KNOWLEDGE AND ATTITUDES OF THE EMIRATI GENERAL PUBLIC TOWARDS BIOBANKING FOR GENOMIC RESEARCH: POLICY IMPLICATIONS

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Abstract

The successful launch, sustainable operations and broad applicability of population-based biobank research relies primarily on public trust, engagement and widespread voluntary participation. In Abu Dhabi, UAE, there were no existing emirate-wide data on the Emirati general public's views regarding establishing a population-based biobank for future genomic research. There were also, no data on their understanding of the benefits, risks and implications of donating biosamples and health information for a biobank for future genomic and other biomedical research.

Study Aims: This study aims to establish the first emirate-wide data regarding the Emirati general public's knowledge and attitudes towards biobanking for genomic research, assess their willingness to participate in a proposed population-based biobank for future genomic research, and explore factors associated with their willingness to participate.

Methods: This study was a cross-sectional, Emirate-wide study in which data were collected through telephone interviews, using a structured survey questionnaire. Eligible participants were adult Emirati volunteers drawn at random from a list of individuals who underwent *Weqaya* screening, as prospective participants of the future biobank project. The sample was equally balanced by gender. The study was conducted over 11 months, from April, 2015 to March, 2016. Quantitative statistical analysis was conducted using Stata Statistical Data Analysis software version 11.2. Basic descriptive summary statistics was performed to address research objectives. Univariate and multivariate analysis were conducted to explore the association between the independent variables and willingness to participate in a population based biobank.

Results: A total of 603 telephone interviews were conducted, 313 males and 290 females. The vast majority of the survey respondents had a positive attitudes about biomedical research, donation of biosamples for research and the potential value of the biobank, as well as had trust in the Health Authority-Abu Dhabi, the custodian of the biobank. However, only a few had good knowledge on biomedical research, genomics or were familiar with biobanking. In addition, there was limited understanding of the potential risks of biobanking for future research and some reported important misconceptions about its potential benefits. The overall probability of those definitely willing to participate in the proposed biobank was 76.6%, 80.8% for males and 71.0% for females, (P=0.005). After adjusting for other covariates, the independent factors associated with willingness to participate in the biobank were: being a male (OR=1.52; 95%CI: 0.96 to 2.39, P=0.07), having good knowledge on biomedical research (OR=10.4; 95%CI: 1.11 to 97.8, P=0.04), perceived altruistic benefits such as 'improve health of future generation' (OR=2.17; 95%CI: 1.44 to 3.63, P<0.001) or 'support medical research' (OR=2.11; 95%CI: 1.36 to 3.46, P=0.001), positive attitudes towards the potential value of the biobank (OR= 2.62; 95%CI: 1.27 to 5.39, P=0.009), definitely accept recontact (OR=3.25; 95%CI: 2.03 to 5.19, P<0.001), definitely desire to receive feedback on individual genomic research results (OR=3.16; 95%CI: 1.84 to 5.54, P<0.001) and family influence on participation (OR=3.19; 95%CI: 1.84 to 5.53, P<0.001).

Conclusions and recommendations: Comparable with findings from other countries, including other Arabs, the Emirati general public were positive about biomedical research and optimistic about the potential value of the biobank, however they had limited knowledge on biomedical research and the concept of biobanking for future genomic research. Exceptionally, the Emirati general public were very

enthusiastic about participation in the biobank, had high trust in the government, tolerated future recontact and had high expectation for returning individual genomic research results. Overall, factors associated with public's willingness to participate in a population-based biobank were context specific and varied across populations. To ensure informed participation and active engagement in the biobank, this study's conclusions support the following recommendation: (i) ensuring ongoing public consultation and empowerment; (ii) developing tailored information and educational resources and (iii) strengthening medical research regulations and establishing a governance framework and structure for biobanks. Future follow-up studies are recommended, to explore the Emirati general public's views on other important areas not addressed in this study, evaluate actual participation after implementation of the biobank project and assess and enhance health and research literacy, to improve trust and overall experience with healthcare system.

Keywords: Population-based biobank; public engagement; participation; willingness to participate; biomedical research; biobanking; knowledge; attitudes; recontact; return of results; health information and communication; Middle-East; Arab; UAE.

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Dedication

This thesis is dedicated to my parents, who have raised me and my brothers in an environment of love and care, taught us to continuously seek higher education and be responsible and giving individuals; my loving husband Raed and my lovely and beautiful princesses, my daughters Jawahara, Razan, Sabah, Dana and Alia, for their understanding and continuous encouragement; my brothers and sister, for their moral support and encouragement, and last but not least, the soul of my mother in-law for her the care and support she gave me and my family.

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List of Abbreviations

AAHRPP	Association for the Accreditation of Human Research Protection Programs
BBRI-ERIC	Biobanking and Bimolecular Resources Research-Infrastructure-European Research Infrastructure Consortium
BRC	Biological Resource Center
CAG	Community Advisory Group
CAP	College of American Pathologists
CIOMS	Council for International Organizations of Medical Sciences
CLIA	Clinical Laboratory Improvement Amendments
CoE	Council of Europe
DHWA	Department of Health Western Australia
EC	European Commission
ELSI	Ethical, Legal and Social Implications
HAAD	Health Authority -Abu Dhabi
HGRD	Human Genetic Research Database
HUGO	Human Genome Organization
IARC	International Agency for Research on Cancer
ICH-GCP	International Conference on Harmonization for Good Clinical Practice
IFs	Incidental Findings
IRB	Institutional Review Board
IRRs	Individual Research Results
ISBER	International Society for Biological and Environmental Repositories
NCDs	Non-Communicable Diseases
NCI	National Cancer Institute
OECD	Organization for Economic Co-operation and Development
OHRP	Office of Human Research Protections

P^3G	Public Population Project in Genetics
RAND	RAND Science and Technology
REC	Research Ethics Committee
SCAD	Statistic Centre Abu Dhabi
SMS	Short Message Service
SOPs	Standard Operating Procedures
UNESCO	United Nations Educational, Scientific and Cultural Organization
WHO	World Health Organization
WMA	World Medical Association

Chapter 1: Introduction

1.1 Context

The United Arab Emirates (UAE), is a Middle Eastern country in Western Asia, located in the southeastern corner of the Arabian Peninsula on the Arabian Gulf, between Oman and Saudi Arabia. It is a federation of seven independent emirates, established in 1971. The UAE Government works at three levels- federal, emirate and municipal. The UAE political system is mix of the traditional and modern political systems that has brought political stability, security and supported the socioeconomic development of the country. The UAE economy is the most diversified in the Arabian Gulf Region, however relied heavily on oil (UAEinteract, n.d.). Since the discovery of oil more than 50 years ago, the UAE underwent major transformation and development and it has become a modern state with a high standard of living (Central Intelligence Agency [CIA], 2016). It is classified as a high income country by the World Bank based on its economic development. The GDP in price market in 2014 was $ 339.5 billion (US 2014 Dollars) (The World Bank, 2016; UN Data, 2016). The per capita GDP in 2014 was $ 66,300, ranking, the UAE as 13 out of the 230 countries in terms of per capita income. The UAE is a high influx country with labor migration from more than 202 nationalities, with a total population of over 9.4 million, according to mid-year 2014. Islam is the official state religion and Arabic is the national language (CIA, 2016; UAEinteract, n.d.; UN Data, 2016)

The emirate of Abu Dhabi is the largest in terms of area (67,340 km^2), accounting for 87% of total land area of the UAE, and has the largest population. According to mid-year 2014 estimates, the population of Abu Dhabi was 2.65 million. Emiratis constitute less than one-fifth (19.1%) of the total population of Abu Dhabi.

The Emirati population is relatively young: 39.1% of the population are below 15 years, 58.5% between 15-64 years and only 2.1% are above 65 years. The gender distribution is fairly balanced, male to female ratio is 1:1.06 (51.5% of total population were males and 48.5% were females). The emirate is divided into three Municipal Regions: Abu Dhabi Central Capital District Region; Al Ain (Eastern) Region and Al Gharbia (Western) Region, Figure 1-1. Almost half of Abu Dhabi Emirati population, 51.6%, lives in Abu Dhabi Central Capital District Region, 42.5% in the Eastern region and a small percentage (5.8%) in the Western region. Urban to rural distribution of the population is 1.5. According to the report, the overall literacy rate among Emiratis was 94.7%, 96.6% in males and 92.6% in females. The life expectancy at birth for males was 75.2 years and for females was 78.7 years (Statistic Centre Abu Dhabi [SCAD], 2016).

Figure 1-1: Abu Dhabi Emirate Regions

(Source: UAEinteract, n.d.)

In the emirate of Abu Dhabi, non-communicable diseases (NCDs), also commonly referred to as chronic diseases, are the leading causes of mortality and morbidity. The major NCDs, comprised of cardiovascular diseases, diabetes, cancer and chronic respiratory diseases, accounted for more than 56.6% of all deaths in 2015. Cardiovascular disease was responsible for 35% of all deaths, followed by cancer at 13.5%, respiratory disease at 5.1%, and endocrine, nutrient and metabolic diseases at 3%. Deaths due to major NCDs have been steadily increasing, and NCDs remain the leading cause of mortality in the emirate (Health Authority-Abu Dhabi [HAAD], 2016a). Globally, it has been forecasted that with an ageing population, and with the epidemiological shift away from communicable diseases, deaths from NCDs will continue to rise. As such, NCDs are a major public health threat, and may hinder the social and economic development of many countries. Innovative and comprehensive solutions for control and prevention of NCDs are needed (Bloom et al., 2011; World Health Organization [WHO], 2013).

The emirate also has high prevalence of risk factors for cardiovascular diseases, including obesity, hypercholesterolemia and diabetes. Data from the *Weqaya* screening program revealed high rates of cardiovascular diseases risk factors in the Emirati population (Hajat, Harrison, & Shather, 2012). The *Weqaya* screening program in its first cycle between 2008 and 2010, screened 94% of the adult Emirati population. The results showed that more than two-thirds of Emirati adult population (71%) had at least one cardiovascular disease risk factor, 67% were either overweight or obese, 19.3% had hypercholesterolemia, 18% were diabetic, and a further 27% had evidence of pre-diabetes (Hajat, Harrison, & Shather, 2012).

Weqaya in Arabic means prevention. *Weqaya* in this context, is a unique screening program that was launched in 2008 in the emirate of Abu Dhabi. It is a population-based screening program for cardiovascular diseases and its risk factors, targeting adult Emiratis of 18 years and above. It includes completing a health and lifestyle questionnaire, anthropometric measurements, clinical examination and collecting blood samples. The screening program is currently provided in more than 60 public and private healthcare facilities distributed across the emirate, in addition to three mobile clinics.

HAAD is the regulatory body of the healthcare sector in the emirate of Abu Dhabi, and reports at the federal level to the UAE Ministry of Health and the National Health Council. It was established in 2007, with the mission to regulate and develop the healthcare sector and to protect the health of individuals. HAAD's main roles are to define the strategy for the health sector, shape the regulatory framework, inspect against regulations, set premiums and reimbursement rates, and monitor the performance of the health care system. In addition, HAAD monitors and analyzes the health status of the population, and drives public health programs (HAAD, 2016b).

Healthcare services in the emirate are provided by both public and private providers. *SEHA*, Arabic word for ‘health’, is the main public provider. It manages most of public healthcare facilities in partnerships with prominent international operators. UAE nationals are covered by *Thiqa* health insurance plan, which provides 'free at the point of care' access to care in both public and privates providers. *Thiqa* is the Arabic word for 'trust' and it is the single-payor health insurance plan for UAE nationals. Expatriates were granted access to healthcare, through mandatory health insurance, introduced in 2006 (HAAD, 2016a).

In 2015, HAAD published a five-year strategy to improve the healthcare sector in the emirate of Abu Dhabi. The new strategy has identified seven strategic priorities and 52 new initiatives. One of key priorities was 'Wellness and Prevention', and to address this priority, activations such as public health community initiatives to enhance community wellness and awareness, and establishing a population-based biobank for genomic research on major chronic diseases were undertaken (HAAD, 2016b). The biobank initiative is based on best practices, and is scheduled to be established 2016-2017. The purpose of the biobank is to provide a resource that supports a diverse range of genomic and biomedical research intended to improve the health and wellness of the Emirati population, as well as to demonstrate its potential to pilot personalized medicine.

The proposed plan for the Abu Dhabi population-based biobank project is to link it to the existing *Weqaya* screening program. Abu Dhabi biobank will be managed by a healthcare provider. Blood samples collected during the screening visit which would otherwise have been discarded, will instead be retained and matched with the detailed behavioral, lifestyle and health information collected via a questionnaire, and deposited in the biobank. All Emirati adults 18 years and above in the emirate of Abu Dhabi will be invited to participate in the population-based biobank research. The target is to recruit 100,000 Emirati adult individuals. Participation in the biobank will be completely voluntary, and samples and health information to be included in the biobank will be deposited only with the participants' permission. Participants also have the option to withdraw the same from the biobank at any time in the future without giving any reason. The biobank will prospectively collect and store biosamples, and update related data every three years, according to the regular *Weqaya* screening cycle.

1.2 Population-based Biobanks

Since the late 1990's, several countries have established population-based biobanks to study the health of population, with particular focus on complex chronic diseases (Rudan, Marusic, & Campbell, 2011). Biobanks are biorepositories that store human biological samples such as, cells, tissues, blood or DNA, as well as related health information for use in genomic and other types of biomedical research (Holzinger & Jurisica, 2014). Population-based biobanks are key resources for a wide range of epidemiological research. The knowledge gained from the contributed biosamples and health information will help understand the gene-behavior contributions to disease risk and health, and develop improved strategies for the prevention, diagnosis and treatment of major chronic diseases and health traits (Knoppers, Zawati, & Kirby, 2012). Such improvements may eventually lead to more precise, individually stratified health care, the so called 'personalized medicine' (Harris et al., 2012; Hewitt & Watson, 2013) .

Population-based biobanks are unique resources, and as such, highly complex in their operations. Since their implementation, a significant number of ethical, legal, and social concerns have been raised among professionals and the public regarding the same (Budin-Ljøsne et al., 2012; Master, Campo-Engelstein, & Caulfield, 2015). Major ethical concerns were related to informed consent, i.e., ensuring that research participants are adequately informed about the risks and benefits of biobank research, especially in the context of long-term storage of biosamples and data, and the uncertainty of future possible multiple uses of biosamples and data in various research (Rahm, Wrenn, Carroll, & Feigelson, 2013). In addition were concerns related to privacy and confidentiality protection. Biobanks collect and store huge quantities of phenotype and genotype data of many individuals, and this may pose information

risks, including loss of privacy, breach of confidentiality and misuse of data – discrimination by a third party such as insurer, employer or others (Fisher & Harrington McCarthy, 2013). Other commonly reported concerns were related to managing and returning individual genomic research findings: when, who and how to return the results (Appelbaum et al., 2014; Bledsoe et al., 2012). There are also concerns about the commercialization of the biobank resources, ownership of data and biosamples, as well as about benefits sharing (Budimir et al., 2011).

Furthermore, the success of biobanks is dependent on public engagement and participation (Critchley, Nicol, Otlowski, & Stranger, 2012; Husedzinovic, Ose, Schickhardt, Frohling, & Winkler, 2015; Nobile, Vermeulen, Thys, Bergmann, & Borry, 2013; Porteri et al., 2014; Watson et al., 2014). Significant social challenges related to population-based biobanks include public engagement and participation, particularly in terms of ensuring informed decision about participation and active engagement in biobank governance structure development (Silverman et al., 2015; Silverman et al., 2013). Several studies show that community consultation and empowerment are believed to be critical in order to increase public trust and wider participation in biobank research, thereby ensuring success, sustainability (McWhirter et al., 2014; Critchley et al., 2012) and broad applicability of population-based biobank research (Marko-Varga et al., 2014; Olson et al., 2014). Moreover, active engagement of participants and the general public in biobank governance framework and structure could help in reaching consensus on endless debates about major ethical, legal and social implications of biobank research (O'Doherty et al., 2011; O'Doherty, Hawkins, & Burgess, 2012), It would also ensure biobank research is conducted in an ethical, locally appropriate manner that respects specific population interests and preferences (Lemke et al., 2010; O'Doherty et al., 2011; O'Doherty et al., 2012).

Population-based biobank is a relatively new concept (Hewitt & Watson, 2013). Most of the experience in the field of national or population-based biobanks comes from Europe (European Commission [EC], 2012). Experience in biomedical research from Arab countries in the Middle-East region is scarce, but growing (Alahmad, Al-Jumah, & Dierickx, 2012; Silverman et al., 2015; Silverman, Edwards, Shamoo, & Matar, 2013). Population-based biobanks were recently introduced in the region by Qatar and Kingdom of Saudi Arabia (Al Kuwari et al., 2015; Alahmad & Dierickx, 2014).

International literature on population-based biobanks is generally limited (Wells et al., 2014). Published studies from Europe and North America found that the general public was not familiar with the biobank, nor the science and technology behind it (Department of Health Western Australia [DHWA], 2010; EC, 2012; Gaskell et al., 2013; Simon et al., 2011). Little was known about their support or concerns on the establishment of population-based biobanks for research (Gaskell et al., 2013).

In general, literature on medical research from the Middle East in general is very scarce. There is a significant gap in knowledge on the general publics' knowledge and attitudes towards participation in a biobank for genomic and other biomedical research. Studies published in Jordan, Egypt, and Saudi Arabia have explored patients' knowledge and opinions regarding biomedical research or disease-specific biobanks (Abou-Zeid et al., 2010; Ahram et al., 2014; Al-Hussaini & Abu-Hmaidan, 2014; Al-Jumah et al., 2011). One national survey in Jordan and another study on biobank participants in Qatar have evaluated the perception of the general public about biobanking and explored factors influencing participation in a

population-based biobank research (Ahram, Othman, & Shahrouri, 2012; 2013; Ahram, Othman, Shahrouri, & Mustafa, 2013; Nasrella & Clark, 2012).

Overall, published studies- international as well as regional- show great variation in the intention to participate in a population-based biobanks across populations and subgroups within the same population. There is also variation in the factors influencing their intention to participate (Ahram et al., 2013; Banks, Herbert, Mather, Rogers, & Jorm, 2012; Critchley et al., 2012; Ridgeway et al., 2013; Sanderson et al., 2013; Tauali et al., 2014; Tupasela et al., 2010). These factors needed to be explored in Abu Dhabi, UAE, in order to ensure higher, wider participation and longer-term engagement of the Emirati general public in the proposed project.

1.3 Problem Statement

There is a growing interest world-wide, as well as in the UAE, to establish a population-based biobank to study and improve the population's health and wellness. The successful launch, sustainable operations and broad applicability of population-based biobank research relies primarily on public trust, active engagement and widespread voluntary participation. In Abu Dhabi, UAE, there were no existing emirate-wide data on the Emirati general public's views, support or concerns regarding establishing a population-based biobank for future genomic research. There were also, no data on their understanding of the benefits, risks and implications of donating biosamples and health information for a biobank for future genomic and other biomedical research.

1.4 Research Significance

This study is the first of its kind in the UAE, and it intends to fill the gaps in knowledge regarding the Emirati general public's views on establishing a population-based biobank for future genomic and other biomedical research, as well as their understanding of the risks, benefits and implications of donating biosamples and health information data to a biobank for future research. It will add to the existing regional and international literature on factors associated with the general public's decision regarding participation in a population-based biobank for future research.

As a novel initiative to be introduced in the UAE and the greater Arab world, it is imperative that we fully understand how best to launch this new initiative, while protecting the interests of the Emirati population of Abu Dhabi. This study can be considered as a first step towards a deliberative community consultation and engagement. It will be used to shape the development of regulations and policies for which a thorough understanding of local context and expectations is essential. It will also support the development of tailored, meaningful and culturally appropriate information resources and communication strategies to improve health and research literacy, while ensuring higher, wider and longer-term public engagement and participation.

1.5 Study Aims and Objectives

1.5.1 Study aims

This study aims to establish the first emirate-wide data regarding the Emirati general public's knowledge and attitudes towards biobanking for genomic research, assess their willingness to participate in a proposed population-based biobank for future genomic research, and explore factors associated with their willingness to participate.

1.5.2 **Study objectives**

To elaborate on the study aims, the following study objectives were included:

1. Assess the Emirati general public's knowledge and attitudes towards biobanking for future genomic and other biomedical research.
2. Explore the Emirati general public's perception of the benefits and risks of biobanking for future research.
3. Assess the Emirati general public's views regarding future recontact and return of biobank research findings, both general aggregate and individual genomic.
4. Estimate the overall probability, at population level, of the Emirati general public's willingness to participate in a proposed population-based biobank and explore gender differences.
5. Identify factors associated with the Emirati general public's willingness to participate in the proposed biobank.
6. Explore the Emirati general public's preferences for various health information and communication channels.

Chapter 2: Literature Review

The databases of PubMed, Web of Science, Scopus and Google were searched using a combination of key words or concepts described in Appendix I. The search was conducted between 15 December 2015 and 31 January 2016. Studies included were those from January 2010 onward, written in English language, have the key words of search in the title or abstract and were full articles. Articles related to disease-oriented biobanks, or on patients' prospective, including minors, were excluded. The review also included important reports, guidelines, book sections and a couple of key biobank studies, older than 2010.

Most of the literature was from North America and Europe, and a few were from Australia, Asia, Africa and the Middle East. The literature from the Middle East was expanded to capture medical research in general as well as biobanking. Most of the international literature on biobanks focus on governance challenges, the ethical, legal and social implications (ELSI) of biobanks.

The literature review summarizes the main aspects related to population-based biobanks. It describes definitions and types of biobanks, purposes of population-based biobanks, biobank set up requirements as well as governance framework and structure. It also covers the ELSI challenges, and strategies for effective and innovative governance. In addition, it provides some examples of existing national and large-scale population-based biobanks in selected countries, including experiences from Arab countries in the Middle East.

2.1 History of Biobanking

The collection of samples and data for research and cohorts studies have been part of educational and medical practice for several years (EC, 2012; Harris et al., 2012; Lee et al., 2012; Li, Guo, Chen, Chen, & Peto, 2012). What is exceptional and novel about biobanks is the large-scale collections of various human biological samples for a wide range of research on various diseases. The creation of large-scale infrastructures or 'industrial size' biobanks have been encouraged by the advancement and innovation that have taken place in two sciences. Firstly, the invention and rapid developments in the field of information and robotic technologies as well as bioinformatics have supported the establishment of biobanks. Bioinformatics facilitated the systemic approach and automization in the collection, linkage and tracking of biosamples and data for diverse research purposes (EC, 2012; Prainsack & Buyx, 2013). Secondly, the advancements in genomics since the beginning of the Human Genome Project in 199, has increased the demand for a large number of high quality biosamples for research and has led to a significant increase in the number of biobanks in recent years (GBI Research, 2011; Zielhuis, 2012).

The term biobank is relatively new. This terminology was first used in the title or abstract in PubMed was in 1996, in relation to a population-based biobank research (Hewitt & Watson, 2013). Over time, other new terminology such as biorepository (International Society for Biological and Environmental Repositories [ISBER], 2001) and biological resource center (BRC) emerged (Organization of Economic Co-operation and Development [OECD], 2007). These terms refer to structured facilities that collect biosamples and relevant data for future research. It collects a wide range of human and non-human biosamples

(De Souza & Greenspan, 2013; Hewitt & Watson, 2013; Parodi, 2015). However, both biorepositories and BRCs collect biosamples from humans and non-humans such as animals, plants, microbes and even the environments, while biobanks typically collect human biosamples (Parodi, 2015). It is noticed that the term biobank is used more commonly in Europe, while the term biorepository, and is used more frequently in the United States (US). This could be because most population-based biobanks, from where the term originated, were established early and abundantly in Europe, while the US lagged behind. Disease-oriented and clinical trials biorepositories or tissue banks were most common in the US.

A directory of global biobanks can be found on specimencentral.com. Most of the existing biobanks are based in North America, mainly the US, followed by Europe; there are a very few in Asia, Australia, Africa and the Middle East. Currently, biobanks are established either within academic, medical or research institutions, pharmaceutical or biotechnology companies, or as stand-alone facilities (Parodi, 2015). They receive funding from not-for-profit organizations such as government, academia, and research bodies, profit-making entities such as pharmaceuticals and private healthcare industry, or could a combination of both (Edwards, Cadigan, Evans, & Henderson, 2014; Hewitt & Watson, 2013).

Biobanks acquire specimens in a variety of ways. The two most common ways are direct donation by individuals or patients, and residual samples from clinical settings (Henderson et al., 2013). Human biosamples collected include whole blood, peripheral blood cells, cord blood, saliva, urine, stool, bone marrow, solid tissues and pathological body fluids. The number of specimens stored could

range from less than 500 to over 50 million (Edwards et al., 2014; Henderson et al., 2013; Hewitt & Watson, 2013). A majority (60%) of the existing biobanks are small in scale, and collect and store samples from less than 100,000 donors. Only a few (10%) collect and store samples from more than one million donors (Kang et al., 2013). Biobanks receive requests from researchers affiliated with academic or research institutions, federal government, hospitals or other clinical setting, pharmaceutical and insurance companies, and health or disease advocacy organizations (Edwards et al., 2014).

2.2 Types and Definitions of Biobanks

There are various types of biobanks; the most common are population-based, disease-oriented, case-control, tissue banks, clinical trials, twin registries and virtual biobanks. Other less common ones are the cord blood, Guthrie card, stem cells, and forensic biobanks, among others (Branković, Malogajski, & MorrÃ, 2014; De Souza & Greenspan, 2013; EC, 2012; Hewitt & Watson, 2013; Parodi, 2015). As per the pan-European Biobanking and Bimolecular Resources Research Infrastructure (BBMRI), biobanks can be classified into population-based biobanks and disease-oriented biobanks (Parodi, 2015).

Population based biobanks aim to discover biomarkers for disease susceptibility within a specified population. They collect biosamples from huge numbers of healthy individuals, mainly germline-DNA isolated from venous blood, as well as comprehensive medical, physical measures and epidemiological-lifestyle and environmental- data (Holzinger & Jurisica, 2014; Parodi, 2015; Riegman et al., 2008). Under this category, Twin cohorts and Twin Registries were included (Parodi, 2015).

Disease-oriented biobanks, or clinical biobanks, aim to discover and validate biomarkers of diseases, genetic and non-genetic, through prospective and/or retrospective collections of tumor and non-tumor samples and their derivatives, such as DNA, RNA or proteins, from people affected with specific diseases. Some collect clinical data, or are sometimes associated with clinical trials (Holzinger & Jurisica, 2014; Parodi, 2015; Riegman et al., 2008). Disease-oriented biobanks may include tissue banks and rare disease biobanks. Rare diseases biobanks, also referred to as genetic biobanks, collect biosamples for diseases of low prevalence, affecting less than one citizen in 2000. Most rare diseases biobanks work through the active participation of patients and patient organizations, and share benefits with them (Parodi, 2015).

Several studies have shown that there is no standardized agreement or definition of the term biobank among biobank personnel and stakeholders. However, it is agreed that biobanks are collections of human biosamples stored for future research use (Boyer, Whipple, Cadigan, & Henderson, 2012; Edwards et al., 2014; Fransson, Rial-Sebbag, Brochhausen, & Litton, 2015; Henderson et al., 2013; Hewitt & Watson, 2013; Shaw, Elger, & Colledge, 2014). The discrepancies in defining the term 'biobank' were mainly with regards to the nature of the collections of related health information, source and number of samples collected, years of storing and types of research. This variation explains the diversity in the types of existing biobanks having different sample collection purposes and research designs. The broad definition of biobank that covers all types, was the one stated by the European Commission "*Biobanks collect biological samples and associated data for medical-scientific research and*

diagnostic purposes and organize these in a systematic way for use by others." (EC, 2012).

Various entities provided definitions for population-based biobanks. In 2006, the Organization for Economic Cooperation and Development (OECD) defined it as "*A collection of biological material and the associated data and information stored in an organized system, for a population or a large subset of a population"* (OECD, 2006). In 2009, the OCED referred to a biobank as a human genetic research database (HGRD) which is "*A structured resource that can be used for the purpose of genetic research and which include: (a) human biological materials and/or information generated from the analysis of the same; and (b) extensive associated information"* (OECD, 2009).

In 2006, the Council of Europe provided a legal definition for the biobank. Chapter 5, Article 17 of the Ministerial Recommendation on Research on Biological Materials of Human Origin, defined it as "*A collection of biological materials that has the following characteristic: i. the collection has a population basis; ii. It is established, or has been converted, to supply biological materials or data derived there from for multiple future research projects; iii. it contains biological materials and associated personal data, which may include or be linked to genealogical, medical and lifestyle data and which may be regularly updated; iv. It receives and supplies materials in an organized manner"* (Council of Europe, 2006).

Other organizations such as The Biobanking and Bimolecular Resources Research Infrastructure—European Research Infrastructure Consortium (BBRI-ERIC), the largest network of 250 established biobanks from Europe, defined the

biobanks as: "*Collections, repositories and distribution centers of all types of human biological samples, such as blood, tissues, cells or DNA and/or related data such as associated clinical and research data, as well as bimolecular resources, including model- and microorganisms that might contribute to the understanding of the physiology and diseases of humans*" (Fransson et al., 2015).

The Public Population Project in Genomics and Society (P^3G), a not-for-profit international consortium dedicated to support international collaboration between population genomics researchers, defined biobanks as "*An organized collection of human biological material and associated information stored for one or more research purposes"* (Fransson et al., 2015).

The International Society for Biological and Environmental Repositories, ISBER, a global forum that harmonizes technical, legal, and ethical issues related to repositories, defined it as *"An entity that receives, stores, processes and/or disseminates specimens, as needed. It encompasses the physical location as well as the full range of activities associated with its operation"* (Fransson et al., 2015).

The European Commission and Department of Health Western Australia summarized important characteristics of population-based biobanks. Population-based biobanks are resources, a) that collect and store human biosamples- mainly blood, saliva and urine, and related health data, that include detailed personal and family health data, environmental exposure and lifestyle data; b) are long-term projects that prospectively and continuously collect biosamples and data; c) associated with research projects in the future that may be undefined at the time of the establishment and data collection; d) provide access to researchers, other

than the custodians of the biobank, for ethically approved research purposes; e) apply coding or anonymization for sample and data to ensure that participants' privacy and confidentiality are protected, but at the same time have, under specified conditions with ethical approvals, the option to re-identify participants to share clinically relevant information; f) focus on public interest to benefit future generations rather than individual participants' benefit; and (g) include established governance structures and procedures to protect participants' rights and interests and ensure quality operations (DHWA, 2010; EC, 2012).

2.3 Purposes of Population-based Biobanks

Population-based biobanks were established in many countries to address important public health and economic development challenges such as complex chronic diseases and health traits. The aim is to improve the population's health and increase the wellbeing of future generations (Al Kuwari et al., 2015; Bravo, Napolitano, Santoro, Belardelli, & Federic, 2013; Imboden & Probst-Hensch, 2013; Kang et al., 2013; Leitsalu et al., 2015; Leitsalu, Alavere, Tammesoo, Leego, & Metspalu, 2015; Li et al., 2012; Marko-Varga, Baker, Boja, Rodriguez, & Fehniger, 2014; Pang, 2013; Rudan et al., 2011). Population-based biobanks are key resources to enhance and promote epidemiological studies, monitor diseases and other health outcomes in the population and accelerate the introduction of personalized medicine.

2.3.1 Enhance and promote epidemiology research

Until recently epidemiology, research ignored genetic variation across populations and subgroups and depended mainly on epidemiological data as well as environmental and lifestyle risk factors to understand causes of diseases

(Brand, Schulte & Probst-Hensch, 2012). The availability of data from the Human Genome Project, genome wide association study (GWAS), whole genome sequencing (WGS) and the genomic revolution shifted the focus to elucidate the role of genomics in the development of various complex diseases and response to treatment since the 1990's (Khoury, 2001cited in King & Nicolae, 2014; Lockhart, Yassin, Weil, & Compton, 2012). Most genetic diseases are caused by multiple genetic factors on multiple genes and only some diseases originated from a single defective gene (Greely, 2007 cited in Kang et al., 2013).

Epidemiology research now focuses on understanding the genetic variations of diseases (genotypes) as well as the interaction of genotype risk factors with environment and lifestyle (phenotypes) risk factors in the development of common diseases and other health outcomes (Kang et al., 2013). These studies require huge numbers of high quality biosamples collected through biobanks (Brand & Probst-Hensch, 2007; GBI Research, 2011; Zielhuis, 2012). Furthermore, it has the potential to support international collaborative studies (Harris et al., 2012; Zielhuis, 2012). The biobank of International Agency for Research on Cancer (IARC) is an example of international collaboration and collection of biosamples from across the world. It contains 5 million biological samples from 1.5 million participants (IARC, 2016).

Biobanks allow multiple uses of their resources, biosamples and data in research, and thus promote simultaneous multiple research activity. In addition, they continuously generate new knowledge and data through their research findings. Secondary data can be used in further research and may provide opportunities for new findings beyond the scope of the original research. Further,

they reduce the burden and discomfort of repeated recontact of participants for data gathering, minimizing breaches to privacy and confidentially and reducing levels of approvals required for use of secondary data (Olson et al., 2014).

2.3.2 **Strengthen epidemiological surveillance**

Until recently, biobanks and surveillance systems were considered as independent from one another (Brand et al., 2012). Surveillance by definition is *"The ongoing, systematic collection, analysis, and interpretation of health data essential to planning, implementing, and evaluating public health practice, closely integrated with the timely dissemination of these data to those who need to know"* (McGraw-Hill Concise Dictionary of Modern Medicine, 2002).

However, population-based biobanks of cohorts with prospective collection of phenotype data can efficiently serve as a useful surveillance system to quantify disease incidence, and monitor various health outcomes of a target population and subgroups of populations (Brand et al., 2012). Such data will provide decision makers with the knowledge to plan, implement and monitor public health preventive programs, as well as improve clinical care (Bravo et al., 2013)

Moreover, many of the established population biobanks were linked to other vital national registries such as population, death, disease specific registries and health information system, which further enhances surveillance and monitoring of disease and health outcomes (Leitsalu et al., 2015; Olson et al., 2014).

2.3.3 **Personalized medicine**

Population-based biobanks are novel technologies and tools that could pave the way to and accelerate the introduction of personalized medicine (Harris et al., 2012; Hewitt, 2011; Husedzinovic et al., 2015; Ioannis, Fotis, Evangelos, & Christos, 2015; McHale, 2011; Zielhuis, 2012). Personalized medicine refers to a medical practice that uses an individual's genetic profile to guide decisions concerning the prevention, diagnosis, and treatment of diseases (Genetic Home Reference, 2016). Biobanks could translate genomic and other biomedical research into advances in clinical care based on genomic profile, risk stratification and advances in pharmaceutical industry (Bravo et al., 2013; Kang et al., 2013; Marko-Varga et al., 2014; Olson et al., 2014; Pang, 2013). Biobanking research will advise in planning effective and targeted disease prevention interventions and public health promotion messages, beside improving clinical care (Bravo et al., 2013; Kang et al., 2013; Pang, 2013)

Clinical genomics requires large sample sizes, such as those in biobanks to achieve statistical power and obtain reliable results, as individually, most genetic variants are likely to have modest or small impacts on phenotypes (Marko-Varga et al., 2014; Olson et al., 2014). Pharmacogenomics is a science interested in determining how new knowledge about human genomes and their products can be translated into discoveries and development of improved drugs. Biobanks help find and validate targets for therapies, and validate the expression level of these targets through diseases biosamples. The new improved drugs are tailored to individualized patient plans based on their genetic makeup, genomic organization and level of target protein expression. Larger samples to support the development of improved targeted therapy could also be attained through regional and

international biobank research collaboration and networks (Branković et al., 2014; Marko-Varga et al., 2014).

Integration of biobanks into healthcare system and linking their databases with other national health databases can support the introduction of personalized medicine (Leitsalu et al., 2015; Marsolo & Spooner, 2013; Olson et al., 2014). The Estonian model is one example of how to utilize the population-based biobank as a resource to support the introduction of personalized medicine. The Estonian population-based biobank, the largest epidemiological cohort in the Baltic region, was established in 2000. Later, after several years of implementation of the biobank, Estonia linked different national health databases with its biobank to enrich the phenotypic content of the biobank database. These include databases on population, death, cancer, tuberculosis and myocardial infarction registries, National Health Information System and Estonian Health Insurance Fund. The vision is to enable the use of such rich data along with molecular profiling data of patients to calculate disease risk and likely drug response, with the aim of introducing personalized medicine (Leitsalu et al., 2015).

2.4 Requirements for Establishing a Population-based Biobank

To set up a population-based or national biobank, principal requirements must be charted out, by the custodian or the operator of the biobank well in advance. These requirements must be clearly communicated to all biobank stakeholders, including public to ensure that it is in alignment with the interests of prospective participants. It include: (a) defining the current and future purpose or mission for the biobank; (b) developing a business plan; (c) developing

governance structure and operational policies, procedures; (d) considering the flexibility of information technology design to enable future collaboration and linkage to other databases; (e) carrying out stakeholder consultation; and (f) providing solutions to transparently publicize information regarding the biobank (DHWA, 2010; Gottweis & Lauss, 2012; Kohane, 2011; Leitsalu et al., 2015; Marsolo & Spooner, 2013; OECD, 2009).

2.4.1 **The purpose of the biobank**

The purpose of population-based biobanks is to carry out genomic and epidemiological research to improve the wellbeing of the population and the future generations. Prior to establishing a biobank, the custodian or the operator of the biobank should have established criteria for sampling and participant selection. This will ensure that the biobank sample size is representative of the targeted population, and that the research results are scientifically appropriate for their intended use (DHWA, 2010; Olson et al., 2014; UK Biobank, 2006; UK Biobank, 2007). Important considerations include a recruitment policy that ensures justice, beneficence, transparency and no discrimination. This is why the current population-based biobanks that are founded on study design have disease focus, epidemiological parameters and mathematical models, and a vision of biobank potentials. They also need to have clearly estimated the size of samples required for recruitment, as well as the age range of participants (DHWA, 2010; Olson et al., 2014).

One example is the UK biobank which recruited 500,000 participants aged 45-69 years. This age group was selected because it involved people at risk of developing a wide range of complex diseases, such as cancer, heart disease,

stroke, diabetes and dementia, over the next few decades (UK Biobank, 2007). Another example is Estonia, where 52,000 participants were recruited, accounting for 5% of adult population of 18 years and above and reflecting the age, sex and geographical distribution of the Estonian population (Leitsalu et al., 2015; Leitsalu et al., 2015). Table 2-1, in section 2.9 provides other examples of population-based and national biobanks and summarizes their sample sizes and participants' age ranges.

2.4.2 **The business plan**

The business plan should be comprehensive, and ensure the sustainability of financial and human resources, as biobanks are unique and different other research facilities, and require a costly infrastructure (O'Doherty & Hawkins, 2010; Olson et al., 2014; Watson et al., 2014). The business plan should explain the financial model throughout the biobank's life span, including the nature and source for funding as well as the assumptions, and identify potential risks and alternatives options of funding in case one source of funding was terminated. The plan should also, carefully estimate and ensure sufficient professional staff required to operate the biobank. In case commercial or international collaboration is planned, this needs to be clearly stated in the plan, and communicated to all stakeholders, including participants (DHWA, 2010).

Most existing population-based biobanks are funded by governments or large charitable or research organizations (Henderson et al., 2013). Table 2-1 in section 2.9 provides a review of the source of funding of selected existing population-based biobanks.

2.4.3 Governance structure, standard operational procedures and policies

The biobank operator should clearly establish its governance structure and framework. The governance structure and framework should be designed to protect the rights and well-being of research participants and ensure that their rights and interests prevail research interests of the biobank operator and users (DHWA, 2010; OECD, 2009).

The biobank operator should have in place a set of standard operational procedures (SOP's) and policies, based on international best practices, to guide key operational decisions (Womack & Mager, 2014). Important SOPs include maintaining records and documenting management procedures; quality assurance procedures, including biosafety, training of staff and knowledge transfer, material handling and documentation procedures; participant recruitment and management procedures, including obtaining informed consent, withdrawal consent and recontact; as well as others (BBMRI Stakeholder's Forum, 2010; DHWA, 2010; National Cancer Institute [NCI], 2011; OECD, 2007; OECD, 2009).

The governance structure, SOP's, and policies, of the biobank needs to be developed and approved by an independent human research ethics committee prior to the establishment of the biobank. Information on the biobank governance and its management should be made publicly available (Critchley et al., 2012; OECD, 2009).

The full potential of biobanks can be achieved only through high quality operations (Artene et al., 2013; De Souza & Greenspan, 2013; Harris et al., 2012; Hewitt, 2011; Womack & Mager, 2014; Zhou, Sahin, & Myers, 2015). Biobanks

should seek certification by accreditation bodies such as the College of American Pathologists, CAP (De Souza & Greenspan, 2013; Hewitt, 2011), International Organization of Standardization Standard, (ISO) 9001 or others, to ensure quality (De Souza & Greenspan, 2013).

The biobank should have in place oversight mechanism to ensure compliance of its management, personnel, collaborators and researchers with legal requirements and ethical principles. Public and transparent reporting on compliance or faults in compliance is obligatory and it should be available to participants and the public (EC, 2012; OECD, 2009; Kaye, 2012b).

An effective and transparent governance structure and framework reassures stakeholders, including the general public that the biobank operation is being managed in an accountable and ethical way (Womack & Mager, 2014).

2.4.4 **Consultation with stakeholders**

Consultation with various stakeholders is a critical step in planning the establishment and sustaining population-based biobank (BBMRI Stakeholder's Forum, 2010; Critchley et al., 2012; DHWA, 2010; EC, 2012; Olson et al., 2014). Biobank custodian or operator should not fear public consultation; instead, they need to facilitate it to share information and views, and to learn what are the appropriate and acceptable biobank operations and policies (Gaskell & Gottweis, 2011). Stakeholders may include participants, the general public, patients groups, industry, scientists, ethicists, clinicians and researchers.

The extent and method of consultation would vary according to groups of stakeholders (BBMRI Stakeholder's Forum, 2010; DHWA, 2010; Gaskell & Gottweis, 2011; O'Doherty et al., 2011; O'Doherty et al., 2012). The biobank

operator or the custodians need to communicate clearly the importance and extent to which their input may influence the establishment and future aims of the biobank. In general, stakeholder consultation should cover the purpose and design of the proposed biobank, its current and future scope, potential risks involved to participants and their families, and the governance structure. In addition, it should explore any particular cultural, religious or other sensitivities that might be important to potential participants (DHWA, 2010).

2.4.5 **Information and education resources**

Information and education resources for the general public and other stakeholders on the biobank initiative should be made available, either in the form of internet-based communications and publications, or through other means of communication. Information on the biobank needs to be easily accessible, transparent and culturally accepted. It should be meaningful to the target audience, and cover the most important aspects of the biobank: background on the custodian/s and senior management, its governance structure, collaborators and the purpose, both current and future, the proposed duration of the biobank, its source of funding, operational policies, risks to participants and risk mitigation plans, research that is being carried out with the biobank resources and its general results, and finally, the contact details for more information (BBMRI Stakeholder's Forum, 2010; DHWA, 2010; EC, 2012).

Publicity plans are essential to increase engagement and participation (Gaskell & Gottweis, 2011; Kelly, Spector, Cherkas, Prainsack, & Harris, 2015; Platt, Bollinger, Dvoskin, Kardia, & Kaufman, 2014; Platt & Kardia, 2015; Watanabe et al., 2011). In order to communicate to the general public and educate

them, tailored strategies appropriate for target audience need to be used, and they should be ongoing to match the change in research technology advancement (Kelly et al., 2015; Platt & Kardia, 2015; Stein & Terry, 2013; Steinsbekk et al., 2013; Wee, Henaghan, & Winship, 2013; Williams, Nemeth, Sanner, & Frazier, 2013). There are various forms of communication strategies to raise public awareness. These include public forums, events, publications, internet-based communications and traditional media among others (Beskow, Burke, Fullerton, & Sharp, 2012; Budimir et al., 2011; Knoppers, Deschenes, Mester et al., 2015; Zawati, & Tasse, 2013; Wallace & Kent, 2011; Watanabe et al., 2011).

2.5 Biobank Governance Framework and Structure

Governance is a new terminology (Hansson, 2011). It is broadly defined as any intentional activity that attempts to control, order or influence the behavior of others. Regulations and governance are sometimes used interchangeably; however, governance is a boarder term (Hansson, 2011; Kaye, 2012b).

The governance framework and structure of a biobank is influenced by the biobank's purpose, design, scale of bioinformatics and communication technologies, potential for commercialization, and building regional or international hubs and networks (EC, 2012; OECD, 2009; O'Doherty & Hawkins, 2010). It could vary according to each country in alignment with its economic, social, legal development and resources infrastructure, including the research capacity of each country (Silverman et al., 2013).

The governance framework consists of a formal structure, which includes the international principles of ethical research, legal instruments and the legally constituted regulatory bodies. In addition, it includes less formal structures that

influence behavior such as, international guidelines and recommendations from professional societies, standard operating procedures (SOP's), professional values and may include community advisory boards (EC, 2012; Hansson, 2011; Kaye, 2012b).

2.5.1 **International principles of ethical research**

Several instrumental documents described the broad principles that should govern the research in human and were the basic of all international laws, policies and guidance for the protection of human participants. The most famous is the Nuremberg Code created in 1949 as a result of the verdict on the 'doctors' trial' on the World War II prisoners at Nuremberg, Germany. It was part of an international legislation due to a UN resolution in December 1946 that brought the Nuremberg trials under the purview of the law. The Code sets ten ethical principles for experimentation on humans. It also established the requirements for informed consent, absence of coercion, properly formulated scientific experimentation, and beneficence towards experiment participants (Health and Human Services, 2005).

Some examples of the most important declarations are, the World Medical Association (WMA) Helsinki Declaration and the United Nations Educational, Scientific and Cultural Organization (UNESCO) declarations. The Helsinki Declaration is considered the gold standard for the conduct of research involving human beings. It was adopted by the 18th WMA General Assembly in 1964 and amended several times, last in 2013. It applies to biomedical research on human subjects and addresses the use of human biosamples. The WMA Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks,

adopted by the 53rd WMA General Assembly, in 2002 and revised recently by the 67th WMA General Assembly in 2016. It address the collection, storage and use of identifiable data and biosamples beyond the individual care of patients (EC, 2012; OHRP, 2016a; WMA, 2013; WMA, 2016). The UNESCO has released two declarations related to human genomic research, both emphasizing the need to protect the data derived from the human genome. The first declaration, 'the Universal Declaration on the Human Genome and Human Research', was made in 1997, and the second 'the International Declaration on Human Genetic Data' in 2003 (EC, 2012; OHRP, 2016a; UNESCO, 2004).

The Belmont Report is one of the most significant set of principles on biomedical research, the 'Ethical Principles and Guidelines for the Protection of Human Subjects of Research', prepared by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979. The report provides an analytical framework to guide the resolution of the ethical problems related to research with human subjects and sets three core principles for research on human subjects: respect for persons, beneficence and justice. It was the basis for the federal US regulation for the protection of human participants in research, the 'Common Rule', such as the Department of Health and Human Services (DHHS) regulations 45 CFR 46 and the Food and Drug Administration (FDA) parallel regulations 21 CFR 50 and 21 CFR 56 (Health and Human Services, 1979; OHRP, 2016b).

2.5.2 **International guidance on best practices**

Several entities such as the Council for International Organizations of Medical Sciences (CIOMS), the World Health Organization (WHO) and the

International Conference on Harmonization for Good Clinical Practice (ICH-GCP), have established key standards and guidelines for the conduct of international research on human participants to encourage best practices and harmonization in biomedical. The first international guidance for biomedical research was 'International Ethical Guidelines for Biomedical Research Involving Human Subjects' prepared by CIOMS in 1982 and subsequently revised in 2002 and the 'International Guidelines for Ethical Review of Epidemiological Studies' in 2009. The WHO developed 'Operational Guidelines for Ethics Committees that Review Biomedical Research' in 2000, the 'Guideline for Obtaining Informed Consent for the Procurement and Use of Human Tissues, Cells, and Fluids in Research' in 2003, 'Handbook for Good Clinical Research Practice (GCP) Guidance for Implementation in 2005' , 'Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants' in 2011 (Alahmad et al., 2012; Artene et al., 2013; De Souza & Greenspan, 2013; EC, 2012; Harris et al., 2012; Kang et al., 2013; Nair & Ibrahim, 2015b; OHRP, 2016a; Silverman et al., 2013).

Other internationally recognized organizations and societies have established international guidance or statements on genomic research or human genomic databases, such as the OCED, the Human Genome Organization (HUGO) and ISBER. The OCED developed 'Best Practices Guideline on Biological Resource Centers' in 2007, which includes a chapter on using human biosamples for research. Later in 2009, it published another guide that addressed the 'use of human biosamples in genetic research titled 'OECD Guidelines on Human Biobanks and Genetic Research Databases'. The HUGO developed 'Statement on the Principled Conduct of Genetic Research' in 1996, 'Statement on

DNA Sampling: Control and Access' in 1998 and 'Statement on Benefit Sharing' in 2000 (EC, 2012; OECD, 2009; OHRP, 2016a). ISBER published 'Best Practices for Repositories: Collection, Storage and Retrieval of Human Biological Materials for Research' in 2005 and further revised in 2008 and 2012. It has addressed topics such as biobank setup, quality assurance and quality control, specimen collection and processing, training, as well as important legal and ethical issues, among others (De Souza & Greenspan, 2013).

2.5.3 **Legal Instruments**

Legal instruments include national laws or Acts that were passed specifically on biobanking activity such as those in Iceland, Estonia, Fenland, Hungary, Denmark, Norway, Sweden, Spain, Bulgaria, Portuguese, Taiwan and China. They could also be integrated with other legislation laws such as those in the UK, France and the Netherlands (Chen, 2014; EC, 2012; Marko-Varga et al., 2014; Office of Human Research Protections [OHRP], 2016; Scott, Caulfield, Borgelt, & Illes, 2012).

These laws or Acts were created to ensure the legal basis for biobanks and important biobanking activities. They address important aspects related to biobanking such as ownership of biobank resources; biosample and data; the form and level of stored personal and health information that could be coupled with the biosample; as well as the who, how and where biosamples could be stored and used over a long period of time.

Other countries such as the US, Canada, and Australia have not passed specific laws or Acts on biobanking; instead, there were several laws, acts and federal regulatory policies- on biomedical research, privacy of personal

information, genetic information non-discrimination, bioinformatics and others- that cover aspects of biobanking activity which vary in extent (Marko-Varga et al., 2014; OHRP, 2016a).

2.5.4 **Regulatory bodies**

Research ethic committee (REC), also named as institutional review board (IRB), independent ethics committee or ethical review board, is essential governance structures to approve biobank establishment and biobank research protocols. The main roles of such regulatory bodies are to oversee the governance, management and operation of the biobank and to ensure compliance with applicable domestic and international legislation, regulations, policies and frameworks. They review the scientific aspect of research or research protocols as well as the use of biosamples (DHWA, 2010; EC, 2012; O'Doherty & Hawkins, 2010). These committees are independent and are formed of experts from the various scientific, legal, ethical and clinical domains, as well as representatives of participants, and members of the general public.

Other regulatory bodies could include a Data Authority Body or its equivalent. They could serve as independent bodies to audit compliance of RECs or IRBs, to monitor access to and the uses of the biosamples and data, adherence to research ethics approvals, as well as access approvals and ensuring that participants' approval is granted during the informed consent process (DHWA, 2010; EC, 2012). In addition, there can be other oversight bodies including a National Health Research Authority or Higher Research Council, or its equivalent. The main role is to reassure that research participants' interests and rights are protected, as it is done in the UK (EC, 2012).

Collaboration and coordination of RECs with such regulatory authorities should be encouraged and obligated by national laws (EC, 2012). RECs should seek accreditation or certification by recognized international bodies or programs to ensure quality and compliance with laws and policies. Several accreditation and certification initiatives such as the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER), and programs such as the Association for the Accreditation of Human Research Protection Programs (AAHRPP) have been adopted by some countries. These facilitate registration, self-assessment and second external reviews, which will add to the RECs' effectiveness (Silverman et al., 2015).

2.5.5 Community advisory groups

Community advisory boards (CABs) or equivalent groups are another form of less formal governance structure. These groups can be the voice of the participants and the general public, and can be part of the decision-making process during planning, implementing and maintaining population-based biobanks (Olson et al., 2014).

