Indiana University-Moi University Academic Research Ethics Partnership

Teaching Skills in International Research Ethics
TaSkR
April 19, 2009 – April 21, 2009
Indianapolis, Indiana

Description of TaSkR Sessions

Support this workshop is provided by grant #R25TW006070 from the Fogarty International Center at the National Institutes of Health.

Overview of TaSkR

This workshop is designed to enable participants to learn pedagogical methods and acquire skills for teaching international research ethics. The workshop is organized around three categories of topics: foundations, applied issues, and case studies. Each presentation will use a pedagogical method appropriate for teaching the topic (not all presentations will be lectures) so the workshop participants can learn through example. We will also hold moderated discussions of pedagogy, "teachable moments," to reflect upon the methods used by the presenters and share ideas for other appropriate pedagogical methods, syllabi preparation, and course development.

Sunday, April 19, 2009

Keynote Address: Introduction to International Research Ethics
James V. Lavery, Ph.D. (University of Toronto)

This keynote will define "International Research Ethics", the historical background against which current concerns for international research ethics have emerged, and key ethical issues underlying the conduct of international health research.

Monday, April 20, 2009

Foundations:

1. **Ethical foundations of international health research**
   Jeremy Sugarman, M.D., M.P.H., M.A. (Johns Hopkins)

   This session focuses on the ethical foundations of international health research. On careful examination, the ethical foundations for research with human subjects largely cohere with common understandings of morality. The foundational ethical principles of research (respect for persons, beneficence, and justice) find application in research

practice, providing three pillars of protection: 1) investigators and sponsors, 2) informed consent, and 3) oversight. Ethical issues that have animated considerable debate in international research are related to each of these pillars. For example, while investigators and sponsors are responsible for ensuring the sound scientific design of research, there have been marked disagreements over the selection of control arms including the use of placebos. Although some of these issues can be resolved using standard principles of research ethics it may be that a broader conceptual model is needed to better understand the issues at hand.

2. **National and international guidelines for the ethical conduct of research**
Kenneth Goodman, Ph.D. (University of Miami)

The navigation of multiple regulatory requirements in international research poses an array of challenges:

1. How do the various guidelines differ?
2. How should and can these differences be addressed?
3. If universal values, including those respecting human rights, underlie the regulations, *why* do the regulations differ?

This presentation will review leading guidelines and kinds of guidelines, give examples of their varying scope and force and address the challenges just enumerated. Fortunately, ethically optimized research will tend to comport with most such laws and guidelines, and differences can generally be managed in a straightforward manner. The greatest burden is in many respects the result of the guidelines' regulatory and compliance functions. Even if, for instance, there is widespread accord on the importance of valid consent, different jurisdictions have varying requirements for *documenting* that subjects have provided valid consent. The obligations to improve the health of populations and reduce health disparities must be met in an environment shaped by well-motivated but sometimes (apparently) burdensome regulatory requirements. Investigators must, in the current parlance, just deal with it.

3. **Ethical considerations and the cultural contexts of research.**
Eunice Kamaara, Ph.D. (Moi University and Indiana University)

While there are global international research ethical issues, it is specific socio-cultural contexts that give meaning to and allow practical application of global ethics. Hence it may be reasonable to refer to 'international research ethics' even though the term raises ethical concerns about who "defines" the prevailing ethical stance (values and principles), for whom, and at whose expense. This session opens a forum for sharing thinking about ethical considerations in research design and practice in view of socio-cultural contexts of the community under study. The study underscores the importance of multi-disciplinary and anti disciplinarily approaches in view of the breadth of relevant cultural considerations ; social; religious; political; economic; ethnic; linguistic; legal; gender etc. Emphasis is put not only on differences but also on the dynamic nature of socio-cultural contexts of research which make them differ not only spatially but also in time and situation. This implies the need to be flexible, critical, creative and

attentive in order to learn and unlearn for adaptation of research ethics to specific socio-cultural contexts. Using a combination of various teaching methods, the session leader discusses the art and science of critically identifying, analyzing and responding ethically to issues in specific research contexts.

