment was carried out among key stakeholders, and the results were used to inform the design of the consent process for the studies in question. This approach has been termed *Rapid Ethical Assessment (REA)*, and has been piloted in two countries; a TB case-contact study and a vaccine trial in The Gambia, and a study on the genetics of podoconiosis in Ethiopia [7-10]. Other researchers have also applied the tool prior to genetic research in Ghana [11].

REA is a brief qualitative intervention designed to map the ethical terrain of the research setting prior to a research team recruiting participants. The model attempts to discover, describe and respond to the ethical issues specific to a particular research setting, and as such should help researchers to address the issues that genuinely matter to proposed participants. The enquiry is linked to the particulars of the research being conducted. For example, a study involving collection of blood samples would be preceded by an assessment of the ethical beliefs and attitudes pertaining to blood, bodily integrity, storage and use of bodily materials alongside a more general enquiry into the understanding of research, the standing of the research team, the local health economy etc. in the community being recruited. As such an REA serves the purpose of connecting ethical principles to contexts and realities on the ground. Its methodology employs a constellation of action research, rapid assessment and ethnography. The average duration of the REA process is 6 weeks, and is performed by an interdisciplinary team composed of subject area researcher, a social scientist and one or more local area experts. The assessment is conducted among key community stakeholders such as potential study participants, community leaders, and field and community workers to inform and guide the research consent process [8-11].

Since REA is a novel approach, it is important to generate convincing evidence on whether it is needed, acceptable and feasible on a larger scale. Even though research has documented the importance of such tools in low-income settings, there is no evidence regarding the feasibility of the approach on a larger scale, were it to be integrated into the existing research appraisal system. If the tool is to be recommended as a routine tool it must be feasible and practical in application. One element of this feasibility is the perceived relevance and acceptability of REA to researchers and research ethics reviewers. It has been assumed that the approach will be well received by the research community and gain acceptance, but this has not been tested. There is therefore a need to assess how REA is perceived by a range of research stakeholders including researchers, ethics committee members and policy makers.

In Ethiopia, a country with significant cultural, religious and linguistic diversity, recently there has been enormous expansion in education at graduate and post-graduate levels. Consequently, the number of health-related research projects has increased greatly over the past decade. These factors make it an ideal place in which to explore new approaches to the ethics of health research. An assessment was performed within the Ethiopian health research community, to explore their perceptions of gaps in the consent process and gather their opinions on the role of REA in improving the consent process.

Methods

Study area

The study was conducted between July and September 2012, in four major Ethiopian health research centres: Addis Ababa University (AAU), the Ethiopian Health and Nutrition Institute (EHNRI), Jima University (JU) and the University of Gondar (UoG). These institutions are prominent Ethiopian centres for health-related research with experienced staff covering a range of health-related disciplines.

Study design and sample-size

A mixed methods approach employing both quantitative and qualitative data collection methods with a sequential explanatory design was used [12]. We included researchers, ethics committee members and research policy makers primarily working in the four institutions. The total sample size required for the quantitative study was 270 individuals. This was determined using a single population formula, with unknown proportion and 90% confidence limits. The sample size for the in-depth interviews was guided by the degree of information saturation based on preliminary analysis during data collection. Accordingly, a total of 19 interview participants were purposively selected.

Data collection

Quantitative data were collected using a web-based (on-line), self-administered questionnaire backed by a paper based interview. The questions were structured and possible responses pre-coded. One open-ended question was included at the end of the questionnaire. The questions were designed based on variables identified through literature reviews including previous work on REA. The questionnaire was pre-tested by administering 15 questionnaires to researchers and academic staff at Saint Paul's Millennium Medical College which is one of the new public medical schools in Ethiopia located in the capital, Addis Ababa. Based on the pre-test, the contents and sequence of some of the questions were revised for coherence and logical flow.

For the on-line data collection, e-mail addresses of researchers were obtained from department heads, institutional mailing lists, institutional web-sites and Institutional Review Boards (IRB) of the four institutions. Through the institution contacts we identified lists of all eligible respondents including researchers and academics with experience of independent research and a post-graduate qualification Exceptions were made to the second criteria when the researcher has many years of research experience. A total of 458 eligible participants were identified – 175 from AAU, 108 from JU, 99 from EHNRI, and 76 from UoG. The sample size (270) was proportionally distributed to the four centres. Respondents were randomly selected from the e-mail list using numbers generated by the RANDBETWEEN function in Excel (Microsoft Office 2007®). A link to the web-based questionnaire using SurveyMonkey® [13] was sent via e-mail to all randomly selected eligible respondents in AAU (103), JU (64), EHNRI (58) and UoG (45). A reminder was sent after 2–3 weeks to those who did not respond to the first e-mail invitation. The on-line survey stayed open for 45 days, and researchers who were not able to fill the on-line survey but preferred paper-based interviews were offered a printed questionnaire. The assistant data collector distributed the questionnaires and collected them at the end.

Qualitative in-depth interviews (IDIs) were used for collecting qualitative data. A question guide for the IDI was finalized after the preliminary analysis of the quantitative survey. The guide included questions around the existing gaps in research ethics, the ethics review process and the informed consent process. Feedback on REA based on further descriptions given by the interviewer, was sought. A total of 19 key informants were interviewed in order to gather more explanatory opinions and deepen information complementing the quantitative findings. Researchers, Research Ethics Committee members and administrators were interviewed. Interviews were conducted by the principal investigator (AA), either in English or Amharic, based on the convenience of the respondent. All interviews were digitally recorded. They were transcribed and translated to English by the research assistant (TA) and back translated by the principal investigator (AA).

Data analysis

The SPSS-based quantitative data summary was downloaded from SurveyMonkey® [13]. Data cleaning and descriptive analysis was performed using SPSS for variables of interest. Responses to the in-depth interviews and the one open-ended question in the on-line survey were analyzed as text and thematically summarized. NVivo9® [14] was used to organize the data. Data were double coded to verify inter-coder reliability. Interpretations were drawn by triangulating both qualitative and quantitative findings.

Ethical considerations

The research was approved by the Institutional Review Board of the College of Health Sciences, Addis Ababa University in Ethiopia and the Research Governance and Ethics Committee at Brighton and Sussex Medical School in the UK. After providing information about the research, consent was obtained from all study participants. The authors declare no conflicts of interest. The research was supported by the Wellcome Trust through Biomedical Ethics Doctoral Fellowship 089769.

Results

After excluding incomplete responses, analysis was conducted on 241 complete responses, which was 89.3% of the intended sample. The majority of the respondents were male (86.3%) and in the 26–35 year old age group (42.7%). Most (82.2%) were from the four target institutions AAU, EHNRI, JU and UoG; the rest were from the Armauer Hansen Research Institute (AHRI) the Federal Ministry of Health (FMOH), the Ministry of Science and Technology (MoST) or the Ethiopian Public Health Association (EPHA), who also were collaborators on research projects with the four main target institutions. More than sixty percent of respondents were either medical or public health professionals and 87.1% had postgraduate or specialty medical education, either Master's degree, clinical residency or PhD; the rest had only undergraduate training with or without post graduate diploma [Table 1].

Most respondents assumed roles as principal investigators (82.2%), or co-investigators (74.3%). About 70% had also taken roles as data collectors or field workers (69.7%) and one quarter had been members of an Ethics Committee. More than a third (34.4%) reported that they had never had any training on research ethics [Table 1]. The types of training courses attended by trained respondents included orientation sessions (36.1%), certified short training courses (43.7%), academic training courses (university courses including diploma and degree level training) (37.3%) and other training courses (such as on-line) (11.4%).

Nineteen researchers, faculty, IRB members and policy makers from AAU, EHNRI, JU and MoST responded to the qualitative study. The majority (14) were male. All the respondents had experience working in various places in Ethiopia. All except one had post-graduate qualifications; the exception was an experienced IRB administrator at AAU.

