ADDIS ABABA UNIVERSITY
COLLEGE OF HEALTH SCIENCES
SCHOOL OF PUBLIC HEALTH

Title: Perspective and Experiences of Researchers regarding Informed Consent for Biorepositories in Ethiopia: A Qualitative Study

By: Siham Mohammed Abdella (BSc.)

Advisors:

1. **Dr. Ayele Belachew (Associate Professor)**
2. **Lealem Minwuyelet (MSc)**
3. **Kalkidan Solomon (Assistant Professor)**

A Thesis Submitted to the School of Public Health, Addis Ababa University, in Partial Fulfilment of the Requirement for Master's of Public Health in Health Research Ethics.

Date: July, 2024
Addis Ababa, Ethiopia

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APPROVAL SHEET

ADDIS ABABA UNIVERSITY

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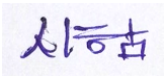
Submitted By:

Siham Mohammed Abdella		July 29, 2024
Full Name	Signature	Date

Approved by:

Advisor:

_____	_____	_____
Full Name	Signature	Date

Internal Examiner:

_____	_____	_____
Full Name	Signature	Date

External Examiner:

_____	_____	_____
Full Name	Signature	Date

Chairperson, department graduate committee:

_____	_____	_____
Full Name	Signature	Date

Contents

Acknowledgment i
Acronym and Abbreviations ii
Abstract iii
1. Introduction 5
1.1. Background 5
1.2. Statement of the Problem 6
1.3. Significance of the Study 7
2. Literature Review 8
2.1. Informed Consent and the Ethical Issues in Genetic and Biobank Research 8
2.2. Types of Consent 8
2.3. The Ethiopian Context 11
3. Conceptual Framework 13
4. Objective 15
4.1. General Objective 15
4.2. Specific Objectives 15
5. Methodology 16
5.1. Study Setting 16
5.2. Study Approach 17
5.3. Study Period 17
5.4. Study Population 17
5.5. Recruitment of Participants 17
5.6. Data Collection tool and procedures 17
5.7. Trustworthiness (Quality assurance) 18
5.8. Data management and analysis 19
5.9. Ethical Considerations 21
5.10. Dissemination of Findings 21
6. Findings 22
7. Discussion 39
8. Conclusion 42
9. References 43

10. Annexes 48

List of Tables

Table 2: Main Themes, Sub-themes, and Codes 20
Table 1: Socio-Demographic Data of Study Participants 22
Table 3: COREQ Checklist 57
Table 4: Code Book 61

List of Figures

Figure 1: Conceptual Framework 14

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Acronym and Abbreviations

AAU - Addis Ababa University

AHRI - Armauer Hansen Research Institute

CHS - College of Health Sciences

CTSA - Clinical and Translational Science Award

EPHI - Ethiopian Public Health Institute

ESTC - Ethiopian Science and Technology Commission

H3Africa - Human Heredity and Health in Africa

IRB - Institutional Review Board

Malaria GEN - Malaria Genomic Epidemiology Network

MoST - Ministry of Science and Technology

MTA – Material Transfer Agreement

NeuroGAP-P - Neuropsychiatric Genetics of African Populations-Psychosis

PGI - Pathogen Genomics Initiative

PI – Principal Investigator

Abstract

Background: Informed consent in biorepository-based research is a highly debated issue in the scientific community. Unlike one-time consent for a specific study, broad consent is required for future use of biospecimens. However, providing sufficient information about future research poses ethical challenges, making informed consent complex. Additionally, the use of complex procedures and terminology can make it difficult for individuals to fully comprehend the scope of their consent. As a result, the question of whether informed consent can be considered valid is a contentious and multifaceted issue. Given the significant increase in genomics and biorepository-based studies in Ethiopia, it is crucial to gain insight into the perspectives and experiences of researchers, sample donors, ethics committees, and other stakeholders involved in biorepositories.

Objective: This study aims to explore and understand the perspective and experiences of researchers concerning informed consent for biorepository-based studies in Ethiopia.

Methods: A qualitative study was conducted among 15 participants recruited using purposive intensity sampling. Face-to-face and virtual in-depth interviews were conducted with the study participants are well-experienced in biomedical research that involved collecting and storing human biospecimens from Addis Ababa University, College of Health Sciences, Ethiopian Public Health Institute, and Armauer Hansen Research Institute. Data were organized using NVivo version 20 and analyzed thematically.

Results: The study reveals that while information is clearly stated on the information sheet, the informed consent process is not flawless, due to complexity of the study, lack of scientific knowledge, traditional beliefs, and communication flaws during information delivery. Moreover, the absence of a standardized informed consent model specifically tailored to genetics and other biorepository-based research emerged as another primary challenge.

Conclusion: Overall, the researchers viewed the informed consent paper positively, yet the consent process was perceived negatively due to participants' poor comprehension. This informs the need for testing comprehension levels before obtaining consent. Future multi-site studies shall be conducted to generate evidence on the opinions and experiences of ethics committees, study participants, and other key stakeholders on informed consent for biorepositories.

Keywords: Consent models, Informed consent process, Biorepository, Genetics, Researchers, Ethiopia

1. Introduction

1.1. Background

Since their inception, biorepositories or biobanks have progressed from small-scale processes focusing on collecting biospecimens for specific studies in pathology settings into sophisticated and complex infrastructures that serve studies in translational research and precision medicine (1–3). Biobank can be defined as an extensive collection and preservation of biospecimens linked to relevant personal and health information held predominantly for use in health and medical research(4). The terms "Biobank" and "Biorepository" are often used interchangeably. In Ethiopian research ethics guidelines, these two terms are also utilized interchangeably(4,5), but it is important to note that there are slight differences between them. Biobanks primarily contain human biospecimens and associated donor information, while biorepositories encompass a wider range of biological samples from all living organisms, including humans and animals, as well as cell and bacterial cultures(4). In this study, the two terms are used interchangeably.

Biorepository-based studies involves sharing data among research institutions, scientists, and collaborating stakeholders for unspecified research and for the re-use of data in secondary research (6). Hence, these features of biobank research make it different from traditional research types.
As a result, researchers and other stakeholders in biobanking research face serious challenges with regard to ethical, social, and legal factors. Some of the issues identified in the literature include sample/data ownership and governance, maintaining participants' confidentiality, return of results to participants, benefit sharing, commercialization, and the informed consent approaches in biobank (7,8).

According to the bioethics principle, one of the criteria for informed consent to be considered "valid" is providing adequate information to potential participants and ensuring that they fully comprehend before giving consent(9). However, it has been difficult to satisfy this criterion in studies involving biorepositories. This is because, it is impossible to provide adequate information about the nature, purpose, and types of research that are likely to be conducted in the future on those biospecimens at the time of seeking consent from a sample donor(10,11). Furthermore, during the informed consent process, participants' comprehension may also be limited since biorepository-based research like genetics and genomics has complex procedures and medical terminologies that are difficult for a

layperson to understand(12,13). The question of whether informed consent can be considered valid in this context remains a complex and contentious issue. Therefore, it is vital to explore and understand the perspectives and experiences of researchers, sample donors, research ethics committees, and other stakeholders of biorepositories.

1.2. Statement of the Problem

The complex nature of biobanks and the preservation of biospecimens for unpredictable future research use have made obtaining valid informed consent challenging. Empirical studies have shown that identifying the best approach to consent for collecting and storing human biological samples and data for future research use has become challenging and controversial among scholars (14,15). Due to this, different models of consent and guidelines are used by various research institutions and biobanks (16). There is an absence of consensus among researchers about which consent model can be considered ethically and legally appropriate in research involving biobanks (14,16).

Biomedical research, including genetic studies and biobanking, is becoming more common in Ethiopia. In response to advancements in science and technology, research ethics guidelines and regulatory policies have been updated and improved(5). Studies have been carried out in Ethiopia to understand communities' views on genomic studies and explore factors influencing the informed consent process (18–20). However, these studies have mainly focused on specific genetic diseases like podoconiosis. To date, no research has been conducted to examine the perspectives of researchers involved in various types of biomedical and genomic studies regarding the informed consent process.

There needs to be a universal framework and harmonization for consent procedures in biobanking research to maximize the potential of biomedical research and scientific breakthroughs by ensuring collaboration and data sharing among different research institutes (21,22).

The perspectives and experiences of researchers and other biobank stakeholders in African countries must be well understood and addressed to develop a universal ethical guideline and regulation regarding informed consent (23). This study aims to explore the perspectives and experiences of researchers in Ethiopia regarding informed consent for biorepository-based research.

1.3. Significance of the Study

The findings of this study will inform policymakers and aid in the development of evidence-based guidelines and policies for informed consent in biobanks in the Ethiopian context. The themes and key concepts that will emerge from this study can serve as a valuable reference and help develop tools or questionnaires for future quantitative research in this topic area. Additionally, this study will contribute to the expanding body of knowledge on research ethics in Africa, fostering collaboration and sharing best practices across the continent.

2. Literature Review

2.1. Informed Consent and the Ethical Issues in Genetic and Biobank Research

The informed consent process is an ongoing exchange of information between the investigator and the study participant. Where adequate information about the study is provided to the potential participant, in a language he/she can easily understand, and they will be able to decide, voluntarily, whether or not to participate in the research. The informed consent document consists of; the information sheet and the consent form(5,24). The basic elements that should be included on the information sheet are; an explanation of the research, its potential risks and benefits, alternative procedures, confidentiality, compensation, contact information for questions, voluntariness of participation, and specific statements regarding the collection of identifiable private information or biospecimens(24).

Respect for autonomy, one of the principles of biomedical ethics, is mainly implemented by obtaining valid informed consent. For informed consent to be considered "valid," it has to fulfill these three criteria: adequate information should be provided for the potential participant, they should have the capacity and competence to understand the information and to consent, and lastly, the consent provided should be voluntary (9,25).

However, achieving these three critical elements of valid consent in biobank research has been challenging. The primary concern starts at the point of sample collection as to whether the individual participant from whom bio samples are taken is well-informed about the specific research and the use of specimens for future research. The classical specific, informed consent is not practical in the case of biobanking research because biological samples and data will be used for various future research, which is impossible to foresee and predefine at the initial time of seeking consent (13). Due to this, alternative models of consent have been introduced and used. Broad consent, Tiered consent, Blanket consent, and Dynamic consent are the standard consent models currently being utilized in genetic and biobank research.

2.2. Types of Consent

2.2.1. **Broad Consent**

Broad consent is the most widely used form of consent for the storage and future use of human biological samples (26). According to the United States Federal Policy for the Protection of Human

Subjects (The Common Rule), broad consent is recommended to obtain a study participant's consent for the storage and secondary research use of identifiable biospecimens and related personal information (24). Broad consent can be defined as consent obtained from participants at the time of sample collection for using their samples in the current study and for unspecified future research studies but with some restrictions and oversight of an ethics committee (27). Broad consent is also understood as consent to a particular type of governance structure that will make decisions regarding the use of the donated sample for future studies while ensuring ongoing communication with sample donors about future use and, if possible, providing a process that allows participants to withdraw samples from the storage facility where they are kept (11,28).

The majority of researchers and other stakeholders in biobank research, both in high-income and low-income countries, preferred the use of broad consent, citing the difficulty and impracticability of re-contacting each participant for re-consent (8,29,30). It would be very expensive to collect biological samples using specific, study-by-study consent and to destroy left-over samples after the study is over (17). Critics have argued that broad consent undermines participants' autonomy since it does not provide specific information about future studies and to what extent their samples and data will be used (7,15).

While most African countries' ethical guidelines endorse the use of broad consent, Zambia, Malawi, and Tanzania do not allow broad consent to be used for biobanking research. Zambia's Health Research Act demands that human biological samples should not be obtained and stored for any future research that is not unspecified (33). In Tanzania, the Guidelines for Health Research stated, "Studies can only be conducted with the explicit consent of the participants, and it is considered unethical to utilize biospecimens for purposes other than those that were initially agreed upon by the participants"(34). The H3Africa (Human Heredity and Health in Africa) initiative, one of the largest genetic research programs comprising 51 projects, recommends broad consent for H3Africa studies. Despite the growing acceptance of the concept of broad consent coupled with a governance structure in Africa (28), Nicki Tiffin argued that this approach could be challenging to implement in developing countries like African nations since they often lack the necessary resources and infrastructure to ensure institutionalized protection of individual rights. According to Tiffin, broad consent can lead to exploitation and abuse if there is a lack of proper guidelines and oversight, particularly in the African population, where most of them are vulnerable (35).

2.2.2. **Tiered Consent**

Tiered consent, also known as multilayered consent, is where participants first consent to the current study. Then, they will be given several options to choose on which specific type of research their biospecimen/data can be used (8,27). In tiered consent, participants are given the option to choose a disease category in which their samples can be used in the future (17). They can also decide who can access their data and which institution or pharmaceutical company. Unlike broad consent, tiered consent provides more autonomy for participants (36) and increases trust as choices are provided to participants (29). However, literature on researchers' views described that tiered consent could be cumbersome and time-consuming to explain to participants, especially where translation is required, and that it is too difficult to capture and store electronically (35). However, if investigators decide to follow this option, they need to develop a good management plan and governance to ensure that the participant's choices are respected (27).

2.2.3. **Blanket Consent**

Blanket consent is another approach to consent where individuals make a one-time choice to donate their samples for future use with no restrictions on the purpose of the research. This lack of restrictions can lead to ethical concerns, such as the usage of samples in future studies that conflict with individuals' fundamental values. Additionally, blanket consent raises concerns about privacy and data protection since there are no limitations on where and how long the donated samples will be stored or shared (37). Hence, it is not preferred by the majority of researchers and research ethics committees. In a qualitative study about biobank stakeholders' opinions towards consent models in South Africa and Malawi, very few (3/34) of the participants preferred blanket consent by claiming that it would allow them to use the donated samples for any type of future research without any limitation (17).

2.2.4. **Dynamic Consent**

A technology-based consent, "Dynamic consent," is a digital platform with an interface that allows sample donors to have an interactive relationship with the researchers (38). Many scholars claim that dynamic consent is the best way to respect an individual's autonomy since it provides detailed information and updates about specific new research projects to the participants and keeps them well informed. At the same time, it provides participants with as much choice and control over their stored sample and data as possible, placing them at the center of biobank governance (38,39). However, this

technology-based consent model can be challenging to adapt in many African countries due to limited internet access and technological infrastructure (36,40).

2.3. The Ethiopian Context

In recent decades, genetics and biorepository-based research in Africa has grown rapidly, with successful initiatives such as the Africa Pathogen Genomics Initiative (PGI), H3Africa, and Malaria GEN (9–11). This advancement in science and technology is crucial for the development of Africa and to improve the people's health on the continent. However, the challenges that come with it are exacerbated in developing countries due to limited capacity and infrastructure and a lack of knowledge and awareness of research and genomics among people in most African countries (12). Although still in its early stages compared to other African countries, the practice of genetic and biorepository-based research has seen a significant increase in Ethiopia in recent years. To mention some of the research projects, "NeuroGAP-P- project," the largest genetics study in Ethiopia, was launched in 2018 by Addis Ababa University, Department of Psychiatry, in collaboration with Harvard University and MIT, where DNA samples from 8,000 participants were collected(41). TBGEN Africa is a collaborative research initiative supported by H3Africa and hosted at AHRI, Addis Ababa. This initiative studies Mycobacterium tuberculosis genotypes and aims to enhance genomic and bioinformatic capacity through research and training (42). One of the objectives of these genomics study projects is to establish a well-developed biobank in Ethiopia. Due to the growth of such kinds of research, the Ethiopian national research ethics guidelines have been revised and updated to ensure they are more comprehensive.

In 1995, the Ethiopian Science and Technology Commission (ESTC), now called the Ministry of Science and Technology (MoST), developed the first National Health Research Ethics Review Guideline. Since then, this guideline has been revised five times with the new edition that the Ministry of Education published in 2022 (5). The fifth edition of the national research ethics review guideline was revised to include guidelines for the practice of genetic and biobanking studies, transfer of human biospecimens, and other complex research areas. It included descriptions of genetic screening, counseling, and research, how participants' rights and welfare can be protected, and that adequate information should be provided during the informed However, the limitation of this guideline is that

it did not describe the different types of informed consent process (43). consent models used in biobanking research. Also, it did not specifically describe the type of consent that is permissible to be used in Ethiopia. But the recent (6th edition), which was issued in the year 2022, have a detail description about the types of informed consent models that are acceptable and appropriate for genetics and biorepository-based studies(5). Studies in other countries found that some researchers could not differentiate broad consent from specific consent, and some also use those terms interchangeably (30). It is crucial to describe the consent types in detail to prevent confusion and to provide accurate guidance to researchers and ethics committees.

Currently, technology-based consent is widely recommended for use in research involving biobanks since it best addresses the ethical and legal issues compared to the other types of consent. However, adopting this type of consent in low-income countries like Ethiopia would be impractical because of limited access to technology and resources (40).

Several empirical studies conducted in various countries have shown that there is no consensus among researchers and stakeholders in biobanks regarding which type of consent for biobanking research is ethically appropriate and preferable (44). This is because different international and national jurisdictions have differing rules and regulations that determine the governance of biobanks. The other reason is that biobanks have too many stakeholders from various backgrounds and professions, with differing views and opinions (8,44). This potentially impacts the efficiency of genomic and biomedical research and could significantly increase the costs of such research (21,45). Making it difficult for data sharing and collaborative research. There needs to be harmonization and international standardization of consent procedures in biobanking research in order to enhance collaboration and data sharing among national and international research institutes, as well as to maximize the benefit of genomic and biorepository-based research for both the advancement of science and health of the population (44).

3. Conceptual Framework

3.1. Description of the Conceptual Framework

The two variables on the top represent researchers' views, opinions, and experiences regarding informed consent in biobank research that are discussed in the literature review. Meanwhile, the two variables on the bottom (blue color) indicate the research questions that will be explored in this study.

Themes and concepts that will emerge from the generated data (blue color) will be compared with the existing themes about the views and experiences of researchers in the literature (variables on the top). To see if there are similarities in opinions and experiences and to identify new views and experiences that are unique from the existing themes in the literature.

The findings of this study will create awareness and aid as a source of knowledge for policymakers in Ethiopia to develop evidence-based ethical guidelines and policies regarding informed consent for biobank research. It will also help as an input by providing information about the Ethiopian context for the international harmonization initiatives of biobanks.

3.2. Figure of the conceptual framework (29,30,46)

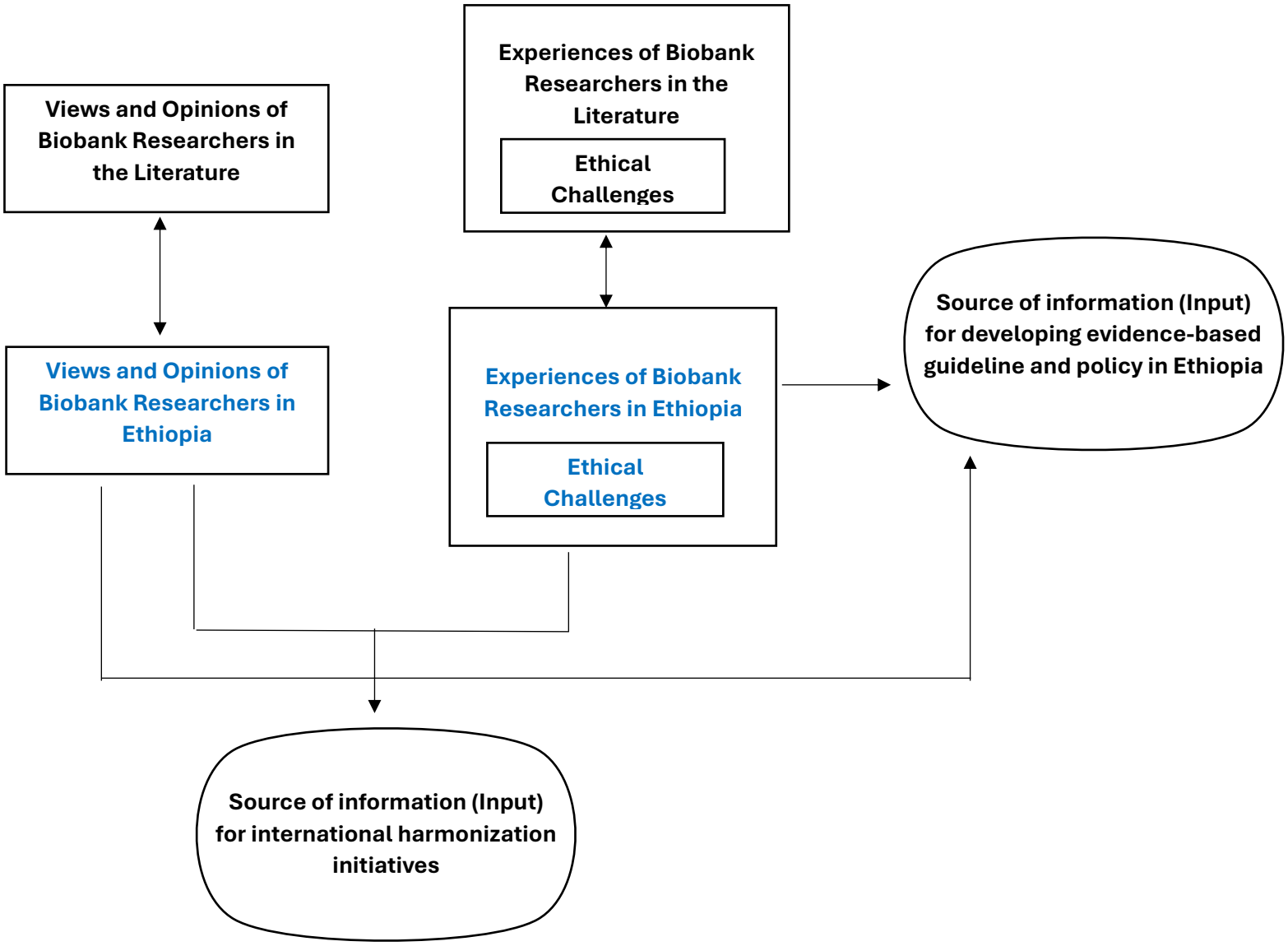

Figure 1: Conceptual Framework

4. Objective

4.1. General Objective

- To explore the perspective and experiences of researchers regarding informed consent for biorepositories in Ethiopia.

4.2. Specific Objectives

- To explore researchers' perspectives towards the informed consent used for biorepositories.
- To describe researchers' experiences with informed consent procedures for biorepositories.
- To explain the ethical challenges researchers face concerning informed consent for biorepositories.

5. Methodology

5.1. Study Setting

The study was carried out at three institutions located in Addis Ababa: Armauer Hansen Research Institute (AHRI), Addis Ababa University College of Health Sciences (AAU, CHS), and Ethiopian Public Health Institute (EPHI). These institutions are chosen because of their reputation as prominent health research centers in Ethiopia, handling various genetic/genomic and biomedical research projects. These research and academic institutions cover several areas, including immunology, molecular biology, and epidemiological and translational research. Moreover, these research institutions collect and store human biospecimens which are used for different biomedical studies from various regions across Ethiopia.

AAU, CHS is a professional health sciences college comprising four schools that encompass the disciplines of medicine, pharmacy, public health, and allied health sciences, in addition to a teaching hospital. This institution is actively engaged in various forms of biomedical research, including the largest human genetics research ever conducted in Ethiopia(47).

AHRI covers several research areas, including immunology, molecular biology, and epidemiological and translational research. AHRI has published more than 900 papers in peer-reviewed journals, mainly in biomedical research. Furthermore, the institute serves as a repository for human biospecimens collected and stored over many years, providing a valuable resource for ongoing and future research endeavors in the realm of medicine (48).

EPHI, which is accountable to the Federal Minister of Health, is the country's primary organization in charge of public health research, training of public health professionals, laboratory verification of public health threats, and emergency response in public health. The institute's primary goal is to guarantee that the nation's public health policies and strategies are grounded in evidence by conducting scientific research on priority health and nutrition issues(49).

5.2. Study Approach

A qualitative study was conducted using the thematic analysis approach, where it is helpful to report the reality, meanings, and experiences of study participants(50).

5.3. Study Period

Data collection and analysis was done from February 09, 2024, to April 20, 2024.

5.4. Study Population

Participants were chosen based using purposive intensity sampling where their intensive and long-term experience of conducting biomedical studies that involves collecting and storing human biospecimens leads to be included. The reason for focusing on those with long-term experience is to have tick and well described data which best address the research question through their knowledge of the informed consent models used in biorepository-based studies. Participants selected from Addis Ababa University were mainly academicians and researchers from the departments of Microbiology, Immunology, Parasitology, and Pathology. While at AHRI, researchers from the Mycobacterial Diseases Research Directorate and the Biotechnology and Bioinformatics Research Directorate were part of this study. Participants from EPHI were mainly from the departments of Pathogen Genomics and Bioinformatics.

5.5. Recruitment of Participants

Purposive intensity sampling was used while recruitment was based on gradual selection where we pre analyze the data and select the next participants based on the findings from the previous data still the actual saturation of ideas has been reached and no new finding were not emerging. In order to have rich data on the research focus we select participants used on the maximum variation in-terms of age, sex education, year of experience, type of research they are involved in. Their profile from the institution's website, google scholar and colleague suggestion have made to properly identify the participants with the selection criteria. Identified researchers were invited to participate in this study through email and in person contact.

5.6. Data Collection tool and procedures

A total of 16 participants were interviewed. The interviews consisted of 12 face-to-face in-depth interviews, three virtual interview, and one email interview. Participants who could not have face-to-face interviews could not do so because two were outside the country for work purposes, one was on

maternity leave, and one had a busy schedule during the data collection period. Interviews were conducted by experienced qualitative researcher and principal investigator. Open ended interview guide was prepared both in English and Amharic. Interviews were conducted in Amharic language, expect for three participants due to the preference of the study participants made it English. All interviews were audio recorded. And the interviews took an average of 33 minutes. All in-depth interviews were conducted in quiet room at the workplace of the participants except for one interview where a background noise was identified when listening to the tape record.

5.7. Trustworthiness (Quality assurance)

The study participants were individuals who have different roles and positions in the research project they were involved in. This helped to capture different perspectives and ensuring triangulation through data sources. Site triangulation was also achieved by interviewing investigators working in different research institutions. The principal investigator held daily debriefing sessions with the interviewer to discuss preliminary findings and identify areas that require modification or further exploration. These sessions also allowed the interviewer to ask questions and clarify any issues that arose during the interviews.

Participants' direct words were quoted and used to support the interpretations of the findings, ensuring their credibility through transparency and evidence-based analysis. The principal investigator has ensured that the transcriptions are accurate and true to the original conversation by reading and listening to the interview recordings(51). To validate the accuracy of the interpretations and conclusions drawn from the data, member checking was conducted. This involved sharing the written report with the participants and obtaining their feedback and validation of the findings(52). While a response from all the participants were not received, the responses received helped ensure that the report accurately reflected the perspectives and experiences of the participants. In the data analysis process, negative cases or ideas that deviate from the emerging concepts were identified and has been written and interpreted on the findings section.

To achieve transferability and dependability of the study, information about the boundaries of the study, and detailed descriptions of data collection and analysis procedures were provided. Along with rich descriptions of the emerging themes and categories provided in the findings section.

To maintain the study's confirmability, the developed codebook, codes, and emerging themes were reviewed by the study advisors to reduce investigator bias. Audit trails such as the recorded audio

files, fieldnotes, and records of changes made in the research process are well documented and made available for advisors and other researchers.

5.8. Data management and analysis

Audio recorded data were transcribed verbatim. A saturation grid was used to check whether data saturation had been reached. A saturation grid was developed by writing down the emerging codes of each interviewed participant in separate papers at daily bases. During this process, new codes were circled to identify them and to compare them with the previous coded data if no new codes or ideas emerged(53). Prior to starting data collection, a two-day training was given for the interviewer and transcriber where it was explained to them about the study topic, procedures, and objectives. Field notes and memos were used to identify insights, patterns, and themes that emerged during the interviews. A codebook was developed based on the codes that emerged from the first three analyzed transcripts using inductive approach. The data were repeatedly read to develop codes and categories. Codes, categories and themes were developed in line with the study's objectives. The data was analyzed using thematic analysis approach and NVivo version 20 software was used to assist in organizing and analysis of the data. Due to its flexibility, a thematic analysis method helps to analyze data and develop codes in both deductive and inductive approach. It offers a more accessible form of analysis, especially for those early in a qualitative research career, since it does not require the detailed theoretical and technological knowledge of other qualitative approaches(54).

Table 1: Main Themes, Sub-themes, and Codes

No.	Main Themes	Sub-themes	Codes
1.	Types of informed consent used		Broad, Specific, Tiered, Both broad and specific consent, Depends on the type of research
2.	Views regarding informed consent	The consent process	Consent process, Respects autonomy, They may not comeback
		Contents of the consent	Well written, No template, Withdraw options
3.	Information comprehension	Participant's comprehension	There is no guarantee of their understanding, Both educated and uneducated
		Reasons for poor comprehension	Lack of knowledge, Information overload, Recruited in a hurry
4.	Building trust	Views regarding establishing trust	A known person and place, Institution's reputation, The consent process, Community engagement Sharing of results & benefits
		Ways to build trust	Telling participants about IRB oversight, Active contacts with participants
5.	The good side of the informed consent		Strength of Broad consent, Options are given, Detail information is provided
6.	Drawback of the consent	Limitations of the consent	No reference for terminology and standardized template, Poor description about withdrawal Translated words
		Limitations related to governance and guideline	Lack of I.C for sample storage from clinical visits No specific guideline, Lack of guidance for withdrawal process, Lack of continuous communication
7.	Challenges faced	Communication challenge and the reasons	Complexity of the study, Emerging field, The word genetics is sensitive, Imperfection during informed consent delivery and our approach, Traditional & religious belief
		Comprehension challenge	
		Challenges unrelated to informed consent	Drawing blood, Lack of capacity to oversight shared samples, Participants ask for results
8.	Recommendations	Consent recommendations	Standardized model, Stop blanket consent, Investigations

	Governance Recommendation for IRB	Community sensitization and engagement, Capacity building, Post approval

5.9. Ethical Considerations

Ethical clearance was secured from Addis Ababa University's, School of Public Health. Permission to conduct the research or an approval letter has been obtained from the three institutions. Before initiating data collection, the participants were clearly informed of the study's purpose and their right to refuse to participate and to withdraw at any time and a written informed consent was obtained from each participant. The interviewer and transcriber/translator signed a non-disclosure agreement to ensure that all confidential information shared during the interview would be kept secure. In order to preserve the confidentiality and dignity of the participants, interviews were conducted in a separate, well-lit, and appropriate room. Participant confidentiality was maintained by instructing participants not to mention their names while audio recording the interviews. Also, participants' names and other identifying information were de-identified from the transcripts.

5.10. Dissemination of Findings

The results of this study will be made available on the Addis Ababa University website, Institutional Repository, for all parties who are concerned with this topic, including policymakers, academicians, and future research ethics students at Addis Ababa University, Johns Hopkins University, and other universities and colleges in Ethiopia. The results will also be published in reputable local or international journals.

6. Findings

6.1. Study Participants Characteristics

Table 1 shows the socio-demographic data of the study participants. Out of the participants, three were female. The age of the participants ranged from 30 to 65 years, with a mean age of 43 years. Their experience in biomedical research varied from 4 years to over 30 years. The participants specialized in various areas, with the majority being medical microbiologists (56%), while others had expertise in pharmacology, immunology, virology, and public health. Additionally, the participants held different roles in the ongoing research project, including Field Coordinator, Principal Investigator, and Co-investigator.

Table 2: Socio-Demographic Data of Study Participants

Code	Sex	Age	Background	Years of experience	Position (Role)
P1	Male	38	Genomic Epidemiologist	15	Program lead
R1	Male	30	Public Health	5	Project Field Coordinator
R2	Male	37	Virologist	14	Team Leader
R3	Female	56	Immunologist	23	P.I.
R4	Male	59	Medical Microbiologist	20	Co-P.I., P.I.
R5	Male	46	Pharmacologist	>8	P.I. /Investigator
R6	Male	51	Immunologist	21	P.I., Co-Investigator
R7	Male	37	Diagnostic and Public Health microbiology	7	Coordinator
R8	Male	40	Researcher/Genomics	4	Research Coordinator
R9	Male	45	Medical Microbiologist	>10	P.I., Co-P.I.
R10	Female	65	Biomedical Scientist	30	P.I. & Co-P.I.
R11	Male	51	Infection Biologist	20	P.I, Supervisor
R12	Male	64	Medical Microbiology	>30	P.I.
R13	Male	40	Medical Microbiology	14	Co-P.I.
R14	Female	32	Medical Laboratory Science &Management	6	Project Manager
R15	Male	43	Medical Microbiology	14	P.I.

Key:

P.I. – Principal Investigator

Co-P. I – Co- Principal Investigator

6.2. Perspectives and Experiences of Researchers

Eight major themes have been identified in this study: types of informed consent used, views regarding informed consent, participants' comprehension, building trust, the good side of informed consent, drawbacks of the consent form, challenges faced, and recommendations.

6.3. Types of Informed Consent Employed

Respondents reported utilizing several types of consent models, including broad, specific, tiered, and blanket consent. However, most of the respondents stated that they mainly use broad consent or specific consent with the option for ethics committees to waive the need for re-consent. In cases where consent cannot be obtained for biobank-related research, the research ethics committee will review the study's goal, potential risks, and benefits on behalf of the participants and may grant an ethics waiver. As it has been stated by the responders, the choice of consent model depends on the type of research project, and one type of consent model is not strictly used.

When responders stated that they use a broad consent model, they described it in different ways. Majority of them gave a description about the consent type by outlining the key components of the informed consent form and noted that it includes permission for potential future studies using the collected samples. Additionally, some respondents expressed uncertainty about categorizing their consent approach as "broad consent," noting its similarity to the concept without fully embracing the label. This might be because they are not familiar with or do not clearly distinguish between the names of different types of informed consent models used in genetics and biobanking studies.

"The informed consent form that we typically use is for a specific research study, but it also covers any future studies related to the primary research. For instance, while the main focus of the study may be on HIV, the consent form will clearly state that the samples may also be used for research related to other infectious diseases." R5

One researcher mentioned that blanket consent was used in a study he was involved in. He stressed out that using a blanket consent for biobank research is problematic, as it can pose different ethical concerns regarding the use of participants' donated samples for future studies that they did not

explicitly agree to. The researcher strongly recommended discontinuing the use of this particular consent model for studies based on biorepositories.

"… and at least for some years, it would be better to refrain from using blanket consent until the time we build a system that will ensure us that things will be ok. But for now, I tend to recommend stopping using a blanket consent form at this stage" (R11)

6.4. Researcher's perspectives

6.4.1. **Views on the informed consent process:** Two respondents have argued that providing sufficient information is not a one-time process. They believe that the consent process cannot guarantee that a study participant's (sample donor's) decision is based on adequate comprehension, as too much information is provided to them at once. Participants require sufficient time to fully understand about the information provided to them. The medical terminologies and study procedures are new to them, and it can be overwhelming to process all at once. Participants also require sufficient amount of time to make a decision whether or not to participate in the study, they may also need to consult with their family members before providing consent. However, as it has been described by respondents, fearing that potential participants or patients will not come back, research staff frequently press for agreement to boost sample size. It is challenging for patients to return and provide information about their decision because of physical impediments in places like Addis Ababa, as well as in the rural areas. Given that researchers sometimes try to finish the consent procedure in a single day, this presents questions.

"What is the research and so on are the standards that a person needs to know. But we are not sure whether they will describe it to them to that level, they probably do but there are many obstacles in the middle. For example, they can't give the paper for a potential participant and tell him to read and come tomorrow because he probably came from far so in order not to lose that participant, they just tell him what the research is and the benefits he will get even if it is not much." (R4)

Respondents have emphasized that in order to ensure the autonomy of participants is respected, it is crucial to focus not only on the information sheet, but also on the quality of the informed consent process (delivery). This indicates that even if the informed consent document is well-written and includes all necessary details, equal effort should be placed on the process of delivering the

information. Without clear and comprehensible information about the study being provided during the informed consent process, it would be impossible to determine if potential participants truly understood the study and agreed to participate based on full comprehension.

"The unique thing about informed consent is that it is not only a written document but also a process. Sometimes the consent form could be prepared perfectly; one reading it could find it very well written. But what is important is also the process." (R3)

6.4.2. **Views on the consent form:** Respondents have pointed out the lack of a standardized template for preparing informed consent specific to biorepository-based studies. They elaborated on this by providing specific examples from their experiences working in developed countries. In these countries, they observed the presence of established guidelines and protocols for informed consent, which included specific templates. These templates were designed to ensure that the information provided to participants was clear and consistent. It has also been noted that researchers face challenges in translating words into the local language. Some words may be lost in translation and might be misunderstood by study participants. When scientific or medical terms are translated into local language, the meaning may not be accurate and can be misinterpreted.

"But there is a problem on preparing a proper template for an informed consent used for biobanks, both by the institution and by the individual… most of the time, we don't have a template." (R1)

Five of the respondents described that they do not prefer using a blanket consent because it does not respect the participant's autonomy in a way that it does not provide adequate information about future uses and may not allow for informed decision-making.

"In my personal opinion, I don't believe that using blanket consent is a good practice. Because it is like saying do whatever you like with the stored sample. This will create many ethical issues. Broad consent should instead be used. Broad consent with good governance system." (R3)

6.4.3. **Participant's (sample donors) comprehension**

There is no guarantee of their understanding: According to the feedback received from respondents, it has been stated that despite providing adequate information on the information sheet, it is still challenging to ensure that potential participants have fully understood the details of the study. This implies that even though the information provided is written and presented in a clear manner, it

may not be enough to convey a complete understanding of the subject matter. There are certain concepts, such as data storage on the cloud, that participants may find vague and challenging to grasp. This highlights the complexity of ensuring participants' full comprehension of the study details. Researchers conducting studies with unique or complex technical aspects may need to test participants' comprehension to ensure they fully understand the information being presented.

6.4.4. **Reasons for poor comprehension**

Lack of scientific knowledge: Researchers mentioned various reasons when asked about the reasons for the sample donor's poor understanding. One of them is the lack of scientific knowledge and knowledge about genetics studies. This could be due to limited access to educational resources and information on genetic research, especially in low-income countries. Comprehending the information provided on the consent process is not only a challenge for the layperson but also for those who are well-educated since those people do not have a background in the biomedical field or that subject matter.

"And in our country like I mentioned, the educated and uneducated, people have limited knowledge especially about studies related to genetics or epigenetics, due to this we are backwards in many things." (R6)

Information overload: The matter of providing too much information for the sample donors or patients is one of the reasons for poor comprehension, as said by one of the respondents. This implicates that participants can find it difficult to grasp the necessary message if too many information is delivered to them at once. Enough time is required for conveying that information in a way they can adequately comprehend.

"...Participants may be provided too much information at once limiting comprehension and consent might not be fully informed." (R7)

Misconceptions: One of the concerning reasons for poor comprehension among sample donors is misunderstandings of the purpose of the research. They often mistake the study for a clinical examination or free treatment, although it is not. Additionally, there are instances where donors may harbor the belief that their blood sample will be utilized for ritualistic or other traditional purposes.

"From what I've seen so far, the main issues they face are misconceptions, such as therapeutic misconception, thinking the sample is going to be used for other purposes. Or that they are going to get diagnosed, or when we bring documents assuming we came to do charity work." (R4)

6.4.5. **Perspectives on Building Trust**

Researchers had different views when asked about establishing trust between the researcher and the participant.

Community engagement is crucial: One of the respondents highlighted the significance of actively involving the community in research endeavors to foster trust. She emphasized the need to engage community representatives and administrative bodies throughout every stage of the research project, including before, during, and after, to ensure ongoing feedback and input from the community, thus strengthening the relationship between researchers and community members.

"…Community engagement is a must, before starting any work or conducting the research. Before getting to meet an individual, when you enter that community as a group, they will ask who we are? Why are we here? So we have to make sure the whole community is aware." *(R10)*

Trust is based on providing full information: trust depends on the ability to provide adequate information about the purpose, the nature, as well as the potential benefits and risks that could occur in participating in the study. It has been emphasized that there needs to be an open communication and transparency about how the participants' data will be used, ensuring that their information will be kept secure and only used for the intended research purposes. Providing clear and understandable information to the participants is also important in building trust and ensuring that they feel comfortable and confident in their decision to participate.

"The informed consent process should base itself on trust established through the communication and delivery of adequate, correct, and appropriate information to participants without withholding "negative" content, or de-emphasizing risks or potentially harmful consequences." (R7)

Building trust is not a one-time process: Building trust cannot be achieved in a single instance or encounter. It requires time and association. The process of gaining informed consent can be complicated or negatively impacted by the fact that trust cannot be established in one meeting. This can be understood from the extract cited next:

"I think… as I said, if the investigator is meeting a study participant for the first time, there is no way you can build trust immediately. They don't know you; you don't know them and so on, ok. So that is what makes it problematic." (R11)

6.4.6. **Ways to build trust:** respondents provided various approaches to establish trust between the investigator and sample donors. These are: Seeking informed consent through a known person and a known location by the community, conducting the consent process in an appropriate manner, creating awareness through community engagement, sharing of results and benefits, as well as informing participants about IRB oversight. Respondents have also mentioned that the institution's reputation has an impact on building trust.

A known person and location: One way to establish trust with potential donors is by seeking their consent in a familiar or formal setting, such as a health center. It is also helpful to have someone they know well and trust seek consent from them. This can help alleviate any concerns or fears they may have about participating in the study.

"From experience when I was working, instead of stopping them in the street and asking them, they prefer it when it is in a health center or other known place… And on top of that having a person known by the community, like a Kebele administration. Otherwise, they will be suspicious of you." (R4)

Informing participants about IRB oversight: When individuals donate their samples to be stored and used for future research, it is important to inform them about the measures taken to protect their data and samples. This can help build trust between the donor and the investigator. One way to do this is by informing them that other bodies, such as the ethics committee, will protect their stored samples and data and that these bodies will review and ensure any future studies comply with ethical standards and guidelines before they are given approval. This way, donors can rest assured that their sample is being handled ethically and responsibly.

"The sample donors will be informed of the storage of samples for future research, the usage of those samples for other studies, and the fact that ethics committees will review those studies. As a research participant one will think that, ok, my samples are collected and stored, I might not be here after a year and they may not be able to contact me for a re-consent. However, other

individuals will review the studies for which my samples will be used. So, in this way, trust will be built." (R3)

6.4.7. **The good side of the informed consent**

Detail Information is provided: researchers were asked about the strength or the good side of the informed consent approach they have used for biorepository-based studies and six of them described that the informed sheet provides all necessary information and clearly state what it entails. Participants (sample donors) were given adequate information, including the study's benefits, possible harms, and the benefits it brings to them and the community as a whole. Additionally, the consent form uses explicit terms to define future research purposes.

Options are given: Two of the researchers that mentioned that they use tiered consent explained that this approach offers benefits as individuals are given the opportunity to choose whether they want their samples to be used for other studies or not and that they can decide whether or not they want their samples to be preserved for a long time.

"The ones that I say are the positive aspects include the fact it provides full rights, including the option to consent for the sample to be used for future studies and the opportunity to have samples preserved long-term. These options make the process somewhat beneficial." (R10)

Strength of Broad consent: One of the researchers explained that broad consent has its advantages as it allows researchers to conduct their studies without the requirement to re-consent, making studies more efficient and cost-effective. As well as it respects participant autonomy by giving them the choice to opt-out, ensuring their rights and interests are protected while still enabling researchers to conduct their investigations in a timely and efficient manner.

"The main strength is flexibility to researchers without the need for additional consent. It maximizes use of resources, shortens time avoiding delays on consent seeking. It facilitates scientific investigations at lower cost and promotes innovation with existing resources. Participant autonomy is respected where there is an option to opt-out." (R7)

6.4.8. **Drawback of the consent form**

Limitations of the informed consent

No standardized consent: One of the respondents, who has experience on an ethics review committee, stated that the types of informed consent models for biorepository-based studies had not been specifically named, such as "Tiered consent," "Broad consent," "Blanket consent," and so on. The respondent went on to emphasize the importance of establishing a standardized consent model that can be used across all biorepository-based studies. The absence of a standardized consent model in Ethiopia may be the reason why most researchers in the study were unsure about categorizing the consent approach as broad, tiered, or blanket. Instead, they provided different descriptions of the informed consent model being used.

"One of the big challenges as individuals and as an institution is we couldn't categorize the consent and name it saying this one is this and that one is that… the thing I see as a limitation is that different projects use different types of formats. It is not the same. But of course, it should not be one size fits all. But it would be great if there was a standard format." (R1)

No reference for terminologies: The lack of reference or framework for terminologies has also been mentioned as one of the limitations of the current informed consents being used. In the process of drafting the consent form, the researchers often rely on Google Translate or ask someone who is proficient in the Amharic language for assistance. They also seek out the services of language translators to ensure that the terminologies used are accurate. However, the absence of support for terminologies is a significant limitation in this process.

Poor description about withdrawal: Most of the respondents (twelve) perceived that the information sheet provides a detail information about the conditions of withdrawal options. For example:

"Yes, from what is written, it is one of the clearly and boldly written ones on the consent form. I mean at any stage, especially these kinds of things have a risk on longitudinal studies." (R2)

However, two of the researcher's responses disagrees with most of the researchers' views. The researcher explained that the information sheet lacks a clear and detail description about the withdrawal options like, when they can and cannot withdraw from the study:

"So, if a participant wants to withdraw, he should be able to do that. But most of the time the consents we use does not give detailed description about the withdrawal. It just mentions like this

this and this. It is written in a similar way as others. This is a gap that we should take a look at. Each study can have unique features in it." (R3)

Drawbacks of broad consent: While most researchers stated that they usually use broad consent and supports its usage for biorepository- based research, they have also, at the same time, recognized the constraints and short comings associated with this consent model. A respondent who has good knowledge about the different types of consent models clearly explained that:

"As for broad consent model, it does not provide participants with adequate information about what specific projects might do with the specimens in the future. It assumes but does not guarantee that the consent obtained is really "informed" as projects are unspecified." (R7)

Lack of informed consent for sample storage from clinical visits: Patients' left over samples like biopsies and blood that has been taken from routine clinical examinations and treatments are usually stored, this is a common practice. However, the practice of seeking written consent from those patients for the purpose of storing their leftover samples is not common. This later can cause ethical issues when those stored samples are needed for research use. Three of the responders have also mentioned the lack of a specific informed consent model that can be used for storing leftover specimens from routine clinical practices.

"Pathology specimens are kept as paraffin blocks and stored indefinitely. If someone later wishes to use them for research, the issue arises because patients did not provide consent for the usage. This lack of consent is due to routine storage practices not being supported by established policies and procedures." (R11)

One of the respondents, who has also been a member of research ethics committee stated that they have encountered a situation where it was difficult to make a decision on whether to approve or not for a study protocol that wanted to use the stored leftover samples, and the fact that this study was stuck for years without getting a decision from them (the ethics committee).

Limitations related to governance and guideline

Lack of guideline for biorepository-based studies: The findings of this study have shown that there are no guidelines prepared by the research institutions specific to the storage of human biospecimens either from clinical practices or for research purposes, a guideline that instructs on how the informed

consent approach should be, how incidental findings should be managed, and how stored samples and data should be governed.

"In the IRB we have prepared a consent form format, just to provide support, even though it is not a standardized one, we have prepared it taking into account what one consent form should have in it. It is just a guide. But, the fact that there is no guiding document for informed consent particularly for biorepositories can be considered as a limitation." (R1)

Lack of monitoring and regulation: Three of the respondents pointed out that after the approval and commencement of studies, there is weak regulatory practice and oversight in terms of the management of stored samples and data, and whether they are being used in accordance with participants' choices.

"But once it is approved, as I have seen, there's no one who even checks how it is going. It requires a renewal every year until the project is finished. But even on national level I don't see any effort to improve future projects by checking how the current one is going." (R4)

According to one researcher, there is currently no guidance available on how to obtain informed consent for using samples from a deceased person. This lack of guidance could raise ethical concerns regarding respect for the deceased individual's autonomy and privacy. Another researcher has pointed out that there is a lack of proper guidance and support for the withdrawal process. He also stated that this may lead to participants not having the opportunity to withdraw due to logistic barriers and the absence of a proper withdrawal procedure.

Lack of continuous communication: One of the researchers pointed out another limitation of the informed consent approach, which is the absence of active and continuous communication between the investigator and sample donors. It is crucial for sample donors to receive updates and new study information, which can only be achieved through continued interaction. The researcher also mentioned that one reason for this could be the limited access and opportunities for online communication.

"The standard consent model does not allow for continued interaction with participants in the study, to receive updates or new information… limited possibilities for or inexperience with online communication for maintaining contact with investigators." (R7)

6.5. Challenges faced

6.5.1. **Communication challenge**: Almost all researchers mentioned that they usually experience challenges communicating with sample donors during the informed consent process. The communication gap may be caused by various reasons as pointed out by the researchers.

Reasons for communication gap

1. **The word genetics is sensitive- Six of the researchers who have worked on human genetics or genomics studies** have explained that when the term "genomics" is mentioned, some individuals may associate it with the idea of their identity being revealed through the submission of their genetic samples. Words such as "DNA" and "Zeremel" (meaning genes in Amharic) may sound intimidating and can elicit fear and uncertainty in an Ethiopian context, where they may misinterpret it as revealing their ethnicity and associated discrimination.

"Well even now people don't know much about what genomics is. So, when you say genomics what comes up in their head is that if they give their samples we will know about their identity." (R4)

A project field coordinator, who seems to have a better understanding of the issue on the ground had said:

"From my view, the full informed consent or information sheet, I don't believe they understand it fully. Because, first, the terminology used or the word "genomics" ... telling the exact word or term causes big fear and other emotions." (R15)

Imperfection during informed consent delivery: Regarding the imperfection during information delivery, responders explained that during the informed consent process, the way investigators or data collectors deliver the information to study participants can be one cause for communication gap. Data collectors or investigators may rush through the consent process to recruit an adequate number of participants. Additionally, they may not be given enough time to think about it, discuss it with their families, and make a decision, as there is a fear of losing potential participants. Health professionals' approach or the manner in which they seek consent can also have a significant impact on the patient's level of comfort, they can feel uneasy to provide consent if the investigator or data collector exhibits aggressive or unique facial expressions. Therefore, it is crucial to consider the patient's comfort and well-being during the implementation process to ensure that the consent is obtained in a respectful and empathetic manner.

"For me, I believe that the consent sheet is better, the problem is with the delivery.…as we have raised in the beginning, not being properly informed during the informed consent process can cause serious effects on some people. Things like reimbursement, direct benefits, if they don't properly understand those things from the beginning, during sample collection, they will ask you about those things as new." (R1)

To address this issue, responders have indicated that they provide ongoing training and support to healthcare professionals (data collectors), allowing them to refine their approach and ensure that their actions are aligned with the best interests of the potential participants.

"We give training for individuals who seek informed consent ... or for the data collectors. How they are supposed to provide information, in what way they have to explain to people." (R15)

2. **Complexity of the study and Emerging field:** Based on the research findings, two-third of the responders contend that genetic or genomics studies are still in their infancy in Ethiopia. These studies are inherently complex, involving multifaceted procedures and medical terminologies that may pose a challenge for the layperson to comprehend.

A genomic researcher expresses his thoughts as follows:

"Another challenge is the complexity of genomic studies; uncertainty of what consequences might follow from mining genomic data and lack of institutional experience." (R7)

3. **Traditional and religious beliefs:** In Ethiopia, it is a common belief among many communities, particularly those residing in rural areas, that the specimens they donate are likely to be utilized for nefarious intents. This perception is deeply ingrained in the cultural fabric of these communities and is a significant barrier for medical research and science in the region. The lack of trust and fear of exploitation have resulted in a reluctance to participate in various clinical studies.

Five of the respondents have a similar view on this issue, one of them stated:

"Umm the other is information sheet ... with the participants... the other challenge is many times people relate it to religious view, they relate it to some conspiracy theory so many times they will not be willing to donate their DNA sample." (R14)

One of the researchers gave a recommendation that participants should be reassured that the study is purely scientific and aims to gather data for research purposes. Emphasizing the potential positive outcomes of their participation may help alleviate any concerns about religious or cultural implications.

"Religion is also associated with it, so it should be made clear that it is not related to religion, it is not related to beliefs, it is not related to culture, but that it has benefits for them." (R5)

6.5.2. **Comprehension challenge:** Almost all researchers explained, whenever they provide information during the consent process, one of the common challenges is lack of comprehension by the potential participants. Especially in genetics or genomics studies, many of the participants do not understand what is explained to them. One reason for this is, the education level of majority of individuals.

"Yes, there are some words they cannot comprehend for example the word DNA the society that understands this word is not many. It is not many, so looking for a direct Amharic translation and explaining to them is very difficult so one ... yes of course, it's written but how many people accept after comprehending or after understanding it is hard to know." (R14)

One of the respondents explained that participants have difficulty comprehending the study information because of the difficult terminologies that could not be fully translated into local languages. She also emphasized that the gap is not only from the participants' side but also from information providers.

"So, when the participant came and reads or is read to him the information sheet, does he understand it to the level intended is put to question, especially in genetics study. First, the terminologies are hard to translate into a simple Amharic word. Not only to Amharic, but also to any local language. It is hard to translate those terminologies, they are also hard to explain." (R10)

6.5.3. **Challenges unrelated to informed consent:** When asked about the challenges they had faced while obtaining informed consent, the investigators described some challenges that are not directly related to the consent process, but some of the mentioned problems were found to be important. Some of them are; challenges related to drawing blood, participants

asking for immediate results, lack of capacity to oversee shared samples, and loss of follow-up.

Participants ask for result: Investigators often encounter difficulties when sample donors or patients demand immediate results. According to the Ethiopian research ethics guidelines, study protocols and investigators must communicate to participants about the return of incidental findings or clinically useful results, including when and by whom this information will be provided. Investigators are also responsible for ensuring that participants fully understand this concept(5). However, in the Ethiopian context, participants may assume that collecting blood or other samples is for diagnostic purposes, and they expect immediate results. Although they have consented to their samples being used for research, they still anticipate receiving results. This indicates either a lack of clear information about the fact that results are not expected immediately, or that they have not fully understood the information provided to them.

"And some of them complain that you don't tell us the results after taking the sample. You see, on some of the research, for instance if we are testing for HIV, we will tell them the results and link them. But in the case of genomics, it is not possible to inform them the results immediately." (R5)

Drawing blood challenge: Five of the researchers mentioned that they usually encounter challenges when collecting blood samples from study participants. Many people are hesitant to provide blood samples, and there have been instances where participants refuse to provide additional samples after initially agreeing to do so. However, this is not seen as an ethical issue. In follow-up studies, participants may not show up for subsequent visits after seeing blood being drawn during the first visit. