PUBLIC PERSPECTIVES ON BIOBANKING IN NIGERIA

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MASTERS OF SCIENCE IN BIOETHICS

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ABSTRACT

Biological samples—such as tissues, blood and cells—are an increasingly important tool for research into human diseases and their genetic and physiological causes. To ease their storage and access, many of these samples are now stored in biobanks. Biobank has just been set up in Nigeria to collect samples for non-communicable diseases research and future researches.

This increased use of biobanking raises several ethical questions which have not been previously adequately explored in Nigeria. Against this backdrop, It became pertinent to get the perspectives of Nigerians on informed consent, confidentiality, secondary use of samples and data over time, return of results and feedback for non-communicable disease research and future research and specimens and data sharing with other biobanks. The use of this specimens and data was described in the consent form so that prospective participants can make informed decisions on how they wish to participate and how their body biological samples as well as data will be used in this research. The specific objectives are to assess Nigerians' public knowledge, attitude and willingness to participate in biobanking research in Nigeria; to explore the understanding of Nigerian public on modern informed consent and perception of the types of consent procedures that is required for biobanking research in Nigeria and the factors that influence it; to determine the public perspectives on secondary use of samples and data, access to medical records, attitude to sharing biospecimens with commercial and non commercial entities, return of result.

The principle of respect for persons would require that biobank policies be informed by the opinions of those for whom the guidelines are being established.

This is the first study on prospective research participation perspectives on the collection, storage and use of blood samples for biobank research in Nigeria which elicited the perspectives of a diverse group of individuals.

This study used qualitative research methods, and conducted 16 Focus Group Discussions and Key Informant Interviews with members of the general public, including people from major and minority ethnic groups, and from people of wide-ranging ages, socio-economic groups in Kano, Enugu, Oyo States and the FCT using topic guides and prompt statements that outline general issues on biobanking of biospecimens. The principle was to explore unprompted knowledge and understanding, then elicit response to facts spelled out in the prompt material. Purposive sampling method was used to select the key informant interview participants. It is often used in qualitative studies to identify groups of people with specific characteristics or circumstances. The purposive sample size was determined on the basis of theoretical saturation, when new data no longer bring additional insights to the research topic. The FGD participants were selected by contact persons in the states.

The results showed that majority of the participants had limited knowledge of biobanking research, but had good knowledge of non-communicable diseases and were willing to donate their specimens for it. A majority of the participants were however, not aware of the risks that may be associated with biobank research. Majority of the discussants supported giving broad consent for the use of their blood and tissue samples for the research. A few participants were particular on the proper observance of the country's law on material transfer agreement to protect their interest as specimens are shared with commercial and non commercial entities and would like a feedback of such collaborations.

The majority view of the participants is to be given general feedback and individual results even if something serious were discovered about their health. A few participants would want the biobank to specify the future uses of their samples as they entertained the fear that research that may be inimical to donors' religious beliefs and research into the production of biological weapon or strains of viruses that could be used to destroy human beings and for cloning or stem cells research may be carried out.

A few participants expressed concern on the possible loss of confidentiality, privacy and information and would like their anonymity. A large proportion of the respondents expressed their desire to let their spouses know before they participate, and those that were not married mentioned their parents, brothers, sisters and relations. A few participants would like to know the benefits or personal gains that will accrue to them from the biobank. They rarely want money in return, but care. Many view participation as a duty, as a chance to help. A few participants would like to get some clarification on ownership and commercial interests issues surrounding the biobank resources.

The overall lesson from this findings.

Respondents in this study demonstrated low levels of awareness of biobanking and its risks but were willing to give broad consent provided researchers were virtuous and did not use samples for morally objectionable research. Most also saw an important role for government, particularly in safeguarding their interest when samples are shipped and shared with commercial and non commercial entities.

KEYWORDS: Biobanking, Public perspectives, Nigeria.

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CERTIFICATION PAGE

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DEDICATION

This work is dedicated to the Almighty God

and

My family

GLOSSARY OF ABBREVIATIONS

CDBI - Canadian Design-Build Institute

DNA - Deoxyribonucleic acid

FCT - Federal Capital Territory

FGD - Focus Group Discussion

H3Africa - Human Heredity for Health in Africa

HIPAA - Health Insurance Portability and Accountability Act

ICGC - International Cancer Genome Consortium

IHVN - Institute of Human Virology, Nigeria

IRB - Institutional Review Board

KII - Key Informant Interview

MRC - Medical Research Council

NBAC - The US National Bioethics Advisory Commission

NCD - Non Communicable Disease

NCI - National Cancer Institute

NHGRI - National Human Genome Research Institute

NIH - National Institute of Health

PaCT - Partnership for Cohort Research and Training

RNA - Ribonucleic acid

UK - United Kingdom

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CHAPTER ONE

1.0 BACKGROUND TO THE RESEARCH

1.1 Background

Biological samples—such as tissues, blood and cells—are an increasingly important tool for research into human diseases and their genetic and physiological causes (Elger & Caplan, 2006). To ease their storage and access, many of these samples are now stored in biobanks. The number of human biological samples in such collections amounted to several hundred million in 1999 in the USA alone—about one sample per US citizen (Eiseman, 2000; Azarow et al., 2003)—and is increasing rapidly (Elger & Caplan, 2006).

The science of biobanking is rapidly changing the face and pace of biomedicine (Conference on Harmonising Biobank Research, 2009). Biobanks can support an unlimited number of future research studies and provide the vast amount of annotated data necessary to tease apart important contributors to complex diseases (Murphy et al., 2009).

Biobanks could help screen for serious but treatable diseases, feeding information into an efficient public health system where results could help individuals, physicians, and policymakers make more informed health decisions (Conference on Harmonising Biobank Research, 2009).

Typical research projects that make use of these biobanks will use DNA from blood or other tissues, data from the participants' present and future medical records, and data from screening questionnaires or physical and laboratory examinations. This is combined with information about lifestyle and environmental factors that can be regularly updated by sending participants new questionnaires (Elger & Caplan, 2006).

Biobanks compile health, environment, and lifestyle information and collect biological specimens from large numbers of individuals, who are often followed for long periods of time (Murphy et al., 2009).

1.2 Ethical problems

Ethical questions are different for prospective biobanks as compared with existing biobanks, which contain samples stored before the discussions on ethical issues started. A characteristic of most prospective biobanks is that samples and data are collected for long-term future use, not just for a single project. Typical examples are the UK Biobank and the Marshfield Clinic's Personalized Medicine Research Project in Wisconsin, USA, both of which are used to study gene–environment interactions (Elger & Caplan, 2006). The potential differences in Nigerian donor expectations and attitudes towards biobank research is unknown and there's obligation on researchers to respect the wishes of participants.

When establishing the collections of samples and related data, it is often impossible to anticipate what studies might emerge, which leaves the matter of participants' consent to such future studies very much in the air (Elger & Caplan, 2006). Indeed, a major ethical problem for prospective biobanks is how to assure participants' consent when it is not known what they are consenting to in terms of future research. The question of the importance and meaning of informed consent is one main reason why international guidelines on biobanks lack any consensus (Elger & Caplan, 2006).

Unlike clinical research, in which the risks primarily involve physical harm, the risks in biobank research are principally those that may follow from a loss of privacy (Ursin, 2008).

1.3 Consent for biobank research

Many biobanks ask participants to provide broad or ‘‘blanket’’ consent at enrolment (UK Biobank, 2009; NUgene Project, 2009; Kaiser, 2009). This approach has been adopted because requesting consent each time a research project seeks to obtain access to samples or information from a biobank poses financial and logistical barriers to researchers and may be overly burdensome to participants. According to the World Health Organization, ‘‘blanket informed consent - is the most efficient and economical approach, avoiding costly re-contact before each new research project’’ (World Health Organization, 2009).

1.4 Biobank guidelines

The creation of new biobanks and the expansion of existing repositories have spawned new guidelines. Some examples are guidelines from the UK Medical Research Council (MRC, 2001), the US National Bioethics Advisory Commission (NBAC, 1999a), the Council of Europe Committee of Ministers (COE, 2006), OHRP (2004) and the Australian National Health and Medical Research Council (1999).

Various scientific associations put together their own guidelines about DNA and tissue banking, and the Council for International Organizations of Medical Sciences, recognizing the importance of biobanks for epidemiological research, revised its guidelines to integrate relevant issues from the biobank debate (CIOMS, 2005). The United Nations Educational, Scientific and Cultural Organization (Paris, France) adopted the International Declaration on Human Genetic Data in October 2003 (UNESCO, 2003), and France, Germany, Canada and Switzerland have all issued their own guidelines for biobanks or genetic databases (CCNE, 2003; Nationaler Ethikrat, 2004; Commission de l’Éthique de la Science et de la Technologie, 2003; Schweizer Akademie der Medizinischen Wissenschaften, 2006).

These guidelines contain clearly divergent recommendations in important areas, which interfere with international collaboration. Not only do different systems exist for the collection of data and the processing of samples, but also the guidelines reflect fundamentally different ethical frameworks (Knoppers, 2005b).

1.5 Research problems

In Nigeria, a biobank and repository has just been set up at the Institute of Human Virology, Abuja Nigeria (IHVN) and will be depending on the available high-quality biospecimens from participants for non-communicable diseases research and for unknown future research projects. It is pertinent to get the perspectives of Nigerians on informed consent, confidentiality, secondary use of samples and data over time, return of results and feedback, specimens and data sharing for the collection of samples for the biobanking research for non-communicable disease research and future research.

Precedence suggest that these issues need to be given careful consideration in order to avoid past mistakes as seen in recent controversy surrounding the use of banked biological samples from the Havasupai tribe in Arizona by Arizona State University researchers (Mello & Wolf, 2010), of which tribal members who provided biospecimens for diabetes research sued the university and the researchers when they discovered that their biospecimens had also been used for schizophrenia and ancestry studies.

The existing guidelines and legal frameworks on informed consent, re-consent and when or whether to provide feedback of research results are marked by significant variations in the rules researches are supposed to follow (Bauer et al., 2004; Gassner, 2007; Gibbons, 2008; Kapp, 2006; Kaye, 2007), and the resulting difficulties for researchers engaged in international collaboration have prompted several attempts of harmonization (Cambon-Thomsen et al., 2007; Gibbons et al., 2007; Knoppers & Saginur, 2005; Knoppers et al., 2006). The principle of respect for persons would require that such policies be informed by the opinions of those for whom the guidelines are being established.

1.6 Research questions

1. What is the Nigerians' public knowledge and attitude and willingness to participate in biobanking research in Nigeria.
2. What is the understanding of Nigerian public on modern informed consent and perception of the types of consent procedures that is required for biobanking research in Nigeria and the factors that influence it?
3. What is the public perspectives on secondary use of samples and data, access to medical records, attitude to sharing biospecimens with commercial and non commercial entities, return of result?

1.7 Justification for the research

Modern non-communicable disease research require the collection of wide variety of biological samples from large number of people and banking these until they can be processed efficiently with new and emerging technologies (Salvaterra et al., 2008; Boyle & Levin, 2008).

Several reports exist on the perspective of Western populations on informed consent, confidentiality, secondary use of samples and data over time, return of results and feedback, specimens and data sharing for the collection of samples for the biobanking research for non-communicable disease research and future research. But, there is limited empirical research on the perspectives of individuals from developing countries towards biobanking (Wendler et al., 2005), including Nigeria.

The limited number of studies of attitude of the population to donation of samples to biobanks in developing country setting like Nigeria is the main justification for this study.

1.8 Aim of Study

The overall aim of this study is to assess public knowledge, attitude and perspectives on biobanking and on collection of human biological specimens for non-communicable disease research and future researches.

1.9 Objectives of the Research

1. To assess Nigerians' public knowledge, attitude and willingness to participate in biobanking research in Nigeria.
2. To explore the understanding of Nigerian public on modern informed consent and perception of the types of consent procedures that is required for biobanking research in Nigeria and the factors that influence it.
3. To determine the public perspectives on secondary use of samples and data, access to medical records, attitude to sharing biospecimens with commercial and non commercial entities, return of result.

1.10 Study Limitation

The number of participants of this study was relatively small. The reason for this was the time limit of the project since it is a research for the award of M.Sc. in Bioethics. The findings from this study are enlightening and useful, but should be treated as a snapshot of current opinion of Nigerian public on biobanking.

GLOSSARY

Beneficence - Doing good.

Bioethics - Ethics of biological research especially of medical techniques

Biobank - Biobanks are repositories that compile health, environment, and lifestyle information and collect biological specimens from large numbers of individuals, who are often followed for long periods of time.

Commercialization - To do, exploit, or make chiefly for financial gain.

Harm - Physical or psychological injury or damage.

Anonymization - A process that removes or replaces identity information from a communication or record.

Biomedical - Study life processes to gain an understanding of health and the methods for diagnosing, analysing and treating disease.

Clinician - A doctor or one who has direct access to a sick person.

Consent - Voluntary agreement

Culture - The custom, belief, art, way of life and social organization of a people

Focus group - It is a form of qualitative research in which a group of people are asked about their perceptions, opinions, beliefs and attitudes towards a study or work.

Interview - An interview is a conversation between two or more people (the interviewer and the interviewee) where questions are asked by the interviewer to obtain information.

Justice - to act or treat a person(s) or matter justly or fairly.

Fairness - free from favouritism, self-interest, or preference in judgment

Dissemination -the act of spreading widely

Key informant - A key informant interview is a loosely structured conversation with people who have specialized knowledge about the topic you wish to understand

Morality - The quality of being in accord with standards of right or good conduct.

Non-maleficence - Do no harm.

Obligation - A moral or legal requirement; duty

Participant - A person who takes part in something.

Respect - To feel or show deferential regard for; esteem.

Privacy - The state of being concealed; secrecy.

Risks - The possibility of suffering harm or loss; danger.

Property rights - the legal right of ownership.

Commodification - the inappropriate treatment of something as if it can be acquired or marketed like other commodities

Biotechnology - Refers to the use of microorganisms such as bacteria or biological substances such as enzymes, to perform industrial or manufacturing processes.

Benefit sharing - is the action of giving a portion of advantages/profits to others

Research - Can be defined as the search for knowledge, or as any systematic investigation, with an open mind, to establish novel facts, usually using a scientific method

Supervisor - A person who supervises workers or students on their work or project.

Trust - Firm reliance on the integrity, ability, or character of a person or thing.

Withdrawal - detachment, as from social or emotional involvement.

Stigmatization - the act of disapproving or condemning

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Definition of Biobanks

The term biobank is relatively new. It appeared in PubMed for the first time in 1996 (Loft & Poulsen, 1996) but was not used with any frequency until 2000. Although the term is used to describe various biological repositories, it originally referred to large population banks of human tissue and related data (Elger & Caplan, 2006).

Biobanks have become an essential part of modern biomedical research. They are repositories that link clinical and family history data with human tissues for medical research (Andrews, 2005). They enable interdisciplinary researches that leverage large datasets for genomic and other types of research.

The large number of human samples (organs, tissues, cells, blood, and other body fluids plus related information) provides biobank users with essential raw materials necessary for advancing biotechnology and human health in the post-genomic era (Frazier et al., 2008).

Biobank research shares an important characteristic with register research and the like, namely that of being a public endeavour to promote the common good (Eriksson & Helgesson, 2005).

The Swedish Act on Biobanks defines the concept ‘biobank’ as ‘biological material from one or several human beings collected and stored indefinitely or for a specified time and whose origin can be traced to the human or humans from whom it originates’(The Swedish National Biobank Program, 2011).

2.2 Uses of Biobanks

Biobanks are used for many purposes including screening for diseases, feeding information into an efficient public health system where results could help individuals, physicians, and policymakers make more informed health decisions (Conference on Harmonising Biobank Research, 2009).

With the human genome available, biobank repositories of DNA samples (preferably combined with health-history data) play a crucial role in the identification of genetic elements associated with complex disorders (Hagen & Carlstedt-Duke, 2004).

During the past few years, interest in biorepositories and biospecimen science has grown tremendously fuelled by several important national and international initiatives (Vaught, 2006). Such recognition has led to exponential growth in the banking of specimens for research purposes (Vaught, 2006).

The science of biobanking is rapidly changing the face and pace of biomedicine. The popular press (*Time Magazine*) christened biobanks as one of 2009's top 10 ideas changing the world today (Conference on Harmonising Biobank Research, 2009). This increased use of biobanking raises several ethical questions which have not been previously adequately explored in the African population (O'Brien, 2009).

A book published by RAND in 1999 (Eiseman & Haga, 1999) surveyed clinics, laboratories, and commercial and government biorepositories in the United States and concluded that more than 300 million biospecimens were being stored for research and patient care. Biospecimen collections were estimated to be growing at a rate of more than 20 million specimens each year.

2.3 Types of biobanks

Biobanks are developed in relation to a research question having its own strategy and specific demands on quality and annotation of the collected samples, resulting in a very heterogeneous concept in Biobanking. Even considering exclusively human samples-related banks for research, there are multiple designs according to the different possible goals (Riegman et al., 2008). In a brief summary, human-driven biobanks include the following types:

2.3.1 Population banks: Their primary goal is to obtain biomarkers of susceptibility and population identity, and their operational substrate is germinal-line DNA from a huge number of healthy donors, representative of a concrete country/region or ethnic cohort (Riegman et al., 2008).

The UK Biobank, launched in 2006, was one of the first large-scale, population-based biobanks. It announced that it reached its goal of obtaining biospecimens from 500,000 Britons aged forty to sixty nine years for "a diverse range of research intended to improve the prevention, diagnosis and treatment of illness, and the promotion of health throughout society"(UK Biobank, 2003).

Similar biobanks have emerged in the United States, including the Personal Genome Project, the NuGene Project, Mayo Clinic Biobank and Kaiser Permanente's Research Program on Genes, Environment and Health (Maschke, 2010). Population-based collections have long existed in the fields of genetic anthropology and history of world populations, although these are also usually small and have been used for academic research (Cambon-Thomsen, 2004).

2.3.2 Disease-oriented banks for epidemiology: Their activity is focused on biomarkers of exposure, using a huge number of samples, usually following a healthy exposed cohort/case–control design, and studying germinal-line DNA or serum markers and a great amount of specifically designed and collected data (Riegman et al., 2008).

2.3.3 Disease-oriented general biobanks: (i.e. tumour banks). Their goals correspond to biomarkers of disease through prospective and/or retrospective collections of tumour and no-tumour samples and their derivates (DNA/RNA/proteins), usually associated to clinical data and sometimes associated to clinical trials. Those data are usually not collected for a concrete research project, except in case of clinical trials, but from the healthcare clinical records. The amount of clinical data linked to the sample determines the availability and biological value of the sample (Riegman et al., 2008).

The samples are used for informing diagnosis and for clinical or therapeutic follow up. Pathology departments, in particular, have collected huge numbers of tissue sections over the years. Transplantations using cells, tissues or organs from unrelated donors have also led to the development of tissue and cell banks for therapeutic use.

The tumour tissue samples are generally obtained immediately after excision, prior to fixation, to ensure optimal preservation of proteins and nucleic acids. It is possible for surgeons or athologists to collect fresh tissue prospectively during their routine dissection procedures. Most tissue banks are “project-driven” tumour banks, which are specialized collections of tumour samples on which their research is based. Systematic collection of all available tumour tissue is much rarer (Yu & Zhu, 2010).

Many tumour tissue banks have been constructed in the United States, Canada, United Kingdom, France and many other countries (Mager et al., 2007; Whyte, 2003).

Biobanks also vary according to the scientific sector in which the samples were collected.

2.3.4 Medical and academic research: Medical genetic studies of disease (especially if rare) have motivated collections that usually consist of small case-or family-based repositories (Cambon-Thomsen, 2004).

2.3.5 Biotechnology domain: Collections of reference cell lines that are well characterized for several relevant characteristics (such as cancer cell lines or antibody-producing cell lines), and stem cell lines of various origin, are mainly used in biotechnology research and development (Cambon-Thomsen, 2004).

2.3.6 Judiciary domain: This sector hosts huge collections of different sources of biological material, data and DNA fingerprints, which have very restricted uses (Cambon-Thomsen, 2004).

Biobanking in Africa is new with biobanks existing in The Gambia (MRC Laboratories), Nigeria (IHVN), Zimbabwe and possibly other countries.

2.4 Informed consent

The concept of informed consent in research ethics evolved gradually over the years, typically in response to major instances of research ethics violations. For example the Nuremberg Code followed the inhuman research experimentations carried out by Nazi doctors during the Second World War. More recently; the foundations of informed consent are being laid by philosophical reflection and empirical research without instances of research misconduct. The principle of informed consent is largely recognised and considered a pillar in the practice of bioethics (Cambon-Thomsen et al., 2007). Informed consent defines the “moral contract” between researchers and the

study participants and setting the framework for the allowable use of biospecimens and data (Elger & Caplan, 2006).

Consent of participants is a core issue (Uranga et al., 2005) since two interests are perceived as being at odds; 1) the protection of data, considering informatic technologies and 2) the importance of data sharing and access by the scientific community. Indeed, "informed consent is one part of honouring the contribution that the person is making to [the] advancement of knowledge" (Clayton, 2005). Informed consent to research includes information about the purpose, methods, risks and benefits of the study (Lipworth et al., 2006), security and access policies, future uses and commercialization.

The Declaration of Helsinki requires that consent be specific to a clearly defined research project. The Declaration states:

> In any research on human beings, each potential subject must be adequately informed of the aims, methods, the anticipated benefits and potential risks of the study and the discomfort it may entail (World Medical Association, 2000, art. 22).

Informed consent allows individuals to exercise their right to decide whether and how their body, its parts and the associated data will be used in research (Sade, 2002). Informed consent does not seem to protect donors, but the research institution (Ducournau, 2007).

Donors rarely read, recall or use the information with which they are provided (Busby, 2006; Hoeyer, 2003; Ducournau, 2007). This type of problem with informed consent is well-known beyond the biobank issue (Sugarman et al., 1999).

True 'informed consent' is strictly defined as specific consent given for well defined uses; the participant is given adequate information about research, the possibility of

dialogue with a professional, and time to think about the implications before a decision is taken (CCNE, 2003, Caze de Montgolfier, 2002; Deschenes et al., 2001; Sade, 2002). Emmauel et al., (2000; 2004) in 2 seminal articles enumerated 7 principles viz; (1) value-enhancements of health or knowledge must be derived from the research; (2) scientific validity-the research must be methodologically rigorous; (3) fair subject selection-scientific objectives, not vulnerability or privilege, and the potential for and distribution of risks and benefits, should determine communities selected as study sites and the inclusion criteria for individual subjects; (4) favourable risk-benefit ratio-within the context of standard clinical practice and the research protocol, risks must be minimized, potential benefits enhanced, and the potential benefits to individuals and knowledge gained for society must outweigh the risks; (5) independent review-unaffiliated individuals must review the research and approve, amend, or terminate it; (6) informed consent-individuals should be informed about the research and provide their voluntary consent; and (7) respect for enrolled subjects-subjects should have their privacy protected, the opportunity to withdraw, and their well-being monitored.

Three of them are relevant to biobanking and genomic research. They are (a) favourable risk-benefit ratio of research (b) informed consent and respect for enrolled participants (c) respect for enrolled subjects-subjects should have their privacy protected, the opportunity to withdraw, and their well-being monitored.

2.5 Informed Consent for Biobanks

Biobanking presents unique challenges to the existing paradigms of the informed consent model in biomedical research. This paradigm is challenged by the very nature of biobanks where often the specific uses that will be made of the samples donated is not known at the time the donation is made thereby precluding discussion of risks, benefits and provision of adequate information on which valid consent can be based.

In biobanking, a sample is taken at a precise moment; it is then used over a number of years with knowledge and research questions evolving over time (Cambon-Thomsen et al., 2007). Indeed, a major ethical problem for prospective biobanks is how to assure participants' consent when it is not known what they are consenting to in terms of future research. The question of the importance and meaning of informed consent is one main reason why international guidelines on biobanks lack any consensus (Elger & Caplan, 2006).

To understand the issues on an international level sometimes means a biobank manager needs both legal and ethical advice (Riegman et al., 2008). On a national level the rules for biobanks which require IRB approval are governed by complex evolving legislation and lack standardized procedures. Therefore, differences in decisions can be found on a local level (Riegman et al., 2008).

2.6 Types of consent for biobanks

There exist a diverse range of views and policies regarding the appropriate consent required to store biological samples and data for future research (Maschke, 2005). Most regulations agree that consent should be free and explicit, and that the requirement for consent should be waived only in exceptional cases—usually when authorized by an ethics committee—or for unidentifiable samples or data (Knoppers, 2005a).

However, the recommended nature and amount of information that should be given to a donor varies from broad or unrestricted to fully restricted or specific consent (Boggio et al., 2007; Hansson et al., 2006). Below are some of the types of informed consent models used by Biobanks:-

2.6.1 The Specific or "Narrow" or restricted Informed Consent - The specific or "narrow" informed consent enumerates all the uses that will be made of donated samples (Salvaterra et al., 2008). Italy, France and Sweden explicitly require specific informed consent (Salvaterra et al., 2008).

2.6.2 The General or "Broad" Consent - Another consent model is the general or "broad" consent which does not necessarily itemize these (Salvaterra et al., 2008). The nature of this consent and how it is obtained, vary widely (Elger & Caplan, 2006). General or broad consent is presumed as an authorization for unlimited research in the present and future unless the donor opts out or requests that their samples are not to be used again in any research (Murphy et al., 2009). In this situation, the consent forms explain that the biospecimens will be stored for researchers to use when needed for whatever type of study they are conducting (Maschke, 2010).

Some genetic research initiatives like the UK Biobank and research in the United States, such as the Personal Genome Project, the Mayo Clinic Biobank and some clinical trials that incorporate genetic studies use the general or "broad consent" approach (Murphy et al., 2009). Iceland, the UK, Switzerland, Estonia, Japan and Latvia largely recommend broad consent models (Maschke, 2005). German guidelines similarly endorse general consent (Nationaler Ethikrat, 2004), as do the recommendations of the UK Human Genetics Commission (2002) and laws in Sweden, Iceland and Estonia, in which a "broad description of the purpose is allowed" (Kaye et al., 2004).

2.6.3 Open or Blanket Consent - Another consent model which is distinguished from General or broad consent is the open or blanket consent. Open or blanket consent is given only once, but covers any use of the material at any time in the future. This is particularly important for scientific research, in which new projects or experiments might be devised years after individuals has given their consent and deposited their biological material. They may even have died in the meantime (Shancheti, 2009).

2.6.4 Tiered Consent - Another approach to consent for biobanking is the "tiered consent." Many researchers collect biospecimens for a specific purpose, which means that individuals give consent to use of their biospecimen only for that purpose. With the tiered approach, the consent form lists different levels of research for which individuals permit or restrict the use of their biospecimens (Maschke, 2010). For example, participant may give consent to use of data only, or data and biological specimen but only for current research or give consent to unrestricted use for any type of research now and in future.

2.6.5 Multi-layered Consent - The US National Bioethics Advisory Commission (NBAC) report on Research Involving Human Biological Materials is more rigorous and requires that research consent forms provide the potential subject with several options, ranging from complete refusal for the use of samples in research, through a series of limited permissions, to allow the coded use of the materials for any type of future study (NBAC, 1999b).

Other countries, such as Denmark, The Netherlands, Spain and Norway, recommend that consent should be informed, and express—but do not clarify—the type of consent that should be sought for biobank research (Knoppers, 2005b).

Some perspectives on consent for biobank are listed in table 1.1 below:

Table 2.1: Perspectives on Consent for Biobanks

Country/year	**Percentage in favour/Population sampled**	**Author**
In 1998, American Health Styles Survey said they were willing to donate samples for genetic research.	43% (1122/2621)	Wang et al., 2001
In 1998, American Health Styles Survey said they were willing to donate samples for storage for future research.	53% (1391/2621)	Wang et al., 2001
In the 2002 general population survey in Singapore, it was found that they were willing to donate blood for genetic research and storage for future research.	40% (217/548)	Wong et al., 2004
In a 2002 survey of British individuals, they were willing to join the UK Biobank even though such participation implies consent to open-ended storage and genetic research.	34% (1,283)	Hapgood et al., 2004
A survey of British dental patients in 2003 found that they would	82% (82/100)	Goodson & Vernon, 2004

donate excess tissue to cancer research if asked.		
In the 2002 Swedish study, they were willing to donate samples for genetic research and long-term storage.	78% (2220/2830)	Kettis-Lindblad et al., 2006
In the 2002, Icelandic public survey, respondents indicated willingness to participate in genetic research in the future.	65% (598/915)	Guqmundsdottir, 2007
In 2003, participants would agree to storage of traceable samples for future research if allowed to choose between various models of consent ranging from renewed consent for each purpose to blanket consent.	94% (853/904)	Nilstun & Hermeren, 2006
In 2004, Irish respondents of a survey were willing to donate excess tissue for non-genetic research and storage for future research.	74% (1703/2294)	Cousins et al., 2005
In Great Britain 2005, postoperative patients in a teaching hospital said they would	96% (184/191)	Bryant et al., 2008

not object to their tissue being used in research.		
In 2007–2008, Americans were willing to participate in a cohort study involving genetic research.	60% (2818/4659)	Kaufman et al., 2008
Uganda were willing to donate their blood sample for future research.	80%	Wendler et al., 2005
Egypt were willing to have their linked blood samples used in genetic research	66%	Abou-Zeid et al., 2010

2.7 Contributions of informed consent

Informed consent helped demarcate what counted as legitimate disagreements concerning the ethics of biobanks; it became the lens through which the "problem of biobanking" was viewed. Academic debate in this field is part of a complex political game (Lindblom, 1959; March & Olsen, 1976; Weiss, 1986).

An almost endless number of concerns have been uttered relating to, for example, commercial genetic research, issues relating to commodification of human tissue, benefit-sharing, risk society, eugenics, fairness, autonomy, dignity, and trust. All these problems seem, however, to have been interpreted through a particular "solution": informed consent (Hoeyer, 2008).

In 1996 two physicians established a company called deCODE Genetics. They had a plan: to establish three related databases in Iceland: 1) the Book of Icelanders containing complete genealogies of the Icelandic population from the settlement to present day, 2) the Health Sector Database (HSD) containing electronic healthcare data and medical records from 1915 onwards, and 3) a genetic database containing blood samples and extracted genetic data from everybody consenting to donate a sample (Merz et al., 2004; Potts, 2002). The analyses of deCODE Genetics that focus on the organizational shortcomings with respect to accommodation of a public health agenda, which simultaneously show that Icelanders are very well informed, fail to go beyond informed consent when looking for solutions to the predicament (Merz et al., 2004; Potts, 2002).

Informed consent seems to have served the managerially helpful role of limiting the problems biobanks are expected to address in their policies (Hoeyer, 2008). The nature of the "problem" that the consent requirement is expected to solve is perceived very differently in various articles. They include:

2.7.1 Respect - Either for dignity, self-determinism, or contributorship (Wendler, 2002).

2.7.2 Privacy - Personal information is sensitive and can cause great concern and even harm if not secured (Frazier et al., 2008). The right to privacy is the right to a personal sphere, free from public attention and interference. It includes the right to keep certain facts about oneself secret. Personal integrity presupposes a certain degree of privacy as well as a certain degree of autonomy. Individuals' personal integrity is disrespected if others intrude into their private life or prevent them from making autonomous decisions about their life (Eriksson & Helgesson, 2005).

2.7.3 Risks and harm - Samples used in biobank research may harm the group to which a participant belongs, and thereby harm the individuals concerned. This harm may arise, for instance, if people outside the group regard the group in a more negative way or treat people belonging to that group in a worse way than others, or by prejudice being spread or strengthened. The harm may also be due to people in the group starting to look at themselves in a different, more negative, way. Thus, a distinction can be made between external and internal harm to groups of people. External harm is connected to factors external to the group, such as changes in attitudes regarding the group. Such changes can cause economic harm, for instance more expensive insurance for group members due to expectations about their behaviour (Eriksson & Helgesson, 2005).
Internal harm, on the other hand, is related to internal changes resulting from the spread of information from biobank research. Loss of self-esteem is an example of internal harm, decline in social functions and bonds another (Eriksson & Helgesson, 2005).

2.7.4 Return of research results and feedback to donors - who would like to know what? Can uncertain results be provided? What about the right not to know? What if there is no disease treatment? (Renegar et al., 2006). Mostly donors are interested in getting access to research results, particularly of relevance to their own health, but the conditions differ widely and national discrepancies also seem to be at stake (Cousins et al., 2005; Hoeyer et al., 2004). The more people feel they need medical research results; the more likely they seem to be to accept donations (Hoeyer, 2008). Policies regarding this issue vary among trials, sponsors, and even locales in which the study is being conducted. In the case of a trial with inclusion criteria requiring that a patient express a specific biomarker for eligibility, the attending physician is usually informed of the results and is responsible for relaying the results to the patient, thus confirming his or her eligibility for trial participation. In the case of a trial in which specimen collection is for correlative or exploratory use, individual results may not be shared with the treating physician or patient. Exploration of genomic or phenotypic predictors of treatment responsiveness or specific disease subsets within a trial are increasingly the examples we see in research. Study reports may include information on biomarker expression, response data, and outcomes, but this is aggregate information rather than information specific to individual participants (Baer et al., 2010).

2.7.5 Property rights - tissue can be an object of ownership and informed consent can help to define this (Charo, 2004).

2.7.6 Commodification - does commercialization of biobanks infringe human dignity? Does it constitute exploitation? (Rose, 2001). The commercial aspects of biobanks is recognised (Rothstein, 2002; Kaiser, 2002; Bellivier et al., 2006), despite the general principle that ‘‘biological materials should not, as such, give rise to financial gains’’, as recalled in the Council of Europe recommendation of (2006). Commercial access to public biobanks is accepted by a majority (Jack & Womack, 2003; Stegmayr & Asplund, 2002); nevertheless, it is viewed more as a necessary evil than as the preferred research infrastructure (Gudmundsdóttir & Nordal, 2007).

2.7.7 Benefit sharing - should donors have a share of potential profits? How will public health goals be addressed in a commercial research infrastructure? (Simm, 2005) Psychological harm can occur, for instance, when patients wrongly form the belief that there will be personal gain from participation in research (the ‘therapeutic misconception’) (Appelbaum et al., 1987). When such expectations are not met, feelings of anger or hopelessness can result.

2.7.8 Dangers of genetic research in general - will this type of research lead to eugenics? Do we want new types of risk knowledge? Are we tampering with Nature or playing God? (Chadwick, 2001; Rose, 2001). Some donors fear that genetic knowledge will be used to generate a kind of society that marginalizes or exterminates minorities; others fear that we will begin to know things that will not benefit us. Still others are mainly worried about the ability of the research agenda to address public health needs. A notion of fairness often seems to be involved, where medical research is supposed to be based on medical needs rather than consumer abilities (Hoeyer, 2008).

2.7.9 Trust - is it a value in itself or a means for other values? (Ashcroft, 2000; Helminski, 1994; Sutrop, 2007). It is of utmost importance to maintain a trusting relationship between participants and the biobank research team (Frazier et al., 2008), in research (National Code of Health Research Ethics, 2007).

2.7.10 Issues of governance - what models can accommodate the concerns listed above? What is the role of Institutional Review Boards/Research Ethics Committees and can the system be rethought to better facilitate biobank research? (Gottweis & Zatloukal, 2007; Caulfield & Outerbridge, 2002).

Intriguingly, informed consent is of little help for donors when figuring out whether a biobank is governed according to the standards and aims that they have (Hoeyer, 2008).

2.7.11 Sharing of data - While data sharing is essential to accelerating scientific discovery, it presents a number of challenges, one of which is balancing the interests of science, the scientist, and the donor. For example, when researchers want to use samples for new purposes, the onerous task of seeking re-consent from donors may slow the process of scientific discovery, yet it is critically important to maintaining public trust (Conference on Harmonising Biobank Research, 2009).

A characteristic of biobank is the potential that the resources donated to the biobank would be distributed to researchers in different parts of the world, far from where the samples were collected (Dushenes & Salle, 2005). As research has become increasingly globalised, ethical issues arise from collaborative international research in which samples are collected in developing countries and then exported for analysis to developed countries. Such international research raises concerns of exploitation, the validity of informed consent from vulnerable populations, appropriate benefit-sharing

between sponsors and participants, and guidelines for regulating types of future research (Dickenson, 2005; Dickenson, 2004; Emmanuel & Weijer, 2000; Capron et al., 2009). Many ongoing international research projects are already rich in collaboration, and they actively solicit input from the research community and generate scientific results by using readily available tools and technologies that facilitate phenotype harmonisation. As an example is a consortium of provincial tumour banks in Canada that has developed a data repository with common tools and data standards (Conference on Harmonising Biobank Research, 2009).

2.7.12 Secondary uses - Secondary uses for stored human samples are nearly always possible even though they are usually not foreseeable at the time of sampling (Steinberg et al., 2002; CCNE, 2003; Godard et al., 2003; Caze de Montgolfier, 2002; Greely, 2001; Nationaler Ethikrat, 2004; Wendler & Emanuel, 2002).The main ethical issues relate to the level of completeness of the information given, the necessity or not of obtaining a new individual consent for each use, and who is going to decide on the issue (Cambon-Thomsen et al., 2007). The collection, storage and use of biological samples in future research raise unique ethical and policy issues that lacked consensus among several national and international documents (Ashburn et al., 2000; Bauer et al., 2004; Maschke & Murray, 2004). Chief among these ethical issues include questions regarding confidentiality, ownership and the commercialisation of stored biological samples.

There is the existence of a diverse range of views regarding the appropriate consent required to store biological samples and data for future research (Maschke, 2005). The views ranges from denying any use, other than that initially stated, to more flexible attitudes (Cambon-Thomsen, 2004). The latter take into account the traceability or not of the individual identity, the kind of further uses that are envisaged in relation to the

original one, the implications of the research for the individual (so-called 'minimal risk' research being more easily allowed), how precisely the use was described at the time of sampling and, finally, the kind of consent that was originally granted (Cambon-Thomsen, 2004).

In 2001, the European Society of Human Genetics published its recommendation on data storage and DNA banking for biomedical research, technical, social and ethical issues, which stated that;

> The full benefits for which the subjects gave their samples will be realized through maximizing collaborative high quality research. Therefore, there is an ethical imperative to promote access and exchange information'' (European Society of Human Genetics, 2001).

Many European guidelines take the view that general or broad consent is acceptable for "unspecified future research use" of samples (CDBI, 2006). For example, the Council of Europe's Steering Committee on Bioethics states in an explanatory memorandum that "When biological materials of human origin and personal data are collected it is best practice to ask the sources for their consent to future use, even in cases where the specifics of the future research projects are unknown" (CDBI, 2006). German guidelines similarly endorse general consent (Nationaler Ethikrat, 2004), as do the recommendations of the UK Human Genetics Commission (2002) and laws in Sweden, Iceland and Estonia, in which a "broad description of the purpose is allowed" (Kaye et al., 2004).

The Council of Europe (COE; Strasbourg, France), in its Convention for the Protection of Human Rights and Dignity of the Human Being, states that, "consent for using body parts for purposes other than that for which they were originally removed should be appropriate according to national laws", but declares in the Additional Protocol to the Convention that consent for such uses should be specific (COE, 1997, 2005). Similarly,

the COE recommendation about research on biological materials of human origin requires specific consent for any foreseen research use and as specific a consent form as possible for unplanned research studies (COE, 2006).

At a national level, every country has different requirements. The Common Rule in the USA calls for voluntary informed consent, and oversight of each research protocol and consent process by a local institutional review board (Merz, 2003). The US National Bioethics Advisory Commission (NBAC) report on Research Involving Human Biological Materials is more rigorous and requires that research consent forms provide the potential subject with several options, ranging from complete refusal for the use of samples in research, through a series of limited permissions, to allow the coded use of the materials for any type of future study (multi-layered consent; NBAC, 1999b). Australia states that consent to the future use of data and tissue in research might be specific, extended or unspecified (Salvaterra et al., 2008).

A model that allows specified research and related future—and often unplanned—investigations allows donors to make informed decisions about the handling of their samples and related data, and therefore respects their right to self-determination (Salvaterra et al., 2008). A common feature of all recommendations and regulations on this issue is that any unplanned use requires an authorization, with or without a new consent, following the consultation of an independent research ethics committee or institutional review board (CCNE, 2003; HUGO, 1999; Knoppers, 1997; White & Gamm, 2002; Nationaler Ethikrat, 2004). This body can itself make authoritative decisions, or can be only consultative with another administrative authority being in charge of the final decision (Cambon-Thomsen, 2004).

2.7.13 Protection of the person - In the context of biobanks, protection of the person is practically synonymous with controlling access to the data and use of such data. This operation ensures that individuals or groups are not discriminated against and that medical and personal information is not disclosed to third parties (such as other family or community members, colleagues, employer or insurance companies). Absolute protection is a central issue in ethical analyses related to biobanks (CCNE, 2003; Godard, et al., 2003; UNESCO, 2003; Caze de Montgolfier, 2002; Knoppers, 1997; Nationaler Ethikrat, 2004; Anderlik & Rothstein, 2001, Nigerian National Code for Health Research Ethics (2007), and is best achieved through anonymized data (NBAC, 1999a; CCNE, 2003; Godard et al., 2003).

When information gets to wrong hands it can result in risk of various forms of non-physical harm. Non-physical harm is usually tied to sensitive information ending up in the wrong hands and being used to the disadvantage of a person. The inflicted harm may be social psychological, or economical. For instance, it has been argued that insurance companies and employers could come to use genetic information to discriminate against people with certain genetic dispositions. This would likely damage the individuals concerned, both economically and socially (Radetzki et al., 2003).

When information to be kept secret (eg regarding paternity or STDs) are communicated to relatives or partners against one's wishes, psychological harm may arise (Eriksson, 2004). Due consideration should be given, and where appropriate special protection should be afforded to human genetic data and to the biological samples. But not all genetic data have the same potential consequences for the person or its family (for example, tests for multifactorial diseases with low predictive value) (Cambon-Thomsen, 2004).

2.7.14 Withdrawal - The right to withdraw is naturally mentioned in all consent forms for clinical assays, but how this can be implemented in practice for samples that are exchanged, data that are distributed in complex databases and, sometimes, for samples that undergo transformation into cell lines that can themselves be exchanged and duplicated needs to be carefully addressed with practical and feasible procedures set up and explained, otherwise it may be a concept with no reality and significance (Cambon-Thomsen et al., 2007). The Declaration of Helsinki states that Medical research involving human subjects 'includes research on identifiable human material or identifiable data' and makes no distinction between research of the latter kind and experimental research when it comes to requirements regarding information and consent. For instance, according to the declaration, every research subject has the right to withdraw consent to participate at any time without reprisal, regardless of whether the research is conducted on their bodies or on their stored biological samples (World Medical Association, 2004).

2.7.14.1 Restricted right to withdraw consent -The demand for unrestricted individual rights to withdraw consent to participation in research is strongly connected to the Declaration of Helsinki from 1964. The notion of an individual's right to stop participation was already very important in the Nuremberg Code of 1947, but there it was conceived rather differently. While the Helsinki Declaration and subsequent documents have given the individual the right to withdraw regardless of reason, the Nuremberg Code conceived of research as a common good and saw experimental subjects as participants in an important humanitarian project, which led to a different view of the right to withdraw.

Clause nine of the code states:

> During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible (The Nuremberg Code, 1947).

There are good reasons why this notion of consent and withdrawal gave way to the view expressed later in the Helsinki Declaration, with its greater emphasis on voluntarism and freedom of choice (Eriksson & Helgesson, 2005). This lends weight to the notion that there is a moral obligation to accept that one's biological samples are stored for and used in future biobank-related medical research. When you use modern medical services, you take advantage of the work done by prior generations. Why should you gain from this and not give something back to future patients? If you expect to receive the best possible treatment, you ought to contribute to the processes by which such treatment is established. If you do not, you are a free rider (Harris & Woods, 2001).
This line of reasoning can be found among research participants. In Swedish biobank research, many patients express their willingness to contribute to research because they sense a duty to do so (Gustafsson et al., 2002; Hoeyer, 2003).

2.7.14.2 Anonymization as a response to request for withdrawal - According to many regulations and guidelines, there is no need to return or destroy a sample when a participant withdraws from a study, since anonymization addresses the substantial ethical problem. The European Society of Human Genetics writes that the use of 'unlinked anonymized samples' secures 'absolute confidentiality' and these samples can thus be used for new purposes without the need to obtain consent (Godard et al., 2003). The International Bioethics Committee (UNESCO) states that;

> Consent to research may be withdrawn by the donor 'unless such data are irretrievably unlinked to an identifiable person' and that the data and biological samples should be dealt with in accordance with the wishes of the donor unless they are irretrievably unlinked (UNESCO, 2004).

The German Nationaler Ethikrat maintains that if samples are anonymized, then 'donor interests calling for protection are not at issue'; therefore, withdrawal of consent need only be responded to with anonymization (Nationaler Ethikrat, 2004). The idea behind this solution is simply that if harms arise due to the spreading of information about specific individuals, then the risks of harm are eliminated altogether by irreversibly destroying the tie between information and individual (Eriksson & Helgesson, 2005). Information derived from tissue or blood samples cannot be used to ones disadvantage if no one knows, or can find out, that the information concerns him. One has the right to end his participation, but since it can be of importance to keep his sample for research, de-identification is performed. It is no longer 'him' who participates, and research can still be performed – all is well (Eriksson & Helgesson, 2005).

2.7.14.3 Limited value of anonymization - However, anonymization has a limited value in protecting participants' interests in the following ways:

2.7.14.3.1 It may not decisively cut the link to specific individual - anonymizing samples in this context means making them irretrievably unlinked to sample donors by having all identifications removed. This can be done by destroying the code keys. We now know this is not enough to guarantee anonymity, as it may still be possible in some cases for individuals possessing sufficient knowledge to identify a donor (Eriksson & Helgesson, 2005).

Further, as soon as genetic information is stored in medical journals, a supposedly anonymous sample can be run against a search of these journals, which may reveal whose sample it is. The publication of databases on the Internet, free for researchers to use, also presents dangers in this respect. If you have access to an identified sample, you can find more samples from the same person by searching databases consisting of

anonymous samples and comparing them with yours. This is no far-fetched fantasy but rather something easily performed with the aid of available technology (Eriksson & Helgesson, 2005).

Therefore, anonymization is not enough but must be accompanied by further measures to be fully effective, such as requiring previous authorization for all searches for matching samples or limiting access to samples (Eriksson & Helgesson, 2005).

2.7.14.3.2 It prevents the use of samples for purposes such as diagnostics - if a sample is de-identified, it can no longer be used for diagnostic purposes. Individuals have an interest in being protected from the dispersal of sensitive information regarding them, but they also have an interest in having their samples available to medical services when needed. Anonymization prevents this. If proper safeguards are in place, the availability interest should carry greater weight than the interest in having additional protection by anonymization (Eriksson & Helgesson, 2005).

2.7.14.3.3 It may not prevent harms to groups - even if no single individual is indicated in research material; there is still a risk that research on an identified group may lead to undesirable consequences for group members. Researchers need to consider this risk before publishing their results. Much has been done regarding these matters in the work on ethical guidelines for research on indigenous populations and the like (Eriksson & Helgesson, 2005).

2.7.14.3.4 It does not rule out wrongdoing - imagine that all these obstacles have been taken care of. Even then, the issue of wrongdoing remains. Consider autonomy: Assume that you have two test tubes of blood stored in a biobank containing 30,000 other blood samples. Also assume that, as a response to your request that your samples be destroyed, those responsible for the biobank instead remove your name from all labels and lists within the premises, as well as any other material used to tie your samples to your name. In what way can their reaction be said to be a proper response to your request? (Eriksson & Helgesson, 2005).

It certainly seems that anonymization does not address the problem in cases like this, as it does in relation to other kinds of harm. The matter no longer concerns risks tied to the use of your samples – risks that may be more or less eliminated – but the very use

itself. If someone says ‘Do not use my samples’, that person’s request has simply not been respected by the use of anonymization (Eriksson & Helgesson, 2005).

For many types of studies, such as longitudinal and epidemiological research, it is absolutely essential that researchers, or at least those in charge of the biobank, have access to the identity of the samples so they can be linked to medical journals and register data as well as data from previous analyses. For quality reasons, researchers may also need to return to the original repository (Eriksson & Helgesson, 2005).

Thus, the ‘anonymization tool’ does not do much moral work. A model in which continued use of identified samples is impossible if withdrawal is requested, and where a request to have one’s sample destroyed results in something else (namely anonymization) is hardly satisfactory. On the one hand, donors’ arbitrary requests to have their samples destroyed are allowed to hinder important research. On the other hand, no matter what reasons people may have in requesting the destruction of a sample or how strong these reasons may be, their request can be met with a denial and continued research on that sample. Thus, anonymization involves a double moral limitation (Eriksson & Helgesson, 2005).

2.8 Dissemination of results, risks and stigmatisation

Results of a study may differ on different levels. It may be the statistical characteristics of the test: sensitivity, specificity, positive or negative predictive values. It may also be the actual result of the test on a given individual, when not yet validated, at the beginning of the research. Or the individual result together with its interpretation from its statistical evaluation, at the end of which is often a complex aggregate (Cambon-Thomsen et al., 2007).

The guiding principle for the dissemination of results is one of comprehensive information prior to any participation in a project, but there may be strong differences

between a patient based study and projects conducted on a scale of population, between a clinical trial form of research and a genetic study of complex diseases that can last for many years (Cambon-Thomsen et al., 2007).

The right to know and the right not to know, a classical concept in genetic research, takes on new complexities in the context of population databanks due to the diversity of the data produced or processed. These data could simply be of statistical interest without any useful individual elements, or they could be of clinical interest with the possible need for genetic counselling and careful interpretation. Individual research results derived from population databanks are often of no clinical interest and can lead to misinterpretations due to the fact that they are based on incomplete information (often, biobanks are not accompanied by access to the participant's complete medical record) (Cambon-Thomsen et al., 2007).

In addition, the rare cases in which validated individual results are provided to participants, there may be the need for genetic counselling measures, which are not anticipated in the research context. Therefore, in many cases, individual reporting is not planned for, since the results are usually aggregated and considered to be of purely scientific interest, but the right to be aware of information about ones self is a counter-balancing principle (Cambon-Thomsen et al., 2007).

The individualistic trend of classical ethics is questioned in the biobank context (Williams, 2005). The individual usefulness (or not) of results, the consideration of potential risks and the stigmatisation merit careful consideration. Due to the sensitive nature of certain genetic data, such data can entail risks of discrimination or stigmatisation within populations or communities. These risks must be recognised, both with respect to recruitment and interpretation of results, by properly informing

participants and by taking action to avoid or minimise their occurrence (Cambon-Thomsen et al., 2007).

Non-physical harm can result in the form of, for instance, stigmatization and discrimination at work as well as anxiety and disturbed relationships with spouses, children, relatives, and friends. Not all risks of harm are related to specific individuals (Clayton, 1995).

However, informing participants of the risks of stigmatisation combined with ‘‘misinformation’’ on the nature of biobanks can have a negative impact on recruitment and can even introduce biases. Providing participants with too many details on the remote possibility of stigmatisation may alarm them and lead them to question the legitimacy and true nature of the proposed research (Cambon-Thomsen et al., 2007).

2.9 Ethical and Legal Frameworks

Different logics of regulation for the use and procurement of biological samples and data have appeared both at the national and international levels, sometimes through specific legally binding instruments or by general regulatory texts (Knoppers, 2005b; Joly et al., 2005; Uranga et al., 2005). For example, the Council of Europe's Steering Committee on Bioethics stated in an explanatory memorandum that:

> When biological materials of human origin and personal data are collected it is best practice to ask the sources for their consent to future use, even in cases where the specifics of the future research projects are unknown (CDBI, 2006).

The NCI Best Practices and other guidelines documents do not establish new policies, but rather provide guidance to biospecimen resources concerning the critical factors to consider when establishing and using a biospecimen collection. At the international level, the International Cancer Genome Consortium (ICGC, 2008) has developed a set of policies for informed consent, custodianship, data access and sharing, and

intellectual property that provides a framework for large, multicentric studies focused on genetics and genomics. Nigerian National Code for Health Research Ethics (2007) focused on research with no mention of biobank research.

However, guidance on these issues is constantly evolving due to advances in technology that make it difficult to assure that biospecimens cannot be used to identify a person, changes in the public perception of the appropriate use of human tissue for research, and considerations on the stringency of informed consent policies regarding future unexpected research uses of biospecimens (Vaught et al., 2010).

It is pertinent to get the perspectives of Nigerians on informed consent for the collection of samples for biobanking, confidentiality; secondary use of samples and data over time; return of results; and data sharing for biobanking for the non-communicable diseases research, and future research use of this specimens and data can be described in the consent form so that prospective participants can make informed decisions on how they wish to participate and how their body biological samples as well as data will be used in this research.

Precedence suggest that these issues need to be given careful consideration in order to avoid past mistakes as seen in recent controversy surrounding the use of banked biological samples from the Havasupai tribe in Arizona by Arizona State University researchers (Mello & Wolf, 2010), of which tribal members who provided biospecimens for diabetes research sued the university and the researchers when they discovered that their biospecimens had also been used for schizophrenia and ancestry studies.

2.10 Non-communicable disease research

The major non-communicable diseases (NCDs) are cardiovascular disease, type 2 diabetes, cancer, chronic lung disease, and depression. In Africa, along with the rest of the developing world, the prevalence of non-communicable diseases is increasing and their etiology may interact with the prevailing epidemic of communicable diseases in yet unknown ways making research into them imperative (Adebamowo & Akarolo-Anthony, 2009). In addition, given the "out of Africa" theory of human evolution, understanding the African genome is a prerequisite to elucidating the genetic etiology of diseases in other populations (Campbell & Tishkoff, 2010). Efforts such as PaCT (a multinational prospective epidemiology cohort study of 500,000 persons in Nigeria, Tanzania, Uganda and South Africa) and Human Heredity for Health in Africa H3Africa led by NIH/NHGRI and Welcome Trust are being developed to increase the number and range of non-communicable disease research projects in Africa and support this with necessary training and infrastructures.

CHAPTER THREE

3.0 RESEARCH DESIGN AND METHODOLOGY

3.1 Research Design

Qualitative research was conducted in Kano State - a State in the predominantly Muslim North and 2 States (Oyo and Enugu) in the predominantly Christian Southern part and the Federal Capital Territory of Nigeria among members of the general public.

The fieldwork was carried out between 12th January and 17th February 2011.