Perceptions about current consent processes and the relevance of REA

A majority of survey respondents (58.9%) believed that the design and preparation of consent processes for research was conducted by the principal investigator without any prior assessment of potential context-specific ethical issues and only 15.4% claimed to be satisfied with the current process by which consent forms are developed and implemented. Some respondents mentioned forms of prior assessment, including stakeholder or sponsor consultations, as shown in Table 2. When asked about their personal evaluation of the current consent process, only 14.5% thought that the best interests of the study participants were sufficiently considered; and only 40.2% thought the consent information and the consent process were adequately

Table 1 Socio-demographic profile of respondents to the online survey, September, 2012 (n = 241)

Variable	Frequency	%
Sex		
Male	208	86.3
Female	33	13.7
Age		
<26	19	7.9
26-35	103	42.7
36-45	71	29.5
46-55	39	16.2
>55	9	3.7
Institution		
Addis Ababa University	87	36.1
Jimma University	49	20.3
EHNRI	35	14.5
University of Gondar	27	11.2
Others (MOH, MOST etc.)	43	17.8
Highest qualification		
Bachelor	20	8.3
MD/DVM	14	5.8
Masters	129	53.5
Specialty	32	13.3
PhD	35	14.5
Others (e.g. PGD)	11	4.6
Major training (multiple responses)		
Biology	28	11.6
Public Health	90	37.3
Social Science	13	5.4
Medicine	63	26.1
Laboratory	33	13.7
Nursing	19	7.9
Others (e.g. Environmental health, health promotion etc.)	63	26.1
Roles in research (multiple responses)		
Lead researcher/ PI	198	82.2
Co-investigators	179	74.3
Data collector	92	38.2
Field Worker	76	31.5
Ethics committee member	62	25.7
Data encoder	23	9.5
Other	19	7.9
Training on research ethics		
Yes	158	65.6
No	83	34.4

Table 2 Opinions of researchers from various Ethiopian institutions on the consent processes and development of REA, September, 2012 (n = 241)

Variables	Frequency	%
How is consent form developed in your experience? (multiple responses)		
By the investigator	142	58.9
With prior ethical assessment	70	29.0
With stakeholder participation/consultation	41	17.0
By the sponsor	17	7.1
Others (research advisors, collaborators, students)	13	5.2
Opinions on consent process		
Do you think all participants understand consent forms well?		
Yes	97	40.2
No	144	59.8
Based on your experiences, are you satisfied with the way the consent process was designed and conducted? (Y/N)		
Yes	37	15.4
No	204	84.6
Do you think that the best interest of study participants is taken in to consideration and adequately addressed through the current ethical appraisal and consent processes?		
Yes	35	14.5
No	206	85.5
Based on your experiences, what do you think are the most common problems in the current consent process?		
Lack of clarity	116	48.1
Inadequate information	82	34
Language	68	28.2
Cultural difference	66	27.4
Undue expectations	64	26.6
Power imbalance	50	20.7
Coercion	19	7.9
Others	11	4.6
Ethical Pre-assessment for Consent Process		
Do you think it is important to contextualize consent forms and consent processes to local settings?		
Yes	230	95.4
No	11	4.6
Do you agree with the idea of the study participant be approached in advance before the start of the study to get input for the development of the consent form and to find out how it should be administered?		
Yes	196	81.3
No	45	18.7
Do you think that study participants should be involved, in the development of consent forms and designing of the consent process so as to make it culture and setting sensitive?		
Yes	171	71
No	70	29
In your opinion, would REA serve adequately addressing the consent process issues and in making sure that ethical issues are very well addressed in a research process?		
Yes	95	39.4
No	146	60.6
From your experiences, is there any initiative so far, is there any initiative that involves the study participants in the development and design of consent information sheet and consent process?		
Yes	29	12
No	212	88

understood by the study participants. The most frequently reported challenges in the consent process were; lack of clarity of the information contained in the information sheet (48.1%), inadequate information (34%), inappropriate language and terminologies used (28.2%), cultural differences (27.4%), undue expectations (26.6%), power imbalances (20.7%) and coercion (7.9%) [Table 2]. The IDI respondents also mentioned gaps such as; language issues, lack of awareness, undue expectations and manipulations by researchers.

Language

The problem of language was repeatedly mentioned as a challenge to the consent process. In Ethiopia it is assumed by researchers that Amharic, the national language, will be used all over the country and can be used for the purposes of obtaining consent. Respondents indicated that the country is rather diverse and multi-ethnic, where there are many other languages and dialects.[a] Failure to understand differences may be problematic. According to the national guidelines, all consent documents in a research protocol need to be translated into the national language, irrespective of the language of data collection which may not be Amharic. This is one of the points highlighted in the checklists of ethics committees and IRBs. A mechanism ensuring local language and appropriate versions of translations are used in the field is lacking. In certain societies, the terms and concepts of research and most medical terminologies do not exist. In addition, concepts of health and disease may be based on local traditional understandings rather than the modern medical models used by researchers.

"When we come to information, there is a problem of language. ... Ethiopia is a diverse country, so even when you translate to Amharic[b], it is hard to bring the understanding. It is hard to translate scientific words to Amharic. ..." [Researcher, AAU].

Lack of awareness about research, health and ethics

Generally there is little awareness or understanding of science and research, especially in those with very low levels of literacy. Thus, participants might consent or decline based on their lack of comprehensive understanding about the research process.

"The society might be where they have no knowledge about research. ... People might also not understand what is written if they can't read. These are [some] loop holes" [Researcher, EHNRI].

"Even, the participants don't know what ... research is ... They don't know whether the research has benefit or harm ... [they] say yes without knowing it" [Researcher, JU].

".....In Ethiopia, [in] most places where research is done, the people don't know how to read and write, so how much do the researchers need to explain?" [Researcher, AAU].

Undue expectations by participants and manipulation by researchers

Due to misconceptions and failure to comprehend the intended purpose of research, especially in rural communities, there is a tendency to expect direct benefits. Undue promises may be given by field workers just for the sake of obtaining consent.

"... (even with) the tone of your voice, you might emphasis mainly the benefit, there might be some persuasion. [And]), they (participants) have to believe in it" [Researcher, JU].

Focus on consent and recruitment

There is a tendency to focus more on the consent i.e. the decision to participate, than on 'informed consent' which should be based on prior information and comprehension. As long as consent is given it is considered alright to negotiate and bargain.

" ... there is a lot of negotiation and bargaining (around consent), which is not a proper way of consent (process) application" [Researcher, JU].

Emphasis on rules and procedures

Respondents felt that there was too much emphasis on fulfilling requirements and procedures rather than on genuine concern for the rights and welfare of study subjects. Researchers cannot proceed without fulfilling these requirements and for most researchers 'research ethics' is about completing paperwork to get the 'ethical clearance letter'. The regulators also focus more on the enforcement of the rules without also creating awareness among researchers and the research community. Most regulators do not explain the reasons why the review is needed. The undue emphasis on rules and procedures has created discouragement on the researchers' side. Researchers expressed their concern that too much emphasis on the rules and procedures my eventually discourage and hamper the progress of research and science.

"Even the Civil law (code) has been too protective, to the extent of not allowing the conduct of trials – Ethics should not hamper Science!" [Researcher, AAU].

Suggestions to improve the current consent process

Based on the open-ended questions, the following major thematic areas were suggested by the survey respondents as ways of improving consent process.

Involvement of the community and potential research participants

Respondents suggested that the community needed to be involved in the research process in various ways such as by including community representatives in ethics committees, and by seeking the opinions of community leaders on potential ethical issues prior to and during research. Suggested mechanisms included approaching and involving the community through Community Advisory Boards (CAB).

Training

Various types of ethics training courses were also suggested by the respondents as important avenues for improving the consent process in developing countries. The training courses might be for researchers, health professionals or the general public. Suggestions were given on how the training courses might be delivered. These included integrating the course into research methodology courses and making them part of undergraduate and postgraduate degrees.

Differentiated approach – depending on the type of research

Participants emphasized the importance of acknowledging differences in contexts and designing approaches accordingly. Using REA depends on prior knowledge of the research design and anticipation of emerging ethical issues. Approaches would depend on the type of research design and the sensitivity of the topic to be addressed by the research, for example clinical trials in which biologic specimen collection takes place.

Pre-assessment

Many appreciated the idea of REA as a way of performing an assessment prior to the actual field study. Involving potential study participants in the assessments was also suggested, while others suggested it would be better to involve the CAB rather than study participants. (See theme 'involvement of community' above).

Field visits

Field visits were suggested, to follow the way in which ethical procedures stated in the protocol were actually being implemented in the field. These visits might be before the study or after the study, to monitor the implementation of consent or any emerging issues, depending on the nature of the study. The mandate of deciding which projects needed the field follow-up, and coordinating follow-up, would be that of the IRB.

Balanced approach, 'not to be a hurdle for research'

Out of concern that too much emphasis on rules and regulations might discourage researchers, respondents mentioned how important it was that ethical regulations did not become a barrier to the research itself. The importance of striking the correct balance was also reflected in informal discussions with researchers.

Perceived relevance and feasibility of REA

Regarding the importance of conducting a pre-assessment to explore potential context specific ethical issues for designing the consent form, 95.4% of the survey respondents agreed it was important to contextualize consent to the setting; 81.3% thought it was important to approach participants before the study to get input into the consent process; 71% thought it was important to involve local people in consent design in some way; 39.4% agreed to the idea of doing an additional and separate rapid assessment of the local situation such as REA before designing the consent process, with just 12% reporting that they already knew of such initiatives. On further inquiry, the following reflections on the relevance of REA were made by researchers and research ethics committee members during IDIs.

Need for strengthening the existing research ethics review system

Participants mentioned that ethics review in Ethiopia is a relatively new phenomenon. The system is not very uniform and relies on the experience of very few individuals. The national guidelines were thought to be old and ripe for review. Thus the need for rigorous and tailored ethics review was mentioned. Respondents emphasized the need for addressing research ethics in proportion to the expansion in health research in the country.

Opinions on the current consent process and consent review process

The consent process is mainly dealt with by individual researchers who in most cases have very little experience or training in research ethics. At times, they may seek counsel from experts. As a result, there is a tendency to perceive ethics review as another bureaucratic step rather than for the scientific and moral merits it may have. Several researchers perceived ethical review as discouraging, as a mere administrative matter. On the other hand, respondents agreed that there needed to be review of certain types of research but not for all research. Most were sceptical about the amount of time it takes for review of simple projects such as secondary data analysis. Coming to the review process, this is done based on what is stated in the protocol, but what happens in the field is not known – there is usually no check on comprehension. Authors of this paper have had similar experiences both as members of IRBs for over two years and as researchers getting ethics approval for research projects. In the IRB meetings, the focus is more on the way the proposal is written and the informed consent designed and written. The only check point closer to the community is the presence of a lay person. The lay person reads all the information sheets during the IRB meetings. Language being one important issue, the lay person usually checks the English version of the information sheet and consent form.

Rapid ethical assessment

Conducting a prior assessment at the beginning of a study with the aim of exploring context-specific ethical issues was considered a good idea by most, but there were concerns surrounding practicality and feasibility. Based on the descriptions given to them of REA, the majority appreciated the tools. However, there was confusion around the term 'rapid'. Many thought that this was about a 'rapid' ethics *approval* process. Further explanation had to be given about the term 'rapid' in REA, that it is a method of assessment used to explore the ethical issues in a relatively quick fashion at the beginning of the study and has nothing to do with speeding up the process of ethics review. Once they had understood the concept and the implied purposes, most respondents saw REA as a tool that would enhance the community's role as a stakeholder in research and would address the community's concerns with regard to ethical issues arising during research. There was agreement among most that in any research, the community needed to be contacted to seek counsel ahead of time regarding their concerns including ethical aspects of the research projects.

"... you don't go to the field with your backpack and say I am from France, and assuming these people are subjects and they will agree, this is what was done in the old days. Now in the community, you have to try to teach them as much as possible, telling them the pros and cons of the research. ... They have to negotiate their benefit" [*Researcher, AAU*].

"Things that are important to the local people might not be important to the others, so to make it relevant to the local people, we need to ask questions like 'do you have any concerns?', 'do you have a question?' at the piloting time. ...collecting this questions and [then] incorporating (addressing) them (the concerns)". [*Researcher, JU*].

Issues to be taken into consideration for REA

Asked whether they would recommend the REA tool for all research projects, many indicated that the approach would depend on the type of research. As REA takes time and additional resources, it might not be feasible to apply it to all research projects. Most mentioned this need to be dictated by the nature of the study. The existence of prior knowledge about the community was suggested as an important issue. If the ethical issues in the setting are already mapped out, there may not be a need to do REA.

"Yes for big research studies, for example clinical trials ... (and for) cohort studies ...it might be possible. ... Around here most research projects are cross-sectional, ... the days of data collection might only take 10 days. If you ask them to do the consent form [based on REA] and if it takes them 3 months, it might not be practical for most people. But for bigger projects, I think it will have a place..." [*Researcher, JU*].

"If we already know [the ethical issues in] our own community there is no use in doing an additional formative assessment." [Researcher, JU].

Discussion

Irrespective of the final conclusions relating to REA, the study highlighted important considerations for improvements in the research ethics system in Ethiopia. Whilst there have been a number of efforts at institutional and national levels to build a competent ethics governance and review system, the views of stakeholders suggest that further work is required. Given the relatively narrow range of individuals surveyed (institutional researchers and regulators), it could be claimed that more comprehensive assessment of the research ethics governance system in Ethiopia is needed before making further remarks. The study also identified clues specifically related to the research consent process in Ethiopia both at information provision and decision-making stages. The findings suggested that REA tools could be considered relevant and potentially feasible in the Ethiopian context in order to address these gaps.

The on-line survey for the quantitative component, which we believe to be one of the first uses of this technique in Ethiopia for health research, was efficient in terms of generating information rapidly. However, researchers who were not accessing their e-mails during the data collection period were not included in the study. On the other hand, a significant proportion of the intended sample size was reached, as respondents were able to answer the survey questions irrespective of their physical availability or current location given internet connectivity. The fact that the respondents themselves were researchers who understood the importance of responding to surveys may have contributed to the high level of compliance [15,16]. It was possible to send reminders and additional invitations on the basis of responses. This may have resulted in selection bias as busy people and those on vacation during the survey might not have responded to the survey. However, we do not know reasons for non-participation and non-response. The study was conducted at the beginning of the academic year, assuming most academics would have time to complete an online survey. The study has demonstrated the potential of using on-line survey tools in Ethiopia among groups such as academics and researchers. The other advantage of conducting the on-line survey was the use of the preliminary findings to shape the qualitative study.

The mix of study respondents is representative of the group targeted for the study; high level researchers and regulators of ethics review systems with considerable research experience. Their current roles and experience in research made them ideal to identify gaps in health research ethics, and to suggest possible ways of addressing them. However, since the study was limited to researchers and regulators, the perspectives of other important stakeholders in health research such as non-researcher health professionals, community members, senior officials and country level policy makers were not included in the study. Another point to note about the respondents is that, despite the fact that most were involved in conducting research, in ethical review or in the development of ethics review guidelines, a significant proportion of respondents had not had any formal training in research ethics. Possible explanations for this include the absence of structured research ethics training courses and the fact that Ethiopia is in the early stages of implementing a universal system of research ethics. One example of this is the recommendation given by the study participants about having a community representative on ethics review committees. This is already included in the national ethics guideline [17], but is not

uniformly implemented. This lack of standardized and structured ethics training is a critical gap, and from the qualitative findings, there are suggestions that it may lead to systemic gaps in the ethical conduct of research. Other studies have documented knowledge gaps among academics and have suggested ways of including ethics training in mainstream curricula [18,19]. In addition, the qualitative study did not include representatives of all academic and research institutions, which makes it difficult to generalize the findings to other settings. Yet we believe that most of the concerns are shared by similar institutions. The use of a mixed-methods design served to triangulate findings as the qualitative assessment provided deeper insight into the survey findings and bridged the gaps in the survey assessments. The online survey enquired, with closed options, into ethical pre-assessments and REA in reference to involvement of potential study participants, without further explanation of the REA concept. With the IDIs it was possible to discuss further, explain the essence of REA and enquire into the involvement of community members beyond study participants. Overall, the study was able to identify key issues relating to research appraisal and explore perceptions surrounding REA.

Respondents' perceptions of existing consent processes were not found to be favourable. Most respondents thought that potential participants understood little about the consent process or the information provided to them. They also thought that participants' best interests were rarely considered, reflecting gaps in communication and the decision-making process. The major gaps for study participants in relation to communication and comprehension included use of incomprehensible specialist terms to explain medical concepts, lack of health and research awareness of participants, undue expectations and manipulation by researchers. The same list of issues could influence decision making, which in turn is influenced by factors such as manipulation by researchers and the local dynamics in decision making. These factors vary from context to context. In Ethiopia ethno-cultural differences are very visible, and they make the use of generic consent forms and consent approaches for varied setting inappropriate.

Traditionally, consent forms have been developed by researchers based on the requirements of an information sheet and a decision page. This approach addresses consent from the perspective of the basic principles in ethics and the major international guidelines. The assumption is that the contents would be relevant fairly standardized irrespective of who the participants are. Sometimes consent forms have been developed by international investigators and 'adapted' purely by translation.

In Ethiopia, communities have varied levels of awareness of public health issues. According to the Ethiopian Demographic Health Surveys (EDHS), levels of understanding vary by characteristics such as area of residence, income, region, religion, ethnicity, and literacy status [20]. Tekola *et al.* reported that words for 'health,' 'research' and 'medical treatment' either do not exist in some languages or are used interchangeably in a confused and confusing way [8]. This may give rise to expectations of medical treatment which confound the decision making processes. Some researchers might be tempted to take advantage of this vulnerability of participants to increase rates of recruitment by either promising unrealistic and unavailable benefits or at least by not challenging misconceptions. Gaps in the consent process are reported elsewhere related to information and communication and decision making and indicate the need for informed consent processes tailored to the context [1,8-10,21-26]. The use of qualitative assessment in the informed consent process for medical research in developing countries have also been reported [27].

Based on previous studies which have employed REA, consent processes have significantly improved in terms of both comprehension and decision making as a result of the knowledge and understanding gained and the steps taken to incorporate it. The key steps were identification of issues prior to and during the conduct of studies and guiding the consent process (including the provision of information) based on those qualitative findings. The REA tool has been recommended for use by researchers who have used them in their respective research [7-11]. The current qualitative findings support the need for pre-assessment to explore potential context-specific ethical issues. Pre-assessment in health research may have various objectives such as testing data collection tools and assessing study feasibility [28-32] and optimizing community engagement [33]. However REA is distinct from these forms of pre-assessment being focused primarily on ethical issues.

It is interesting that a significant proportion of the respondents mentioned they were aware of the role of some form of pre-assessment and stakeholder participation in exploring ethical issues. However, the extent of actual use of pre-assessment was not measured, and neither was any quantitative assessment made of the techniques that might already be used by researchers. The qualitative responses revealed that *ethical* pre-assessment are not widely used, and that the term may be used to refer to feasibility studies or piloting of tools. Genuine ethical pre-assessment is rare, and stakeholder participation usually refers to involvement of community representatives in identifying the problem to be investigated rather than the consent process *per se*, [34-36]. There are fewer experiences of pilot studies for ethical pre-assessment, and these were limited to the specific research projects under consideration and did not investigate the openness of researchers to their wider scale use [37-39].

Currently in Ethiopia, there is no established mechanism in place to assess the community risks, vulnerabilities and benefits beyond what is written in the application submitted for approval. Most IRB reviews are based on a simple Risk-Benefit assessment of the submitted proposal and an assessment of whether the consent form meets an acceptable standard and is written well. However, one important parameter in IRB formats is 'Involvement of the community in the research'. Again, in practice this assessment of community involvement is based solely on what has been included in the proposal, and refers mainly to involvement in the development of the research question, which is understandable given that one of the implicit principles in community health research, is that 'community concern' is an important criterion.

A 'pre-assessment' which includes the community would reduce the reliance of the IRB on making a judgment based on the written scientific proposal alone. Community engagement approaches, which aim to create awareness and a sense of ownership by the community, are becoming more popular. These approaches often work with and through community groups such as Community Advisory Boards. Community engagement is also used as a process of influencing change in the community through provision of information, negotiation, local capacity building and empowerment [33,40]. Community engagement might also be used to address ethical issues around research [26,41-43]. Community engagement and REA share some overlaps, since they both address community issues and share qualitative methodological approaches. However, REA is primarily conducted by a REA team (a multi disciplinary team of researchers) and employs rapid ethnographic research methods, while community engagement will more commonly seek to involve community members and to engage over a longer period than suggested for REA. The two are not mutually exclusive.

The study documented considerable interest in REA as a tool to improve the research consent process. However, respondents were concerned about the potential burden REA would put on the researcher in terms of time and other resources. There is a concern that REA may unnecessarily delay small, cross-sectional research projects into less sensitive topics. One suggestion made was to conduct REA as part of the traditional pre-test during community based studies. However, the objectives and duration of such pre-tests vary considerably. Some are rapid and done in a day or two and would not permit REA, which required about 4–6 weeks in the earlier studies [8,10]. Other types of pilot studies such as feasibility studies for randomized trials would be ideal in terms of integrating REA. The studies so far employing the REA method have documented its significant contribution in identifying important ethical issues in the research context [10,11]. However, such studies have not assessed the usability of the tool by the research community. As REA is an additional tool which requires time and expertise, research teams need to take this into account when planning their project. It is then important to be clear about what resources are required so that researchers can take this into consideration. In addition, REA findings might possibly raise issues relevant to study design and therefore might best be done in advance of most pre-tests.

According to the findings of the current study, the 'rapid' aspect of the REA tool was at times confused with the idea of expediting the review process. Some respondents were confused about the terminology as they tended to understand that the tool was 'rapid' and was meant for accelerating the ethical review process. Most of the researchers indicated that the current appraisal process takes too long and there is a need for finding a way to improve this. They were intrigued to learn that REA entails additional time and resources.

Whether REA should be applicable to all studies depends on a number of issues such as the nature of the study, the characteristics of study participants, the nature of the issue under investigation and the availability of resources. Whilst it is important to avoid crude generalisations and stereotyping when setting ethical standards, it is possible to learn from similar cases. Sometimes earlier studies of a similar nature will provide information on which consent processes can be designed. Clinical trials and studies that include vulnerable subjects or sensitive issues would often require REA. In clinical trials and classical longitudinal studies, there are a number of encounters with the study subjects. This would allow plenty of room for addressing consent issues. Such longitudinal studies require repeated and long term encounters between researchers and the community. As the consent process is repeated, it can be improved. Some communities are better informed about science and research than others and are well known to the researcher. In localities where health systems are well accessed and previous research has been conducted, the community generally has a better understanding of health research and the anticipated ethical issues will already be familiar to researchers. REA is therefore likely best reserved for communities that are not well researched and are less familiar to researchers.

The main objective of the current study was to assess the attitudes of the research community towards the REA tool and their views on its perceived relevance. In this paper we did not intend to explore the issue of practical feasibility beyond recording the perceived relevance and applicability of the tools as expressed by researchers and research ethics reviewers. Perceived relevance of the

tool is different from its practicality and feasibility which need to be explored further. Expressed demand and acceptability of an approach are important components in assessing feasibility but are not sufficient [44]. However this study has clearly demonstrated the openness of researchers to considering the introduction of such a tool and suggests that they might willingly collaborate in developing a feasible intervention.

Limitations

Qualitative data analysis was done in English while conducting the analysis in the language of data collection would have been preferred. Community representatives were not included in the study and the assessment regarding the research ethics review system in Ethiopia was primarily based on perception of researchers and ethics committee members. We used post graduate training as a proxy indicator of research experience which may not always be correct as there are variations in the profiles of post graduate programs.

Condusion

REA tools and techniques were found to be highly relevant and acceptable to the Ethiopian research community, however practical challenges were anticipated in the actual implementation. Research ethics and its review systems are relatively new in Ethiopia, though the country has national guidelines and structures in place to regulate ethics in health-related research. Even though there is rapid expansion of health and medical research activities due to acceleration of post graduate education, there is a lack of capacity in ethics review systems, particularly in the newly-founded Universities. The current review process has demonstrated critical gaps in ensuring reliable consent processes. The problems arise from three distinct areas; those embedded in the health research review system, those related to researchers and those related to the general public. REA is not a panacea but the introduction of a manageable level of pre-assessment of research settings would provide researchers, ethics reviewers and policy makers, with a manageable amount of data relevant to all the issues raised here as challenging and/problematic in an Ethiopian context. For this reason the applicability and practical feasibility of REA needs to be further explored, and the openness of researchers to embracing this tool needs to be capitalized upon in the interests of future research participants.

Endnotes

[a]Ethiopia is a country of over 80 million inhabitants with over 80 ethnic groups and more than 80 different languages spoken while Amharic is considered as the official working language.

[b]The Ethiopian official working language.

Abbreviations

AAU: (Addis Ababa University); AHRI: (Armauer Hansen's Research Institute); CAB: (Community Advisory Board); EDHS: (Ethiopian Demographic Health Survey); EHNRI: (Ethiopian Health and Nutrition Research Institute); EPHA: (Ethiopian Public Health Association); FMOH: (Federal Ministry of Health); IDI: (In-depth Interview); IRB: (Institutional Review Board); JU: (Jimma University); KII: (Key-informant Interview); MoST: (Ministry of Science and Technology); REA: (Rapid Ethical Appraisal); UoG: (University of Gondar).

Competing interests

The author(s) declare that they have no competing interests (financial and non-financial). The study was financially supported by Wellcome Trust (WT) through Biomedical Ethics Doctoral Fellowship 089769. However WT has no any part in the execution of the study and write-up.

Authors' contribution

AA, GD, and BF designed the study. MN, HM and YF critically evaluated and made progressive suggestions on the initial study design. AA developed study instruments and collected and organized data with TA. AA and TA did data collection and analysis including transcriptions, initial coding and double coding. All authors (AA, GD, BF, MN, TA, YF and HM) were involved in the write up of the manuscript and in the critical review of drafts. All authors read and approved the manuscript.

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Annex G.1.2. Manuscript on Ethiopian Medical Journal

Adamu Addissie, Gail Davey , Melanie Newport, Bobbie Farsides, Yeweyenhareg Feleke. *Ethiop Med J, 2015, Vol. 53, Supp. 1*

ORIGINAL ARTICLE

FEASIBILITY OF RAPID ETHICAL ASSESSMENT FOR THE ETHIOPIAN HEALTH RESEARCH ETHICS REVIEW SYSTEM

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ABSTRACT

One of the challenges in the process of ethical medical research in developing countries, including Ethiopia, is translating universal principles of medical ethics into appropriate informed consent documents and their implementation. Rapid Ethical Assessment (REA) has been suggested as a feasible approach to meet this application gap. In the past few years REA has been employed in few research project in Ethiopia and have been found to be a useful and practical approach. Feasibility assessment of REA for the Ethiopian research setting was conducted between 2012-2013 in order to inform the subsequent introduction of REA into research ethics review and governance system in the country. REA was found to be an appropriate, relevant and feasible venture. We argue that REA can be integrated as part of the ethics review and governance system in Ethiopia. REA tools and techniques are considered relevant and acceptable to the Ethiopian research community, with few practical challenges anticipated in their implementation. REA are considered feasible for integration in the Ethiopian ethics review system.

Key words: Rapid Ethical Assessment, Feasibility, Research Ethics, Ethiopia

INTRODUCTION

The inflexible use of international ethical guidelines in health research have prompted investigators to seek an approach for adapting these guidelines to local situations. Studies have emphasized the importance of addressing local context, especially in the developing world where there is a disconnection between what is assumed by researchers and the practical reality [1-3]. Rapid assessment techniques have been documented to play important role in improving research consent process in developing countries by understanding and addressing contexts. One of those approaches suggested for further use is named as *Rapid Ethical Assessment or Appraisal* (REA) [4-7]. *Rapid Ethical Assessment (*REA*)* is a brief qualitative intervention designed to map the ethical terrain of the research setting preferably prior to a research team starts recruiting participants with the purpose of connecting ethical principles to contexts and realities on the ground. REA attempts to discover, describe and respond to the ethical issues specific to a particular research setting, and as such should help researchers to address the issues that genuinely matter to proposed study participants and their community. The assessment is conducted among key stakeholders to inform the design of the particular research project. Its findings are utilised to inform and guide the research consent process; ranging from the conception and development of the consent form, to the way consent is obtained. REA as a methodology employs constellation of action research, rapid assessment and ethnography. This makes the approach a multi-mix, multi-disciplinary approach with overlaps between various techniques. REA employs an ethnographic qualitative design with a blend of anthropologic ethnographic enquiry, action research and rapid assessment techniques (4-7). REA were serially piloted in Ethiopia. During these rounds of interventions the feasibility of REA for integration into the current research ethics review and governance system was assessed. In this paper we summarise the key findings from the REA intervention employed so far in Ethiopia and key considerations for integrating REA in to the ethics governance in Ethiopia.

MATERIALS AND METHODS

Feasibility assessment on REA in the Ethiopian context was conducted based on REA piloted in to three different community based studies in to five loca-

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tions in Ethiopia, in 2012-2013. The locations were Ayra in Easters Ethiopia, Soddo and Butajira in Southern Ethiopia, Mekele Zuria from Northern Ethiopia, and Zeway from South Central Ethiopia (Figure 1). During the pilots, observations and documentations of REA implementation processes were done. This was preceded by an acceptability assessment where researchers, ethics review committee members and policy makers from academic institutions such as Addis Ababa University (AAU), Jimma University (JU), Ethiopian Health and Nutrition Institute (EHNRI), University of Gondar (UoG) were interviewed. In addition two REA workshops were conducted among researchers to collect feedback about REA. (Figure 1)

Figure 1. The five REA Pilot locations in Ethiopia, 2012/2013.

Based on data from the different phases of the REA project, feasibility analysis was conducted to determine feasibility in terms of time, cost and skill were assessed to answer the following question; how much does REA cost? what skills are needed? are the skills transferable? who will conduct the REA, the researcher or another expert? Is REA acceptable to researchers? Is it possible to integrate the tool into existing research ethics appraisal systems? Is it user-friendly and cost effective?

We explored how REA might be integrated into the existing research governance and ethical review system based on opinions from researchers and research ethics stakeholders, our observations and documentation of how the REA fitted into the pilot research projects, and the reflections and feedback from REA workshop participants. Thematic analysis of qualitative data based on cycles of coding were conducted . We then triangulated findings from all three phases of the project to identify relevant themes related to the various components of feasibility. Transcripts, memos and summaries of interviews, discussions and observations were coded to identify patterns and emerging themes in line with the variables of interest. Following the coding of responses using themes, we categorized and synthesized the results thematically. Thematic variables used to measure the various components of feasibility included attitude and perception about REA, satisfaction with REA, suitability of REA, perceived demand and expressed intent to use REA, actual use of REA, expertise and resources needed and available for REA (such as time, financial costs, human resources), training and skills needed, efficiency of implementation in terms of adaptability and flexibility; accommodation of the tool into the system and scalability.