Lunch Session:

The ten most important things to know about research ethics
Kenneth D. Pimple, Ph.D. (Indiana University)

Laws, regulations, policies, and rules regarding research ethics, research with human subjects, the responsible conduct of research, etc., abound. No newcomer to the field should feel embarrassed or intimidated by the mountains of advice and guidance he or she encounters. Many of these laws (etc.) are intricate, subtle, convoluted, minutely specific, and bewildering, even when they are necessary and useful. This presentation will show that the core issues in research ethics are not complicated, alien, or, with one exception, applicable only to research. The ten most important things to know about research ethics include rules (or commandments) and advice. They provide a solid foundation for understanding and critiquing the import of laws (etc.) as well as a helpful guide to research behavior. The ten things to know are:

1. Be honest.
2. Be fair.
3. Do no harm.
4. Do good research.
5. Know and follow the rules.
6. Bad rules should be changed, not broken.
7. Be a good citizen.
8. When in doubt, ask questions.
9. Listen to the still, small voice of your conscience, especially when it is threatened to be overwhelmed by the loud, insistent voice of stress.
10. If you suspect unethical behavior, proceed cautiously.

Applied Issues in International Research Ethics:

4. **Informed consent: theory and practice in international collaborative research**
Elizabeth Heitman, Ph.D. (Vanderbilt University)

The 2002 CIOMS *International Ethical Guidelines for Biomedical Research Involving Human Subjects* defines twenty-six specific points of information that the investigator must provide to a potential research subject before asking him or her to participate in a research project. The information must be in language or other form of communication that the individual can understand and his or her consent must be documented. CIOMS' Guidelines and other similar documents also recommend that investigators consider cultural factors important to the study population in the provision of information and the method of requesting consent. After an overview of CIOMS' 26 required points of information by the presenter, participants in this session will engage in role playing different scenarios where the nature and the complexity of the protocol,

and the language, literacy, scientific understanding, and self-perception of the target research population pose challenges to informed consent process.

5. **Review and approval of international research: The role of IRBs and Ethics Review Committees**
   Duncan Ngare, DrPH. (Moi University)

   This presentation critically analyzes the merits and limitations of IRBs/Ethics Review committees in developing country settings, as well as their role in the development of international collaborative partnerships. This will begin with a historical look at the history and goals of these committees and will examine their function in international research.

6. **Responsible conduct of research: The case of authorship**
   Kimberly A. Quaid, Ph.D. (Indiana University)

   The publication of research results in respected scientific journal accomplishes several goals. In addition to adding to the body of new scientific findings, it allows the evaluation of results and places them in the context of the larger body of scientific knowledge. Published work also credits the contributions and ideas of other scientists whose previous work has been built upon in the current research. It allows other researchers to expand and to contribute further by providing accurate descriptions of the experiments performed and the methods used. Finally, the list of authors attributes credit for the research and establishes who accepts responsibility for the accuracy and integrity of the work. The issue of what merits authorship on a scientific paper is a matter of great importance and some contention within the scientific community. In this session we will discuss the requirements of authorship and the proper ways to acknowledge those who may have contributed to the research in some way, but whose contributions do not reach a level justifying authorship.

Tuesday, April 21, 2009

Case Studies

The Case Studies are designed to allow workshop participants to delve into a more detailed examination of ethical issues in international research. Participants will sign up for two of the four sessions when they register for the meeting.

- **The use of traditional/complementary and alternative medicine in the management of HIV/AIDS in Western Kenya**

  Eunice Kamaara, PhD (Moi University and Indiana University)
  Thomas S. Inui, M.D. (Regenstrief Institute, Indiana University)

  This session will be conducted as a roundtable forum for exploring fundamental ethical issues embedded in an emerging community-based, community-participatory research initiative in Western Kenya. Discussants will learn and teach at the same time as they

uncover ethical issues in the case under study: The use of traditional healing practices as co-therapies for HIV in AMPATH patients. Discussants are asked to prepare for their participation in this session by prior reading of the brief research abstract of proposed research. Ideal preparation would also entail reading of the report of pilot work. This session should illuminate the importance and limitation of applied case studies in teaching international ethics. The group may also discuss the advantages of a holistic approach to teaching and learning international research ethics, as opposed to specific disciplinary approaches. The "holistic approach" calls for critical review of research from conception through design, implementation and reporting. This approach requires open-mindedness, flexibility, and willingness to listen, learn, unlearn and adapt to different research contexts. You'll have come to the session to discover what we mean by this assertion!