2.6 Review of medical research and biobank ethics and governance in the Middle-East

The extent of research ethics capacity and their development vary widely in the countries of the region (Silverman et al., 2013). Medical research experience in the Arab countries of the Middle East region is limited compared to other regions of the world (Nair, Ibrahim, & Celentano, 2013); however, it is growing rapidly now. The inadequacy of research governance structure in the region has attracted pharmaceutical companies to the region and the number of

clinical trials has increased dramatically over the last two decades (Alahmad et al., 2012; Silverman et al., 2015; Silverman et al., 2013).

A review biomedical research regulations and guidance from the Arab countries of the Middle East region is limited. In fact, some countries such as Oman and Yemen do not have anything in place, while Syria refers to Helsinki Declaration and the CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects (Alahmad et al., 2012; H. Silverman et al., 2013). Five countries have national laws that address research on human participants. Two of them had laws specifically on medical research 'Law of Clinical Trials' Jordan passed in 2001, and another recent one 'System of Ethics of Research on Living Subjects' in Saudi Arabia in 2010. The other three countries have laws on medical ethics or medical liabilities in general, and include some language on medical research such the one that the UAE passed in 2008, Lebanon in 1994 and in Egypt in 2003 (Alahmad et al., 2012; OHRP, 2016a; Silverman et al., 2013).

In the UAE, the Federal Medical Liability Law No. (10) of 2008, recently revised in 2016, and the Cabinet resolution No (33) of 2009 concerning the Implementation Regulation of the Federal Medical Liability Law 2008, cover some regulations on medical research. Article 8 of the resolution stated, the requirement for preauthorization, list the authorizing authorities and mandate that research practices must comply with international guidance on best practices and *Sharia* (Islamic) laws. Article 9, stated the approved sites for research, the process and conditions of informed consent. In Abu Dhabi Emirate, HAAD had published the Healthcare Policy Manuals, in 2012. Chapter V of the Healthcare Regulator

Manual, covered research oversight bodies and their roles, authorization requirements for facilities and investigators, and treatment of personal data. The Healthcare Provider, Professional and Insurer policy manuals contains provisions that cover protection of personal data and duties relating to data management and confidentiality. However, the implementation of this policy is confined to Abu Dhabi Emirate (HAAD, 2016c).

Regional guidelines on research on human participants are scarce. The few available guidelines are the UAE's 'Guidance for Conducting Clinical Trials Based on Drugs/Medical Products & Good Clinical Practice' developed in 2006, 'HAAD Data Standards and Procedures' developed in 2008 that covers the collection, storage, access use and publication of personal and health data and the obligations to respect privacy and confidentiality, 'Standard Operating Procedures for Research Ethics Committees' developed in 2012 that encloses some language on biobanking, and 'HAAD Guidelines for Patient Consent' revised in 2016 which covers conditions required for informed consent for medical research purpose (HAAD, 2016d; Alahmad et al., 2012). Saudi Arabia developed 'Clinical Trial Requirement Guidelines' in 2005 and revised it in 2008. Sudan published 'National Guidelines for Ethical Conduct of Research Involving Human Subjects' in 2008, Bahrain 'Ethical Guidelines for Health Research 'in 2009, Kuwait 'Ethical Guidelines for Biomedical Research' in 2009 and Qatar 'Guidelines, Regulations and Policies for Research Involving Human Subjects' in 2009 (Alahmad et al., 2012; OHRP, 2016a; Silverman et al., 2013).

Generally, the existence as well as the number of RECs in the region is limited. It has been observed that as a response to increased clinical trials in the

region, the number of RECs is increasing and recently several institutions in the region have established departments and units for medical research ethics (Silverman et al., 2015; Ten Have, 2006).

Biobanking has been recently introduced in the Middle East region by a few countries such as Qatar, Saudi Arabia and Jordan. There were no specific laws or acts on biobanking activities or genomic research (Alahmad et al., 2012; OHRP, 2016a; Silverman et al., 2013). The existing guidelines do not cover important practices and procedures on biobanking activities. The governance structure pertaining to biobanking activity in the Middle East region, in the form of legal instruments or guidance is still to be developed (Alahmad et al., 2012).

2.7 ELSI Challenges of the Population-based Biobanks

Governance of population-based biobanks is a huge challenge for ethicist, scientist and biobank stakeholders, including participants. Existing medical research ethics legislation and regulations are not sufficient to address biobank's legal and ethical aspects (Marko-Varga et al., 2014; EC, 2012), for the following reasons. First of all, population-based biobanks are not seen merely as a research infrastructure, it represents major public investment and interests (O'Doherty et al., 2011). Secondly, biobanks are long-term prospective projects, and many risks pertaining to biobanking operations, future innovations and potentials cannot be fully predicted at the time of establishment. Thirdly, they involve complex bioinformatics and communication operations, including the potential for linking biobank databases with other vital and health databases and registries which requires them to ensure that the data remain potentially re-identifiable (EC, 2012; Olson et al., 2013; Otlowski, 2012). A fourth consideration is that biobank research involves storage of genetic data that may be considered as personal

identifiers (Otwolski 2013) and may involve multiple use of its resources, biosample and data, across various research projects and investigators. And fifthly, biobanks have a wide range of stakeholders including participants, public, researchers and their research organizations, as well as commercial and government entities. This adds to the challenge in terms of complexity of governance arrangements required, including laws, protocols, ethical guidelines and contracts.

Finally, there are growing efforts towards globalization as well as building regional and international networks for research to increase the efficiency of genomic research. This implies sharing biobanks' resources with other research facilities outside the country of donation (Artene et al., 2013; EC, 2012; Gitter, 2013; Gottweis & Lauss, 2010; Gottweis, Gaskell, & Starkbaum, 2011; Harris et al., 2012; Otlowski, 2012; Prainsack & Buyx, 2013; Womack & Mager, 2014). Biobank challenges can be broadly classified as legal, ethical and social. These challenges will be described below in detail.

2.7.1 **Legal challenges.**

2.7.1.1 Regulations and guidelines

Major challenges is lack of appropriate or insufficient regulation for biobank research. Currently countries that have implemented population-based biobanks are either in the process of developing new legislation or revising their existing medical ethics legislation to cover important aspect of biobanking activities (Budin-Ljøsne et al., 2012).

Only a few countries have defined and passed new national laws or acts specifically addressing biobanking activity, while others have integrated

biobanking related laws into other laws, or passed decrees or rules to cover some aspects of biobanking (Marko-Varga et al., 2014; OHRP, 2016a). In the Middle East, there are significant gaps in the development of legislation, laws or guidelines related to medical research as well as biobanking activity.

Passing national legislation is often an extensive and lengthy process that does not keep pace with the rate of dynamicity and innovation of in the field of biobanking, and would not be sufficient to cope with the many risks raised in a timely fashion. In addition, revisions and updates of existing laws require substantial investments of time. Such was the case of Norway, where their existing national legislation needed revision in order to accommodate new requirements for genome sequencing that were not covered by their Biotechnology law. To this end, the law has to undergo regular revision (Budin-Ljøsne et al., 2012).

Moreover, there is little attention being paid to ensuring that these acts or laws are flexible and consider the regional and global trends in biobank research networks in such way that national legislation is in harmony with other jurisdictions (Budin-Ljøsne et al., 2012).

On the other hand, legislations on biobanking activity may be burdensome or restrictive rather than facilitative (Budin-Ljøsne et al., 2012; Stjernschantz Forsberg, Hansson, & Eriksson, 2011). An example is the French national legislation for biobanking activity that was fragmented and integrated with other legislation. The challenges with such fragmentation are that they require obtaining separate authorizations for specific biobanking activities which is time consuming and burdensome for researchers (Budin-Ljøsne et al., 2012). In Italy, the Italian

Personal Data Protection Code for General Authorization for the Processing of Genetic Data allows samples to be stored for research, but requires specific written consent for each new research study.

Other regulatory challenges are related to the international codes and declarations such as the Nuremberg Code, Declaration of Helsinki and the UNESCO Declarations. All these codes and declarations have not been ratified into international law, and have no legal force behind them (Alahmad et al., 2012; EC, 2012; Marko-Varga et al., 2014).

International guidelines for best practices, as mentioned earlier, from WHO, CIOMS, ICH-GCP and others from North America, Europe and those developed in the Middle East region, even if available and widely shared to encourage standardization and harmonization, do not have legal statements and are non-binding in nature (Alahmad et al., 2012; EC, 2012; Marko-Varga et al., 2014; Silverman et al., 2013). Adherence guidelines are completely voluntary and vary in degree across countries, particularly in the Middle East region (Alahmad et al., 2012; Lahey, 2013; Nair & Ibrahim, 2015a; Nair & Ibrahim, 2015b; Silverman et al., 2015; Silverman et al., 2013).

A very limited number of regional guidelines based on International guidance were developed in the Arab countries of the Middle East. However, when compared with the international guidelines such as the CIOMS, ICH-GCP and other International guidelines, they have many deficiencies with regard to the protection of human participants. These deficiencies vary in type and number from one country to another, posing major risks on the protection of research and biobank participants (Alahmad et al., 2012).

2.7.1.2 *Oversight bodies*

One of the common challenges with regards to oversight bodies is that these committees usually have no legal status, and as such, no power of enforcement (EC, 2012; Kaye, 2012b; Marko-Varga et al., 2014). Only Sweden has passed an act to legalize the role of REC (Marko-Varga et al., 2014).

In addition, the definition and standardization of RECs structure and roles vary worldwide. Few countries such as Estonia, Italy, France, Finland, Austria, China and India have defined and regulated the structure and roles of RECs (O'Doherty & Hawkins, 2010). Some countries have created their own guidelines, the UAE is the one and only country from the Arab Middle East region to have done that (Nair et al., 2013).

In the context of regional networks or globalization, IRB or REC decisions might vary among regions and countries, and their power of enforcement is restricted only to their own jurisdiction. Also, since there is no mutual recognition of research ethic committee decisions, each regional or global research protocol must be submitted to own country for ethics approval, which duplicates efforts. Furthermore, these committees face the challenge of having to investigate non-compliance by secondary (external) researchers not based in their countries (EC, 2012).

Additional challenges from Arab Middle East countries include the low number of existing RECs, insufficient training of members in the field of research ethics, limited human and financial resources, and lack of diversity in members. There are unmet needs for conducting audits or secondary external reviews by

independent regulators, or registration to internationally recognized accreditation programs or initiatives (Silverman et al., 2015; Silverman et al., 2013).

Furthermore, there are no gold standard tools to evaluate the effectiveness of RECs with regard to ethical quality of reviews or the impact of RECs on research practices (H. Silverman et al., 2015).

2.7.2 **Ethical challenges.**

Protection of participants' rights and interests is the central concept behind effective biobank governance. The considerable ethical challenges related to informed consent, withdrawal of consent, privacy and confidentiality protection, return of research results and commercialization will be described below.

2.7.2.1 Informed consent

Informed consent is the most frequent ethical issue pertaining to biobank research that has been raised and addressed in the literature (Budimir et al., 2011; Caulfield et al., 2014; Master & Resnik, 2013). The fundamental principle of research governance that includes biobank research is to ensure autonomy, respect and protection of research participants, while keeping the research interests in consideration (EC, 2012; OECD, 2009; Otlowski, 2012).

Informed consent is one way to respect a participant's rights and dignity, so that they exercise autonomy and make decisions about matters in light of their own values. Respect of autonomy implies respect of human dignity and rights. The consent process involves protecting research participants through providing them with the necessary information transparently and honestly in order to fairly assess risks (Otlowski, 2012). It is also seen as a process to honor research

participants' contributions to advance medical research and generate new knowledge (Clayton, 2005 cited in Otlowski, 2012).

Informed consent is a process by which research participants voluntary confirm willingness to participate in research after being informed on all related aspects pertaining to that particular research that will help them to make a decision about participation, and is documented by means of a written, signed, and dated form (International Council for Harmonisation [ICH], 1996).

Informed consent is a requirement of the Nuremberg Code (Health and Human Services, 2005) and is reflected in a number of international declarations such as, the Declaration of Helsinki and the Universal Declaration on the Human Genome and Human Right. For example, article 26 of the Declaration of Helsinki states: *"In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail..."* (World Medical Association [WMA], 2013). This essential requirement is reflected as well in all national legislations and regulations, guidelines on research on human participants.

The major ethical concern related to informed consent is whether research participants are adequately informed about risks and benefits of biobank research. The challenges are in the appropriate selection of information-what, how, who and the amount- and consent policy (Hansson, 2011).

The consent form or document could vary by type of research; however, guidelines on best practices, such as those of the ICH-GCP, WHO, CIOMS and

others, require that the informed consent document should cover specific basic requirements in order to provide information needed to make an informed consent about participation. This basic information includes title of the research, details regarding the researcher and the organization conducting the research, purpose of the research, participant responsibility, risks, benefits, duration of research, storage of sample and ways it will be discarded, protection of data and confidentiality measures, the right to withdraw without penalty or loss of benefits and contact details for more information (ICH, 1996; Nair et al., 2013; Nair & Ibrahim, 2015a; Nair & Ibrahim, 2015b; WHO, 2002).

To obtain informed consent about participation at the time of recruitment, the research consent form should meet the fundamental requirements of a biobank consent form, based on guidelines mentioned above, as well as the legal requirements of the country. It is also equally important to ensure that participants are able to comprehend the information provided in the form. The consent form should focus on providing the most important and relevant information on the biobank research from the participants' perspective. It should be in a simple and short format; so a one page consent form outlining the most important information in a straightforward, easily readable language is suggested (Beskow et al., 2010; Sheehan, 2011). More detailed information can be provided to interested participants in the form of supplementary information or FAQ's (Beskow et al., 2010; Beskow, Dombeck, Thompson, Watson-Ormond, & Weinfurt, 2015).

The consent form needs to be in a readable and simplified language in order to address language barriers and ensure health literacy (ICH, 1996; Nair et al., 2013; Nair & Ibrahim, 2015a; Nair & Ibrahim, 2015b; WHO, 2002).

Moreover, the consent process must ensure voluntary participation and must be sensitive to and respectful of the cultural, social, and religious differences of participants (Hansson, 2011).

In the context of regional or international networks or hubs, generic consent is often required. Most countries do not have a generic model of informed consent form for biobank research, and the requirement of consent may vary according to research studies (Beskow et al., 2015; Budin-Ljøsne et al., 2012). This issue makes it hard for biobanks to determine from the original consent form the specific research purposes for which the resources, biosamples and data could be used and shared, as well as an understanding of which resources can be considered as intellectual property of the biobank (Budin-Ljøsne et al., 2012). This issue is even more complicated in cases of resources from deceased individuals (Budin-Ljøsne et al., 2012; Tasse, 2011).

With regard to consent policy, according to WHO's 'Guideline for Obtaining Informed Consent for the Procurement and Use of Human Tissues, Cells and Fluids in Research', there are three main consent policies in medical research on humans. These are fully restricted or 'narrow' or 'specific' consent, partially restricted or 'tiered' consent and unrestricted or 'broad' consent. In fully restricted consent, the participant consents to the use of the biosamples and/or data to the immediate specific research only. In partially restricted, the participant consents to the use of the biosamples and/or data in the immediate research as well as in future research of a specified type or types, and up to a specified time in the future. In the unrestricted, the participant consents to the use of the biosamples

and/or data in the immediate research, as well as future research of any kind and at any time (Otlowski, 2012; WHO, 2002).

The assumption made by most scientists and researchers about research participants' expectations and interests is that they prefer specific consent policy, as this gives them the control over the way their contributions, biosample and data will be used, especially genetic data; it is the optimal approach that certainly addresses the ethical principles of informed consent (Otlowski, 2012). However, it is thought that specific consent maximizes participant autonomy at the expense of research expansion and convenience (Master et al., 2015). In addition, specific consent would require recontact of participants for every linkage and reuse of their samples and data for research. This approach would not be appropriate for large scale and long-term operations of population-based biobank research. It is burdensome on participants as it might cause inconvenience and unnecessary intrusion into their private lives. It might also affect the scientific value of the initiative as it increases the risk of high dropout of research subjects and/or introduces consent bias. In addition, practicing it is burdensome and impractical for the biobank as it implies additional time, logistics and costs to biobanks; besides, acquisition of consent is impossible from deceased donors (D'Abramo, Schildmann, & Vollmann, 2015; Otlowski, 2012; Porteri, Pasqualetti, Togni, & Parker, 2014; Steinsbekk, Kare Myskja, & Solberg, 2013). Ethically, specific consent holds participants accountable to understanding risks and benefits of research (Beauchamp, 2011; Otlowski, 2012).

The International Bioethics Committee of UNESCO, WHO, other researchers and biobank scientists support broad consent policy as valid and

appropriate policy for a population-based biobank research (D'Abramo et al., 2015; Master et al., 2015; Otlowski, 2012; Sheehan, 2011). In fact, there is a growing academic, scientist and international support to broad consent (Master et al., 2015; Otlowski, 2012). Those who support broad consent argue that since participants are provided with information that covers all aspects relevant to an individual's choice, then that is an appropriately informed individual consent. If the information given is general, covering all risks and benefits of potential future research that might be conducted using biobank resources as specified in an agreement or consent form, and if those resources are used only for biomedical research and not for any other purpose such as in forensics or by immigration authorities, then broad consent is considered to be informed consent (Hansson, 2011).

Another supporting argument relies on the precise meaning of informed consent, which is enabling participants to choose to accept certain risks for the sake of possible benefits according to their plans (Sheehan, 2011). In the case of biobank research, it is assumed that the risks, compared to benefits, are generally considered as low. The risks are related to privacy and come with the right to withdraw, while biobank research itself is socially valuable, and participation in biobank research is seen a duty and an expression of solidarity to support medical research (D'Abramo et al., 2015; Master & Resnik, 2013; Prainsack & Buyx, 2013).

Furthermore, those who support broad consent rely on: (i) the option of withdrawal of consent at any time as a granted right for all participants; (ii) the role and ethical accountability of governance structure (the REC) in assessing the

risks and benefits for participants, and ensuring that adequate privacy protection measures and anti-discrimination policies are in place (D'Abramo et al., 2015; Master & Resnik, 2013; Otlowski, 2012; Sheehan, 2011); (iii) ongoing review of participants' consent to ensure that the use of samples and data are consistent with the consent given, and for approved purposes and governance of the biobank (Hansson, 2011); and (iv) ensuring ongoing communication with research participants on the biobank research directions and possible use of its resources, which gives a sense of control to participants. This communication could be through updates on a website, newsletter via emails or other means of communication (Otlowski, 2012).

Some researchers believe that adding 'Exclusion Clauses' to biobank participant consent forms gives research participants more control on the use of their contributions for research as it enables participants to indicate certain types of research that they do not wish to allow their contribution to be used. It also limits the sharing of biosamples and data with specific research organizations such as international researchers and insurance companies. Another advantage is that it increases transparency and promotes accountability to biobank research, thereby increasing trust. However, exclusion clauses are written by researchers, and as such, participants might have some difficulty understanding it, or they might not represent participant concerns (Joly et al., 2015; Master & Resnik, 2013; Master et al., 2015). In addition, this model is useful and applicable for small-scale or disease-oriented biobanks, and is not practical for population-based biobank research (Master & Resnik, 2013; Master et al., 2015).

In cohort and retrospective biobank research, the most common types of consent policy used are the specific and the broad consents (Fullerton & Lee, 2011). Table 21 provides examples of informed consent policies in the existing national and population-based biobanks in selected countries.

Research participants' views and preferences regarding biobank research's informed consent policy might differ from theoretical justifications or scientists' views (D'Abramo et al., 2015). In fact published studies and systemic reviews showed variations across population and subgroups of same population. Some studies and systemic showed that the general public prefer the specific one time consent approach (D'Abramo et al., 2015; Eder, Gottweis, & Zatloukal, 2012; Husedzinovic et al., 2015; Lewis, Clotworthy, Hilton, Magee, Robertson, Stubbins, & Corfield, 2013a; Lipworth et al., 2011; Platt et al., 2014; Tauali et al., 2014), while other recent studies and systemic reviews, including a study from Jordan, Middle East, showed a preference for broad consent (Ahram et al., 2013; Allen & McNamara, 2011; Caulfield et al., 2012; Ewing et al., 2015; Garrison et al., 2015; Joly, Dalpe, So, & Birko, 2015; Kelly et al., 2015; Lemke, Halverson, & Ross, 2012; Lipworth et al., 2011; Platt et al., 2014; Porteri et al., 2014; Simon et al., 2011).

Studies showed that public preference regarding the type of consent depended on whether they were offered different options for consent - including narrow or specific consent. It also depended on whether they could clearly understand the biobank logistics as well as the research risks and benefits for them as individual and as a society (D'Abramo et al., 2015; Garrison et al., 2015; Tomlinson et al., 2015). Furthermore, preference to broad consent was determined

by certain demographic characteristics such as ethnicity (Ewing et al., 2015; Garrison et al., 2015; Joly et al., 2015; Platt et al., 2014), level of education, income (Platt et al., 2014) and gender (Garrison et al., 2015). Female respondents and those with unfavorable demographic characteristics and minorities favored specific consent (Garrison et al., 2015; Lewis, Clotworthy, Hilton, Magee, Robertson, Stubbins, & Corfield, 2013a; Platt et al., 2014).

2.7.2.2 Withdrawal of consent

The ability to withdraw consent without penalty or loss of benefits is one of the rights explicitly established by the Nuremberg Code as well as in all research ethics declarations and guidelines, such as Helsinki Declaration, the UNESCO International Declaration on Human Genetic Data, HUGO statements and CIOMS guidelines and others. These guidelines and declarations agree and emphasize that the right to withdraw from research has five characteristics: it is immediate, absolute, unconditional, complete and untradeable (Holm, 2011).

For example, in article 26 of Helsinki Declaration, it was stated that "a potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal" (WMA, 2013). The UNSECO International Declaration on Human Genetic Data provided two options for complete withdrawal of consent: either to destroy any use of data and biosamples, or keep them with full anonymization. In addition, it requires that destruction of biosamples and data are done in accordance with the wishes of the research participants (Alahmad & Dierickx, 2014; Melham et al., 2014; UNESCO, 2004) and with due respect to their cultural heritage and religious beliefs (Alahmad & Dierickx, 2014; OECD, 2009). The more recent CIOMS

International Guidelines for Ethical Review of Epidemiological Studies (2008) recognizes that withdrawal of consent in epidemiology or population studies can be challenging and might take several forms (Council for International Organizations of Medical Sciences [CIMOS], 2008; Melham et al., 2014).

Withdrawal of consent is granted to all participants in research on human subjects, as reflected in all international principles and guidelines, as well as national legislations and regulations on research on human participants. However, the extent and characteristics of right to withdraw in the context of biobank research is not similar to that of traditional medical or clinical research. Careful attention needs to be given to what withdrawing consent actually means in the context of biobank research (Melham et al., 2014; Otlowski, 2012).

The biobank collects and stores biosamples and massive personal, genomic, environmental, lifestyle and medical data that is digitized to make them easily replicable and distributable, then aggregated and integrated into large sets of 'big data' and sometimes are allowed commercial access. The data is then shared with a variety of collaborators and networks outside the biobank, which makes individual data difficult to trace (Kaye, 2012b; Melham et al., 2014). Likewise, data published as part of aggregate data set cannot be meaningfully withdrawn from the public domain. Moreover, the previous use of biosample and data cannot be undone, therefore withdrawing of consent in the biobank research setting in reality means preventing future use of previously collected biosamples and data, rather than cessation of intervention (Melham et al., 2014).

Existing population-based biobanks have defined or adopted various policies regarding withdrawal of consent, primarily 'all or none' or 'tiered'

strategies. The adoption of various policies depends on the operational capacity of the biobank to deal with withdrawal of consent requests (Melham et al., 2014). Withdraw of consent might mean (i) no further contact; (ii) no further ongoing collection of data and no further contact; or (iii) complete withdrawal of samples and data from future use in any new research. Complete withdrawal of consent might include complete destruction of samples and data or irreversible anonymization. It is important that research participants are aware of these implications and understand the meaning of each option of withdrawal of consent in the biobank setting in order to make an informed consent about participation in the biobank (Hansson, 2011; Melham et al., 2014).

Also it is important to have an opt-out registry, such as that in Denmark and Norway, to monitor informed consent processes and ensure that participants understand their right to opt out (Budin-Ljøsne et al., 2012).

2.7.2.3 Privacy and confidentiality

Biobanks carry high informational risks as they collect and store huge quantities of phenotype and genotype data of many individuals and from various sources, and may routinely recontact participants to update their phenotype data (Hansson, 2011). The major information risks of biobanks are (i) risk of misuse of data, particularly genetic data, that could result in discrimination of participants by third parties such as insurance companies, employers or commercial entities, or stigmatization of individuals or subgroups of the populations; (ii) loss of privacy as a result of collecting a lot of information including genotype data from various sources such as medical records, registries and national database; (iii) potential breach of confidentiality as a result of indirect disclosure of data over time, or re-

identification of research participants (Budimir et al., 2011; Caulfield et al., 2014; Evers et al., 2012; Fisher & Harrington McCarthy, 2013; Gitter, 2013; Hansson, 2011; Laurie et al., 2010; Petrini, 2012).

Protection of research participant identity is one of the fundamental principles of research ethics (Heeney, Hawkins, de Vries, Boddington, & Kaye, 2011). As stated in article 24 of Helsinki Declaration, "*Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information*" (WMA, 2013). As well as, mandated in all existing national legislations and regulations on research on human participants.

To protect against the misuse of data, several guidelines insist that access to biobank data is granted only to researchers, and only for research purposes. For example, the OCED 2009 guidelines on HBGRD stated, *"These Guidelines set out that the HBGRD should not grant access to or disclose participants' human biological materials or data to third parties for non-research purposes, except when required by law. For example, the operators of the HBGRD should not make available participants' human biological materials or data to third parties such as insurers, employers, law enforcement agencies or other civil-law agencies for non-research purposes"* (OECD, 2009).

Biobanks have the obligation to protect research participant identity while maximizing the use of data for research (EC, 2012; Kaye, 2012b). For that, biobanks may adopt several levels of protection of personal data, but none provides complete protection (Greely, 2007 cited in Budimir et al., 2011). Most scientists prefer coding of data in the belief that it is the standard research practice and the appropriate solution to protect privacy (Budimir et al., 2011; EC, 2012).

Coding means that the biobanks remove participant identifiers and replace it with a code. The code is then encrypted for use by researchers. However, data and sample sources must remain potentially re-identifiable to the biobank custodian to allow future recontact and ongoing linkage of various sources of data to the specific individual (EC, 2012; Kaye, 2012b).

Anonymization is another privacy protection strategy and considered the ideal way to protect personal data (Budimir 2011). Anonymization prevents participant re-identification through deleting the coding keys linking data and samples to participant's identifiers (OECD, 2009). It provides additional confidentiality and privacy protection over coded data. However, it is impossible to guarantee anonymity, especially when heath data are used in different contexts or genomic data are involved (Mostert, Bredenoord, Biesaart, & van Delden, 2015).

'Anonymize or consent' strategies are well-accepted ethical positions in research as methods to protect privacy (Laurie et al., 2010; Hansson, 2011). Consent respects a participant's autonomy to make decisions regarding privacy risks (Kaye, 2012b; Laurie et al., 2010). Anonymization and coding is another conventional approach used to eliminate the need for consent or other legal requirements (Mostert et al., 2015), or to justify broad consent policies as it eliminates the need for re-consent in future research on the same samples and data (secondary research) (Whitley, Kanellopoulou, & Kaye, 2012). However, anonymization reduces research utility (Budimir et al., 2011; A. K. Hawkins & O'Doherty, 2011; Laurie et al., 2010), makes it difficult to recontact participants for future research, return of research results or withdrawal of consent, and is

considered disrespectful to participants (Budimir et al., 2011; Thorogood et al., 2014).

However, privacy in the context of genomic research poses additional challenges. It is believed that the effectiveness of traditional research measures to protect privacy, such as coding and anonymization are questionable in the context of biobank genomic research, and cannot guarantee absolute protection (Greenbaum, Sboner, Mu, & Gerstein, 2011; Heeney et al., 2011; Kaye, 2012b; Laurie et al., 2010; Thorogood & Zawati, 2015).

The new whole genome sequencing technologies produce rich and more detailed information that is specific and unique to individuals (Greenbaum et al., 2011). The advancements in bioinformatics has made re-identifying research participants from a small amount of genetic and/or clinical data increasingly possible (Heeney et al., 2011). Additionally, the development of biobank research networks and increased data sharing make it difficult to guarantee complete confidentiality (McGuire et al., 2011). Similarly, human genome sequence datasets and information are increasingly available publicly outside the controlled environment of medical research. People can now obtain access to their own genome data through direct-to-consumer companies (Lumley & Rice, 2010). They can also trace their biological relatives through ancestor-tracing companies (Kaye, 2012b).

In addition to scientists' views, published studies on the willingness of general public to participate in population-based biobanks report that privacy and confidentiality are the most common concerns expressed by the general public from various populations and sub-populations, including the Middle East (Ahram,

Othman, Shahrouri, & Mustafa, 2013; De Vries et al., 2016; Eder et al., 2012; Gaskell et al., 2013; Halverson & Ross, 2012a; Igbe & Adebamowo, 2012; Joly et al., 2015; Kerath et al., 2013; Lemke et al., 2010; Melas et al., 2010; Nasrella & Clark, 2012; Overby et al., 2015; Pullman et al., 2012; Rahm et al., 2013; Ridgeway et al., 2013; Simon et al., 2011; Spruill et al., 2014).

2.7.2.4 Return of research results

The return of research findings in the field of medical research is limited to general or aggregate outcome of research. As stated in article 26 of Helsinki Declaration, "*All medical research subjects should be given the option of being informed about the general outcome and results of the study."*(Knoppers, Zawati, & Senecal, 2015; WHO, 2002; WMA, 2013).

The return of results in clinical trials on drugs and medicine is the norm, however it is challenging in genomic research and biobank research (Knoppers et al., 2015). According to researchers, there are four approaches for returning genomic results in whole genome sequencing: (i) return only panels of specific genes or targeted sequencing to reduce the potential for incidental findings; (ii) return results if they meet specific criteria, such as ACA, analytical validity, clinical significance and actionability; (iii) ad hoc case-by-case determination; or (iv) no return.

Analytic validity means that the test can accurately and reliably identify a particular genetic characteristic; an actionable finding is a finding that is considered actionable if there are identified therapeutic or preventive interventions that have the potential to alter the course of the disease or condition; and clinical significance means an accurate and actionable research finding (Knoppers et al.,

2013). The most recent conclusion revolving consensus of researcher participants and panel experts is that researchers are obliged to return at least some incidental results of genomic research to research participants (Appelbaum et al., 2014).

Existing population-based biobanks typically return two types of results to participants: initial assessment and general outcomes results. Initial assessment results might include blood pressure, BMI and other tests often in the form of a written summary (Al Kuwari et al., 2015; Knoppers et al., 2013; Smith & Aufox, 2013; Wallace & Kent, 2011; Zawati, Knoppers, & Thorogood, 2014). In case any of these results are abnormal or merit clinical interference, participants will be recommended to visit their healthcare providers for proper management (Al Kuwari et al., 2015; Knoppers et al., 2013; Wallace & Kent, 2011). The aggregate and general research outcomes, according to obligation of various research ethics standards, should be shared in an ongoing fashion, and through any communication channels: website, newsletter, publication or other (Beskow et al., 2012; Budimir et al., 2011; Knoppers et al., 2013; Wallace & Kent, 2011; Watanabe et al., 2011).

With regard to genetic research results, biobank policies vary (Terry et al., 2012; Wolf et al., 2012). Most existing population-based biobanks have adopted a no return policy, and this should be reflected in the consent form. Other biobanks, mostly disease-oriented, have opted to return genetic research results, although this option varies widely. Those offering research results may offer either incidental findings (IFs) alone to participants, or only individual research results (IRRs), whereas others consistently offer both IFs and RRs (Terry et al., 2012). IFs are unforeseen research findings that have potential health or reproductive

importance, are discovered during the course of research but are beyond its objectives. On the other hand, IRR are research results discovered during the course of research which concern an individual participant and have potential health or reproductive impact (Knoppers et al., 2013). Although the conditions for returning IFs and IRRs may be similar, returning IFs might be more challenging as it may fall beyond the particular field of expertise of the researcher (Knoppers et al., 2013). In the US, in order for biobank research to return individual genomic research results, the analysis must be performed in a validated Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory (Smith & Aufox, 2013).

Researchers who support 'restrictive disclosure policy', i.e., no return of genetic research results (Bredenoord, Kroes, Cuppen, Parker, & van Delden, 2011), argue that first, population-based biobank research is epidemiological in nature, and intended to produce generalizable knowledge for future potential research. Such results are neither validated nor intended for diagnostics nor clinical information on individuals, and therefore researchers are not required to return individual results (Solberg & Steinsbekk, 2012; Wallace & Kent, 2011) nor provide counseling (Budimir et al., 2011). Secondly, biobanks are an infrastructure for future research, which means that it is difficult to obtain informed consent for participants on undiscovered outcomes which might be significant, or of limited value right at the time of recruitment (Wallace & Kent, 2011).

Thirdly, the moral obligation to return results in research depends on the depth of relationship between researchers and participants (Beskow et al., 2010; Bledsoe et al., 2012; Solberg & Steinsbekk, 2012). In the biobank context, most

research is secondary, and researchers might be in different facilities, countries or occur in the future. Therefore, there may be less obligation to return results (Beskow et al., 2010). Fourthly, recontact for returning results requires retaining the link for identification of research participants, which increases the risk of breaching confidentiality and endangering privacy (Bledsoe et al., 2012).

A fifth argument is that it might be harmful for research participants through causing unnecessary worries of potential future disease in those who believe they are healthy (Solberg & Steinsbekk, 2012); there are also chances of being psychologically, socially or economically harmed in being informed about research findings the clinical utility and accuracy of which is uncertain (Budimir et al., 2011; Viberg, Hansson, Langenskiold, & Segerdahl, 2014). Sharing research findings after many years of giving consent might cause confusion or inconvenience to participants (Viberg et al., 2014). Disclosure of genetic research results may yield IRPs and/or IFs that might mislead participants and promote therapeutic misconceptions, i.e., inaccurately attributing therapeutic intent to research (Bredenoord et al., 2011; Halverson & Ross, 2012c; Solberg & Steinsbekk, 2012; Zawati et al., 2014).

Last, but not least, it may imply the need for additional resources such as experts, genetic counselors and funding to do so (Black et al., 2013; Bledsoe et al., 2012; Bledsoe et al., 2013; Knoppers et al., 2013).

In contrast, many researchers support a qualified return of individual results to participants and consider that not returning results is untenable and needs to be challenged. They believe that disclosure of results to participants reflects a respect for the participants' autonomy and right to know (Wallace &

Kent, 2011). Moreover, there are other researchers who believe that beneficence obligates researchers to disclose data for research participants to maximize benefits and minimize harms. The information returned in time can change their lifestyle and prevent future potential risk of diseases (Viberg et al., 2014). Others argue that reciprocity between researchers and participants can be sustained by returning individual research results (Gaskell et al., 2013).

Although returning individual results is not an obligation for traditional research, there are ongoing debates whether researchers bear the duty to analyze and return genomic research result findings, including the IFs and IRRs. In fact, there is recent consensus among experts for an obligation to return genetic research results, both the IFs and IRRs, if they meet the ACA criteria, and if, during the process of informed consent or subsequently, the research participant has opted to receive individual genetic results (Black et al., 2013; Bredenoord et al., 2011; Christenhusz, Devriendt, & Dierickx, 2013; Jarvik et al., 2014; Knoppers et al., 2012; Knoppers et al., 2015; Lemke et al., 2010; Lemke et al., 2012; Smith & Aufox, 2013; Terry et al., 2012; Viberg et al., 2014).

Returning research results is context specific. Although the majority of published studies, from various populations and sub- populations, showed that there is growing desire and high expectations among research participants and the general public to receive their aggregate and individual genetic research results (Al-Hussaini & Abu-Hmaidan, 2014; Allen et al., 2014; Bollinger, Scott, Dvoskin, & Kaufman, 2012; Haga et al., 2013; Halverson & Ross, 2012a; Karlson, Boutin, Hoffnagle, & Allen, 2016; Lemke et al., 2010; Lipworth et al., 2011; Meulenkamp et al., 2010; O'Daniel & Haga, 2011; Streicher et al., 2011),

other studies reported that returning genetic research results, was perceived as a concern that would discourage their participation in biobank research (Al-Jumah et al., 2011; Hassona, Ahram, Odeh, Abu Gosh, & Scully, 2016; Rodriguez, Torres, & Erwin, 2013).

2.7.2.5 Commercialization

Population-based biobanks are often established as publicly funded facilities by government or academia (Budimir et al., 2011; Edwards et al., 2014; Henderson et al., 2013; Hewitt & Watson, 2013). Nevertheless, biobanks are costly resources, both in terms of logistics infrastructure and expertise (Beier & Lenk, 2015; Diaferia, Biunno, & DeBlasio, 2011; Gottweis & Lauss, 2012; Turner, Dallaire-Fortier, & Murtagh, 2013), while generating minimal short-term returns (Kozlakidis, Mant, & Cason, 2012). Therefore, researchers believe that in order to manage the costs of establishment and maintenance, biobanks must operate as business enterprises as well as being part of a scientific infrastructure (McDonald et al., 2014).

Some researchers believe that commercialization is seen as inevitable (Beier & Lenk, 2015; Budimir et al., 2011), first for financial support to ensure long-term sustainability of biobank operations (Caulfield et al., 2014; Joly et al., 2015; Turner et al., 2013). Second, to facilitate the translation of useful technologies and practices into biobank research, thereby maximizing research potential. This is believed to advance biomedical knowledge, provide improved treatment opportunities, and lead to better healthcare - introduction of personalized medicine (Caulfield et al., 2014; Evers, Forsberg, & Hansson, 2012; Nicol & Critchley, 2012). Both interests, financial support and advancement of

technology, while being different, should not be seen as opposing (Evers et al., 2012).

Commercialization of population-based biobanks are globally recognized (Evers et al., 2012). Commercialization in biobank research, in its broader sense, might involve a number of activities. It could refer to the commercialization of the biobank resources, data or samples; commercialization of research results or products generated as a result of utilizing the biobank resources (Beier & Lenk, 2015; Caulfield et al., 2014; Evers et al., 2012); or it might refer to building partnerships or receiving funds from private companies such as pharmaceutical, medical devices, biotech companies or others (Caulfield et al., 2014).

The most common ethical concerns raised in relation to commercialization are: ownership and benefit sharing. Who should own the property rights to biosamples and genetic information and who should share benefits or profits generated from the donated or altruistically contributed biosamples and data, the researcher, the biobank, companies, research participants or the community. (Budimir et al., 2011; Petrini, 2012; Turner et al., 2013; Tutton, 2010).

The ethical dilemma of ownership raised from debates about human biosamples and data including genetic information are whether they are seen as proprietary right or extension of personal right (Hawkins et al., 2013). The laws and regulations regarding ownership of human biological materials varies across countries and in some countries it has not been decided yet (Beier & Lenk, 2015; Caulfield et al., 2014). Researchers argue that denying ownership of their own biological material and data to research participants might discourage participation in biomedical research (Gitter, 2013).

In terms of benefit sharing it is important ensure justice to research participants and balance commercial interests against public good and values of the biobank (Budimir et al., 2011; Nicol & Critchley, 2012; Turner et al., 2013) and prevent commercial exploitation against fairness for research participants and open science, unrestricted knowledge production and sharing (Birch, 2012; Evers et al., 2012; Gitter, 2013; Joly et al., 2015).

Population-based biobanks are public resources and therefore their benefits and knowledge generation should be shared by all, in order to improve the health of population (Evers et al., 2012). The HUGO Statement on Human Genomic Database, Recommendation 1, stated that ''*Knowledge useful to human health belongs to humanity. Human genomic databases are a public resource. All humans should share in and have access to the benefits of databases*'' (Human Genome Organization [HUGO], 2002).

Commercial rights for patency and intellectual property should not dominate or prevent knowledge sharing and open science. Recommendation 6, of the HUGO Statement, stated that researchers and commercial entities are acknowledged to ''*have a right to a fair return for intellectual and financial contributions to databases*,'' but ''*fees should not restrict the free flow of scientific information and equitable access*'' (HUGO, 2002).

Researchers argue that the dilemma of property rights of biosamples and data could be resolved by benefit sharing (Ram, 2015). Open science, or sharing benefits with individuals and the community at large in terms of knowledge to improve the health of the population could be a motivating factor to research participants (Gitter, 2013).

In terms of other forms of benefit sharing with research participants, the HUGO clearly distinguishes two forms of remuneration for research participants: direct compensation and benefit sharing (Ram, 2015; Ridgeway et al., 2013). The HUGO Statement on the Principle Conduct of Genetic Research, 1996, recommends prohibiting "*undue inducement through compensation for individual participants, families and population*". However, as the statement clearly articulates, *'This prohibition does not include agreements with individuals, families, groups, communities or populations that foresee technology transfer, local training, joint ventures, provision of healthcare or information, infrastructures, reimbursement of costs, or the possible use of a percentage of any royalties for humanitarian purposes*" (HUGO, 1996). With expanded commercialization of genetic research and contribution from private sector that exceed government contribution, Recommendation 6 of the HUGO Statement on Benefit Sharing in 2000 requires that *"profit-making entities dedicate a percentage (e.g. 1% - 3%) of their annual net profit to healthcare infrastructure and/or to humanitarian efforts*" (HUGO, 2000).

2.7.3 **Social challenges**

Existing published studies found that the general public were not familiar with biomedical research, genomics nor biobanking (Abou-Zeid et al., 2010; Ahram et al., 2014; Al-Hussaini & Abu-Hmaidan, 2014; Al-Jumah et al., 2011; Allen & McNamara, 2011; DHWA, 2010; EC, 2012; Eder et al., 2012; Gaskell et al., 2013; Godard, Ozdemir, Fortin, & Egalite, 2010; Igbe & Adebamowo, 2012; Luque et al., 2012; Millon Underwood, Buseh, Kelber, Stevens, & Townsend, 2013; Moriya, Inoue, Ikeuchi, Ishii, & Motojima, 2014; Nasrella & Clark, 2012;

Rodriguez et al.,. 2013; Simon et al., 2011; Streicher et al., 2011; Tauali et al., 2014; Tupasela et al.,2010).

In addition great variation in the willingness to participate in a population-based biobanks across populations and subgroups within the same population. there was also variation in the factors influencing willingness to participate (Abou-Zeid et al., 2010; Ahram et al., 2013; Banks et al., 2012; Critchley et al., 2012; De Vries et al., 2016; Gaskell et al., 2013; Halverson & Ross, 2012a; Lewis, Clotworthy, Hilton, Magee, Robertson, Stubbins, & Corfield, 2013a; Ma et al., 2012; Millon Underwood et al., 2013; Overby et al., 2015; Ridgeway et al., 2013; Sanderson et al., 2013; Tauali et al., 2014; Toccaceli et al., 2014; Tupasela et al., 2010). These factors will be elaborated later in the discussion and comparison with this study results.

Studies also showed diversity in terms of public's views, preferences and concerns about biobank procedures and policies, such as the consent procedure (Ewing et al., 2015; Garrison et al., 2015; Joly et al., 2015; Lewis et al., 2013a; Platt et al., 2014), privacy and confidentiality protection (Ahram et al., 2013; De Vries et al., 2016; Eder et al., 2012; Gaskell et al., 2013; Halverson & Ross, 2012a; Igbe & Adebamowo, 2012; Joly et al., 2015; Kerath et al., 2013; Lemke et al., 2010; Melas et al., 2010; Nasrella & Clark, 2012; Overby et al., 2015; Pullman et al., 2012; Rahm et al., 2013; Ridgeway et al., 2013; Simon et al., 2011; Spruill et al., 2014), returning individual genetic research results (Al-Hussaini & Abu-Hmaidan, 2014; Al-Jumah et al., 2011; Allen et al., 2014; Bollinger et al., 2012; Haga et al., 2013; Halverson & Ross, 2012a; Karlson et al, 2016; Lemke et al., 2010; Lipworth et al., 2011; Meulenkamp et al., 2010; O'Daniel & Haga, 2011;

Rodriguez et al., 2013; Streicher et al., 2011), as described earlier. The biobank initiator or custodian in selecting the appropriate biobank policies will need to consider the characteristics and perspectives of potential participants (Dove et al., 2012; Joly et al., 2015; Kaye, 2012b; Kelly et al., 2015; O'Doherty et al., 2011; O'Doherty et al., 2012; Platt et al., 2014; Simon et al., 2011).

The success of biobanks is dependent on public active, long-term engagement and wider, voluntary participation (Critchley et al., 2012; Husedzinovic, Ose, Schickhardt, Frohling, & Winkler, 2015; Marko-Varga et al., 2014; Nobile, Vermeulen, Thys, Bergmann, & Borry, 2013; Olson et al., 2014; Porteri et al., 2014; Watson et al., 2014). Public engagement and participation is expressed in the ability to make informed decisions regarding participation in biomedical research as well as in empowering and taking active role in the development of biobank governance framework, such as representation in REC, advisory committees or patients' advocacy groups (Silverman et al., 2015; Silverman et al., 2013).

Public engagement and empowerment is greatly influenced by many factors. These include the political system and its stability, social and economic development, research ethics capacity and bodies (Silverman et al., 2015; Silverman et al., 2013), legal and regulatory structure and stage of development (Kaye, 2012), healthcare and information technology (Nair et al., 2013), health and research literacy- knowledge on diseases, research processes and technologies (Budin-Ljøsne et al., 2012; Nair et al., 2013; O'Doherty & Hawkins, 2010; O'Doherty et al., 2011; Silverman et al., 2013) and an understanding of their rights as participants in research (Nair et al., 2013; Silverman et al., 2013).

Public engagement and consultation during all phases of the biobank project lifecycle is crucial. Efforts need to be made by the initiator or the custodian of the biobank, to ensure that public are actively and transparently engaged and empowered. It is believed that public engagement ensure biobank research is conducted in an ethical, locally appropriate manner (Lemke et al., 2010; O'Doherty et al., 2011; O'Doherty et al., 2012). Furthermore, public engagement is also one way to reach to a consensus to the long debatable discussion on biobank research concerns (O'Doherty et al., 2011; O'Doherty, Hawkins, & Burgess, 2012). Last, public engagement increase public trust on biobank and ownership and therefore improve participation and long-term engagement (Critchley et al., 2012; Husedzinovic et al., 2015; McWhirter et al., 2014; Nobile et al., 2013; Watson et al., 2014).

There are various models of community engagement, empowerment and meaningful public input on biobank policies and governance. These include surveys, forums, focus group discussions, democratic public deliberations, innovative web 2.0 communication solutions and others (Dove et al., 2012; Joly et al., 2015; Kaye et al., 2015; Longstaff & Burgess, 2010; O'Doherty & Hawkins, 2010; O'Doherty & Hawkins, 2010; O'Doherty et al., 2012; O'Doherty, Ibrahim, Hawkins, Burgess, & Watson, 2012; O'Doherty & Burgess, 2013; Steinsbekk et al., 2013; Teare, Morrison, Whitley, & Kaye, 2015). There is no universal magic strategy to establish smooth dialogue with the general public and the potential biobank participants, as different cultures and traditions require different approaches (Gottweis et al., 2011).

Health literacy is another crucial empowerment strategy to increase community control over health, and to make appropriate informed decisions (Sorensen et al., 2012) including participation in medical research and through understanding their rights as research participants. It gained global attention in the last few years due to associations with social determinant of health, health behavior and health outcomes, utilization of health care services and the quality of healthcare systems (Nutbeam, 2008; Sorensen et al., 2013). Improved health literacy leads to gaining skills and capabilities required to engage in a range of health-enhancing actions such as skill of social organization and advocacy, skill of negotiation and self-management, active engagement in social actions for health, and participation in changing social norms and practices (Nutbeam, 2008).

Public are more likely to participate and engage in population-based biobank research if they are aware of its existence, importance and social benefits, and are familiar with its operations (Gaskell & Gottweis, 2011).

2.8 Models and Solutions for Biobank Governance Challenges

Many researchers argue that traditional governance structures cannot deal with the unique challenges of biobank research described above (DHWA, 2010; EC, 2012; Gottweis & Lauss, 2012; O'Doherty & Hawkins, 2010; O'Doherty et al., 2011; Olson et al., 2013; Olson et al., 2014). Various models and solutions for effective, innovative governance have been proposed to overcome biobank governance challenges. A few will be described below.

2.8.1 Models

One model proposed is adaptive governance. This model relies on four principles to ensure sustainable and effective governance of biobank. These are:

firstly, recognize biobank participants as a collective body. Biobanks are a large public investment, and their objectives are for public benefit; therefore, it is very important to involve the broad community in active engagement to shape policies. Secondly, trustworthiness. Public trust is essential for biobanks to increase participation and ongoing engagement. Trustworthy biobanks need to have fair recruitment policies and community representation, make available transparent reports to the public on compliance or faults to compliance, undergo regular auditing by an independent regulatory body to monitor adherence to laws and policies, and to ensure financial sustainability. Thirdly, governance structures must be adaptive to the dynamic nature of biobank; they should be built up and improved over time, and incorporate innovative technology solutions. Finally, there must be alignment in the nature of the biobank in terms of purpose, size, collaborators and the specific governance structural framework adopted (O'Doherty & Hawkins, 2010).

A second model proposed by a few researchers is the solidarity-based governance model. This model originated from the field of politics and social science. It relies on the principle that all individuals are part of this society and in return, individuals have an obligation toward the society, which includes helping others. This model shifts from a restrictive autonomy-focused one towards a more harm mitigating one, and a commitment to veracity without affecting the respect for individual values. It implies that researchers can appeal to the solidarity of individuals, as these individuals have benefitted from earlier research and will possibly benefit from future research. Participants still have the right to refuse or withdraw participation at any time. Solidarity in this model implies that participants are willing to accept certain potential costs, the risk of harm and the

inconvenience that may rise as result of participation, to assist others (Hens, Nys, Cassiman, & Dierickx, 2011; Prainsack & Buyx, 2013). In this context, it is assumed that participants agree to allow the use of their samples and data in research other than what was originally envisioned, as long as it is consistent with the overall values and purposes of the biobank. Therefore, it supports the use of broad consent. It also shifts efforts and financial resources from risk mitigation strategies to more of educational and research activities. Likewise, from the biobank's prospective, this model assumes that the biobank governance structure and policies will ensure treating participants as partners in research, to whom the biobank owes respect and veracity. Efforts must be made to ensure and maintain participants' trust. The idea of open science, as well as data access and sharing with various researchers, relies on the principle of solidarity. Data or benefit sharing becomes a contractual obligation of researchers towards society at large (Prainsack & Buyx, 2013).

Integrating population-based biobanks into the healthcare system is another model to address some challenges associated with biobank governance, including financial sustainability and ongoing recruitment and engagement of participants (Kaye, 2012a). Furthermore, institutionalization of biobanks supports the introduction of personalized medicine, and the translation of research results into clinical care (Harris et al., 2012; Kaye, 2012a; Wyld, Smith, Hawkins, Long, & Ward, 2014). One recent example is the Estonia biobank (Leitsalu et al., 2015; Leitsalu et al., 2015) described earlier. Another example is the Million Veteran Program (MVP), a mega-biobank launched by the US Department of Veterans Affairs in 2011 to establish a national longitudinal study of veterans for future genomic and other biomedical research (Gaziano et al., 2016). It is summarized in

Table 21. The successful integration of biobanks into healthcare systems relies on early planning and collaboration of all stakeholders (Wyld et al., 2014).

2.8.2 **E-governance solutions**

Several e-governance solutions such as 'ELSI by design' were proposed and designed in order to overcome the ethical, and other legal and social implications, and to consider international dimensions. These technology-based solutions are built to be integrated with traditional governance structure and not replace it (EC, 2012; Kaye, 2012b; Kaye et al., 2015; Williams et al., 2013). Examples of such solutions are Dynamic Consent, Wiki-governance and DataSHIELD.

Dynamic Consent is one of the models proposed to overcome ethical concerns related to one-off static consent. Dynamic Consent requires governance mechanisms that involve information and communication technologies (ICT) solutions such as Web 2.0, which allow participants to engage as much as they choose. Participants, through digital communication, can interface and control different privacy settings and decide who is allowed to access their de-identified information and/or contact details. In addition, this system allows researchers to streamline recruitments, and enable participant recontact (Kaye et al., 2015; Steinsbekk et al., 2013; Teare et al., 2015).

Dynamic Consent is not a replacement for existing consent approaches, but rather a tool that could facilitate the process of obtaining consent (Kaye et al., 2015; Williams et al., 2013). This approach is believed to address a few ethical concerns, as well as the public preference to specific consent. This increases transparency, which in turn increases trust in biobank activities, and an ongoing

engagement and communication with biobank will align with the ongoing nature of biobank research (Gottweis et al., 2011; Platt & Kardia, 2015; Stein & Terry, 2013; Steinsbekk et al., 2013; Watanabe et al., 2011; Wee et al., 2013; Williams et al., 2013).