RESULTS

REA feasibility results are presented in three categories; its acceptability to intended end-users; practicality in its implementation; and dynamics of its integration into the current system and potentials for further expansion.

Acceptability of REA to intended users: The researchers who were interviewed generally had positive perceptions about REA and thought this is a useful approach. Their main concern however was the practicality of the REA approach. As conducting a rapid qualitative study to improve consent process is a new concept, many had to ask more to learn before understanding it.

Researchers who employed REA were happy with the outcomes of the REA process and appreciated the experience. They expressed their appreciation and satisfaction with the feedback they obtained for the consent processes of their studies. REA workshop participants appreciated the relevance of REA and the descriptions and illustrations used. They were very excited to learn about this new technique and expressed interests to know more in due course. Participants also said that the tools appear to suitably address very important aspect of research in low income settings.

Researchers and ethics committee members interviewed appreciated the contribution of REA towards improving the standards of medical research. They appreciated the fact that REA creates a good opportunity for researchers to understand their research community in relation to the research process and particularly the consent process. Respondents expressed general acceptance towards REA and considered the principles governing REA and its application to be similar to the principles behind pre-test studies conducted before the actual studies.

> *If the participants understood [the community] well, this will simplify the process of research. I think it is a very good idea. ... Especially in Ethiopia and [other] developing countries, [where] there are diverse cultures, lot of surprises will be there waiting for you [in the community], so I think it is a good idea. This can [even] be included in the guideline(s).*
> [Academician and Researcher, AAU]

REA respondents expressed their concerns that some researchers might resist REA as a mainstream tool. Possible reasons included the additional work burden that it might result, and not being able to understand its benefits fully. This was considered especially important in the early stages of introducing REA. Introducing REA as a pre-requisite for ethical appraisal and as a mandatory requirement without adequate awareness and background work might be very unpopular. Accordingly, training and awareness raising were considered vital along with continued negotiation and demonstration of the benefits of REA.

> *Putting it (REA) as a [mandatory] requirement might bring resistance among researchers...[just] because it is a new thing. People resist new things because of lack of knowledge. So it should be done slowly, showing it in other studies, showing its benefit. When they see the benefits, if one study is done properly it will be a base for another study, it will be like that. Eventually it will grow slowly as a culture (among researchers).* [Academician and researcher, AAU]

During discussions with researchers about REA, there was a lot of confusion regarding the term 'rapid ethical assessment'. Many thought this meant a tool to speedily address the ethical approval process. It took considerable discussion to clarify this. REA workshop participants initially misunderstood the term 'Rapid Ethical Assessment. As many researchers are frustrated with the current very protracted ethical appraisal process, they thought this tool was intended to speed up the review process and were surprised to learn that REA involves addition of a step or process. When they heard more and got more informed, they were not disappointed, but appreciated the importance of this new tool and considered using it despite the demands it creates on researchers. Overall, researchers approached for this assessment expressed concerns that REA might be an additional burden to researchers in terms of time and budget. Other respondents stressed the need for awareness raising and training on REA. Some were concerned about too much involvement with the community before the actual data collection might bring about contamination of the instrument and measurement bias during the field research.

Practicality of REA in its Implementation Process:
It was mentioned that REA might become an additional burden both to the individual researcher and the research governance system (including ethical review) due to the additional pressure and burden on the researcher by increasing the process and steps of research and increased complexity of the review process.

> *This (REA) will increase the bureaucracy and make the process long, and it complicates the ethical process .... I don't think we need another body for this. No need of additional review. It will increase the time [needed for the review]. Then you have to pass [through] all this to start working. It lengthens the steps. As you make it more organizational, it will increase the complexity specially in our environment which is already bureaucratic. It is bureaucratic in [responding]. [As] the capacity level is low, they (the review systems) need to be [first] strengthened.* [IRB member and Researcher, EHNRI]

Respondents felt that applicability would depend on the type of research under consideration. To introduce REA not in blanket fashion for all research, but only for selected type of research projects based on criteria such as risk level and anticipated ethical issues (e.g. community-based research, invasive procedures, biological specimens involved) appeared more sensible.

> *It depends up on the research question, ... so if there was a check list .. based on the research question... like clinical trial, ... sensitive issues, like genetic studies, in remote areas, vulnerable population.*
> [IRB member and researcher, AAU]

Others suggested that it would be difficult to introduce REA based on the research-type, risk and harm levels, as it would be difficult to foresee risks in research. To address this dilemma, an all-inclusive approach of national REA was suggested.

It will be better if it is not like that, it is hard to classify research a priori, which one does harm. It is hard to decide in the beginning. It is hard to predict what research could do to the society, you can't say "let me do formative [REA] for this one and not for this one".
[IRB member and Researcher, JU]

This refers to doing a 'one-off' REA at the national level to map out all possible ethical issues at the national level for subsequent use by researchers. This point is further presented in detail under the section on integration below.

Instead of doing REA for every study separately, it was suggested that REA be done at a national level to map out existing ethical considerations in the various ethnic and cultural groups. Then the issues and recommendations could be included in a national document as a guideline (catalogue) researchers could use this information as a reference for research in a specific setting .

Instead of doing a formative assessment (REA) for all research which is tedious, there should be a guideline (guiding document). You can do a [national] survey (REA), and put it on the guideline, saying this is the Ethiopian community [and], if you want to get a signed consent you should do like this [depending on the site]. Otherwise if you come to [do REA in] all research, one it might be different what each researcher will bring (find), [and] there might be conflicting outcome, the formative [REA findings] that you bring (find) is (could be) different from what another person might bring, there might not be a common ground. [IRB, Researcher and academician, JU]

According to the respondents, important resource considerations included time and cost. It was stressed by participants that the approach is resource-intensive and may not be practical time-wise. Considering time as an important factor, there was a dilemma about how much time is enough to be allocated. The issue of cost and the implication of additional cost needs for REA was mentioned. Most local research projects operate under meagre budgets, and REA will be another competing factor for the budget available. During the REA pilot studies, we documented resource inputs required for REA implementation.

It needs a lot of resource [including] time. When we start a research, there are deadlines and time constraints. To study exhaustively we need time, so it depends on resource and time. If the area is far, it is hard to go there and do it and come. Making it as a requirement is a little hard. [Academician and researcher, AAU]

Costing: In the REA pilot studies, the budget planning took into consideration line items such as personnel costs, transportation and field instrument as well as data management and analysis costs. Average costing per REA amounted to 42,812.5 Ethiopian Birr (ETB) (approximately £1500 or 2250 USD). This excludes the costs of other items which were not directly paid for such as IT equipments and software. Compared to field research budgets of the individual research projects, the REA cost ranged from 1.92% in Adami-Tulu (Zeway) to 4.99 % in both Ayra and Soddo. The overall details of field costs of the four different locations are presented in Table 1.

Table 1 Field site project costing compared to REA costs for the four REA pilot sites, 2012-2013.

Site	Parent project research cost estimates			Proportion of cost of REA* against project cost
	ETB	USD	GBP	%
Butajira	748,850	39,413	26,275	5.72
Adami Tulu	2,233,000	117,526	78,351	1.92
Ayra	856,662.5	45,087	30,058	4.99
Soddo	856,662.5	45,087	30,058	4.99

* Average cost per REA ~ 42,812.5 ETB

Time: This took into account the time needed per project for planning (preparation for field work) and implementation (time in the field). Each of the days spent on the field were longer than normal working days (on average, 12 hours a day spent on field work and analysis.

Overall, the average time range for REA was 4 to 6 weeks (including initial analysis); 3-5 weeks for the data collection and field work, and one week to compile the summary findings and communicate back to the researcher (Table 2).

Table 2 Time taken by REA Field Work for five REA pilot sites, 2012-2013

Site	Time Period	Total Duration
Butajira	November/December, 2012	6 weeks
Adamu Tulu	January/March, 2013	5 weeks
Wollega	Mid March/April, 2013	4 weeks
Soddo	Mid April/May, 2013	4 weeks
Mekele	July/August, 2013	4 weeks

Manpower: Manpower needed for REA included the REA team and its technical expertise. The profile of personnel involved in terms of professional expertise and other characteristics for each pilot project and field sites are presented below (Table 3).

Table 3. REA team composition (number and expertise) for the different REA pilot sites, 2012-2013.

Project	No of REA team members	Team Composition and Expertise (#)
Butajira	5	Anthropologist (1); Public Health professional (2); Expert insiders (2)
Adami-Tulu	5	Health professional and PI (1); Public Health Professional (2); Anthropologist (1); Expert Insider (1):
Ayra	5	Anthropologist (1) ; Public Health professional (2); Expert Insider (1); PI of the Cervical Cancer Project (1)
Soddo	5	Anthropologist (1); Public Health professional (2) Expert Insider (1); PI of the Cervical Cancer Project (1)
Adigdom	5	Anthropologist (1); Public Health professional (2) Expert Insider (1); PI of the Cervical Cancer Project (1)

1 USD ~ 19 ETB ; 1 GBP ~ 28.5 ETB
Refers to the research into which the REA is to be employed.

Feasibility of Integrating REA to Existing System: Study respondents considered the process of REA integration to be a time-taking process. To this effect, integration was thought to happen at two levels: a) integration with the research project to be conducted; and b) integration into the existing ethics system and guidelines.

As part of integrating REA into individual research projects, it was recommended to integrate REA into pre-test phases of research. REA and pre-test studies were thought to share similar principles in improving the implementation of research during field data collection. Integrating REA to the main study would simplify the issue of ethical clearance for REA component of the project as the REA would be approved together.

> *Integrating it (REA) to the pre-test phases is better than doing it alone. It will also save time. Because whatever you do, you test them on the pre-test and it will be an input when you do your main study. I think this will be good. When clinical trial is done, ... they do the background (pilot) study. I think this thing is already there. ... you need to add this in there.... carrying it out at the pre-test or pilot time is good. Because it is(it gets) already approved [together].* [Academician and researcher, AAU]

When it comes to system integration, it was mentioned repeatedly that REA needs to be mainstreamed and should be part of the existing guidelines for research and ethical governance. The country circumstances in terms of ethno-cultural diversity to be taken in to consideration, as a justification for including it in the guideline. While it is possible to include REA in the guidelines, this would need to be accompanied by continuous capacity building and training.

> *This (REA) can be included in the guideline, ... adding it (REA) to the guideline allows them [researchers] to think about it ... [and include it in their protocol] ... but ... do they see the guideline? The most important things are ... continuous trainings for investigators.*
> [Academician and researcher, AAU]

However, mainstreaming REA into the current research governance system is not an easy process. Caution in application was advised in order to keep the approach as simple as possible. Participants expressed the need for more workshops as a means for dissemination and expansion of REA to wider audiences.

> *Research is premature in Ethiopia. What I suggest is if we simplify this (the REA introduction process) and help the researchers, and protect the society.* [Researcher and academician, JU]

DISCUSSION

Based on the feasibility analysis practical issues and considerations in applying REA for further use in the Ethiopian setting were identified. REA implementation appears feasible, yet some areas require caution and must be addressed in parallel. According to models suggested by researchers who have conducted feasibility assessment in public health interventions, three general categories are considered important [8] [9].

End-user related feasibility: Potential end-users of REA are researchers, ethics committee members and REA team members. There are two levels of acceptance by end-users, the first one concerns perceptions and attitudes towards the REA, while the second level is more practical where end-users agree to use it. Researchers and ethics committee members acknowledged the need for REA as an approach which would address these gaps. Acceptability is expressed through user's perspectives and perceptions; how do researchers, the REA team and the wider research ethics community accept the tool.

Since REA is a very new approach, concerns about potential resistance were expressed. According to Rogers' theory on "diffusion and adoption of innovation", the rate at which a new approach diffuses for use by its users depends on the nature of the end-users [10]. While only a few will adopt the innovation immediately, the majority take time. A few will never adopt the new technology at any cost. While it is too early to appreciate the whole dynamics of REA acceptance by its end users, the model is worth considering [11]. The other reasons for resistance include practicality, the potential cost and time burdens and researchers' perceptions about the current ethical approval system. Despite this, the pilots showed that researchers could actually engage with REA and integrate it into their research project. This was chiefly because researchers were convinced in the added value of REA in improving the consent process and increasing the quality of the research process.

Process-related feasibility: Implementation of an intervention is a continuous process which starts with planning and making sure what is planned is exe-

cuted [8]. Three important resource considerations in the process of employing REA included cost, time and manpower.

It was possible to conduct REA at a reasonable cost of 42,815.5 Birr per REA. In view of the benefits one gets from the REA, the budget it consumes seems reasonable. Several factors might have contributed in attaining this reasonable cost. We tended to be conservative in expenditure and negotiated minimum possible pricings for items and personnel. Though the REA costs were covered by a separate budget, when we compared the ratio of budget spent for each REA, this ranged between 1.92 % and 5.72 % of the overall budget allocated for the parent research projects. Researchers need to plan well in advance to cater for the budget needs, by considering REA as part of the overall research proposal and accordingly budget for it part of the main research project.

On average it took 4-6 weeks to conduct REA. Rapid assessments are generally considered to be conducted in an average of 6 weeks [2]. Previous researchers have conducted REA in range of 5 to 7 weeks [6] [7]. Despite such short durations, very useful findings were generated. This may convince end-users that REA can generate useful results in a reasonably short period of time. Considering the fact that researchers may spend weeks or months waiting for ethical review [12], planning a 6 week REA does not seem unrealistic.

Regarding manpower, the average number of professionals needed was 5 per REA team. The number was reasonable and manageable as a group for creating a group dynamics. In rapid assessments it is recommended that the team need not be big in number [2]. In rapid ethnography, it is recommended that the rapid process is augmented by involvement of a mix of professionals who have a good team dynamics. It was possible to implement this in our pilot REAs. The REA team was composed of a mix of individuals from different disciplines as well as members from the study area who were considered to be key informants and were in some senses 'gate-keepers' to the community during the field work. The social scientist member had the role in making sure that the qualitative designs were properly done, and advised the whole REA process. Health professionals helped the team in exploring the health issues in the research and their public health and clinical implications. The outsiders brought new issues to the community, while insiders helped in balancing views and avoiding assumptions from outside [2]. It was possible to train other experts to do REA and to transfer REA skills and expertise into the pool of identified personnel.

The flexible and adjustable nature of REA helped meeting practical challenges in the process of implementation throughout the phases of pilots. During the field survey, some of the challenges of implementation which required adaptation included timing and duration. During analysis of REA findings, the provision for iterative analysis and daily-debriefings helped a lot in providing usable results for researchers on time. Important considerations regarding communication of feedback were timing (when to disclose information - during, before or after the actual survey) and format (written or verbal). There was room for flexibility in choosing from the stated options.

System-related Feasibility: The integration of REA into the existing system depends on a number of factors. All feasibility considerations discussed earlier such as acceptability and applicability are important considerations for integration, as integration is a process rather than a one-off event. New approaches pass through a number of phases and steps before they fully integrate into routine practice [13]. Suggestions given as to make effective ways of charting the integration of REA included integrating REA into the pre-test phases of studies; including REA in the National Research Ethics guidelines; and conducting a National Survey of ethical issues using REA.

Most research project have a pre-test phase to check the tools and make revisions and adjustments accordingly[14, 15]. REA and pre-test would share the principle of adjusting the tool and the process based on field experiences. However they have two distinct and separate objectives and would be difficult put them together. Though the duration of pre-test studies may vary from project to project, they are mostly completed in a couple of days. Whereas REA needs an average of 4-6 weeks depending on the circumstances in the field. Pre-tests are conducted in a population other than the actual population but with some shared similarity to avoid contamination, while REA studies are conducted in the population to be included in the main study, with focus on the ethnocultural and ethical issues related to the actual target population.

Development of REA to the level of national guidelines is a process that takes time. Issues eligible for inclusion in national guidelines require awareness raising and advocacy, a series of workshops and finally buy-in from a higher governing body at na-

tional level. In this case, the responsible body would be the Ministry of Science and Technology. The three Ethiopian national ethics guidelines had to pass though these stages [16]. During the recent revision of the national research ethics guideline, attempts were made to introduce the concept of REA, however, this may be premature given low levels of awareness and the lack of extensive documentation on REA. Respondents also doubted the practicality of introducing REA to all research projects and suggested a differentiated approach depending on the type of research. In addition they argued that the findings of one research REA might be applied to a similar research project, avoiding the need to repeat REA. Application of ethical checks based on checklist and criteria have been commonly practised even for a consent process. Based on those criteria and level of risk assumed IRBs can prescribe practical approaches (Belmont, ICH) (17,18)

As part of introducing REA for national usage, a 'national REA' was suggested as a one-off ethnographic survey in all the ethno-cultural pockets in Ethiopia with the objective of mapping out ethical issues. The results would be collected for reference for future studies. This was thought to be more feasible and cost-effective approach, than prescribing REA for every study. The suggestion was made with the assumption that the ethical issues identified for one piece of research could be reasonably applied to another. Such multi-sited approaches have been suggested and discussed by other researchers [19, 20]. However, contexts and realities are not static and the same is true with ethical issues associated with them, weakening arguments for this approach. In addition, assessing ethical issues in the absence of a planned research project is far from ideal. Ethical issues are a function of settings as well as the research question and study design being proposed. Based on experiences so far, REA discloses 'unexpected' ethical issues related to a specific project. Thus, merely studying the context will not be enough. REAs are done in the reality of the setting and the issues and not in general terms. Earlier work has also indicated drawbacks of such approaches [20]. On the other hand conducting national REA would be a hugely expensive exercise and time-consuming, whose findings would be severely limited. Project-specific REAs will definitely be of use to the proposed project, leaving the question of which projects should be preceded by REA.

Limitations: In documenting feasibility outcomes we relied on outcome measurement in the absence of comparison groups. Cost-feasibility and cost-effectiveness studies that employ economic models and cost-effectiveness analysis were beyond the scope of the current project.

Conclusions: Based on the findings, application of the REA tool and its integration into the existing research governance system in Ethiopia appears feasible. However some practical concerns will need to be addressed in parallel. There is a good level of recognition and acceptability of REA by its end users; researchers and ethics community. REA is flexible and adaptable to circumstances, settings and needs. The resources needed for REA are not different from most research and with proper planning and transdisciplinary collaboration it should be possible to implement REA in research projects conducted in Ethiopia. REA results were conveyed to researchers in a reasonably short period and were feasible.

It was possible to demonstrate the potential to integrate REA into the current research review and governance system at two levels; within individual research project; and into the existing research governance system. Integration within research proposals has the advantages of an integrated review and efficiency in planning and resource management. Acceptability and practical feasibility of the approach, cost-effectiveness and flexibility for easy adoption, all contribute as key factors for successful integration. Integration with pre-tests seems unrealistic as the two have distinct and separate objectives, timings and settings.

However, concerns remain that REA might place additional burdens on researchers and the research governance system. Main issues identified were time and budget constraints, 'contamination' related to the data collection instrument, the flexibility in modifying the consent form in the field might affect the quality and standards of the IRB approved consent forms and procedures. Creating understanding about REA is not automatic and many potential stakeholders had misunderstandings and unworkable expectations. Conducting national REA to generate a national 'catalogue' of ethical issues also appears unrealistic as it would be very expensive and its findings would not reflect the unique dilemmas related to individual projects.

Recommendations are made in three areas: a) Continuous awareness raising through workshops for researchers, research ethics committees and regulators, with the aim to promote REA and its use. In addition the researchers there is need to design a mechanism to involve data collectors and field work-

ers in the conduct of REA. b) It is advised to follow a differentiated approach to develop criteria for projects requiring REA than a more general one as projects have their own peculiarities. There is a need to guide researchers opting to use REA in relation to the resource and skill needs and the planning considerations so as to have a practical financial and time budgeting. The costing need to be made based on the realistic market for the listed items, with an adequate time and man power allocated. As much as possible the REA plan need to be integrated into the initial research proposal development. As part of wider use the model of implementation where REA is an integral part of the research project is to be further pursued. There is a need to further document resource feasibility of REA with a cost-benefit analysis. c) For wider implementation, documented guidelines in applying REA need to be developed. In preparation for wide scale application continue working on awareness and capacity building of various stakeholders at institutional and policy levels.

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Annex G. 2 Copy of Ethical Clearance

Addis Ababa University Medical Faculty Institutional Review Board	SOPs AAUMF 008 Version 2.0 Effective date: 1 Feb. 2009 Page 13 of 13
Title: 3.2. Use of Study Assessment Form	

ANNEX 3
Form AAUMF 03-008

IRB's Decision

Meeting No: 032/2011 Date (D/M/Y): February 09/2011
Protocol number: 002/11/SPH. Assigned No.....

Protocol Title: Adoption of Rapid ethical appraisal as a practical method for assessing ethical issues relating to biomedical research project in Ethiopia.	
Principal Investigators:	Dr. Adamu Addissie
Institute:	AAU- MF School of Public Health
Elements Reviewed (AAUMF 01-008) :	☑ Attached ☐ Not attached
Review of Revised Application ☐ Yes ☐ No	Date of Previous review:
Decision of the meeting:	☑ **Approved** ☐ Approved with Recommendation ☐ Resubmission ☐ Disapproved

I. Elements approved- 1. Protocol Version No. .....
2. Protocol Version Date.....
3. Informed consent Version No. .....
4. Informed Consent Version Date .....

II. Obligations of the PI-
1. Should comply with the standard international & national scientific and ethical guidelines
2. All amendments and changes made in protocol and consent form needs IRB approval
3. The PI should report SAE within 10 days of the event
4. End of the study, including manuscripts and thesis works should be reported to the IRB

III. **TO ESTM** ☐

Institution Review Board (IRB) Approval: Period from **24/02/2011** to **23/02/2013**

Follow up report expected in
3 Months ___ 6 months ✓ 9 months_____ one year____

Chairperson, IRB
Prof. Yeweyenhareg Feleke
Signature _____
Date: 24/02/11

P.H.R.O. AAU. F.M.H.S. Institutional Review Board Office (IRB) Faculty of Medicine ADDIS ABABA UNIVERSITY

Associate Dean for Postgraduate and Research
Signature _____
Date _____

Annex G. 3. Copy of Wellcome Trust Award Letter

wellcome trust

Private and Confidential

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E-mail: p.woodgate@wellcome.ac.uk

Your Ref:
Our Ref: 089769/Z/09/Z

Wednesday 9 September 2009

Dear Professor Newport

I am writing to let you know that the Trust has agreed to provide Dr Adamu Addissie a Wellcome Trust Three Year PhD Studentship in Biomedical Ethics, under your sponsorship.

A grant of up to £96,939 has been awarded to University of Sussex for this purpose.

The grant has been given a notional start date of 01/10/09 and is intended to provide support as follows:

RING-FENCED FUNDS:	Total
STUDENT Dr Adamu Addissie (three months per annum in UK)	14,749
STUDENT Dr Adamu Addissie (nine months per annum in Ethiopia)	12,728
FEES FOR STUDENT BSMS overseas fees for three years	38,448
Sub Total	**£65,921**

TRANSFERABLE FUNDS:	Total
TRAVEL TO MEETINGS	1,500
EQUIPMENT Development of database	1,500

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