3.2 Research Setting - the research was carried out in Enugu, Kano, Oyo States and the Federal Capital Territory.

3.2.1 Enugu State

Enugu State is in the South East Geo-Political Zone of Nigeria. Its capital town is Enugu from which the state derives its name. It was carved out of the old Anambra State on 27th August, 1991. The State is located between 7° 10′N and 7° 45′N of equator, and on longitude of 7.4878°E and latitude of 6.4231°N. It is bounded on the North by Kogi/Benue States, on the South by Abia/Imo states, on the East by Ebonyi State and West by Anambra State. Igbo and English are the medium of communication. Most, 98% of the populations are Christians while the remainder belongs to other religious sects. The state is noted for its coal deposit, the largest in Africa. Other mineral resources found in the state include limestone, iron-ore and bauxite. The state is the headquarters of the former Eastern Region of Nigeria. This is the **Coal City State** of Nigeria. In the 2006 Population and Housing Census, Enugu State is made up of 1,596,042 males and 1,671,795 females.

3.2.2 Kano State

The state is located in the North West Geo-Political Zone of Nigeria. Its capital is Kano City. The state is historically a commercial and agricultural state known in the past for its groundnut pyramids. It has many tourist and cultural centres which include the colourful Annual Durbar, museums, monuments, leather works and craft. Some notable dams in the state are Challewa and Tiga Dams. The State is known as **Centre of Commerce.** In the 2006 Population and Housing Census, Kano State is made up of 4,947,952 males and 4,453,336 females. Kano State was created on May 27, 1967 from part of the Northern Region, Kano State borders Katsina State to the north-west, Jigawa State to the north-east, Bauchi and Kaduna States to the south. Hausa is the major language of communication. Islam is the religion that dominates the State with a little percentage of Christians, who are mainly found in the cities.

3.2.3 Oyo State

The State is located in the South West Geo-Political Zone of the country. Its capital town is Ibadan, once reputed as the largest city in Africa. It is bounded on the South by Osun State, on the East by Ogun State, on the North by Kwara State and on the West by the Republic of Benin. The Yoruba are overwhelmingly the major ethnic group, although some minorities such as the Hausas, Igbos, and Fulanis live peacefully with the indigenes. The state is predominantly Christians. In the 2006 Population and Housing Census, Oyo State is made up of male 2,802,432 female 2,778,462 Major towns in the state are Oyo of the famous Oyo Empire, Ogbomoso, Iseyin and Saki. The tourist attractions include Agodi Botanical Garden, Mapo Hall, Ado-Awaye Suspended Lake, Ido Cenotaph and Igbeti Hills. Some of the mineral resources found in the state are marble, clay, kaolin, iron ore, cassiterite and dolomite. This is the **Pacesetter State** of Nigeria.

3.2.4 Federal Capital Territory (FCT), Abuja

The Territory is located in the North Central Geo-Political Zone of Nigeria. FCT Abuja is the capital of Nigeria. It occupies a land area of 7,753.9 Sq. Km. The Territory shares boundaries with Kaduna, Kogi, Nassarawa and Niger States. It took over formally from Lagos in December 12, 1991 when the Federal Government, then under General I.B. Babangida, relocated it to Abuja and signed into law, documents formally proclaiming the Federal Capital Territory, Abuja as the capital of Nigeria.

On the world map Abuja lies between latitude $8^0$25": and $9^0$20": North of the Equator and longitude $6^0$45": and $7^0$39": East of the Greenwich Meridian. This geography places it at the centre of Nigeria and within the region generally referred to as the middle belt zone and covers about 8000km it is located in the North Central Zone of Nigeria. And it lies north of the Niger-Benue trough. Abuja is bordered on the north by Kaduna State, Plateau State to the east and south east, Kogi to the south west and to the west. It is deliberately shaped like a heart to signify its position as the heart of Nigeria. The dominant religion in the FCT is Christianity, followed by Islam. A few people however, still practice their traditional religion. There are many Churches and Mosques scattered in various parts of the territory. In the 2006 Population and Housing Census, the FCT is made up of male733,172 female 673,067.

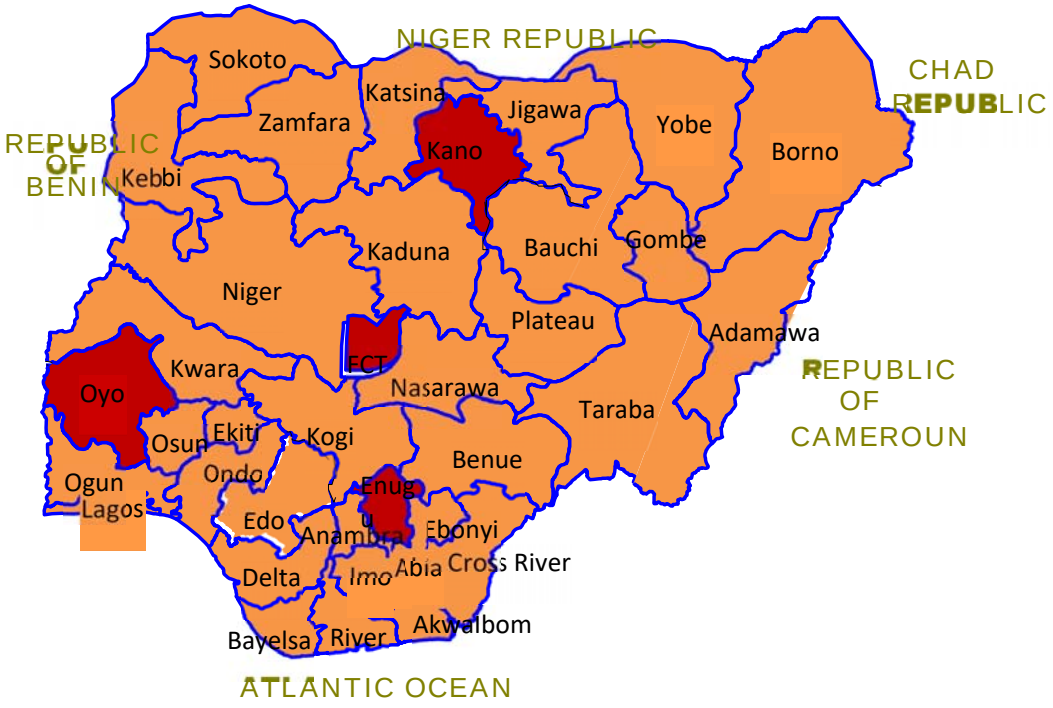

Figure 3.1: Map of Nigeria showing the sampled states and the FCT

3.3 Methodology

3.3.1 Focus Group Discussions-Sixteen Focus Group Discussions (FGDs) were conducted with members of the general public, including people from major and minority ethnic groups, and from people of wide-ranging ages, socio-economic groups, using agreed topic guides and prompt statements that outline general issues on biobanking of biospecimens, informed consent; confidentiality; secondary use of samples and data over time; return of results; and data sharing in biobanking research. The principle was to explore unprompted knowledge and understanding, then elicit response to facts spelled out in the prompt material. The material comprised statements describing human biological samples and their use, and the proposed sample collection for biobanking research on non communicable diseases.

One FGD was conducted for males and a separate one for females in 2 settings; one rural, one urban in **Enugu, Kano** and **Oyo** States as well as the **FCT**as shown in tables 3.1 and 3.2. The participants were selected by a contact person in the states prior to the interview. The FGD participants were select by contact persons in the states. Each FGD consisted of 8 to 10 participants and were balanced in terms of gender, age (Adults older than 18 years only), socio-economic status and religious affiliation. The FGDs were moderated by the researcher with interpretation by a native of Gbagi, Hausa, Igbo and Yoruba. The FGDs were audio-taped and lasted an average of one hour. Copy of the FGD guide is attached as appendix 1.

All participants in the FGD gave informed consent after they had been adequately informed about the study. The consent form is appendix 2.

Table 3.1: Matrix of FGD participants' selection among the males general population in 2 LGAs each of Enugu, Kano, Oyo States and FCT.

Level of Literacy	**1 Urban LGA**		**1 Rural LGA**		**Total persons**
	Young	**Adult**	**Young**	**Adult**	
	Male	**Male**	**Male**	**Male**	
Literate	**2**	**2**	**2**	**2**	8x4States=32
Illiterate	**2**	**2**	**2**	**2**	8x4States=32
Total	**4**	**4**	**4**	**4**	**64**

Table 3.2: Matrix of FGD participants' selection among the females general population in 2 LGAs each of Enugu, Kano, Oyo States and FCT.

Level of Literacy	**Urban LGA**		**Rural LGA**		**Total persons**
	Young	**Adult**	**Young**	**Adult**	
	Female	**Female**	**Female**	**Female**	
Literate	**2**	**2**	**2**	**2**	8x4States=32
Illiterate	**2**	**2**	**2**	**2**	8x4States=32
Total	**4**	**4**	**4**	**4**	**64**

3.3.2 Key Informant Interviews (KII) - were conducted to elicit information about informed consent; confidentiality; secondary use of samples and data over time; return of results; willingness to participate; specimens and data sharing in biobanking research among spokesperson/opinion leader (male and female) of the communities; community leaders, Christian and Muslim religious leaders, government officials, administrators scientists, ethicists, teachers, students, medical doctors, nurses, pharmacists, people with non-communicable disease, and relatives of patient with non-communicable disease.

Purposive sampling method was used to select the KIIs participants to represent a broad range of views and experiences, using the concept of maximum variation (Crabtree & Miller, 1999). The purposive sample size was determined on the basis of theoretical saturation, when new data no longer bring additional insights to the research topic (Mack et al., 2005). Experience has shown that a sample size of 12 to 20 is commonly needed when looking for disconfirming evidence or trying to achieve maximum variation (Crabtree & Miller, 1999). The purposive sampling method is often used in qualitative studies to identify groups of people with specific characteristics or circumstances (Patton, 2002). Table 3.3 – 3.5 below shows the distribution of categories of KIIs that were conducted in **Enugu, Kano, Oyo** States and the **FCT**. The interview guides was semi-structured and scenario-based and updated after the FGDs to elicit more in-depth responses, using follow-up questions, prompts and probes. See the guide which is attached as appendix 3.

The key informant interviews were conducted by the researcher, with interpretation in the local language (Gbagi, Hausa, Igbo, and Yoruba) where necessary. The key informant interviews were audio-taped and lasted an average of 30 minutes.

All KII participants gave consent after being adequately informed about the study. The consent form is appendix 4.

Table 3.3: Matrix of KII participants' selection among the general population in 2 LGAs each of Enugu, Kano, Oyo States and FCT

Category	**Urban LGA**	**Rural LGA**	**Total**
Community leader	1	1	2x4States=8
Spokesperson/Opinion leader (male)	1	1	2x4States=8
Spokesperson/Opinion leader (Female)	1	1	2x4States=8
Christians & Christian religious leader	1	1	2x4States=8
Muslim & Muslim religious leader	1	1	2x4States=8
Traditionalist	1	1	2x4States=8
Total	**6**	**6**	**48**

Table 3.4: Matrix of KII participants' selection among the middle and upper level income population and health professionals in one Urban LGAs of Enugu, Kano, Oyo States and FCT.

Category	**Urban LGA**	**Total**
Govt. official	1	1x4States=4
Administrator	1	1x4States=4
Scientist	1	1x4States=4
Ethicist	1	1x4States=4
Teacher	1	1x4States=4
Student	1	1x4States=4
Medical Doctor	1	1x4States=4
Nurse	1	1x4States=4
Pharmacist	1	1x4States=4
Patient with non-communicable disease	1	1x4States=4
Relative of patient with non-communicable disease	1	1x4States=4
Research participant in the past	1	1x4States=4
Total	**12**	**48**

Table 3.5: Matrix of KII participants' selection considering educational levels in the population in one Urban LGAs of Kano, Oyo Enugu States and Federal Capital Territory.

Education	**Number**	**Total**
Secondary school/ no degree	**2**	2x4States=8
Diploma	**2**	2x4States=8
Bachelor's degree	**2**	2x4States=8
Master's degree	**2**	2x4States=8
Doctorate or professional degree	**2**	2x4States=8
Total	**10**	**40**

3.4 Consequences and benefits of the study for the local community, environment and participants

This study is beneficial to society because it elicits the public's attitude to biobanking and provides a rational basis for the specification of the ethical guidelines for biobanking. This kind of research does not come with a duty of beneficence toward specific individuals, only an obligation to assure confidentiality and produce as much useful generalizable knowledge as possible (Forsberg et al., 2009). Thus, the benefits to the participants are indirect.

3.5 Risk/Harm

The major risks in this study are breach of confidentiality, the time of respondents and the risk that participants may find some of the questions uncomfortable. In order to reduce these risks, all questions were asked in such a way that they were not offensive to the participants. Records were kept under lock and key and no personal identifiers were collected. Other measures that were employed to safeguard information included encrypting computer databases, limiting geographic detail, and suppressing cells in tabulated data.

3.6 Justice and Fairness

Participation in this study is non-discriminatory of any category of people or community member.

3.7 Responsibility/Litigation

It is hoped that no litigation will arise as a result of the research, as the names of the participants were not collected and exposed to the public that could lead to stigmatization and or otherwise. Codes were used instead of names.

3.8 Method of Data Analysis

The audio-taped FGDs and KIIs were transcribed by the researcher who was also the interviewer, immediately on return from the field and verified prior to analysis which was done manually to facilitate thematic coding, evaluation and analysis. The recorded voices have been exported into the computer hard disk and kept confidential by the researcher and will be destroyed in due course.

3.9 Dissemination of Result of Study

Part of the result was presented at the Joint Conference of the African and Southern African Societies Human Genetics in Cape Town, South Africa from 6 - 9th March, 2011, and the Joint Meeting of National Health Research Ethics Committee (NHREC) and Research Ethics Committees (RECs) in Nigeria – November 26, 2011. The results shall be presented at other scientific fora in future. The thesis shall be kept at the library of the University of Ibadan and Institute of Human Virology Nigeria for reference purposes, while the findings of the study will be disseminated through publication in a reputable journal.

3.10 Ethical approval

The research protocol for this study was approved by the **NATIONAL HEALTH RESEARCH ETHICS COMMITTEE, FEDERAL MINISTRY OF HEALTH, ABUJA,** just because the research was carried out in other states in addition to Oyo State were the University of Ibadan is located.

CHAPTER FOUR

4.0 FINDINGS

4.1 Key Informant Interview demographic characteristics

There were 66 participants. The age of the participants ranged from 19 to 75 years (mean was 43.4 years). There were 51 (77.3%) males and 15 (22.7%) females. Twenty four (36.4%) were Muslim and 42 (63.6%) were Christians. Their occupations were Medical Doctors (3), Nurses (5) Pharmacist (1), Ethicists (2), Scientists (4), Government officials (4), Administrators (2), Teachers (4), Students (4), Muslim leaders (4), Christian leaders (4), lawyers (3), Male spokesperson/Opinion leaders (7), Female spokesperson/Opinion leaders (7), Community leaders (7), Traditionalist (1), Patient with NCD (3) and relatives of patients with NCD (1). See table 4.1

Table 4.1: Key Informant Interview demographic characteristic

S. No.	State	LGA	Village	Setting	Tribe	Number sampled	Sex	
1	Enugu	Nkanu West	Ojiagwu Agbani	Rural	Igbo	5	Male	3
							Female	2
		Enugu North	Enugu	Urban	Igbo	14	Male	9
							Female	5
2	Kano	Kura	Azoren Waje	Rural	Hausa	4	Male	3
							Female	1
		Ungogo	Gayawa	Urban	Hausa	12	Male	11
							Female	1
					Others	1	Male	1
3	Oyo	Oluyole	Idi Ayunre	Rural	Yoruba	5	Male	3
							Female	2
		Egbeda	Manatan Arolu	Urban	Yoruba	10	Male	9
							Female	1
4	FCT	Bwari	Ushafa	Rural	Gbagi	4	Male	3
							Female	1
		AMAC	Karu	Urban	Gbagi	7	Male	6
							Female	1
					Others	4	Male	3
							Female	1
	Total	**8**	**8**	**8**		**66**		**66**

4.2 Attitude of the Key Informant Interviewees to biobank and other related issues

4.2.1 Medical Doctors, Pharmacist and Nurses

4.2.1.1 Knowledge of biobank and collection of human biological specimens for non-communicable disease research.

The respondents were told, through statements on the inform consent form, that the Biobank just established in Nigeria will be collecting human biological samples for use in non-communicable disease research and future researches. They saw it as a welcome development. From the first probe, only one Medical Doctor knew something about biobank, while the others and the nurses knew little about biobank research. However, after given them an overview of biobanks, in their own words, they related it to the commercial bank and defined it from that perspective.

> *Biobank is a machine that stores specimen for accessing what is wrong with people.*
> Female Pharmacy Technician/spokesperson urban B3 - Kano

> *We all know the meaning bank, bank is a storage pot. When you say bio it has to do with blood tissues or any chemical issue stored in the bank.*
> Male Medical Doctor urban D9 - Enugu

> *Biobank is storage facility for biological samples.*
> Female Pharmacist urban D18 - Enugu

4.2.1.2 Understanding of, and Attitudes to research and non-communicable disease research.

The knowledge of and attitudes to medical research and non-communicable diseases varied widely among these health personnels. They have good understanding of the subject and are very willing to participate in the biobank research.

> *Non-communicable diseases as the name goes, are diseases common to the upper echelon or classes of people, they are diabetes and the*

likes. Research is about studies, try to find out one or two things and gaining inference from that.
Male Medical Doctor urban C2- FCT

Research is something that people or researchers do to get something that they want. Non-communicable diseases are not transferable.
Female Pharmacy Technician/spokesperson urban B3 - Kano

Research is wanting to know about something, like if there is a health or social problem or condition. You get in-depth to know why this thing happened, how it happened, what will be done to manage that condition. And non-communicable diseases are diseases that are not transmitted by vectors, they are diseases of multifactoral courses that also require more than one intervention to control.
Male Medical Doctor urban B6 - Kano

Non-communicable diseases are usually pathological response by the body to our physiological systems. They also have some genetic connotation to some extent. They are equally as serious as communicable ones.
Female Pharmacist urban D18 - Enugu

Research is something to be done about a particular thing, the way to use that thing, to know more about that thing.
Female Nurse rural A12 - Oyo

Their sources of information and influence on knowledge and attitudes surrounding medical research and non-communicable disease research were the media – television, newspapers, magazines, journals and informed scientists. Journal and television documentaries were the most widely used.

4.2.1.3 Consent for the biobank research

Asking consent showed the value the participants have. The majority of these participants preferred restricted consent as compared to broad and/or tiered consent. However some of them that would give the restricted consent said they may eventually give broad consent if they are given feedback.

I prefer the restricted consent of which you have to come for another consent if you want to use my specimen for other researches.
Female Pharmacy Technician/spokesperson urban B3 - Kano

I think the broad consent is total consent and the restricted is partial consent. I will choose the broad consent.
Male Medical Doctor urban C2 - FCT

I prefer the tiered consent, but may thereafter give a broad consent if I am given feedback on what has been done with my specimen.
Male Medical Doctor urban B6 - Kano

I will pick restricted consent as my option.
Male Medical Doctor urban D9 - Enugu

I prefer the consent that will be for the immediate and forget about it (i.e tiered consent).
Female Nurse rural A12 - Oyo

4.2.1.4 Feelings about having the donated specimens and data shared by different researchers or shipped for further research.

Most participants in these group of respondents wouldn't like the sharing of their specimens with other researchers without re-consenting. Only few individuals wouldn't mind the sharing of their specimen with other researchers provided the non-communicable disease researchers trust what the other researchers would do with their specimens.

Provided you trust them you can go ahead and give other researchers my specimen.
Female Pharmacy Technician/spokesperson urban B3 - Kano

If I did not give a broad consent then I do not permit you to share my specimen with other researchers.
Male Medical Doctor urban B6 - Kano

My consent has to be obtained again before you share my specimen with other researchers. Am a health worker I know what am heading to.
Male Medical Doctor urban D9 - Enugu

You can share my specimen with other researchers, I do not have problem with that. You may also take the samples to others countries as long as it is not used for human cloning and things that Christianity will frown at.
Female Pharmacist Urban D18 - Enugu

No, do not give my specimens to other researchers. Since you are the one I trust in and gave my sample to, do not give to others. You are free to take it outside the country for further analysis.
Female Nurse rural A12 - Oyo

4.2.1.5 Someone they must tell before giving consent for the biobank research

The participants that will inform their spouses before participating in the biobank research were in the majority. They are of the belief that their spouses will not be happy when they get to know of it later. Only a few respondents said they do not have to let anybody know.

I will not participate in the research if I did not tell my husband.
Female Nurse urban C1 - FCT

My wife will feel bad if I do not let her know before participating.
Male Nurse/Spokesperson urban C7- FCT

I will tell my husband, and he will feel bad if I did not do so. Since I am under him , he need to know all about what I want to do.
Female Pharmacy Technician/spokesperson urban B3 - Kano

I do not need to inform anybody before I participate in the research, except if it a drug trial. This is because of our experience during the Pfizer drug trial in Kano.
Male Medical Doctor urban B6 - Kano

For medicolegal reasons I do have to tell anybody before I participate. There's an age you will reach that you do not need to tell anybody before you do so.
Male Medical Doctor urban D9 - Enugu

I don't have to inform anybody before I take part in the research.
Male Medical Doctor urban C2 - FCT

I will notify my husband and my children of my interest to participate. There's no way I will not tell them, they will not like it if they get to know later.
Female Nurse rural A12 - Oyo

4.2.1.6 Feedback and receiving news from the biobank research

The participants in this group felt that access to individual research results had significant implications. Several of them thought it would be very important to receive

feedback and general news about studies done through the biobank, though with pre-counselling. A few participants were not bothered.

> *I would like to be given feedback, especially my personal results because through telling me I will know what to do.*
> Female Pharmacy Technician/spokesperson urban B3 - Kano

> *I should be given counselling before am given any feedback. It should involve pre-counselling.*
> Male Medical Doctor urban D9 - Enugu

> *It is important for me to know, if the biobank discover something serious about my health, they should let me know.*
> Female Pharmacist Urban D18 - Enugu

> *I should be give feedback even when it is discovered that I have a serious case. I could be given news as well.*
> Female Nurse rural A12 - Oyo

4.2.1.7 Perception of benefits of participating in biobank research

The majority view of the respondents was that the research will lead to drugs discovery that could help in the management of diseases. A few participants said the research will help them get medication if they are discovered to have health problems. The benefits accruing to the participants need to be clearly stated, since in many cases, there's no direct benefits to patients from donation of biospecimens for biobank research.

> *Biobanking can be lead to discoveries that can enhance and improve the management of diseases. It can help you to be more careful.*
> Male Medical Doctor urban C2 - FCT

> *If I have one of the conditions, a cure or its management can be found which I or people around me will benefit from.*
> Male Medical Doctor urban B6 - Kano

> *It is a one step access to specimens for research and experiments. If there's problem in my family, it might be traced to my genetic coding or lineage, and it might be through my specimens or that of my family member collected over time.*
> Female Pharmacist Urban D18 - Enugu

> *If my specimen is tested and I have disease, the direct drugs to be used could be given to me.*
> Female Nurse rural A12 - Oyo

If a patient that has a health problem can get medication from this research I am indirectly helped as I am part of the community.
Female Pharmacy Technician/spokesperson urban B3 - Kano

4.2.1.8 Future use of the specimens from the biobank research

Majority of the participants were sceptical on the kind of research that will be carried out in the future as no examples of future uses could be given. A few were not bothered on the use of their samples for future research.

I do not mind if the sample will be kept and used indefinitely.
Male Medical Doctor urban C2 - FCT

I may not want to be involved in future researches as I do not know the type of researches that will be carried out.
Male Medical Doctor urban B6 - Kano

4.2.1.9 Concerns about the Biobank research

The majority of the concerns of these respondents included misuse of information, confidentiality and the possibility of discovery of deadly disease on them. A few of them could not express what their concerns were as they do not have detail information on the operations of biobanks.

A participant was particularly uncomfortable about research that will involved human cloning which she said is unethical. Another participant said if the blood is not collected in the hospital setting he will not donate as he was worried that his blood could be used for rituals.

The issue of confidentiality has to be put into consideration, also if any, you inform the participant of a possible deadly disease or worsening of his situation.
Male Medical Doctor urban C2 - FCT

I do not know the risk of biobank research now. I need further knowledge about it to be able to say the risk involved.
Female Pharmacy Technician/spokesperson urban B3 - Kano

There may be some risk. If you are someone who want to know what happens to your specimen you may feel disturbed. Any breach of confidentiality can make me change my mind. That is if someone meet me somewhere and said I learnt you gave your sample for a research.
Male Medical Doctor urban B6 - Kano

Everything has its own risk. I think biobank has its own risk. One can be infected by those tissues stored in the bank. There can be occupational hazards.
Male Medical Doctor urban D9 - Enugu

I do not have any concern, I think it does not have any risk.
Female Nurse rural A12 - Oyo

My fear and concern is that the samples may be used for unethical practices in the future such as human cloning, thereby deviating from the intended purpose of the biobank.
Female Pharmacist Urban D18 - Enugu

If my specimen will not be collected at the hospital I will not give it, because collecting it in the hospital will assure me that you will not use it for ritual.
Male Nurse/Spokesperson urban C7- FCT

4.2.1.10 Religious or cultural issues on biobank research

One of the participants was bothered if the biobank will carry out research on human cloning that is contrary to her religious belief. Others do not think biobank is against their religion or culture.

Anything related to health, my Muslim religion is not against it.
Female Pharmacy Technician/spokesperson urban B3 - Kano

Like I mentioned before, the samples may be used for unethical practices such as human cloning which will interfere with my Christian belief. Uncertainty on this and limited knowledge on the religious implication on my action can make me change my mind of participating in the research.
Female Pharmacist Urban D18 - Enugu

I don't think there's any religious or cultural view that is against biobank research.
Female Nurse rural A12 - Oyo

4.2.1.11 Access to medical records for the biobank research

A majority of interviewees said that permitting access to their medical record would not affect their decision of participating. Some participants believed it will help them get clarifications on some things about themselves.

> *Access to my medical records wouldn't change anything.*
> Male Medical Doctor urban D9 - Enugu

> *You are helping me so I will not feel bad. There are some things which I may not understand, but through the research it will become clear.*
> Female Pharmacy Technician/spokesperson urban B3 - Kano

> *It depend on how you use my medical records, since it is not an issue of identification, no problem.*
> Male Medical Doctor urban B6 - Kano

> *Having access to my medical records won't change anything.*
> Male Medical Doctor urban C2 - FCT

> *You know that medical record is supposed to be something secret, so it has to be with my consent.*
> Female Nurse rural A12 - Oyo

4.2.2 Religious Leaders and Members

4.2.2.1 Knowledge of biobank and collection of human biological specimens for non-communicable disease research.

A majority of the respondents showed interest in the proposed sample collection for biobanking and some of then found it much easier than others to understand and say what it is all about.

> *Biobank is where they keep blood for research.*
> Male Christian Leader rural D3 - Enugu

> *Biobank is where blood is stored for researching on infections.*
> Male Christian Leader rural C13 - FCT

> *Biobank is used for carrying out research on non-communicable diseases like cancer and diabetes.*
> Male Muslim Leader urban B6 - Kano

4.2.2.2 Understanding of, and Attitudes to research and non-communicable disease research.

The knowledge of, and attitudes of the participants to medical and non-communicable disease research varied widely. The majority of the participants had good knowledge of research. They believe it will help to gain insight into the unknown, discover new things and to solve problems.