- **Pediatric assent for a study of antiretroviral therapy dosing: A case study examining assent and consent for vulnerable populations within an international research collaboration**

  Winstone M. Nyandiko, MBChB, MMED (Moi University)
  Rachel Vreeman, M.D., M.S. (Indiana University)

  Multinational collaborators in health research face particular ethical challenges when conducting studies involving vulnerable populations such as children. We will use an example from our first attempt to implement pediatric assent in the AMPATH partnership to highlight the ethical and procedural issues related to pediatric assent that must be considered for multinational, pediatric studies.

  Participants in this session will consider the case of a study assessing the pharmacokinetics or metabolism of an antiretroviral medication for HIV-infected children in western Kenya. The study procedures required the children to be hospitalized overnight and to have multiple blood samples drawn. The investigators and ethics review boards wrestled with whether to implement pediatric assent and how assent might be obtained.

  We will consider relevant domestic, professional, and international guidelines for assent and consent in pediatric research subjects, and we will discuss the particular ethical challenges related to pediatric assent in the Kenyan context. Session participants will learn how contextual issues related to the view of children and the role of children in Kenyan society impact the ethics assessment. Moreover, session participants will consider the approaches and methods that could be used to teach a case related to pediatric research and pediatric assent and consent.

- **Early access of MK-0518 in combination with an optimized background antiretroviral therapy (OBT) in highly treatment experienced HIV-infected patient with limited to no treatment options**

  Alan Breier, M.D. (Indiana University)
  Edwin Were, MBChB, MMED, MPH (Moi University)

  In this case study, Moi-IRB approval was sought for a research whose main objective was to document adverse experiences while taking a drug, MK-0518 (an integrase inhibitor), offered in combination with optimized background therapy. The choice of drugs for OBT was recommended to be based on genotypic and phenotypic resistance testing. This drug was to be offered to patients who had limited or no treatment options by reason of resistance to available ARVs. While preliminary studies had shown that the drug safety profile similar to other ARVs in use, it was infrequently associated with a few severe and potentially fatal adverse experiences. Extensive laboratory monitoring was required for safety monitoring while on the drug. The sponsor, per the protocol, undertook to provide free study drug for up to 3 months after FDA registration of the drug and study related injury compensation as provided for in the study insurance. The sponsor did not undertake to provide any further support.

  This study was to be implemented in Academic Model Providing Access to Health Care (AMPATH) – Moi teaching Hospital and Moi University Eldoret which though a large HIV care institution, had no access to routine viral load tests and had absolutely no capacity for resistance testing of any sort. Patient's ARV management is monitored by use of CD4 cell estimations.

  Drs Breier and Were will use this case study to explore appropriate methodologies for facilitating learning about key ethical principles of international research including fair benefits and standard of care.

- **Biobanks/Health Information Technology**

  William Tierney, M.D. (Indiana University)
  Martin Were, M.D., M.S. (Indiana University)

  In 2001, Indiana University School of Medicine (Indianapolis, USA) and Moi University School of Medicine (Eldoret, Kenya) created one of the first electronic health record systems in sub-Saharan Africa. This system now contains records for over 98,000 patients who have made more than 350,000 primary-care clinic visits. The system has also evolved into the AMPATH Medical Record System which currently stores records for over 90,000 HIV-positive patients enrolled in the AMPATH Program. Data in the electronic records are used for clinical care, practice management, retrospective epidemiological research, and for recruiting patients into prospective research studies. This workshop will explore ethical issues surrounding implementation and use of electronic health records in resource-limited settings.

Finding what you need? Access to information resources
Jere Odell, MA, MLS (Indiana University)

This session reviews information resources (and search strategies for finding them) for international research ethics education and research. An anticipation of potential barriers to access and an exploration of what possible solutions follow this brief review: what are the information needs and what can we do to satisfy them?

Evaluation of the Workshop
Daphne Muzoora, MBChB, MA, MS (Indiana University)

Because this is the first of eight planned TaSKR workshops, we would like to take the opportunity to get feedback and suggestions from the participants in a discussion format. This will not replace written evaluations, but is intended to help us plan for the next TaSkR to find out if our goals were met, if the participants felt this was helpful, and solicit other suggestions for topics, methods, or other areas of improvement for the next TaSKR.

Plan for the next TaSkR
Duncan Ngare, DrPH (Moi University)

The next TaSkR workshop will be held at Moi University in February of 2010. Duncan Ngare will take a few moments to describe his plans for this workshop.

Closing Remarks
Eric Meslin, Ph.D (Indiana University)