However, they do not address the concept of reciprocity as a feature of engagement as participants contribute their samples and data, and in return they are interested in being aware of how their contributions are used in research. They also like to receive information on general research results that utilize their samples and data (Hobbs, Starkbaum, Gottweis, Wichmann, & Gottweis, 2012; Nobile et al., 2013; Steinsbekk et al., 2013; Wee et al., 2013). Additionally, this model is subject to privacy regulation within the country, the information technology infrastructure, and the availability of its management cost (D'Abramo et al., 2015).

Wiki-governance is another collaborative solution recently proposed for large scale, population-based biobanks to avoid the issues raised with small biobanks including the top-down governance structure, and to ensure a more active and ongoing participation from all stakeholders. It is a web 2.0-based solution, using a social-media driven HTTP Secure online digital forum through which registered stakeholders, mainly research participants, and others such as researchers and collaborators can submit their proposal for digital governance structure, research protocols, strategies and policies online. Suggestions received as comments, or as part of discussion then shape the policy content that will be modeled into workable policies and guidelines with the help of policy experts and the biobank management committee. This collaborative ongoing effort is believed

to increase buy-in of all stakeholders to the biobank governance structure and policies, and to ensure that it is crafted in partnership with the research participants and other stakeholders rather than imposed by others (Dove et al., 2012; Joly et al., 2015). Nonetheless, some researchers argue that this solution is complex, abstract and time-consuming (Joly et al., 2015).

DataSHIELD is another e-governance solution, especially valuable for collaborative studies and global governance. This solution is designed to protect research participant privacy and confidentiality, while facilitating and promoting collaborations and access of researchers to individual-level data (EC, 2012; Gaye et al., 2014; Wallace & Kent, 2011). Further, DataSHIELD has the potential to protect the intellectual property of researchers in biobanks (Gaye et al., 2014). It enables simultaneous parallelized analysis of the individual-level, harmonized data of several studies, without the need for these data to leave the database. It also enables the return of data inquiries in the form of anonymous summary statistics or aggregate results (Dove et al., 2012; EC, 2012; Gaye et al., 2014; Wallace & Kent, 2011; Wolfson et al., 2010).

This solution requires the setup of a dedicated data computer (DC) at each collaborating center. The DC is set up with the necessary softwares such as OPAL instance or R instance, and appropriate firewall protections. OPAL is the core database application which has been developed by OBiBa, and R is an open source software for statistical computing. The commands are sent from a central analysis computer (AC) to several DCs (Gaye et al., 2014; Murtagh et al., 2012; Wallace & Kent, 2011).

2.9 Regional Experience and Summary of Selected International Biobanks

Biobanking was introduced recently in the Middle East region by a few countries. Iran has a disease-oriented National Tumor Biobank, Israel and Cyprus established biobanks including a national population-based biobank (SpecimenCentral.com, 2016). Turkey is planning a national biobank soon (Daily Sabah, 2015). The experience from the Arab countries of the Middle East region is also new. Described below are existing biobanks in the region.

The first experience in the Arab countries was Qatar biobank. Qatar is a small country, with total population of 2.5 million in 2015, of which Qataris, at 300,000 formed 14% of the total population (Al Kuwari et al., 2015; Qatar Biobank, 2016). The Qatar biobank was established in 2010 by the Qatar Foundation, in collaboration with Hamad Medical Corporation and the Supreme Council of Health. It is supported by experts from Imperial College London. Qatar biobank is a population-based biobank that aims to study the influence of genes, environment and lifestyle in common diseases. It targets 60,000 participants (one fifth of Qatari population), both Qataris and long-term residents (>15 years) aged 18 years and above. Recruitment started in December 2012, and is ongoing. These invitations are planned to be extended to younger population between 14-17 years (Al Kuwari et al., 2015) at a later stage. Participation involves completing a health and lifestyle questionnaire, collection of biosamples (blood, urine and saliva), and a series of noninvasive measurements such as anthropometry, body composition, bone health, cognitive function, grip strength, retinal and disc imaging, measurements of cardiovascular, respiratory and lung functions. Participants are informed about the possibility of recontact or invitations for subsequent future

visits. Qatar biobank follows international and national ethical guidelines, and is compliant with Islamic religious principles. Qatar biobank is working in partnership with Rice University in Huston, Texas, to develop policies on the ethical implications of biomedical research. Qatar biobank implements ISO 9001 QMS (Al Kuwari et al., 2015; Qatar Biobank, 2016).

Another example is the Saudi biobank. It was established in 2011 by the King Abdullah International Medical Research, which is a part of the National Guard Health Affairs (NGHA) in affiliation with P^3G. The Saudi biobank is funded by two governmental organizations: the King Abdul Aziz City for Science and Technology and King Abdullah International Medical Research. The NGHA serves a community population of 2.5 million with nearly 60,000 patients a year, and has 4 large hospitals and 60 health centers. It is a population-based and disease oriented biobank, and aims to collect from the catchment area 100,000 samples from the public aged 10-70 years, in addition to 100,000 patients with certain diseases. The population-based biobank collects health and lifestyle data, non-invasive measurements, and samples of blood and urine. Recruitments started in 2013 and was ongoing until 2016. Saudi biobank follows international and national ethical guidelines, and is compliant with Islamic principles (Alahmad & Dierickx, 2014; Alahmad, Hifnawy, & Dierickx, 2015). The establishment and development of the biobank SOPs were supported by P^3G (Public Population Project in Genomics and Society, 2012).

The third example is from Jordan. The King Hussein Cancer Centre Biobank (KHCCBIO), Jordan's first biobank, was established in November 2011 in one of the most well-known, comprehensive cancer care centers in the Middle

East, which caters to 3500 cancer patient annually. It is a disease-oriented biobank, specifically for cancer, and aims to collect 10,000 samples over 10 years from cancer patients in Jordan and neighboring countries. Samples and related clinical data will be collected and used in research for the purpose of developing biomarkers and potentially diagnostic products. The KHCCBIO is supported by the Seventh Framework Programme (FP7) and funded by the European Union (Barr et al., 2014; Chen & Pang, 2015). The SOPs were developed based on the guidelines of the Molecular Medicine Ireland (MMI), St James' Hospital and Trinity College Dublin. It will also implement ISO 9000 QMS to ensure high quality research, and meet any future regulatory requirements (Barr et al., 2014).

Table 2-1, summarizes the regional experience, besides providing examples of some selected international population-based or large-scale biobanks (>200,000 participants). It provides information on the year of establishment, number of participants, their age ranges, recruitment status, source of funding and integration with the healthcare system. Moreover, presents comparisons of policies pertaining to informed consent, withdrawal application, future contact and individual genetic research results return.

Table 2-1: Examples of existing national and large-scale population-based biobanks in selected counties.

Name /Country	Year	Type	Participants Size/status	Source of funding	Consent policy	Withdrawal Applications	Future contact	Genetic Result return	Embedded in HCS	Reference
Estonian Genome Project (Estonia) geenivaramu.ee	2000	PB	52,000 (18 + y) Target 1 million Ongoing	Non-profit Gov. & Research entities	Broad consent	2 stages, 1) before coding right to withdraw/ 2) after coding; data destroyed	Yes	Yes (in pilot phase 2015-8)	Yes. NHIS	Leitsalu et al., 2015& Leitsalu et al., 2015, Al Ahmad et al. 2014, Website
Spanish National DNA Bank (Spain) bancoadn.org	2004	PB & DO	NA	Non-profit	Broad consent	Destruction or anonymization of the sample	NA	NA	Yes. NHS	Morente et al, 2011, Sak et al., 2012
UK biobank (UK) ukbiobank.ac.uk	2006	PB	500,000 (45–69 y) Enrolled	Non-profit Gov. & charitable funding	Broad consent	3 options; No further contact/No further access/No further use	Yes	No	Yes. NHS	Website, Al Ahmad 2014b
Canadian Partnership for the Tomorrow Project (Canada) partnershipfortomorrow.ca	2008	PB	300,000 (35-69 y) Enrolled	Non-profit	Broad consent	No further use of data, samples, and destruction of codes.	Yes	No	No	Website, Fortin et al. 2011
Research Program on Genes, Environment, and Health (US)	2009	PB	500,000 Adult members of Kaiser Permanente Enrolled	Non-profit Kaiser Foundation	Broad consent	Right to withdraw authorization to use protected health information	Yes	No	Yes. NIH database & MR	McCulloch, E., 2013
Swedish National Biobank Program (Sweden) bbmri.se	2010	PB	70,000 (40–60 y) Enrolled	Non-profit	Specific informed consent	3 options; No further contact/ No further access/No further use	NA	NA	No	Scott et al., 2012, website
Million Veteran Program (US) research.va.gov/mvp/	2011	PB	400,000 Veteran Target 1million Ongoing	Non-profit Department of Veterans Affairs	Broad consent (opt in)	NA	Yes	NA	Yes. VA Healthcare System	Gaziano et al., 2016

PB: Population-based, DO: Disease Oriented, NA: Not available, NHS; National Health Services, NHIS; National Health Information System

Continue Table 2-1

Name , Country website	Year	Type	Size (age)	Source of funding	Consent policy	Withdrawal Applications	Future contact	Genetic Result return	Embedded in HCS	Reference
Biobank Japan (Japan) biobankjp.org	2003	DO	300,000 patients affected with 47 diseases. Enrolled	Non-profit	Broad consent	NA	NA	NA	Yes	Lee et al., 2012, Yoshizawa 2014, Kang et al., 2013, Scott et al., 2012
China Kadoorie Biobank (China) ckbiobank.org	2004	PB	510,000 (35-74 y) Enrolled	Non-profit Kadoorie Foundation & Wellcome Trust	Broad consent	NA	No. periodic survey of 10,000	NA	No	Yoshizawa 2014, Li 2015, website
Taiwan Biobank (Taiwan) biobank.org.tw	2005	PB & DO	200,000 (30-70 y) & 100,000 patients Enrolled	Non-profit Government	Broad consent	cease providing any biological specimen, withdraw, or change the scope of the use	NA	NA	No	Fan et al, 2015 P^{3}G website Yoshizawa 2014
Korea Biobank Project (S Korea) /koreabiobank.re.kr	2008	PB & DO	300,000 (40–69 y) & 200,000 patients Enrolled	Non-profit Government	NA	NA	NA	NA	NA	Cho 2012, Lee 2012, Yoshizawa 2014
Qatar Biobank (Qatar) qatarbiobank.org.qa	2010	PB	60,00 (18 + y) Qatari & long-term residents Ongoing	Non-profit Government	Broad consent	NA	Yes	No. Assessment results return if consented yes	Yes.	Al Kuwari et al., 2015, website
Saudi Biobank (Saudi) kaimrc.med.sa	2011	PB & DO	Target 100,000 (10-70y) & 100,00 patients Ongoing	Non-profit	Broad consent	3 options. No further contact, No further and access, Use of fully irreversible anonymized samples & data	Yes	NA	Yes. NGHA Network	Al Ahmad et.al 2014 & 2015, P^{3}G Newsletter 2012

PB: Population-based, DO: Disease Oriented, NA: Not available, NHS; National Health Services, NGHA; National Guard Health Affairs

2.10 Summary of the Literature Review

To summarize, there are different types of biobanks, which can be broadly categorized into population-based and disease-oriented biobanks. Most of existing biobanks are disease-oriented. Population based biobanks are more common in Europe than other parts of the world; however, it is expanding worldwide since the 1990s.

Population-based biobanks aim to discover biomarkers for disease susceptibility within a specified population through collection and storage of biosamples and comprehensive data on personal and family health, as well as environmental exposures and lifestyle from a large number of healthy individuals. It focuses on publics' interests and benefits rather than individual participants' benefits. It aims to improve wellness and health of future generations.

Population-based biobanks are invaluable resources to promote epidemiological and genomic research to improve populations' health, monitor diseases and other health outcomes, and pave the way to accelerating personalized medicine. Biobanks will advise on planning effective and targeted disease prevention interventions and health promotion messages for public health, as well as on methods to improve clinical care, based on genomic profiles and risk stratification.

To establish a population-based biobank, a number of basic requirements need to be developed, approved well in advance, and communicated to all stakeholders. These requirements must be developed based on guidance best practices, in compliance with international regulations, and in consultation with stakeholders: most importantly potential biobank participants and the general public.

Biobank governance structures include formal and less formal structures. The governance framework of a biobank is influenced by the biobank's purpose, design, scale of bioinformatics and communication technologies, potential for commercialization, and building regional or international networks. The development of biobank legal instruments varies across countries, and there is a huge gap in the Middle East region. The role of RECs is important in order to oversee research and the use of biobank resources. Other important oversight bodies might include National Research Council or Data Protection Committee or its equivalent that could regulate REC's. Others such as community advisory groups are important to present the voice of research participants.

Population-based biobanks are unique initiatives, and their governance is a huge challenge worldwide. Ethicists have raised several ethical, legal and social concerns. Legal instruments have their own challenges. There are a number of international gold standards declarations and guidelines on best practices; these could be used as references to ensure high quality operations and protection of participants' rights, but they do not have legal standing. Most common ethical challenges include ensuring informed consent of participants, ability to withdraw consent and its implications, privacy protection of personal and genetic data, return of individual genetic research results, and the potential for commercialization of biobanks. Important social challenges include the engagement and empowerment of general public in terms of informed consent participation and active involvement in biobank governance.

A majority of researchers argue that the traditional biobank governance structure cannot deal with the unique challenges of modern biobanks research. Various models and e-solutions for effective and innovative governance have been proposed to overcome biobank governance challenges.

Biobanking experience of Arab countries in the Middle East is humble yet growing. Qatar biobank, established in 2010, is the first and only true national population-based biobank in the region, and offers promising regional experience. This is followed by the Saudi biobank established in 2013, which is both population-based and disease-oriented.

Chapter 3: Methods

This chapter describes the study methodology, including the main research questions, study design, recruitment of study participants, sampling of participants and sample survey size, survey development and administration, study independent variables and main outcome variable, coding of data, statistical analysis and data limitation. In addition, it highlights matters pertaining to the protection of research participants and related issues.

3.1 Research Questions and Hypothesis

3.1.1 Research questions

Our main research questions concerned about (i) estimating the overall probability, at the population level, of the Emirati general public's willingness to participate in a population-based biobank for genomic research and (ii) elucidating factors associated with their decision to participate.

3.1.2 Hypothesis

We assumed that there would be a significant difference in the probability of willingness to participate in the proposed population-based biobank, by gender. This assumption was based on findings from a regional study from Saudi Arabia, a country which has a similar context and cultural background as Abu Dhabi, UAE. There it showed that being female was associated with willingness to participate in biomedical research. It increase likelihood of participation by two and a half folds (Adjusted OR=2.53, 95%CI; 1.69 -3.77, $P < 0.01$). (Al-Jumah et al., 2011).

3.2 Conceptual Framework

To guide this study, a conceptual model was created as given in Figure 3-1. It describes major factors that could influence the general public's engagement and participation in a population-based biobank. The conceptual framework guided the development of a survey questionnaire as well as the interpretation of results, their implications for policy development and recommendations of future research.

The conceptual model was developed on the basis of reviewing the literature as well as on my understanding of the issues related to governance challenges of population-based biobank. In particular, it looked at the social challenges and factors influencing the general public engagement and participation in biobank research, as well as the key requirements for the setup of a biobank and innovative models and e-solutions to overcome governance challenges. It was also based on my observations and experience in planning, implementing and monitoring various public health programs and initiatives in Abu Dhabi, in addition to several other factors, which are included in the framework.

The conceptual framework groups identify relevant factors into proximal and distal factors, and illustrate some of the complex relationships among these variables. Proximal (direct) factors are subcategorized into individual and biobank-related factors. Individual factors include (i) socio-demographic characteristics such as age, gender, education level, income, marital status, parental status, insurance, place of residence, religion, ethnicity and others; and (ii) perceived risks and benefits of biobanking for future research to self, family

and society at large, including a history of family or personal chronic diseases that might motivate participation in biobank research.

The biobank related factors include: (iii) biobank model or design features of purpose, method of recruitment and collection of biosample and data, type of biosample to be collected, initiator, custodianship, collaborators, source of funding including potentials for commercialization, and integration with healthcare system or accompanying clinical services provided at time of donation. It also includes (iv) biobank standard procedures and governance, consent and withdrawal of consent, protection of participants' privacy and confidentiality, methods to recontact, return of research results, as well as ownership and benefits sharing, among others.

Distal factors include: (i) health and medical research literacy; (ii) healthcare system factors, experience with healthcare services and trust in key actors such as the government, healthcare providers, research institutions and researchers; (iii) health information and communication technologies, strategies used in biobank operation, governance, and communication with various stakeholders, most importantly participants and the general public; and (iv) the social, economic and legal development of the country and socio-cultural context and influences.

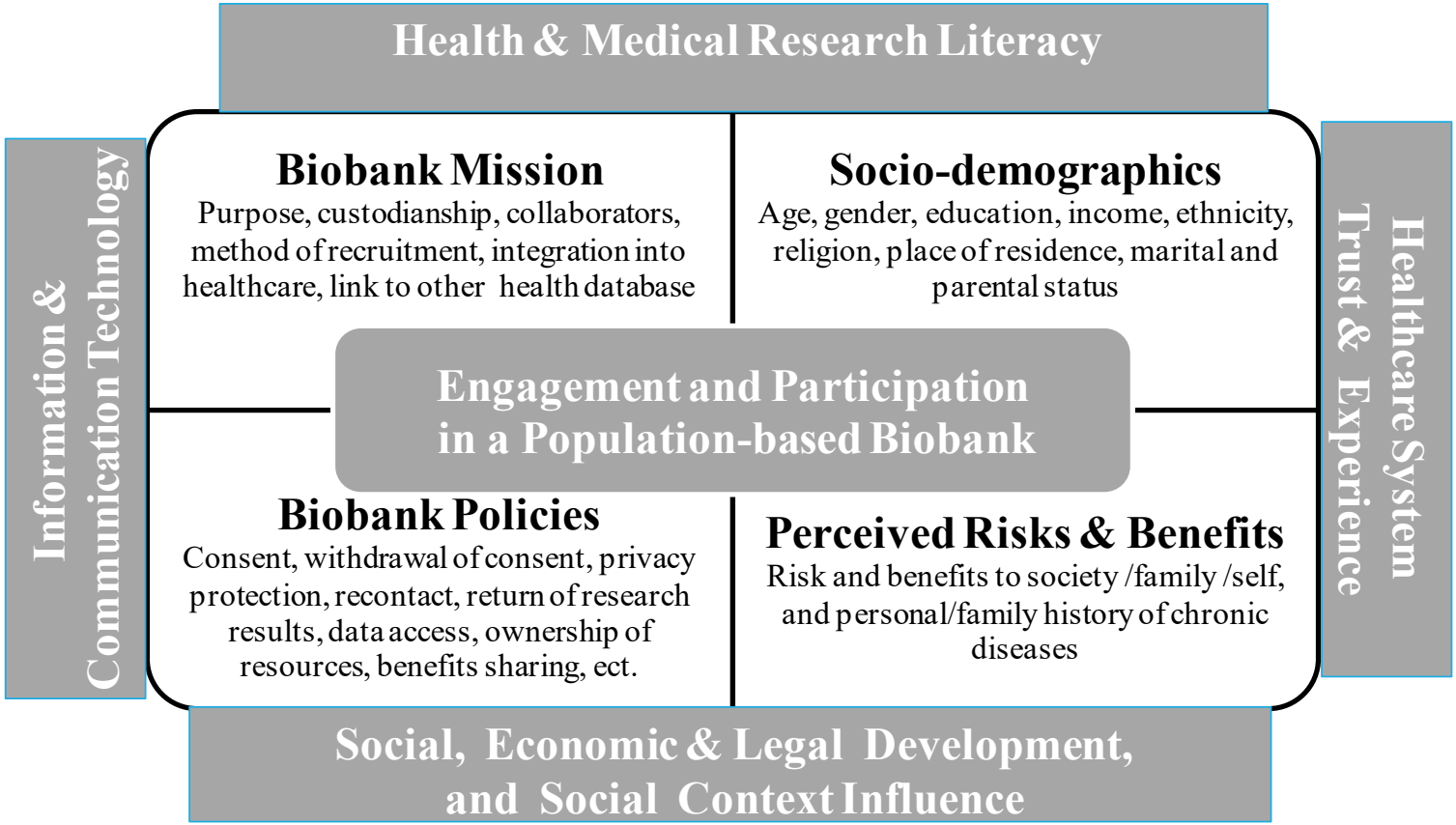

Figure 3-1: Conceptual framework: Factors influencing public's participation and engagement in population-based biobanks

3.3 Study Design

The study in Abu Dhabi was cross-sectional and emirate-wide. Data was collected through telephone interviews using a structured survey questionnaire. Eligible participants comprising adult Emirati volunteers were drawn at random from a list of individuals who underwent *Weqaya* screening as the prospective participants of the biobank project. The study was conducted over 11 months, from April 2015 to March 2016.

3.4 Study Participants

Participants eligible for this study were those who underwent *Weqaya* screening during the period of July 1, 2012- March 31, 2015. They were adult Emiratis 18 years and above, residing or working in the emirate Abu Dhabi, and covered by *Thiqa* insurance plan. *Thiqa* is the Arabic word for 'trust' and is a single-payor health insurance plan for UAE nationals.

3.5 Sampling and Sample Size

The study subjects were selected through the random sampling of a list of individuals who underwent *Weqaya* screening during the above-mentioned period, using Stata Statistical Data Analysis software version 11.2. The list was derived from Daman Insurance Company which administers the *Thiqa* insurance plan. Since two-thirds of the list comprised females, a stratified sampling method was used to adjust for gender in order to ensure that the samples represent the true population gender distribution (1:1) and would be eligible to test the specified hypothesis. Within each gender, an equivalent set of random samples were selected. A sample size of 600 individuals was considered adequate for the purpose of this study.

The sample size calculation is shown in detail in Appendix II. The sample size was estimated based on various assumptions. First, it was based on an overall estimated true population proportion of willingness to participate in the population-based biobank. Several estimated true population proportions were assumed, both lower and higher than the two regional studies from Jordan and Saudi Arabia. The study from Jordan was recent, and it showed that 64% of the Jordanian adults in a national-wide survey were willing to participate in a biobank (Ahram, Othman, Shahrouri, & Mustafa, 2013). The Saudi study showed that 78.4% of Saudi participants, outpatients at a hospital in Riyadh City, were willing to donate their leftover samples for biomedical research (Al-Jumah et al., 2011). Assuming an accepted margin error of the true population proportion of 3% or 4%, the sample size was calculated using the equation, SE of p^= square root of p*(1-p)/n.

Another estimate of sample size was based on the hypothesis. The null hypothesis assumes no gender-based difference in the proportion of willingness to participate in population-based biobank. The sample size for two sample proportions was calculated using Stata, assuming a 5% level of significance and a study power of 90%, the various assumed overall population proportion used above, and the various assumed differences in proportions by gender.

The final sample size decided was based on an overall probability of willingness to participate was close to that of the study from Saudi Arabia, at 78.4%, assuming difference by gender of 10 to 12%, as this was closer to our proposed method for acquiring biosample and health information that were left over. The sample size was then inflated, assuming a response rate of 70% for the telephone survey. This assumption was based on a recent small-scale experience of a phone

survey conducted by HAAD - Public Health team on Emiratis' satisfaction regarding the *Weqaya* screening program in 2013.

It is worth highlighting that during the first month of conducting the surveys, we experienced a high rate of invalid telephone numbers. Re-sampling of a larger sample size on the original list was done in order to account for that, and to reach the target of 600 completed surveys.

3.6 Survey Development and Administration

This section describes in detail the survey questionnaire development and refinement, as well as its administration. Arabic and English versions of the final survey questionnaire are provided in Appendix III.

3.6.1 Survey development and refinement

3.6.1.1 Survey development

The data were collected using a structured questionnaire. The development of the survey questionnaire was first informed by the literature. The initial version of the questionnaire was adapted from published instruments used in studies that focused on reported factors influencing the general public's decision to participate in a population-based biobank (Ahram, Othman, & Shahrouri, 2013; Kerath et al., 2013; Kettis-Lindblad, Ring, Viberth, & Hansson, 2006; Lewis, Clotworthy, Hilton, Magee, Robertson, Stubbins, & Corfield, 2013a; Sanderson et al., 2013; Simon et al., 2011; Wells et al., 2014).

3.6.1.2 Review by experts

The questionnaire was revised for content validity and for clarity of language by the Thesis Advisory Committee, a panel of experts that have the knowledge and

expertise in bioethics, health behavior, epidemiology, biostatistics and public health from Johns Hopkins University and UAE University.

3.6.1.3 Translation

The survey was initially developed in English, and a forward translation into Arabic was done by the primary investigator. The translation was first done using Google translation, and refined by the primary investigator and the research project team using simple and concise wording and paraphrasing to ensure that the translation was conceptually the equivalent of the original. It was then sent to an independent bilingual expert in English literature whose mother tongue is Arabic, along with background information on the purpose of this study in order to revise and match the Arabic and English versions. The final step of the translation was a backward translation by another independent bilingual public health staff who was not involved on this research and has no knowledge of the initial English version of the questionnaire. Both English versions were compared and found conceptually similar.

3.6.1.4 Cognitive testing interviews

Cognitive testing using face to face interviews was conducted on a small group of Emirati adults: 16 men and women that have characteristics similar to those of the study participants, in term of age, level of education and socioeconomic level, to pretest the questionnaire. The cognitive interview questionnaire is provided in Appendix IV. The group that participated in the interviews comprised the family, relatives and colleagues of the research team from HAAD, who are outside the medical or public health profession. The primary investigator developed a cognitive testing interview guide, and trained the research assistants to conduct the interviews and collect information. The cognitive testing interviews process and guide was

informed by the literature (Wells et al., 2014; Willis G, 2005). The purpose of these interviews was to test respondents' understanding of each question and their ability to provide accurate answers. It tested the questionnaire for clarity of the questions, and helped to tailor response options. In addition, it ensured the cultural and contextual appropriateness of the survey questions, responses and instructions.

Based on the findings from the cognitive testing interviews, and taking into consideration the mode of administration as telephone survey, it was decided that the questions needed to be refined further in order to make them simple and concise. Some questions and responses were paraphrased or shortened, and some deemed unnecessary, and introductory paragraphs and complex, problematic questions were deleted. The changes were incorporated into both Arabic and English versions of the questionnaire. The English version was then reviewed for a final time for language by a public health professional colleague who is a native speaker of English.

3.6.1.5 Presetting

Finally, the questionnaire was field pretested by the research assistants on a sample of 15 individuals - friends and colleagues - through conducting a phone survey to check for the reliability of the questionnaire, to assess the average time needed to complete the survey, as well as to ensure that study participants answered all of the questions during the field calls.

3.6.1.6 Final questionnaire

The final questionnaire, Appendix III, comprised 29 questions, the majority of which were closed-ended, multiple-choice questions. The question on age was open-ended, and in some questions, the participants were given the opportunity to provide comment or responses other than those listed. At the end of the questionnaire,

participants were also given the opportunity to provide general comment if any. All questions had the option of 'don't know/not sure' and 'refused to answer'.

The questions were designed to assess the factors described in the conceptual framework. It captured nine major domains: 1) demographic profile of the study participant; their 2) awareness of biomedical research and biobanking; 3) attitudes towards biomedical research and biobanking; 4) willingness to participate in a population-based biobank; 5) perception of risks and benefits of biobank research and health status; 6) socio-cultural context and influence; 7) healthcare system experience and trust; 8) public's views concerning recontact and return of research results; and 9) preferred health information and communication strategies.

To ensure better understanding of the research participants about the topic of the research, some questions, particularly those related to biosamples, biomedical research and genomics, included explanations of some terms. In some cases, an introductory paragraph was given prior to asking questions. This step was particularly important to overcome the anticipated biomedical research and biobanking illiteracy. For example, biomedical research was explained as "the medical research that involves the use of biological samples such as blood, urine or tissue". Participation in medical research was explained as, "donating blood or tissue for research or taking part in a trial for testing an experimental treatment". Genomics was defined as "the relation of human genes with health."

To ensure better understanding and informed decision-making regarding willingness to participate in population-based biobank, the following introductory paragraph was included. This paragraph defined a biobank, explained the proposed

model for establishing it, explained what participation in biobank research entailed, and reviewed the process of consent and its withdrawal.

"Biobanks are like a library that stores large numbers of samples along with related health information for several years for the purposes of medical research.

The Health Authority is planning to establish a population-based biobank in Abu Dhabi during the year. It will be managed by a healthcare provider. The purpose of the Biobank is to provide a resource that can support a diverse range of research, intended to improve the health of the Emirati population. Through this research, we hope to identify the genetic causes and variations of diseases common to the Emirati population. These include diabetes, heart disease, cancer and asthma, among others. It will also help to find new ways to prevent and treat these diseases in ways that are specifically tailored to Emiratis. It is hoped that this research will benefit current and future generations.

Blood and urine samples collected during the Weqaya screening program, which would otherwise have been discarded, would instead be retained, matched with the health information collected via a questionnaire, and deposited in the biobank. The biobank will store samples and health information in a de-identified manner. Personal identifying information such as name, insurance number or date of birth will be removed and replaced by codes. The researchers using the samples will not know whom they came from.

All adults 18 years and over in the emirate of Abu Dhabi will be invited to participate in the biobank. Participation in the biobank will be voluntary, and participants must give their permission for their samples and health information to be

included in the biobank. Participants have the option to withdraw from the biobank at any time in the future without giving any reason."

3.6.2 **Survey administration**

3.6.2.1 ***Data collection team***

The survey was administered by trained volunteers. Majority of volunteers were university students from the College of Medicine, UAE University (UAEU). Others were from Abu Dhabi University (ADU), New York University Abu Dhabi (NYAD), the Higher Colleges of Technology (HCT), and the Petroleum Institute. Volunteers also included interns in the course of their rotation to acquire the required training skills within the Department of Non-communicable Disease (NCD) — Public Health Division, Health Authority - Abu Dhabi. Additionally, some researchers were members of HAAD, NCD Department, Cardiovascular Diseases Section. Volunteer listings are provided in, Appendix V.

3.6.2.2 ***Recruitment of volunteers***

The UAEU student volunteers were recruited through the Head of Public Health Institute, Faculty of Medicine, the co-investigator of this study. Other university student volunteers were recruited through their coordinators in their respective universities, as the HAAD training section had an established communication with several universities for internship programs or training rotations. Email communication was sent to the coordinators of public health/health science institutes within these universities. The email communication provided background information on the study, the specific roles and responsibilities of the volunteers, expectations and appreciation. The co-investigator and coordinators of other universities sent an email communication with these details to all their students to

sign up as volunteers. The confirmed list was sent to the research assistants at HAAD to start the process of communication and training. The department interns were recruited by direct invitation. Signing up was completely voluntary, and there was no momentary reward offered for participation in the research study.

Although a few male volunteers signed up for this study, none completed the process of training. All volunteers who conducted the interviews were females, which was believed to give a sense of reassurance to the survey respondents.

3.6.2.3 Training of volunteers

All volunteers were supervised and supported by the research assistants throughout the period of data collection. All volunteers received training, signed a confidentiality agreement and received all the necessary documents including a summary presentation on the study, copies of the survey questionnaire in Arabic and English, the consent form, the participant information form and data dictionary. All these documents are available in, Appendices III, V, VI, and VII. The training session was interactive and lasted two hours. The training presentation provide background on the *Weqaya* Screening program, the proposed plan for the biobank, details of the study, acceptable conduct during the telephone interviews and how to respond to difficult situations that might occur. At least three pretesting telephone interviews were conducted by each volunteer with a research assistants member. The first field call of each volunteer was attended by the research team. Ongoing supervision and support was provided by the research team.

3.6.2.4 Data collection tool and data entry

The selected method for data collection was telephone surveys as it is a convenient, as well as time and money saving method for data collection, particularly

recommended for large and geographically scattered sample. It is a common tool for data collection, and is being increasingly used worldwide, especially by business and market research companies (Szolnoki & Hoffmann, 2013).

Unlike face-face interviews, self-administered surveys or online surveys, the telephone surveys minimize interviewer effects including social desirability bias, and allow for complex issues or questions to be clarified, thus ensuring understanding of the questions. It also provides a high level of anonymity which was extremely relevant in this study, given the unfamiliarity and sensitive nature of the topic and questions (Szolnoki & Hoffmann, 2013).

The data were collected directly into the online survey during the telephone interviews. The aim was to ensure good quality data (reducing the errors of manual data entry) and a faster method for processing, handling and storing the data gathered from telephone interviews.

All the telephone interviews were conducted in Arabic, and data were captured and entered using the Arabic online version of the Survey Monkey® tool. Volunteers receive an active link of the study Survey Monkey®. Each interview had a unique I.D. number that was entered in the online survey once consent was granted. These unique numbers were shared with volunteers through the same excel sheet that contained the list of potential participants and their contacts details.

3.6.2.5 Telephone interview procedure

Each volunteer received a weekly list of participants to first contact by email. The lists were sent using password protected Excel® sheets. All calls were attempted using fixed line telephones of either HAAD or the University. HAAD allocated

workstations for volunteers, and each participating university provided an office for their volunteers to conduct the calls.

The list contained two or three phone numbers for each potential participant. Volunteers called only the mobile phone numbers of participants and the phones were allowed to ring until they disconnected. If an alternative mobile number was available, the volunteer tried that as well. A maximum of three contact attempts were made for each participant. The calls were made between 9:00am and 1:00 pm, and 4:00 - 7:00 pm on weekdays, avoiding prayer and lunch times. These times were anticipated to be convenient for most participants. The weekly list of contacts was then returned to the research assistants by each volunteer at the end of the week with remarks in order to monitor the outcomes of calls and number of surveys conducted.

3.6.2.6 Confidentiality and study verification procedure

At the beginning of each call, the procedure for selection of the telephone numbers was briefly explained to potential participants. Volunteers read out the consent to each participant, and on receiving the same, the volunteer signed a hardcopy of the consent form. If the interviewee agreed to participate but at another time, or did not complete the survey at the time but was willing to continue later, the information, time and date were recorded on the consent form, and they were contacted later. Telephone numbers were not recorded on the consent form or the online survey questionnaire. Instead, unique survey numbers were recorded.

On obtaining consent to take part in this study, additional information on the study, including the study verification procedures, was offered to participants. Where an interviewee showed interest knowing more about the study, volunteers either shared the information written in the participant information form verbally, or gave

participants the option to have a copy sent by e-mail. The participant information form included the details of the primary investigator and their phone numbers in order to allow participants to verify the authenticity of the calls.

A couple of callbacks to volunteers were made during the course of data collection, mainly asking for other general inquires. These callers were referred to HAAD customer care.

3.6.2.7 Appreciation for volunteers

At the end of data collection, the volunteers as well as HAAD research team received a 'Thank you' letter signed by the primary and co-investigators, which is provided in Appendix VIII. Both volunteers and research assistants were duly mentioned and acknowledged in this study. Additionally, enthusiastic and high performing volunteers received small gifts in recognition of their extraordinary efforts.

3.7 Variables

3.7.1 Independent variables

3.7.1.1 *Demographic characteristics*

Demographic variables included gender, age, education level, employment and average monthly household income, region of residence, marital status, and parental status. Data on gender and region of residence were already provided in the Daman original list. Gender was confirmed during calls, as well as by the name printed on the consent form. Both variables were then entered manually along with the other collected data. All demographic question response options were multiple choice, except age assessed with an open-ended question and subsequently summarized into categories.

3.7.1.2 Health and medical research literacy

Health and medical research literacy were assessed by 8 questions. Three questions asked about the level of self-rated knowledge on biomedical research or medical research that involves human biosamples, understanding of genomics or the relation between human genes and health, and familiarity with the term 'biobank'. The responses were on a three-point Likert scale ranging from 'no knowledge' to 'good knowledge'. The other two questions assessed previous experience of blood donation or participation in medical research. The responses options included 'yes', 'no' and 'don't know/not sure'. Attitudes towards biomedical research and biobanking were assessed through three questions. Participants were asked to agree with the statement 'medical research improves patient health' and the response options were on a five-point Likert scale ranging from 'strongly disagree' to 'strongly agree'. Participants were also asked about the importance of donating biosamples for medical research, and the value of the biobank in generating new information to improve health. The response options to these questions were also on a five-point Likert scale ranging from 'not at all important/valuable' to 'extremely important/valuable'.

3.7.1.3 Socio-cultural context influence

The influence of social norms or socio-cultural context affecting public engagement and participation in the biobank was assessed through two questions. The first question asked about the willingness of other family members to participate in the biobank. The response options were on four-point scale of 'definitely yes', probably yes, 'probably no' and 'probably yes'. The other question asked about influencers on making the decision about participation. The response options were, 'entirely by yourself,' 'with the help of a family member or a friend', or 'with help from

a doctor or other healthcare provider'. There was also an option to state other influencers on their decision to participate.

3.7.1.4 Perceived benefits and risks of biobanking for research

Perceived benefits and risks related to participation in a population-based biobank were assessed by exploring reasons that would motivate them (perceived benefits) or make them concerned (perceived risks) about taking part in the biobank. The response options to both questions were a list of risks and benefits to society, self or family, including an option to provide additional reasons. Survey respondents were encouraged to select up to three reasons. Perceived benefits (motives) were then grouped in three major categories: (i) altruistic motives such as improving the wellness and health of future generations or supporting medical research; (ii) moral motives such as donation being a charitable act; (iii) egoistic (personal) benefits such as obtaining cure or better treatment for the condition of self or family members.

Health status of participants or their close family relative - with regards to diagnosis with chronic diseases, such as diabetes, asthma, heart disease, cancer, genetic condition or others - was assessed. Health status could be a motivator for participation, and might be associated with therapeutic misconception. The responses to health status questions included 'yes', 'no' and 'don't know/not sure'.

3.7.1.5 Healthcare system: Public trust and experience

The healthcare system related factors public trust and experience were assessed in three questions. The first asked about experience with healthcare services in the emirate of Abu Dhabi and the responses were on three-point Likert scale 'mostly negative', 'neutral' or 'mostly positive'. The second asked about trust in healthcare providers and the response was on a three-points Likert scale 'low',

'moderate' and 'high'. The third question asked about Trust in HAAD as a government entity supervising the biobank initiative, in terms of assessing risks and benefits of the biobank to the Emirati population. The response was on five-point Likert scale ranging from 'strongly disagree' to 'strongly agree'.

3.7.1.6 Public views on future recontact and return of research results

Participants were asked to imagine the scenario where they have agreed to participate in the biobank, then were asked the following three questions about certain biobank procedures: (i) if they would accept to be recontacted in the future (ii) if they like to receive general information regarding biobank research, and (iii) if they would like to receive information regarding their own genetic risk of health condition. The response options were on a four-point scale: 'definitely yes', 'probably yes', 'probably no', 'definitely yes'.

3.7.1.7 Health information and communication technologies

Preferred health information communication strategies was assessed in two questions. The first question asked about the preferred source for health information, particularly to learn more about the biobank, and the second question asked about the preferred means of communication to receive general research results of the biobank and updates. Participants were given the option to select up to three sources. The response to both questions was a list of sources, including an option to provide additional responses.

3.7.2 **The outcome variable**

The main outcome (dependent) variable is willingness to participate in a population–based biobank. Participants were given an introductory paragraph about

the proposed model for the future biobank, the purpose, the likely method of recruitment and requirements for participation. It was emphasized that participation in the biobank is voluntary. Willingness to participate was assessed by a single question. To ensure a clear position toward participation, a four-point scale was provided 'definitely would participate', 'probably would participate', 'probably would not participate' and 'definitely would not participate'.

3.8 Data Management and Interpretation

Before data collection, few validation rules and warning messages were built in the online Survey Monkey®, to ensure that all values were within accepted ranges, all questions were answered, and that the skipped questions jumped to the next relevant question. Online messages warned interviewers about entering invalid values or leaving incomplete answers. Volunteers were trained and provide with data dictionary. The data dictionary was considered essential to enhance the consistency of the data collected, minimize intrapersonal variation and standardize responses to participants' queries (if any).

During data collection, online survey interviews data were regularly monitored, almost on weekly basis. Duplicates surveys were removed. Volunteers were encouraged to complete incomplete interviews, one additional call attempted was tried only. Data was downloaded and saved on monthly basis, to avoid data loss.

After data collection, complete data were exported from Survey Monkey® as an excel spreadsheet. All the raw responses data were in Arabic. Responses were then coded as per the survey's original category codes. Gender and region data were entered manually into the excel spreadsheet. Data was assessed for completeness, anomalous values and duplicates. Data were lined up in proper columns and rows and

then imported to Stata Statistical Data Analysis software version 11.2 (Stata Corp, College Station, TX). An identifier was created, variables were named and labeled and duplicates were assessed. Finally, summaries were conducted to identify outliers and check for completeness and consistency of data.

Variables were subsequently recoded into new categories based on the literature of similar studies, and to ensure adequate number per category to run the statistical analysis. Table 3-1, below summarize the new categories and labels. Ordinal data from Likert-like variables were collapsed and dichotomized into two categories. All five-points Likert scale variables on attitudes were dichotomized into: agree (include strongly agree or agree) versus disagree (strongly disagree, disagree, neutral or not sure), important (include very or extremely important) versus not important (include not at all, somewhat, moderately important or not sure), and similarly, valuable versus not valuable.

All three-points scale Likert variables on trust in healthcare providers and experience on healthcare services were dichotomized into high trust or mostly positive, versus others (include moderate/neutral, low/mostly negative or not sure). Data on knowledge was dichotomized into good knowledge versus limited knowledge (include no, some knowledge or not sure). All four-point yes/no scales were dichotomized into definitely yes versus others (include probably yes, probably no, definitely no or not sure), while in the two-point yes/no scale, the 'no' included no and not sure. Age was presented as continuous data as well as categories: 18-24, 25-34, 35-54, 55-64, 65 years and above. Region of residence was collapsed into two categories since only five participants were from the Al Gharbia (Western) region. The codes were Abu Dhabi City versus other regions.

Table 3-1: Recoding and interpretation of study variables.

Variable name	Interpretations
Independent Variables	
Gender	1= Females 2=Males
Age	1=18-24 2=25-34 3= 35-54 4=55-64 5= 65+
Region of residence	1= Abu Dhabi City 2= Other regions
Highest education attained	1=Lower education (<Secondary) 2=Higher education (≥Secondary)
Current employment status	1=Others (including household duties/ students /retired/ unemployed) 2= At work
Monthly household income	1= Lower income (< 20,000 AED) 2= higher income (≥20,000 AED)
Marital status	1= Others (include single/widow/divorced) 2=Married
Parental status	1= No 2=Yes
Ever diagnosed with chronic diseases: Personal/Family	1=No (include No/NS) 2=Yes
Ever donated blood/ Ever participated in medical research	1= No (include No/NS) 2=Yes
Familiar with 'biobank'	1=No (include No/NS) 2=Yes
Knowledge on: Biomedical research/ genomics	1= Limited (No, some knowledge & NS) 2= Good knowledge
Experience with healthcare services	1=Others (include mostly negative/neutral/NS) 2=Mostly positive
Trust in healthcare providers	1= Others (include low/ moderate/NS) 2=High
Medical research improves patients' health	1=Disagree (include strongly disagree/disagree/neutral/NS) 2= Agree (include agree/ strongly agree)
Trust HAAD to assess risks & benefits of biobank	1=Disagree (include strongly disagree/disagree/neutral/NS) 2= Agree (include agree/ strongly agree)
Donating biosamples for research is	1= Not important (include not at all /somewhat /moderately important/ NS) 2= Important (include very/extremely important)
Biobank as a resource is …..	1= Not valuable (include not at all /somewhat /moderately valuable/ NS) 2= Valuable (include very/extremely valuable)
Decision to participate is made	1= Help of others (family members or friends/a doctor or healthcare provide /others) 2=Entirely by myself
Accept future recontact	1= Others (include definitely no/ probably no/probably yes/ NS) 2= Definitely yes
Desire for feedback	1= Others (include definitely no/ probably no/probably yes/ NS) 2= Definitely yes (strong desire)
Family participation	1= Others (include Definitely no / probably no/ probably yes/ NS) 2= Definitely willing (Definitely yes).
Outcome Variable	
Willingness to participate	1= Others (include Definitely no / probably no/ probably yes/ NS) 2= Definitely willing (Definitely yes).

3.9 Statistical Analysis

Quantitative analysis of the data was conducted using Stata Statistical Data Analysis software version 11.2 (Stata Corp, College Station, TX). Basic descriptive summary statistics and complex statistical analysis were conducted to address the research questions and objectives.

Most of the variables were categorical data, nominal or ordinal. Age was a continuous variable, and was subsequently categorized. Few questions have 'other' as a response to explore probe further responses. Those responses were subsequently summarized into categories and presented in the results.

Descriptive summary statistics were estimated for all variables using numbers and frequencies for categorical data, as well as mean and standard deviation for continuous data in order to identify outliers and other distributional characteristics that may influence regression, and to describe basic features of the data.

Comparison by age, gender and education was conducted for all study variables. Additional comparisons, where appropriate and relevant, were conducted for some variables to examine the difference by other demographic characteristics, health status, knowledge and attitudes towards biomedical research or healthcare system experience and trust.

Comparisons between groups were tested using Chi-squared ($\chi 2$) test or using Fisher's exact test where appropriate for non-ordered categories, Kruskal-Wallis for ordinal non-parametric distribution (Likert-type variables) and Students' *t*-tests for differences in continuous group means. A two-sided *P*-value of less than 0.05 was considered to assess statistical significance.

It is worth mentioning that the analysis of the five-point Likert scale attitudinal variables using both Kruskal Wallis test (using all the five categories and not sure categories) and Chi-squared ($\chi 2$) test (using two categories) yielded same statistical significance associations. Therefore, final analysis presented in the results section was for Chi-squared ($\chi 2$) test.

The association of the independent variables with the outcome variable, i.e., the willingness to participate in a population-based biobank, was examined by conducting univariate (binary logistic regression) and multivariate (multiple logistic regression) analysis. From the univariate analysis, the crude odds ratios (OR) with 95% confidence intervals (95% CI) on all independent variables were estimated. Wald *P* value was determined from testparm and considered significant if it was less than 0.05.

Associations that were found to be significant at univariate analysis were then entered into a multivariate analysis to generate the final model of factors that were independently associated with the willingness to participate in a population-based biobank.

Before running the final model, multicollinearity among the significant independent variables from the univariate analysis was first examined by running multiple regressions instead of logistic regression, and calculating the variance inflation factors (VIF). There were no significant correlations among the independent variables, and the mean VIF was below 2.0.

Secondly, the final model was selected through the use of both forward and then backward stepwise procedures, with P=0.05 as cut-off for inclusion or exclusion of variables. The candidate sets of significant independent variables entered into the

model were: gender, education, employment status, ever donated blood, knowledge on biomedical research, attitudes: to HAAD ,biomedical research, donation of biosamples and the value of the biobank, accept recontact, desire for return individual genomic research results , family participation (influence), influencers on decisions about participation, and the perceived benefits 'improve the health and wellness of future generation', 'support medical research', and 'donation is a charitable act'. Since gender is a key variable to test the pre-specified hypothesis, it was forced into the model using lock in term. The final model selected from backward and forward stepwise procedure included: gender, knowledge on biomedical research, attitudes towards the biobank, accept recontact, desire for return individual genomic research results, family willingness (influence), perceived benefits: 'improve the health and wellness of future generation' and 'support medical research'. For double checking, the Akaike's Information Criteria (AIC) was calculated for several models with different variables, the final model selected had the lowest AIC.

Thirdly, the overall fitness of the model was assessed using Hosmer-Lemeshow test. The observations were partitioned into 10 equal-sized groups according to their predicted probabilities. The observed and expected numbers of predictor variables were compared, and the chi-square statistics suggests that there is no evidence of lack of fit: P= 0.28.

Lastly, a sensitivity analysis for missing data was conducted by including the missing data as a separate category in the model as ‘unknown', and by analyzing only the complete data to decide the final model. The results were almost the same.

Both the crude and adjusted odds ratios for significant independent variables associated with the willingness to participate were summarized and compared in a table.

3.10 Data Limitation

A few issues arose during data collection. While conducting phone surveys, the online Survey Monkey® skipped two pages for 47 participants. As a result, the responses to questions 15-20 (recontact, return of individual and general research results, preferred communication technology, personal and family history of diagnosis with chronic disease) were missing for 47 participants. These as well as the 'refused to answer' questions were treated as missing data. Missing data was included as a separate category 'unknown', and accounted for during the sensitivity analysis for final model selection.

The denominator (N) was slightly different for each variable as during the analysis and tabulation, only complete data, including 'don't know/not sure' as a response were included. In addition, few questions were skipped; for example, Q 26 on parental status was not asked of singles for cultural reasons. Question 11 on motives was limited to those who were willing to participate (probably/definitely yes or not sure about participation), question 12 on concerns were asked only to those who were not willing to participate (probably/definitely no). Question 18 on communication technology was limited to those willing to receive general information on biobank research.

3.11 Ethical Consideration and Protection of Research Participants

This study was reviewed and approved by Al Ain Medical District Human Research Ethics Committee (AAMDHREC) on February 15, 2015. The IRB approval is included in Appendix IX.

Study participants were well informed about the study prior to participation, and their verbal consent was taken and documented by volunteers. All consent forms were collected by the primary investigator at the end of the study. Consent forms were scanned and stored in a secured file as soft copy format. Hard copies were shredded.

The study risks were minimal: there was no intervention, nor access to medical records. Inconvenient times were avoided, and calls were limited to three attempts in case of no response or a response of call later. The survey was anonymous, and no identifiers were attached to individual responses. Participation was completely voluntarily, and participants were informed that they could refuse to answer any question, stop and continue at another time, or withdraw at any time without any consequences.

The survey questions and responses were tested to ensure cultural sensitivity. During the pretest period, the telephone surveys were piloted to assess the average time required to complete each survey.

The primary investigators had successfully completed a research ethics training course. The training received by the volunteers included fundamentals of research ethics as well as signed confidentiality agreements. The study participants' list was received from Daman in a password protected CD. Contact details were shared with the volunteers as a password protected excel sheet through e-mail communication. A generic password code was created and sent once in separate email

to all volunteers. At the end of the survey, the primary investigator instructed all volunteers and research assistants to delete all previous email communications that contains the protected excel sheet for lists of contacts.

The Survey Monkey® surveys were uploaded to secure file, and the online survey data were deleted. After completing this study, the survey raw data, scanned copy of the consent forms, and the participants contact list will be stored for two years in a secure location, to be accessed only by the primary investigator.

Chapter 4: Results

4.1 Response Rate

3,758 phone numbers were called in this study. A maximum of three attempts were made for each participant, during varying days and times. We experienced high rates of invalid telephone numbers. This was undoubtedly due to the duration between the original *Weqaya* screening, and the timing of this sample survey. Figure 4-1, summarizes the phone numbers attempted and outcomes.

A total of 603 telephone interviews were conducted with 313 men and 290 women. The overall response rate was 71.7%, which is considered satisfactory in the light of the low exposure of the general public to any type of research, and the newness and possible sensitivity of the topic addressed. It was close to what was anticipated during sample size estimation.

Of the 603 interviews, six participant interviews (1%) were stopped abruptly, and the participants refused to continue the survey. One stopped at the main research outcome question regarding the willingness to participate in the proposed biobank. The other five participants stopped at question number 13, which was related to family participation in the biobank. Interestingly, for those five participants, the surveyors were able to capture the perceived concerns and benefits of participation in a biobank for future research, as outlined in questions number 11 and 12.

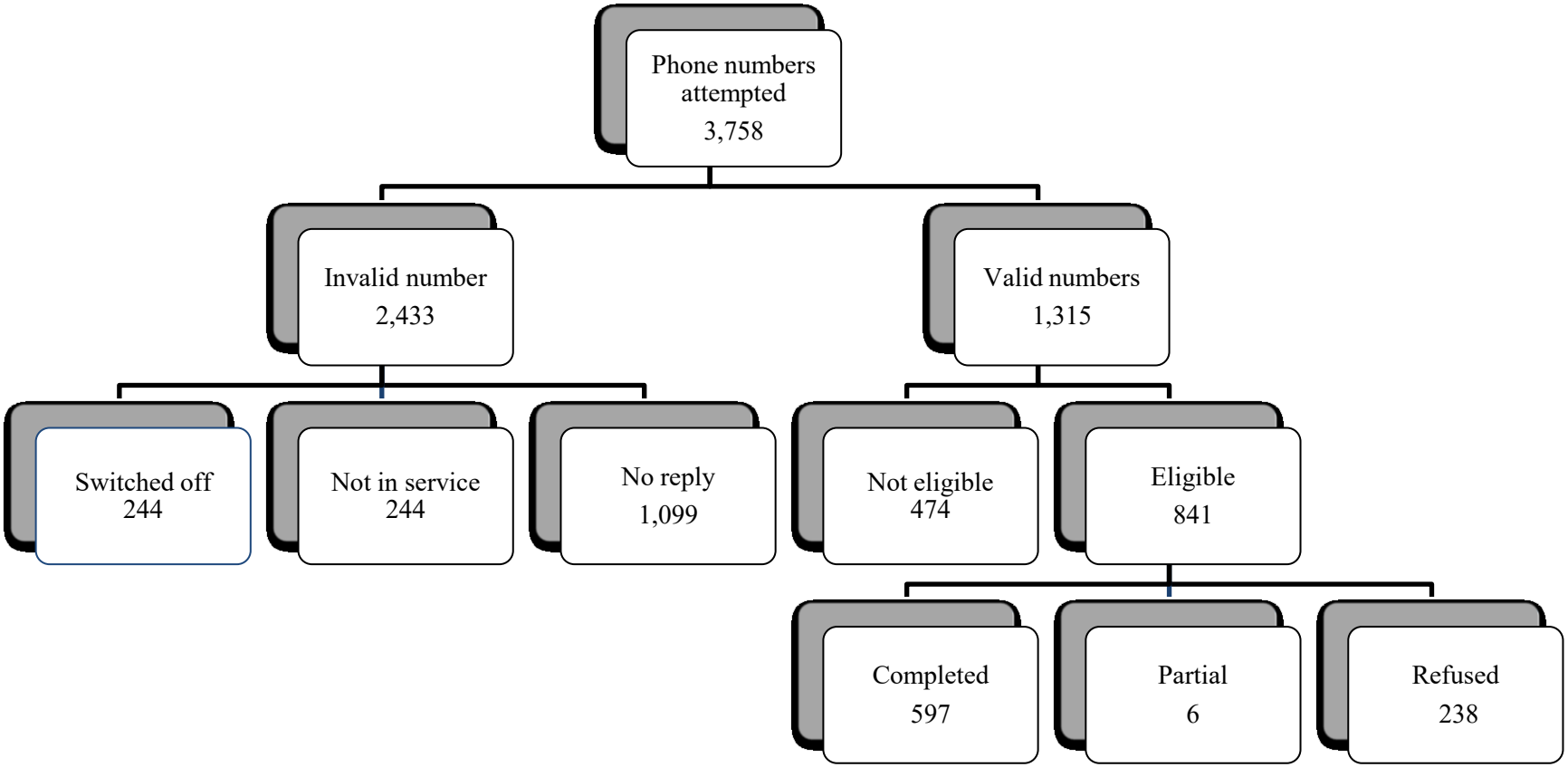

Figure 4-1: Profile of phone numbers attempted and outcomes

In general, the survey questions were well tolerated by participants. The questions that survey respondents refused to answer were primarily those related to demographic data about education, employment, marital and parental status, family history of chronic diseases and the monthly household income. For these reasons, these questions were kept until the end of the interview. The refusal rate was very low for all questions ranging from 0.1% to 0.7%. The question on income had the highest refusal rate of 27%.

4.2 Demographic Profile of the Survey Respondents

Table 4-1, describes the demographic profile of the survey respondents, and provides comparisons with the overall Emirati general population of the emirate of Abu Dhabi based on latest population estimates of mid-2014 as reported by the Statistics Center of Abu Dhabi (SCAD, 2016). All comparisons, except for education, were made among adult Emiratis between the ages of 20 to 79 years, where the population estimate for educational attainment of Emiratis aged 10 years and over, as well as that of the labor force was used, which included the employed and unemployed estimates for the Emirati population of 15 years and over. Further comparisons of the demographic profile by gender was conducted and presented in Table 42.

Ages of the survey respondents ranged from 19 to 79 years, and their mean age was 37.9 (SD ± 10.9 years). The most frequent age group represented in the study sample was 35-54 (47.8%), followed by the age group 25-34 years (36.3%). Compared with the general Emirati population, the younger age group of 18-24 years was less represented in the study (7.1% versus 19.3% of total Emirati population in

the age group 20-24). The middle aged group (35-54 years) was therefore over-represented (47.8% versus 34.3% of total Emirati population).

Although the study sample was stratified by gender, and equal number of random samples were taken from both genders, males appeared to be slightly more enthusiastic, curious, and therefore accepting of taking part in the study than females; the study samples were 51.9% males versus 48.1% females. The gender distribution of the survey respondents was consistent, and considered representative of the general Emirati population which was 51.3% males and 48.7% females. Female participants were generally younger than males (mean age for females was 35.6 years compared to 39.9 years for males, ($P<0.001$).

Regarding the highest educational attainment, the largest proportion of survey respondents, 214 out of 590 (36.4%), completed college or university, followed by 206 (34.9%) who reported that they had completed secondary school. While 47 of the survey respondents (7.9%) had completed higher education, i.e., Masters or PhD, there were a few, 27 (4.6%), who did not attend school or had less than primary education. Compared to the general population (10 years and older), survey respondents were better educated. The proportion of survey respondents with higher education, completed secondary school or higher, was higher (79.1% versus 47.2% of the general Emirati population). It was noticed that those with higher education were more likely to be males (84% of all males versus 75% of all females, $P=0.006$) and younger than those with lower education, less than secondary school, (mean age was 35.7 years versus 45.9 years, $P<0.001$).

Table 4-1: Demographic profile of the survey respondents and comparison with Abu Dhabi Emirati general population, (20-79 years).

Characteristics	N (%)	Emirati Population (%)
Gender	N=603 (%)	
Male	313 (51.9)	(51.3)
Female	290 (48.1)	(48.7)
Age (years)	N=603 (%)	
Mean ±SD	37.9±10.9	
Age groups		
18-24	43 (7.1)	(19.3)~
25-34	219 (36.3)	(36.4)
35-54	288 (47.8)	(34.3)
55-64	36 (6.0)	(6.4)
65+	17 (2.8)	(3.5)
Region of residence	N=603 (%)	
Abu Dhabi City	261 (43.3%)	(51.6)
Al Ain (Eastern) Region	337 (55.9%)	(42.5)
Al Gharbia) Western Region	5 (0.8%)	(5.8)
Highest education attained	N=590 (%)	^
Did not attend school or less than primary	27 (4.6)	(16.1)
Completed primary school	30 (5.1)	(15.8)
Completed intermediate school	64 (10.9)	(19.6)
Completed secondary school	206 (34.9)	(24.4)
Completed college or university	214 (36.3)	(19.9)
Completed Master or PHD	47 (7.9)	(3.2)
DK/NS	2 (0.3)	(1.0)
% Employed of the total labor force	N= 392 (%)	#
At work	367 (93.6)	(88.5)
Unemployed	25 (6.4)	(11.5)
Monthly Household income in AED	N=436 (%)	
< 20,000	92 (21.1)	-
20,000 to 39,999	186 (42.7)	-
40,000 to 59,999	53 (12.2)	-
60,000 to 79,999	16 (3.7)	-
> 80,000	15 (3.4)	-
DK/NS	74 (16.9)	-
Marital status	N=592 (%)	
Single	86 (14.5)	-
Married	481 (81.3)	-
Separated/divorced	17 (2.9)	-
Widowed	8 (1.35)	-
Parental status	N=506 (%)	
No	37 (7.5)	-
Yes	469 (92.5)	-

*SD= Standard Deviation

^ The population Estimate present education attainment of Emiratis 10 years and over

Emirati labor force, age 15 years and over.

Table 4-2: Demographic profile of the study participants, by gender.

Characteristics	**Males 313 (51.9%)**	**Females 290 (48.1%)**	***P* value†**
Age (years)	N=603 (%)		
Mean ±SD	39.9 ±11.6	35.6±9.7	<0.001
Age groups			0.002
18-24	14 (4.5)	29 (10.0)	
25-34	103 (32.9)	116 (40.0)	
35-54	159 (50.8)	129 (44.5)	
55-64	24 (7.7)	12 (4.1)	
65+	13 (4.2)	4 (1.4)	
Region of residence	N=603 (%)		0.04
Abu Dhabi City	148 (47.3)	113 (39.0)	
Al Ain (Eastern) Region	161 (51.4)	176 (60.7)	
Al Gharbia) Western Region	4 (1.3)	1 (0.3)	
Highest education attained	N=588 (%)		0.006
Did not attend school or less than primary	8 (2.6)	19 (6.7)	
Completed primary school	9 (3.0)	21 (7.4)	
Completed intermediate school	32 (10.5)	32 (11.3)	
Completed secondary school	110 (36.2)	96 (33.8)	
Completed college or university	111 (36.5)	103 (36.3)	
Completed Master or PHD	34 (11.2)	13 (4.6)	
Current employment status	N=590 (%)		<0.001
At work	248 (81.9)	119 (41.5)	
Unemployed	8 (2.6)	17 (5.9)	
Student	8 (2.6)	21 (7.3)	
Retired	37 (12.2)	5 (1.7)	
Home duties/(other)	2 (0.7)	125 (43.5)	
Monthly Household income in AED	N=362(%)		0.01
< 20,000	42 (18.0)	50 (24.6)	
20,000 to 39,999	108 (46.4)	78 (38.4)	
40,000 to 59,999	36 (15.5)	17 (8.4)	
60,000 to 79,999	12 (5.2)	4 (11.9)	
> 80,000	8 (3.4)	7 (43.5)	
Marital status	N=592 (%)		0.001
Single	35 (11.5)	51 (17.8)	
Married	263 (86.2)	218 (76.0)	
Separated/divorced	6 (2.0)	11 (3.8)	
Widowed	1 (0.3)	7 (2.4)	
Parental status	N=506 (%)		0.2
No	16 (5.9)	21 (8.9)	
Yes	254 (94.1)	215 (91.1)	

*SD= Standard Deviation
† P (2 sided) determined from chi-square or Fisher exact tests and t-tests for difference of group means.

Most of the survey respondents, 337 out of 603 (55.9%), were residing in Al Ain (Eastern) region, 261 (43.3%) in Abu Dhabi city, and only five (0.8 %) in the Al Gharbia (Western) region. Participants from Eastern region were slightly over-represented in the study sample (55.9 % of all participants, compared to 42.5% in the general Emirati population), and there was less representation from the Western region (0.8 % versus 5.8% in the general Emirati population). There were gender differences by region: Abu Dhabi residents were 56.7% males versus 43.3% females, (P=0.04). No difference of education attainment was seen by age (P=0.06) or by region (P=0.36).

The distribution of survey respondents by employment status revealed that most of them, 367 out of the 590 (62.2%), were gainfully employed, followed by those doing home duties 127 (21.5%). Only 67 (11.3%) were unemployed or retired, and 29 (4.9%) were students. According to SCAD, the labor force includes employed and unemployed individuals aged 15 years and above. The percentage of employed survey respondents was higher than that of the general Emirati population (15 years and above), 93.6% compared to 88.5%. In addition, those employed were predominantly males (81.9% of males versus 41.5% of all females, P<0.001), younger than those of other employment status (mean age was 36.9 years compared with 39.1 years, P=0.009), and tended to be highly educated (90% of those had higher education were at work versus 75% lower education, P<0.001).

As anticipated, the question on monthly household income was the most sensitive one; of the 597 survey respondents who completed the survey, 161 refused to answer this question. Of those who answered (N=436), 92 participants (21.1%) reported a monthly household income of less than 20,000 AED (<$5,450), 186

(42.7%) reported 20,000-39,000 AED ($5,450-10,627), 53 (12.2%) reported 40,000-59,000 AED ($ 10,900- 16,075) 31 (7.1%) reported 60,000 AED or more (>$ 16,350), and 74 (16.9%) were not sure. Those with monthly household income of 20,000 AED or more were more likely to be males (60.7% males versus 39.3% females, P=0.01), younger (mean age 37.1 years compared with 42.4 years for those of income of <20,000 AED, P<0.001), having higher education (88.5% higher education compared with 54.4% lower education, P<0.001), and were employed (82.8% versus 58.4% other employment status, P<0.001).

The majority of study participants, 481 out of 592 (81.3 %), were married, 86 (14.5%) were single, and 25 (4.2%) were either divorced or widowed. There were significant differences in marital status by gender. Those who were married were more likely to be males (54.7% males compared with 45.3% females, P=0.001) and older (mean age 39 years versus 32.6 years for other marital status, (P<0.001). No difference in marital status was found by education status (P=0.46).

Parental status was assessed by asking the survey respondents whether they had children. This question was answered only by those who were ever married, including widows or separated, N=506. Singles were not asked this question for cultural reasons. The vast majority of ever married survey respondents, 469 (92.5%) indicated that they have children; only 37 (7.5%) had no children. Those who indicated that they have children were older than those who did not: mean age 39.9 years compared to 32.3 years, (P<0.001). There were no differences in parental status by gender or education (All P>0.05).

4.3 Health and Medical Research Literacy

4.3.1 Knowledge on biomedical research and biobanking

Participants were asked to self-rate their own level of knowledge on biomedical research - medical research that involves the use of human biological samples such as blood, urine or tissue, their understanding of genomics - the relation between human genes and health, and how familiar they were with the term 'biobank'.

Figure 4-2, illustrates that vast majority of the survey respondents, 573 out of the 602 (95.2%), had limited knowledge about biomedical research or were not sure, and only 29 (4.8%) indicated that they had good knowledge. There were no differences in knowledge about biomedical research by age, gender or education (All P> 0.05).

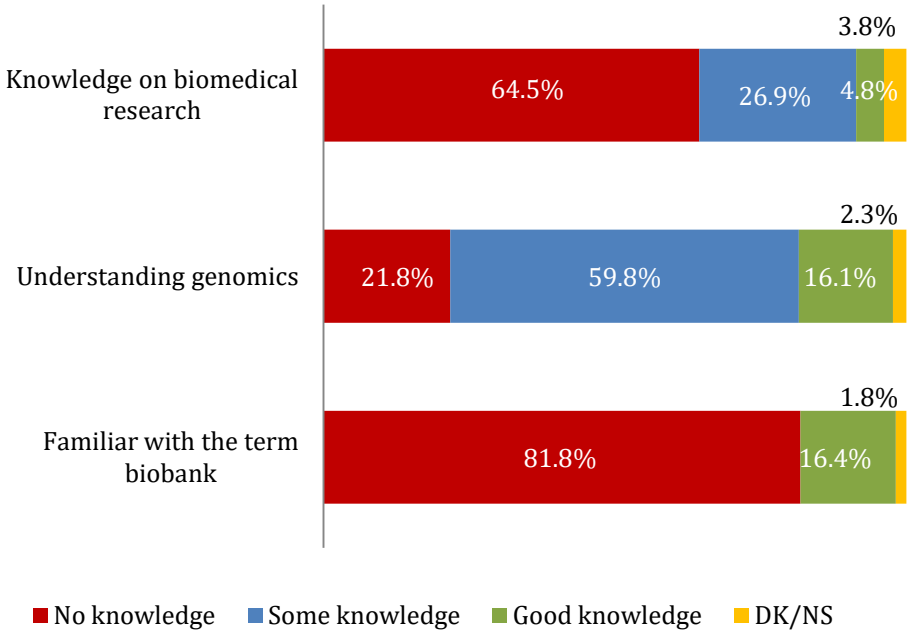

Figure 4-2: Self-rated knowledge on biomedical research and biobanking, N=602.

Similarly, the majority of study participants, 505 out of the 602 (83.9%), reported limited knowledge on genomics, while only less than one-fifth (16.1%) reported having good knowledge. Those reported to have good knowledge on genomics had higher education (P<0.001). There were no gender or age differences found in this regard (P= 0.47).

Concerning the familiarity with the term 'biobank', only 99 out of the 603 (16.4%) survey respondents were familiar with it; however, the vast majority were not familiar, as 493 (81.8%) had never heard about this term before and 11 (1.8%) were not sure. Those who were familiar with the term biobank tended to have good knowledge on biomedical research (P=0.02) and genomics (P=0.001), higher monthly household income of >20,000 AED (P=0.02), positive attitude to donation of biosamples for research (P=0.05), and a family history of chronic diseases (P=0.02). No association with gender, age, education status, knowledge on biomedical research, genomics or previous participation in medical research or blood donation (All P>0.05) was found.

4.3.2 **Previous donation and participation in medical research**

Previous experience with donation of blood and participation in medical research was assessed. Of the 603 study participants, 256 reported previous donation of blood (42.5%), while 336 (55.7%) had never donated blood and 11 (1.8%) were not sure. Those who gave a history of a prior blood donation were more likely to be male (P<0.001), older (mean age 39 years versus 37 years for those who never donated, P=0.03) and have higher education (P<0.001).

Only 36 out of the 603 (6.0%) survey respondents indicated that they had ever participated in medical research, such as donation of blood or tissue for research or

taken part in a trial for testing a new experimental treatment. The vast majority 562 (93.2%) had never participated, and five (0.8%) were not sure. No difference in prior history of being a research participant was found for age, gender or education (All P>0.05).

Further analysis of previous participation in medical research by previous blood donation, healthcare system experience and trust, knowledge and attitude towards biomedical research and biobanking, as well as personal or family history of chronic diseases showed that survey respondents who indicated previous participation in medical research were more likely to donate blood (P=0.007), and have high trust in healthcare providers (P=0.01). However, no difference was shown by experience with healthcare services, trust in HAAD, knowledge and attitude to biomedical research and biobanking, and health status (All P>0.05).

4.3.3 **Attitudes towards biomedical research and biobanking**

Participants were asked about their attitudes towards biomedical research, the importance of donation of biosamples for medical research, and the value of biobanking to generate new information to improve health. In general, the majority of the survey respondents had a positive attitude towards biomedical research and biobanking for research. Figure 4-3, graphically displays the responses.

The vast majority of survey respondents, 548 out of 603 (90.9%), agree that medical research leads to improvement in patients' health. Very few disagreed, 15 (2.5%), were neutral, 18 (4.6%), or were not sure, 12 (2.0%). Those who had positive attitudes towards medical research had good knowledge of genomics (P=0.02) and had trust in HAAD, (P<0.001). Gender, age, education, personal and family history of

chronic diseases, and knowledge of medical research or biobank did not seem to influence survey respondents' attitudes towards medical research (all P>0.05).

Moreover, a majority of survey respondents believed that it is important that people donate biosamples for medical research, 508 out of the 603 (84.3%). The rest believed that it is moderately important 55 (9.1%), not important, 19 (3.2%), or were not sure 21 (3.5%). Those who believed that it is important to donate biological samples for research were older than others (mean age 38.3 years versus 35.6 years, P=0.03), had good knowledge in genomics (P=0.008), had a positive attitude to medical research (p<0.001), and had higher rates of chronic diseases than others (P=0.02). Attitudes toward donation of biosamples for research did not vary by gender, education or family history of chronic diseases (All P>0.05).

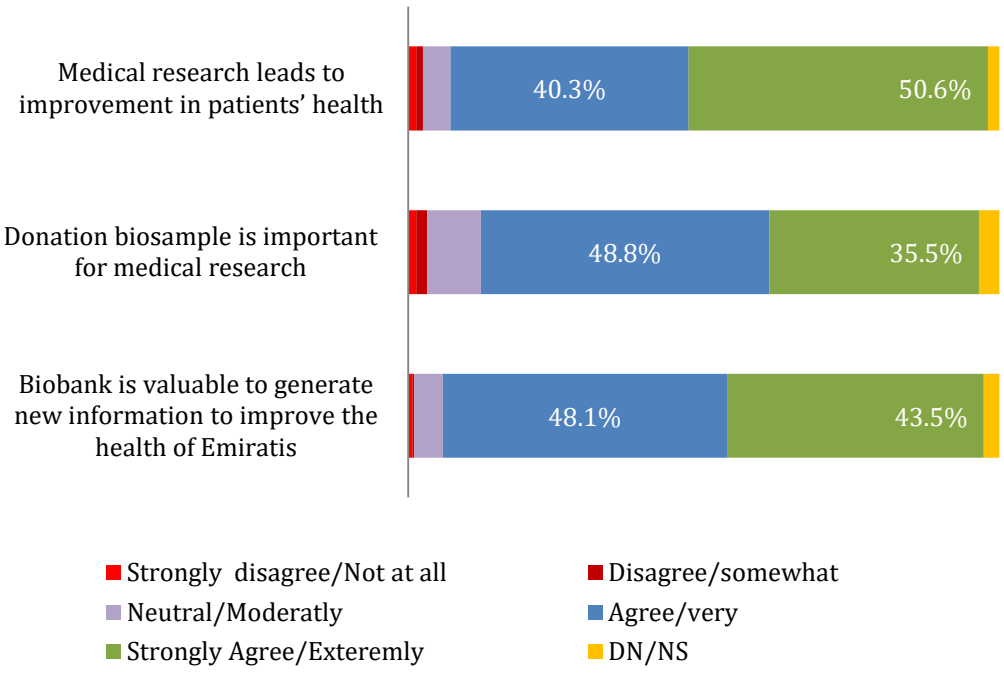

Figure 4-3: Attitudes towards biomedical research and biobanking, N=603.

A vast majority of survey respondents, 552 (91.6%), believed that the biobank would be a valuable resource to generate new information to improve the health of Emiratis. Others believed that it is moderately valuable 29 (4.8%), not valuable, six (1.0%), or were not sure, 16 (2.7%). Those with a positive attitude to the value of the biobank had positive attitude to medical research and donation of biosamples (both P<0.001), had high trust in healthcare providers (P=0.01) and HAAD (P<0.001), and mostly positive experience with healthcare services in Abu Dhabi (P=0.008). Attitudes toward the biobank did not vary by gender, age, education, knowledge on biomedical research and biobank, personal or family history of chronic diseases (all P>0.05).

4.4 Healthcare System Experience

Healthcare system experience factors were assessed using three questions. Figure 4-4 graphically illustrates the main findings.

Participants were asked to describe their general experience with healthcare services in the Emirate of Abu Dhabi. A large proportion of participants, 334 out of 547 (61.1%), reported mostly positive experiences, while 181 (33.1%) were neutral and 21 (3.8%) thought it was mostly negative. Only 11 (2.0%) survey respondents were not sure. Those with mostly positive experience were slightly older than others, mean age 38.5 years versus 36.5 years (P=0.03). Experience with healthcare services in Abu Dhabi did not vary by gender, education, personal or family history of chronic diseases (all P>0.05).

Participants were further asked to rate their trust in healthcare providers. Only 198 out of the 546 survey respondents (36.3%) indicated that their trust in healthcare providers was high. The largest proportion 289 out of the 546 (59%) indicated that

they were moderately trustful, further 8.3% had low trust and 2.6% were not sure. Gender, age, education, personal and family history of chronic diseases did not influence survey respondents' trust in healthcare providers (all P>0.05). It was observed that those who have high trust in healthcare providers were more likely to report mostly positive experiences with healthcare services (P<0.001), have positive attitude to medical research (P=0.01) and an understanding of the value of the biobank (P=0.01).

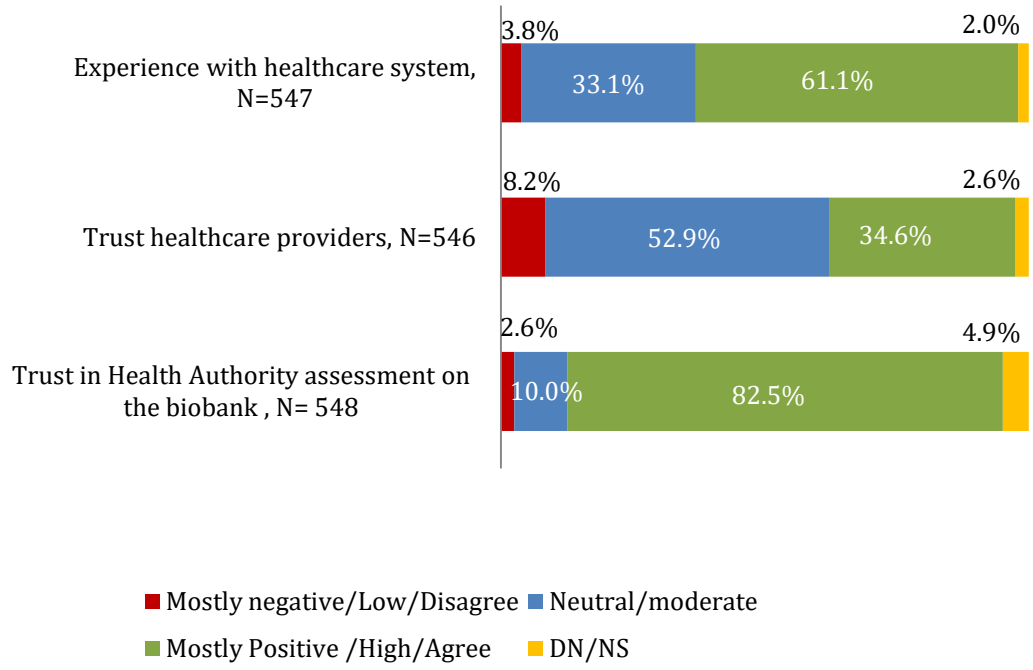

Figure 4-4: Healthcare system experience and trust.

Finally, they were asked about their trust in the capability of Health Authority-Abu Dhabi (HAAD) to assess the risks and benefits of the biobank for the Emirati population. This question received the highest favorable response among all

questions related to the healthcare system experience and trust. The vast majority of the study participant had trust in HAAD, 452 out of the 548 (82.5%). Others were either neutral (10.0%), disagreed (2.6%) or were not sure (2.6%). Those who have trust in HAAD had mostly positive experience with healthcare services in the emirate of Abu Dhabi (P<0.001), high trust in healthcare providers (P<0.001), and a positive attitude to medical research (P<0.001), donation for research (p=0.01) and the value of the biobank (P<0.001). Gender, age, education and personal or family history of chronic diseases did not influence trust in HAAD (all P>0.05).

4.5 The Socio-Cultural Context and Influence

Social-cultural influences on decision-making regarding possible participation in the biobank was assessed by asking survey respondents whether they think that other family members would be influenced by their participation and would be willing to do the same, as well as by assessing the influencers on their own decision to participate.

Out of the 597 survey respondents, 247 (41.4%) reported that their family members would definitely be willing to participate in the biobank. Of the others, 246 (41.2%), reported that they would probably be willing, 38 (6.4%) were not willing, and 66 (11.1%) were not sure, as shown in Figure 4-5. Gender, age and education did not seem to influence family willingness to participate in the biobank (All P>0.05).

When asked about people that might be help in making a decision regarding biobank participation, the majority, 422 out of the 594 (71.0%), preferred to make the decision entirely by themselves, 81 (13.6%) preferred to make the decision with help from family members or friends, 83 (14%) with help from a doctor or other healthcare provider, and 7 (1.2%) were not sure. Those who preferred to make the decision

about participation with help from others - family members, friends, a doctor, or healthcare providers - were more likely to be females (P<0.001), those with lower education status (P=0.001), are not employed (P<0.001), and had a monthly household income of less than 20,000 AED (P=0.001). No difference was seen by age.

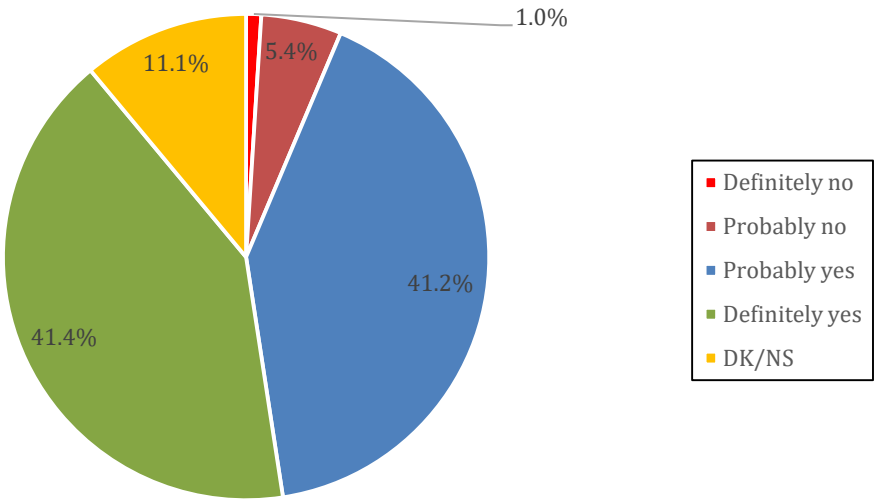

Figure 4-5: Family willingness to participate in the biobank, N=597.

Further assessment by family participation was done to explore the possible influences of social network on decisions regarding participation in the proposed biobank. Those who preferred to make the decision about participation with help from others (family members, friends, a doctor or healthcare providers) were more confident about family participation than those who made decision by themselves, 75.3% versus 24.7% (P=0.05).

4.6 Perceived Benefits and Risks of Biobanking for Future Research

Personal and close family relative history of chronic diseases was assessed as a potential motivator for participation in the biobank. Perceived benefits and risks of biobank for future research were assessed by exploring reasons that would motivate (perceived benefits) or concern (perceived risks) them when it comes to the decision to take part in the future biobank. Survey respondents were encouraged to select up to three possible reasons.

4.6.1 History of chronic diseases

Almost one-quarter (25.7%), 141 out of the 549 survey respondents, reported that they had been diagnosed with a chronic disease, 408 (73.6%) were free of chronic diseases, whereas four (0.7%) were not sure. No gender differences were found for self-reported history of a personal chronic disease (P=0.18). Those with personal history of a chronic disease were older (mean age 43.3 versus 35.9 years, P<0.001), more likely to have a close family relatives with chronic diseases (P=0.02), and had lower education (P<0.001).

On the other hand, a majority of survey respondents, 369 out of 544 (67.8%), indicated a positive history of a close family relative with a chronic diseases, 172 (31.6%) had no family history, and three survey respondents (0.6%) were not sure. No differences were found by gender, age or education in family history (all P>0.05).

4.6.2 Perceived benefits of biobanking for future research

Perceived benefits can be broadly clustered into: (i) altruistic motives such helping future generation or support medical research; (ii) moral motives such as believing that donation is a charitable act; or (iii) personal (egoistic) motives such as

therapeutic benefits to self or family members, as categorized by researchers (Luque et al., 2012; Nobile et al., 2013).

The most common motive to participate in a biobank was altruistic: to improve the health and wellness of future generations, (72.7%), and to support research (60.9%), followed by moral motives, e.g., donation is a charitable act (51.4%). Less frequent reasons cited by survey respondents were therapeutic benefits; reasons such as obtaining better treatment or cure for family members motivated only one-third (32.0%), and obtaining better treatment or cure for one's own condition motivated 15.8%, , Figure 4-6.

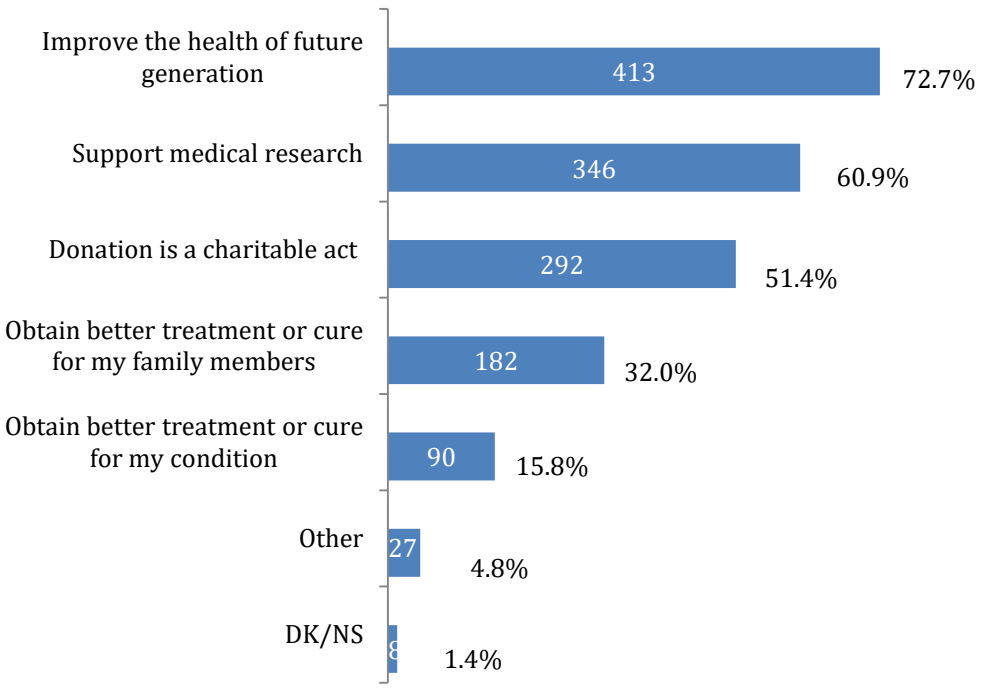

Figure 4-6: Perceived benefits of biobanking for future research, N=568.

Twenty-seven participants (4.8%) pointed out other motives such as development opportunities for the country, reduced need to travel abroad for treatment, and personal curiosity: gaining knowledge and better understanding of the biobank and its function.

Overall rankings of motives by gender were relatively similar, except for the motive 'donation is a charitable act' which ranked third for males while it was the second most common motivator for females. In addition, it was observed that 'improving the health and wellness of future generations' motivated those with higher education (P=0.005), having a good knowledge of genomics (P=0.001) and a positive attitude towards donation of biosample for research (P=0.005), biobanking (0.006) and trust in HAAD (P0.001). No differences by age, gender or history of chronic diseases (P>0.05) were seen in the factors that motivated them to participate in the proposed biobank.

Similarly, 'support medical research' tended to motivate males (P=0.02), those with higher education (P<0.001), had good knowledge on genomics (P=0.007) and biobanking (0.04), as well as those who had a positive attitude to donating biosample for research (P=0.005) and biobanking (0.006), and had previously donated blood (P0.004). There was no association with age or history of chronic diseases (All P>0.05).

Furthermore, 'Donation is charitable act' motivated those who had positive attitudes towards the donation of biosample for research and understood the value of the biobank (P<0.001). No association with age, gender, education, previous donation of blood, or history of chronic disease was found for this motivator (all P>0.05).

Obtaining better treatment for family members tended to motivate females more than males (P=0.03), those with good knowledge on genomics (P=0.01), and a history of close family members with chronic diseases (P=0.004). No association of this motivator was found with age, education, or personal history of chronic diseases (all P>0.05).

Likewise, obtaining better treatment or cure for one's own condition motivated older participants (mean age 40.8 years versus 37.3 years, P=0.005) and those who had a personal history of chronic diseases (P=0.01). No association with gender, education or family history of chronic diseases (all P>0.05) was found for this motivator.

4.6.3 **Perceived risks of biobanking for future research**

As illustrated in Figure 4-7, a substantial proportion (38.2%) of those who were not willing to participate in the biobank, N= 34, were also not sure about the potential concerns regarding donation of biosamples, and health information for future biomedical, particularly genomic, research. Nonetheless, the most frequent concerns reported were those regarding genomic research (23.5%), lack of belief in medical research (23.5%), concerns regarding loss of privacy (14.7%) and breach of confidentiality (5.9%).

Other concerns pointed out by survey respondents were concerns such as being too sick or not healthy (11.8%), lack of knowledge about risks and benefits of the biobank (8.8%), being too busy (5.9%), transportation barriers (5.9%), lack of trust in healthcare services (2.9%), or being too old (2.9%) or were only willing to donate biosamples (2.9%) and not information.

Those who 'were not sure' about the potential concerns of taking part in the biobank research were mainly those who had limited knowledge on genomics (P=0.01), had never donated blood (P=0.002), had negative attitude to donation of biosample for research (P=0.02) and the biobank (P<0.001). No association with other variables assessed were found (All P>0.05).

Those who did not believe in medical research had limited knowledge on biomedical research (P=0.05), had negative attitudes on the biobank (P=0.003), and did not trust HAAD (P<0.001). No association with other variables addressed was detected (All P>0.05).

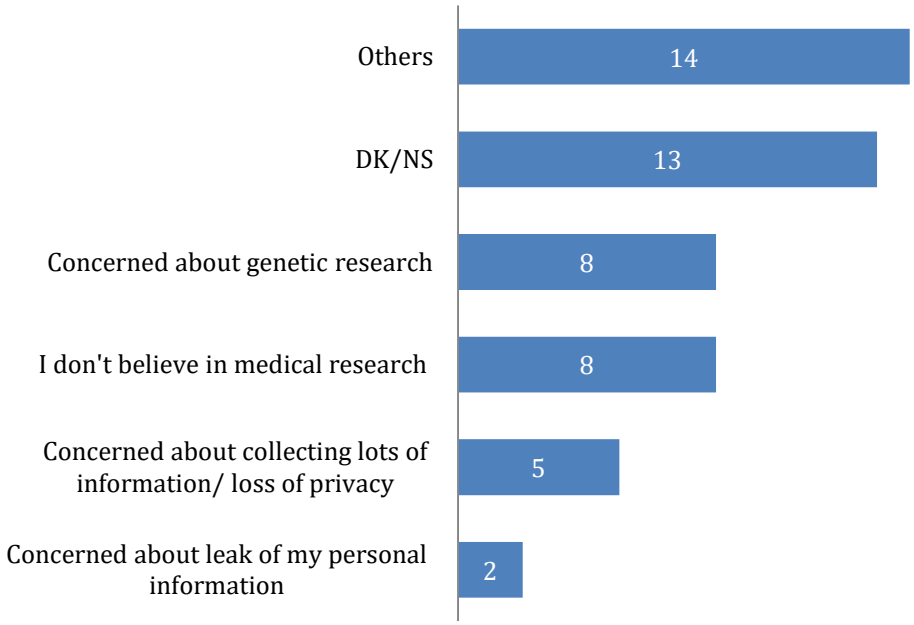

Figure 4-7: Perceived risks of biobanking for future research, N=34.

Those who were concerned about ‘genomic research’, 'loss of privacy' and 'breach of confidentiality' were those who believed that the biobank would not be

valuable as resource, and did not trust HAAD (all P<0.05). No association with other variables tested were found (All P>0.05).

4.7 Public Views on Future Recontact and Return of Results

Participants were asked to consider a hypothetical situation where they agreed to participate in the biobank. They were then asked whether it would be acceptable for them to be contacted in the future by the biobank to ask for new information, additional assessments and tests, or to donate more blood, and whether they wanted feedback on individual genomic or general research results. A large proportion of the study respondents, 402 out of 594 (67.7%), indicated that it is definitely acceptable for them to be recontacted by the biobank sometime in the future. Others found this probably acceptable 136 (22.9%), and only a few found this to be not acceptable 42 (7%) or were not sure 14 (2.4%). Those who indicated that they would definitely accept to be recontacted by the biobank were more likely to be males (P=0.004), highly educated (P=0.007), had previously donated blood (P<0.001), were familiar with the term biobank (P= 0.047) and had positive attitudes towards medical research, donation of biosamples and the biobank (All P<0.001), and had trust in HAAD (P=0.01). No differences by age were noted (P=0.77).

There was a strong desire for the return of individual research results; 499 out of the 595 (83.9%) stated that they definitely wanted to receive information on any condition that could be a risk in the future. Others responded probably yes, 48 (8.0%), did not want to receive such information, 36 (6.1%), or were not sure, 12 (2.0%). Those who had a strong desire for the return of individual research results were found to be more likely to have higher education (P=0.005), good knowledge on genomics (P=0.008), were familiar with the term biobank (P=0.009), had previously

donated blood, and had positive attitudes to medical research, donation of biosamples for research, the biobank and HAAD (All P<0.001). No other differences in response were found by gender or age (All P>0.05).

Similarly, there was a strong desire for feedback on general information on the research conducted by the biobank; 421 out of 595 (70.8%) indicated that they definitely wanted to receive such feedback. Other indicators included 'probably yes' 107 (8.0%), 'do not want to receive such information', 55(9.2%), or were not sure 12 (2.0%). Those who expressed a strong desire for feedback or general information on research conducted by the biobank were more likely to have higher education (P=0.001), were familiar with the term biobank (P<0.001), had previously donated blood (P<0.001) and had a positive attitude toward donation of biosamples for research (P<0.001), the biobank, (P=0.004), and HAAD (P<0.001). No differences in response were found by gender or age (All P>0.05).

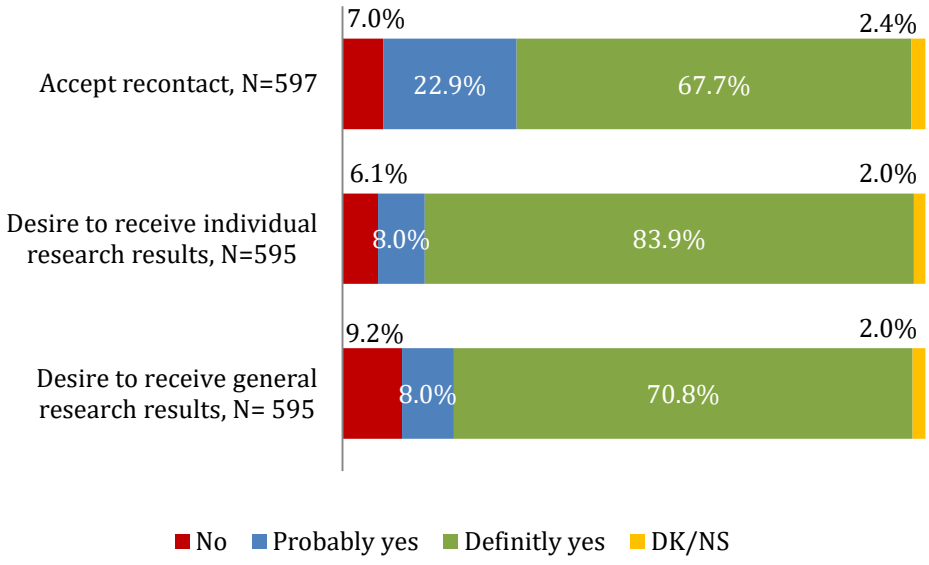

Figure 4-8 : Public views on recontact and return of research results.

4.8 Willingness to Participate in the Population-Based Biobank

Participants were given an introduction about the proposed plan for establishing the population-based biobank in Abu Dhabi, and were asked whether they would participate in the biobank, voluntarily donating for future genomic research, the residual biosamples (blood or urine) and the health information collected during their *Weqaya* screening visit.

One participant did not answer this question and decided to end the survey at this point, while 602 of the survey respondents answered this question. **Error! eference source not found.**, illustrates the responses. Remarkably, the vast majority of the survey respondents did not mind donating residual biosamples and accompanying health information to the proposed biobank; 458 out of 602 (76.1%) indicated that they would definitely participate in the proposed biobank, and a further 100 (16.6%) indicated that they would probably participate. Only a minority 34 (5.7%) were not willing to participate or were not sure 10 (1.7%).

Males were more likely to participate in the proposed biobank compared to females; 80.8% of males were definitely willing to participate in the biobank versus 71.0% of females (P=0.005).

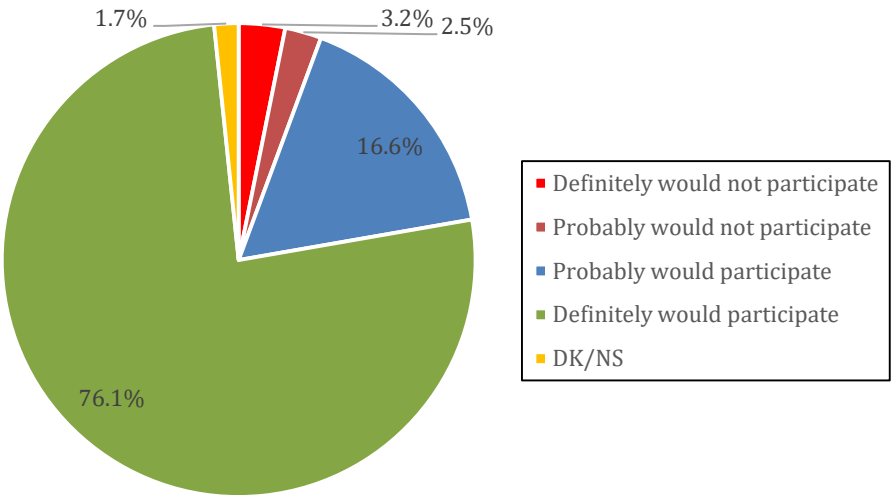

Figure 4-9: Willingness to participate in the population-based biobank, N=602.

4.9 Factors Associated with Participation in a Population-based Biobank

As mentioned earlier, the outcome variable, 'willing to participate in the proposed population-based biobank', was dichotomized into two categories: definitely willing to participate versus others, which included those who responded with probably yes, probably no, definitely not or were not sure. Those definitely willing to participate were the majority, 458 out of the 602 study respondents (76.1%), while others were 144 (23.9%).

Explored below are the independent variables that were associated with the definite willingness of the Emirati general public to participate in the proposed population-based biobank, based on factors described in the conceptual framework presented in Chapter 2. As the model was described in the introductory paragraph to our study participants, we had not explored the association with various biobank models in our study. In addition, the health information and the preference for communication technologies were examined in order to advise communication

strategies to improve health and research literacy, and to increase the publicity of the biobank.

Table 4-3, presents the significant independent variables associated with the definite willingness to participate in a population-based biobank, from both the univariate analysis as well as after adjustment from the multivariate analysis.

Significant demographic factors associated with increased willingness to participate in the proposed biobank were gender, higher education attainment and employment status. Being a male increased the likelihood of willingness to participate by 71% (Crude OR=1.71: 95% CI: 1.17 to 2.05, P=0.005). Higher education, having completed secondary school or higher, increased the likelihood of willingness to participate by 72% (Crude OR=1.72: 95% CI: 1.10 to 2.67, P=0.02). Currently employed increased the likelihood of willingness to participate in the biobank by 84% (Crude OR=1.84: 95% CI: 1.25 to 2.69, P=0.002).

Altruistic and moral motives were significantly associated with an increased likelihood of participation of the Emirati general public in the proposed biobank. The likelihood of willingness to participate in the biobank showed a three-to-fourfold increase among those who were motivated by the benefits 'improving the health of future generations', 'support medical research' and 'donation is charitable act' (Crude OR=4.0: 95% CI: 2.70 to 5.92, P<0.001) , (Crude OR=3.73: 95% CI: 2.50 to 5.54, P<0.001) and (Crude OR=2.68: 95% CI: 1.80 to 4.00, P<0.001) respectively.

Factors related to biobank operations and policies were all associated with a willingness to participate in the biobank. Accepting recontact increased the likelihood of willingness to participate in the biobank almost six-folds (Crude OR=5.69: 95% CI: 3.79 to 8.55, P<0.001), returning individual genomic research results also

increased it six-folds (Crude OR=5.84: 95% CI: 3.67 to 9.28, P<0.001), and returning general biobank research results increased it by almost fourfold (Crude OR=3.66: 95% CI: 2.46 to 5.46, P<0.001).

Only two factors related to knowledge and attitudes towards biomedical research and biobanking were significant in our study. Self-reported good knowledge on biomedical research increased the likelihood of willingness to participate in the biobank fourfold (Crude OR=4.42: 95% CI: 1.04 to 18.8, P=0.04), and previous donation of blood increased it by 96%, (Crude OR=1.96: 95% CI: 1.31 to 2.92, P=0.001).

Among factors related to healthcare system, only trust in HAAD, the government authorities supervising the biobank, as key actor increased the likelihood of willingness to participate by 82% (Crude OR=1.82: 95% CI: 1.12 to 2.98, P=0.02). Other factors such as trust in healthcare providers and experience with healthcare services in Abu Dhabi were not associated.

Social influence in terms of family participation increased the willingness to participate in the biobank almost six-folds (Crude OR=5.69: 95% CI: 3.45 to 9.36, P<0.001), and a preference to make decision by own self increased it almost threefold (Crude OR=2.63: 95% CI: 1.76 to 3.92, P<0.001).

After adjusting for other covariates, the significant independent factors associated with a willingness to participate in the biobank were: being a male (Adjusted OR=1.52; 95%CI: 0.96 to 2.39, P=0.07), having good knowledge on biomedical research (Adjusted OR=10.4; 95%CI: 1.11 to 97.8, P=0.04), perception of altruistic benefits such as 'improve health of future generation' (Adjusted OR=2.17; 95%CI: 1.44 to 3.63, P<0.001) and 'support medical research' (Adjusted OR=2.11;

95%CI: 1.36 to 3.46, P=0.001), having a positive attitude towards the biobank (OR= 2.62; 95%CI: 1.27 to 5.39, P=0.009), willingness to definitely accept recontact (Adjusted OR=3.25; 95%CI: 2.03 to 5.19, P<0.001), having an expectation of individual genomic research findings being returned (Adjusted OR=3.16; 95%CI: 1.84 to 5.54, P<0.001), and family influence on participation (Adjusted OR=3.19; 95%CI: 1.84 to 5.53, P<0.001).

Table 4-3: Factors associated with definitely willingness to participate in a population-based biobank.

Independent factors	Crude			Adjusted*		
	OR	95% CI	*P*-value†	OR	95% CI	*P* value†
I. Demographic characteristics						
Gender (Male vs. Females)	1.71	1.17-2.05	0.005	1.48	0.94- 2.36	0.07
Highest education attained (Higher vs. Lower education)	1.72	1.10-2.67	0.02			
Current employment status (At work vs. Others)	1.84	1.25-2.69	0.002			
II. Health and medical research literacy						
Ever donated blood (Yes vs. No)	1.96	1.31-2.92	0.001			
Knowledge on biomedical research (Good vs. Limited knowledge)	4.42	1.04-18.8	0.04	10.4	1.11-97.8	0.04
Biobank as a resource would be. (Valuable vs. Not valuable)	4.99	2.77-9.02	<0.001	2.56	1.23-5.32	0.01
Medical research improves patients' health (Agree vs. Disagree)	1.95	1.08-3.49	0.03			
Donating biosamples for research is. Important vs. Not important)	3.39	2.14-5.38	<0.001			
III. Healthcare system experience and trust						
Trust HAAD (Agree vs. Disagree)	1.82	1.12-2.98	0.02			
IV. Perceived benefits of biobanking for future research						
Improve the health future generation (Yes vs. No)	4.0	2.70-5.92	<0.001	2.11	1.31-3.38	0.002
Support medical research (Yes vs. No)	3.73	2.50-5.54	<0.001	2.19	1.37-3.49	0.001
Donation is a charitable act (Yes vs. No)	2.68	1.80-4.00	<0.001			
V. Biobank related procedures and policies						
Accept future re-contact (Definitely yes vs. Others)	5.69	3.79-8.55	<0.001	2.80	1.74-4.51	<0.001
Desire for feedback on own genomic results (Definitely yes vs. Others)	5.84	3.67-9.28	<0.001	2.55	1.45-4.49	0.001
Desire for feedback on general information (Definitely yes vs. Others	3.66	2.46-5.46	<0.001			
VI. Social-cultural context and influence						
Family influence (participation) (Definitely willing vs. Others)	5.69	3.45-9.36	<0.001	3.19	1.83-5.57	<0.001
Decision to participate is made by: Myself vs. Help of others	2.63	1.76-3.92	<0.001			

*Final model adjusted for male gender, good knowledge on biomedical research, positive attitudes towards the biobank, altruistic motives, accept recontact, strong desire for return of individual research results and family influence.
†Wald p value determined from testparm.

4.10 Preferred Health Information and Communication Channels

Figure 4-10 and Figure 4-11, present preferred health information and communication channels. They rank them by survey respondents' preference.

4.10.1 **Preferred sources for health information**

All participants responded to this question, N=603. The top three preferences for sources for health information and to learn about the biobank were internet-based communication including websites or social media (62.9%), followed by personal communication by a doctor or other healthcare providers (39.6%) and printed educational materials in the form of booklets or a brochure (23.5%). An additional few preferred television (19.5%) or public seminars (11.8%).

A small minority of survey respondents (2.7%) pointed to other sources of information. These were mobile text messages such as the short message service (SMS), and publications such as articles in magazines or newspapers. One of the survey respondents was not interested at all to search for information on the biobank.

The analysis of preference of various sources of health information by gender revealed that the overall rankings of preferred sources of health information were quite similar for both genders. However personal communication by a doctor or other healthcare provider and booklets or brochures were preferred by females more than males (all $P<0.001$), while publications such newspapers were preferred by males more than females ($P=0.04$).

Preferences by age revealed that internet-based communications as a source of health information were what younger survey respondents (mean age was 35.6 years compared with 41 years, $P<0.001$) preferred, while print media (newspapers) and

television were preferred by older participants (mean age 41 years compared with 37 years, all P <0.05).

Preference for sources of health information vary by highest education attained and employment status, wherein highly educated participants and those employed preferred websites or social media (both P≤0.001). On the other hand, less educated participants preferred personal communication by a doctor or other healthcare provider (P=0.006), or family members, friends or neighbors (P=0.03), and television (P=0.03). Those employed also preferred the website as the primary source of information (69% versus 53% other employment status, P=<0.001). No difference were found by geographical region (All P>0.05).

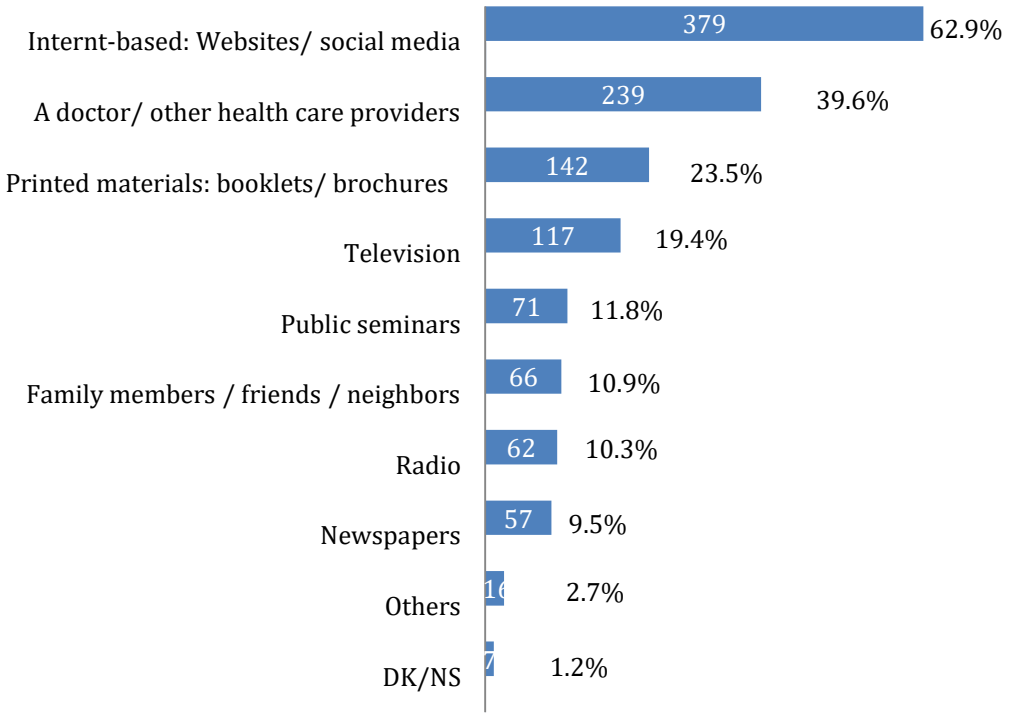

Figure 4-10: Preferred sources for health information, N=603.

4.10.2 **Preferred health communication channels**

The preferred communication technology for general information on research and updates of the biobank and feedback on the same was SMS (68.8%), followed by emails (34.6%). A few preferred mobile phone applications (15.6%) or website (11.7%).

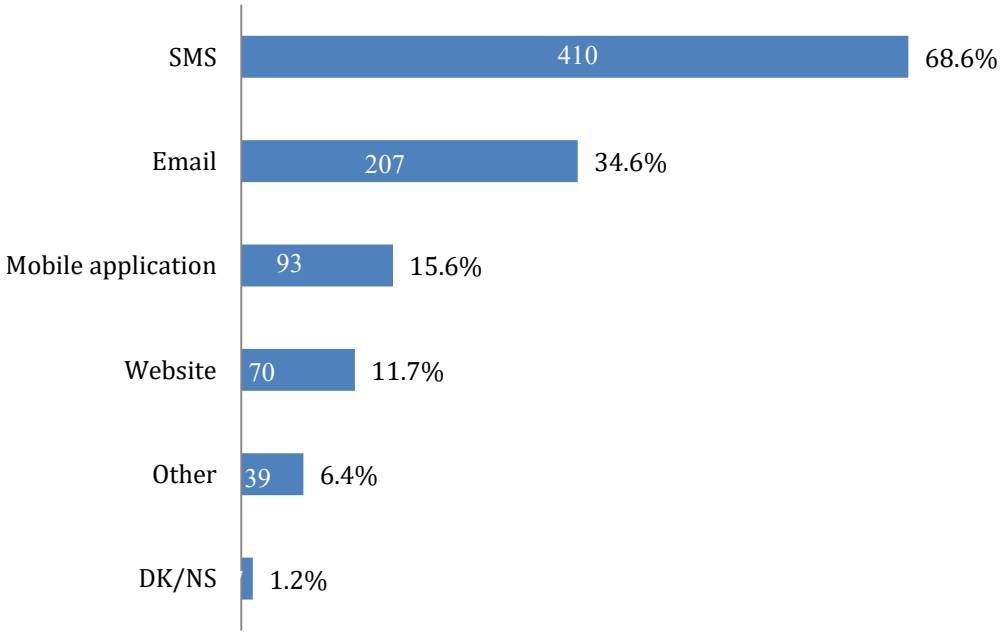

Figure 4-11: Preferred health communication channels, N=598.

A very few survey respondents (6.4%) mentioned other communications channels. These were direct phone calls from the biobank staff, or through personal communication by a doctor or trusted healthcare providers, social media or publications such as newspapers or magazines.

Overall rankings of preferred communication technologies was quite similar for both genders. However it was noticed that females tended to prefer SMS as a communication tool for feedback of research results slightly more than males (51.2%

females compared with 48.8% males, P=.03), while males tended to prefer emails more than females (58.9% of males compared to 41.6% females, P=0.01). Highly educated participants preferred email (P<0.001), followed by websites (P=0.049), while those who were gainfully employed preferred emails (P=0.001). No difference in preference for communication technology was found by age (All p>0.05).

4.11 Summary of Results

The overall response rate to the study was 71.7%, considered satisfactory and close to what was anticipated during sample calculation. A total of 603 telephone surveys were conducted among 313 men and 290 women. Of the 603 interviews, 597 interview were completed, while six interviews were stopped abruptly, and participants refused to continue the survey. Overall, the survey questions were well tolerated by participants. Questions that survey respondents refused to answer were those related to demographic data, particularly monthly household income.

The age of survey respondents ranged from 19-79 years and the average was 37.9 years (±10 years). The demographic profile of the study respondents revealed that they were older, more likely to be residing in Eastern Region, were employed and better educated compared to the general Emirati adult population of Abu Dhabi. By design, the gender distribution mirrored the general population. Nonetheless, men were more likely to be married, older, living in Abu Dhabi city, better educated, employed and therefore had higher household income. Those with higher education were more likely to have had a history of previous blood donation, and a good knowledge in biomedical research and genomics.

In general, awareness on biomedical research and biobanking in terms of previous experience and knowledge was very limited. Only 6% of survey respondents

reported ever having participated in medical research and 42% had ever donated blood. Those reported as having ever participated in medical research were more likely to donate blood, and had high trust in healthcare providers.

Regarding self-rated knowledge, only 4.8% indicated good knowledge of biomedical research, 16.1% had good knowledge of genomics and 16.4% were familiar with the term biobanking. Those who were familiar with the term biobank also tended to have good knowledge on biomedical research and genomics, higher monthly household income (more than 20,000 AED), a positive attitude to donation of biosamples for research, and a family history of chronic diseases.

In general, there were very positive attitudes towards biomedical research and biobanking for future research. The vast majority of the survey respondents believe that the biobank would be valuable as a resource to generate new information to improve the health of Emiratis (91.6%), that medical research leads to improvements in patients' health (90.9%), and that it is important to donate biosample for research (84.3%). Those who had positive attitudes towards the biobank tended to have a positive attitude to medical research and donation of biosamples for research, trust in HAAD, high trust in healthcare providers, and mostly positive experience with healthcare services in Abu Dhabi.

With regard to the health care system experience and trust, overall experience with healthcare services in the Emirate of Abu Dhabi was not satisfactory, as only 61.1% considered it a mostly positive experience. Those who had a mostly positive experience were slightly older than others, and had high trust in HAAD. In addition, only 36.3% of the survey respondents had high trust in healthcare providers. High trust in healthcare providers was associated with previous participation in medical

research, mostly positive experiences with healthcare services, trust in HAAD and a positive attitude to medical research and the value of the biobank. Moreover, trust in HAAD, the custodian of the biobank, to assess risks and benefits of biobanks to improve the health of Emirati population was high (82.5% agree). Those who had trust in HAAD also had mostly positive experience with healthcare services in the emirate of Abu Dhabi, reported having high trust in healthcare providers, and had a positive attitude to medical research, donation of biosample for research, and the value of the biobank.

A majority of survey respondents (83%) believed that their participation in the biobank might be seen as positive gesture, and would encourage their family to participate as well, and 41.4% reported that their family would definitely participate in the biobank. Majority (71%) preferred to make the decision about participation by themselves; others with the help of a doctor or other healthcare provider, or other family member/s (14%). Those who preferred to make the decision about participation with the help of others were more likely to be female, having lower education status, not employed, and having lower monthly household income (less than 20,000 AED).

The most common perceived benefits of biobanking for future research as cited by the survey respondents were altruistic: improving the health and wellness of future generation, and supporting medical research. The common characteristics of survey respondents who mention these motives had higher education, an understanding of genomics, and a positive attitudes towards donation of biosamples for research and the value of the biobank. Moral motives such as donation being a charitable act were mentioned next, mainly by survey respondents who had positive

attitudes towards donation of biosamples for research, and understood the value of the biobank. Perceived therapeutic benefits such as obtaining better treatment or cure for family members or their own condition were cited less frequently. It motivated mainly those with a family and personal history of chronic diseases respectively.

On the other hand, when it came to perceived concerns of those not willing to participate, it seemed that the larger proportion were not sure about the potential concerns of the biobank research. These respondents lacked the knowledge of genomics, had never donated blood, had negative attitudes towards donation of biosamples, and questioned the value of the biobank. Nonetheless, survey respondents pointed out three common concerns, mainly about genomic research: not having belief in medical research, and concerns about privacy and confidentiality. Apparently the common characteristics for those who raised these concerns were negative attitudes to HAAD and the biobank (all $P<0.05$).

When assessing survey respondents' views regarding recontact and desire for feedback on biobank research, a large proportion (67.6%) indicated that they would definitely accept recontact in the future by the biobank staff for additional assessment, donation or information. They had a strong desire for feedback on their own genomic risks of diseases: 83.9% indicated that that would definitely want to receive such feedback. They also had a high interest in receiving general information on biobank research, with 70.8% indicating ‘definitely yes’. Common characteristics of those who definitely accepted future recontact, and had high expectations for both individual and general research results had higher education, familiarity with the term biobank, had previously donated blood, and had a positive attitude towards donation for biomedical research, the value of the biobank and trust in HAAD.

The proposed model of biobanking was introduced to the survey respondents; i.e., incorporating the biobank project into the existing *Weqaya* screening program. A vast majority of the survey respondents (92.7%) did not mind donating biosamples and health information to the biobank for future research, and majority (76.1%) were very optimistic and definitely willing to participate in the same, voluntarily donating residual biosamples (blood or urine) and the health information collected during their *Weqaya* screening visit for the biobank for future genomic research. The overall probability of willingness to participate in the proposed biobank was higher in males compared to females; 80.8% of males were definitely willing to participate in the biobank compared with 71.0% of females (P=0.005).

After adjusting for other covariates, willingness to participate in a population-based biobank were significantly associated with being male, having good knowledge of biomedical research, altruistic motives, a positive attitude towards the biobank, acceptance of future recontact, a desire for feedback on of individual research results, and family influence on participation. These factors were independently shown to have positive associations with a willingness to participate in a population biobank.

The top three sources for health information were website or social media, personal communication by a doctor or healthcare provider, and printed materials (booklets or brochures). The top three communication technology to share general information on biobank research were SMS followed by emails and mobile phone applications. In general, health information and communication channel preferences varied by gender, age, level of education and employment status. No association was found by region of residence or other demographic characteristics. Overall, internet-based communications such as website, social media and emails as well as SMS were

found to be popular and preferred as trusted channels for health information and communication, particularly by highly educated Emiratis. Those with lower education levels preferred personal communication by a doctor, other healthcare providers, family members or friends, public seminars and TV reports. These communication channels are important to consider while planning publicity strategies for the biobank, as well as to improve medical research literacy among general public.

Chapter 5: Discussion and Implications

Population-based biobanks are invaluable as national resources and infrastructure to advance biomedical research, monitor diseases and other health outcomes, and accelerate the introduction of personalized medicine. They have been implemented in many countries to improve the wellness and health of future generations. Population-based biobanks focus on population benefits and interests rather than directly assisting individual participants.

The successful launch, sustainable operations and broad applicability of population-based biobank research relies primarily on public engagement and widespread voluntary participation. In order to ensure higher, wider and longer-term public engagement and participation, biobank information resources, communication strategies, as well as biobank regulations and policies need to be tailored to local contexts that respect the specific interests of the general public and their preferences, and meet local expectations.

This cross-sectional study was the first of its kind, a large-scale study representative of the entire Emirati population of the emirate of Abu Dhabi. The study aimed to establish the first emirate-wide data regarding the Emirati public's knowledge and attitudes towards biobanking for genomic research, assess their willingness to participate in a proposed population-based biobank for future genomic research, and explore factors associated with their willingness to participate.

The overall response rate to the study was 71.7%, considered satisfactory and close to what was anticipated during sample calculation. The data collection method of telephone interviews was the first reported experience from the region, and what

we had wanted to explore for use in future sociological and public health research. It can be recommended for use in future studies.

Overall, our study demonstrated that the Emirati general public are very positive about biomedical research, optimistic about the potential value of the population-based biobank for the Emirati population, and had high trust in HAAD, the custodian of the biobank. They were enthusiastic about participation in the biobank, voluntarily donating residual biosamples (blood or urine) and health information to the biobank for future genomic and other biomedical research. The overall probability of participation in the proposed biobank was 76.1%. Males were more willing to participate in the proposed biobank than females, 80.8% compared with 71.0%, (P=0.005).

After adjusting for other covariates, factors that were significantly and positively associated with the willingness of the Emirati general public to participate in a population-based biobank were: being male, having good knowledge of biomedical research, positive attitudes towards the value of the biobank, altruistic motives – to improve the health and wellness of future generation and support medical research, family influence on participation, accepting future recontact and a desire for the return of individual genomic research results.

In the following sections, we will discuss findings addressing our study objectives in relation to other regional and international studies that explored public knowledge and attitudes towards biobanking for future research: willingness to participate in a population-based biobank, perception of the benefits and risk of participation, public view on recontact and the return of research results, factors associated with public decision to participate in a population-based biobank, and

views on preferred health and information communication technologies to promote and update on biobank research. In addition, we will highlight our study strengths and limitations, and conclude with their implications for practice and recommendations for future follow up research.

5.1 Knowledge and Attitudes towards Biomedical Research and Biobanking

The Emirati general public's understanding about biomedical research in general, genomics and biobanking in particular, was very limited. Only few people reported good knowledge on biomedical research (4.8%), and genomics (16.1%), or having heard about the term biobank (16.4%). These findings were expected, and consistent with all studies reviewed from various populations and socioeconomic subgroups in the US, Canada, Europe, Australia, Asia, and Africa, including Arab countries of the Middle East region. Majority of these populations and subgroups reported having limited or no knowledge about biomedical research (Allen & McNamara, 2011; Eder et al., 2012; El Obaid et al., 2016; Gaskell et al., 2013; Godard, Ozdemir, Fortin, & Egalite, 2010; Igbe & Adebamowo, 2012; Nasrella & Clark, 2012; Rodriguez et al., 2013), particularly genetics and genomic research (Allen & McNamara, 2011; Godard et al., 2010; Luque et al., 2012; Millon Underwood et al., 2013; Moriya et al., 2014; Streicher et al., 2011), and unfamiliarity with the term biobank (Eder et al., 2012; Gaskell et al., 2013; Hassona et al., 2016; Igbe & Adebamowo, 2012; Nasrella & Clark, 2012; Ridgeway et al., 2013; Simon et al., 2011; Tauali et al., 2014; Tupasela et al., 2010).

Previous engagement or participation of the Emirati general public in medical research, such as donating blood or providing tissue for research or taking part in a trial for testing an experimental treatment, was very low: only 6% of survey

respondents had ever participated in medical research. This was expected from an Arab country of the Middle East, as highlighted by Nair on research capacity of the region (Nair et al., 2013). Similarly, a study from Egypt reported that only 6% of patients attending urban and rural hospitals and clinics had ever participated in health-related research, which included taking part in surveys (Abou-Zeid et al., 2010). The study in Saudi Arabia reported that 20.7% of the outpatient surveyed had ever participated in health-related research (Al-Jumah et al., 2011). On the contrary, rates from samples of the general public from the UK and the US- including studies on under-represented subgroups such as African Americans- were higher compared to our study. In the UK, a study by Lewis, Clotworthy, Hilton, Magee, Robertson, Stubbins, & Corfield (2013b) reported 14% of a sample of the general public have ever participated in medical research, and in four studies across the US which included underserved communities, 14-33% gave such history (Lemke et al., 2012; Millon Underwood et al., 2013; Rodriguez et al., 2013; Simon et al., 2011).

Furthermore, 42.5% of the Emirati general public reported previous blood donation. Blood donation is a proxy act for altruism (Ewing et al., 2015). Our findings were consistent with a regional and two international studies, from Saudi Arabia and the US, where it was reported at 43.1%, 45.5% and 53.5%, respectively (Al-Jumah et al., 2011; Kerath et al., 2013; Overby et al., 2015). It is worth mentioning that these three studies were based on convenience samples of patients from outpatient clinics and were not representative of population surveys.

Our study indicated that the vast majority of the Emirati general public were very positive about the potential role of biomedical research in improving patient' health (91%, agreed) and the importance of donation of biosamples for medical

research (84% believed it is important). This finding was consistent with all other studies across various populations: Arabs, Africans, Asians, Europeans, Australians, Canadians and Americans (Abou-Zeid et al., 2010; Ahram et al., 2012; Ahram et al., 2013; Al-Hussaini & Abu-Hmaidan, 2014; Al-Jumah et al., 2011; Hassona et al., 2016; Igbe & Adebamowo, 2012; Lewis, Clotworthy, Hilton, Magee, Robertson, Stubbins, & Corfield, 2013b; Ma, Seals, Tan, Lee, & Toubbeh, 2014; Ma et al., 2012; McWhirter et al., 2014; Moodley, Sibanda, February, & Rossouw, 2014; Overby et al., 2015; Porteri et al., 2014; Sanderson et al., 2013; Toccaceli et al., 2014; Tupasela et al., 2010); including underrepresented subgroups- such as African American or Hawaiian communities (Sanderson et al., 2013; Tauali et al., 2014). This was also the same specifically with respect to support of genetic or genomic research (Kerath et al., 2013; Melas et al., 2010; Moriya et al., 2014; Streicher et al., 2011).

Overall, the vast majority of the Emirati general public were supportive of the establishment of a population-based biobank and optimistic about the potential value of the biobank as a resource of generating new information to improve Emiratis' health (91.6% believe it would be a valuable resource). This finding was similar to that of other studies from Saudi Arabia, Qatar, Jordan, Nigeria, Finland, Australia, the US and Canada, where a majority of the general public were very positive about the value of biobanks, and believed that population-based biobanks have potential benefits to improve community health (Ahram et al., 2013; Al-Jumah et al., 2011; Critchley et al., 2012; Godard et al., 2010; Halverson & Ross, 2012b; Igbe & Adebamowo, 2012; Kerath et al., 2013; Lemke et al., 2012; Lewis, Clotworthy, Hilton, Magee, Robertson, Stubbins, & Corfield, 2013b; Pullman et al., 2012; Simon et al., 2011; Tauali et al., 2014; Tupasela et al., 2010).

5.2 Perceived Benefits and Risks of Biobanking for Future Research

We found great commonality with other studies in commonly cited reasons for perceived benefits and risks of biobanking for future research. However, the rankings of these perceived benefits or risks differ across populations and subgroups, in addition to a few specific benefits and risks that are particular to some population or subgroups. We believe that these differences mirror the countries social and economic development, healthcare system model and insurance coverage, biobank model (particularly methods of collection of biosample and health information), biobank governance framework, advancement of health information and communication technologies, health and medical research literacy.

5.2.1 Perceived benefits of biobanking for future research

Commonly cited perceived benefits that motivate the public to participate in a population-based biobank can be grouped into three main categories: altruistic, moral and egoistic (personal) benefits.

Overall, the Emirati general public seems to report similar perceived benefits commonly cited in the literature. Largely altruistic benefits were the primary and the most frequently cited, mainly improving the health and wellness of future generation (72.7%) and supporting medical research (61%). This was particularly evident among highly educated Emiratis. Altruistic benefits were followed by moral motives. More than half of the study participants (51.4%) cited it as a charitable act to participate, which was evident among those with positive attitudes regarding donation of biosamples for research and the value of the biobank.

However, our study also reported a few misconceptions regarding perceived benefits to biobank research, mainly therapeutic misconceptions (expectations of

treatment in return for donation) due to confusion between clinical care and medical research (Halverson & Ross, 2012b; Halverson & Ross, 2012c; Nobile et al., 2013) . Some of the Emirati general public cited therapeutic benefits to family members (32%) or self (15.8%) as the perceived benefit for participation. Therapeutic benefits motivated mainly those with personal or family history of chronic diseases. Similarly, another participant believed that the biobanks would reduce traveling abroad for medical care. Diagnostic misconception was cited by one participant 'to discover a medical concern, if any'. Diagnostic misconception means there is an expectation for personal health-related information in return for the donation (Nobile et al., 2013).

Table 5-1, summarizes and compares perceived benefits cited by the literature as motives for the general public to participate in a population-based biobank. Consistent with our study findings, altruistic motives were the most commonly cited ones (primary motives) by most of the studies from various populations in the UAE, China, Italy, France, Australia Canada and the US (Allen & McNamara, 2011; El Obaid et al., 2016; Godard et al., 2010; Lemke et al., 2012; Luque et al., 2012; Ma et al., 2012; Overby et al., 2015; Pullman et al., 2012; Rahm et al., 2013; Spruill, Gibbs, Laken, & Williams, 2014; Streicher et al., 2011; Toccaceli et al., 2014). Many of these studies include underrepresented groups such as African American, Hispanic, Latinos and native Hawaiians (Halverson & Ross, 2012b; Rodriguez et al., 2013; Sanderson et al., 2013; Tauali et al., 2014). This was also consistent with researchers' conclusions which acknowledged that the public would tend to view population-based biobanks as public goods established primarily for public benefits, and thus tend to act altruistically (Pullman et al., 2012). Moral motives were cited in the literature as secondary motives, similar to our study findings (El Obaid et al., 2016; Ma et al., 2012; Porteri et al., 2014).

Table 5-1: Perceived benefits of biobanking for future research, cited in the literature.

Perceived benefits (motives)	**Cited by**
Benefits cited by our and other studies	
Altruistic motives • Improve the health and wellness of future generation • helping others (same race, others in general, future patients) • Support or contributing for research • Opportunity to develop new drugs • Betterment of humanity/ Help human kind	Frequent motives, cited by 17 other studies from: UAE, China, France, Italy, Australia Canada and the US (including sub-populations-African American, Hawaiian, Hispanic, Latinos)
Moral motives • Donation is charitable act • Religious permission • Citizenship/ national obligation/ Patriotism/ Responsible citizen • Humanistic gesture • Personal worth and empowerment	Frequent motive , cited in seven other studies from UAE, Qatar, Jordan, Qatar, China, France and Italy and Australia
Egoistic (personal) motives • Therapeutic benefits (misconception)- obtain better treatment or cure for own condition / for family members • Improve understanding of personal/family chronic diseases	Cited by five other studies from Nigeria, UK, Netherland and two from the US
Others motives • Development opportunity for the country • Personal curiosity and improve understanding on biobank and genomic research.	Cited by studies from , Qatar, Jordan and US
Benefits cited by other studies, but not our study participants	
Other Egoistic (personal) • Free healthcare: clinical encounter /check ups • Financial incentive	Cited by four studies, from the UAE, Jordan, and the US
Benefits reported only by our study participants	
• Reduce traveling abroad for medical care • Diagnostic benefits (misconception)	Our study only

In contrast to our findings, moral motives were the primary ones for other Arabs, from Jordan and Qatar as well as samples studied from Australia. Moral motives cited by these studies were religious permission, national obligation and being a responsible citizen, respectively (Ahram et al., 2013; Nasrella & Clark, 2012). Egoistic benefits mainly those of therapeutic nature and diagnostic advantage or clinical assessment associated with donation- were mentioned as primary motives in studies from Nigeria, the UK and the Netherlands (Igbe & Adebamowo, 2012; Lewis, Clotworthy, Hilton, Magee, Robertson, Stubbins, & Corfield, 2013b; Meulenkamp et al., 2010), and as secondary motives from the US (Halverson & Ross, 2012b; Lemke et al., 2010; Streicher et al., 2011; Teare et al., 2015), while there were the least frequent motives mentioned by Emiratis in our study.

Other motives mentioned by our study participants and cited in other studies were, personal curiosity to improve the understanding of biomedical research and biobanking, as reported from the US (Sanderson et al., 2013). Some also identified this as a development opportunity that raises the profile of the country, as reported from Qatar (Nasrella & Clark, 2012). Motives not cited in our study included financial compensation (Hassona et al., 2016; Luque et al., 2012; Rodriguez et al., 2013).

5.2.2 **Perceived risks of biobanking for future research**

Common perceived risks of biobanking for future research cited in the literature by various populations and research ethics advocates were informational risks to privacy and confidentiality, unlimited future research, managing and returning results, and commercialization concerns of ownership and benefits sharing. Our study indicated the Emirati general public has limited understanding of the risks of donation

of biosamples and health information for biobank future research; this could be explained by the limited knowledge and participation in medical research in general. More than one-third (38.2%) of those unwilling to participate were not sure about potential risks. Others have reported concerns, consistent with those commonly cited in the literature. These were, concerns about genomic research (23.5%); negative attitudes to medical research (23.5%); concerns of loss of privacy- sharing private information regarding self or family members; medical or genetic data (14.7%); and concerns of breach of confidentiality- through a leak of personal information or identification (5.9%).

Table 5-2, summarizes perceived risks (concerns) cited in the literature as barriers for the general public to participate in a population-based biobank. Consistent with our study, common concerns reported in the literature were confidentiality concerns of leakage of personal identification or misuse of data (stigma or discrimination by third party: insurer, government or employer). These have been reported by many other studies from the UAE, Qatar, Jordan, Nigeria, European countries, US and Canada (El Obaid et al., 2016; Gaskell et al., 2013; Halverson & Ross, 2012a; Hassona et al., 2016; Igbe & Adebamowo, 2012; Joly et al., 2015; Nasrella & Clark, 2012; Overby et al., 2015; Rahm et al., 2013; Ridgeway et al., 2013; Simon et al., 2011; Spruill et al., 2014). Privacy concerns have also been reported in Jordan, Europe, the US and Canada (Ahram et al., 2013; De Vries et al., 2016; Eder et al., 2012; Gaskell et al., 2013; Halverson & Ross, 2012a; Kerath et al., 2013; Lemke et al., 2010; Melas et al., 2010; Pullman et al., 2012). Concerns about genomic research (misconduct by unethical use of biosamples, contradictory to religious belief, integrity, or mistrust in researcher, fear of genetic research results) were reported from Nigeria, China, Sweden, the UK and the US (Igbe &

Adebamowo, 2012; Lemke et al., 2010; Lewis, Clotworthy, Hilton, Magee, Robertson, Stubbins, & Corfield, 2013b; Luque et al., 2012; Ma et al., 2012; Overby et al., 2015; Rodriguez et al., 2013; Sanderson et al., 2013; Simon et al., 2011; Tauali et al., 2014). Other commonly reported concerns were negative attitudes towards medical research in general (Lemke et al., 2010; Overby et al., 2015), concerns of lack of knowledge on biomedical research as reported from a study from the UAE and two from the US (El Obaid et al., 2016; Luque et al., 2012; Spruill et al., 2014), and practical barriers of time, transportation or logistic as reported from our study participants, as well as in studies from the US (Ridgeway et al., 2013; Sanderson et al., 2013).

In contrast to our study findings, common concerns that were cited in the literature, but not by our study participants, were: concerns of commercialization - public versus commercial interests in terms of ownership of biosamples, benefits sharing and data sharing, which were reported from several studies from South Africa, the UK, the US and Canada (Godard et al., 2010; Joly et al., 2015; Moodley et al., 2014; Tauali et al., 2014). Concerns were also raised about unlimited future research as reported in Jordan and South Africa (Ahram et al., 2013; Moodley et al., 2014). In addition, less common concerns reported include exporting biosamples or research being conducted outside the country or by foreign researchers, as reported from Egypt, as well as from Nigeria, South Africa, the UK and Hawaiian communities in the US (Abou-Zeid et al., 2010; Igbe & Adebamowo, 2012; Lewis, Clotworthy, Hilton, Magee, Robertson, Stubbins, & Corfield, 2013b; Tauali et al., 2014); lack of personal relevance or benefits as reported from the samples from the UAE, Jordan, Sweden and the US (Ahram et al., 2012; Ahram et al., 2013; El Obaid et al., 2016; Melas et al., 2010; Rodriguez et al., 2013; Sanderson et al., 2013); concerns regarding

the procedure- such as drawing blood as reported from Jordan and the US (Hassona et al., 2016; Luque et al., 2012; Sanderson et al., 2013); and finally, sustainability of resources and infrastructure of the biobank, as reported from Nigeria (Igbe & Adebamowo, 2012).

Table 5-2: Perceived concerns of biobanking for future research, cited in the literature.

Perceived risks (concerns)	**Cited by**
Concerns reported by our study participants and other studies	
• Concern of confidentiality- data insecurity (leakage of identification) or miss use of data (stigma or discrimination by third party: insurer, government or employer)	Frequent concern, reported by our study as well as 12 other studies from UAE, Qatar, Jordan, Nigeria, Europe , US and Canada
• Concerns of loss privacy- sharing private information regarding personal or family, medical or genetic data	Frequent concern, reported by our study and other eight studies from Jordan, Europe, the US and Canada
• Concern about genomic or biomedical research- miss conduct (unethical use of biosamples, contradicting to religious believes)/ Integrity or miss trust in researcher /fear of genetic research results	Our study, as well as studies from Nigeria, China , Sweden, US and UK
• Negative attitudes to medical research- Do not believe /do not trust	Our study and two studies from the US.
• Practical barriers: time (too busy), transportation or other logistics barrier	Our study and two studies from the US.
• Lack of knowledge on biomedical research	Our study and another three studies from UAE and US
Concerns reported by other studies but not our study participants	
• Concerns of commercialization: public versus commercial interests : ownership of biosamples and benefits and data sharing	Cited in 6 studies from South Africa, UK, US, and Canada.
• Exporting biosamples outside the country, research conducted outside the country	Cited in 5 studies from Egypt, Nigeria, South Africa, UK and Hawaiians
• Lack of personal relevance/benefits - non disclosure of research results/ compensation	Cited in six studies from UAE, Jordan, Sweden, and the US
• Unlimited future research	Cited in two studies from Jordan and, South Africa
• Concerns or negative perception about the procedure - example: blood draw/needles	Cited in three studies from Jordan and the US
• Sustainability of biobank infrastructure and resources	Cited in one study from Nigeria
Concerns reported by our study participants but not by other studies	
• I am not healthy (too sick)/too old • Lack of trust in healthcare diagnostic services	Our study only

5.3 Public Views on Recontact and Return of Research Results

Although recontact and re-identification of research participants is one of the major ethical and legal challenges frequently mentioned, the vast majority of the Emirati general public did not perceive future recontact as a negative concept or barrier, and did not object. In fact, a majority (68%) of the Emirati general public were definite about accepting future recontact by the biobank staff for additional assessment tests, donation of more blood or the provision of new information, other than that collected routinely through the periodic *Weqaya* screening program. Emiratis were definite about accepting future recontact were more likely to be males, highly educated, had previously donated blood, were familiar with the term biobank, and had positive attitudes towards medical research, donation of biosamples and the biobank, and trusted HAAD.

Consistent with our study, high acceptance was also reported from a study in the US, from participants of a biobank, where vast the majority (93%) had no concerns about updating researchers with health information (Mester et al., 2015). However, in contrast to other studies from Arab countries, in Jordan and Egypt many respondents favored no future recontact (Abou-Zeid et al., 2010; Ahram et al., 2013; Hassona et al., 2016).

Managing and returning research results have raised ethical and legal concerns. However, a vast majority of the Emirati general public had high expectations and a strong desire for returning biobank research results, both individual genomic and general aggregate research results, with higher interest in individual research results (i.e., their own genomic risk findings). The characteristics of Emiratis who had high expectations for returning biobank research results, both individual and

general research results, were those who had previously donated blood, were familiar with the term biobank and had positive attitudes towards medical research, donation of biosamples and the biobank, and trusted HAAD.

In fact, the public in various populations and subgroups had a high interest and expectations for returning both individual genomic and general aggregate research results. This was reported in most studies conducted on samples from various populations; including other Arabs in Saudi Arabia, Jordan and Egypt (Abou-Zeid et al., 2010; Ahram et al., 2013; Al-Hussaini & Abu-Hmaidan, 2014; Al-Jumah et al., 2011; Alahmad, Hifnawy, Abbasi, & Dierickx, 2016; Allen & McNamara, 2011; El Obaid et al., 2016; Mester et al., 2015; Meulenkamp et al., 2010; Moriya et al., 2014; Porteri et al., 2014; Sanderson et al., 2013; Streicher et al., 2011; Tauali et al., 2014). Updating the public and research participants on the aggregate research results reflected the respect the biobank accorded to the participants. It increased public and participants' trust in biobanks, besides increasing awareness, and therefore participation (Mester et al., 2015). Furthermore, recently there has been widespread consensus among experts about the obligation to return individual genomic research results, both the incidental findings and individual research results, if it met the ACA criteria of analytical validity, clinical significance and actionability, and if the research participant had opted to receive individual genomic results during the consent process or subsequently (Black et al., 2013; Bredenoord et al., 2011; Christenhusz et al., 2013; Jarvik et al., 2014; Knoppers et al., 2012; Knoppers et al., 2015; Lemke et al., 2010; Lemke et al., 2012; Smith & Aufox, 2013; Terry et al., 2012; Viberg et al., 2014). Some studies probed the preferences of individual genomic research results based on the actionability or clinical significance of the findings (Beskow et al., 2012; Watanabe et al., 2011), explored public attitudes

towards disclosing genomic data with various third parties (Alahmad et al., 2016), or further probed on the frequency about communication of general research results (Mester et al., 2015). This was not explored in our study and can be evaluated later in future research.

In contrast to our study findings, few studies one in the US on a sample from a Latino community, and two in Jordan and Saudi Arabia on outpatients, favor no feedback on individual genomic research results. In fact they perceived it as concern that would discourage their participation in biobank research (Al-Jumah et al., 2011; Hassona et al., 2016; Rodriguez et al., 2013).

5.4 Willingness to participate in a Population-based Biobank

A vast majority of the Emirati general public (92.7%) did not mind donating residual biosamples and health information to the biobank for future genomic research. A recent small-scale qualitative study on participants enrolled in a biomedical research in Abu Dhabi reported that 95% of the 42 participants did not mind having their biosamples and blood stored for future research (El Obaid, et al., 2016).

The overall probability of willingness, definitely willing, to participate in the proposed biobank was 76.1%. Willingness to participate in the biobank in our study refers to voluntarily donating residual biosamples (blood or urine) and the health information collected during their *Weqaya* screening visit to the biobank for future genomic research and other biomedical research.

When comparing other studies, the Emirati general public were more enthusiastic about participation in the biobank compared with other Arabs. Two studies from Jordan reported that 64% of the general public were willing to be a

biobank donors (Ahram et al., 2012) and another recent reported 55.9% (Hassona et al., 2016). In Saudi Arabia, although overall probability of those willing to donate blood or allow use of excess surgical samples in future biomedical research was on average 78.4%, those who were strongly willing were only 48.9% on average, 57.3% for blood and 34.4% for surgical samples (Al-Jumah et al., 2011). In China, one study, reported that 61.7% of the general public were willing to donate clinical leftover biosamples to biobank for future research (Ma et al., 2012). Our findings were close to those of the studies from Italy, Finland and the United States, which cited rates of 86%, 83% and 78%, and 80% (with opt in consent), respectively, with regards to their willingness to donate to a biobank for research (Kaufman, Bollinger, Dvoskin, & Scott, 2012; Lemke et al., 2012; Porteri et al., 2014; Tupasela et al., 2010).

A possible explanation to high willingness to participate compared with other Arabs, is that the proposed biobank model, is planned to be integrated to a running screening program, that already collect comprehensive data, provide free checkups and assessments, as well as the method of collection of biosamples is convenient, residual blood or urine instead of direct donation or surgical tissues.

5.5 Factors Associated with Public's Willingness to participate in a Population-based Biobank

Factors associated with public's willingness to participate in a population-based biobank were summarized in the conceptual framework presented in Chapter 2. This section will describe the significant factors associated with the willingness to participate in a population-based biobank from our study as well as from the reviewed literature.

Table 5-3: Summary of literature on significant independent factors associated with public's willingness to participate in a population-based biobank.

Independent Factors	Consistent findings Significant in our and/or other studies	Contrasting findings Significant in other studies
Demographic characteristics	• Higher education • Employment • Gender*	• Age • Annual household income • Region of residence/Rural: urban distribution • Religion ^ • Ethnicity^
Perceived benefits (motives)& risks (concerns)	• Motive: improve wellness and health of future generation* • Motive: support research * • Motive: donation is charitable act	• Motive: therapeutic/health benefits • Motives: financial compensation • Concerns: privacy and confidentiality • Concern: misuse /misconduct of research
Biobank operations and policies	• Accept recontact * • Desire for returning individual generic results * • Desire for returning general aggregate results ~	
Knowledge & Attitudes towards biomedical research & biobanking	• Ever donated blood • Self-reported good knowledge on biomedical research* • Medical research improves patients' health • Donation of biosample for research is important • Biobanks are valuable resources to generate new information to improve health *	• Previous participation in medical research • Familiarity with biobank • Self-reported good knowledge or understanding genomics
Healthcare system factors- Trust & experience	• Trust government /entity supervise the biobank - HAAD	• Trust healthcare institution/providers • Trust researchers/biobank/research institution^
Social-cultural context influence	• Family influence (participation)*~ • Decision is made with help of self- versus others~	

*Remained significant at multiple logistic regression
~Not explored for association with willingness to participate in other studies
^ not explored in our study

Overall, compared with other studies from other populations, including other Arabs there were great variation in factors associated with the willingness to participate in a population-based biobank. Table 5-3, provides a summary of the significant independent factors associated with public' willingness to participate in a biobank as gleaned from the reviewed literature, and compares them with those from our study. It highlights significant independent factors that were not explored in our study or in other studies, and those that remained significant in our study after adjusting for other covariate.

5.5.1 **Demographic characteristics**

Demographic characteristics that were associated with the Emirati general public's willingness to participate in a population-based biobank were also reported in other studies. Higher education attainment, i.e., completion of secondary or higher level of education, was positively associated with the likelihood of willingness to participate (Crude OR=1.72: 95% CI: 1.10 to 2.67, P=0.02). Higher education was the most frequently reported significant demographic characteristic, cited in the studies from eight other countries: Jordan, Saudi Arabia, Egypt, China, as well as from Europe, Australia and the US (Abou-Zeid et al., 2010; Ahram et al., 2012; Ahram et al., 2013; Al-Jumah et al., 2011; Critchley et al., 2012; De Vries et al., 2016; Gaskell et al., 2013; Ma et al., 2012; Toccaceli et al., 2014).

Similarly currently employed had significantly associated with the willingness of the Emirati general public to participate in the biobank (Crude OR=1.84: 95% CI: 1.25 to 2.69, P=0.002). Employment had also been reported as a significant factor associated with increased willingness to participate in studies from three countries:

China, Australia and the US (Banks et al., 2012; De Vries et al., 2016; Ma et al., 2012).

A third significant demographic factor was gender; being a male increased the likelihood of willingness to participate (Crude OR=1.71: 95% CI: 1.17 to 2.05, P=0.005). Gender was found to be significant in three other studies. The study from Europe - on 32 countries- was consistent with ours, it shows that being male was associated with an increased likelihood of participation in population-based biobank research (Gaskell et al., 2013), while the study from Saudi Arabia-conducted on out-patient volunteers, and another from the US recoded that being a female increased the likelihood of participation in biomedical research or biobank (Al-Jumah et al., 2011; Ridgeway et al., 2013).

Factors such as age, annual household income, ethnicity, religion and rural-urban distribution were found significant in studies from Jordan, China, the UK, the US and Australia (Ahram et al., 2012; Ahram et al., 2013; Al-Jumah et al., 2011; Banks et al., 2012; De Vries et al., 2016; Lewis, Clotworthy, Hilton, Magee, Robertson, Stubbins, & Corfield, 2013b; Ma et al., 2012; Ridgeway et al., 2013), but unexpectedly and in contrast, did not show significant association in our study. Religion and ethnicity were not explored in our study participants, as all were Emirati and universally Muslim.

5.5.2 **Perceived benefits and risks of biobanking for future research**

In our study, altruistic and moral motives had significant association with an increased likelihood of participation of the Emirati general public in the proposed biobank. Altruistic motives such as, 'improve the health of future generations' and 'support medical research' increased the likelihood of willingness to participate in the

biobank four-folds (OR=4.0: 95% CI: 2.70 to 5.92, P<0.001) and (OR=3.73: 95% CI: 2.50 to 5.54, P<0.001), respectively. Moral motive, i.e., 'donation is charitable act', increased the willingness to participate three-folds (OR=2.68: 95% CI: 1.80 to 4.00, P<0.001).

Consistent with our study, altruistic motives were found to be positively associated with willingness to participate in a biobank in a study from the US (Overby et al., 2015). Also moral motives- religious permission, was found to be positively associated with willingness to be a biobank donor in a study from Jordan (Ahram et al., 2013; Al-Jumah et al., 2011).

In contrast to our findings, a sample studied in Jordan reported personal (egoistic) motives such as financial compensation as an independent factor associated with the increased willingness to participate in a biobank (Hassona et al., 2016). Similarly therapeutic benefits were reported in Australia (Critchley et al., 2012). However these motives were not significant independent factors in our study.

Furthermore, in our study, concerns of biobanking for future research did not negatively influence the willingness to participate. However, privacy and confidentially concerns were significant enough in a few studies from 32 European countries as well as the US to negatively influence the decision to participate in a biobank (De Vries et al., 2016; Gaskell et al., 2013; Overby et al., 2015; Ridgeway et al., 2013). Similarly, concerns of misconduct or unethical use of biosamples was reported from China (Ma et al., 2012).

5.5.3 **Biobank operations and policies**

Accepting recontact, increased the willingness of the Emirati general public to participate in the population based biobank almost four-folds (Crude OR=5.69: 95%

CI: 3.79 to 8.55, P<0.001). However, this contrasted with the study from Jordan, where recontact was associated with less willingness to be a biobank donor (Ahram et al., 2013).

Returning individual genomic research results increased willingness of the Emirati general public to participate in the population based biobank six-folds (Crude OR=5.84: 95% CI: 3.67 to 9.28, P<0.001). Two other studies from Jordan and the US reported significant positive associations with the public's decision to participate in a biobank (Ahram et al., 2013; Halverson & Ross, 2012a), while another study -on dental outpatients from Jordan found that returning results significantly reduced willingness to be a biobank donor (Hassona et al., 2016).

Returning general biobank research results and recontact were found to be associated with Emiratis willingness to participate (Crude OR=3.66: 95% CI: 2.46 to 5.46, P<0.001). However, the association with willingness to participate was not explored in other studies in the published literature.

5.5.4 **Health and medical research literacy**

Consistent with our findings, self-reported good knowledge on biomedical research increased the willingness of the Emirati general public to participate in the biobank, (Crude OR=4.42: 95% CI: 1.04 to 18.8, P=0.04). It was also reported as a significant independent factor in other studies from Saudi Arabia, the UK and other European countries (Al-Jumah et al., 2011; Gaskell et al., 2013; Lewis, Clotworthy, Hilton, Magee, Robertson, Stubbins, & Corfield, 2013a; Lewis, Clotworthy, Hilton, Magee, Robertson, Stubbins, & Corfield, 2013b).

Significant independent factors reported in other studies but not significant in our study included self-reported good knowledge in genomics as reported in Egypt

(Abou-Zeid et al., 2010), and familiarity with the term biobank- in terms of having previously heard about it or understanding its risks and benefits as reported in the US (Millon Underwood et al., 2013). Likewise, previous participation in research was reported in Saudi Arabia and the US to be associated with increased willingness to participate in biobank (Al-Jumah et al., 2011; Millon Underwood et al., 2013)

Attitudes towards biomedical research, donation for research and the value of the biobank to improve population health, increased the Emirati general public's willingness to participate in the biobank: crude OR were 1.95, 3.39 and 4.99, respectively. Positive attitudes to biomedical research was a significant independent factor that increased the public's willingness to participate in a biobank in a study from the US (De Vries et al., 2016).

5.5.5 **Healthcare system: Public trust and experience**

Public trust in key actors were the second commonly reported factor correlated with the decision to participate in a biobank. Public trust and overall experience with the healthcare system and research its key actors (government, medical or research institutions, healthcare providers and researchers) have an important role in the decision to participate in a biobank. This was cited in many studies (Abou-Zeid et al., 2010; Brand et al., 2012; Critchley et al., 2012; Gaskell et al., 2013; Halverson & Ross, 2012a; Igbe & Adebamowo, 2012; Joly et al., 2015; Lemke et al., 2010; Lemke et al., 2012; Lewis, Clotworthy, Hilton, Magee, Robertson, Stubbins, & Corfield, 2013a; Lewis, Clotworthy, Hilton, Magee, Robertson, Stubbins, & Corfield, 2013b; Overby et al., 2015; Ma et al., 2012; Master & Resnik, 2013; McWhirter et al., 2014; Millon Underwood et al., 2013; Moodley et al., 2014; Platt & Kardia, 2015; Tauali et al., 2014). However, most of these studies were qualitative or quantitative, and did not

examine the association of these factors as independent variables for public's willingness to participate in the biobank.

The Emirati general public trust in government authorities, HAAD, as the custodian of the biobank was high (82.5%). Trust in HAAD increased the likelihood of willingness to participate by 82%, (Crude OR=1.82: 95% CI: 1.12 to 2.98, P=0.02). Trust in HAAD was associated with mostly positive experiences with the healthcare services in the emirate of Abu Dhabi, high trust in healthcare providers, and positive attitudes to medical research and donation for research to the biobank.

Consistent with our study, the pan European study showed that trusting biobank key actors such as the government was associated with increased willingness of Europeans to participate in the biobank (Gaskell et al., 2013).

We reported unsatisfactory experiences with healthcare services in the emirate of Abu Dhabi (only 61% considered it mostly positive), and very low trust in healthcare providers (34.6% only had high trust). Trust in healthcare providers was associated with previous participation of Emiratis in medical research, positive attitudes to medical research and the value of the biobank, and mostly positive experiences with the healthcare services. Both factors were not associated with the willingness to participate in the biobank.

In contrast to our finding, two studies from China and from the US showed that trusting medical institutions (Ma et al., 2012) and healthcare providers (Millon Underwood et al., 2013) were independent factors that increased public' willingness to participate in the biobank.

Furthermore, one study explored the association of willingness to participate with trust in biobank as independent variable, and found it to be a significant positive association (Critchley et al., 2012). However, trust in biobank or research institutions was not explored in our study but can be evaluated later in future follow up research, after the establishment of the biobank.

5.5.6 **Social-cultural influences**

Consistent with the theories of donations to biobank research summarized by (Lipworth et al., 2011), who concluded that the decision to participate in a biobank is always socially situated, and it could be the result of relational activity to family, or the influence of pressure or respect from friends, or seeking approval from healthcare providers. A majority of Emirati general public believed that their participation in the biobank might be seen as a positive gesture, and would encourage their families to participate as well. This is an expected finding and was consistent with the findings from a preliminary study conducted in Abu Dhabi, UAE itself (El Obaid et al., 2016). This was also reported in a study from Nigeria, where some members liked to inform and discuss their participation with a family member prior to participating (Igbe & Adebamowo, 2012)

Social influence in terms of family participation was only explored as an independent variable in our study, and was found to be strongly associated with the willingness to participate in the biobank, (Crude OR=5.69: 95% CI: 3.45 to 9.36, P<0.001); but this association was not explored in other studies.

5.6 Preferred Health Information and Communication Channels

The Emirati general public's views and preferences regarding various health information and communication channels were assessed in our study as important

factors influencing the general public's engagement and participation in the population-based biobank research. These views would be considered while deciding on communication strategies for the biobank's publicity plans and improving health and research literacy.

There was a noticeable overall preference for internet-based communications website, social media and emails as well as mobile phones test messages (SMS) as trusted channels for health information and communication. This was particularly evident among highly educated Emiratis. Those with lower education preferred personal communication by a doctor, other healthcare providers, family members or friends, public seminars and TV reports.

These tools are considered relatively inexpensive and convenient methods of communication with the potential to be dependable sources for health information, and for receiving general research results and biobank updates, moreover allowing for two-way and wider engagement (Mester et al., 2015). These can be utilized as the culturally trusted and accepted communication strategies for publicity and social marketing plans, and can be considered for use as e-governance solutions, to overcome potential biobank governance challenges.

In general, the preference of the Emirati general public for health information and communication channel varied by gender, age, level of education and employment status. Similarly, when we compare our findings with other, we found great variation by population and subgroups of same population. Table 5-4 and Table 5-5, compare our study findings with those of other studies. The only common preferred tool for sharing the biobank general research results and updates across all population was the websites.

Table 5-4: Preferred source for health information.

Country	**Design & participants**	**Preferred health information &communication channels**
UAE-Our study	Quantitative study, N=603 of general Emirati	• Website & social media • Personal communication by a healthcare provider (doctor/others) • Brochures/pamphlets • Television (TV) • Public seminars • personal communication by family members or friends • Other traditional media: Radio/newspapers
UAE (El Obaid et al., 2016)	Qualitative study, N=42 Emirati enrolled on a cohort study	• Social media (Twitter/Face book/Instagram) • Religious leaders/ community celebrities • Traditional media (TV, Radio, Newspaper)
Qatar (Nasrella & Clark, 2012)	Qualitative stud, N=100 general public enrolled in Qatar biobank)	• Media outlets • Public forms/social events • Community biobank champions
US (Spruill et al., 2014)	Qualitative study, N= 67 from general US public (6 counties)	• Sending letters • Pamphlets • Personal communication by a healthcare provider t time of hospital discharge • Public seminars (community/church)
US- Latino community (Rodriguez et al., 2013)	Qualitative study, N= 28 from Latino community	• Media out let: Radio/newspaper • pamphlets at healthcare facilities • Personal communication by a healthcare provider • community activity/seminars

Table 5-5: Preferred communication channel to share biobank updates.

Country	Design & participants	Preferred health information &communication channels
UAE-Our study	Quantitative study, N=603 of the Emirati general	• Mobile phone short message services (SMS) (86.6%) • Email (34.6%) • Mobile applications (15.6%) • Website (11.7%) • Others 6%): direct phone call from biobank staff, personal communication by a healthcare provider, social media, publication in newspaper or magazines
US (Mester et al. 2015)	Quantitative study, N= 1,267 enrollee of Cleveland clinic biobank	• Paper newsletter (65.7%) • Emailed newsletter (61.7%) • Website, blogs (29.8%) • Phone call from researcher (26.6%) • Online discussion (15.7%) • Direct in person updates (15.5%) • Face book (8.9%) • YouTube (6.1%) • Twitter feed (0.9%)
Dutch (Meulenkamp et al., 2010)	Quantitative study, N=1,163 general Dutch and (N=515 patients)	• Letters (41%) • Meeting (19%) • Website (12%) • Publication-articles in newspaper or magazine (4%) • Scientific publication 3% • No preference (17%)
Italy (Porteri et al. 2014)	Quantitative study, N=145 family members of patients attending OPD	• Direct in person updates (51%) • Website (34%) • Publications-articles in newspaper or magazine (15%)

5.7 Strengths and Limitations

5.7.1 Strengths

We believe that the findings from our study are robust and trustworthy for the following reasons. To begin with, this study was the first large-scale, emirate-wide study to explore the Emirati general public's knowledge and attitudes regarding biobanking for future genomic research, to assess their willingness to participate in a proposed population-based biobank, and to explore factors associated with their willingness to participate in the biobank. The sample size was believed to be adequate for the purpose of this study as was estimated prior to commencing it, based on several assumptions, and to reach high study power of 90%.

Secondly, the study subjects were the target population for the proposed biobank, who were selected at random using Stata Statistical Data Analysis software version 11.2 from a list of healthy individuals from the Emirati general public who underwent *Weqaya* screening between July 1 2012- March 31 2015. A stratified sampling method was used to adjust for gender to ensure that the sample represents the Emirati general public in terms of gender distribution (1:1) and test a prior hypothesis where two-thirds of the screening list had comprised females.

Thirdly, the questionnaire was adapted from published instruments and revised by experts to ensure content validity. It was then translated into Arabic and a backward translation to English done to ensure that they both produced identical versions of the questionnaire. Cognitive interviews were conducted to ensure clarity of the questions, and test survey respondents' ability to provide accurate answers. Based on the cognitive interviews, a few changes were made to the final survey. The final questionnaire was then pretested and piloted to assess the average time to

complete the survey, and to ensure that study participants answer all of questions during the field calls. Interviewers were trained to increase reliability and reduce interviewer bias. The first few calls were attended by the research team.

Fourthly, the telephone interview used as a tool for data collection in this study was extremely valuable. It helped reach a large and geographically scattered sample, was efficient in terms of time and resources. It also minimized interviewer effects including social desirability bias, and provided a high level of anonymity which was extremely relevant in this study, given the unfamiliarity and sensitive nature of the topic and questions. Moreover, it yielded a satisfactory response rate of 71.7%, especially when compared with two studies conducted in Australia and the United States using similar methods. The latter two studies yielded response rates of 22.9% and 64% respectively (Critchley et al., 2012; Simon et al., 2011). The higher the response rate, the better the representation of the Emirati general public views on the subject. One of the reasons could be the personalization in our approach and the use of mobile phones rather than landlines.

Lastly, the data were collected and entered directly into the online Survey Monkey® tool during the telephone interviews. This has reduced errors as well as the time that manual entry of data would have taken. It also helped faster data processing, handling and storing.

5.7.2 **Limitations**

There were several limitations to our study. First, our findings was based on cross-sectional data, which gives an indication of knowledge and views on biobanking for future genomic research from a sample of the Emirati general public at a specific

point in time. However, the direction of relationships between willingness to participate and potential correlates could not be determined.

Furthermore the random selection was performed on a list of motivated people who had undergone *Weqaya* screening. The survey respondents were disproportionally older, highly educated, more likely to be employed and residing in Al Ain, when compared with the general Emirati population. Also had high personal and family history of chronic diseases, suggesting some evidence of a selection bias and limiting external validity. Therefore study results should be carefully interpreted. Worth to mention that these characteristics were not significantly associated with the willingness to participate in the final model. In addition, this study can be described as deliberative engagement because it does not seek population representation. Furthermore, whether our results were generalizable to other Emiratis would require further study.

Secondly, there was no published validated instrument that could be used to assess the knowledge and attitudes on biobank research in any language. Our questionnaire was used for the first time in this study, thus was not validated by a previous and independent sample.

Thirdly, a few questions were removed from the final version of the questionnaire due to time constraints, as some of those questions were incomprehensible to most of participants during the cognitive interviews before the survey was fielded. These question were: exploring willingness to donate other biosamples (saliva, tissue, etc...), various consent policy options, trust in a range of research organizations, and categories of individual genomic research results to be

returned for participants. It will be interesting to explore these areas in future follow up studies.

Finally, when comparing the survey non-respondents and respondents, non-respondents were older than survey respondents (mean age was 41.3 years, ±SD 14.9 versus 37.9 years, ±SD 10.9), more often females (58% versus 48.1%), and more likely to be residents of Abu Dhabi, the capital city (52.9% versus 43.3%). This might have introduced non-response bias; however, the non-response rate in our study was very low, 28.3%.

5.8 Conclusions

The Emirati general public had limited knowledge on biomedical research, the concept of biobanking for future research and its related risks, and reported a few important misconceptions about perceived benefits of biobanking. However, they were positive about biomedical research and optimistic about the potential value of the biobank. These were comparable to findings from other countries, including other Arabs. Remarkably, the Emirati general public were enthusiastic about participation in the biobank, had high trust in the government, tolerated future recontact and had high expectations for returning individual genomic research results. However, reported low trust in healthcare providers and unsatisfactory experiences with healthcare services. Overall, factors associated with the general public's willingness to participate in a population-based biobank were context specific and varied by populations' characteristics.

5.9 Policy Implications

In order to ensure informed decision-making about participation and long-term engagement in the biobank, this study's conclusions support the following

recommendation: (i) ensuring ongoing public engagement and empowerment; (ii) developing tailored and meaningful informational and educational resources to increase publicity on biobank and improve health and medical research literacy; and (iii) strengthening medical research regulations and establishing a governance framework and structure for biobanks.

5.9.1 **Public engagement and empowerment**

Our study recommends consultation and active engagement of the Emirati general public during all phases of this new project's lifecycle- planning, implementation and monitoring. The aim is to meet their needs and expectations, as well as to protect their rights. Ongoing and active engagement will empower the Emirati general public, build trust and ownership for this project, thereby ensuring successful and wider participation.

We call for a series of deliberative discussions or surveys to be conducted, utilizing the popular internet-based communications strategy - website, blogs or social media platforms (Face book/YouTube, Twitter and others), as well as direct communication through public forums, focus group discussions or health centers meetings, particularly engaging females and less educated Emiratis. These communications can be conducted by trusted professionals or HAAD experts in this field, as well as by inviting research participants to share their experiences. The findings of such ongoing engagement should be continuously incorporated and taken into consideration while developing the biobank educational and informational resources, publicity plans, as well as biobank governance.

Furthermore, we call for active engagement and adequate representation of the Emirati general public, who are the potential biobank participants, in all research

governing committees related to the biobank such as the supreme research council (example Abu Dhabi Health Research Council), research ethics committees (example Abu Dhabi Research Ethics Committee and other RECs), advisory committees and others, to ensure that their interests, specific concerns and culture-sensitive topics are prioritized and addressed.

5.9.2 **Development of information and education resources**

One of the principal mandates of the establishment of the biobank is developing educational and informational resources for the Emirati general public and other stakeholders as well as developing a publicity plan as part of the biobank implementation plan.

The educational and informational resources including, most importantly, the consent form, should aim at improving the Emirati health and research literacy, and the ability to obtain, read, and understand information on biomedical research and biobanking processes and technologies, all necessary to facilitate informed decision-making about participation.

The information needs to be tailored and meaningful. It should address the gaps in knowledge about biobanking for biomedical research: the process, technologies and risks, besides clarifying misconceptions about potential benefits. In addition, it should provide information about important policies and procedures to protect privacy and confidentiality and the return of research results, especially in view of high acceptance for recontact and high expectation for individual research results. Moreover, it should provide general information on the biobank, the duration of storing biobank resources, as well as types and number of potential future research. The collaborators, source of funding and any plans for commercialization must also

be clearly and directly mentioned. Furthermore, the information should be balanced, capitalizes on potential social benefits while highlights the potential risks related to biobanking for future research.

The informational and educational resources should use simple language to overcome health and research literacy barriers, and be culturally appropriate. For that, we recommend thorough pre-testing (appraisal) of the informational and educational resources through conducting formative focus group discussions which ensure that it is readable, can be comprehended by the Emirati general public, and is culturally appropriate.

Lastly, they must be accessible to all. Publicity plans need to be in ongoing fashion and utilize appropriate communication strategies for the target audience. These include popular internet-based communication sources such as websites, blogs, social media platforms and email for wider engagement, especially for the young, educated generation. In addition, doctors and other healthcare providers must be empowered with updates and knowledge to be valuable sources for information on the biobank, especially for Emiratis with lower education. Moreover, we should consider conducting a series of public forums, seminars and discussions to spread awareness among community members to use the power of social-cultural networks in addition to traditional media such as television, radio and newspapers. Attention should be given to targeting females and Emiratis with less education to ensure a wider and more representative participation in the biobank.

5.9.3 **Strengthen medical research regulations and establish biobank governance structure and framework**

Evidently, there is a need to strengthen medical research ethics regulations and establish biobank governance structure and framework in Abu Dhabi, UAE. Currently, there is no specific federal law or local decree on research on human participants. Furthermore, existing medical research ethic regulations- the Medical Liability Law and the Cabinet Resolution (33) on the implementation of Medical Law Liability, the Healthcare Regulator Policy Manual and HAAD guidelines- are not comprehensive or scattered in different other medical practices laws or standards. Last and most important, existing medical research ethics, are not sufficient to address biobanking legal and ethical aspects. This is particularly true in the following areas: informed consent and options for withdrawal of consent; protection of privacy and confidentiality, as well as the form and level of stored personal data, particularly genomic data; who, how and where biosamples could be stored and used long term; access to biobank resources and potentials for regional and international research collaborations; commercialization of biobank resources, ownership and benefit sharing; and bioinformatics regulations. Therefore, HAAD, as the regulator of health in Abu Dhabi, has an important role in governing such an initiative to protect the rights and interests of the Emirati population, meet their expectations and retain the high trust it enjoys.

We strongly believe that top priority in term of legal governance instruments that need to be developed in the UAE should be given to passing a specific law for research on human participants, with explicit focus on human genome research and biobanking activity. Most countries that have established a national or population-based biobank have passed either a separate law or a decree specifically on

biobanking or incorporated some language into other laws relating to research on human participants. We believe that this is of crucial importance. This law can be drafted on the basis of regional experience from Saudi Arabia, Taiwan and China as well as other international experiences that comply with Islamic laws, and consider global collaboration and harmonization.

Passing a national law is not easy in any country; however, the process in the UAE is clear, and time at hand may be relatively shorter compared to other countries. Yet, this is a crucial step as it will be the only federal legally binding governance tool. This step is usually lead by Ministry of health. It will require consultation with stakeholders, including other health authorities, research and academia institutions, and Islamic affairs including most importantly, the community members. According to researchers from the region, for laws and regulations on biobanking to be passed, it is very important that these laws are relevant in context, and complies with Islamic law, especially the Holy Quran, Sunna and other sources including International Islamic Fiqh Academy (Alahmad & Dierickx, 2014; Fadel, 2010).

A second priority is to pass a decree at the emirate level to provide the legal basis for establishing the biobank and cover important legal and ethical issues. For that HAAD needs to take the lead since this first large scale experience will be established in the emirate of Abu Dhabi. This decree needs to define the principle requirements for establishing a biobank and govern important biobank policies, principally the informed consent and options of withdrawal of consent; privacy and confidentiality protection, the form and level of stored personal data particularly human genome data and recontact of research participants; return of individual genomic research results; who, how and where biosamples could be stored, used long

term and disposed; access to biobank resources for research and non-research purposes; ownership and benefit sharing of biobank resources; and regulate bioinformatics.

While working on the federal law and local decree, it is important to establish the UAE guideline on 'Human Subject Research Conduct', similar to the other regional experience such as Qatar, Saudi Arabia, Kuwait, Bahrain and Sudan. This guidelines should govern important ethical aspects and issues pertaining to research on human participants, including most importantly human genome research. It can be developed on the basis of international guidance such as the CIOMS, WHO and ICH-GCP. Additionally, establish the 'Guidelines on Human Biobanks'. This guidelines should provide guidance for the establishment, governance, operation, access, use and discontinuation of biobanks. It can be drafted based on the international guidance such as the OECD Guidelines on Human Biobanks and Genetic Research Databases, as well as others .

Moreover, HAAD has to ensure that the biobank operator has established its governance structure and framework, SOP's and policies and that it is approved by independent REC or other oversight bodies. These SOP's and policies should comply with international guidance of best practices, while addressing the Emirati general public concerns and meeting local expectations. This is particularly true with regard to informed consent, withdrawal of consent, as well as recontact and privacy and confidentiality protection, managing individual genomic research results and other important areas.

HAAD as a regulator need to monitor closely the performance of research facilities, including the future biobank and the REC's. It is vital to ensure that all

operations comply with domestic and international research ethics principles, regulations and guidelines. This can be achieved through conducting regular audits, secondary external reviews by independent bodies, or mandate registration to internationally recognized accreditation programs. In addition, HAAD must continuously monitor and evaluate the biobank's outcomes, to ensure that it is achieving its ultimate goal, improving the health and wellness of the Emirati population and future generations.

Finally, HAAD to reactivate and empower the role of the Abu Dhabi Health Research Council. This is essential to ensure that research participants' interests and rights are always protected, as well to advice the research agenda, development and revision of research ethics regulations and guidelines in Abu Dhabi emirate.

5.10 Recommendations for Future Follow-up Research

This is a new line of initiative, and one that will require patience, attention to sensitivities, and the rights of human subjects. Further follow up research is recommended in order to confirm our findings as well as to explore Emiratis' views on important areas that were not covered by our study. These areas are: willingness to donate other types of biosamples (saliva, tissue, etc.), other methods of acquiring biosamples (direct donation, residual surgical samples), accepted categories of individual genomic research results to be returned to participants, preference for various consent policy options, and trust in a range of research organizations (such as healthcare facilities, universities, pharmaceutical or diagnostic companies, inside and outside UAE). The follow-up study needs to be designed in such a way as to minimize our study limitations, and consider fair representation of the Emirati general public.

Our study explored the willingness to participate in a proposed biobank; however, the findings may not necessarily correlate with actual future behavior of Emiratis. The study by Johnsson et al., 2010, showed that there were differences in the theoretical and actual participation in various European biobanks. Therefore it is important to carefully monitor public participation and engagement after the implementation of the population-based biobank, and conduct further follow up studies to assess actual participation, compare findings, and explore barriers (if any).

Considering the limited biobank research literacy, unsatisfactory positive experience with healthcare services, and exceptionally low trust in healthcare providers, we recommend a study to assess health literacy of Emirati population. Health literacy, in addition to promoting community empowerment, improves the overall experience with healthcare services including the navigation and utilization of health services across the continuum of care, communication with healthcare providers, as well as understating and analyzing the risks and benefits of various health interventions (Berkman, Sheridan, Donahue, Halpern, & Crotty, 2011; Nutbeam, 2008; Sorensen et al., 2012; Sorensen et al., 2013). This study will help improve health literacy, enhance trust in healthcare providers and institutions, thereby increasing engagement and participation in the biobank.

Additional value of the proposed study will be to develop and validate an Arabic language version of the European Health Literacy Survey Questionnaire (HLS-EU-Q), a comprehensive tool that assesses health literacy, health service use, community participation and other determinants of (Sorensen et al., 2013).

References

Abou-Zeid, A., Silverman, H., Shehata, M., Shams, M., Elshabrawy, M., Hifnawy, T., et al. (2010). Collection, storage and use of blood samples for future research: Views of Egyptian patients expressed in a cross-sectional survey. *J Med Ethics, 36*, 539-547. doi:10.1136/jme.2009.033100

Ahram, M., Othman, A., & Shahrouri, M. (2012). Public perception towards biobanking in Jordan. *Biopreservation and Biobanking, 10*(4), 361-365. doi:10.1089/bio.2012.0010

Ahram, M., Othman, A., & Shahrouri, M. (2012). Public support and consent preference for biomedical research and biobanking in Jordan. *European Journal of Human Genetics*, *21*(5), 567–570. doi:10.1038/ejhg.2012.213

Ahram, M., Othman, A., Shahrouri, M., & Mustafa, E. (2013). Factors influencing public participation in biobanking. *European Journal of Human Genetics*, *22*(4), 445–451. doi:10.1038/ejhg.2013.174

Ahram, M., Zaza, R., Ibayyan, L., Dahbour, S., Bahou, Y., El-Omar, A., et al. (2014). Towards establishing a multiple sclerosis biobank in Jordan. *The International Journal of Neuroscience, 124*(11), 812-817. doi:10.3109/00207454.2014.886204

Al Kuwari, H., Al Thani, A., Al Marri, A., Al Kaabi, A., Abderrahim, H., Afifi, N., et al. (2015). The Qatar biobank: Background and methods. *BMC Public Health, 15*, 1208-015-2522-7. doi:10.1186/s12889-015-2522-7

Alahmad, G., Al-Jumah, M., & Dierickx, K. (2012). Review of national research ethics regulations and guidelines in middle eastern Arab countries. *BMC Medical Ethics, 13*, 34-6939-13-34. doi:10.1186/1472-6939-13-34

Alahmad, G., & Dierickx, K. (2014). Confidentiality, informed consent and children's participation in the Saudi biobank governance: A comparative study. *Eastern Mediterranean Health Journal, 20*(11), 682-689.

Alahmad, G., Hifnawy, T., Abbasi, B., & Dierickx, K. (2016). Attitudes toward medical and genetic confidentiality in the Saudi research biobank: An exploratory survey. *International Journal of Medical Informatics*, *87*, 84–90. doi:10.1016/j.ijmedinf.2015.12.015

Alahmad, G., Hifnawy, T., & Dierickx, K. (2015). Ethics of children's participation in a Saudi biobank: An exploratory survey. *Genetics in Medicine*, *18*(8), 806–813. doi:10.1038/gim.2015.164

Al-Hussaini, M., & Abu-Hmaidan, A. (2014). Use of human surplus biospecimens in research: A survey from a cancer centre. *Eastern Mediterranean Health Journal, 20*(6), 378-384.

Al-Jumah, M., Abolfotouh, M. A., Alabdulkareem, I. B., Balkhy, H. H., Al-Jeraisy, M. I., Al-Swaid, A. F., et al. (2011). Public attitude towards biomedical research at outpatient clinics of king abdulaziz medical city, Riyadh, Saudi Arabia. *Eastern Mediterranean Health Journal, 17*(6), 536-545.

Allen, J., & McNamara, B. (2011). Reconsidering the value of consent in biobank research. *Bioethics, 25*(3), 155-166. doi:10.1111/j.1467-8519.2009.01749.x

Allen, N. L., Karlson, E. W., Malspeis, S., Lu, B., Seidman, C. E., & Lehmann, L. S. (2014). Biobank participants' preferences for disclosure of genetic research results: Perspectives from the OurGenes, OurHealth, OurCommunity project. *Mayo Clinic Proceedings*, *89*(6), 738–746. doi:10.1016/j.mayocp.2014.03.015

Appelbaum, P. S., Parens, E., Waldman, C. R., Klitzman, R., Fyer, A., Martinez, J., et al. (2014). Models of consent to return of incidental findings in genomic research. *The Hastings Center Report, 44*(4), 22-32. doi:10.1002/hast.328

Artene, S. A., Ciurea, M. E., Purcaru, S. O., Tache, D. E., Tataranu, L. G., Lupu, M., et al. (2013). Biobanking in a constantly developing medical world. *The Scientific World Journal, 2013*, 1-5, 343275. doi:10.1155/2013/343275

Banks, E., Herbert, N., Mather, T., Rogers, K., & Jorm, L. (2012). Characteristics of Australian cohort study participants who do and do not take up an additional invitation to join a long-term biobank: The 45 and up study. *BMC Research Notes*, *5*(1), 655. doi:10.1186/1756-0500-5-655

Barr, M., Souan, L., MacGabhann, P., Muller, J., Al Ashhab, M., Jasser, M., et al. (2014). The establishment of an ISO compliant cancer Biobank for Jordan and its neighboring countries through knowledge transfer and training. *Biopreservation and Biobanking*, *12*(1), 3–12. doi:10.1089/bio.2013.0072

BBMRI Stakeholder's Forum. (2010). *BBMRI: A step closer. stakeholder's forum report*. Brussels: BBMRI.

Beauchamp, T. L. (2011). Informed consent: Its history, meaning, and present challenges. *Cambridge Quarterly of Healthcare Ethics*, *20*(04), 515–523. doi:10.1017/s0963180111000259

Beier, K., & Lenk, C. (2015). Biobanking strategies and regulative approaches in the EU: Recent perspectives. *Journal of Biorepository Science for Applied Medicine, 3*, 69-81. doi:10.2147/bsam.s64578

Berkman, N. D., Sheridan, S. L., Donahue, K. E., Halpern, D. J., & Crotty, K. (2011). Low health literacy and health outcomes: An updated systematic review. *Annals of Internal Medicine*, *155*(2), 97-107. doi:10.7326/0003-4819-155-2-201107190-00005

Beskow, L. M., Burke, W., Fullerton, S. M., & Sharp, R. R. (2012). Offering aggregate results to participants in genomic research: Opportunities and challenges. *Genetics in*

Medicine : Official Journal of the American College of Medical Genetics, 14(4), 490-496. doi:10.1038/gim.2011.62

Beskow, L. M., Dombeck, C. B., Thompson, C. P., Watson-Ormond, J. K., & Weinfurt, K. P. (2015). Informed consent for biobanking: Consensus-based guidelines for adequate comprehension. *Genetics in Medicine : Official Journal of the American College of Medical Genetics, 17*(3), 226-233. doi:10.1038/gim.2014.102

Beskow, L. M., Friedman, J. Y., Hardy, N. C., Lin, L., & Weinfurt, K. P. (2010). Developing a simplified consent form for biobanking. *PloS One, 5*(10), e13302. doi:10.1371/journal.pone.0013302.

Birch, K. (2012). Knowledge, place, and power: Geographies of value in the bioeconomy. *New Genetics and Society, 31*(2), 183-201. doi:10.1080/14636778.2012.662051

Black, L., Avard, D., Zawati, M. H., Knoppers, B. M., Hebert, J., Sauvageau, G., et al. (2013). Funding considerations for the disclosure of genetic incidental findings in biobank research. *Clinical Genetics, 84*(5), 397-406. doi:10.1111/cge.12190

Bledsoe, M. J., Clayton, E. W., McGuire, A. L., Grizzle, W. E., O'Rourke, P. P., & Zeps, N. (2013). Return of research results from genomic biobanks: Cost matters. *Genetics in Medicine : Official Journal of the American College of Medical Genetics, 15*(2), 103-105. doi:10.1038/gim.2012.105

Bledsoe, M. J., Grizzle, W. E., Clark, B. J., & Zeps, N. (2012). Practical implementation issues and challenges for biobanks in the return of individual research results. *Genetics in Medicine : Official Journal of the American College of Medical Genetics, 14*(4), 478-483. doi:10.1038/gim.2011.67

Bloom , D.E., Cafiero, E.T., Jané-Llopis, E., Abrahams-Gessel, S., Bloom, L.R., Fathima, S., Feigl, A.B., Gaziano, T., Mowafi, M., Pandya, A., Prettner, K., Rosenberg, L.,

Seligman, B., Stein, A.Z., & Weinstein, C. (2011). The Global Economic Burden of No communicable Diseases. Geneva: World Economic Forum

Bollinger, J. M., Scott, J., Dvoskin, R., & Kaufman, D. (2012). Public preferences regarding the return of individual genetic research results: Findings from a qualitative focus group study. *Genetics in Medicine : Official Journal of the American College of Medical Genetics, 14*(4), 451-457. doi:10.1038/gim.2011.66

Boyer, G. J., Whipple, W., Cadigan, R. J., & Henderson, G. E. (2012). Biobanks in the united states: How to identify an undefined and rapidly evolving population. *Biopreservation and Biobanking, 10*(6), 511-517. doi:10.1089/bio.2012.0034

Brand, A., Schulte, T., & Probst-Hensch, N. M. (2012). Biobanking for public health. In P. . Dabrock, J. Taupitz & J. Ried (Eds.), *Trust in biobanking* (pp. 3-20) Springer Berlin Heidelberg.

Brand, A. M., & Probst-Hensch, N. M. (2007). Biobanking for epidemiological research and public health. *Pathobiology : Journal of Immunopathology, Molecular and Cellular Biology, 74*(4), 227-238. doi:10.1159/000104450

Branković, I., Malogajski, J., & Morré, S. A. (2014). Biobanking and translation of human genetics and genomics for infectious diseases. *Applied & Translational Genomics*, *3*(2), 30–35. doi:10.1016/j.atg.2014.04.001

Bravo, E., Napolitano, M., Santoro, F., Belardelli, F., & Federic, A. (2013). The Italian hub of population biobanks as a potential tool for improving public health stewardship. *Biopreservation and Biobanking, 11*(3), 173-175. doi:10.1089/bio.2012.0064

Bredenoord, A. L., Kroes, H. Y., Cuppen, E., Parker, M., & van Delden, J. J. (2011). Disclosure of individual genetic data to research participants: The debate reconsidered. *Trends in Genetics : TIG, 27*(2), 41-47. doi:10.1016/j.tig.2010.11.004

Budimir, D., Polasek, O., Marusic, A., Kolcic, I., Zemunik, T., Boraska, V., et al. (2011). Ethical aspects of human biobanks: A systematic review. *Croatian Medical Journal, 52*(3), 262-279. doi:10.3325/cmj.2011.52.262

Budin-Ljøsne, I., Harris, J. R., Kaye, J., Coppers, B. M., Tassé, M., Bravo, E., et al. (2012). ELSI challenges and strategies of national biobank infrastructures. *Norsk Epidemiologi, 21*(2), 155-160. doi:10.5324/nje.v21i2.1487

Caulfield, T., Burningham, S., Joly, Y., Master, Z., Shabani, M., Borry, P., et al. (2014). A review of the key issues associated with the commercialization of biobanks. *Journal of Law and the Biosciences,* , 94-110. doi:10.1093/jlb/lst004

Caulfield, T., Rachul, C., & Nelson, E. (2012). Biobanking, consent, and control: A survey of Albertans on key research ethics issues. *Biopreservation and Biobanking, 10*(5), 433-438.doi:10.1089/bio.2012.0029

Central Intelligence Agency. (2016). *The world fact book- United Arab Emirates.* Retrieved January 3, 2016, from https://www.cia.gov/library/publications/the-world-factbook/geos/ae.html

Chen, H., & Pang, T. (2015). A call for global governance of biobanks. *Bull World Health Organ, 93*, 113-117. doi:10.2471/blt.14.138420

Chen, I. (2014). Challenges in regulating biomedical research; the human subjects research act and the human biobank management act in Taiwan. *Clinical Evaluation, 42*(2), 459-466.

Christenhusz, G. M., Devriendt, K., & Dierickx, K. (2013). To tell or not to tell? A systematic review of ethical reflections on incidental findings arising in genetics contexts. *European Journal of Human Genetics : EJHG, 21*(3), 248-255. doi: 10.1038/ejhg.2012.130

Council for International Organizations of Medical Sciences. (2008). *International ethical guidelines for epidemiological studies* . Geneva: CIOMS.doi:10.1093/aje/kwp334

Clayton, E. W. (2005). Informed consent and biobanks. *The Journal of Law, Medicine & Ethics : A Journal of the American Society of Law, Medicine & Ethics, 33*(1), 15-21.doi:10.1111/j.1748-720x.2005.tb00206.x

Council of Europe. (2006). *Recommendation rec(2006)4 of the committee of ministers to member states on research on biological materials of human origin.* Retrieved December 17, 2015, from https://wcd.coe.int/ViewDoc.jsp?id=977859 doi:10.1515/9783110186406.387

Council of Europe. (1997). *Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine: Convention on human rights and biomedicine.* Retrieved December 30, 2015, from http://www.coe.int/en/web/conventions/full-list/-/conventions/rms/090000168007cf98

Critchley, C. R., Nicol, D., Otlowski, M. F., & Stranger, M. J. (2012). Predicting intention to biobank: A national survey. *European Journal of Public Health, 22*(1), 139-144. doi: 10.1093/eurpub/ckq136

D'Abramo, F., Schildmann, J., & Vollmann, J. (2015). Research participants' perceptions and views on consent for biobank research: A review of empirical data and ethical analysis. *BMC Medical Ethics, 16*, 60-015-0053-5. doi: 10.1186/s12910-015-0053-5

Daily Sabah. (2015, November/23). Turkish university set to launch country's first biobank. *Daily Sabah,*

De Souza, Y. G., & Greenspan, J. S. (2013). Biobanking past, present and future: Responsibilities and benefits. *AIDS (London, England), 27*(3), 303-312. doi: 10.1097/qad.0b013e32835c1244

De Vries, R. G., Tomlinson, T., Kim, H. M., Krenz, C. D., Ryan, K. A., Lehpamer, N., et al. (2016). The moral concerns of biobank donors: The effect of non-welfare interests on willingness to donate. *Life Sciences, Society and Policy, 12*, 3-016-0036-4. Epub 2016 Mar 11. doi:10.1186/s40504-016-0036-4

Department of Health Western Austerlia. (2010). *Guidelines for human biobanks, genetic research databases and associated data.*Department of Health Western Australia.

Diaferia, G. R., Biunno, I., & DeBlasio, P. (2011). Comprehensive outsourcing biobanking facility to serve the international research community. *Biopreservation and Biobanking, 9*(2), 191-194. doi:10.1089/bio.2011.0002

Dove, E. S., Joly, Y., & Knoppers, M. B. (2012). Power to the people: A wiki-governance model for biobanks. *Genome Biology, 13*(158), 1-8. doi:10.1186/gb-2012-13-5-158

Eder, J., Gottweis, H., & Zatloukal, K. (2012). IT solutions for privacy protection in biobanking. *Public Health Genomics, 15*(5), 254-262. doi:10.1159/000336663

Edwards, T., Cadigan, R. J., Evans, J. P., & Henderson, G. E. (2014). Biobanks containing clinical specimens: Defining characteristics, policies, and practices. *Clinical Biochemistry, 47*(4-5), 245-251. doi:10.1016/j.clinbiochem.2013.11.023

El Obaid, Y., Al Hamiz, A., Abdulle, A., Hayes, R. B., Sherman, S., & Ali, R. (2016). Perceptions and attitudes towards medical research in the United Arab Emirates: Results from the abu dhabi cohort study (ADCS) focus group discussions. *PloS One, 11*(3), e0149609. doi:10.1371/journal.pone.0149609

European Commission. (2012). *Biobanks for europe. A challenge for governance* No. EUR 25302 EN). Luxembourg: European Union.

Evers, K., Forsberg, J., & Hansson, M. (2012). Commercialization of biobanks. *Biopreservation and Biobanking, 10*(1), 45-47. doi:10.1089/bio.2011.0041

Ewing, A. T., Erby, L. A., Bollinger, J., Tetteyfio, E., Ricks-Santi, L. J., & Kaufman, D. (2015). Demographic differences in willingness to provide broad and narrow consent for biobank research. *Biopreservation and Biobanking, 13*(2), 98-106. doi:10.1089/bio.2014.0032

Fadel, H. E. (2010). Ethics of clinical research: An islamic perspective. *Journal of the Islamic Medical Association of North America, 42*(2), 59-69. doi:10.5915/42-2-5512

Fan, C., Hung, T., & Yeh, C. (2015). Taiwan Regulation of Biobanks. *J Law Med Ethics*, *43*(4), 816–26. doi:doi: 10.1111/jlme.12322.

Fisher, C. B., & Harrington McCarthy, E. L. (2013). Ethics in prevention science involving genetic testing. *Prevention Science : The Official Journal of the Society for Prevention Research, 14*(3), 310-318. doi:10.1007/s11121-012-0318-x

Forsberg, J. S., Hansson, M. G., & Evers, K. (2013). International guidelines on biobank research leave researchers in ambiguity: Why is this so? *European Journal of Epidemiology, 28*(6), 449-451. doi:10.1007/s10654-013-9815-x

Fortin, S., Pathmasiri, S., Grintuch, R., & Deschênes, M. (2011). 'Access arrangements' for Biobanks: A fine line between facilitating and hindering collaboration. *Public Health Genomics*, *14*(2), 104–114. doi:10.1159/000309852

Fransson, M. N., Rial-Sebbag, E., Brochhausen, M., & Litton, J. E. (2015). Toward a common language for biobanking. *European Journal of Human Genetics, 23*(1), 22-28.doi: 10.1038/ejhg.2014.45

Fullerton, S. M., & Lee, S. S. (2011). Secondary uses and the governance of de-identified data: Lessons from the human genome diversity panel. *BMC Medical Ethics, 12*, 16-6939-12-16. doi:10.1186/1472-6939-12-16

Garrison, N. A., Sathe, N. A., Antommaria, A. H., Holm, I. A., Sanderson, S. C., Smith, M. E., et al. (2015). A systematic literature review of individuals' perspectives on broad

consent and data sharing in the united states. *American College of Medical Genetics,* , 1-9. doi:10.1038/gim.2015.138

Gaskell, G., & Gottweis, H. (2011). Biobanks need publicity. *Nature, 471*(7337), 159-160.

Gaskell, G., Gottweis, H., Starkbaum, J., Gerber, M. M., Broerse, J., Gottweis, U., et al. (2013). Publics and biobanks: Pan-European diversity and the challenge of responsible innovation. *European Journal of Human Genetics : EJHG, 21*(1), 14-20. doi:10.1038/471159a

Gaye, A., Marcon, Y., Isaeva, J., Laflamme, P., Turner, A., Jones, E. M., et al. (2014). DataSHIELD: Taking the analysis to the data, not the data to the analysis. *International Journal of Epidemiology, 43*(6), 1929-1944. doi:10.1093/ije/dyu188

Gaziano, J. M., Concato, J., Brophy, M., Fiore, L., Pyarajan, S., Breeling, J., et al. (2016). Million veteran program: A mega-biobank to study genetic influences on health and disease. *Journal of Clinical Epidemiology, 70*, 214-223. doi:10.1016/j.jclinepi.2015.09.016

GBI Research. (2011). *Biobanks: 2011 yearbook. survey report.* No. GBIHC083MR)GBI Research.

Genetic Home Reference. (2016). Retrieved January 10, 2016, from https://ghr.nlm.nih.gov/glossary=personalizedmedicine

Gitter, D. M. (2013). The challenges of achieving open source sharing of biobank data. In Pascuzzi, G., Izzo, U. & Macilotti, M. (Eds.), *Comparative issues in the governance of research biobank* (1st ed., pp. 165-189) Springer-Verlag Berlin Heidelberg. doi:10.2139/ssrn.1598400

Godard, B., Ozdemir, V., Fortin, M., & Egalite, N. (2010). Ethnocultural community leaders' views and perceptions on biobanks and population specific genomic research: A

qualitative research study. *Public Understanding of Science (Bristol, England), 19*(4), 469-485. doi:10.1177/0963662509104721

Gottweis, H., Gaskell, G., & Starkbaum, J. (2011). Connecting the public with biobank research: Reciprocity matters. *Nature Reviews.Genetics, 12*(11), 738-739. doi:10.1038/nrg3083

Gottweis, H., & Lauss, G. (2010). Biobank governance in the post-genomic age. *Personalized Medicine, 7*(2), 187-195.

Gottweis, H., & Lauss, G. (2012). Biobank governance: Heterogeneous modes of ordering and democratization. *Journal of Community Genetics, 3*(2), 61-72. doi: 10.2217/pme.10.4

Greenbaum, D., Sboner, A., Mu, X. J., & Gerstein, M. (2011). Genomics and privacy: Implications of the new reality of closed data for the field. *PLoS Computational Biology, 7*(12), e1002278. doi: 10.1371/journal.pcbi.1002278

Haga, S. B., Rosanbalm, K. D., Boles, L., Tindall, G. M., Livingston, T. M., & O'Daniel, J. M. (2013). Promoting public awareness and engagement in genome sciences. *Journal of Genetic Counseling, 22*(4), 508-516. doi: 10.1007/s10897-013-9577-3

Hajat, C., Harrison, O., & Shather, Z. (2012). A profile and approach to chronic disease in Abu Dhabi. *Globalization and Health, 8*, 18-8603-8-18. doi:10.1186/1744-8603-8-18 doi:10.1186/1744-8603-8-18

Halverson, C. M., & Ross, L. F. (2012a). Attitudes of African-American parents about biobank participation and return of results for themselves and their children. *Journal of Medical Ethics, 38*(9), 561-566. doi:10.1136/medethics-2012-100600

Halverson, C. M., & Ross, L. F. (2012b). Engaging african-americans about biobanks and the return of research results. *Journal of Community Genetics, 3*(4), 275-283. doi:10.1007/s12687-012-0091-3

Halverson, C. M., & Ross, L. F. (2012c). Incidental findings of therapeutic misconception in biobank-based research. *Genetics in Medicine : Official Journal of the American College of Medical Genetics, 14*(6), 611-615. doi:10.1038/gim.2011.50

Hansson, M. G. (2011). The need to downregulate: A minimal ethical framework for biobank research. In J. Dillner (Ed.), *Methods in biobanking* (pp. 39-57) Humana Press.

Harris, J. R., Burton, P., Knoppers, B. M., Lindpaintner, K., Bledsoe, M., Brookes, A. J., et al. (2012). Toward a roadmap in global biobanking for health. *European Journal of Human Genetics : EJHG, 20*(11), 1105-1111. doi:10.1038/ejhg.2012.96

Hassona, Y., Ahram, M., Odeh, N., Abu Gosh, M., & Scully, C. (2016). Factors influencing dental patient participation in biobanking and biomedical research. *Medical Principles and Practice : International Journal of the Kuwait University, Health Science Centre, 25*(4), 323-328.

Hawkins, A. K., & O'Doherty, K. C. (2011). 'Who owns your poop?': Insights regarding the intersection of human microbiome research and the ELSI aspects of biobanking and related studies. *BMC Medical Genomics, 4*, 72-8794-4-72. doi:10.1186/1755-8794-4-72

Hawkins, N., Kanellopoulou, N., Kaye, J., Melham, K., Boddington, P., Curren, L., et al. (2013). Ownership of biomedical information in biobanks. In G. Pascuzzi, U. Izzo & M. Macilotti (Eds.), *Comparative issues in the governance of research biobank* (1st ed., pp. 77-86) Springer-Verlag Berlin Heidelberg.

Health and Human Services. (1979). *The Belmont report.* Retrieved January 20, 2016, from http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

Health and Human Services. (2005). *The Nuremberg code.* Retrieved January 20, 2016, from http://www.hhs.gov/ohrp/archive/nurcode.html

Health Authority-Abu Dhabi. (2012). *Healthcare Regulator Policy Manua*l. Retrieved January 15, 2016, from https://www.haad.ae/HAAD/LinkClick.aspx?fileticket=VyAME-Ojlm8%3d&tabid=1276

Health Authority- Abu Dhabi. (2016a). *Health Statistics 2015*. Retrieved December 18, 2015 from http://www.haad.ae/HAAD/LinkClick.aspx?fileticket=KeJK5ZsIuns%3d&tabid=1516

Health Authority- Abu Dhabi. (2016b). *About HAAD.* Retrieved January 4, 2016, from http://www.haad.ae/haad/tabid/59/Default.aspx

Health Authority- Abu Dhabi. (2016c). *HAAD Policies.* Retrieved January 18, 2016, from https://www.haad.ae/haad/tabid/1487/Default.aspx

Health Authority- Abu Dhabi. (2016d). *Healthcare (Facilities & Professionals) Standards*. Retrieved January 18, 2016, from http://www.haad.ae/haad/tabid/820/Default.aspx

Heeney, C., Hawkins, N., de Vries, J., Boddington, P., & Kaye, J. (2011). Assessing the privacy risks of data sharing in genomics. *Public Health Genomics, 14*(1), 17-25. doi:10.1159/000294150

Henderson, G. E., Cadigan, R. J., Edwards, T. P., Conlon, I., Nelson, A. G., Evans, J. P., et al. (2013). Characterizing biobank organizations in the U.S.: Results from a national survey. *Genome Medicine, 5*(1), 3. doi:10.1186/gm407

Hens, K., Nys, H., Cassiman, J. J., & Dierickx, K. (2011). Risks, benefits, solidarity: A framework for the participation of children in genetic biobank research. *The Journal of Pediatrics, 158*(5), 842-848.doi:10.1016/j.jpeds.2010.12.036

Hewitt, R. E. (2011). Biobanking: The foundation of personalized medicine. *Current Opinion in Oncology, 23*(1), 112-119. doi:10.1097/cco.0b013e32834161b8

Hewitt, R. E., & Watson, P. (2013). Defining biobank. *Biopreservation and Biobanking, 11*(5), 309-315. doi:10.1089/bio.2013.0042

Hobbs, A., Starkbaum, J., Gottweis, U., Wichmann, H. E., & Gottweis, H. (2012). The privacy-reciprocity connection in biobanking: Comparing German with UK strategies. *Public Health Genomics, 15*(5), 272-284. doi:10.1159/000336671

Holm, S. (2011). Withdrawing from research: A rethink in the context of research biobanks. *Health Care Analysis : HCA : Journal of Health Philosophy and Policy, 19*(3), 269-281.doi: 10.1007/s10728-011-0194-8

Holzinger, A., & Jurisica, I. (2014). Knowledge discovery and data mining in biomedical informatics: The future is in integrative, interactive machine learning solutions. In A. Holzinger, & I. Jurisica (Eds.), *Interactive knowledge discovery and data mining in biomedical informatics. state-of-the-art and future challenges* (pp. 1-18) Springer Berlin Heidelberg. doi:10.1186/1471-2105-15-s6-i1

Human Genome Organization. (1996). *HUGO ethics committee: Statement on the principled conduct of genetics research.* Retrieved December 30, 2015, from http://www.eubios.info/HUGO.htm

Human Genome Organization. (2000). *HUGO ethics committee: Statement on benefit-sharing.* Retrieved December 30, 2015, from http://www.eubios.info/BENSHARE.htm

Human Genome Organization. (2002). *HUGO ethics committee - statement on human genomic databases.* Retrieved December 30, 2015, from http://www.eubios.info/HUGOHGD.htm

Husedzinovic, A., Ose, D., Schickhardt, C., Frohling, S., & Winkler, E. C. (2015). Stakeholders' perspectives on biobank-based genomic research: Systematic review of

the literature. *European Journal of Human Genetics : EJHG, 23*(12), 1607-1614. doi:10.1038/ejhg.2015.27

International Council for Harmonisation. (1996). *Guidance for industry E6 good clinical practice: Consolidated guidance* ICH.

Igbe, M. A., & Adebamowo, C. A. (2012). Qualitative study of knowledge and attitudes to biobanking among lay persons in Nigeria. *BMC Medical Ethics, 13*, 27-6939-13-27. doi:10.1186/1472-6939-13-27

Imboden, M., & Probst-Hensch, N. M. (2013). Biobanking across the phenome - at the center of chronic disease research. *BMC Public Health, 13*, 1094-2458-13-1094. doi:10.1186/1471-2458-13-1094

International Agency for Research on Cancer. (2016). *IARC Biobank*. Retrieved January 16, 2016, from http://ibb.iarc.fr/

International Society for Biological and Environmental Repositories. (2001, *Newsletter, 1 (1)*

Ioannis, K., Fotis, D., Evangelos, B., & Christos, N. (2015). Fundamental principles of human biobank development. *Quality in Primary Care, 23*(2), 97-102.

Jarvik, G. P., Amendola, L. M., Berg, J. S., Brothers, K., Clayton, E. W., Chung, W., et al. (2014). Return of genomic results to research participants: The floor, the ceiling, and the choices in between. *American Journal of Human Genetics, 94*(6), 818-826. doi: 10.1016/j.ajhg.2014.04.009

Johnsson, L., Helgesson, G., Rafnar, T., Halldorsdottir, I., Chia, K. S., Eriksson, S., et al. (2010). Hypothetical and factual willingness to participate in biobank research. *European Journal of Human Genetics : EJHG, 18*(11), 1261-1264. doi:10.1038/ejhg.2010.106

Joly, Y., Dalpe, G., So, D., & Birko, S. (2015). Fair shares and sharing fairly: A survey of public views on open science, informed consent and participatory research in biobanking. *PloS One, 10*(7), e0129893. doi:10.1371/journal.pone.0129893

Kang, B., Park, J., Cho, S., Lee, M., Kim, N., Min, H., et al. (2013). Current status, challenges, policies, and bioethics of biobanks. *Genomics & Informatics, 11*(4), 211-217.doi:10.5808/gi.2013.11.4.211

Karlson, E. W., Boutin, N. T., Hoffnagle, A. G., & Allen, N. L. (2016). Building the partners HealthCare biobank at partners personalized medicine: Informed consent, return of research results, recruitment lessons and operational considerations. *Journal of Personalized Medicine, 6*(1), 10.3390/jpm6010002. doi:10.3390/jpm6010002

Kaufman, D., Bollinger, J., Dvoskin, R., & Scott, J. (2012). Preferences for opt-in and opt-out enrollment and consent models in biobank research: A national survey of veterans administration patients. *Genetics in Medicine : Official Journal of the American College of Medical Genetics, 14*(9), 787-794. doi:10.1038/gim.2012.45

Kaye, J. (2012a). Embedding biobanks as tools for personalised medicine. *Norsk Epidemiologi, 21*(2), 169-175. doi:10.5324/nje.v21i2.1490

Kaye, J. (2012b). The tension between data sharing and the protection of privacy in genomics research. *Annual Review of Genomics and Human Genetics, 13*, 415-431. doi:10.1146/annurev-genom-082410-101454

Kaye, J., Whitley, E. A., Lund, D., Morrison, M., Teare, H., & Melham, K. (2015). Dynamic consent: A patient interface for twenty-first century research networks. *European Journal of Human Genetics, 23*(2), 141-146. doi:10.1038/ejhg.2014.71

Kelly, S. E., Spector, T. D., Cherkas, L. F., Prainsack, B., & Harris, J. M. (2015). Evaluating the consent preferences of UK research volunteers for genetic and clinical studies. *PloS One, 10*(3), e0118027. doi:10.1371/journal.pone.0118027

Kerath, S. M., Klein, G., Kern, M., Shapira, I., Witthuhn, J., Norohna, N., et al. (2013). Beliefs and attitudes towards participating in genetic research - a population based cross-sectional study. *BMC Public Health, 13*, 114-2458-13-114.doi:10.1186/1471-2458-13-114

Kettis-Lindblad, A., Ring, L., Viberth, E., & Hansson, M. G. (2006). Genetic research and donation of tissue samples to biobanks. what do potential sample donors in the Swedish general public think? *European Journal of Public Health, 16*(4), 433-440. doi:10.1093/eurpub/cki198

King, C. R., & Nicolae, D. L. (2014). GWAS to sequencing: Divergence in study design and analysis. *Genes, 5*(2), 460-476. doi:10.3390/genes5020460

Knoppers, B. M., Abdul-Rahman, M. (2016). Biobanks in the literature. In Elger, B., Biller-Andorno, M., Mauron, A., & Capron, A.M. (Eds.), *Ethical Issues in Governing biobanks: Global Prospective* (2nd ed., pp. 13-23) Routledge , New York, USA. ISBN: 978-1-315-58028-9.

Knoppers, B. M., Deschenes, M., Zawati, M. H., & Tasse, A. M. (2013). Population studies: Return of research results and incidental findings policy statement. *European Journal of Human Genetics : EJHG, 21*(3), 245-247. doi:10.1038/ejhg.2012.152

Knoppers, B. M., Zawati, M. H., & Kirby, E. S. (2012). Sampling populations of humans across the world: ELSI issues. *Annual Review of Genomics and Human Genetics, 13*, 395-413.doi:10.1146/annurev-genom-090711-163834

Knoppers, B. M., Zawati, M. H., & Senecal, K. (2015). Return of genetic testing results in the era of whole-genome sequencing. *Nature Reviews.Genetics, 16*(9), 553-559. doi:10.1038/nrg3960

Kohane, I. S. (2011). Using electronic health records to drive discovery in disease genomics. *Nature Reviews.Genetics, 12*(6), 417-428. doi:10.1038/nrg2999

Kozlakidis, Z., Mant, C., & Cason, J. (2012). Bridging the financial gap through providing contract services: A model for publicly funded clinical biobanks. *Biopreservation and Biobanking, 10*(4), 357-360. doi:10.1089/bio.2012.0009

Lahey, T. (2013). The ethics of clinical research in low- and middle-income countries. In J. L. Bernat, & H. R. Beresford (Eds.), *Handbook of clinical neurology* (pp. 301-313)

Laurie, G., Mallia, P., Frenkel, D. A., Krajewska, A., Moniz, H., Nordal, S., et al. (2010). Managing access to biobanks: How can we reconcile individual privacy and public interests in genetic research? *Medical Law International, 10*, 315-337. doi:10.1177/096853321001000404

Lee, C. I., Bassett, L. W., Leng, M., Maliski, S. L., Pezeshki, B. B., Wells, C. J., et al. (2012). Patients' willingness to participate in a breast cancer biobank at screening mammogram. *Breast Cancer Research and Treatment, 136*(3), 899-906. doi:10.1007/s10549-012-2324-x

Leitsalu, L., Alavere, H., Tammesoo, M. L., Leego, E., & Metspalu, A. (2015). Linking a population biobank with national health registries-the Estonian experience. *Journal of Personalized Medicine, 5*(2), 96-106. doi:10.3390/jpm5020096

Leitsalu, L., Haller, T., Esko, T., Tammesoo, M. L., Alavere, H., Snieder, H., et al. (2015). Cohort profile: Estonian biobank of the Estonian genome center, university of Tartu. *International Journal of Epidemiology, 44*(4), 1137-1147. doi:10.1093/ije/dyt268

Lemke, A. A., Halverson, C., & Ross, L. F. (2012). Biobank participation and returning research results: Perspectives from a deliberative engagement in south side Chicago. *American Journal of Medical Genetics.Part A, 158A*(5), 1029-1037. doi:10.1002/ajmg.a.34414

Lemke, A. A., Wu, J. T., Waudby, C., Pulley, J., Somkin, C. P., & Trinidad, S. B. (2010). Community engagement in biobanking: Experiences from the eMERGE network. *Genomics, Society, and Policy / ESRC Genomics Network, 6*(3), 35-52.

Lewis, C., Clotworthy, M., Hilton, S., Magee, C., Robertson, M. J., Stubbins, L. J., et al. (2013a). Consent for the use of human biological samples for biomedical research: A mixed methods study exploring the UK public's preferences. *BMJ Open, 3*(8), 10.1136/bmjopen-2013-003022. doi:10.1136/bmjopen-2013-003022

Lewis, C., Clotworthy, M., Hilton, S., Magee, C., Robertson, M. J., Stubbins, L. J., et al. (2013b). Public views on the donation and use of human biological samples in biomedical research: A mixed methods study. *BMJ Open, 3*(8), 10.1136/bmjopen-2013-003056. doi:10.1136/bmjopen-2013-003056

Li, L., Guo, Y., Chen, Z., Chen, J., & Peto, R. (2012). Epidemiology and the control of disease in china, with emphasis on the Chinese biobank study. *Public Health, 126*(3), 210-213.doi:10.1016/j.puhe.2011.11.012

Lipworth, W., Forsyth, R., & Kerridge, I. (2011). Tissue donation to biobanks: A review of sociological studies. *Sociology of Health & Illness, 33*(5), 792-811. doi:10.1111/j.1467-9566.2011.01342.x

Lockhart, N. C., Yassin, R., Weil, C. J., & Compton, C. C. (2012). Intersection of biobanking and clinical care: Should discrepant diagnoses and pathological findings be returned to research participants? *Genetics in Medicine : Official Journal of the American College of Medical Genetics, 14*(4), 417-423. doi:10.1038/gim.2012.11

Longstaff, H., & Burgess, M. M. (2010). Recruiting for representation in public deliberation on the ethics of biobanks. *Public Understanding of Science (Bristol, England), 19*(2), 212-224. doi:10.1177/0963662508097626

Lumley, T., & Rice, K. (2010). Potential for revealing individual-level information in genome-wide association studies. *Jama, 303*(7), 659-660. doi:10.1001/jama.2010.120

Luque, J. S., Quinn, G. P., Montel-Ishino, F. A., Arevalo, M., Bynum, S. A., Noel-Thomas, S., et al. (2012). Formative research on perceptions of biobanking: What community members think. *Journal of Cancer Education : The Official Journal of the American Association for Cancer Education, 27*(1), 91-99.doi:10.1007/s13187-011-0275-2

Ma, J. X., Seals, B. F., Tan, Y., Lee, R., & Toubbeh, J. (2014). Using mixed methods to examine perceptions and willingness to participate in bio-specimen banking in diverse Asian American. *Journal of Community Medicine & Health Education, 4*(3), 1000283. doi:10.4172/2161-0711.1000283

Ma, Y., Dai, H., Wang, L., Zhu, L., Zou, H., & Kong, X. (2012). Consent for use of clinical leftover biosample: A survey among chinese patients and the general public. *PloS One, 7*(4), e36050. doi:10.1371/journal.pone.0036050

Marko-Varga, G., Baker, M. S., Boja, E. S., Rodriguez, H., & Fehniger, T. E. (2014). Biorepository regulatory frameworks: Building parallel resources that both promote scientific investigation and protect human subjects. *Journal of Proteome Research, 13*(12), 5319-5324. doi:10.1021/pr500475q

Marsolo, K., & Spooner, S. A. (2013). Clinical genomics in the world of the electronic health record. *Genetics in Medicine : Official Journal of the American College of Medical Genetics, 15*(10), 786-791.doi:10.1038/gim.2013.88

Master, Z., Campo-Engelstein, L., & Caulfield, T. (2015). Scientists' perspectives on consent in the context of biobanking research. *European Journal of Human Genetics : EJHG, 23*(5), 569-574. doi:10.1038/ejhg.2014.143

Master, Z., & Resnik, D. B. (2013). Incorporating exclusion clauses into informed consent for biobanking. *Cambridge Quarterly of Healthcare Ethics : CQ : The International*

Journal of Healthcare Ethics Committees, 22(2), 203-212. doi:10.1017/s0963180112000576

McCulloch, E. S. (2013). Balancing Privacy and Progress: Biobanks and Genome Sequencing. *BioScience*, *36*(5), 333–334. doi:doi: 10.1525/bio.2013.63.5.6

McDonald, J. A., Vadaparampil, S., Bowen, D., Magwood, G., Obeid, J. S., Jefferson, M., et al. (2014). Intentions to donate to a biobank in a national sample of African Americans. *Public Health Genomics, 17*(3), 173-182. doi:10.1159/000360472

McGraw-Hill Concise Dictionary of Modern Medicine. (2002). The McGraw-Hill Companies, Inc.

McGuire, A. L., Basford, M., Dressler, L. G., Fullerton, S. M., Koenig, B. A., Li, R., et al. (2011). Ethical and practical challenges of sharing data from genome-wide association studies: The eMERGE consortium experience. *Genome Research, 21*(7), 1001-1007. doi:10.1101/gr.120329.111

McHale, J. V. (2011). Accountability, governance and biobanks: The ethics and governance committee as guardian or as toothless tiger? *Health Care Analysis : HCA : Journal of Health Philosophy and Policy, 19*(3), 231-246. doi:10.1007/s10728-011-0195-7

McWhirter, R. E., Critchley, C. R., Nicol, D., Chalmers, D., Whitton, T., Otlowski, M., et al. (2014). Community engagement for big epidemiology: Deliberative democracy as a tool. *Journal of Personalized Medicine, 4*(4), 459-474. doi:10.3390/jpm4040459

Melas, P. A., Sjoholm, L. K., Forsner, T., Edhborg, M., Juth, N., Forsell, Y., et al. (2010). Examining the public refusal to consent to DNA biobanking: Empirical data from a Swedish population-based study. *Journal of Medical Ethics, 36*(2), 93-98. doi:10.1136/jme.2009.032367

Melham, K., Moraia, L. B., Mitchell, C., Morrison, M., Teare, H., & Kaye, J. (2014). The evolution of withdrawal: Negotiating research relationships in biobanking. *Life*

Sciences, Society and Policy, 10, 16-014-0016-5. Epub 2014 Oct 5. doi:10.1186/s40504-014-0016-5

Mester, J. L., Mercer, M., Goldenberg, A., Moore, R. A., Eng, C., & Sharp, R. R. (2015). Communicating with biobank participants: Preferences for receiving and providing updates to researchers. *Cancer Epidemiology, Biomarkers & Prevention : A Publication of the American Association for Cancer Research, Cosponsored by the American Society of Preventive Oncology, 24*(4), 708-712. doi:10.1158/1055-9965.epi-13-1375

Meulenkamp, T. M., Gevers, S. K., Bovenberg, J. A., Koppelman, G. H., van Hylckama Vlieg, A., & Smets, E. M. (2010). Communication of biobanks' research results: What do (potential) participants want? *American Journal of Medical Genetics.Part A, 152A*(10), 2482-2492. doi:10.1002/ajmg.a.33617

Millon Underwood, S., Buseh, A. G., Kelber, S. T., Stevens, P. E., & Townsend, L. (2013). Enhancing the participation of African Americans in health-related genetic research: Findings of a collaborative academic and community-based research study. *Nursing Research and Practice, 2013*, 749563. doi:10.1155/2013/749563

Moodley, K., Sibanda, N., February, K., & Rossouw, T. (2014). 'It's my blood': Ethical complexities in the use, storage and export of biological samples: Perspectives from south African research participants. *BMC Medical Ethics, 15*, 4-6939-15-4. doi:10.1186/1472-6939-15-4

Morente, M. M., Cereceda, L., Luna-Crespo, F., & Artiga, M. J. (2011). Managing a Biobank network. *Biopreservation and Biobanking*, *9*(2), 187–190. doi:10.1089/bio.2011.0005

Moriya, H., Inoue, I., Ikeuchi, M., Ishii, N., & Motojima, M. (2014). Survey of attitudes of Japanese women toward Genetic/Genomic research. *Journal of Empirical Research on Human Research Ethics : JERHRE, 9*(3), 29-38. doi:10.1177/1556264614540597

Mostert, M., Bredenoord, A. L., Biesaart, M. C., & van Delden, J. J. (2015). Big data in medical research and EU data protection law: Challenges to the consent or anonymise approach. *European Journal of Human Genetics,* , 1-5. doi:10.1038/ejhg.2015.239

Murtagh, M. J., Demir, I., Jenkings, K. N., Wallace, S. E., Murtagh, B., Boniol, M., et al. (2012). Securing the data economy: Translating privacy and enacting security in the development of DataSHIELD. *Public Health Genomics, 15*(5), 243-253. doi:10.1159/000336673

Nair, S. C., & Ibrahim, H. (2015a). GCP compliance and readability of informed consent forms from an emerging hub for clinical trials. *Perspectives in Clinical Research, 6*(2), 104-108. doi:10.4103/2229-3485.154012

Nair, S. C., & Ibrahim, H. (2015b). Informed consent form challenges for genetic research in a developing arab country with high risk for genetic disease. *Journal of Genetic Counseling, 24*(2), 294-299.doi:10.1007/s10897-014-9763-y

Nair, S. C., Ibrahim, H., & Celentano, D. D. (2013). Clinical trials in the Middle East and North Africa (MENA) region: Grandstanding or grandeur? *Contemporary Clinical Trials, 36*(2), 704-710. doi:10.1016/j.cct.2013.05.009

Nasrella, E., & Clark, B. (2012). Public attitudes towards participation in biobank Qatar [Abstract]. *Qatar Foundation Annual Research Forum Proceedings, BMP78* doi:*10.5339/qfarf.2012.bmp78*

National Cancer Institute. (2011). *NCI best practices for biospecimen resources.* NCI.

Nicol, D., & Critchley, C. (2012). Benefit sharing and biobanking in Australia. *Public Understanding of Science (Bristol, England), 21*(5), 534-555. doi:10.1177/0963662511402425

Nobile, H., Vermeulen, E., Thys, K., Bergmann, M. M., & Borry, P. (2013). Why do participants enroll in population biobank studies? A systematic literature review. *Expert Review of Molecular Diagnostics, 13*(1), 35-47. doi:10.1586/erm.12.116

Nutbeam, D. (1986). Health promotion glossary. *Health Promotion (Oxford, England), 1*(1), 113-127. doi:10.1093/heapro/1.1.113

Nutbeam, D. (2008). The evolving concept of health literacy. *Social Science & Medicine (1982), 67*(12), 2072-2078. doi:10.1016/j.socscimed.2008.09.050

O'Doherty, K. C., & Burgess, M. M. (2013). Public deliberation to develop ethical norms and inform policy for biobanks: Lessons learnt and challenges remaining. *Research Ethics, 9*(2), 55-77. doi:10.1177/1747016113488858

O'Daniel, J., & Haga, S. B. (2011). Public perspectives on returning genetics and genomics research results. *Public Health Genomics, 14*(6), 346-355. doi:10.1159/000324933

O'Doherty, K. C., Burgess, M. M., Edwards, K., Gallagher, R. P., Hawkins, A. K., Kaye, J., et al. (2011). From consent to institutions: Designing adaptive governance for genomic biobanks. *Social Science & Medicine (1982), 73*(3), 367-374. doi:10.1016/j.socscimed.2011.05.046

O'Doherty, K. C., & Hawkins, A. (2010). Structuring public engagement for effective input in policy development on human tissue biobanking. *Public Health Genomics, 13*(4), 197-206. doi:10.1159/000279621

O'Doherty, K. C., Hawkins, A. K., & Burgess, M. M. (2012). Involving citizens in the ethics of biobank research: Informing institutional policy through structured public deliberation. *Social Science & Medicine (1982), 75*(9), 1604-1611 doi:10.1016/j.socscimed.2012.06.026.

O'Doherty, K. C., Ibrahim, T., Hawkins, A., Burgess, M., & Watson, P. (2012). Managing the introduction of biobanks to potential participants: Lessons from a deliberative public forum. *Biopreservation and Biobanking, 10*(1), 12-21. doi:10.1089/bio.2011.0029

Office for Human Research Protection. (2016a). *International compilation of human research standards.* Retrieved January 17, 2016, from http://www.hhs.gov/ohrp/international/index.html

Office for Human Research Protection. (2016b). *The Belmont Report.* Retrieved January 20, 2016, from https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html

Olson, J. E., Bielinski, S. J., Ryu, E., Winkler, E. M., Takahashi, P. Y., Pathak, J., et al. (2014). Biobanks and personalized medicine. *Clinical Genetics, 86*(1), 50-55 doi:10.1111/cge.12370.

Olson, J. E., Ryu, E., Johnson, K. J., Koenig, B. A., Maschke, K. J., Morrisette, J. A., et al. (2013). The mayo clinic biobank: A building block for individualized medicine. *Mayo Clinic Proceedings, 88*(9), 952-962 doi:10.1016/j.mayocp.2013.06.006.

Organization of Economic Co-operation and Development. (2006). *Creation and governance of human genetic research databases*. Paris: OECD.

Organization of Economic Co-operation and Development. (2007). *Best practice guidelines for biological resource centers*. Paris: OECD.

Organization of Economic Co-operation and Development. (2009). *OECD guidelines on human biobanks and genetic research databases*. Paris: OECD.

Otlowski, M. F. (2012). Tackling legal challenges posed by population biobanks: Reconceptualising consent requirements. *Medical Law Review, 20*(2), 191-226. doi:10.1093/medlaw/fwr035

Overby, C. L., Maloney, K. A., Alestock, T. D., Chavez, J., Berman, D., Sharaf, R. M., et al. (2015). Prioritizing approaches to engage community members and build trust in biobanks: A survey of attitudes and opinions of adults within outpatient practices at the university of maryland. *Journal of Personalized Medicine, 5*(3), 264-279. doi:10.3390/jpm5030264

Pang, T. (2013). Genomics for public health improvement: Relevant international ethical and policy issues around genome-wide association studies and biobanks. *Public Health Genomics, 16*(1-2), 69-72. doi:10.1159/000341500

Parodi, B. (2015). Biobanks: A defintion. In D. Mascalzoni (Ed.), *Ethics, law and governance of biobanking* (pp. 15-19) Springer Netherlands.

Petrini, C. (2012). Ethical and legal considerations regarding the ownership and commercial use of human biological materials and their derivatives. *Journal of Blood Medicine, 3*, 87-96. doi:10.2147/jbm.s36134

Platt, J., Bollinger, J., Dvoskin, R., Kardia, S. L., & Kaufman, D. (2014). Public preferences regarding informed consent models for participation in population-based genomic research. *Genetics in Medicine : Official Journal of the American College of Medical Genetics, 16*(1), 11-18. doi:10.1038/gim.2013.59

Platt, J., & Kardia, S. (2015). Public trust in health information sharing: Implications for biobanking and electronic health record systems. *Journal of Personalized Medicine, 5*(1), 3-21. doi:10.3390/jpm5010003

Porteri, C., Pasqualetti, P., Togni, E., & Parker, M. (2014). Public's attitudes on participation in a biobank for research: An italian survey. *BMC Medical Ethics, 15*, 81-6939-15-81. doi:10.1186/1472-6939-15-81

Prainsack, B., & Buyx, A. (2013). A solidarity-based approach to the governance of research biobanks. *Medical Law Review, 21*(1), 71-91. doi:10.1093/medlaw/fws040

Public Population Project in Genomics and Society. (2012). P^{3}G Member Capsule Update. *P3G Newsletter, Fall 2012*. http://p3g.org/sites/default/files/site/default/files/P3G_Newsletter_Fall_2012_0.pdf

Pullman, D., Etchegary, H., Gallagher, K., Hodgkinson, K., Keough, M., Morgan, D., et al. (2012). Personal privacy, public benefits, and biobanks: A conjoint analysis of policy priorities and public perceptions. *Genetics in Medicine : Official Journal of the American College of Medical Genetics, 14*(2), 229-235. doi:10.1097/gim.0b013e31822e578f

Qatar Biobank. (2016). Qatar Biobank for medical research. Retrieved January 20, 2016, from http://www.qatarbiobank.org.qa/about-us

Rahm, A. K., Wrenn, M., Carroll, N. M., & Feigelson, H. S. (2013). Biobanking for research: A survey of patient population attitudes and understanding. *Journal of Community Genetics, 4*(4), 445-450. doi:10.1007/s12687-013-0146-0

Ram, N. (2015). Book review: Body banking from the bench to the bedside . *Harvard Law Review, 129*, 491.

Ridgeway, J. L., Han, L. C., Olson, J. E., Lackore, K. A., Koenig, B. A., Beebe, T. J., et al. (2013). Potential bias in the bank: What distinguishes refusers, nonresponders and participants in a clinic-based biobank? *Public Health Genomics, 16*(3), 118-126. doi:10.1159/000349924

Riegman, P. H., Morente, M. M., Betsou, F., de Blasio, P., Geary, P., & Marble Arch International Working Group on Biobanking for Biomedical Research. (2008). Biobanking for better healthcare. *Molecular Oncology, 2*(3), 213-222. dio:10.1016/j.molonc.2008.07.004

Rodriguez, E. M., Torres, E. T., & Erwin, D. O. (2013). Awareness and interest in biospecimen donation for cancer research: Views from gatekeepers and prospective

participants in the latino community. *Journal of Community Genetics, 4*(4), 461-468. doi:10.1007/s12687-013-0152-2

Rudan, I., Marusic, A., & Campbell, H. (2011). Developing biobanks in developing countries. *Journal of Global Health, 1*(1), 2-4.

Sak, J., Pawlikowski, J., Goniewicz, M., & Witt, M. (2012). Population biobanking in selected European countries and proposed model for a Polish national DNA bank. *J Appl Genetics*, *53*, 159–165. doi:DOI 10.1007/s13353-012-0082-4

Sanderson, S. C., Diefenbach, M. A., Zinberg, R., Horowitz, C. R., Smirnoff, M., Zweig, M., et al. (2013). Willingness to participate in genomics research and desire for personal results among underrepresented minority patients: A structured interview study. *Journal of Community Genetics, 4*(4), 469-482. doi:10.1007/s12687-013-0154-0

Scott, C. T., Caulfield, T., Borgelt, E., & Illes, J. (2012). Personal medicine--the new banking crisis. *Nature Biotechnology, 30*(2), 141-147. doi:10.1038/nbt.2116

Shaw, D. M., Elger, B. S., & Colledge, F. (2014). What is a biobank? differing definitions among biobank stakeholders. *Clinical Genetics, 85*(3), 223-227. doi:10.1111/cge.12268

Sheehan, M. (2011). Can broad consent be informed consent? *Public Health Ethics, 4*(3), 226-235. doi:10.1093/phe/phr020

Silverman, H., Sleem, H., Moodley, K., Kumar, N., Naidoo, S., Subramanian, T., et al. (2015). Results of a self-assessment tool to assess the operational characteristics of research ethics committees in low- and middle-income countries. *Journal of Medical Ethics, 41*, 332-337. doi:10.1136/medethics-2013-101587

Silverman, H., Edwards, H., Shamoo, A., & Matar, A. (2013). Enhancing research ethics capacity in the middle east: Experience and challenges of a fogarty-sponsored training

program. *Journal of Empirical Research on Human Research Ethics : JERHRE, 8*(5), 40-51. doi:10.1525/jer.2013.8.5.40

Simon, C. M., L'heureux, J., Murray, J. C., Winokur, P., Weiner, G., Newbury, E., et al. (2011). Active choice but not too active: Public perspectives on biobank consent models. *Genetics in Medicine : Official Journal of the American College of Medical Genetics, 13*(9), 821-831. doi:10.1097/gim.0b013e31821d2f88

Sleem, H., El-Kamary, S. S., & Silverman, H. J. (2010). Identifying structures, processes, resources and needs of research ethics committees in egypt. *BMC Medical Ethics, 11*, 12-6939-11-12. doi:10.1186/1472-6939-11-12

Smith, M. E., & Aufox, S. (2013). Biobanking: The melding of research with clinical care. *Current Genetic Medicine Reports, 1*(2), 122-128. doi:10.1007\s40142-013-0014-6

Solberg, B., & Steinsbekk, K. S. (2012). Managing incidental findings in population based biobank research. *Norsk Epidemiologi, 21*(2), 195-201. doi:10.5324/nje.v21i2.1494

Sorensen, K., Van den Broucke, S., Fullam, J., Doyle, G., Pelikan, J., Slonska, Z., et al. (2012). Health literacy and public health: A systematic review and integration of definitions and models. *BMC Public Health, 12*, 80-2458-12-80. doi:10.1186/1471-2458-12-80

Sorensen, K., Van den Broucke, S., Pelikan, J. M., Fullam, J., Doyle, G., Slonska, Z., et al. (2013). Measuring health literacy in populations: Illuminating the design and development process of the european health literacy survey questionnaire (HLS-EU-Q). *BMC Public Health, 13*, 948-2458-13-948. doi:10.1186/1471-2458-13-948

SpecimenCentral.com.(2016). Contact us today . Retrieved January 10, 2016, from http://specimencentral.com/biobank-directory/

Spruill, I. J., Gibbs, Y. C., Laken, M., & Williams, T. (2014). Perceptions toward establishing a biobank and clinical data warehouse: Voices from the community. *Clinical Nursing Studies, 2*(3), 97-106. doi:10.5430/cns.v2n3p97

Statistic Centre Abu Dhabi. (2016). *Statistical yearbook of abu dhabi 2015*. Abu Dhabi, UAE: SCAD. Retrieved January 4, 2016 from https://www.scad.ae/

Stein, D. T., & Terry, S. F. (2013). Reforming biobank consent policy: A necessary move away from broad consent toward dynamic consent. *Genetic Testing and Molecular Biomarkers, 17*(12), 855-856. doi:10.1089/gtmb.2013.1550

Steinsbekk, K. S., Kare Myskja, B., & Solberg, B. (2013). Broad consent versus dynamic consent in biobank research: Is passive participation an ethical problem? *European Journal of Human Genetics : EJHG, 21*(9), 897-902. doi:10.1038/ejhg.2012.282

Stjernschantz Forsberg, J., Hansson, M. G., & Eriksson, S. (2011). Biobank research: Who benefits from individual consent? *BMJ (Clinical Research Ed.), 343*, d5647. doi:10.1136/bmj.d5647

Streicher, S. A., Sanderson, S. C., Jabs, E. W., Diefenbach, M., Smirnoff, M., Peter, I., et al. (2011). Reasons for participating and genetic information needs among racially and ethnically diverse biobank participants: A focus group study. *Journal of Community Genetics, 2*(3), 153-163. doi:10.1007/s12687-011-0052-2

Szolnoki, G., & Hoffmann, D. (2013). Online, face-to-face and telephone surveys—Comparing different sampling methods in wine consumer research. *Wine Economics and Policy, 2*(2), 57-66. doi:10.1016/j.wep.2013.10.001

Tallacchini, M. (2013). Human tissues in the 'Public space': Beyond the Property/Privacy dichotomy. In G. Pascuzzi, U. Izzo & M. Macilotti (Eds.), *Comparative issues in the governance of research biobanks* (1st ed., pp. 87-103) Springer-Verlag Berlin Heidelberg.

Tasse, A. M. (2011). Biobanking and deceased persons. *Human Genetics, 130*(3), 415-423. doi:10.1007/s00439-011-1049-y

Tauali, i. M., Davis, E. L., Braun, K. L., Tsark, J. U., Brown, N., Hudson, M., et al. (2014). Native hawaiian views on biobanking. *Journal of Cancer Education : The Official Journal of the American Association for Cancer Education, 29*(3), 570-576. doi:10.1007/s13187-014-0638-6

Teare, H. J., Morrison, M., Whitley, E. A., & Kaye, J. (2015). Towards 'Engagement 2.0': Insights from a study of dynamic consent with biobank participants. *Digital Health, 0*(0), 1-13. doi:10.1177/2055207615605644

Ten Have, H. (2006). The activities of UNESCO in the area of ethics. *Kennedy Institute of Ethics Journal, 16*(4), 333-351. doi:10.1353/ken.2006.0024

Terry, S. F., Christensen, K. D., Metosky, S., Rudofsky, G., Deignan, K. P., Martinez, H., et al. (2012). Community engagement about genetic variation research. *Population Health Management, 15*(2), 78-89. doi:10.1089/pop.2011.0013

The World Bank. (2016). *United Arab Emirates.* Retrieved January 3, 2016, from http://data.worldbank.org/country/united-arab-emirates

Thorogood, A., Joly, Y., Knoppers, B. M., Nilsson, T., Metrakos, P., Lazaris, A., et al. (2014). An implementation framework for the feedback of individual research results and incidental findings in research. *BMC Medical Ethics, 15*, 88-6939-15-88. doi:10.1186/1472-6939-15-88

Thorogood, A., & Zawati, M. H. (2015). International guidelines for privacy in genomic biobanking (or the unexpected virtue of pluralism). *The Journal of Law, Medicine & Ethics : A Journal of the American Society of Law, Medicine & Ethics, 43*(4), 690-702. doi:10.1186/1472-6939-15-88

Toccaceli, V., Fagnani, C., Gigantesco, A., Brescianini, S., D'Ippolito, C., & Stazi, M. A. (2014). Attitudes and willingness to donate biological samples for research among potential donors in the italian twin register. *Journal of Empirical Research on Human Research Ethics : JERHRE, 9*(3), 39-47. doi:10.1177/1556264614540601

Tomlinson, T., De Vries, R., Ryan, K., Kim, H. M., Lehpamer, N., & Kim, S. Y. (2015). Moral concerns and the willingness to donate to a research biobank. *Jama, 313*(4), 417-419. doi:10.1001/jama.2014.16363

Tupasela, A., Sihvo, S., Snell, K., Jallinoja, P., Aro, A. R., & Hemminki, E. (2010). Attitudes towards biomedical use of tissue sample collections, consent, and biobanks among finns. *Scandinavian Journal of Public Health, 38*(1), 46-52. doi:0.1177/1403494809353824

Turner, A., Dallaire-Fortier, C., & Murtagh, M. J. (2013). Biobank economics and the 'Commercialization problem'. *Spontaneous Generations, 7*(1), 69-80. doi:10.4245/sponge.v7i1.19555

Tutton, R. (2010). Biobanking: Social, political and ethical aspects. *Encyclopedia of Life Sciences,* , 1-7.

UAEinteract (n.d.). *Al Gharbia rakes in Dh300b in projects*.Retrieved January 1, 2016, from http://www.uaeinteract.com/docs/Al_Gharbia_rakes_in_Dh300b_in_projects/52110.htm

UK Biobank. (2006). *UK biobank: Report of the integrated pilot phase*UK Biobank.

UK Biobank. (2007). *UK biobank: Protocol for a large-scale prospective epidemiological resource*UK Biobank.

UN Data. (2016). *United Arab Emirates.* Retrieved January 3, 2016, from http://data.un.org/CountryProfile.aspx?crName=United%20Arab%20Emirates

United Nations Educational, Scientific and Cultural Organization. (2002). *Human genetic data: preliminary study by the IBC on its collection, processing, storage and use.* Retrieved January 17, 2016, from http://portal.unesco.org/shs/en/files/2138/10563744931Rapfinal_gendata_en.pdf/Rapfinal_gendata_en.pdf

United Nations Educational, Scientific and Cultural Organization. (2004). International declaration on human genetic data. Retrieved January 17, 2016, from http://portal.unesco.org/en/ev.php-URL_ID=17720&URL_DO=DO_TOPIC&URL_SECTION=201.html

Viberg, J., Hansson, M. G., Langenskiold, S., & Segerdahl, P. (2014). Incidental findings: The time is not yet ripe for a policy for biobanks. *European Journal of Human Genetics, 22*(4), 437-441. doi:10.1038/ejhg.2013.217

Wallace, S. E., & Kent, A. (2011). Population biobanks and returning individual research results: Mission impossible or new directions? *Human Genetics, 130*(3), 393-401. doi:10.1007/s00439-011-1021-x

Watanabe, M., Inoue, Y., Chang, C., Hong, H., Kobayashi, I., Suzuki, S., et al. (2011). For what am I participating? the need for communication after receiving consent from biobanking project participants: Experience in japan. *Journal of Human Genetics, 56*(5), 358-363. doi:10.1038/jhg.2011.19

Watson, P. H., Nussbeck, S. Y., Carter, C., O'donoghue, S., Cheah, S., Matzke, L. A. M., et al. (2014). A framework for biobank sustainability. *Biopreservation and Biobanking, 12*((1)), 60-68. doi:10.1089/bio.2013.0064

Weber, A. S., Verjee, M. A., Musson, D., Iqbal, N. A., Mosleh, T. M., Zainel, A. A., et al. (2011). Patient opinion of the doctor-patient relationship in a public hospital in qatar. *Saudi Medical Journal, 32*(3), 293-299.

Wee, R., Henaghan, M., & Winship, I. (2013). Dynamic consent in the digital age of biology: Online initiatives and regulatory considerations. *Journal of Primary Health Care, 5*(4), 341-347. doi: 10.1071/HC13341

Wells, K. J., Arevalo, M., Meade, C. D., Gwede, C. K., Quinn, G. P., Luque, J. S., et al. (2014). Development and validation of the biobanking attitudes and knowledge survey (BANKS). *Cancer Epidemiology, Biomarkers & Prevention : A Publication of the American Association for Cancer Research, Cosponsored by the American Society of Preventive Oncology, 23*(3), 374-382. doi:10.1158/1055-9965.epi-13-0746

Whitley, E. A., Kanellopoulou, N., & Kaye, J. (2012). Consent and research governance in Biobanks: Evidence from focus groups with medical researchers. *Public Health Genomics*, *15*(5), 232–242. doi:10.1159/000336544

Williams, P. H., Nemeth, L. S., Sanner, J. E., & Frazier, L. Q. (2013). Thematic analysis of cardiac care patients' explanations for declining contribution to a Genomic research-based Biobank. *American Journal of Critical Care*, *22*(4), 320–327. doi:10.4037/ajcc2013838

Willis G. (2005). *Cognitive interviewing: A tool for improving questionnaire design*. Thousand Oaks, CA: Sage.

Wolf, S. M., Crock, B. N., Van Ness, B., Lawrenz, F., Kahn, J. P., Beskow, L. M., et al. (2012). Managing incidental findings and research results in genomic research involving biobanks and archived data sets. *Genetics in Medicine*, *14*(4), 361–384. doi:10.1038/gim.2012.23

Wolfson, M., Wallace, S. E., Masca, N., Rowe, G., Sheehan, N. A., Ferretti, V., et al. (2010). DataSHIELD: Resolving a conflict in contemporary bioscience--performing a pooled analysis of individual-level data without sharing the data. *International Journal of Epidemiology*, *39*(5), 1372–1382. doi:10.1093/ije/dyq111

Womack, C., & Mager, S. R. (2014). Human biological sample biobanking to support tissue biomarkers in pharmaceutical research and development. *Methods*, *70*(1), 3–11. doi:10.1016/j.ymeth.2014.01.014

World Health Organization. (1998). *Report of a WHO meeting on ethical issues in medical genetic*. *Proposed international guidelines on ethical issues in medical genetics and genetic services.* Retrieved January 15, 2016, from http://www.who.int/genomics/publications/en/ethicalguidelines1998.pdf

World Health Organization. (2002). *Handbook for good clinical research practice (GCP): Guidance for implementation*. Geneva: World Health Organization. http://apps.who.int/prequal/info_general/documents/gcp/gcp1.pdf

World Health Organization. (2013). *Global action plan for the prevention and control of non-communicable diseases 2013-2020*. Geneva: World Health Organization. http://apps.who.int/iris/bitstream/10665/94384/1/9789241506236_eng.pdf

World Medical Association. (2013). *WMA declaration of helsinki - ethical principles for medical research involving human subjects* . Retrieved December 28, 2015, from http://www.wma.net/en/30publications/10policies/b3/

World Medical Association. (2016). *WMA Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks* . Retrieved December 28, 2016, from http://www.wma.net/en/30publications/10policies/d1/

Wyld, L., Smith, S., Hawkins, N. J., Long, J., & Ward, R. L. (2014). Introducing research initiatives into healthcare: What do doctors think? *Biopreservation and Biobanking, 12*(2), 91-98. 10.1089/bio.2013.0069

Yoshizawa, G., Ho, C. W.-L., Zhu, W., Hu, C., Syukriani, Y., Lee, I., et al. (2014). ELSI practices in genomic research in east Asia: Implications for research collaboration and public participation. *Genome Medicine*, *6*(5), 39. doi:10.1186/gm556

Zawati, M. H., Knoppers, B., & Thorogood, A. (2014). Population biobanking and international collaboration. *Pathobiology : Journal of Immunopathology, Molecular and Cellular Biology, 81*(5-6), 276-285. doi:10.1159/000357527

Zhou, J. H., Sahin, A. A., & Myers, J. N. (2015). Biobanking in genomic medicine. *Archives of Pathology & Laboratory Medicine, 139*(6), 812-818. doi:10.5858/arpa.2014-0261-ra

Zielhuis, G. A. (2012). Biobanking for epidemiology. *Public Health*, *126*(3), 214–216. doi:10.1016/j.puhe.2011.12.007

Appendix I: Search Strategy

Concept 2		**Concept 1**
Definition Design/Set up/ Establish Ethics/Ethical Legal ELSI Governance Public trust Consent/Informed consent Withdrawal Confidentiality/Privacy Return of research findings/results Re-contact/Future contact Commercialization/ Ownership/Benefits sharing UAE/Arab/ Middle-East Attitudes/ /Prospective/Views/ Perception Knowledge/ literacy Benefits/Motives/Barriers/Concerns/Risks Community/Public/ Population- engagement /participation intention to participate Personalized medicine Epidemiology Surveillance Public health Factors /Predictors for participation/willingness to participate Health information and Communication Health literacy	AND / OR	Biobank* OR Bio bank* OR population biobank OR population-based OR national biobank OR genomic research OR genetic research OR biomedical research

- Refined: Search was limited to 2010 onwards, English language, full text articles, concepts in tiab (**Ti**tle /**Ab**stract)
- Excluded from search: patients (including) minors/ disease oriented biobank
- The search was conducted between 15 December 2015 and 31 January 2016.
- Terms for search are concept #1 and/or Concept #2. Found in PubMed (n= 384), Web of science (n=202), Scopus (n= 108).
- Total included (n= 267)

Appendix II: Sample Size Calculation

Estimation of the sample size from overall estimated true population proprtion .

SE of p^ = sequare root square root of p*(1-p)/n

SE of p^ +/- 3%	overall proprtion	Sample size	Inflated for 0.7% RR	SE of p^ +/- 4 % *	Sample size	Inflated for 70%
	0.5	1111	1587		625	893
	0.64	1024	1463		576	823
	0.76	811	1158		456	651
	0.78	763	1090		429	613
	0.8	711	1016		400	571
	0.84		853		336	480

Estimation of sample size based on the hypothesis : null hypothesis= no difference in proprtion by gender. Estimatied using Stata, command: **sampsi P1 P2, power(.9) alpha(.05)**

alpha =.05

Power=0.9

				estimated diffrences			
				0.1	0.12	0.15 *	0.2
	Overall	0.5	Female	0.55	0.56	0.57	0.6
			Male	0.45	0.44	0.42	0.4
Sample size				1088	418	490	280
Inflated for a response rate 70%				1554	597	700	400
	Overall	0.54	female	0.59	0.6	0.61	0.64
			male	0.49	0.48	0.46	0.44
Sample size				1080	754	488	278
Inflated for a response rate 70%				1543	1077	697	397
based Jordan study	Overall	0.64	female	0.69	0.7	0.71	0.74
			male	0.59	0.58	0.56	0.54
Sample size				1004	702	456	258
Inflated for a response rate 70%				1434	1003	651	369
	Overall	0.76	female	0.81	0.82	0.84	0.86
			male	0.71	0.7	0.69	0.66
Sample size				802	562	358	134
Inflated for a response rate 70%				1146	803	511	191
based SA study	Overall	0.78	female	0.83	0.84	0.85	0.88
			male	0.73	0.72	0.7	0.68
Sample size				758	530	348	196
Inflated for a response rate 70%				1083	757	497	280
	Overall	0.8	female	0.85	0.86	0.88	0.9
			male	0.75	0.74	0.73	0.7
Sample size				708	496	316	184
Inflated for a response rate 70%				1011	709	451	263
	Overall	0.84	female	0.89	0.9	0.92	0.94
			male	0.79	0.78	0.77	0.74
Sample size				602	422	268	158
Inflated for a response rate 70%				860	603	383	226

Appendix III: Survey Questionaire

Participant Code No: 0000

Q1. Have you ever donated blood?
1 = No
2 = Yes

77= DK/NS
99= Refused

Q2: Have you ever participated in medical research, for example donated blood or tissue for research or taken part in a trial for testing an experimental treatment?
1 = No
2 = Yes

77= DK/NS
99= Refused

Q3: How would you describe your own level of knowledge about medical research that involves the use of biological samples, such as blood, urine or tissue?
1= No knowledge
2= Some knowledge
3= Good knowledge

77= DK/NS
99= Refused

Q4: How much do you know about the relationship between human genes and health?
1= No knowledge
2= Some knowledge
3= Good knowledge

77= DK/NS
99= Refused

Q5: To what extent do you agree with the following statement? Medical research leads to improvements in patients' health
1= Strongly disagree
2= Disagree
3= Neutral
4= Agree
5= Strongly Agree

77= DK/NS
99= Refused

Q6: How important do you think it is for people to donate biological samples such as blood, urine or tissue, for medical research?
1= Not at all important
2= Somewhat important
3= Moderately important
4= Very important
5= Extremely important

77= DK/NS
99= Refused

Q7: Are you familiar with the term biobank?

1 = No
2 = Yes

77= DK/NS
99= Refused

Q 8: If you wanted to learn more about the biobank, please select the sources of information that you prefer

[SELECT UP TO 3]

1= Family members / friends / neighbours
2= Booklets or brochures
3=A doctor or other health care providers
4=Websites or social media
5=Newspapers
6=Radio
7=TV
8=Public seminars
9=Other, please specify _____

77= DK/NS
99= Refused

[READ OUT TO PARTICIPANT]

Biobanks are like a library that stores large numbers of samples along with related health information for several years for the purposes of medical research.

The Health Authority is planning to establish a population-based biobank in Abu Dhabi, during this year. It will be managed by a healthcare provider. The purpose of the Biobank is to provide a resource that can support a diverse range of research intended to improve the health of the Emirati population. Through this research we hope to identify the genetic causes and variations of diseases common to the Emirati population. These include diabetes, heart disease, cancer and asthma, among others. It will also help to find new ways to prevent and treat these diseases in ways that are specifically **tailored** to Emiratis. It is hoped that this research will benefit current and future generations.

Blood and urine samples collected during the ***Weqaya*** screening program, which would otherwise have been discarded, would instead be retained, matched with the health information collected via a questionnaire and deposited in the biobank. The biobank will store samples and health information in de-identified manner. Personal identifying information, such as name, insurance number or date of birth will be removed and replaced by codes. Researchers using the samples will not know whom they came from.

All adults 18 years and over in the Emirate of Abu Dhabi will be invited to participate in the biobank. Participation in the biobank will be completely voluntary and participants must give their permission for their samples and health information to be included in the biobank. Participants have the option to withdraw from the biobank at any time in the future without giving any reason.

Q9: How valuable do you think the biobank would be to generate new information to improve the health of Emiratis?

1= Not at all valuable
2= Somewhat valuable
3= Moderately valuable
4= Very valuable
5= Extremely valuable

77= DK/NS
99= Refused

Q10: If you were asked to participate in the biobank; by voluntarily donating otherwise discarded blood and urine samples and health information for research, how likely would you be to participate?

1= Definitely would not participate **[SKIP TO 12]**
2= Probably would not participate **[SKIP TO 12]**
3= Probably would participate
4= Definitely would participate

77= DK/NS
99= Refused

Q11: What are the main reasons you would participate in the biobank?
[SELECT UP TO 3]

1= Donation is a charitable act
2= Support medical research
3= Improve the health of future generation
4= Obtain better treatment or cure for my family members
5= Obtain better treatment or cure for my condition
6=Other, **please specify**

- _____
- _____
- _____

77= DK/NS
99= Refused

Q12. What are the main reasons you would NOT participate in the biobank?
[SELECT UP TO 3]

1= I don't believe in medical research
2= Concerned about genetic research
3= Concerned about collecting lots of information/ loss of privacy
4=Concerned about identification of the source of samples/ leak of my personal information
5= Other, **please specify**

- _____
- _____
- _____

77= DK/NS
99= Refused

Q 13: Do you think that your family members would be willing to participate in the biobank?

1= Definitely no
2= Probably no
3= Probably yes
4= Definitely yes

77= DK/NS
99= Refused

Q14: If you were invited to participate in the biobank, would you prefer making the decision to participate.....

1=Entirely by yourself,
2=With help from a family member or a friend
3=With help from a doctor or health care provider
4=Other, please specify_____

77= DK/NS
99= Refused

Q15: Imagine you have agreed to participate in the biobank, would it be acceptable for you to be contacted by the biobank sometime in the future to ask for new information, additional assessments tests or to donate more blood?

1= Definitely no
2= Probably no
3= Probably yes
4= Definitely yes

77= DK/NS
99= Refused

Q16: If you agreed to participate in the biobank, would you like to receive feedback related to a condition you have or could be at risk of in the future?

1= Definitely no
2= Probably no
3= Probably yes
4= Definitely yes

77= DK/NS
99= Refused

Q 17: Would you like to receive general information about research being conducted by the biobank?

1= Definitely not **[SKIP TO 19]**
2= Probably not **[SKIP TO 19]**
3= Probably yes
4= Definitely yes

77= DK/NS
99= Refused

Q18: How would you like to receive the general information about the biobank research? [SELECT UP TO 3]

1=Website
2= SMS
3= Mobile applications
4= Email
5=Other, please specify _____

77= DK/NS
99= Refused

Q19: Have you ever been diagnosed with an illness or condition that required continuous treatment or frequent medical attention, for example diabetes, heart disease, asthma, cancer, a genetic condition or something else?

1 = No
2 = Yes

77= DK/NS
99= Refused

Q20: Has a close family member such as a brother, sister, father, mother or child ever been diagnosed with an illness or condition that required continuous treatment or frequent medical attention?

1 = No
2 = Yes

77= DK/NS
99= Refused

Q 21: Generally, how would you describe your experience with healthcare services in the Emirate of Abu Dhabi?

1= Mostly negative
2= Neutral
3= Mostly positive

77= DK/NS
99= Refused

Q 22: How would you rate your trust in healthcare providers, in the Emirate of Abu Dhabi?

1= Low
2=Moderate
3= High

77= DK/NS
99= Refused

Q 23: To what extent do you agree with the following statement? I trust the Health Authority to assess the risk and benefits of the biobank for the Emirati population.

1= Strongly disagree
2= Disagree
3= Neutral
4= Agree
5= Strongly Agree

77= DK/NS
99= Refused

Now I would like to ask some general questions about you and then we will be finished.

Q24: What is your age?

_____

Q 25: What is your current marital status?

1=Single **[SKIP TO 27]**
2=Married
3=Separated/divorced
4=Widowed

77= DK/NS
99= Refused

Q26: Do you have children?

1 = No
2 = Yes

77= DK/NS
99= Refused

Q27: What is the highest education level you have completed?

1=Did not attend school or less than primary
2=Completed primary school
3=Completed intermediate school
4=Completed secondary school
5=Completed college or university
6=Completed Master or PHD

77= DK/NS
99= Refused

Q28: What is your current employment status?

1 = At work
2 = Unemployed
3 = Student
4 = Retired
5 = Home duties/(other)

77= DK/NS
99= Refused

Q29: What is the average total monthly income received by your HOUSEHOLD in AED?

1=Less than 20,000
2=20,000 to 39,999
3=40,000 to 59,999
4= 60,000 to 79,999
5=Greater than 80,000
77= DK/NS
99= Refused

Do you have any other comments you would like to share with us about the topics raised in this questionnaire?

[CLOSE]

That was my last question. Thank you for your time and cooperation. Good-bye.

INTERVIEWER COMMENTS:

رمز تعريف المشارك : 0000

س1: هل سبق لك التبرع بالدم ؟
1= لا
2= نعم

77=لا أعرف / غير متأكد
99= أرفض الإجابة

س2: هل تطوعت للمشاركة في أبحاث طبية، مثل التبرع بعينات دم أو أنسجة لصالح أبحاث أو أختبار علاج مطور ؟
1= لا
2= نعم

77=لا أعرف / غير متأكد
99= أرفض الإجابة

س3 : كيف تصف مستوى معرفتك بالأبحاث الطبية التي تجرى على العينات الحيوية (مثل: الدم ،البول أوالأنسجة) ؟
1= ليس لدي معلومات
2= بعض المعلومات
3= معلومات جيدة

77=لا أعرف / غير متأكد
99= أرفض الإجابة

س4 : كيف تصف مستوى معرفتك بالوراثة وتأثيرها على صحة الأنسان ؟
1= ليس لدي معلومات
2= بعض المعلومات
3= معلومات جيدة

77=لا أعرف / غير متأكد
99= أرفض الإجابة

س5: إلى أي مدى توافق على أن الأبحاث الطبية تسهم في تحسين صحة المرضى ؟
1= لا أوافق بشدة
2= لا أوافق
3= محايد
4= أوافق
5= أوافق بشدة

77=لا أعرف / غير متأكد
99= أرفض الإجابة

س6 : برأيك، ما مدى أهمية تبرع الأفراد بالعينات الحيوية (مثل: الدم ،البول أو الأنسجة) لصالح الأبحاث الطبية ؟
1= غيرمهم إطلاقا
2 = قليل الأهمية
3= متوسط الأهمية
4= هام جداً
5= في غاية الأهمية

77=لا أعرف / غير متأكد
99=أرفض الإجابة

س7 : هل سبق لك أن سمعت بمصطلح البنك الحيوي؟
1= لا
2= نعم

77= لا أعرف / غير متأكد
99= أرفض الإجابة

س8: إذا أردت أن تعرف المزيد عن البنك الحيوي، ما هي مصادر المعلومات التي تفضلها ؟
[يمكن تحديد 3 خيارات]
1= أفراد العائلة/ الأصدقاء / الجيران
2= كتيبات أو نشرات طبية
3=الطبيب أو العاملين في المجال الصحي
=مواقع إلكترونية أو سائل التواصل الإجتماعي
5=الصحف
6=الراديو
7=التلفزيون
8=محاضرات عامة
9=أخرى، يرجى التحديد:_____

77= لا أعرف / غير متأكد
99= رفض الإجابة

[يُقرأ ما يلي على المشارك ثم يُطرح السؤال]

و الآن سأعطيك نبذة عن مشروع البنك الحيوي .
البنك الحيوي عبارة عن مستودع يخزن مجموعة كبيرة من العينات الحيوية والمعلومات الصحية المتبرع بها، لسنوات عديدة بهدف توفرها للأبحاث الطبية المتنوعة في المستقبل.

خلال هذا العام ، تعتزم هيئة الصحة إنشاء بنك حيوي في إمارة أبوظبي، يدارمن قبل أحد مقدمي الخدمات الصحية ويهدف لإنشاء بنية تدعم تطور الأبحاث الطبية .وتأمل الهيئة من خلال الأبحاث الواسعة النطاق، التوصل إلى تحديد الأسباب الوراثية (الجينية) للأمراض المزمنة الشائعة مثل: السكري وأمراض القلب والسرطان والربو والأمراض الوراثية وغيرها، و إيجاد طرق مطورة للوقاية والعلاج من تلك الأمراض ، بطريقة أكثر تلاؤما مع المجتمع الإماراتي والحفاظ على صحة الأجيال القادمة.

سيتم جمع و إيداع العينات المتبقية من فحص **"وقاية"** وهي : الدم والبول؛ بدلاً من إتلافها، بالإضافة إلى المعلومات الصحية التي يتم جمعها من خلال الإستبانة ، في البنك الحيوي وذلك بعد الموافقة على المشاركة في البنك الحيوي. يحتفظ البنك الحيوي بالعينات والمعلومات الصحية بطريقة غير معرفة، أي يتم إزالة المعلومات الشخصية التعريفية مثل الاسم ورقم التأمين الصحي وتاريخ الميلاد و غيرها واستبدالها برموز لضمان حماية هوية المتبرعيين. وتقدم للباحثين بطريقة مجهولة المصدر بحيث لا يتمكن الباحثون من التعرف على صاحبها.

و ستدعو هيئة الصحة جميع المواطنين البالغين (18 سنة وما فوق)، في إمارة أبو ظبي للمشاركة في البنك الحيوي. و ستكون المشاركة في البنك الحيوي طوعية. كما يمكن للمشاركين سحب الموافقة على تخزين العينات والمعلومات الصحية في أي وقت في المستقبل دون الحاجة للتبرير وإبداء الأسباب.

س9: إلى أي مدى تقيم فائدة مبادرة البنك الحيوي للتوصل لمعلومات جديدة تسهم في تحسين صحة المواطنين ؟
1=غيرمفيد إطلاقا
2 = قليل الفائدة
3= متوسط الفائدة
4= مفيد جداً
5= في غاية الفائدة

77=لا أعرف / غير متأكد
99=أرفض الإجابة

س10 : إذا طلب منك المشاركة في البنك الحيوي، أي التبرع الطوعي ببقايا عينات الدم و البول ، بدلاً من إتلافها و المعلومات الصحية لصالح الأبحاث؛ فإلى أي مدى يمكن أن تكون موافق على المشاركة؟

1= بالتأكيد لن أشارك **[انتقل إلى س 12]**
2= ربما لن أشارك **[انتقل إلى س 12]**
3= ربما سأشارك
4= بالتأكيد سأشارك

77= لا أعرف / غير متأكد
99=أرفض الإجابة

س 11 : ما هي الأسباب التي شجعتك على إبداء الموافقة للمشاركة في البنك الحيوي؟
[يمكن تحديد 3 خيارات]

1= التبرع عمل خيري
2= تشجيع الأبحاث الطبية
3= لصالح صحة الأجيال القادمة
4= للتوصل لعلاج مطوَّر أو شفاء لأفراد عائلتي
5= للتوصل لعلاج مطوَّر أو شفاء لحالتي
6= أسباب أخرى، يرجى التحديد:

1=_____
2=_____
3=_____

77= لا أعرف / غير متأكد
99= أرفض الإجابة

س12. إذكر الأسباب التي يمكن أن تقف حائلاً دون مشاركتك في البنك الحيوي؟
[يمكن تحديد 3 خيارات]

1= لا أعتقد بفائدة الأبحاث الطبية
2= متخوف من الأبحاث الوراثية
3= متخوف من جمع الكثير من المعلومات عني /(فقدان الخصوصية)
4= متخوف من التعرف على مصدر العينات/(تسرب معلوماتي التعريفية)
5=أسباب أخرى، يرجى التحديد

1=_____
2=_____
3=_____

77= لا أعرف / غير متأكد
99= أرفض الإجابة

س 13: برأيك، هل سيوافق أفراد عائلتك على المشاركة في البنك الحيوي ؟

1= بالتأكيد لا
2= ربما لا
3= ربما نعم
4= بالتأكيد نعم

77= لا أعرف / غير متأكد
99= أرفض الإجابة

س14 : برأيك، من بإمكانه مساعدتك في إتخاذ قرارك بشأن المشاركة في البنك الحيوي؟

1= من تلقاء نفسك مباشرةً
2= أحد أفراد العائلة أو الأصدقاء
3= الطبيب أو أحد العاملين في المجال الصحي
4=آخرون ، يرجى التحديد _____

77= لا أعرف / غير متأكد
99= أرفض الإجابة

[يُقرأ ما يلي على المشارك ثم يُطرح السؤال]

س 15: بفرض أنك وافقت على المشاركة في البنك الحيوي، فهل تقبل أن يقوم البنك الحيوي بالإتصال بك مستقبلاً، من أجل طلب التبرع بالمزيد من الدم أو تحديث المعلومات أو عمل فحوصات إضافية ؟

1= بالتأكيد لا
2= ربما لا
3= ربما نعم
4= بالتأكيد نعم

77= لا أعرف / غير متأكد
99= رفض الإجابة

س 16: إذا وافقت على المشاركة في البنك الحيوي، فهل تود أن تتلقى إفادة عن حالة صحية قد تعاني منها أو ربما تتعرض لها مستقبلاً؟

1= بالتأكيد لا
2= ربما لا
3= ربما نعم
4= بالتأكيد نعم

77= لا أعرف / غير متأكد
99= أرفض الإجابة

س 17: هل ترغب في أن تصلك معلومات عامة عن أنواع و نتائج أبحاث البنك الحيوي ؟

1= بالتأكيد لا **[انتقل إلى س 19]**
2= ربما لا **[انتقل إلى س 19]**
3= ربما نعم
4= بالتأكيد نعم

77= لا أعرف / غير متأكد
99= أرفض الإجابة

س 18: كيف تفضل أن تصلك المعلومات العامة عن أنواع ونتائج أبحاث البنك الحيوي؟ من خلال.....

[يمكن تحديد 3 خيارات]

1= الموقع الإلكتروني
2= رسائل نصية قصيرة
3= تطبيقات هاتفية
4=البريد الألكتروني
5= طرق آخرى (يرجى التحديد)_____:

77= لا أعرف / غير متأكد
99= أرفض الإجابة

س 19: هل تعاني من مرض مزمن يستدعي تناول علاج دائم أو رعاية طبية مستمرة (مثل: السكري، أمراض القلب ، الربو، السرطان، أمراض وراثية أوغيرها من الأمراض) ؟

1= لا
2= نعم

77= لا أعرف / غير متأكد
99= رفض الأجابة

س20: هل يعاني أحد أفراد عائلتك (مثل: الأب، الأم، الأخوة أو الأبناء) من مرض مزمن يستدعي تناول علاج دائم أو رعاية طبية مستمرة (مثل: السكري، أمراض القلب ، الربو، السرطان، أمراض وراثية أوغيرها من الأمراض) ؟
1= لا
2= نعم

77= لا أعرف / غير متأكد
99= رفض الأجابة

س 21: كيف تصف تجربتك مع الخدمات الصحية عموماً في إمارة أبوظبي؟
1= سلبية عموماً
2= أحياناً سلبية و أحياناً إيجابية
3= إيجابية عموماً

77= لا أعرف / غير متأكد
99= أرفض الإجابة

س 22: كيف تقيم ثقتك في ألأطباء و العاملين في المجال الصحي عموماً في إمارة أبوظبي؟
1= ضعيفة
2= متوسطة
3= عالية

77= لا أعرف / غير متأكد
99= رفض الإجابة

س 23: إلى أي مدى تتفق مع العبارة التالية : أثق بدورهيئة الصحة-أبوظبي في تقييم فوائد و مخاطر مشروع البنك الحيوي؟
1= لا أوافق بشدة
2= لا أوافق
3= محايد
4= أوافق
5= أوافق بشدة

77=لا أعرف / غير متأكد
99= أرفض الإجابة

نحن على وشك الانتهاء من الاستبانة الآن ، وأود أن أطرح بعض الأسئلة العامة عنك

س 24: كم عمرك ؟

_____

77= لا أعرف / غير متأكد
99= رفض الأجابة

س 25: ما هووضعك الاجتماعي الحالي؟
1= أعزب **[انتقل إلى س 27]**
2= متزوج
3=مطلق/منفصل
4= أرمل

77= لا أعرف / غير متأكد
99= رفض الأجابة

س 26: هل لديك أطفال؟
1= لا
2= نعم

77= لا أعرف / غير متأكد
99= رفض الأجابة

س 27: ما هو أعلى مستوى تعليمي لك؟
1= لم أدخل المدرسة أو لم أكمل الإبتدائية
2= أكملت الابتدائية
3= أكملت المتوسطة
4= أكملت الثانوية
5= أكملت الكلية أو الجامعة
6= أكملت الماجستيرأوالدكتوراه

77= لا أعرف / غير متأكد
99= رفض الأجابة

س 28: ما هو وضعك الوظيفي الحالي؟
1= على قيد العمل
2= لا أعمل
3= طالب
4= متقاعد
5= ربة منزل /أخرى

77= لا أعرف / غير متأكد
99= رفض الأجابة

س 29 : ما هو متوسط دخل أسرتك الإجمالي الشهري ،بالدرهم الإماراتي ؟
1= أقل من 20,000
2=20,000 إلى 39,999
3= 40,000 إلى 59,999
4= 60,000 إلى 79,000
5= 80,000 أو أكثر

77= لا أعرف / غير متأكد
99= أرفض الإجابة

هل توجد لديك أية ملاحظات بشأن الموضوعات المطروحة في هذه الاستبانة و ترغب في ذكرها

6

[النهاية]

انتهت الأسئلة. وشكراً لك على حسن تعاونك . مع السلامة .

تعليقات الباحث:

Appendix IV: Cognitive Interview Consent and Questionnaire

Cognitive Interview for Testing the Biobank Survey

Instructions to the respondent:

[READ TO PARTCIPANTS]

Thank you for agreeing to participate in this interview. The purpose of this project is to learn about the views of the Emiratis regarding, the storage and use of biological samples for medical research to improve the health of the population
We need to find out if the questions make sense to everyone and if everyone understands the questions in the same way. Your interview will help us find out how the questions are working.
This interview will last about one hour. Many of these questions will seem repetitive and even somewhat strange or personal. This is because we are testing the questions, and we need to understand what people are considering when they form an answer. Please do your best to answer the questions as you understand them.
Everything that you tell me is confidential and will be kept private. If you do not want to answer a question, please tell me and I will move to the next question. Before we begin, do you have any questions?

شكرا للموافقة على المشاركة في هذه المقابلة. الغرض من هذة الدراسة هو معرفة آراء مواطني دولة الإمارات العربية المتحدة فيما يتعلق، بتخزين واستخدام العينات البيولوجية للبحوث الطبية لتحسين صحة السكان.

نحن بحاجة إلى معرفة ما إذا كانت الأسئلة منطقية للجميع وإذا كان الجميع يفهم الأسئلة بنفس الطريقة.
سوف تساعدنا المقابلة معك في معرفة ذلك و سوف تستمر هذه المقابلة حوالي ساعة واحدة. وكثير من هذه الأسئلة تبدو متكررة وحتى غريب نوعا ما أو شخصية. هذا هو لأننا نختبر الأسئلة، ونحن بحاجة إلى فهم كيف يفكر الناس و كيف يتوصولون للإجابة على هذه الأسئلة . يرجى بذل قصارى جهدكم للرد على الأسئلة حسب ما فهمتها. كل ما تقوله سيكون في غاية السرية .
إذا كنت لا تريد الإجابة على أي سؤال، من فضلك قل لي وسوف ننتقل إلى السؤال التالي.
وقبل أن نبدأ، هل لديك أي أسئلة

Respondent #.....

Demographic data			Remarks & suggestions
Gender	☐ Female ☐ Male		
Age **	_____ years	☐ 18-24 ☐ 25-34 ☐ 35-44 ☐ 45-54 ☐ 55-64 ☐ 65+	
Marital Status	☐ Single ☐ Married ☐ Separated/divorced ☐ Widowed		
Parental Status	☐ Yes ☐ No		
Education	☐ Did not attend school /no formal qualification ☐ Completed primary school ☐ Completed intermediate school ☐ Completed secondary school ☐ Completed college or university ☐ Completed Master or PHD		
Employment status	☐ At work ☐ unemployed ☐ Student ☐ Retired ☐ Housewife/ (other)		
Household income ^^	☐ Less than 20,000 ☐ 20,000 to 39,999 ☐ 40,000 to 59,999 ☐ 60,000 to 79,999 ☐ Greater than 80,000		

** Note if asking age in years was sensitive and respondent prefer to answer the age category

^^ Note if it was very sensitive to ask about the household income

س1: هل سبق لك التبرع بالدم؟

1= نعم

2 = لا

أسئلة للتحقق:

أ) كيف تتذكر ذلك؟

ب)ماذا يعني لك مصطلح التبرع بالدم؟

ج)هل كان من السهل أم الصعب الإجابة على هذا السؤال؟

النتائج /الملاحظات

التعديل المقترح

س2: ؟ هل سبق لك المشاركة في أبحاث طبية (مثل: التبرع بالدم أوبالأنسجة لبحثٍ طبيٍ، أو المشاركة في تجارب سريرية (مثل: تلقي علاج أو لقاح تجريبي) ؟

1= نعم

2= لا

أسئلة للتحقق:

أ)هل يمكن ان تعيد السؤال بكلمات من عندك؟

ب) ماذا يعني لك مصطلح أبحاث طبية؟

ج) كيف تتذكر ذلك؟

النتائج /الملاحظات

التعديل المقترح للسؤال

س3: هل قام أحد أفراد عائلتك أو أصدقائك بالمشاركة في أبحاث طبية ؟

1= نعم

2= لا

أسئلة للتحقق:

أ) هل يمكن ان تعيد السؤال بكلمات من عندك؟

ب) كيف تتذكر ذلك؟

ج) هل كان من السهل أم الصعب الإجابة على هذا السؤال؟

النتائج /الملاحظات

التعديل المقترح للسؤال

س4 : كيف تصف مستوى معرفتك بالأبحاث الطبية التي تنطوي على استخدام عينات من الأنسجة البشرية ؟

1=معرفة ضعيفة

2= معرفة متوسطة

3= معرفة جيدة

أسئلة للتحقق:

أ) ماذا يعني لك مصطلح عينات من الأنسجة البشرية؟
ب)هل يمكن ان تعيد السؤال بكلمات من عندك؟
ج) كيف توصلت إلى إجابتك ؟

النتائج /الملاحظات

التعديل المقترح للسؤال

س5 : الجينات (المورثات) هي جزء من الحمض النووي، الموجود في نواة الخلايا ، و تحمل معلومات وراثية تنتقل من الآباء إلى الأبناء. كيف تصف مستوى معرفتك بالعلاقة بين الجينات وصحة الإنسان ؟

1=معرفة ضعيفة
2= معرفة متوسطة
3= معرفة جيدة

أسئلة للتحقق:
أ) ماذا يعني لك مصطلح الجينات؟
ب)هل يمكن ان تعيد السؤال بكلمات من عندك؟
ج) كيف توصلت للإجابة ؟

النتائج /الملاحظات

التعديل المقترح للسؤال

الأبحاث الطبية التي يتم فيها استخدام العينات البيولوجية، بما فيها الدم أواللعاب أو البول أو الأنسجة، تسهم في تحسين فهمنا للأمراض و تطوير اختبارات طبية لتشخيص هذه الأمراض واكتشاف علاجات مطورة لها. إن ما نشهده اليوم من تطورٍ ملحوظٍ في الفحوصات وأنواع العلاج هو نتيجة تبرع أفراد في السابق للأبحاث الطبية.

س6 : في رأيك : هل تعتقد أن الأبحاث الطبية تسهم في تحسين صحة المرضى ؟

1= نعم
2= لا

أسئلة للتحقق:
أ)ما فائدة الأبحاث الطبية التي تستخدم العينات البشرية ؟
ب)هل يمكن ان تعيد السؤال بكلمات من عندك؟
ج) لماذا تعتقد ذلك؟

النتائج /الملاحظات

التعديل المقترح للسؤال

على مقياس من 1 إلى 5 (باعتبار 1 غير مهم على الإطلاق و 5 في غاية الأهمية) ، في رأيك : ما مدى أهمية تبرع الأفراد بالعينات للأبحاث الطبية ؟

1= غيرمهم على الإطلاق
2= غيرمهم
3= محايد
4= هام
5= غاية في الأهمية

أسئلة للتحقق:

أ)هل يمكن ان تعيد السؤال بكلمات من عندك؟
ب)لماذا تعتقد ذلك؟
ج) هل كان استخدام مقياس من 1-5 سهل الأستخدام ؟ ماذا يعني لك مقياس 3 ؟

النتائج /الملاحظات

التعديل المقترح للسؤال

س8:هل تقبل بالتبرع بما قد يتبقى من العينات بعد الانتهاء من فحوصات أو إجراءت طبية تخصك؛ و ذلك لاستخدامه في الأبحاث الطبية ؟ مثل:

أ. دم
ب. بول
ج. لعاب
د. أنسجة، بما في ذلك أنسجة سرطانية

1= نعم
2 = لا

أسئلة للتحقق:
أ)هل يمكن ان تعيد السؤال بكلمات من عندك؟
ب) لماذا توافق/لا توافق على ذلك ؟
ج) هل كان من السهل أم الصعب الإجابة على هذا السؤال؟

إضافي في حالة التردد
د) لاحظت ترددك في الإجابة على السؤال، أخبرني بماذا تفكر؟

النتائج /الملاحظات

التعديل المقترح للسؤال

س9 : هل سبق لك أن سمعت بمصطلح البنك الحيوي أو المستودع الحيوي ؟
1= نعم
2= لا

أسئلة للتحقق:

أ)هل يمكن ان تعيد السؤال بكلمات من عندك؟
ب) كيف توصلت للإجابة ؟
ج) هل كان من السهل أم الصعب الإجابة على هذا السؤال؟

النتائج /الملاحظات

التعديل المقترح للسؤال

س10: إذا كنت تود معرفة المزيد عن البنك الحيوي، ما هي مصادر معلوماتاك التي تفضلها ؟
[ممكن أختيار 3 خيارات]
1=كتيبات أو نشرات
2=أفراد العائلة/ الأصدقاء / الجيران
3=العاملين الصحيين
4=الإنترنت
5=الصحف
6=الراديو
7=التلفزيون
8=محاضرات عامة
9=أخرى

أسئلة للتحقق:
أ)هل يمكن ان تعيد السؤال بكلمات من عندك؟
ب) كيف توصلت للإجابة ؟
ج) ماذا يعني لك مصطلح العامليين الصحيين ؟
د) هل ممكن ان تفكر في وسائل أخرى تفضلها و لم تذكر هنا؟

النتائج /الملاحظات

التعديل المقترح للسؤال

مقدمة البنك الحيوي

س11: باستخدام مقياس من 1-5 (باعتبار 1 غيرقيم إطلاقاً و 5 قيم للغاية)، في رأيك هل سيسهم البنك الحيوي ، كمشروع، في تحسين صحة المجتمع الإماراتي؟
المقياس:
1=غير قيم إطلاقا
2=غيرقيم
3=محايد
4=قيم
5=قيم للغاية

أسئلة للتحقق:

أ) ماذا يعني لك مصطلح البنك الحيوي؟
ب)هل يمكن ان تعيد السؤال بكلمات من عندك؟
ج) لماذا تعتقد ذلك؟

النتائج /الملاحظات

التعديل المقترح للسؤال

12 : إذا طلب منك المشاركة في البنك الحيوي المقترح إنشاؤه في العام المقبل (أي التبرع الطوعي بالعينات و المعلومات الصحية لاستخدامها في الأبحاث)؛ فإلى أي مدى يمكن أن تكون راغباً في المشاركة فيه ؟
1= بالتأكيد سأشارك
2= ربما سأشارك
3= ربما لن أشارك
4= بالتأكيد لن أشارك

أسئلة للتحقق:
أ)هل يمكن ان تعيد السؤال بكلمات من عندك؟
ب) ماذا تعني لك المشاركة بالبنك الحيوي؟
ج) هل هناك إجابة آخرى لم تذكر؟

النتائج /الملاحظات

التعديل المقترح للسؤال

س 13 : ما هي الأسباب الرئيسية التي شجعتك على إبداء الموافقة بالمشاركة في البنك الحيوي المقترح؟

الأجابة؟

-1

-2

-3

أسئلة للتحقق:

أ)هل يمكن ان تعيد السؤال بكلمات من عندك؟

ب) إذكر 3 أسباب رئيسية ؟

ب) هل كان من السهل أم الصعب الإجابة على هذا السؤال؟

النتائج /الملاحظات

التعديل المقترح للسؤال

س14. ما هي الأسباب الرئيسية أو العوائق التي قد تمنعك من المشاركة في البنك الحيوي المقترح؟

الأجابة؟

-1

-2

-3

أسئلة للتحقق:

أ)هل يمكن ان تعيد السؤال بكلمات من عندك؟

ب) إذكر 3 أسباب رئيسية ؟

ب) هل كان من السهل أم الصعب الإجابة على هذا السؤال؟

النتائج /الملاحظات

التعديل المقترح للسؤال

س 15: في اعتقادك ، هل من المحتمل أن يوافق أفراد عائلتك على المشاركة في البنك الحيوي المقترح؟

1= نعم

2= لا

أسئلة للتحقق:

أ) هل يمكن ان تعيد السؤال بكلمات من عندك؟

ب) كيف تحققت من ذلك ؟

النتائج /الملاحظات

التعديل المقترح للسؤال

س16 : إذا دُعيت للمشاركة في البنك الحيوي المقترح، فهل ستفضل اتخاذ القرار حول المشاركة .....

1= من تلقاء نفسك مباشرةً
2= بمساعدة أحد أفراد العائلة أو الأصدقاء
3= بمساعدة الطبيب أو العاملين الصحيين
4=بمساعدة موظف الاستقبال
5= بمساعدة أحد العاملين في البنك الحيوي.
6=أخرون[يرجى التحديد]

أسئلة للتحقق:

أ)هل يمكن ان تعيد السؤال بكلمات من عندك؟
ب) كيف توصلت للإجابة ؟
ج) هل ممكن ان تفكر في أشخاص أخرون لهم تأثير في إتخاذ قرارك؟

النتائج /الملاحظات

التعديل المقترح للسؤال

هناك طريقتان للحصول على إذنك بالمشاركة في البنك الحيوي ، هما:

الموافقة الصريحة ، وهي تعني أن يتم الاستئذان منك على وجه التحديد و توقيع استمارة للموافقة على ما إذا كنت ترغب في إيداع العينات (المتبقية بعد فحص 'وقاية') والمعلومات الصحية الخاصة بك في البنك الحيوي.

عدم التصريح بالموافقة مما يعني **افتراض** عدم ممانعتك في إيداع العينات (المتبقية بعد فحص 'وقاية') والمعلومات الخاصة بك في البنك الحيوي **ما لم يُذكرعكس ذلك تحديداً**. وعليه سيُطلب منك توقيع استمارة فقط في حالة عدم موافقتك على إيداع العينات و المعلومات في البنك الحيوي.

س 17 أ: أي من الطريقتين السالفتيْ الذكر لأخذ الموافقة على المشاركة في البنك الحيوي تفضلها إذا اقتضى الأمر؟

1= الموافقة الصريحة
2= عدم التصريح بالموافقة
3= لا تفضيل
4= لا شيء مما سبق
5= أخرى **[يُرجى التحديد]**_____

أسئلة للتحقق:

أ) هل كان من السهل أم الصعب الإجابة على هذا السؤال؟
ب) ماذا يعني لك مصطلح **الموافقة الصريحة** ؟
ج) ماذا يعني لك مصطلح **أستبعاد الموافقة؟**
د) هل كان من المفيد لك في اجابتك، قراءة الفقرة السابقة للسؤال ؟

النتائج /الملاحظات

التعديل المقترح للسؤال

المؤسسات التي تقوم بالأبحاث الطبية تعمل بشكل فردي، أو في الغالب بالتعاون مع بعضها لإجراء أبحاث واسعة النطاق
س 18: هل تأيد أن تقوم المؤسسات التالية ..... بأبحاث البنك الحيوي المعتمدة؟ س 18: هناك العديد من المؤسسات التي تقوم بالأبحاث الطبية. هذه المؤسسات تعمل بشكل فردي، أو في الغالب بالتعاون المشترك مع بعضها البعض لإجراء أبحاث واسعة النطاق. هل تؤيد أن تقوم المؤسسات التالية..... بأبحاث البنك الحيوي؟

أ. المستشفيات الحكومية
ب. المستشفيات الخاصة
ج. مؤسسات أكاديمية (تعليمية)/ مؤسسات للأبحاث الطبية
د. شركات الأدوية أو المعدات التشخيصية
ه. مؤسسات بحثية خارج دولة الإمارات العربية المتحدة

1= نعم
2= لا

أسئلة للتحقق:
أ)هل يمكن ان تعيد السؤال بكلمات من عندك؟
ب) ماذا يعني لك مصطلح شركات المعدات التشخصية؟
ج) هل شكلت الفقرة الأولى أي فرق في فهمك للسؤال؟ هل السؤال ,واضح من دونها؟
د) كان من السهل أم الصعب الإجابة على هذا السؤال؟

النتائج /الملاحظات

التعديل المقترح للسؤال

19: يخزن البنك الحيوي العينات والمعلومات الصحية بطريقة غير معرفة. ومع ذلك، في بعض الأحيان قد يتطلب الأمر إعادة تعريف العينات والمعلومات الصحية للاتصال بالمشاركين، وغالباً ما تكون معاودة الأتصال محدودة و مراقَبة من البنك الحيوي. وعلى فرض أن تكون قد وافقت على المشاركة في البنك الحيوي فهل ستقبل معاودة الاتصال بك لاحقاً لأجل....
أ. طلب المزيد من المعلومات الصحية (من خلال تعبئة استبانة إضافية)
ب.عمل فحوصات إضافية
ج. لإعطائك نتائج ما وجد الباحثون في العينة الخاصة بك، في حال كون هذه المعلومات قابلة للاستفادة منها في الوقاية أو علاج حالة تعاني منها أو قد تكون عرضة للإصابة بها مستقبلاً.
د. لإعطائك نتائج ما وجد الباحثون في العينة الخاصة بك، بغض النظر عن كون هذه المعلومات هامة أو قابلة للاستفادة منها في الوقاية أو علاج حالة تعاني منها أو قد تُصاب بها مستقبلاً.

1= نعم، أقبل
2= لا، غير مقبول

أسئلة للتحقق:
أ) كيف تأكدت من ذلك؟
ب) هل تعرف ما هو نوع من المعلومات قد يجد الباحث ؟
ج) هل شكلت الفقرة الأولى أي فرق في فهمك للسؤال؟ هل السؤال ,واضح من دونها؟

النتائج /الملاحظات

التعديل المقترح للسؤال

لكل نعم في س 19، أسال س 20]

س 20: في رأيك، من سيكون أفضل شخص لتولي إعادة الاتصال بك ؟
1= الطبيب أو أحد العاملين الصحيين
2=عامل في البنك الحيوي،
2= الباحث
3=لا يوجد تفضيل /كلاهما مقبول ،
4= شخص آخر؟

أسئلة للتحقق:

أ)هل يمكن ان تعيد السؤال بكلمات من عندك؟
ب) كيف توصلت للإجابة ؟
ج) هل كان من السهل أم الصعب الإجابة على هذا السؤال؟

النتائج /الملاحظات

التعديل المقترح للسؤال

س 21: قد يكون مثيرًا للاهتمام لدى بعض الناس أن يتعرفوا على أنواع الأبحاث التي تجرى في البنك الحيوي. برأيك، ما هي أفضل طريقة للحصول على المعلومات العامة عن الأبحاث الطبية؛ بما في ذلك الأبحاث عن حالة معينة قد يتم فيها استخدام عيناتك ؟

1= الموقع الإلكتروني
2= رسائل نصية قصيرة
3= نشرة إخبارية دورية
4= البريد الإلكتروني
5= طريقة آخرى (يرجى التحديد)
6= غير مهتم لتلقي المعلومات

أسئلة للتحقق:

أ)هل يمكن ان تعيد السؤال بكلمات من عندك؟
ب) هل ممكن ان تفكر في وسائل أخرى للتواصل ، لم تذكر هنا؟

النتائج /الملاحظات

التعديل المقترح للسؤال

س 22: بشكل عام، كيف تصف تجربتك مع نظام الرعاية الصحية في إمارة أبوظبي؟

1= إيجابية غالباً
2= سلبية غالبا
3= لا يمكن/ لا أرغب في اتخاذ موقف محدد

أسئلة للتحقق:

أ)هل يمكن ان تعيد السؤال بكلمات من عندك؟
ب) لماذا تعتقد ذلك ؟
ج) ماذا يعني إيجابية/ سلبية غالبا لبالنسبة لك؟

النتائج /الملاحظات

التعديل المقترح للسؤال

س 23: هل تثق في قدرة هيئة الصحة-أبوظبي على قياس وتقييم مخاطر وفوائد مبادرة البنك الحيوي للمجتمع الإماراتي؟

1= نعم
2= لا

أسئلة للتحقق:

أ)هل يمكن ان تعيد السؤال بكلمات من عندك؟
ب) كيف توصلت الى ذلك

النتائج /الملاحظات

التعديل المقترح للسؤال

س 24: هل سبق و أن تم تشخيصك بمرض مزمن أو إعاقة ، تستدعي الرعاية الطبية المستمرة أو المراجعة الطبية المتكررة (مثلاً: السكري، أمراض القلب ، الربو، السرطان ، أمراض وراثية، تشوهات خلقية)؟

1= نعم
2= لا

أسئلة للتحقق:

أ)هل يمكن ان تعيد السؤال بكلمات من عندك؟
ب) ماذا يعني لك مصطلح مرض مزمن؟

النتائج /الملاحظات

التعديل المقترح للسؤال

س25: هل سبق أن تم تشخيص أحد أفراد عائلتك بمرض مزمن أو إعاقة ؟

1= نعم
2= لا

أسئلة للتحقق:

أ) هل يمكن ان تعيد السؤال بكلمات من عندك؟
ب) كيف تتذكر ذلك؟
ج) هل كان من السهل أم الصعب الإجابة على هذا السؤال؟

النتائج /الملاحظات

التعديل المقترح للسؤال

Q1: Have you ever donated blood?

1 = Yes
2 = No

2. Probes
a) how do you remember this ?
b) what does the term donation mean to you?
c) was is easy or hard to answer this question?

3. Results

4. **Suggested revision**

Q2: **Have you ever participated in medical research? (e.g. donated blood or tissue for research, took part in a clinical trial such as a trial testing an experimental treatment or vaccine)?**

1 = Yes
2 = No

2. Probes
a) Can you repeat the question in your own words?
b) what does medical research?
c) how do you remember this?

3. Results

4. **Suggested revision**

Q3: Have any of your family members or friends taken part in medical research?

1 = Yes
2 = No

2. Probes
a) can you repeat the question in your own words?
b) how do you remember this?
c) was is easy or hard to answer this question?

3. Results

4. **Suggested revision**

Q4: **How would you describe your own level of knowledge about medical research that involves the use of human tissue samples?**

1=No knowledge
2=Some knowledge
3= Good knowledge

2. Probes
a) what does the term human tissue sample mean to you?
b)can you repeat the question in your own words?
c) how did you arrive to the answer?

3. Results

4. **Suggested revision**

Q5: **Genes are part of DNA that is stored in the cells' nucleus; and carry the hereditary information passed from parents to children. How much do you know about the relationship between human genes and health?**

1=No knowledge
2=Some knowledge
3=Good knowledge

2. Probes
a) what does human tissue sample mean to you?
b)can you repeat the question in your own words?
c) how did you arrive to the answer?

3. Results

4. **Suggested revision**

Medical research on human samples like blood, saliva, urine and tissues, can help to improve our understanding of what keeps us healthy. Also it can lead to the development of new tests to diagnose certain diseases or to improved treatments. Many of the tests and treatments used **today** resulted from people donating samples for research **previously**.

Q6: **Do you believe that medical research, on human samples, leads to improvements in patients' outcomes?**

1 = Yes
2 = No

2. Probes
a) how can medical research on human sample be useful?
b) can you repeat the question in your own words?
c) why do you believe?

3. Results

4. **Suggested revision**

Q7: **On a scale of 1 to 5 with (1 being Extremely unimportant and 5 being Extremely important, how important you think it is for people to donate samples for medical research?**

SCALE:

1=Extremely unimportant
2=Unimportant
3=Neutral
4= Important
5=Extremely important

2. Probes

a) can you repeat the question in your own words?
b) why you think this?
ذ) was the scale from 1-5 easy to use? what does scale 3 means to you?

3. Results

4. **Suggested revision**

Q 8: Would you agree to donate the following types of samples ..... for medical research, if they were part (leftover) of necessary medical tests or procedures?

a. blood
b. saliva
c. urine
d. tissue ; including cancerous tissue

1 = Yes
2 = No

2. Probes

a) can you repeat the question in your own words?
b) why would you agree/disagree?
c) was is easy or hard to answer this question?

3. Results

4. **Suggested revision**

Q9: Have you ever heard the terms biobank or biorepository?

1 = Yes

2 = No

2. Probes

a) can you repeat the question in your own words?
b) how did arrive to this?
c) was is easy or hard to answer this question?

3. Results

4. **Suggested revision**

Q 10: If you want to learn more about the biobank, please select the sources of information that you prefer to use.

[SELECT UP TO 3]

1=Booklets/ brochures
2=Family members / friends / neighbors
3=Healthcare providers
4=Internet
5=Newspapers
6=Radio
7=TV
8=Public seminars
9=Other_____

2. Probes
a) can you repeat the question in your own words?
b) how did arrive to this?
c) what does the term healthcare providers means to you?d) can you think of other preferred sources, not mentioned here?

3. Results

4. **Suggested revision**

Paragraph on biobank

Q11: Using a scale of 1 to 5 (1 being Extremely invaluable and 5 Extremely valuable), how valuable you do think, the biobank is as a resource, to improve the health of Emiratis?
SCALE:

1=Extremely invaluable
2= Invaluable
3=Neutral
4=Valuable
5=Extremely valuable

2. Probes
a) what does the term biobank mean to you

b) can you repeat the question in your own words?
c) why you think this?

3. Results

4. **Suggested revision**

Q12: If you were asked to participate in the proposed biobank, in the next year, by voluntarily donating samples and health information for research, how likely would you be willing to participate?

1= Definitely would participate
2= Probably would participate
3= Probably would not participate
4= Definitely would not participate

2. Probes
a) can you repeat the question in your own words?
b)what does your participation in the biobank involve?
c) have you thought of other response?

3. Results

4. **Suggested revision**

Q13. What are the main reasons for you to consider participating in the proposed biobank?

2. Probes
a) can you repeat the question in your own words?
b) mention 3 most important reasons
c) was is easy or hard to answer this question?

Response:
1-
2-
3-

Other Results

4. **Suggested revision**

Q14. What are the main reasons that you would <u>NOT</u> encourage you to consider participating in the proposed biobank?

2. Probes

a) can you repeat the question in your own words?
b) mention 3 most important reasons
c) was is easy or hard to answer this question?

Response:
1-
2-
3-

Other Results

4. **Suggested revision**

Q 15: Do you think that some of your family members would agree to participate in the proposed biobank?

1 = Yes
2 = No

2. Probes
a) can you repeat the question in your own words?
b) how sure are you about that?

3. Results

4. **Suggested revision**

Q16: **If you were invited to participate in the proposed biobank, would you prefer making the decision to participate.....**

1=Entirely by yourself,
2=With help from a family member or a friend
3=With help from your doctor or health care provider
4= With the clerk at the check in
5=With help from someone at the biobank, or
6=Others

2. Probes
a) can you repeat the question in your own words?
b) how did arrive to this?
c) can you think of other people how may influence your decision?

3. Results

4. **Suggested revision**

There are different approaches to how we can ask for your permission to include otherwise discarded blood or urine sample and health information in the biobank. These are :

Opt-in means that you will be asked **specifically** for your permission and sign a form, if you want your leftover samples and health information to be deposited in the biobank.
Opt-out means that it is assumed that you have no objection, to deposit your leftover samples and health information in the biobank, unless you **specifically** say otherwise. In that case, you would be asked to sign a form only if you DO NOT want your samples and health information included in the biobank.
Q17: Of these two approaches, to include samples and health information in the biobank, which, if any, do you prefer? [REVIEW OPTIONS IF NECESSARY]

1=Opt-in
2=Opt-out
3=No preference
4=None of the above
5=Other [SPECIFY

2. Probes
a) was is easy or hard to answer this question?
b) what does the term opt in mean to you
c) what does the term opt out mean to you?
d) was it useful for you to answer to read out the paragraph?

3. Results

4. **Suggested revision**

Research organizations work individually, and often in-collaboration to carry out large scale research.

Q18: Would you agree to allow the following organizations..... to carry out the approved biobank research?

a) Public hospitals
b) Private hospitals
c) Academic Institutions or Medical Research Organizations
d) Pharmaceutical or Diagnostic companies
e) Research organizations outside the UAE

Scale:
1=yes
2=No

2. Probes
a) can you repeat the question in your own words?
b) what the term diagnostic companies mean to you
c) Did the first sentence improve your understanding to Q ? or the Q is clear even without it?
d) was is easy or hard to answer this question?

3. Results

4. **Suggested revision**

(Biobanks store samples and health information in unidentified status. However, in some condition, it might be necessary for identifying information to be re-linked for the purpose of re-contacting participants. This is usually monitored by the biobank and are limited. Now, imagine that you have agreed to participate in the biobank.)

Q 19: Would it be acceptable for you to be contacted, in the future, in order to.....

a. Ask you for new information (complete additional questionnaire)
b. Ask you for additional assessments tests
c. Contact you and give you information about what researchers found from your sample if the information could be used to prevent or treat a condition that you have or could be at risk to develop.
d. Contact you and give you information about what researchers found from your sample regardless of whether or not the information could be used to prevent or treat a condition that you have or could be at risk to develop.

Response:
1= Yes, acceptable
2=No, not acceptable

2. Probes
a) how sure you are about this?
b) do you understand what type of information the researcher might find?
c) Did the first sentence improve your understanding to Q ? or the Q is clear even without it?

3. Results

4. **Suggested revision**

[FOR EACH 'YES' TO 19a-d, ASK 20]
Q20: Who would be the best person to establish initial re-contact with you?
1= Your physician or healthcare provider
2= A member of the biobank staff,
3=The researcher
4=You have no preference,
5=Or someone else?

2. Probes

a) can you repeat the question in your own words?
b) how did arrive to this?
c) was is easy or hard to answer this question?

3. Results

4. **Suggested revision**

Q21: How would you like to get general information on medical research including research on a particular condition that might use your sample?

1=Website
2= SMS
3= Newsletter
4= Email
5=Others (please specify) _____
6=Would not be interested in additional information

2. Probes
a) can you repeat the question in your own words?
b) can you think of other communication channels, not mentioned here?

3. Results

4. **Suggested revision**

Q 22: **Generally, how would you describe your experience with healthcare system in the Emirate of Abu Dhabi?**

1=Mostly positive
2=Mostly negative
3=Cannot/do not want to take a definite position

2. Probes
a) can you repeat the question in your own words?
b) why do you think that?
c) what does mostly positive/negative mean to you?

3. Results

4. **Suggested revision**

Q 23: Do you trust Health Authority Abu Dhabi's ability to assess the risks and benefits of the biobank initiative, to the Emirati population?

1 = Yes
2 = No

2. Probes
a) can you repeat the question in your own words?
b)how sure you are about that?

3. Results

4. **Suggested revision**

Q24: Have you ever been affected (or diagnosed) by a long-standing illness or disability

which required continuous or frequent medical attention (e.g. diabetes, heart disease, asthma, cancer, a genetic condition, congenital anomalies)?

1 = Yes
2 = No

2. Probes
a) can you repeat the question in your own words?
b) what does the term long standing illness or disability mean to you?

3. Results

4. **Suggested revision**

Q25: Has a close family member ever been affected by a long-standing illness or disability?

1 = Yes
2 = No

2. Probes
a) can you repeat the question in your own words?
b) how do you remember this?
c) was is easy or hard to answer this question?

3. Results

4. **Suggested revision**

Appendix V: Volunteer List and Supporting Materials

List of Volunteers

	Name	University
1	Noura Salem Mohammed	UAE University
2	Moyassar Al Tatari	UAE University
3	Rawand Mazen Jean	UAE University
4	AlYazia Aziz AlAzeezi	UAE University
5	Baraa Ibrahim Mohamed	UAE University
6	Sheikha Humaid Al Ameri	UAE University
7	Alia Sulaiman AlAnsari	UAE University
8	Sara Ali Saeed Alhadrami	UAE University
9	Aysha Khaled Al Marzooqi	UAE University
10	Maryam Abdulla Al Aghbari	UAE University
11	Aysha Khaled Al Marzooqi	UAE University
12	Tahani Ahmed Al Saadi	UAE University
13	Nujood Ahmed Al Zaabi	UAE University
14	Eman Abdulrazaq Al Bastaki	UAE University
15	Batool Abbas Al balooshi	UAE University
16	Hind Obaid Al Mukhattin	UAE University
17	Alaa MAl Tawil	Abu Dhabi University
18	Aya Yousef Ismail	Abu Dhabi University
19	Aya Nizar Khatab	Abu Dhabi University
20	Maram Sami Hijjah	Abu Dhabi University
21	Shereena Almehrizi	New York University Abu Dhabi
22	Dana AlHosani	New York University Abu Dhabi
27	Aisha AlHemeiri	New York University Abu Dhabi
28	Khuloo Saeed Alshemeili	Higher College of Technology-Intern
29	Jawaher Raed Al Haddad	Petroleum Institute
30	Razan Raed Al Haddad	Petroleum Institute
31	Alya Al Otiba	HAAD- NCD Department
32	Hamda Al Mansori	HAAD- NCD Department
33	Kaltham Al Obidly	HAAD- NCD Department
34	Shamma Al Mammari	Family Medicine Resident-Intern

Data Dictionary

المصطلحات المتكررة

هيئة الصحة أبوظبي	هي الجهة التنظيمية و التشريعية لقطاع الصحة في إمارة أبوظبي- **لا تقدم أي خدمات طبية**
فحص وقاية	فحص للمواطنين البالغين (18 سنة فما فوق) **فقط** ،للكشف المبكر عن عوامل الخطورة المسببة لأمراض القلب. يجرى كل 3 سنوات في المراكز و المستشفيات الحكومية و الخاصة.
الأبحاث الطبية	أبحاث تتم على عينات حيوية أو تجارب سريرية على سبيل المثال اختبار علاج تجريبي أو لقاح . و لا تشمل الدراسات الإستطلاعية عن الأراء أو المعرفة (الإجابة عن إستبيانات)
العينات الحيوية	بما فيها السوائل: كالدم واللعاب و البول و الأنسجة كالخلايا: البويضة، الحيوان المنوي، أو الأعضاء الجلد أو الدهون أو كلى و غيرها
البنك الحيوي	عبارة عن مستودع يخزن مجموعة كبيرة من العينات الحيوية والمعلومات الصحية المتبرع بها، لسنوات عديدة بهدف توفرها للأبحاث الطبية .
الجينات	الجينات (المورثات) هي جزء من الحمض النووي، الموجود في نواة الخلايا ، و تحمل معلومات وراثية تنتقل من الآباء إلى الأبناء
العاملين في المجال الصحي	أمثلة : التمريض، الصيادلة، فنين أشعة أو مختبر ، المسعفين
الخدمات الصحية	أي خدمات صحية في المراكز أو المستشفيات أو المختبرات – الحكومي و الخاص
الحالة الوظيفية- **قيد العمل**	قيد العمل تشمل: عمل كامل أو جزئي- خاص /حكومي- بأجر أو تطوعي- موظف أو صاحب مؤسسة
الحالة الوظيفية-**لا أعمل**	رجل أو سيدة في سن العمل **قادر على العمل** و لكنه متوقف أو عاطل الآن أو في انتظار عمل أو **غير قادر على العمل بسبب مرض أو إعاقة**
الحالة الوظيفية-**ربة منزل**	**تنطبق على السيدات فقط** : أعمال منزلية-تربية أطفالها وغيرها سيدة لم ترغب او تتقدم لطلب العمل مطلقا أو لم تعمل سابقا
الحالة الوظيفية-**متقاعد**	**عمل سابقا ووصل الى سن التقاعد**
مرض مزمن	مرض يستدعي **تناول الأدوية الدائم أو الرعاية الطبية المستمرة** (مثل: السكري، أمراض القلب ، الربو، السرطان، الروماتيزم، الثلاسيميا، إلتهاب المفاصل، الإكتئاب ، الخرف، أمراض وراثية أوغيرها من الأمراض)
دخل الأسرة الشهري	الدخل الشهري للإسرة: يتضمن مجموع الرواتب و الإيرادات و دخول الأيجارات في الشهر **الأسرة التي يعيش معها حالياً**، سواء كانت خاصة(nuclear) أو جماعية (extended)

Knowledge and Attitudes and Perspective of Abu Dhabi's National Population towards Biobanking

Prepared by: Rana Luqman
Afrah Al Jaberi
Non-Communicable Disease – PHR - HAAD

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Appendix VI: Consent Form

2015 | دراسة عن مستوى المعرفة والتوجهات حول البنك الحيوي

استمارة موافقة

[إسم المشارك:_____. رمز التعريف الخاص بالمشارك_____]

السلام عليكم ، اسمي **[أذكر اسمك]** ، باحث من كلية الطب بجامعة الإمارات و أعمل على دراسة تقوم بها هيئة الصحة– أبوظبي.

هل لديك عدة دقائق لعرض هذه الدراسة ؟

- نعم. **[أكمل]**
- **لا**. و لكن هناك رغبة للمشاركة في وقت لاحق.**[سجل الوقت** :_____**و التاريخ**_____**]**
- **لا [أشكر المشارك]**

أخترنا رقم هاتفك عشوائياً من ضمن قائمة المواطنين الذين أكملوا فحص وقاية في المراكز الصحية.

هذه الدراسة هامة و تهدف إلى التعرف على آراء المواطنين تجاه الأبحاث الطبية. رأيك كفرد مهم و يسهم في التخطيط للخدمات الصحية في الإمارة.

المشاركة في هذا الإستبيان أختيارية و سرية ، ويستغرق الإستبيان حوالي 10 دقائق. يمكنك الرفض على الإجابة على أي سؤال أو إنهاء المشاركة في أي وقت.

هل توافق على المشاركة في هذه الدراسة؟

☐ نعم. **[وثق الموافقة الشفهية أدناه و أكمل الإستبانة]**

☐ **لا. [أشكر المشارك على إعطائك الوقت]**

الباحث الحاصل على الموافقة

لقد قرأت هذا النموذج للمشارك . وقدمت شرحاً عن البحث و الرد على الأسئلة بشكل يرضي المشارك. في رأيي، قد أثبت المشارك فهم للمعلومات المقدمة. وقد حصلت على موافقة شفهية للمشاركة في هذه الدراسة.

إسم الباحث:_____

التوقيع_____التاريخ_____

VERBAL CONSENT FORM

[Participant Name: _____, Percipient code number_____]

Hello, my name is **[Your Name]**; I am a researcher from UAE University working on a study conducted by the Health Authority Abu Dhabi (HAAD).

Do you have few minutes to discuss the study?

- **Yes**. [Continue]
- **No,** but interested to participate in another time. [Record Time: _____, Date_____]
- No. [Thank him/her for their time]

Your mobile phone number was called from a random sample of nationals who have undergone Weqaya screening test..

This study is important and is currently being conducted to learn about Emiratis views of regarding biomedical . Your opinion is valuable to HAAD and will guide planning and monitoring healthcare initiatives in the Emirate of Abu Dhabi.

Participation in this survey is voluntary and strictly confidential. This survey should take no longer than 10 minutes. You may choose to not answer any question or withdraw at any time, without any consequences.

Do you agree to participate in this study?

☐ Yes. **[Document oral consent below and continue with the interview. Inform subject that they will receive an information sheet regarding the study for their records via email.]**

☐ No. **[Thank him/her for their time].**

Name of Subject:

Person Obtaining Consent

I have read this form to the subject. An explanation of the research was provided and questions were answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension to the information. The subject has provided oral consent to participate in this study.

Name and Title (Print)_____

Signature of Person Obtaining Consent _____Date_____

Appendix VII: Participant Information Form

2015 | دراسة عن مستوى المعرفة والتوجهات حول البنك الحيوي

استمارة معلومات للمشارك

عزيزي المشارك

تقوم هيئة الصحة–أبوظبي بالتعاون مع كلية الطب بجامعة الإمارات في عمل دراسة عن مستوى المعرفة والتوجهات تجاه البنك الحيوي.تهدف الدراسة إلى التعرف على آراء المواطنين تجاه الأبحاث الطبية و مبادرة البنك الحيوي ، وذلك من أجل تحسين صحة المجتمع الإماراتي . رأيك كفرد في المجتمع في غاية الأهمية لهيئة الصحة بأبوظبي و سوف يساعد في التخطيط للخدمات الصحية في إمارة أبوظبي.

تم إختيار رقم هاتفك من ضمن عينة عشوائية من المواطنين الذين أكملوا فحص وقاية في المراكز الصحية ، في إمارة أبوظبي، في الفترة ما بين 2012–2014.

المشاركة في هذه الدراسة أختيارية و سرية. الإستبانة عبارة عن28 سؤال و يستغرق إكمالها حوالي 10 دقيقة . يمكن الرفض على الإجابة على أي سؤال أو إنهاء المشاركة في أي وقت.

لا توجد فوائد مباشرة أو مخاطر من المشاركة في هذا الإستبانة.

تمت الموافقة على هذه الدراسة من قبل هيئة الصحة و لجنة البحث العلمي الأخلاقية لمنطقة العين الطبية (مستشفى توام).

لمزيد من المعلومات أو في حال رغبتك في الحصول على نتائج الدراسة بعد انتهائها ، يمكنك التواصل مع الباحث الرئيسي للدراسة:

د. جلاء طاهر– مدير إدارة الأمراض غير السارية –قطاع الصحة العامة.هاتف مباشر: 02-5048816،

البريد اللأكتروني: jtaher@haad.ae.

شكرا للمشاركة في هذه الدراسة، رأيكم يهمنا.

و تفضلوا بقبول فائق الأحترام،،،

د. جلاء طاهر

مدير إدارة الأمراض غير السارية

دائرة الصحة العامة–هيئة الصحة أبوظبي

PARTICIPANT INFORMATION SHEET

Dear Participant

The non-Communicable Disease Department, Health Authority Abu Dhabi (HAAD); in collaboration with Medical Collage, UAEU University is conducting a research named "Abu Dhabi Biobank: Knowledge and Attitudes Study.

This study is conducted to learn about the views of the UAE Nationals' regarding, the storage and use of biological samples for medical research to improve the health of the population. Your opinion is valuable to HAAD and will guide planning and monitoring healthcare initiatives in the Emirate of Abu Dhabi.

Your mobile phone number was called from a random sample of nationals who have undergone Weqaya screening test, between 2012 and 2014.

This survey consists of 30 questions which should take no longer than 10-15 minutes.

The answers you provide are strictly confidential and you may choose to not answer any one question at any time, you just need to let me know and we will move forward. If at any time you need to stop and continue at another time, do let me know and we can re-schedule. You are also free to withdraw at any time, without any consequences.

Your name will not be attached to the answers you provide, so your confidentiality is protected. There are no direct benefits from participating in this study and risks are similar to those typically encountered in your day to day life.

The study is reviewed and approved by HAAD and Al Ain Medical District Human Research Ethics Committee **(AAMDHREC)**

Thanks for your taking part in this study. Your participation is valuable to HAAD

For more information on this study or to receive a summary of result at the end of study, you may contact the Research lead at HAAD: Dr Jala Taher, telephone number: 02-5048816, e-mail: jtaher@haad.ae

Yours sincerely;

Dr Jala Taher
Non-Communicable Disease Department
Public Health & Research Division- HAAD

Appendix VIII: Volunteers Thank You Letter

جامعة الإمارات العربية المتحدة
United Arab Emirates University

UAEU College of Medicine and Health Sciences

Institute of Public Health
PO Box 17666, Al Ain, United Arab Emirates
Tel: +971 3 713 7559 Fax: +971 3 767 2022

28/3/2016

Noura Salem Nasser
UAE University

Letter of Appreciation

Dear Noura

On behalf of the research team, we would like to personally thank you for your recent contribution of time and effort in collecting data for the "Knowledge and Attitudes Towards Abu Dhabi Biobank" research.

This would not have been a success without your help and that of your fellow volunteers from other universities.

You have done some great work during the past few months. I hope that it was a rewarding research experience and will add value to your academic and career development.

Once again, the research team thanks you for your effort and contribution.

Yours sincerely,

Dr Jala Taher
Manager, Non-Communicable Disease Department
HAAD
Primary Investigator

Dr Iain Blair
Chairman, Institute of Public Health College of Medicine
UAEU
Co-Investigator

Appendix IX: IRB Approval

UAEU College of Medicine and Health Sciences

جامعة الإمارات العربية المتحدة
United Arab Emirates University

15th February 2015

Dr. Jala Asaad Taher
Dept. Manager
Public Health & Research Division
Health Authority
Abu Dhabi, UAE

Dear Dr. Jala,

Re: Al Ain Medical District Human Research Ethics Committee - Protocol No. 15/05 - Knowledge and Attitudes of Abu Dhabi's National Population towards Biobanking. Policy Implications.

Thank you very much for submitting your application to the Ethics Committee.

Your submitted documents were reviewed by the committee and I am pleased to provide you ethical approval of your project.

May I reiterate, should there be any ethical concern arising from the study in due course the Committee should be informed.

Annual reports plus a terminal report are necessary and the Committee would appreciate receiving copies of abstracts and publications should they arise.

I wish to take this opportunity to wish you success with this important study.

This Ethics Committee is an approved organization of Federal Wide Assurance (FWA) and compliant with ICH/GCP standards.

With kind regards,

Yours sincerely,

Dr. Fawaz Torab
Chair, Al Ain Medical District Human Research Ethics Committee

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هاتف 2000 767 3 971+ فاكس 2001 767 3 971+
www.cmhs.uaeu.ac.ae

Appendix X: Student CV

DR. JALA ASSAD TAHER
P.O. BOX - 132828, ABU DHABI
UNITED ARAB EMIRATES.
MOBILE +97150 2198800
jtaher1@jhu.edu
jtaher@haad.ae

CURRICULUM VITAE

PRESENT POST: MANAGER, NON-COMMUNICABLE DISEASE DEPARTMENT (NCD), PUBLIC HEALTH DIVISION, HEALTH AUTHORITY ABU DHABI.

ACADEMIC QUALIFICATIONS:

- DR- PH HEALTHCARE LEADERSHIP & MANAGEMENT, JOHN HOPKINS, BALTIMORE- THESIS SUBMITTED
- MPH HEALTHCARE LEADERSHIP & MANAGEMENT, JOHN HOPKINS, BALTIMORE- 2011
- MSC MOTHER & CHILD HEALTH, INSTITUTE OF CHILD HEALTH, UNIVERSITY COLLEGE OF LONDON, UNITED KINGDOM- 2000
- MBBS- COLLEGE OF MEDICINE & MEDICAL SCIENCES, KING FAISAL UNIVERSITY, SAUDI ARABIA- 1993

PROFESSIONAL WORK EXPERIENCE

A. MANAGER, NON-COMMUNICABLE DISEASE DEPARTMENT	PUBLIC HEALTH AND RESEARCH DIVISION, HEALTH AUTHORITY ABU DHABI. JUNE 2013- SEPTEMBER 2013
HEAD, CANCER CONTROL & PREVENTION	PUBLIC HEALTH AND POLICIES HEALTH AUTHORITY ABU DHABI. NOVEMBER 2010- JUNE 2013
SENIOR PROGRAM MANAGER	GLOBAL INITIATIVE FOR BREAST CANCER AWARENESS IN PARTNERSHIP WITH SUSAN G KOMEN AND INSTITUTE OF INTERNATIONAL EDUCATION, SAN FRANCISCO PUBLIC HEALTH PROGRAMS, HEALTH AUTHORITY ABU DHABI. MARCH 2008- OCTOBER 2010
BREAST CLINICIAN & FIRST READER FOR SCREENING MAMMOGRAMS	HEALTH SCREENING PROGRAM FOR WOMEN & CHILDREN- MINISTRY OF HEALTH NATIONAL BREAST CANCER SCREENING PROGRAM NATIONAL BREAST CANCER SCREENING PROGRAM JANUARY 2000 – MARCH 2008
SENIOR HOUSE OFFICER- GENERAL SURGERY:	AL JAZEIRA & CENTRAL HOSPITALS MINISTRY OF HEALTH DECEMBER 1994 – SEPTEMBER 1999
INTERNSHIP	AL JAZEIRA, CENTRAL AND MAFRAQ HOSPITALS MINISTRY OF HEALTH OCTOBER 1993- DECEMBER 1994

MAJOR ACHIEVEMENTS

1. PLAN, IMPLEMENT AND EVALUATE VARIOUS PUBLIC HEALTH PROGRAMS.
2. DEVELOPED HAAD NCD CONTROL STRATEGY AND REVIWED NUMBER OF NATIONAL STRSTEGIES DEVELOPED A NUMBER OF POLICIES AND STANDARDS IN THE AREA OF CANCER CARE; SCREENING, DIAGNOSIS AND MANAGEMENT
3. ON NCD CONTROL, DRUG ADDICTION & REHABILITATION
4. ESTABLISHED THREE POPULATIONS –BASED CANCER SCREENING PROGRAMS AND THE h HPV VACCINATION CATCH UP PROGRAM , IN ABU DHABI
5. DESIGNED THE CANCER SURVEILLANCE SYSTEM TO ESTABLISH ABU DHABI CENTRAL CANCER REGISTRY
6. DESIGNED AND IMPLEMENTED VARIOUS INFORMATIONAL RESOURCES AND HEALTH PROMOTION CAMPAIGNS TO PROMOTE HEALTHY LIFESTYLE AND INCREASE CANCER SCREENING RATES
7. DESIGNED AND CONDUCTED SEVERAL CME CURRICULUM FOR HEALTHCARE PROFESSIONALS
8. LEAD HUGE ADVOCACY EFFORTS AND ESTABLISHED INTER-SECTORIAL COLLABORATION AMONG VARIOUS ORGANIZATION TO SUPPORT CANCER CONTROL
9. COLLABORATE IN A NUMBER OF RESEARCH AND PUBLICATION IN CANCER CARE

PUBLICATIONS:

1. PROSPECTS AND CHALLENGES IN THE INTRODUCTION OF HUMAN PAPILLOMAVIRUS VACCINES IN THE EXTENDED MIDDLE EAST AND NORTH AFRICA REGION. AISHA O JUMAAN, SOHA GHANEM, JALAA TAHER, MHAMMED BRAIKAT, SALAH AL AWAIDY, GHASSAN S DBAIBO. VACCINE (IMPACT FACTOR: 3.49). 12/2013; 31S6:G58-G64. DOI: 10.1016/J.VACCINE.2012.06.097. SOURCE: PUBMED

2. BARRIERS TO BREAST CANCER SCREENING AND TREATMENT AMONG WOMEN IN EMIRATE OF ABU DHABI. WALAA K SABIH, JALAA A TAHER, CAROL EL JABARI, COTHER HAJAT, SALIM M ADIB, OLIVER HARRISON. ETHNICITY & DISEASE (IMPACT FACTOR: 0.92). 01/2012; 22(2):148-54. SOURCE: PUBMED

3. THE CHANGING FACE OF FEMALE BREAST CANCER IN ABU DHABI AND THE UNITED ARAB EMIRATES: IMPLICATIONS FOR BREAST CANCER CONTROL STRATEGY. MPH CAPSTONE, JOHNS HOPKINS, 2011.

4. MATERNAL WORK AND PREGNANCY OUTCOME. MSC DISSERTATION UCL INSTITUTE OF CHILD HEALTH, (2000).
   HTTP://WWW.UCL.AC.UK/ICH/SERVICES/LIBRARY/RESOURCES/IGHDISSERTATIONS/GLOBALHEALTHTITLES

AWARDS:

- ABU DHABI AWARD FOR EXCELLENCE IN GOVERNMENT PERFORMANCE (ADAEP), 2015. RANKED #3 IN SPECIALIST FIELD
- RASHID AWARD FOR SCIENTIFC OUTSTANDING, 2001

MEMBERSHIP

- EMIRATE MEDICAL ASSOCIATION
- HONOROY MRMBERSHIP - MOAAZARA CANCER PATIENTS SUPPORT GROUP
- NUMBER OF LOCAL AND NATIONAL COMMITTEES FOR CANCER REGISTERATION, CANCER CONTROL, NCD CONTROL, DRUG ADDICTION & REHABILITATION

LANGUAGES:

ARABIC : MOTHER TONGUE
ENGLISH : GOOD WRITTEN & SPOKEN SKILLS

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NATIONALITY : UAE NATIONAL
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