> *Specifically when they are talking about research, it is all about quest for something that is not glaring yet. It is to acquire the real fact about it, if it is possible and the necessary solution, and ways of making such a thing materialised. I feel research is part of discovering new things. I will participate in the research, but it depends on the quantity of blood they may need. I feel if it is a research to discover something tomorrow, it is not a problem to me, I can donate free.*
> Male Christian Leader urban C11 - FCT

> *Research has to do with in-depth searching, analysis, collation of data for a particular purpose, especially for finding solution to a particular problem.*
> Male Christian leader rural C13 - FCT

> *Research is finding out what happens before a solution is gotten.*
> Male Muslim Leader urban C6 - FCT

> *Research is something you don't know and you want to know more.*
> Male Muslim Leader urban A9 - Oyo

> *Non-communicable disease are diseases that cannot be transferred from one person to another through contact, such as diabetes, cancer, hypertension, cardiovascular disease, like congestive heart failure and depression.*
> Male Christian Leader rural D3- Enugu

> *I do not know what non-communicable diseases is.*
> Male Christian Leader rural C13 - FCT

> *Research is to clarify about what is secret.*
> Male Christian Leader urban A13 - Oyo

> *I am well aware of non-communicable diseases*
> Male Muslim Leader rural B14 - Kano

Their sources of information and influence on research were the media – television, newspapers, magazines and public enlightenment – were their main source of

information and influence on knowledge and attitudes surrounding medical and non-communicable disease research.

> *I get information from people that come from ministry of health that enlightens us.*
> Male Christian Leader rural D3 - Enugu

4.2.2.3 Consent for the biobank research

The majority of the respondents said they will give broad consent. An individual would not participate, while another participant believed that the biobank researchers will still go ahead and use his specimen for other researches even if he chooses the restricted consent.

> *I think that the broad consent you mentioned is okay by me, which is for as long as it is going to be of help to humanity.*
> Male Christian Leader urban C11 - FCT

> *Informed consent has to do with me giving my consent or making what we call informed choice that is based on knowledge. I will give the broad consent for the research.*
> Male Christian Leader rural D3 - Enugu

> *Even if I did not allow them they will still go ahead and use my specimen. What is the need choosing a particular consent*.
> Male Muslim Leader urban C6- FCT

> *I do not want to participate in the biobank research, and my reasons are personal to me.*
> Male Muslim Leader Urban B7 - Kano

> *I will give the restricted and the broad consent.*
> Male Christian Leader urban A13 - Oyo

> *I will ask you to continue using my specimen for other research if it will not harm me.*
> Male Muslim Leader urban A13 - Oyo

> *I will give the restricted consent.*
> Male Muslim Leader rural B14 - Kano

4.2.2.4 Feelings about having their donated specimens and data shared by different researchers or shipped for further research

Only a few of the participants tend to show some disagreement on the sharing of their sample with other researchers. The majority wouldn't mind the sharing of their specimens. A participant expressed confidence on USA as the only country he would like his specimen to be sent to based on what he had heard about their meticulous way of handling medical problems and researches, and the value they have on human lives, which most Africans don't have.

> *I particularly defer, the person I gave the authority over my blood should also be able to use my blood and be confidential about it, it shouldn't be extended to another researcher.*
> Male Christian Leader urban C11 - FCT

> *I will not feel bad if you share my specimen with other researchers provided it will be for a good purpose. Some people may come from other west African country, I will not give them my sample as I do not know what they will do with it. Now we are afraid people take blood for a different things.*
> Male Christian Leader rural C13 - FCT

> *You may share my specimen with other researchers. You can send it to any country that does well in research or are competent in research, for example USA. My reason is based on the little I have heard about their meticulous way of handling medical problems and on researching, and what I heard about the value they have on human lives, they value human lives a lot, most Africans don't value human lives.*
> Male Christian Leader rural D3 - Enugu

> *If I have given my specimen, it is wholehearted. Why should I worry myself about which researcher is using it or the country of shipment.*
> Male Christian Leader urban A13 - Oyo

> *You should not share my sample, other researchers should do their own work and collect their samples.*
> Male Muslim Leader urban A13 - Oyo

> *If I am told before time you can go ahead and share. You may also send it abroad, it could be any country.*
> Male Muslim Leader rural B14 - Kano

4.2.2.5 Someone they must tell before giving consent for the biobank research

A major proportion of the respondents said they must let their spouses know. Others mentioned their children and parents. A few of them do not think it is necessary to inform anybody.

> *As a family man, I should be able to consult my wife. My family will feel bad if I do not tell them.*
> Male Christian Leader urban C11 - FCT

> *I will give my consent since it has to do with health. It is immaterial to tell any body, because I am independent, I am autonomous.*
> Male Christian Leader rural D3 - Enugu

> *I will inform my wife, children and my parents before giving consent to participate in the research. This is because if something negative happens as a result of my participation, they will get to know it and blame me.*
> Male Christian Leader rural C13 - FCT

> *Not until I consult anybody before I give consent, am old enough to give consent.*
> Male Muslim Leader urban C6 - FCT

> *I will inform my father before I participate in the research.*
> Male Muslim Leader rural B14 - Kano

4.2.2.6 Feedback and receiving news from the biobank research

A majority of the participants would like to be given feedback on the research and would want to know if it became apparent that they had some serious diseases. Though it would be unwelcome news, it would be preferable to hear it earlier rather than later. It would allow more time to prepare for the outcome, and the more warning the better. One of the participant believed that feedback could be a motivation to enlighten others about the biobank research.

> *I will appreciate feedback, because it will add to my own knowledge base. I think you should give me my result but if you feel you will not give it to me there's no problem.*
> Male Christian Leader rural D3 - Enugu

They should give us feedback on the research. That's why we gave them our sample. It will also help us to enlighten others about the biobank research.
Male Christian Leader rural C13 - FCT

I would like to receive feedback. And when my result is favourable, it will encourage me to continue my participation.
Male Muslim Leader urban C6 - FCT

I am however interested in the general news on the biobank, even though I do not want to participate.
Male Muslim Leader urban B7 - Kano

I will need feedback of the research.
Male Christian Leader urban A13 - Oyo

I will require feedback.
Male Muslim Leader urban A13 - Oyo

I should be given feedback and news about the research. If something serious about my health is discovered I should be informed, including news. I will not be happy if I am not given my individual result.
Male Muslim Leader rural B14 - Kano

4.2.2.7 Perception of benefits of participating in the Biobank research

The participants believed that the biobanking research will help in the effective management of non-communicable diseases. Some participants mentioned the benefit of keeping the specimens for a long time for future use and how they stand to benefit indirectly from the research.

The research can help me if they find sickness in me, and if I am cured I have been helped.
Male Christian Leader rural C13 - FCT

The specimens can easily be reached and research upon, and could be stored for a long period of time. Though, I do not have non-communicable diseases there are those who are related to me that have it. By the time there's positive outcome of the research, I stand to benefit indirectly, because my relations or sibling who may be affected could be treated.
Male Christian Leader rural D3 - Enugu

Biobank research can be beneficial, if peoples' specimen are used for research, and there's success.
Male Muslim Leader urban B7 - Kano

It is for future prevention. It will help me in the future.
Male Christian Leader urban A13 - Oyo

With this research I will get to know what is happening to me.
Male Muslim Leader urban A13 - Oyo

The research will help in the management of some of this serious diseases(non-communicable). The specimens can be kept for a long time for future studies.
Male Muslim Leader rural B14 - Kano

4.2.2.8 Concerns about the Biobank research

The few participants that were a bit knowledgeable on research had some concerns, while others who were less informed often do not have concerns. There were concerns about possible deviation from the objective of the research. The issue of confidentiality was emphasised. Overall, the religious leaders believed their followers will be willing to take part in the research.

If they take your blood and there's no feedback you won't know what they did with the blood. The disadvantaged part of it is if they didn't do the work very well, or they are not doing the work they way it supposed. If people get to know about it they will be discouraged.
Male Christian Leader rural C13 - FCT

Some of those samples if they are not well managed or well stored or well preserve they could infect people who are lethal. For instance if they are expose to bacterial contamination while in the biobank, they could be a source of infection to those who are lethal. If the researchers are not diligent enough to sought out the solution to the diseases, but just collected data and not making use of them that could be a source of concern.
Male Christian Leader rural D3 - Enugu

Biobank is new to me, I wouldn't know if it has risk.
Male Muslim Leader Urban B7 - Kano

If I discover any wrong step that is taken in the course of the research I will withdraw my participation.
Male Christian Leader urban A13 - Oyo

Since I do not know much about biobank, I wouldn't know the risk involved in it. I will have concern if you sell my blood.
Male Muslim Leader rural B14 - Kano

4.2.2.9 Religious or cultural issues on biobank research

No single participant had any religious or cultural view on biobank research.

A participant said the bible has some aspects that laid emphasise on how to help people out of their condition which is what the biobank does.

> *I think the thing the bible emphasised is how to help people out of their condition, so the bible specify things in helping people much, so God has given them the wisdom, I don't think there's any thing wrong with the research. It will help people out of problems.*
> Male Christian Leader rural C13 - FCT

> *I have not found anything that contradict it (biobank research). Am not a cultural practitioner, I don't partake in most of the culture because of my Christian belief because most of the cultural belief contradicts the Christian beliefs and ethics.*
> Male Christian Leader rural D3 - Enugu

> *My refusal to participate is not due to religious or cultural issues.*
> Male Muslim Leader urban B7 - Kano

> *My religion is not against it, but there's divine healing.*
> Male Christian Leader urban A13 - Oyo

> *My religion is not against biobanking research.*
> Male Muslim Leader urban A13 - Oyo

> *My religion is not against this kind of research.*
> Male Muslim Leader rural B14 - Kano

4.2.2.10 Access to medical records for the biobank research

A majority of interviewees said that providing access to their medical record would not affect their decision about participating. A participant said he does not go to the hospital and so do not have medical records.

> *I will not feel bad if you have access to my medical records.*
> Male Christian Leader urban A13 - Oyo

> *I do not have any medical record.*
> Male Muslim Leader urban A13 - Oyo

> *I will not be worried if you have access to my medical records.*

Male Muslim Leader rural B14 - Kano

4.2.3 People with non-communicable diseases and their relatives

4.2.3.1 Knowledge of biobank and collection of human biological specimens for non-communicable disease research.

Individuals suffering from diseases and those individuals' relatives tended to be better informed and more accepting of the use of biological specimen in the biobank research.

> *Bank is where we store things, money or anything you want to store. Biobank is were we store specimens that are collected from human being for study in order to benefit human kind.*
> Male Hypertensive patient/student urban C3 - FCT

4.2.3.2 Understanding of, and Attitudes to research and non-communicable disease research.

In their understanding of, and Attitudes to research and non-communicable disease research, they perceived research as that which focused on finding cures, solving problems and discovering drugs for diseases. In broad terms, they believed its purpose was focused on improving the health of the humanity.

> *In my understanding of research, it can be considered in two ways;1. Re- means looking at it again;2. Search- means study. When you combine the two it means you are studying something that was there before either to put it in a proper way to get result. Non-communicable diseases are like neglected diseases because not much is known or being done about them by the government, even though they are very dangerous. Infact, they are all silent killers.*
> Male Hypertensive patient/student urban C3 - FCT

> *Research is used to determine the fact on something and how it will be done to achieve an objective. I know about non-communicable diseases. When I was tested, I was told that I am hypertensive.*
> Male Hypertensive patient urban B8 - Kano

> *Research is to test someone that is not well to ascertain what is wrong with him.*
> Relation of hypertensive patient urban B9 - Kano

Their Sources of information and influence on research were the media – television and newspapers.

4.2.3.3 Consent for the biobank research

A majority of the participants supported giving restricted consent for the proposed biobank research.

> *I do not want to participate in the research just because of my health condition. I am always very careful.*
> Male Diabetic patient urban C10 - FCT

> *Each time you want to conduct other studies with my specimens I would prefer you re-contact me (i.e tiered consent).*
> Male Hypertensive patient/student urban C3 - FCT

> *I will give the restricted consent.*
> Male Hypertensive patient urban B8 - Kano

> *I will give the broad consent.*
> Relation of Hypertensive patient urban B9 - Kano

4.2.3.4 Feelings about having their donated specimens and data shared by different researchers or shipped for further research

A majority of the participants would permit the sharing of their specimens with other researchers. Only a participant would like re-consenting before his specimen is taken abroad for further studies and would like to know the outcome of such a shipment.

> *I will not feel bad if my specimen is shared, but I should give consent if you want to send abroad, and it doesn't matter whether the researcher is local or international. I would like to know the outcome of the international shipment.*
> Male Hypertensive patient/student urban C3 - FCT

> *You may go ahead and give my specimen to other researcher. You may also take it abroad.*
> Male Hypertensive patient urban B8 - Kano

> *If you believe there's no problem giving my sample to other researchers, you can go ahead. You may also send my sample abroad. But if you want to use my sample for HIV research I should be told.*
> Relation of Hypertensive patient urban B9 - Kano

4.2.3.5 Someone they must tell before giving consent for the biobank research

These respondents do not think they are obliged to tell anybody before participating in the research.

> *It is a personal thing. I will not discuss with anyone before participating in the research.*
> Male Hypertensive patient/student urban C3 - FCT

> *I do not need to tell anybody before I participate in the research.*
> Male Hypertensive patient urban B8 - Kano

> *I won't tell anybody before I participate.*
> Relation of Hypertensive patient urban B9 - Kano

4.2.3.6 Feedback and receiving news from the biobank research

Personal feedback was also seen to be important and could be given to their relations if giving them directly could have negative effects. If people were voluntarily donating samples it was only fair to give them information that came to light about themselves as a result of the samples being used.

> *I would like to be given news and information on the biobank research.*
> Male Hypertensive patient/student urban C3 - FCT

> *I am sure I will be given feedback especially my result.*
> Male Hypertensive patient urban B8 - Kano

> *If it is possible for me to know the result it is OK. But if you feel it will be a problem to me, you may tell any of my relations that you feel should know.*
> Relation of Hypertensive patient urban B9 - Kano

4.2.3.7 Perception of benefits of participating in the biobank research

A majority of the respondents believe that the research will lead to drugs discovery that could assist them or their family members in the future. Some participants said the research will help in informing them on some potentially unknown diseases. In many

cases, there will be no direct benefit to patients from donation of biospecimens for research. This needs to be made clear.

> *The research is for further improvement of mankind, and drugs can be manufactured through the research. It will bring about discovery. Since I am a victim of this non-communicable research, I will benefit personally.*
> Male Hypertensive patient/student urban C3 - FCT

> *Certainly, I will benefit from the research and possibly get cured of this hypertension.*
> Male Hypertensive patient urban B8 - Kano

> *If I have any infection it can be known through the research.*
> Relation of Hypertensive patient urban B9 - Kano

4.2.3.8 Concerns about the biobank research

These participants with diseases and their relatives were more supportive and had fewer reservations. A participant mentioned loss of confidentiality or privacy as the only concern he had.

> *If confidentiality is not kept, and the information I gave is used against me I will withdraw my participation.*
> Male Hypertensive patient/student urban C3 - FCT

> *I do not have any worry about the biobank as it does not have any risk.*
> Male Hypertensive patient urban B8 - Kano

> *I do not have any concern on biobank. I also do not know if it has any risk.*
> Relation of Hypertensive patient urban B9 - Kano

4.2.3.9 Religious or cultural issues on biobank research

No single participant had any religious or cultural view on biobank research.

> *It is not because of any religious or cultural reasons that I said I will not participate. It is just because of the health condition I am passing through.*
> Male Diabetic patient urban C10 - FCT

> *I personally do not have any religious or cultural belief that is against it. But some religious groups do not believe in donation of blood.*

Male Hypertensive patient/student urban C3 - FCT

There's no any religious or cultural belief that is against the biobank research.
Male Hypertensive patient urban B8 - Kano

4.2.3.10 Medical record access for the biobank research

A majority of the discussants said that the researchers can have access to their medical records. The rationale for collecting information was understood by these respondents, especially people with diseases.

Collection of information from my medical record will not affect my participation, because I know it is something that I need to do.
Male Hypertensive patient/student urban C3 - FCT

You can go ahead to access my medical records.
Male Hypertensive patient urban B8 - Kano

I have no problem allowing you access to my medical records.
Relation of Hypertensive patient urban B9 - Kano

4.2.4 Spokesperson/opinion Leaders and Lawyers

4.2.4.1 Knowledge of biobank and collection of human biological specimens for non-communicable disease research.

Biobank research was not known, but had meaning and associations for most of the respondents. Many of these respondents were enthusiastic about biobank research. Generally the better it was understood, the more positive their view. The more informed and positive view was that it could be of great importance in identifying health problems, and treatment of disease. Some of their perception of biobank after an overview, which was expressed in their own words are mentioned below;

In biobank, information are gathered for further use.
Female Spokesperson urban C9 - FCT

Biobank is just like collecting blood and keeping it somewhere for research. It is different from medical research in that they will not

give you treatment like what the doctors do in hospital when you go there.
Female Spokesperson rural C12 - FCT

The term bio means life, the bank is a kind of storage. The biokank might connote organic materials that are kept in a specialized place for storage. Those organic materials can include diseases, blood samples and biomaterials.
Male Lawyer (1) D11- Enugu

I do not have anything to say about biobank, since I have not seen it.
Male Spokesperson urban B10 - Kano

I know about bank where I can deposit my money, I do not know about biobank.
Male Spokesperson urban A7 - Oyo

4.2.4.2 Understanding of, and attitudes to research and non-communicable disease research.

Their understanding of, and Attitudes to research and non-communicable disease research were different based on personality and outlook on life. Majority of them were knowledgeable on research. Some of them said they would have no concerns if asked to donate samples; others seemed more anxious and would want to know how soon the research would start. They regarded research as a tool in medicine to get solution to problems, and felt it might have long-term benefits for themselves and their relatives. For some it was overdue but nevertheless welcome. A few were not knowledgeable in non-communicable diseases. For example, one of them said HIV and TB were non-communicable diseases. One of them believed that one way a non- communicable disease can be transferred is through blood transfusion.

Non-communicable diseases are diseases that cannot be transferred from one person to another.
Female Spokesperson rural D5 - Enugu

What I understand about research is that, may be you have a particular problem that has no solution, so with research it will assist you to be able to get solution. Research is all about findings. Finding

out about something you did not know before. And non-communicable disease cannot be transferred to another person.
Female Spokesperson urban C9 - FCT

May be you have a particular problem that has no solution. With research you be able to get solution to your problem or what you are looking for. Non-communicable diseases are diseases that you cannot get just like that except by blood transfusion, or any contact, such as ulcer and fever, unlike TB which is communicable.
Female Spokesperson rural C12 - FCT

Research is where they store the blood for researching infections. Research is to bring out something inside something.
Male Spokesperson urban D8 - Enugu

Research is something which a person can use in order to know something which is worrying somebody and health. An example of non-communicable disease is headache.
Male Spokesperson rural D1 - Enugu

Research is collecting data and information for a purpose.
Male Spokesperson rural C14 - FCT

Research is an advanced study. Finding out something that is in existence but is not known by man".
Male Lawyer (1) D11 - Enugu

Research is something you want to know deeper of it.
Female Spokesperson urban A5 - Oyo

Research is an in-depth study about a particular subject, coming with specific answer about a specific subject. Non-communicable is a disease that a carrier cannot give to another person.
Male Lawyer urban (2) D12 - Enugu

I do not know what you meant by research.
Male Spokesperson urban B10 - Kano

Research is grass root development.
Male Spokesperson urban A7- Oyo

Research in the area of human health is to find out what is wrong with the person, to know the steps to take, the drugs that could be used to cure it. Non-communicable diseases are things like HIV, TB, cancer and diabetes.
Male Spokesperson rural B15 - Kano

Their sources of information and influence on research were by chatting with their colleagues and the media such as television, newspapers, and magazines.

4.2.4.3 Consent for the biobank research

A majority of the participants would want re-contact for another consent for any future research with their specimens. Some of them reluctantly gave go ahead that samples can be used for further studies only if they cannot be reached again.

> *I will prefer that the researchers come to me for another consent for future use of my sample. I will give consent for non-communicable diseases research only (i.e. tiered consent).*
> Female Spokesperson urban C9 - FCT

> *I should be re-contacted if my sample will be used for another research, this is because it gives me more security (i.e. tiered consent).*
> Male Lawyer urban (2) D12 - Enugu

> *Informed consent means to have my consent. If I give my consent for non-communicable disease research, and you people want to carry out another research you should come and meet me for another consent (i.e. tiered consent). But if I cannot be reached, you can go ahead.*
> Female Spokesperson rural C12 - FCT

> *I would like to be informed before my specimen is used for another research (i.e. tiered consent). Even when I have moved away from my previous location, inquiries should be made at my previous location for my where about.*
> Male Spokesperson rural D1 - Enugu

> *I cannot tell you now of the type of consent I will give for the research, until I get details of the research, because blood can be used to do another thing. In the alternative I will seek further clarification from someone who is more knowledgeable.*
> Male Spokesperson urban D8 - Enugu

> *My specimen can be used for as many researches as possible since it is for good.*
> Male Spokesperson rural C14 - FCT

> *If you collect my specimen you can use it for anything.*
> Female Spokesperson rural D5 - Enugu

> *I will give consent for both the restricted and broad consent.*
> Male Lawyer (1) D11 - Enugu

> *I will give consent for the restricted consent.*
> Male Spokesperson urban B10 - Kano

> *I will give broad consent.*

Female Spokesperson urban À5 - Oyo

I will give the broad consent since it is research on human health.
Female Spokesperson rural B12 - Kano

4.2.4.4 Feelings about having their donated specimens and data shared by different researchers or shipped for further research

A majority of the participants would permit the sharing of their specimen with other researchers. A majority were also not bothered if their samples are taken to other countries for further research. A few respondents did not want their samples sent to other African countries as they do not have faith on them. A participant would like to know the purpose, and the person that will benefit from taking the specimens abroad. Another participant would like an undertaken to be written before his specimen is taken abroad.

As long as it will bring progress to people you can share my specimen with other researchers. If it is sent abroad and something is discovered I would like to know.
Female Spokesperson rural C12 - FCT

If the researchers are from one of the west African countries for example I will not give them my specimen, because we are not from the same country and I don't know what they will do with my blood there. But as far as Nigeria is concerned and you are one of my brother I know there is nothing that you discover that you will not let us know. I am afraid since people take blood for other things. They can however take my sample abroad (outside Africa).
Male Spokesperson rural D1 - Enugu

For me there no problem if you share my specimen with other researchers. For example when I was doing my diploma programme, I went to another place to obtain my data and they agreed to share with me. If I have a disease and they want to take my specimen abroad, they should let me know. Though my reason is to get the information so that I can seek for solution.
Male Spokesperson rural C14 - FCT

I will like you to share my specimen with other researchers because it is not only one person that knows everything.
Male Spokesperson rural D1- Enugu

I have to get further advise from my senior brother before I permit you to take my specimen abroad or share it with other researchers.

Male Spokesperson urban D8 - Enugu

You can go ahead and share my specimen with other researchers provided you maintain confidentiality. If you take my specimen to advanced countries I have more confidence, because I know some Africans does not report research findings correctly. There's a kind of falsehood embedded in some of African science which is not based on facts and figures nor based on empiricism. But before sending my God given parts abroad, you should tell me the purpose, and the person that will benefit from this arrangement.
Male Lawyer (1) D11 - Enugu

If you want to take my specimen abroad for a good purpose, no problem. It is when you are taking for ritual purposes that I will not be happy.
Male Spokesperson rural C14 - FCT

That is why I say I will not give absolute consent because you may want to do anything you want. I need a bit of information for me to allow you share with other researchers and to take it abroad.
Male Lawyer (2) D12 - Enugu

If you trust the researcher, you can go ahead and give them my specimen. You may also take it abroad.
Male Spokesperson urban B10 - Kano

I will allow you to take it abroad and to share with other researchers.
Female Spokesperson urban A5 - Oyo

You should not share my specimen with other researchers since I did not know them as I know you. I should be told when you want to take it abroad, so that you will write an undertaking.
Male Spokesperson urban A7 - Oyo

I won't feel bad if you share my specimen with other researchers or take it abroad for further analysis. It doesn't matter the country you take it to.
Female Spokesperson rural D5 - Enugu

If you think it necessary to share my specimen with other researchers you can go ahead. When I give my specimen it is whole heartedly. You can also take it abroad.
Female Spokesperson rural B12 - Kano

4.2.4.5 Someone they must tell before giving consent for the biobank research

Majority of the respondents said they will let their spouses, parents, brothers and relations know before they participate in the research. They are of the opinion that if

the research has a negative boomerang they will be blamed for not consulting before participating.

> *The first person I will inform is my husband, the people around me comes second; either my chief and people around me. Because if it bounds back on me, they will get to know and will not be happy.*
> Female Spokesperson urban C9 - FCT

> *I will inform my senior brother before I participate, because he knows more than me.*
> Male Spokesperson urban D8 - Enugu

> *I will tell my mum and my uncle before I participate. As their child, if I want to do anything like that I supposed to inform them, though am now a grown up woman.*
> Female Spokesperson rural C12 - FCT

> *I will inform my wife and my children before I participate, and if possible my parents, because if any thing happened and they get to know about it, they will feel bad that I did not tell them before participating.*
> Male Spokesperson rural C14 - FCT

> *By now I have a partner, I will discuss such a research with her, and I will gain from her. She will feel somehow if I did not tell her. There's nothing different between her and me.*
> Male Spokesperson rural D1- Enugu

> *No, as an adult I don't think I will discuss with anybody before I participate.*
> Male Lawyer urban (2) D12 - Enugu

> *I will let my parents know before I participate.*
> Male Spokesperson urban B10 - Kano

> *I will tell my husband that is closer to me before I participate.*
> Female Spokesperson rural B12 - Kano

4.2.4.6 Feedback and receiving news from the biobank research

There were demand for feedback by majority of the participants. They felt that it would be important for donors to have the right to feedback on anything that emerged from their own sample, and felt that this would have to be handled carefully. There was also

interest in getting feedback on the discoveries or developments made as a result of the research.

It should be established when the donor agreed to take part whether he or she wanted to be informed about any disease or condition he or she might have. Allied to this, some people felt that a mechanism should be in place to provide support for those who were discovered to have certain diseases or conditions.

> *I will feel bad if no feedback is given to me, because I want to know my result. If you know what your problems are you will look for solution.*
> Female Spokesperson rural C12 - FCT

> *Even if I am not given any feedback I should be told when the specimen will be taken abroad. Let it be that they are taking the specimen abroad for a good thing (research).*
> Male Spokesperson rural C14 - FCT

> *If something serious is discovered about me I should not be given feedback on it.*
> Female Spokesperson urban C9 - FCT

> *I would like to be given feedback on the research as it will help me to take precautionary measures. It will help me to know the type of food I will eat, know how to manage myself appropriately to lengthen my life. They should also make available publications that will inform me.*
> Male Lawyer (1) D11 - Enugu

> *I would like to be given feedback of the research. I will not however feel bad if I am not given any feedback.*
> Male Spokesperson urban B10 - Kano

> *I should be given feedback of the research even when something serious is discovered about me.*
> Female Spokesperson urban A5 - Oyo

> *You should tell me of any serious discovery about me if there's rescue.*
> Male Spokesperson urban A7 - Oyo

> *I want feedback about the research and I would like you people to tell me if you discover something serious about my health. Though I will not feel bad if you do not give me feedback, but it will be good you give me feedback.*
> Female Spokesperson rural D5 - Enugu

I should be informed if there's something serious about my health and if you can help you go ahead and do so. I should be given news of the research as well. There's no problem if am not given my personal result.
Female Spokesperson rural B12 - Kano

4.2.4.7 Perception of benefits of participating in Biobank research

The perception of benefits were to do with the advances in the area of drugs development for cure and preventative treatments.

Biobank can be used for health matters, for future development and so on. The specimens in it can be used tomorrow to save my life and that of my children.
Female Spokesperson urban C9 - FCT

If there's a problem that has no solution, through biobank research the doctors or researchers can get a solution. They will be able to come up with drugs as well. There are diseases that we may not know about them personally, but through the research we will know about them and their solution.
Female Spokesperson rural C12 - FCT

It will be of benefit to me if they take my blood and find out the disease that I have. I will also benefit from the medicine that will be produced which will be used to cure the disease. Like now I am somebody who is having arthritis on my two legs if they can use my specimen and give me cure it will be a benefit to me.
Male Spokesperson rural D1 - Enugu

Just as they say that people with sickle cell anaemia do not have malaria, I do not know whether it is AS or SS that will not have the malaria. It is by comparing cells that researchers know that people with sickle cells don't have malaria. It is from research that we know that the white men are prone to some diseases than the blacks. It is when you have the biodata of the black and white men that you can know their immunity or weaknesses to some diseases.
Male Lawyer (2) D12 - Enugu

The benefit of biobank research is that it can be used for testing blood. If there are other benefits I wouldn't know now.
Male Spokesperson urban B10 - Kano

I do not know any benefit that one can get from it".
Female Spokesperson urban A5 - Oyo

By using the biobank it will be very easy to detect diseases that has come my way.

Female Spokesperson rural D5 - Enugu

I am helped if I am research upon on non-communicable disease.
Female Spokesperson rural B12 - Kano

4.2.4.8 Concerns about the Biobank research

The main concern was the general issue of donors' anonymity when information is being made available in the public domain. Some of the participants would not like the biobank to use their specimens for something that is out of God's way, or will not please God. Another participant wouldn't like his specimen to be used for cloning or stem cells research. Another participant would not donate semen, tissue from his eyes or tissue from his anus. A participant referred to research that could lead to the production of biological weapon or a strain of virus that could be used to destroy human beings as negative and would not like his specimen to be used for it.

If the researchers are not sincere it is a risk. If they keep to their words, it is an achievement.
Female Spokesperson urban C9 - FCT

Provided the biobank will not be used for something that is out of God's way, but for as long as it is for our own good I wouldn't have any problem.
Female Spokesperson rural C12 - FCT

My concern is that they may use the biobank for something that will not please God, for example occultism. From the research, those that did not know they had disease will get to know it. It may be HIV/AIDS and it will affect them psychologically. I will feel bad if they keep our specimens without carrying out research on them, because I believe they will get back to one of us as a feedback if they carry out research on our specimen. If there's segregation whereby they give some people feedback and I am not given I will not be happy.
Male Spokesperson rural C14 - FCT

I cannot tell if biobank has risk or not as I have not used it before. This is the first time I am hearing of biobank.
Male Spokesperson urban D8 - Enugu

I may have objection if you want to use my specimen for cloning or stem cells research. Nobody would like to hear any secret information he has given in confidence being broadcasted somewhere. Lets say

you are now watching TV and they are having a programme on national geographic, and it is about a research that was done and your name comes up. They used your real name, used everything just to show that the programme was authentic, meanwhile, the doctors call it confidential information.
Male Lawyer urban (2) D12 - Enugu

I will worry if the biobank research has to do more with my private life, say I am asked to bring my semen, to collect a tissue from my eye or tissue from my anus. I don't know when someone may want to exploit me for his own gain.
Male Lawyer (2) D12 - Enugu

I will be concerned if the biobank research will have a negative effect on my parents.
Male Spokesperson urban B10 - Kano

Everything about life has risk, so biobank has risk but I do not know the risk now.
Male Spokesperson urban A7 - Oyo

I don't think biobank has any risk, instead it helps to cure people. I will change my mind of participating if there's not specific outcome that can be used to cure the people.
Female Spokesperson rural D5 - Enugu

If the researchers are unfaithful and broadcast information about us, I will withdraw my participation. If they do not keep information they collect from us secret I can withdraw.
Female Spokesperson urban C9 - FCT

It is a risk if they use the specimens for something else other than what they obtained consent to do.
Female Spokesperson rural C12 - FCT

If I have admitted that biobank can be used to store a germ, a microbe, and some of them can be terrible and dangerous when they get into man, unless there's safety and security of that bank, it is a problem. If Newcastle disease or a germ causing Newcastle disease is stored in the bank for further studies or a virus is stored in the bank and it is not well stored within a given ambient temperature required and it escapes into a farm it is a problem. It can cause epidemics. If the researcher is irresponsible and does not obey the code and conduct of the profession and he leaks secret, and does not maintain high degree of confidentiality I will file out from participating. I wouldn't allow you to use my specimen for everything they call research some research could be negative. Somebody could carry out research to produce biological weapon to kill other human being. I won't permit this. If my specimen is used to produce a strain of virus to destroy human beings, I wouldn't like it.

Male Lawyer (2) D12 - Enugu

I do not think I have any concern that will make me withdraw my participation.
Female Spokesperson rural B12 - Kano

4.2.4.9 Religious or cultural issues on biobank research

The participants had no view on religion or culture. They assume that biobank in Nigeria is new and they do not know if religion and culture will be against it.

Since biobank is not widespread, in future we will know if religion and culture will reject it.
Female Spokesperson urban C9 - FCT

We go to the hospital, so I do not think it is against my culture and religion.
Female Spokesperson rural C12 - FCT

Am a free thinker. My religion cannot prevent me from participating in biobank research.
Male Lawyer (2) D12 - Enugu

Anything that does not go contrary to the constitution, religion is not against it. Culture is not also against it. That's why we go to hospital for help.
Male Spokesperson rural D1 - Enugu

Biobank research does not affect my culture or religion because it is for good.
Male Spokesperson rural C14 - FCT

I do not have any cultural or religious belief that is against biobank research.
Male Spokesperson urban B10 - Kano

Biobank research is not against my religion.
Female Spokesperson urban A5 - Oyo

Am a Christian, biobank is not against my religion.

Male Spokesperson urban A7 - Oyo

I do not have any cultural or religious view on biobank.
Female Spokesperson rural D5 - Enugu

There no religious or cultural view against the biobank.
Female Spokesperson rural B12 - Kano

4.2.4.10 Medical record access for the biobank research

Respondents were told that information gathered on volunteers would be stored on computer. When the rationale for gathering information on donors was explained, worries tended to dissipate. Though, confidentiality was considered a significant issue in light of the need for personal medical records along with the specimens. As some were seriously concerned about confidentiality and felt that if this is handled with kids gloves they might be discourage and may withdraw their participation. The request for information from medical records were seen by many of the participants to be okay. They felt they had nothing to hide. For many it caused little worry, for several reasons, they believed that if information is properly encoded or encrypted it will not be accessible to people unauthorized.

> *I should be informed before you go for my medical records.*
> Male Spokesperson urban A7 - Oyo
>
> *There's no problem if you go for my medical records.*
> Female Spokesperson rural C12 - FCT
>
> *There no problem if you have access to my medical records, provided it is used to further medical science.*
> Male Lawyer (1) D11 - Enugu
>
> *I will feel bad if I am not informed before they obtain information from my medical records.*
> Male Spokesperson rural C14 - FCT
>
> *I don't think there's anything I may want to hide in my medical records, but there should be a level of confidentiality.*
> Male Lawyer urban (2) D12 - Enugu
>
> *You can have access to my medical records.*
> Male Spokesperson urban B10- Kano
>
> *I won't feel bad if you have access to my medical records.*
> Female Spokesperson rural D5 - Enugu
>
> *I will permit you access to my medical records.*
> Female Spokesperson rural B12 - Kano

4.2.5 Ethicists and Scientists

4.2.5.1 Knowledge of biobank and collection of human biological specimens for non-communicable disease research.

Donation of biological specimen for research especially biobank research was believed by this participants to be useful in saving lives. Majority of them knew about biobank. In their definition, they associated the biobank with blood bank.

> *I have heard of it before, but do not know what it was all about. But it is just like blood bank. I think blood sample will be kept in it and used for research. And I will give my sample as it may help other people.*
> Male Scientist urban C8 - FCT

> *Biobank is just like when you talk about bank where you keep things, preserve them, to be used at a later time for other things. Bio means (living tissues, human biological specimens) being kept in a special place preserved over time to enable future use of such things for one thing or the other. Sometimes you can use them for research or another purpose.*
> Male Ethicist urban D6 - Enugu

> *I just could perceive now what biobank means, whereby specimen can be stored to maintained the status of the specimen as longs as the biobank could do it.*
> Male Scientist urban D7 - Enugu

> *Biobank is a machine used to diagnose blood products.*
> Male Scientist urban B2 - Kano

4.2.5.2 Understanding of, and Attitudes to research and non-communicable disease research.

Their understanding of, and Attitudes to research and non-communicable disease research were positive. They had good understanding of research and were supportive of biobank research and felt that it had many potential benefits.

> *I'm hypertensive, non-communicable disease research will help me.*
> Male Scientist urban D7 - Enugu

Research is carrying out a test and knowing the problem affecting the individual.
Male Scientist urban C8 - FCT

It is important and key to development and technology. It is a way of solving problems, gaining insight into problems or circumstances surrounding our life and the world.
Male Scientist urban D7 - Enugu

Research is the scientific method of getting information.
Male Scientist urban B2 - Kano

Research is fact finding to provide improvement on a particular situation. It is a scientific and systematic way of generating data to provide solution to societal problems .
Male Ethicist urban A10 - Oyo

Their main sources of information and influence on research were the media – television, newspapers, magazines and journals.

4.2.5.3 Consent for the biobank research

A majority of the participants supported broad consent. A participant was sceptical on the type of research that will be done with his specimen and will prefer to give a restricted consent. Another participant would like to give a restricted consent if his specimen will be used for commercial purposes so that the ownership will be clearly defined in terms of the benefits that will accrue to him from the research.

Informed consent should be voluntary, should be genuine, and there should be no form of coercion, manipulation and they should provide me with enough information to enable me understand what you are saying and to enable me give consent, without holding a gun to my head or influencing me with some money to influence my decision. I will give the restricted consent to participate or I may wave that to the IRB if am not around.
Male Ethicist urban D6 - Enugu

I will give the broad consent for the research.
Male Scientist urban C8 - FCT

It is to help humanity, I don't think I will place restriction on the consent I will give.
Male Scientist urban D7 - Enugu

I will give the restricted consent because if I give the broad I do not know the type of research you will do with my specimen.
Male Scientist urban B2 - Kano

The type of consent I will give will depend on the truthfulness of the researcher. If it is not going to be used for commercial purpose, well I will give the broad consent. Because it will be useful for further research that will enhance health care delivery in the society. But if it is going to be used for commercial purpose I will be interested in the restricted one so that the ownership will be clearly defined in terms of the benefits accruing to me from it.
Male Ethicist urban A10 - Oyo

4.2.5.4 Feelings about having their donated specimens and data shared by different researchers or shipped for further research

All the participants would permit the sharing of their specimens with other researchers provided they were given this option from the onset, and would like to know the outcome of such collaboration. Some were particular on the proper observance of the country's law on material transfer agreement to protect the participants interest.

To share my specimen is OK but they need to inform me so that I can give my consent. If they want to take it out of the country there's no problem but it also depends on why they want to take it out of my country. What else, it is just to give me enough information. Whether they test is in China or the test it in Nigeria, am not sure that should really boarder us much.
Male Ethicist urban D6 - Enugu

I won't feel bad if my specimen is shared by other researchers.
Male Scientist urban C8 - FCT

You can share my specimen with other researchers, but I would like to know their discoveries on the specimens.
Male Scientist urban D7 - Enugu

It doesn't matter if you share my specimen as long as it is for research, and any information coming from such collaboration can broaden my horizon.
Male Scientist urban D7 - Enugu

It is OK to take them abroad if the government cannot provide the facilities. It is good to get to the root of the matter if they cannot do it here in Nigeria. But there should be proper agreement about how the samples will be transferred and used here and outside Nigeria. They

should stick to the Nigerian law on material transfer, from that participants interest will be protected. You can give to other researchers once the agreement is able to protect my interest.
Male Ethicist urban A10 - Oyo

4.2.5.5 Someone they must tell before giving consent for the biobank research

All of these participants do not think they need to inform anybody before they participate in the research. A participant said he may just ask his spouse opinion which will not prevent his participation. Another participant will possibly raise the issue in the nuclear family for wider participation.

I will not tell my wife, and my family will not mind much if I do not inform them. I am in control of myself.
Male Scientist urban D7 - Enugu

I will just discuss with my wife just to get her opinion. That will not prevent me from participating.
Male Ethicist urban D6 - Enugu

I do not need to discuss with any one before I give my consent.
Male Scientist urban C8 - FCT

I will not tell anybody before I participate.
Male Scientist urban B2 - Kano

As a man I don't need to tell anybody, except for the fact of my religion that talks about equality and respect for one another in the family it's something that we may have to discuss in the nuclear family, so that all of us will participate together.
Male Ethicist urban A10 - Oyo

4.2.5.6 Feedback and receiving news from the biobank research

Virtually all of these group of participants said that if they donated their specimen they would appreciate feedback on what the research had discovered or achieved. This would help in assuring them that their involvement had been worthwhile and could also sustain their interest. One of the participant recognized that it may be possible for a participant to know if he/she is likely to have a particular disease in the future.

Some were of the opinion that participants should be given the option to be informed about any disease or condition that is discovered about them in the course of the research, but there should be prior counselling.

> *I should be given feedback, but you have to find the way of telling me. Any information that is useful to me I wouldn't mind.*
> Male Ethicist urban D6 - Enugu

> *I would like to be given feedback.*
> Male Scientist urban C8 - FCT

> *I should know, you rather know your status, that's when you can manage the situation. If it is possible I would like to receive news and information on the research.*
> Male Scientist urban D7 - Enugu

> *I should be given my results as it will enable me to take care of the problem. I am also interested in news from the research.*
> Male Scientist urban B2 - Kano

> *If something serious is discovered about me I should be told. That is the beauty of it. Because that is one of the reasons that biobank is good. You can even project that this individual is likely to have this disease in the future. If I am not given my result I can even go to court. I will enter agreement that you will give me my result.*
> Male Ethicist urban A10 - Oyo

4.2.5.7 Perception of benefits of participating in Biobank research

A majority of the respondents believe that the research will benefit them either directly or indirectly. Some participants said the research will help in informing them on some potentially unknown diseases. The biobank research was a welcome idea to all of them.

> *It can be used to run some test if you want to discover drugs and cure some sickness. It can be used to develop drugs for HIV. Like HIV or hepatitis that do not have drugs, the research could bring out cure.*
> Male Scientist urban C8 - FCT

> *As far as I am concerned, the benefits outweighs the risk. As a person if you have a biobank established in Nigeria I will see myself as a stakeholder. And being in the bioethics world too we know what a biobank mean to those of us in the research world. As a person I stand to gain a lot.*
> Male Ethicist urban D6 - Enugu

I cannot perceive any benefit to me as a person, but I think I will benefit from it as a human being, as a Nigerian, if it gets to working, but I cannot perceive any personal benefits from it. There are a lot of non-communicable diseases in Nigeria right now and it is growing by the day.
Male Scientist urban D7 - Enugu

Because the biobank will provide preventive measures, it is worthwhile to participate in it. It will be useful not only for me as an individual, but for the generation to come.
Male Ethicist urban A10 - Oyo

4.2.5.8 Future use of the samples collected for biobank research

One of the participants believed that one cannot predict the future use of these specimens, but would be rest assured if the IRB gives approval for such research.

One thing about the future is that you cannot project into the future. For now, I cannot clearly envisage what will make me change my mind. Any research that will be of benefit to mankind I wouldn't mind. But if there's any research that has ulterior or negative effects, I wouldn't like my specimen to be used for such research. Since I will not know which research they will carry out, but once the IRB has approved the research I don't have any problem.
Male Ethicist urban D6 - Enugu

4.2.5.9 Concerns about the biobank research

A participants brought out the issue of risks and harm as his concerns of which samples used in biobank research may harm the group to which a participant belongs, and thereby harm the individuals concerned. This harm may arise, for instance, if people outside the group regard the group in a more negative way or treat people belonging to that group in a worse way than other. The harm may also be due to people in the group starting to look at themselves in a different, more negative way.

My worry has to do more with the integrity and competence of the researchers.
Male Ethicist urban D6 - Enugu

My worry is that the samples may not be preserved well. And if nothing is done with the sample for a long time, that can make me to change my mind.

Male Scientist urban C8 - FCT

The specimens can place the users to risk, but not the donor.
Male Scientist urban D7 - Enugu

Since I am not familiar with biobank research I may not know the risk involved in it.
Male Scientist urban B2 - Kano

There's some risk attached to the biobank. The first one is the issue of identity. Because through it the identity of the individual in the family and the generation is at stake. It can reveal about the individual, about the community, the generation that has passed and other things is at stake, and can reveal so many things about the. Secondly, the issue of confidentiality is also important. To what extent will the mangers of biobank keep secret the of the information about the individual, about the family and the community generally. It can easily disrupt the smooth relation in the society, just as it happened within the Jews in the US. I have forgotten the name of the disease that was common among the Jews and they have to detect it through biobanking. It was leading to discrimination in terms of marriage which was a result of inter marriage within the Jews. So it can lead to discrimination. If a disease is common with a particular group, people will not like to marry them. It can also lead to exploitation. If the terms of the use of the biobank is not clearly defined at the beginning you may find out that people will start using it for commercial purpose without the knowledge of the people that donated the samples.
Male Ethicist urban A10 - Oyo

4.2.5.10 Religious or cultural issues on biobank research

A participant stressed the fact that some religion where faith healing hold sway, biobanking will be seen as questioning God since knowledge belong to God. That the traditionalist will look at the researchers as witches or wizards for collecting blood. Other participants do not have any religious or cultural view on biobank research.

Am a Christian I do not know of any cultural restriction.
Male Ethicist urban D6 - Enugu

I do not have any religious or cultural views on biobank.
Male Scientist urban C8 - FCT

My religion and culture does not stop me from participating in biobank research.
Male Scientist urban B2 - Kano

Religion wise it can be a problem. In some religion where faith healing and I believe in God is strong people will be asking why do I have to question God? The knowledge belong to God. We do not know how the traditionalist will look at it especially the issue of blood letting in Africa, where they think that the persons that collect blood are witch.
Male Ethicist urban A10 - Oyo

4.2.5.11 Access to medical records for the biobank research

Some participants would want to be informed before having access to their medical record, while other interviewees said that providing access to their medical record would not affect their decision about participating.

If the option of access to my medical records is brought up and I give my consent for that, there's no problem.
Male Ethicist urban D6 - Enugu

You can have access to my medical records, no problem.
Male Scientist urban B2 - Kano

I will not feel happy for you to have access to my medical records without my knowledge. I need to be consulted that my record is going to be used for that purpose. It is a respect for my person.
Male Ethicist urban A10 - Oyo

4.2.6 Teachers and Students

4.2.6.1 Knowledge of biobank and collection of human biological specimens for non-communicable disease research.

Biobanking was not a familiar term to the participants, but it was appreciated and referred to as a source of development in the area of health.

Biobank is a situation where information is gathered for future health matters and development.
Male Student urban A2 - Oyo

Biobanking is the collection of sample of blood from individuals which will be used to develop a nation healthically.
Male Teacher urban C5 - FCT

Biobank is used to carry out researches on very serious diseases and their cure.

Male Teacher Urban B5 - Kano

4.2.6.2 Understanding of, and Attitudes to research and non-communicable disease research.

The majority view and Attitudes to research and non-communicable disease research of the participants were in support of non-communicable disease research.

> *The concept research means findings, trying to find out the possibility of things, going out in length in other to get variables, like one is given topic to identify and find out certain situation or event within a geographical region or place. Finding out something and getting solution.*
> Male Teacher urban C5 - FCT

> *Research is when you did not know about a particular thing and you want to know more about it and how to conquer that thing. Non-communicable disease cannot be easily gotten from another person.*
>
> Male Student urban A2 - Oyo

> *Research is a particular course of something.*
> Male Teacher urban A6 - Oyo

> *A communicable disease is what is transferred from one person to another, just like a parasite that feed on another person. A non-communicable disease can not be transferred to another person.*
> Male Teacher urban C5 - FCT

> *Research is about finding out what is going on.*
> Female Student urban D10 - Enugu

Their sources of information and influence on research were the media – television, newspapers, magazines and journals.

4.2.6.3 Consent for the biobank research

The majority of the participants thought it appropriate to permit a restricted consent. Only few of the participants were in support of broad consent.

> *I prefer the restricted consent for the research.*
> Male Teacher Urban C5 - FCT

> *I would give the restricted consent.*
> Female Student urban D10 - Enugu

Restricted consent is the one I prefer.
Male Teacher urban B5 - Kano

I will give the broad consent.
Male Student Urban B6 - Kano

I prefer restricted consent.
Male Student urban A2 - Oyo

I will give a broad consent which is to say beyond this particular research.
Male Teacher urban A6 - Oyo

4.2.6.4 Feelings about having their donated specimens and data shared by different researchers or shipped for further research

A majority of the participants said it was okay to share their specimen with other researchers. One of those who would not like a sharing of their specimen with other researchers mentioned UK and America as the countries he wouldn't like his specimen to be sent to.

If it is for the progress of the nation and to improve individuals too, you can share my specimen with other researchers, there's no problem.
Male Teacher Urban C5 - FCT

I do not permit you to share my specimen with other researchers. They should come to be for their own samples. And I wouldn't like you to send my specimen abroad because I do not know their plans. But if it is because you want to use a better technology abroad, I should give my consent before you take it there. I won't want you to take the specimen to England and America. That is my personal decision.

Male Teacher urban B5 - Kano

I would not like you to share my specimen with other researchers. They should come and explain there research to me and collect their own samples. You may go ahead and send my specimen abroad.

Male Student Male B6 - Kano

If that is the only way that we can get better result, there's no problem, you can share with other researchers and also send the specimen abroad.

Male Student urban A2 - Oyo

You can share my sample with other researchers.

Male Teacher urban A6 - Oyo

4.2.6.5 Someone they must tell before giving consent for the biobank research

This participants mentioned an array of persons they will tell before participating in the biobank research. They mentioned their spouses, brothers, sisters, parents and relations.

What God has ordained or what God has joined together there's no separation. Therefore, our mind must always move at the same time and our thinking should work together. If am doing something I have to let my spouse know. Am using the Christian religious views. I need to discuss my privacy with my wife.
Male Teacher Urban C5 - FCT

My relations will know before I participate.
Female Student urban D10 - Enugu

I will consult my parents before participating in the research.
Male Teacher Urban B5 - Kano

I will tell my parents.
Male Student Urban B6 - Kano

I will tell my immediate brother and sister before I participate.
Male Student urban A2 - Oyo

4.2.6.6 Feedback and receiving news from the biobank research

Majority of the respondents were of the opinion that they should be given feedback, especially their individual results.

I would like to get my result.
Female Student urban D10 - Enugu

I should be given feedback. That is the objective of research. And I will not feel happy if am not given my result.
Male Teacher Urban B5 - Kano

I would like feedback on the research.
Male Student Urban B6 - Kano

I will need feedback because that is the essence of giving my sample.
Male Student urban A2 - Oyo

I will not be happy if I am not given my result. I want my result.
Male Teacher urban A6 - Oyo

4.2.6.7 Perceptions of benefits of the biobank research

All the participants believed it will help in identifying problems and possibly give solutions. Some of them were particular about the personal gains they will get from the biobank.

biobank will be useful in the case of accident or deformity in a human being or help either in an immediate accident situation. It will insure immediate medical treatment in times of accident.
Male Teacher urban C5 - FCT.

Biobank has benefits. If someone has a health problem, it can detect it.
Male Teacher Urban B5 - Kano

The biobank is beneficial. If I participate, I will know my health status and can treat myself thereafter.
Male Student Urban B6 - Kano

If drugs can be produced to help society it can be one of the advantages or benefit.
Male Student urban A2 - Oyo

It will allow the participant to know the status of his health.
Male Teacher urban A6 - Oyo

4.2.6.8 Future use of the samples from the biobank research

A majority of the participants had no comments about the future use of their specimens, but earlier on choose the restricted consent. A participant who had some fears on the kind of research that might be conducted, felt they would want repeat consent in the event of their sample and information being used in new or different ways.

Am concerned on what my specimen will be used for in the future. I hope they will get us informed on what they are using our samples to do.
Male Teacher urban C5 - FCT

4.2.6.9 Concerns about biobank research

A participant would be concerned if the biobank research will involve him committing a good part of his time that will affect his job.

> *I will be concerned if my participation in the research will affect my primary assignment or stress me up.*
> Male Student urban A2 - Oyo

> *I do not think it has any risk.*
> Male Teacher urban A6 - Oyo

4.2.6.10 Religious or cultural issues on biobank research

No single participant had any religious or cultural view on biobank research.

> *I do not know of any religion and culture issue that is against biobank research.*
> Male Student Urban B6 - Kano

> *I do not have any religion and culture issue against biobank research, since it is something that can help to advance once life and help you about your health. It is when you are healthy that you can practice your religion.*
> Male Student urban A2 - Oyo

> *My culture or religion is not against biobank research.*
> Male Teacher urban A6 - Oyo

> *Religion even teach about health, because a healthy person is a Godly person. We cannot run away from health and religion. A healthy person will be able to participate in religious activity. We are now in a modern world, issues of culture are getting buried.*
> Male Teacher urban C5 - FCT

> *My religion and culture is not against biobank research.*
> Male Teacher Urban B5 - Kano

4.2.6.11 Medical record access for the biobank research

A majority of interviewees said that providing access to their medical record would not affect their decision about participating.

> *There no sacred cow on anything like that, it is my medical history.*
> Male Teacher Urban C5 - FCT

> *You are free to use my medical records.*

Male Teacher Urban B5 - Kano

I do not have problem allowing you access to my medical records. Since it will lead to the betterment of my health, I have no problem.
Male Student urban A2 - Oyo

You can use my medical history as it will help you to know more about me even when I am giving you false information.
Male Teacher urban A6 - Oyo

4.2.7 Community Leaders and Traditionalist

4.2.7.1 Knowledge of biobank and collection of human biological specimens for non-communicable disease research.

None of the community leaders knew about biobank research, but expressed their views of biobank after an overview.

Biobank is new to me and I do not have any information about it, if not now that you are telling me about it.
Male Community Leader urban B4 - Kano

Biobank is a place where you put the specimen of someone's problem for a number of years so that when the result comes you will find a solution to this problem.
Male Community Leader rural D2 - Enugu

I am grateful for your explanation on biobank research which you came for. Previously some individuals came and interviewed us, later they came to collect our specimen. We later discovered that they took our specimen for HIV test. Is it right to do so without telling their objectives.
Male Community Leader rural B13 - Kano

4.2.7.2 Understanding of, and Attitudes to research and non-communicable disease research.

As regards their understanding of, and Attitudes to research and non-communicable disease research their views varied widely. Some were clearly very knowledgeable, while others were relatively uninformed. They were eager to participate in the biobank research.

Non-communicable disease is a disease that doesn't affect another person from a carrier.
Male Community Leader rural D2 - Enugu

I am aware about non-communicable disease because I have a relation that is diabetic.
Male Community Leader urban B4 - Kano

Research is when something happen to somebody like disease, you want to know what caused it.
Male Traditionalist and previous research participant urban A8 - Oyo

I do not know anything about research, not until you come to me. You are here for a research.
Male Community Leader rural D2 - Enugu

Research is finding out something that was not well known to you. It may be in the area of drugs research or obtaining knowledge that will be useful to the nation.
Male Community Leader urban B4 - Kano

Research is just to acquire knowledge.
Male Community Leader urban A4 - Oyo

I do not know what research is.
Male Community Leader rural B13 - Kano

Their sources of information and influence on research was the television**.**

4.2.7.3 Consent for the biobank research

A majority of the participants supported giving the restricted consent for the proposed biobank research. The few of them that gave the broad consent felt that once specimens had been taken they would have no chance in how they were used, and seemed to trust the biobank researchers to use them properly.

I do not know anything about informed consent before now. I will give consent for the continues use of my sample for other researches other than this one.
Male Community Leader rural D2 - Enugu

I will give the restricted consent because I do not know the research that will be carried out in the future.
Male Community Leader urban B4 - Kano

I will give the restricted consent, because I will require feedback before it is used for future research.
Male Community Leader urban A4 - Oyo

I will give broad consent if the research will not harm me.
Male Traditionalist and previous research participant urban A8 - Oyo

I will give consent for the restricted consent, because I would like feedback.
Male Community Leader rural B13 - Kano

4.2.7.4 Feelings about having their donated specimens and data shared by different researchers or shipped for further research

A majority of the participant will not feel bad if their specimen is shared with other researchers or sent abroad, but some would want to re-consent, while others would like to know the outcome.

I won't feel bad if you share my specimen with other researchers or send my it abroad, since it is for the benefit of all Nigerians. But it will be nice you let me know before sending it abroad.
Male Community leader rural D2 - Enugu

Since I did not give broad consent, I will not permit a sharing of my specimen. The other group of researchers are supposed to approach me for their own specimens. I will have no objection if you want to take it abroad for analysis, provided other participants allow that.
Male Community Leader urban B4 - Kano

I wouldn't like you to share my specimens with other researchers. It should be analysed in Nigeria and not taken outside the country. I know we can do things without outside influence.
Male Community Leader urban A4 - Oyo

You can share my specimen and also take it to any country. I would also like to know the progress you are making.
Male Traditionalist and previous research participant urban A8 - Oyo

You may give other researchers my specimen for their research.
Male Community Leader rural B13 - Kano

4.2.7.5 Someone they must tell before giving consent for the biobank research

A majority of the respondents said they will not consult anybody before participating in the research, only an individual would let his spouses know. Others mentioned their uncle and people around them as a way of creating awareness.

> *There no need discussing with anyone before I participate. It is best known to me.*
> Male Community Leader rural D2 - Enugu

> *I will first of all, find out from my uncle before I participate, since my father is late.*
> Male Community Leader urban B4 - Kano

> *I will let my wife know before I participate.*
> Male Community Leader urban A4 - Oyo

> *I will tell people around me, even outside my family, as a way of creating awareness.*
> Male Traditionalist and previous research participant urban A8 - Oyo

> *I will give my specimen without consulting any body.*
> Male Community Leader rural B13 - Kano

4.2.7.6 Feedback and receiving news from the biobank research

The participants response was that they would want personal feedback, particularly if important information were discovered about their health. A few participants would not want to know; for example, they would not wish to be told about an incurable disease that they might have.

> *I would like you people to come and tell me so that I know how to find the solution.*
> Male Community Leader rural D2 - Enugu

> *Receiving news and my personal result from the research is important to me since I will be more aware of my health and be informed about health issues.*
> Male Community Leader urban B4 - Kano

> *I should be told if something serious is discovered about me. I will feel bad if I am not given my result.*
> Male Community Leader urban A4 - Oyo

I need feedback on my result. Since I will give you my specimen on trust, I will require feedback, and if it is not done I will be worried.
Male Traditionalist and previous research participant urban A8 - Oyo

I wouldn't like feedback on any thing that is serious on my health, but I would like general feedback or news.
Male Community Leader rural B13 - Kano

4.2.7.7 Perception of benefits of participating in the biobank research

A majority of these group of participants believe the biobank has some potential benefits.

I don't think it has any risk but benefit. When the research is done and a solution is found, it can be used to take care of the problem.
Male Community Leader rural D2 - Enugu

I am convinced that the biobank has benefits. Though I wouldn't say what the benefits are.
Male Community Leader urban B4 - Kano

If there's an infection that has no cure, a cure could be discovered from the research.
Male Community Leader rural B13 - Kano

4.2.7.8 Future use of the specimens from the biobank research

A participant gave a condition that if future research will not contradict his religion, his specimen could be used.

If my specimen will be used in a way that will not contradict my religion, it can be used in the future.
Male Community Leader urban B4 - Kano

4.2.7.9 Concerns about the biobank research

A participants would be concerned if there's no trust in the research. Another would be worried if the specimen will be used for another research other than non-communicable disease.

I have not seen a biobank and I do not know much about it and so do not know if it has any risk.
Male Community Leader urban B4 - Kano

We have never seen it before we do not know how it is going to work. If it is something that we are conversant with we would know the risk involved.
Male Community Leader urban A4 - Oyo

If there's no trust I will change my mind.
Male Traditionalist and previous research participant urban A8 - Oyo

I do not think it has any risk or things of concern. I will only get worried if you use it for something else other than what you told me.
Male Community Leader rural B13 - Kano

4.2.7.10 Religious or cultural issues on biobank research

No single participant had any religious or cultural view on biobank research.

My religion and culture does not distract me from participating in biobank research.
Male Community Leader rural D2- Enugu

My Muslim religion is not against research. Muslim religion involves research. I am not aware of any cultural issue against biobank research.
Male Community Leader urban B4 - Kano

In the account of health, nothing forbids biobank research.
Male Community Leader urban A4 - Oyo

My religion is not against biobank research.
Male Traditionalist and previous research participant urban A8 - Oyo

There's no religion or culture that said you should not give your blood for research.
Male Community Leader rural B13 - Kano

4.2.7.11 Access to medical records for the biobank research

A majority of interviewees said they will allow access to their medical records. A participant said he does not go to the hospital and so do not have medical records.

I won't feel bad if you have access to my medical records.
Male Community Leader rural D2 - Enugu

I have no problem with allowing you access to my medical records.
Male Community Leader urban B4 - Kano

It is not so much nice to have access to my medical records but there's nothing we can do.
Male Community Leader urban A4 - Oyo

I do not go to hospital, so I do not have any medical records.
Male Traditionalist and previous research participant urban A8 - Oyo

There's no problem if you have access to my medical record. But let me ask, If I do not have medical records, what will you do?
Male Community Leader rural B13 - Kano

4.2.8 Government officials and Administrators

4.2.8.1 Knowledge of biobank and collection of human biological specimens for non-communicable disease research.

Four Government officials and 2 Administrators took part in the research. They were not well informed about the issues surrounding biobank research and the issues surrounding the use of human biological samples for research. Non of the participants have heard of biobank before, but defined it in their own words after they were given an idea of what it is. All the Government officials and Administrators were basically in favour of the use of human biological samples for medical research.

Biobank is used for storing specimen like tissues and used for research to know more or find a cure for a particular disease.
Male Administrator urban D13 - Enugu

Biobank is an attempt to obtain a kind of information and things that will be helpful to further human life. They could be blood or tissues.
Male Administrator urban C4 - FCT

biobank is just like a bank where information is stored about life, whether genotype analysis.
Male Government Official urban B1 - Kano

I don't know much about biobank. But when you say bio, it has to do with biology. When I heard about it I began to think about biodata, bio this and bio that. May be it has something to do with humans?
Male Administrator/previous research participant urban B11 - Kano

Bio is life, bank is where you keep something, as a place you want to secure something for a long period.
Male Government Official A1 - Oyo

4.2.8.2 Understanding of, and Attitudes to research and non-communicable disease research.

The understanding of, and Attitudes to research and non-communicable disease research was high, majority of the participants defined and explained research and non-communicable diseases well. They were all willing to participate in the non-communicable diseases research.

> *I know a little bit about research because I participated in many health related and other researches. And it is the process of finding out something. Either attitude or knowledge or a kind of situation in a given environment.*
> Male Administrator/previous research participant urban B11 - Kano

> *I participated in non-communicable disease research some years back, so I know about it. It is something that is hereditary and not contagious.*
> Male Administrator/previous research participant urban B11 - Kano

> *Research is to carry out something that you did not know, that you want to know more of it. When you want to get new technique or something that is going on or you want to get breakthrough in what is happening in a situation that is bothering people around you.*
> Male Government Official urban A1 - Oyo

> *Research is a step towards improving human life. Non-communicable disease are disease that are a problem in the society today.*
> Male Administrator urban C4 - FCT

> *Research means to have new ideas relating the object of the study. It means you want to probe further. A non-communicable disease does not pass over to another person by staying in the same room with that person. Or may be a virus that gets into another person. They are disease like cancer. The non-communicable diseases are troublesome diseases.*
> Male Administrator urban D13 - Enugu

> *Research is very important and key to development of science and technology. And without research we cannot produce remedy to many of the disease. Without research there cannot be machinery to improve the livelihood of man. It is from research that we are able to discover transport and machinery and medicine.*
> Male Government Official urban B1 - Kano

The sources of information and influence on research of the government official were the media – television, newspapers, magazines and friends.

4.2.8.3 Consent for the biobank research

One of the respondents choose the tiered consent. This model would allow him to maintain control over how his specimen will be used. The majority were in support of the broad consent, with one of them not totally confident that the biobank researchers will respect the views of persons who want the restricted or tiered consent.

> *I prefer the tiered consent, because it will make me relevant in what is going on. At least I will know each time what they want to do, and if I am interested in that particular segment of the research I will say go ahead. So that anyone I am not interested in or if it doesn't please me, if it is frivolous for instance I will not give my consent for such a research.*
> Male Administrator urban D13 - Enugu

> *Once I have given consent, I have given consent. It is to improve human lives.*
> Male Administrator urban C4 - FCT

> *As far as it is for the pursuit of human development, I will give broad consent.*
> Male Government Official urban B1 - Kano

> *I will give the broad consent. Holistically I give the sample.*
> Male Administrator/previous research participant urban B11 - Kano

> *Who am I to know that you are not using my blood for other research. Since my identity will not be disclosed, I will give broad consent. I even heard that a professor that died recently gave his body for research.*
> Male Government Official A1 - Oyo

4.2.8.4 Feelings about having their donated specimens and data shared by different researchers or shipped for further research

All the participants were in support of sharing their specimen with other researchers and sending them abroad for further studies.

> *My specimen can be shared with other researchers or sent abroad for further studies.*

Male Administrator urban C4 - FCT

If the researchers will be faithful and will not deviate from the good objectives of the research and possibly publish the finding for the general public, they can go ahead and share with other researchers. If there's good collaboration and the specimens will be properly handled by labelling them very well it is OK.
Male Administrator urban D13 - Enugu

We are still talking about consent. I have given you my consent to share and send my specimen abroad.
Male Administrator/previous research participant urban B11 - Kano

When I give my specimen you can share and take abroad no problem.
Male Government Official A1 - Oyo

4.2.8.5 Someone they must tell before giving consent for the biobank research

A majority of respondents do not think it is necessary to inform anybody before they participate in the biobank research. Only an individual would like to tell his spouse and children.

I don't have to tell anybody before I participate in the research.
Male Administrator urban D13 - Enugu

I am old enough to give consent and stand by my words.
Male Administrator urban C4 - FCT

There's nobody I need to talk to before I participate in the biobank research.

Male Government Official urban B1 - Kano

I will tell my wife and my children before I participate.
Male Government Official A1 - Oyo

4.2.8.6 Feedback and receiving news from the biobank research

The majority of the participants thought it is important for them to receive individual feedback, with prior counselling.

I think there's a professional way of handling this, i.e trough counselling before telling it to the person. If they handle it well I don't mind. If they will not handle it well, I will prefer that they don't tell me at all. Getting news and update is good it will help the public to get aware.

Male Administrator urban D13 - Enugu

I will be happy to receive feedback so that I can ask counsel on my health status and getting treatment.
Male Administrator urban C4 - FCT

It is important for me to receive feedback as it will help me understand my health. I may not need general news. I will be in the dark if I am not given my result.
Male Government Official urban B1 - Kano

I preferred to be given feedback. If something positive comes out of the research, I would like to know so that I can take corrective measures.
Male Administrator/previous research participant urban B11 - Kano

You should tell me if there's something serious that is discovered about me.
Male Government Official A1 - Oyo

4.2.8.7 Perception of benefits of participating in the biobank research

A majority of participants believe that the research will lead to beneficial outcomes now and in the future.

Research helps researchers and humanity in general to know better.
Male Administrator urban D13 - Enugu

I may not know of any benefits of biobank research as such, but I believe it is helpful. It could be helpful to me or my children tomorrow.
Male Administrator urban C4 - FCT

It can benefit me in the short and long term. It can benefit me and my descendants.

Male Government Official urban B1 - Kano

Whatever one does will have an objective. I believe preserving blood somewhere has a purpose. With further studies on the blood kept will be beneficial. Like what is happening now in the case of diabetes, people are becoming aware to check their sugar level at intervals. If research was conducted on this disease, there will be some way forward to the disease.
Male Administrator/previous research participant urban B11 - Kano

4.2.8.8 Future use of the specimens from the biobank research

The majority are not bothered on the future use of their specimen. A participant would first give the tiered consent and if the outcome of that research was good he will give the broad consent for future researches.

> *If I am given information on the first research and I judge it to be progressive, I will give you consent for future researches (i.e. tiered consent).*
> Male Administrator urban D13 - Enugu

4.2.8.9 Concerns about the biobank research

The participants were welcoming of the intention of the use of their specimen to do research on non-communicable diseases, there were however, some reservations expressed about the finer points of the intended use of the specimen. They entertain the fear that the researchers may deviate from the original objectives of the research into something they might find objectionable. Another participant was worried about the epileptic power supply in Nigeria which he believe will affect the research.

> *We experience power failures here and there in Nigeria. It is important to keep the specimen in the state that they were obtained from the donor. I wouldn't mind if my specimen will be used for non-communicable disease research. But if it is no longer non-communicable disease, them I should mind.*
> Male Administrator urban D13 - Enugu

> *I will have concern if the motive of the research is not exactly what I was told.*
> Male Administrator urban C4 - FCT

> *Biobank has no risk. It is an important aspect of development in medicine. But I will have concern it the researchers deviate from the objectives explained to us.*
> Male Government Official urban B1 - Kano

> *If care is not taken with the specimen, there will be contamination or cross infection. If things are not handled in an aseptic way there will be contamination by the workers and maybe infecting participants. I will have concern if the research will expose me. What ever element I have on my health, if I was not informed and I see it on the print media or hear it over the air, that is the only thing that I will be angry about.*

Male Administrator/previous research participant urban B11 - Kano

I don't think biobank has any risk, since you are not taking the blood for rituals.
Male Government Official A1 - Oyo

There's nothing that will make me change my mind of participating.
Male Government Official A1 - Oyo

4.2.8.10 Religious or cultural issues on biobank research

No single participant had any religious or cultural view on biobank research. A participant pointed out that if the outcome of the biobank research is favourable, any contrary culture to biobank research will give way.

I do not have any religious or cultural view on biobank.
Male Administrator urban D13 - Enugu

I do not have any religious or cultural view that is against the biobank. I think even in the religious angle you realize that our people once they know that what you are embarking upon is helpful, they will always support.
Male Administrator urban C4 - FCT

Personally I do not have any religious or cultural belief that is against the biobank.
Male Administrator/previous research participant urban B11 - Kano

We are just knowing of biobank now but in the future we may know if our religion or culture will be against it. But for now they are not against the biobank.
Male Government Official A1 - Oyo

4.2.8.11 Access to medical records for the biobank research

All the discussants would allow access to their medical records. In having access a participant again stressed the need for confidentiality.

There's nothing wrong in having access to my medical records, provided there's confidentiality.
Male Administrator urban D13 - Enugu

Having access to my medical records will not in any way affect my opinion to participate in the research.
Male Administrator urban C4 - FCT

I will not feel unhappy for you to have access to my medical records.
Male Administrator/previous research participant urban B11 - Kano

It is necessary. But due to poverty many don't go to hospitals for them to have medical records.
Male Government Official A1 - Oyo

4.3 The Focus Group Discussant Demographic Characteristics

There were 123 participants. Their ages range from 18 to 70 years (mean 36.2 years). 61 (49.6%) were males and 62 (50.4%) females. 39 (31.7%) were Muslim and 84 (68.3%) Christians. Their occupations were students (19, 15.5%), housewives (20, 16.3%), business persons (24, 19.5%), farmers (18, 14.6%) and civil servants (21, 17.1%). The rest (21, 17.1%) belonged to a wide variety of occupations. See table 4.2

These were categorized into:

Literate and illiterate urban males; Literate and illiterate rural males; Literate and illiterate urban females and Literate and illiterate rural females.

Table 4.2: The Focus Group Discussant Demographic Characteristics

S.No.	State	LGA	Village	Setting	Ethnic group	Number sampled
1	Enugu	Nkanu West	Ojiagwu Agbani	Rural male	Igbo	8
				Rural female	Igbo	8
		Enugu North	Enugu	Urban male	Igbo	8
				Urban female	Igbo	8
2	Kano	Kura	Azoren Waje	Rural male	Hausa	8
				Rural female	Hausa	8
		Ungogo	Gayawa	Urban male	Hausa	8
				Urban female	Hausa	8
3	Oyo	Oluyole	Idi Ayunre	Rural male	Yoruba	9
				Rural female	Yoruba	9
		Egbeda	Manatan Arolu	Urban male	Yoruba	8
				Urban female	Yoruba	8
4	FCT	Bwari	Ushafa	Rural male	Gbagi	7
				Rural female	Gbagi	8
		AMAC	Karu	Urban male	Gbagi	5
				Urban female	Gbagi	5
5	Total					123

4.4 Attitude of the Focus Group Discussants to biobank and other related issues

4.4.1 Literate and illiterate urban males

4.4.1.1 Knowledge of biobank and collection of human biological specimens for non-communicable disease research.

Biobank research was well accepted by these participants. Some participants from the northern part of the country that had the Pfizer trial experience said that since it is not drugs trial like the one conducted by Pfizer, they were ready to participate in the research. They perceived the biobank to be a good instrument for preserving specimens for biomedical research.

> *Biobank is where specimens are kept for later use.*
> FGD Male urban D17 - Enugu

> *Biobank is where you store blood. For example blood for transfusion.*
> FGD Male urban D17 - Enugu

> *Another meaning I read from your biobank is that it is a place where you can keep specimens for your research, in case there is a disease that occurs and you want to cure it. You can take some specimens from the biobank and research to take care of the problem.*
> FGD Male urban D17 - Enugu

> *In biobank, the blood can be kept for a long time without deteriorating.*
> FGD Male urban C16 - FCT

> *I have heard about biobank before. I have not been asked anything about it not until today. It is different from blood bank and money bank, this one is for research.*
> FGD Male urban C16 - FCT

> *Biobank is used to store blood and used for research to get positive result.*
> FGD Male urban C16 - FCT

> *Biobank is used for preservation of blood and tissues, which ordinarily if you keep them in a cold box there's duration of time that it can be preserved, but for the biobank it can be preserved for a long period of time. Whatever time a specimen is taken out it will be fresh as if it was just taken from a persons body.*

FGD Male urban B19 - Kano

Biobank will find out diseases that we did not understand.
FGD Male urban B19 - Kano

4.4.1.2 Understanding of, and Attitudes to research and non-communicable disease research

Their understanding of, and Attitudes to research and non-communicable disease research was quite varied. Some had good perception of non-communicable diseases, while others thought them to be malaria. They believed that research is for solving problems.

Non-communicable disease cannot affect another person.
FGD Male urban D17 - Enugu

An example of non-communicable disease is malaria.
FGD Male urban D17 - Enugu

Research means investigating and finding out either disease medicine or what.
FGD Male urban D17 - Enugu

Research means testing several times until the correct thing is found.
FGD Male urban D17 - Enugu

By the concept research it means finding out, so that a solution can be administered.
FGD Male urban C16 - FCT

Non-communicable disease are not transferable but are difficult to heal.
FGD Male urban C16 - FCT

Research can be defined as fighting things that are happening in our environment, or to know deeply about something.
FGD Male urban A13 - Oyo

If there's no problem there's no research. Research is for problems.
FGD Male urban A13 - Oyo

Research is the various steps taken to understand sickness. For the biobank research, individuals will not be given their results, but a general outcome will be derived.
FGD Male urban B19 - Kano

Non-communicable disease is not communicable, even from blood or urine contact.
FGD Male urban B19 - Kano

4.4.1.3 Feelings about having their donated specimens and data shared by different researchers or shipped for further research

All the participants accepted the sharing of their specimen with other researchers, provided the researchers are genuine and competent. A participant would like other researchers to meet him for their specimen. Some were worried that sharing the specimens with other researchers outside Nigeria could possibly make them discover things about Nigerians that could lead to stigmatization and discrimination.

If you are sure that they are genuine researchers, you can give them my specimen. The specimen can be sent to other countries, but they should not use my specimen for animal research.
FGD Male urban D17 - Enugu

Other researchers should make their efforts to meet us for their own specimen.
FGD Male urban D17 - Enugu

If I give my specimen the researchers are free to take it to any country abroad for analysis.
FGD Male urban A13 - Oyo

You can take it anywhere for analysis, and the specimen can be used in future studies.
FGD Male urban A13 - Oyo

Since the research is for the development of Nigeria, you should use the specimen within the country. Other countries are not giving us their specimen, as such you should not give them our specimen.
FGD Male urban B19 - Kano

My opinion is that the other researchers should be competent and from reliable sources. Be sure their objectives are okay.
FGD Male urban B19 - Kano

I wouldn't like you to give them our specimen as they will discover things about us and begin to discriminate against Nigerians.
FGD Male urban B19 - Kano

You the researchers should do what you think will benefits Nigeria as regards the sharing and shipping of specimen.
FGD Male urban B19 - Kano

4.4.1.4 Consent for the biobank research

The majority of the discussants lend their support for the broad consent. A few were for the restricted and the tiered consent. One of those that supported the broad consent said that if the Federal Ministry of Health deems it fit to approve the research, he will give the broad consent.

I will prefer to give broad consent so that the aim and objectives of keeping it there can be achieved.
FGD Male urban D17 - Enugu

I will give you the broad consent.
FGD Male urban C16 - FCT

I will give the restricted consent.
FGD Male urban C16 - FCT

I will give the broad consent.
FGD Male urban C16 - FCT

I should be re-informed before they use my specimen for other researches.
FGD Male urban C16 - FCT

They can use my specimen indefinitely and for any research.
FGD Male urban C16 - FCT

I will give the restricted consent.
FGD Male urban A13 - Oyo

I will give the restricted consent.
FGD Male urban B19 - Kano

If the Federal Ministry of Health believe that the research is beneficial and they gave their permission, then I will give the broad consent.
FGD Male urban B19 - Kano

Since I have faith in the research and gave my specimen, I will also give the broad consent.
FGD Male urban B19 - Kano

4.4.1.5 Someone they will tell before giving consent for the biobank research

The majority of the participants would like to inform their spouse and children. Others would like to tell their parents and brothers. Some of the participant prefers the accent of the community leader instead of individual consent.

> *I will inform my wife and children.*
> FGD Male urban D17 - Enugu
>
> *I will discuss with my dad.*
> FGD Male urban D17 - Enugu
>
> *I will have to inform my senior brother.*
> FGD Male urban D17 - Enugu
>
> *I will discuss with my wife.*
> FGD Male urban C16 - FCT
>
> *I will inform my wife and my children.*
> FGD Male urban A13 - Oyo
>
> *I will inform my parents.*
> FGD Male urban A13 - Oyo
>
> *I will tell my father, if he permit me I will participate.*
> FGD Male urban B19 - Kano
>
> *The community leader and the community health officer should be inform on behalf of the community. The moment they permits the research, all the community members will respectfully participate.*
> FGD Male urban B19 - Kano
>
> *Like my colleague just mentioned. It is the explanation of the community leader and health worker that will be well taken when you come for such a research.*
> FGD Male urban B19 - Kano
>
> *I will tell my wife before I participate.*
> FGD Male urban B19 - Kano

4.4.1.6 Feedback and receiving news from the biobank research

The majority of the participants expected some feedback on their individual health and developments in the research on a more general scale. That it was better to know about their health rather than finding out by surprise, and that care could be given by the

researchers in the event of being given bad news. They also reiterated the need for counselling before feedback is given.

> *If you collect my blood, it will hungry me to get my result.*
> FGD Male urban D17 - Enugu

> *I want to get feedback on the research.*
> FGD Male urban D17 - Enugu

> *I will want feedback, for example if they discover HIV on me, I will get myself prepared for death or take precautions so that I will live longer than the time I would have died.*
> FGD Male urban D17 - Enugu

> *I will not feel happy if I am not given my result.*
> FGD Male urban A13 - Oyo

> *I should be given my individual result as well as general feedback, but with prior counselling. The feedback will show the progress that the researchers are making.*
> FGD Male urban B19 - Kano

> *If someone is not given feedback, what is the benefit of the research?*
> FGD Male urban B19 - Kano

> *If it is discovered that I have a serious disease I should be helped with medication as well.*
> FGD Male urban B19 - Kano

> *I would like feedback with counselling.*
> FGD Male urban B19 - Kano

> *I should not be given my personal result.*
> FGD Male urban B19 - Kano

> *The researchers should study someone's mood and to see if he can accommodate the news before telling him.*
> FGD Male urban B19 - Kano

4.4.1.7 Perception of benefits of participating in the biobank research.

The participants believed the biobank has benefits which included drugs development that could help us now and future generations.

> *After the biobank researchers have carried out the research and drugs was able to be developed, it can impact positively on the society.*
> FGD Male urban C16 - FCT

Though we have not seen the biobank, but I believe it has benefits.
FGD Male urban A13 - Oyo

I can benefit from the research in the long run if I do not have the disease now.
FGD Male urban B19 - Kano

It can help us know our problems, it can help generations to come.
FGD Male urban B19 - Kano

If I donate for the research and there's outcome, I have help and the research has helped the society.
FGD Male urban B19 - Kano

4.4.1.8 Concerns about the biobank research

The concern of these participants were centred on fear of use of their specimens for animal research. Other concerns express by the discussant in the study typically revolve around confidentiality, and benefit-sharing. Others were worried that the individual results or community feedback may be leaked or published by the researchers that will place someone or the community in danger of discrimination. Some would be concerned if the research will be against their religious beliefs.

My concern is that they may use my specimen to carry out research on animals.
FGD Male urban D17 - Enugu

I will be concerned if the information gathered from us will not be kept confidential.
FGD Male urban C16 - FCT

I don't have any concern since I do not know if biobank has risk.
FGD Male urban C16 - FCT

I do not have concern. Biobank does not have risk.
FGD Male urban C16 - FCT.

My concern is that they may ask me for tissues, which I am not ready to give. I will give only blood.
FGD Male urban C16 - FCT

I do not have any concern as the biobank do not have any risk.
FGD Male urban A13 - Oyo

My concern about the biobank research is that it may involve repeated visits, which will affect my job as a civil servant.
FGD Male urban A13 - Oyo

What will be the benefits that will accrue to us if we participate?
FGD Male urban A13 - Oyo

Biobank does not have any risk.
FGD Male urban B19 - Kano

My perceived risk is that secret may not be kept. Take an instance if someone is diabetic and someone else got the information, he may be affected psychologically.
FGD Male urban B19 - Kano

If individual results will be disclosed to other persons, it could lead to stigmatization of such individuals.
FGD Male urban B19 - Kano

Provided the individual results or community feedback will not be leaked or published by the researchers that will place someone or the community in danger of discrimination in time of employment.
FGD Male urban B19 - Kano

If there's anything that will be against my religion, then I will have concern.
FGD Male urban B19 - Kano

Any part of the research that contradicts my religion will be a source of concern that will cause my withdrawal.
FGD Male urban B19 - Kano

If the researchers have persons that do not have good human relations will cause us to withdraw our participation.
FGD Male urban B19 - Kano

4.4.1.9 Religious or cultural issues on biobank research

The participants had no religious or cultural view on biobank research.

No, my culture and religion is not against biobank research.
FGD Male urban D17 - Enugu

As a traditionalist, I have nothing against the biobank.
FGD Male urban C16 - FCT

There's no religious or cultural view on biobank.
FGD Male urban A13 - Oyo

My religion is not against research.
FGD Male urban B19 - Kano

There are portions in the Quaran were we were told to go and obtain health.
FGD Male urban B19 - Kano

Our culture and religion is not against biobank research.
FGD Male urban B19 - Kano

If one is not well he cannot worship God properly.
FGD Male urban B19 - Kano

4.4.1.10 Access to medical records for the biobank research

Some participants were initially cautious and wanted to know more on what the medical records will be used for. With some explanations, the participant had no problem allowing access to their medical records. They understood the need for medical records and other information.

I will not feel bad if you will use my medical records.
FGD Male urban D17 - Enugu

Having access to my medical records is okay by me provided it is something that will save other peoples life.
FGD Male urban C16 - FCT

It will be good if you have access to my medical record. It is possible that in the records, the treatment that I am given by my doctor may not be the appropriate one, the researchers can advise my doctor to use the appropriate medication.
FGD Male urban B19 - Kano

4.4.2. Literate and illiterate rural males

4.4.2.1 Understanding of, and Attitudes to research and non-communicable disease research

These participants had some good understanding of research and non-communicable diseases. They also lend their support for the biobank research.

Research is the way something is done to find out particular problems. It can be blood or urine that will be used.
FGD Male rural B21- Kano

Research is used to find out the infections that are worrying people which ordinarily cannot be seen except through research.
FGD Male rural B21- Kano

Examples of non-communicable diseases are cancer and paralysis.
FGD Male rural B21- Kano

Researching is for knowledge.
FGD Male rural A15 - Oyo

Research is digging deep.
FGD Male rural A13 - Oyo

Research is finding out details of something.
FGD Male rural A13 - Oyo

Research is getting an information on what you do not know.
FGD Male rural A13 - Oyo

Non-communicable diseases cannot be transmitted through the air.
FGD Male rural C18 - FCT

4.4.2.2 Feelings about having their donated specimens and data shared by different researchers or shipped for further research

The participants accepted to share their specimen with other researchers, provided that there's guarantee that unethical research will not be done with their specimens, and that those running the biobank are trustworthy.

I do not want you to share my specimen with other researchers. I will prefer that the other researchers approach me for their specimen.
FGD Male rural B21- Kano

If the researchers will be faithful, you can go ahead and give them my specimen. You can also take the specimen abroad. Just be sure of their competence. It can be any country.
FGD Male rural B21- Kano

4.4.2.3 Consent for the biobank research

The majority of participants preferred the broad consent compared to the restricted consent. Though, some of those that gave the broad consent said they will also give the restricted.

> *I will prefer the restricted consent, because it will enable me have a grip of the situation and receiving of feedback.*
> FGD Male rural B21- Kano
>
> *I will prefer the broad consent for the biobank research.*
> FGD Male rural B21- Kano
>
> *I will give the broad consent for the research.*
> FGD Male rural B21- Kano
>
> *I prefer the restricted consent.*
> FGD Male rural A13 - Oyo
>
> *Restricted consent is preferred by me.*
> FGD Male rural A13 - Oyo
>
> *I will give both broad and restricted consent.*
> FGD Male rural A13 - Oyo
>
> *I will give both broad and restricted consent.*
> FGD Male rural A13 - Oyo
>
> *I will choose the broad consent.*
> FGD Male rural A13 - Oyo

4.4.2.4 Someone they will tell before giving consent for the biobank research

Some of these participants said they will inform there parents. The majority will not need to tell anybody before participating.

> *I will tell my father before I participate in the research.*
> FGD Male rural B21 - Kano
>
> *I will tell my parents before I participate.*
> FGD Male rural B21 - Kano

4.4.2.5 Feedback and receiving news from the biobank research

A majority of the participants would want feedback.

I would want to be given feedback.
FGD Male rural B21 - Kano

If we are given feedback, it will enable us to take care of our problem.
FGD Male rural B21 - Kano

If I am not given feedback there's no problem.
FGD Male rural B21 - Kano

4.4.2.6 Perception of benefits of participating in the biobank research

A majority of the respondents believe that drugs can be developed from the research which could assist them or the members of their family.

With the biobank research, a person's health status will be known and taken care of.
FGD Male rural B21 - Kano

At present we do not have true cure for cancer, hypertension and paralysis, but with the biobank research it is possible to develop the drugs that will cure them.
FGD Male rural B21 - Kano

Biobank will be useful in storing samples for a long time without their deterioration.
FGD Male rural B21 - Kano

Biobank will help discover diseases and their cure.
FGD Male rural C18 - FCT

The medicine for non-communicable disease can be discovered.
FGD Male rural A13 - Oyo

The benefit of biobank that I know is that the specimen will be collected once and for all.
FGD Male rural A13 Oyo

4.4.2.7 Concerns about the biobank research

One the concerns were that researchers might use the samples to make money. They entertained the fear that the biobank might not be sustained.

My concern is that the researchers can build our hope and later abandon the research. They may be unable to maintain the equipments. I am advising that adequate care should be taken on the equipments.

FGD Male rural B21 - Kano

My concern is that the biobank researchers may just preserve the specimens without doing anything with them.
FGD Male rural C18 - FCT

I hope the research is not to achieve personal interest but the interest of the public. There was a time I donated blood free, but it was sold by the hospital. I hope this will not be the same thing.
FGD Male rural C18 - FCT

4.4.2.8 Religious or cultural issues on biobank research.

This group of participants had no religious or cultural issues on biobank research.

Sincerely, I have no religious or cultural belief that is against the biobank.
FGD Male rural B21 - Kano

Biobank is not against my religion or culture.
FGD Male rural B21 - Kano

4.4.3 Literate and illiterate urban females

4.4.3.1 Knowledge of biobank and collection of human biological specimens for non-communicable disease research.

The participants were not aware of biobank, but after given them an overview of biobank, they were able to defined it the way they perceived it.

Biobank is a machine used for doing research.
FGD Female urban D16 - Enugu

Biobank is used for storing specimen for a long time.
FGD Female urban D16 - Enugu

Biobank is not like blood bank, but blood is preserved in it for research and not for donation.
FGD Female urban B18 - Kano

4.4.3.2 Understanding of, and Attitudes to research and non-communicable disease research

This respondents were very willing to participate in the non-communicable disease research. They saw it as a worthwhile venture. Their knowledge of, and attitudes to research and associated issues varied widely. Some were clearly very knowledgeable, while others were not.

> *Research is to find out and know the problems disturbing somebody.*
> FGD Female urban B18 - Kano
>
> *Research is to investigate what is wrong with someone.*
> FGD Female urban B18 - Kano
>
> *Non communicable disease are not transferable unlike HIV, measles TB.*
> FGD Female urban B18 - Kano
>
> *Non-communicable diseases are not passed from one person to another, and they do not have definite cure.*
> FGD Female urban B18 - Kano
>
> *Non-communicable diseases are not transferable*
> *Others* FGD Female urban B18 - Kano
>
> *Research is a means of finding better way of maybe doing things. Most effective ways of doing things.*
> FGD Female urban D16 - Enugu
>
> *Research is that you want to know the true colour and nature of that thing.*
> FGD Female urban A14 - Oyo
>
> *One of the non-communicable disease is AIDS.*
> FGD Female urban C17 - FCT
>
> *Research is finding out a particular thing that has not been known before.*
> FGD Female urban C17 - FCT

4.4.3.3 Consent for the biobank research

The majority of these participants preferred the broad consent as compared to tiered consent.

I will choose the broad consent for the research.
FGD Female urban D16 - Enugu

I prefer the broad consent.
FGD Female urban D16 - Enugu

I will choose broad consent.
FGD Female urban D16 - Enugu

I will prefer broad consent.
FGD Female urban D16 - Enugu

I would prefer you come back to me for another consent, because you may not be doing something that will favour me (tiered consent).
FGD Female urban C17 - FCT

I will prefer that you come back for another consent (i.e. tiered consent).
FGD Female urban C17 - FCT

I will give the broad consent.
FGD Female urban C17 - FCT

If they want to use my specimen for another research they should get back to me (i.e. tiered consent).
FGD Female urban C17 - FCT

I would want them to come back for another consent (i.e. tiered consent).
FGD Female urban C17 - FCT

I will give consent for the broad.
FGD Female urban A13 - Oyo

I will give the broad consent
FGD Female urban B18 - Kano

I too will give the broad consent
FGD Female urban B18 - Kano

I will give the broad consent.
FGD Female urban B18 - Kano

I will give the broad consent.
FGD Female urban B18 - Kano

4.4.3.3 Feelings about having their donated specimens and data shared by different researchers or shipped for further research

They said they would be prepared to donate specimens for biobank research since it will be used to improve their conditions and that of others. They would also permit the sharing of the specimen and data with other researchers provided they are competent. Some will prefer the sharing to be done with Nigerian researchers only.

> *No, my specimen should not be given to another researcher. The other researchers should come directly to us for their specimens.*
> FGD Female urban D16 - Enugu

> *It can be taken to any country, provided they are competent.*
> FGD Female urban D16 - Enugu

> *You can share my specimen with Nigerian researchers only.*
> FGD Female urban B18 - Kano

> *We need feedback on the specimens that may be taken outside Nigeria for further analysis*
> FGD Female urban B18 - Kano

> *Since it is for progress, you can share with other researchers.*
> FGD Female urban B18 - Kano

4.4.3.4 Someone they must tell before giving consent for the biobank research

Among the participants, only one participant said she will tell her sister before participating. All other respondents would like to let their spouses know before they participate.

> *I will tell my husband before I participate.*
> FGD Female urban D16 - Enugu

> *I will let my husband know before I participate.*
> FGD Female urban D16 - Enugu

> *I will let my husband know.*
> FGD Female urban D16 - Enugu

> *I will tell my husband before I participate.*
> FGD Female urban C17 - FCT

I will tell my sister before I participate.
FGD Female urban C17 - FCT

I will tell my husband before I participate.
FGD Female urban C17 - FCT

I will not participate without telling my husband.
FGD Female urban A13 - Oyo

I will inform my husband before I participate.
FGD Female urban A13 - Oyo

I will tell my husband and children.
FGD Female urban A13 - Oyo

I will tell my parents.
FGD Female urban B18 - Kano

I will tell my husband before I participate.
FGD Female urban B18 - Kano

I will tell my husband before I participate in the research.
FGD Female urban B18 - Kano

I will tell my husband before I participate. Infact he will not be happy if I hide it from him.
FGD Female urban B18 - Kano

4.4.3.5 Feedback and receiving news from the biobank research

A majority of the participants thought it would be very important to receive feedback and general news about studies done through the biobank. A few were not bothered. A few of them were of the opinion that participants should be given their individual results. One of the them would not like to receive her results for reasons of fear.

If we will not be given individual results, whatever you are seeing in the research should be disseminated, so that we will know that it is yielding results.
FGD Female urban D16 - Enugu

If something serious is discovered about me, I should be told so that I will know when am dieing.
FGD Female urban D16 - Enugu

I would not like to know my result because I will die of fear.
FGD Female urban C17 - FCT

I would like to know my result.
FGD Female urban C17 - FCT

I should be given my result.
FGD Female urban A13 - Oyo

I will need my result.
FGD Female urban A13 - Oyo

We should be given feedback, it will help us.
FGD Female urban B18 - Kano

We need feedback especially my results.
FGD Female urban B18 - Kano

We need our results and other information
Others FGD Female urban B18 - Kano

4.4.3.6 Perception of benefits of participating in the biobank research

A majority of the discussant have the deep seated feelings that biobank research is beneficial and could lead to drugs discovery that would benefit them or their family members. One of them had the belief that if someone has a problem he/she can approach a nearby biobank to research on the problem. One of the participant ask of the benefits that they will get for participating in the research.

If I participate in the biobank research, when the remedy comes I will be one of the beneficiary.
FGD Female urban D16 - Enugu

Biobank will benefit our future generation. It will bring out a better way of managing the problem of non-communicable diseases. So directly and indirectly we are benefiting.
FGD Female urban D16 - Enugu

Biobank can help save life. If you have biobank close to you and you have a problem, you can approach them to research on your problem.
FGD Female urban C17 - FCT

I have not seen a Biobank I cannot say if it has risk.
FGD Female urban A13 - Oyo

What are the benefits that we will get for participating in the research?

FGD Female urban A13 - Oyo

When somebody's blood is put in the biobank, it helps to find the drugs that can be used to cure diseases.
FGD Female urban D16 – Enugu
biobank has benefits, it can be used for research for the purpose of development of drugs for non-communicable diseases.
FGD Female urban B18 - Kano

It can benefits not only use that are living now, but will also benefit our generation yet unborn
FGD Female urban B18 - Kano

It will help to reduce the incidence of non-communicable diseases
FGD Female urban B18 - Kano

4.4.3.7 Concerns about the Biobank research

The concerns that the majority of these respondents expressed included the problem of erratic power supply, inadequate maintenance culture, unfaithfulness, breach of confidentiality and deviation from the original plans of the biobank research on non-communicable diseases into unethical research. They will also be worried if there's no outcome of the research.

my concern about the biobank research is the erratic power supply in Nigeria.
FGD Female urban D16 - Enugu

My concern is that the researchers will not allow me access to my result.
FGD Female urban D16 - Enugu

My worry is that if you go to most health facilities in Nigeria there are many equipment that are not maintained or put to use. I hope it will not be the same thing with the biobank. Are we matured to handle the biobank?.
FGD Female urban D16 - Enugu

I will be worried if we are not seeing the effectiveness of the research.
FGD Female urban D16 - Enugu

My concern is how you can maintain the biobank with the poor light situation we have in Nigeria.
FGD Female urban C17 - FCT

My concern is that the workers in the biobank, how faithful are they?
FGD Female urban C17 - FCT

I will have concern if the researchers will not do what they tell us from the beginning.
FGD Female urban A13 - Oyo

Biobank has no risk but benefits, so there's no cause for alarm.
FGD Female urban B18 - Kano
We will be worried if there's no outcome of the research.
FGD Female urban B18 - Kano

If the research will maintain confidence there's no problem.
FGD Female urban B18 - Kano

Provided everything will be kept secret, I won't have any concern.
FGD Female urban B18 - Kano

4.4.3.8 Religious or cultural issues on biobank research

Non of the participant had any religious or cultural view on biobank research.

Biobank is not against my religion or culture. But the Jehovah witnesses will not give blood.
FGD Female urban D16 - Enugu

I have no religious or cultural belief against biobank.
FGD Female urban C17 - FCT

No cultural or religious issue on biobank.
FGD Female urban A13 - Oyo

Our religion even require us to do research.
FGD Female urban B18 - Kano

Sincerely, our culture is not against biobank research.
FGD Female urban B18 - Kano

4.4.3.9 Access to medical records for the biobank research

The majority of the discussants were ready to provide access to their medical record. Only one participant would like to be contacted again to give another consent for her medical record access.

The fact that I have given you my consent, I should not worry, you can have access to my medical records.

FGD Female urban D16 - Enugu

Collecting my medical history, I should give you consent, isn't it ?.
FGD Female urban D16 - Enugu

I will not feel bad if you have access to my medical records.
FGD Female urban C17 - FCT

There's no problem, you can have access to my medical record.
FGD Female urban A13 - Oyo
I will permit access to my medical records, but what if I do not have medical records?
FGD Female urban B18 - Kano

You can have access to my medical records.
FGD Female urban B18 - Kano

You can use my medical records.
Others FGD Female urban B18 - Kano

4.4.4 Literate and illiterate rural females

4.4.4.1 Knowledge of biobank and collection of human biological specimens for non-communicable disease research.

The participants viewed biobank as something that will help improve human health and bring about scientific, technological and medical sciences advancement. After an overview they had these to say;

Biobank helps to bring out what type of disease a person is suffering from.
FGD Female rural D14 - Enugu

Through the biobank , a drug can be known for the cure of disease.
FGD Female rural D14 - Enugu

Biobank is used to find out the cause of the persons disease, so as to find out the cure.
FGD Female rural D14 - Enugu

When somebody's blood is put in the biobank, it helps to find the drugs that can be used to cure diseases.
FGD Female rural D14 - Enugu

I was not aware of biobank before now.

FGD Female rural C19 - FCT

I do not know any thing about biobank before now.
FGD Female rural C19 - FCT

I do not know any thing about biobank before now.
FGD Female rural C19 - FCT

4.4.4.2 Understanding of, and Attitudes to research and non-communicable disease research

Majority of these participants had good understanding of research and non-communicable disease research.

What I understand about research is that it is aimed at getting to know the type of diseases affecting the people, so as to know how to treat the diseases.
FGD Female rural D14 - Enugu

Research is about trying to know the type of disease we have and how the people can be treated.
FGD Female rural D14 - Enugu

Research helps us to know the type of disease we have and the drugs to be produced for the treatment.
FGD Female rural D14 - Enugu

Research is just to find details of something.
FGD Female rural A16 - Oyo

Research can help us to know information that we did not know before.
FGD Female rural A16 - Oyo

Research is to find out what is wrong with someone's health.
FGD Female rural B20 - Kano

I agree with the definition above.
Other Females FGD rural B20 - Kano

I know of cancer which is a non-communicable diseases, I have seen body suffering from it.
FGD Female rural D14 - Enugu

I have seen someone's with breast whose cancer was cut and the cover it with cotton wool.
FGD Female rural D14 - Enugu

I know two types of cancer. The one inside the body and the one on somebody's breast.
FGD Female rural D14 - Enugu

know that cancer is a non-communicable disease.
FGD Female rural D14 - Enugu

An example or non-communicable disease is ulcer.
FGD Female rural C19 - FCT

An example or non-communicable disease is hypertension and malaria.
FGD Female rural C19 - FCT

4.4.4.3 Consent for the biobank research

Majority of the discussants supported giving restricted consent to use their blood and tissue samples for the proposed biobank research. A participant would first give the tiered consent, and if she is pleased with that initial research will go ahead to give the broad consent or withdraw if not satisfied.

I prefer the tiered consent of which I have to give you another consent.
FGD Female rural D14 - Enugu

I prefer the restricted consent for the research.
FGD Female rural D14 - Enugu

I will choose restricted consent.
FGD Female rural D14 - Enugu

I will prefer restricted consent.
FGD Female rural D14 - Enugu

I will give the broad consent.
FGD Female rural B20 - Kano

I will give the broad consent.
Other Female FGD rural B20 - Kano

Use my sample for only non-communicable disease research. The reason is that I may decide to withdraw my participation (tiered consent).
FGD Female rural A16 - Oyo

I will choose the restricted consent for the research.

FGD Female rural A16 - Oyo

I will choose the restricted consent.
FGD Female rural A16 - Oyo

4.4.4.4 Feelings about having their donated specimens and data shared by different researchers or shipped for further research

Most do not mind the shipment of their samples to other countries for further research, but would want to receive feedback on the result of any analysis done. Only a respondent prefer America believing the are more competent. A few of them preferred local researchers to international for reasons of proximity.

My fear is that my specimen may be given to somebody who is not a competent researcher. The result of such a person cannot be trusted and it can cause me anxiety.
FGD Female rural D14 - Enugu

Let my specimen be shared with other researchers, I do not mind.
FGD Female rural D14 - Enugu

I prefer my specimen to be given to a local researcher. He is nearer to me, and he will be able to relate with me. I can also ask him of my result.
FGD Female rural D14 - Enugu

If my sample is taken abroad, I would like to know the outcome.
FGD Female rural D14 - Enugu

My specimen can be taken to any country, provided they are competent.
FGD Female rural D14 - Enugu

I prefer that my specimen be taken to America because they can best discover causes of sicknesses.
FGD Female rural D14 - Enugu

Only biobank ask my permission, the other researchers should also make effort to contact me for their sample. They can be taken abroad, I have no problem with that.
FGD Female rural B20 - Kano

No, do not want you to share my specimen, let the other researchers approach us. You can take the specimen abroad.
Other female FGD rural B20 - Kano

Since it is for good, you can share my specimen with other researchers, and take abroad for further studies.
FGD Female rural C19 - FCT

You can share my specimen with other researchers. You can also take it abroad for further analysis provided it will not be used for something that is against my Christian religion.
FGD Female rural C19 - FCT

Do not give other researchers my specimen. Do not take my specimen outside Nigeria for further studies.
FGD Female rural A16 - Oyo

If other research come and meet you, do not give them my specimen. You can however take it outside Nigeria for further analysis.
Other FGD Female rural A16 - Oyo

4.4.4.5 Someone they must tell before giving consent for the biobank research

A majority of these women respondents said they must let their spouses know. Others would tell their sisters, brothers and family members. Others intend to publicise it in the churches.

I will tell my sister and my brother before I participate.
FGD Female rural D14 - Enugu

I will not let anybody know because it is going to be my decision to participate.
FGD Female rural D14 - Enugu

I will not seek anybody's opinion before I participate, because what is good is good. It is good for the world.
FGD Female rural D14 - Enugu

I will not ask someone's opinion before I participate. When I get to the church I will spread the news.
FGD Female rural D14 - Enugu

If I tell my family that I want to participate, they will be happy because it is not a bad thing at all. It is to help us.
FGD Female rural D14 - Enugu

My people will be happy about this whole research. They will not be worried if I want to participate.
FGD Female rural D14 - Enugu

I will seek the consent of my husband to participate.
FGD Female rural B20 - Kano

I will seek the consent of my husband to participate.
Other female FGD rural B20 - Kano

I will inform my husband so that he will know what I want to do.
FGD Female rural A16 - Oyo

4.4.4.6 Feedback and receiving news from the research

With the probe on whether they would like to be contacted if something serious was discovered about them during the course of the research, a large majority of the discussants answered in the affirmative. Reasons for their decisions included the possibility of access to beneficial new medical knowledge. A large majority of the participants said it would be very important to receive general news about studies being done through the Biobank. Some participants would like the feedback which will help then to know if the research is contributing to society health.

I would like to be given my result.
FGD Female rural D14 - Enugu

I want to know my results.
FGD Female rural D14 - Enugu

I would like to know my result, whether it is good or bad.
FGD Female rural D14 - Enugu

I would like to know my result.
FGD Female rural D14 - Enugu

I would like to know my result, because you don't hide disease. The research can even be published.
FGD Female rural D14 - Enugu

We should be given feedback whether good or bad.
FGD Female rural B20 - Kano

With the feedback if there's drug we can be given.
FGD Female rural B20 - Kano

If you are not given feedback you will not know the position of things regarding your health.

FGD Female rural B20 - Kano

If diseases are discovered, people should be made to know about them.
FGD Female rural C19 - FCT

If something serious is discovered about me I should be told. I would also like to receive news about the biobank. I will not feel happy if you do not give me my results.
FGD Female rural C19 - FCT

If something serious is discovered about me I should be informed.
Other FGD Female rural C19 - FCT

I should be given feedback even if it is something serious about my health.
FGD Female rural A16 - Oyo

I should be given feedback and news.
Other FGD Female rural A16 - Oyo

4.4.4.7 Perception of benefits of participating in the biobank research.

These group of participants had good perception of the benefits of biobank research.

Biobank can be lead to development of drugs. For instance, the whiteman who developed paracetamol used some people in their research.
FGD Female rural D14 - Enugu

biobank is of benefit not to me alone, but for the whole world. It is not for one persons benefits.
FGD Female rural D14 - Enugu

Biobank can help us to know about the diseases we are suffering from and the drugs to cure it.
FGD Female rural D14 - Enugu

Biobank can help us to know about the diseases we are suffering from and the drugs that can make it go.
FGD Female rural D14 - Enugu

You may not know of something but the biobank research may reveal it.
FGD Female rural B20 - Kano

Biobank will bring awareness on diseases.
FGD Female rural C19 - FCT

biobank is used for researches on other diseases that have not been discovered and for curing them.
FGD Female rural C19 - FCT

If there's faith on the biobank research and cooperation between the researchers and the participants it bring about benefits.
FGD Female rural C19 - FCT

If my specimen is taken for research, the disease that I may not know about can be discovered and treated.
FGD Female rural C19 - FCT

Drugs can be developed for diseases from the biobank.
FGD Female rural A16 - Oyo

As a person, if a disease is discovered on me in the course of the biobank research, I could be treated.
FGD Female rural A16 - Oyo

There are more advantages than disadvantages of the biobank research.
FGD Female rural A16 - Oyo

4.4.4.8 Future use of specimens from the biobank research.

The participants would like to re-consent before their specimens are used for future studies. This was why they earlier on said they will choose the restricted consent. They want to be sure of the kind of research that will be done before they give consent.

I should be informed before other studies are done on my specimen in the future.
FGD Female rural C19 - FCT

I am also of the opinion that I should be informed before other studies are done on my specimen the in future.
FGD Female rural C19 - FCT

4.4.4.9 Concerns about the biobank research

When the discussants were asked what their concerns were, some were concerned on the sustainability of the project and if their samples will be used for other research other than non-communicable research. Those that could not say what will make them change their mind were few.

I will have concern when this biobank research that I hope will be of benefit to humanity is terminated half way.
FGD Female rural B20 - Kano

I do not have any concern on biobank research.
Other female FGD rural B20 - Kano

I would like to know what my blood is being used for in the biobank, if not I will be disturbed.
FGD Female rural D14 - Enugu

4.4.4.10 Religious or cultural issues on biobank research

No participant had any religious or cultural view on biobank research.

The biobank is not against my religion or culture.
FGD Female rural D14 - Enugu

Any research that has to do with human health, I do not think religion or culture is against it.
FGD Female rural B20 - Kano

We do not know of any religious or cultural belief that is against the biobank research.
Other female FGD rural B20 - Kano

I do not have any religious or cultural view that is against the biobank research.
FGD Female rural A16 - Oyo

4.4.4.11 Access to medical records for the biobank research

A majority of the discussants said that the researchers can have access to their medical records.

I will not be annoyed if you have access to my medical records.
FGD Female rural D14- Enugu

I will not feel bad if you have access to my medical records.
FGD Female rural D14 - Enugu

Since it is part of the research no problem if you have access to my medical records
FGD Female rural B20 - Kano

You can have access to our medical records.
Other Female rural B20 - Kano

I have no problem with you having access to my medical records.
FGD Female rural C19 - FCT

You can have access to my medical records.
FGD Female rural A16 - Oyo

You can use my medical records.
FGD Female rural A16 - Oyo

There's no problem you can use my medical records.
Other FGD Female rural A16 - Oyo

CHAPTER FIVE

5.0 DISCUSSION

This is the first study on prospective research participation perspectives on the collection, storage and use of blood samples for biobank research in Nigeria which elicited the perspectives of a diverse group of individuals.

1. Knowledge and attitude to biobanking research and non-communicable disease - Participants in this study had limited knowledge of biobanking research, but had good knowledge of non-communicable diseases.

2. Willingness to participate - The results of this study showed that majority of the respondents were willing to donate their samples for non-communicable disease research and for future research. Previous studies in Western countries (eg, USA, UK, Sweden, Japan, Iceland) and one from Uganda, a resource-limited country in Africa (Wendler et al., 2005) showed that most individuals were willing to donate their blood sample for future research (Kettis-Lindblad et al., 2006; Nilstun & Hermeren, 2006; Guqmundsdottir, 2007; Goodson & Vernon, 2004; Bryant et al., 2008).

Only a few participants would not like to participate in the biobank research and it agrees with other studies (Chen et al., 2005; Goodson & Vernon, 2004). The groups most likely to abstain were those with higher education. In other studies the social group most likely to abstain differ between national contexts; for example, in the US ethnic minorities and people with poor education will typically abstain (Wendler & Emanuel, 2002), while in Sweden it seems to be younger men with higher education who are least likely to participate (Hoeyer et al., 2004; Kettis-Lindblad et al., 2007).

3. **Informed consent and consent types** - Majority of the discussants in the study supported giving broad consent to use their blood and tissue samples for the proposed biobank research. While a minority of the participants would like to initially consent

to the restricted and later give consent for the broad if the researchers demonstrates that they are virtuous custodians of donated samples. The support for broad consent in this study agrees with a study carried out in Durham, North Carolina of which 85% of the respondents endorsed broad consent (Beskow & Dean, 2008). Germany, Iceland, the UK, Switzerland, Estonia, Japan and Latvia largely recommend broad consent models (Maschke, 2005).

A few participants prefer the Specific or "Narrow" or restricted informed consent and it agrees with Italy, France and Sweden which explicitly require specific informed consent (Salvaterra et al., 2008).

4. Specimens and data sharing over time – a few participants were particular on the proper observance of the country's law on material transfer agreement to protect the participants interest about how the samples will be transferred and used here and outside Nigeria. This dependence on government approval as a guarantor reflects the perception that the individual is not able to monitor usage of donated samples on their own, but had the strong belief that the government is in the best position to ensure proper usage of the banked materials. They would like to know the outcome of such collaboration. A minority of the respondents in this study did not want their samples sent to other African countries. They do not believe that other African countries were competent enough to work on their samples. The finding contrast with the opinions of the Ugandan, most of whom stated that they would allow their samples to be sent to a neighbouring countries (Tanzania or Kenya) or to the UK or the USA (Wendler et al., 2005).

5. Return of result and feedback - the majority view is to be given general feedback and their individual results even if something serious were discovered about their health, but with pre-counselling. This would help in assuring them that their

involvement had been worthwhile and divulging of the results could also sustain their interest. Some said, though it would be unwelcome news, it would be preferable to hear it earlier rather than later. It would allow more time to prepare for the outcome. Another study involving Ugandan individuals showed that half of the respondents wanted the results of the research to be shared with them (Wendler et al., 2005). In a study of American (Wendler & Emmanuel, 2002) and Irish (Cousins et al., 2005) participants, they seem to want research results irrespective of the availability of treatment options in contrast to Swedes and in particular rural Swedes, who prefer getting individual results only when they are of validated clinical use (Hoeyer et al., 2004; Kettis-Lindblad et al., 2006).

The traditional practice of not giving research participants any information from a study that relates specifically to them is being re-evaluated in the context of genetic research (Maschke, 2010). Many commentators now argue that there are ethical and legal obligations to give individuals their test results under some circumstances (Kohane & Taylor, 2010; Kohane et al., 2007). For instance, when results could have an impact on their health or reproductive decisions.

6. Secondary use of samples - A few participants that are knowledgeable on research would want the biobank to specify the future uses of their samples. They entertained the fear that the researchers may deviate from the original objectives of the research into research that might be against their religious belief such as the production of biological weapon or a strain of virus that could be used to destroy human beings and for cloning or stem cells research. Those that were not comfortable would like to re-consent to be sure of what they will allow. This agreed with other studies, of which re-consent was reported to be the clear expectation in these studies (Korts et al., 2004)

Another study showed that a large majority of African-Americans would permit unlimited future research with their biological samples (Chen et al., 2005).

There has been a lack of consensus regarding the type and quality of informed consent needed to collect and store samples for future, unspecified research (Johnstone et al., 2001). Although it is agreed that consent documents should address future use, it is often difficult to fully explain the scope of what that use may encompass.

The repeated reference to this issue highlights the high level of religious observances in the study population. Biobank research can creates moral harm when samples are used for research that the participants would object strongly to.

7. Confidentiality - A few participants expressed concern on the possible loss of confidentiality, privacy and information and would like the anonymity of the participants and data will be ensured. It agrees with UK-based studies which found that donors have a number of worries relating to confidentiality (Levitt & Weldon, 2005). About half of the participants thought there were no risks involved in biobank research, while a few brought out the issue of harm to the group to which a participant belongs, and thereby harm the individuals concerned. This harm may arise, for instance, if people outside the group regard the group in a more negative way or treat people belonging to that group in a worse way than other. The harm may also be due to people in the group starting to look at themselves in a different, more negative way.

Also, the risk of identifying individual solely by genetic materials in the future cannot be ruled out. Such technology may emerge, potentially making de-identified specimens and their associated data identifiable in the future. Much like fingerprints, biospecimens may one day be traceable back to the individuals who donated them (Baer et al., 2010).

8. Autonomy - A large proportion of the respondents expressed their desire to let their spouses know before they participate, and those that are not married mentioned their

parents, brothers, sisters and relations. Respecting someone's autonomy is respecting that person's right to decide and act.

9. Concerns – several concern were raised which include the following;

(a) benefits sharing: a few participants would like to know the benefits or personal gains that will accrue to them from the biobank. They rarely want money in return, but care. Many, but not all, view participation as a duty, as a chance to help. It agrees with other studies in U.S., Canada, the UK, Norway, Sweden, Austria and France (Hoeyer, 2010). Other studies have highlighted how people in the European welfare states see participation as a sort of obligation that is part of benefiting from universal healthcare and medical science (Busby, 2006; Hoeyer, 2003).

(b) ownership and commercial interests issues: A few participants would like to get some clarification on ownership and commercial interests issues surrounding the biobank resources. Some years ago, discussion in the literature on ownership largely stemmed from the infamous Moore case in California where unauthorized research uses of bodily materials led to a property claim by the donor (*Moore v. Regents of California* 1990; *cert denied* 1991). While Mr. Moore lost his property claim, the principle of obtaining an informed consent to research uses of samples and genetic information was established. Such a requirement exists irrespective of the "property" or "person" characterization and allows a person to exercise a right of control. In the case of a "gift" however, ownership passes upon donation (*Washington Univ. v. Catalona* 2007). The quest for clarification in relation to commercial interests in this study agrees with another study in UK (Levitt & Weldon, 2005). The participants do not find themselves in a position to personally control this issues and do not find informed consent helpful in reaching this end as was seen in other studies (Barr, 2006; Hoeyer, 2004).

(c) sustainability: A few participants were bordered that the project might be abandoned half way just as many laudable projects have been abandoned in Nigeria.

10. Religious or cultural issues on biobank: No single participant had any religious or cultural view on biobank research. The participant pointed out that if the outcome of the biobank research is favourable, any contrary culture to biobank research will give way.

11. Access to medical records: confidentiality was considered a significant issue in light of the need for personal medical records along with the specimens. The request for information from medical records were seen by many of the participants to be okay. They felt they had nothing to hide. For many it caused little worry, for several reasons, they believed that if information is properly encoded or encrypted it will not be accessible to people unauthorized. Most surveys in Sweden and USA, seem to find that a majority of potential donors expect to have a say about usage of tissue and medical records (Eriksson, 2007; Hull et al., 2008) though exceptions exist (Nilstun & Hermerén, 2006). The success of large-scale population genetic databases depends on individuals being motivated to freely donate samples and to allow access to their medical records. People therefore need to trust those responsible for the collection, storage and use of their personal data (Levitt & Weldon, 2005).

5.1 CONCLUSIONS AND RECOMMENDATIONS

1. Knowledge and attitude to biobanking research and non-communicable disease - Since the participants in this study had limited knowledge of biobanking, biobank scientists need to incorporate significant initiatives for population engagement and education about biobanks and its value in modern research, through campaigns using the services of medical doctors, community and religious leaders.

2. Willingness to participate - The proposed biobank sample collection was well accepted in principle, largely because biobank research was understood to have benefits, although it is clear that many of them do not think through the implications fully as they were presented with the idea.

3. **Informed consent and consent types** - Consent is an important issue for the biobank's at the start and in the future for its continuing success. The participants should be given enough information that will enable them make informed decision on the type of consent they would like to give (broad, restricted, tiered, etc).

4. Specimens and data sharing over time - The sharing of data is usually desired by researchers and participants alike, but both the advantages and possible risks need to be explained to the participants.

5. Return of result and feedback - Biobank should devise ways to provide feedback on individual results by stating who should give the feedback to the participants and possibly set up machinery and resources for pre and post-counselling for the feedback. Explanation of the specific information or type of feedback the participants have right to know should be given at the outset, which will include the type of diseases or conditions. The feedback on results accruing to an individual's health should be handled with utmost care. There should be information to participants on when publications will

be available on the general outcome of the studies either trough the print media or the Web sites established for this purpose for use by the participants with Internet access.

6. Secondary use of samples - it will be appropriate to addressed the topic of future use of specimens and provide on the consent form, specific information about the storage and future use of biological materials, the treatment of related data and the right of donors to refuse consent to the storage or future use of the collected samples. The dependence on government approval as a guarantor before samples are sent to other countries for further research which reflects the perception that the individual is not able to monitor usage of donated samples on their own, calls for government strong regulation or guideline on the usage of donated samples and control of biobanks activities in Nigeria.

7. Confidentiality - It is important that the biobank researchers discuss with the participants on the nature of any risks involved including risk of physical harm and any risks related to privacy and confidentiality and uncertainties. A unique degree of confidentiality should be kept to assure the privacy of participants through adherence to legally defined principles and rules.

8. Concerns

(a) benefits sharing: Since in the study, a few participants would like to know the benefits that will accrue to them in terms of treatment if found to have diseases, effort should be made to clearly state in the consent form the likely benefits that the participant will get as recompense and recognition of donors' altruism in participating in the study.

(b) ownership and commercial interests issues: It is important to clarify in the consent process, ownership issues surrounding biobank resources whether it is a national or private property. Participants should be clearly informed that they will not

receive financial gain from any new treatments developed through research conducted on their specimens.

(c) sustainability: there is the need to ensure sustainability of the biobank and to provide mechanisms for equitable and appropriate access to biospecimen.

9. The result of this study highlight the need to carefully document population attitudes to elements of modern scientific research and its impact on consenting process.

10. A further study is recommended using quantitative research methods to explore more fully the knowledge, and attitudes of Nigerians on biobank research.

11. The strength of our study included, diversity of the study sample and the geographical spread of respondents. We ensured adequate representation of sexes, age, religions and tribes.

12. The number of participants of this study was relatively small. The reason for this was the time limit of the project since it is a research for the award of M.Sc. in Bioethics in the University of Ibadan.

13. The findings from this study are enlightening and useful, but should be treated as a snapshot of current opinion of Nigerian public on biobanking.

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APPENDIXES

APPENDIX 1

Samples specification.

1. Participants from Oyo State

A1- Male Government Official urban

A2 - Male Student urban

A3 - Male Christian Leader urban

A4 - Male Community Leader urban

A5 - Female Spokesperson urban

A6 - Male Teacher urban

A7 - Male Spokesperson urban

A8 - Male Traditionalist/previous research participant urban

A9 - Male Muslim Leader urban

A10 - Male Ethicist/hypertensive

A11 - Male Scientist rural

A12 - Female Nurse rural

A13 - Male FGD urban

A14 - Female FGD urban

A15 - Male FGD rural

A16 - female FGD rural

2. Participants from Kano

B1- Male Government Official urban

B2 - Male Scientist urban

B3 - Female Pharmacy Technician/Spokesperson urban

B4 - Male Community Leader urban

B5 - Male Teacher urban

B6 - Male Student urban

B7 - Male Muslim Leader urban

B8 - Male Hypertensive patient urban

B9 - Male relative of hypertensive patient urban

B10 - Male Spokesperson urban

B11- Male Administrator/previous research participant urban

B12 - Female Spokesperson rural

B13 - Male Community Leader rural

B14 - Male Muslim Leader rural

B15 - Male spokesperson rural

B16 - Male Medical Doctor urban

B17 - Male Nurse Christian urban

B18 - Female FGD urban

B19 - Male FGD urban

B20 - Female FGD rural

B21- Male FGD rural

3. Participants from the federal capital territory (FCT)

C1 - Female Nurse urban

C2 - Male Medical Doctor urban

C3 Male Hypertensive patient/Student urban

C4 - Male Administrator urban

C5 - Male Teacher urban

C6 - Male Muslim Leader urban

C7 - Male Nurse/Spokesperson urban

C8 - Male Scientist urban

C9 - Female Spokesperson urban

C10 - Male Diabetic Patient urban

C11 - Male Christian leader urban

C12 - Female Spokesperson rural

C13 - Male Christian Leader rural

C14 - Male Spokesperson rural

C15 - Male Community Leader rural

4. Participants from Enugu State

D1 - Male spokesperson rural

D2 - Male Community Leader rural

D3 - Male Christian leader rural

D4 - Patient with NCD

D5 - Female Spokesperson rural

D6 - Male ethicist urban

D7 - Male Scientist urban

D8 - Male Spokesperson urban

D9 - Male Medical Doctor urban

D10 - Female Student urban

D11 - Male Lawyer 1 urban

D12 - Male Lawyer 2 urban

D13 - Male Administrator urban

D14 - Female FGD rural

D15 - Male FGD rural

D16 - Female FGD urban

D17 - Male FGD urban

D18 - Female Pharmacist urban

APPENDIX 2

FOCUS GROUP DISCUSSION FOR PUBLIC PERSPECTIVES ON BIOBANKING IN NIGERIA - Topic Guide

General public and ethnic groups

Instructions: Hand out consent form. Give adequate opportunity for questions. Collect the informed consent forms.

- Warm-up with personal details (family, employment, spare time interests)
- (briefly) attitudes towards health, treatment of disease and developments in medicine.

1. Awareness of research
2. Would you like to participate in research?
3. Would you want to discuss it with anyone, and if so, who?
4. How do you imagine members of your **family** would respond?
5. What do you understand by informed consent for biobank research or what would you want scientists to discuss with you before you give permission for your samples to be used in research?
6. What type of consent would you prefer?

   (A) Broad consent – If I agree to do the study, I don't want to be contacted each time. I'm going to agree to just give my information and be done with it.

   (B) Tiered consent – Use the sample for only non-communicable disease research and call me every single time a researcher wants to do a study with my sample in the future (note: ask of what happens after death, should we keep coming back to the family for permission? Who is the most important person to

give permission? Supposing there is disagreement among the family members what should the researchers do?

(C) Restricted consent – I would rather want you to give me a list of the options of the researches you want to do with the sample.

7. What you know, feel about Non Communicable Diseases (NCD)
8. How keen are you to participate in NCD research
9. Awareness of, and attitudes towards, biobank generally
10. Key association/perceived uses of biobank research
11. Overall, how do you regard **biobank research compared with medical research** in general? (Note any misunderstandings surrounding medical and biobank research. Is it associated more with **general biological investigation** or more with bigger **'single issue'** research {e.g., Cancer, heart disease})? Note their level of understanding of genomics.
12. Perceptions of benefits and risks of biobank research
13. Key concerns about biobank research
14. Sources of information and **influences on perceptions** (probe for health professionals, media, friends and family, scientific community)
15. Do you believe it might have a place in your own lives and if so, how?
16. Did you know that it could be used in work to combat disease and develop more effective drugs?
17. Do you have any **religious or cultural views** on biobank research?
18. How do you feel about the idea that your blood will be kept indefinitely?
19. How does collection of information on your medical history affect your opinion about participating in the Biobank research?

20. What kinds of things would make you change your mind about participating in the Biobank research or what do you have as concern?
21. If researchers discovered something serious about your health, do you think they should let you know?
22. How important would it be to you to be able to get general news about studies being done through the Biobank research?
23. How would you feel about being contacted at a later time to participate in additional research?
24. How do you feel about having your donated samples shared by different researchers?
25. Does your opinion vary depending on whether the researchers are local or international?
26. What do you think about having your samples sent abroad for analyses?
27. In case of such international shipment, what would you like to know about what happens to the samples?
28. Which country would you prefer for you sample to be sent to?
29. Would you like to pick research studies your samples can be used in?
30. What do you think about the statement, ‘‘You should not expect to get individual results from research done with your blood’’?

NOTE: Does this remind them of any **news or stories** they have seen or heard?

Reaction to idea in principle – what are their **first thoughts and feelings**?

Understanding of intended use, applications and potential benefits

What issues are raised, and what concerns do people have about it? (Note references to: **anonymity/confidentiality**; **consent**; mechanics of collection, sample collection and **storage**; **future use** of samples; **ownership** of samples; co-production,

involvement of **commercial interests,** the relationship between donors to the owners of the biobank, Trust and distrust, compensation for expenses incurred, provision of medical care).

APPENDIX 3

Health Research Ethics Committee (HREC) assigned number: NHREC/01/01/2007

FOCUS GROUP DISCUSSION FOR PUBLIC PERSPECTIVES ON BIOBANKING IN NIGERIA - Consent form

Thank you for agreeing to participate in this discussion group. We are interested in learning about your beliefs and opinions about research, Non Communicable Diseases biobanking and the donation of specimen for research. We would like to hear what everyone thinks so please feel free to express your views even if you disagree with the general views of this group. All comments whether negative or positive are important. The discussion will be recorded so that none of your comments are omitted and a report will be prepared from the transcripts.

The study however involved the risk/harm of confidentiality and social injuries due to the nature of some questions. Records will be kept under lock and key, limiting access to confidential records, discarding personal identifiers from data collection forms and computer files. Other measures that will be employed to safeguard information will include encrypting computer databases, limiting geographic detail, and suppressing cells in tabulated data.

You may not benefit directly from the outcome of the study but the result will be used to carry out research on NCDs to improve human life that will be beneficial to society at large.

Completing this form means that you have given consent to participate in this research.

What are Non Communicable Diseases and the purpose of Biobanks?

The purpose of the Biobanks is to collect and store tissue samples (such as blood) and health information for use in medical research. Researchers can do many kinds of studies using these materials to learn more about cardiovascular disease, type 2 diabetes, cancer, chronic lung disease, and depression which are the major non-communicable diseases (NCDs). Some may use the samples and information to look for new ways to diagnose, treat, and maybe even prevent or cure these health problems. Others may use them to study how genes affect health and disease, or how genes affect response to treatment (genes, which are made of DNA, give the instructions for building all the proteins that make our bodies work). Some of these studies may lead to new products, such as drugs or tests for diseases.

Researchers often study tissue or blood from people who have health problems and from people who do not. The research is meant to gain knowledge that may help people in the future.

Confidentiality:

All information collected in this study will be given code numbers and no name will be recorded. This cannot be linked to you in anyway and your name or any identifier will not be used in any publication or reports from this study.

Voluntariness:

Your participation in this research is entirely voluntary.

Consequences of participants' decision to withdraw from research and procedure for orderly termination of participation:

You can also choose to withdraw from the research at anytime. Please note that some of the information that has been obtained about you before you chose to withdraw may have been modified or used in reports and publications. These cannot be removed

anymore. However the researchers promise to make good faith effort to comply with your wishes as much as is practicable.

Statement of person obtaining informed consent:

I have fully explained this research to _____ and have given sufficient information, including about risks and benefits, to make an informed decision.

DATE:_____SIGNATURE: _____

NAME: _____

Statement of person giving consent:

I have read the description of the research or have had it translated into the language I understand. I have also talked it over with the doctor to my satisfaction. I understand that my participation is voluntary. I know enough about the purpose, methods, risks and benefits of the research study to judge that I want to take part in it. I understand that I may freely stop being part of this study at any time. I have received a copy of this consent form and additional information sheet to keep for myself.

DATE: _____SIGNATURE: _____

NAME: _____

WITNESS' SIGNATURE (if applicable): _____

WITNESS' NAME (if applicable): _____

This research has been approved by the National Health Research Ethics Committee of the Federal Ministry of Health, Abuja and the Chairman of this Committee can be contacted at the Institute of Human Virology, Abuja, FCT. The phone numbers is

08033520571. In addition, if you have any question about your participation in this research, you can contact the principal investigator,

Igbe, Michael Adikpe

West African Bioethics Training Programme,

Department of Surgery,

Faculty of Clinical Sciences,

University of Ibadan, Nigeria.

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Mobile: 08055101831

PLEASE KEEP A COPY OF THE SIGNED INFORMED CONSENT.

APPENDIX 4

PUBLIC PERSPECTIVES ON BIOBANKING IN NIGERIA - Guide for Key Informant Interview for the general population, the middle and upper level income population in 2 LGAs of FCT, Kano, Oyo and Enugu States.

1. What do you know about research? _____

_____

2. Would you like to be a potential participant in it?_____

3. What do you understand by informed consent or what would you want scientists to discuss with you before you give permission for your samples to be used in research?_____

4. What type of consent do you prefer?

(a) If I agree to do the study, I don't want to be contacted each time. I'm going to agree to just give my information and be done with it (broad consent).

(b) Use the sample for only non-communicable disease research and call me every single time a researcher wants to do a study with my sample in the future (tiered consent).

(c) I would rather want you to give me a list of the options of the researches you want to do with the sample (restricted)

5. Would you want to discuss it with anyone? _____

6. If yes to Q5, who? _____

7. How do you imagine members of your **family** would respond?

_____

8. What do you know, feel about Non Communicable Diseases (NCD)?

_____

9. How keen (interested) are you to participate in NCD research?

_____

10. What do you know about biobanks or repositories generally?

_____

11. Key associations/perceived uses of biobank research?

_____

12. What are your perceptions of benefits and risks of biobank research?

_____

13. If there is benefit, what is the benefit?

_____

14. What is your sources of information and **influences on perceptions**

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15. Do you believe it might have a place in your own live? _____

16. If yes to Q15, how? _____

17. Did you know that it could be used in work to combat disease and develop more effective drugs?_____

18. Do you have any **religious or cultural views** on biobank research?

_____

19. If yes to Q18, how? _____

20. Overall, how do you regard **biobank research compared with medical research** in general?_____

21. How do you feel about the idea that your blood will be kept indefinitely?

22. How does collection of information on your medical history affect your opinion about participating in the Biobank research?

_____

23. What kinds of things would make you change your mind about participating in the Biobank research or what do you have as concern?

_____

24. If researchers discovered something serious about your health, do you think they should let you know? _____

25. How important would it be to you to be able to get general news about studies being done through the Biobank research? _____

26. How would you feel about being contacted at a later time to participate in additional research?_____

27. How do you feel about having your donated samples shared by different researchers?_____

28. Does your opinion vary depending on whether the researchers are local or international?_____

29. What do you think about having your samples sent abroad for analyses?

_____

30. In case of such international shipment, what would you like to know about what happens to the samples? _____

31. Would you like to pick research studies your samples can be used in?_____

32. What do you think about the statement, ‘‘you should not expect to get individual results from research done with your blood’’?

APPENDIX 5

Health Research Ethics Committee (HREC) assigned number: NHREC/01/01/2007

KEY INFORMANT INTERVIEW FOR PUBLIC PERSPECTIVES ON BIOBANKING IN NIGERIA - informed consent template

Thank you for agreeing to participate in this discussion group. We are interested in learning about your beliefs and opinions about research, Non Communicable Diseases, biobanking and the donation of specimen for research. We would like to hear what you think so please feel free to express your views. All comments whether negative or positive are important. The discussion will be recorded so that none of your comments are omitted and a report will be prepared from the transcripts.

The study however involved the risk/harm of confidentiality and social injuries due to the nature of some questions. Records will be kept under lock and key, limiting access to confidential records, discarding personal identifiers from data collection forms and computer files. Other measures that will be employed to safeguard information will include encrypting computer databases, limiting geographic detail, and suppressing cells in tabulated data.

You may not benefit directly from the outcome of the study but the result will be used to carry out research on NCDs to improve human life that will be beneficial to society at large.

Completing this form means that you have given consent to participate in this research.

What are Non Communicable Diseases and the purpose of Biobanks?

The purpose of the Biobanks is to collect and store tissue samples (such as blood) and health information for use in medical research. Researchers can do many kinds of studies using these materials to learn more about cardiovascular disease, type 2 diabetes, cancer, chronic lung disease, and depression which are the major non-communicable diseases (NCDs). Some may use the samples and information to look for new ways to diagnose, treat, and maybe even prevent or cure these health problems. Others may use them to study how genes affect health and disease, or how genes affect response to treatment (genes, which are made of DNA, give the instructions for building all the proteins that make our bodies work). Some of these studies may lead to new products, such as drugs or tests for diseases.

Researchers often study tissue or blood from people who have health problems and from people who do not. The research is meant to gain knowledge that may help people in the future.

Confidentiality:

All information collected in this study will be given code numbers and no name will be recorded. This cannot be linked to you in anyway and your name or any identifier will not be used in any publication or reports from this study.

Voluntariness:

Your participation in this research is entirely voluntary.

Consequences of participants' decision to withdraw from research and procedure for orderly termination of participation:

You can also choose to withdraw from the research at anytime. Please note that some of the information that has been obtained about you before you chose to withdraw may have been modified or used in reports and publications. These cannot be removed

anymore. However the researchers promise to make good faith effort to comply with your wishes as much as is practicable.

Statement of person obtaining informed consent:

I have fully explained this research to _____ and have given sufficient information, including about risks and benefits, to make an informed decision.

DATE:_____SIGNATURE: _____

NAME: _____

Statement of person giving consent:

I have read the description of the research or have had it translated into the language I understand. I have also talked it over with the doctor to my satisfaction. I understand that my participation is voluntary. I know enough about the purpose, methods, risks and benefits of the research study to judge that I want to take part in it. I understand that I may freely stop being part of this study at any time. I have received a copy of this consent form and additional information sheet to keep for myself.

DATE: _____SIGNATURE: _____

NAME: _____

WITNESS' SIGNATURE (if applicable): _____

WITNESS' NAME (if applicable): _____

This research has been approved by the National Health Research Ethics Committee of the Federal Ministry of Health, Abuja and the Chairman of this Committee can be contacted at the Institute of Human Virology, Abuja, FCT. The phone numbers is

08033520571. In addition, if you have any question about your participation in this research, you can contact the principal investigator,

Igbe, Michael Adikpe

West African Bioethics Training Programme,

Department of Surgery,

Faculty of Clinical Sciences,

University of Ibadan, Nigeria.

EMAIL: igbemichael@yahoo.com

Mobile: 08055101831

PLEASE KEEP A COPY OF THE SIGNED INFORMED CONSENT.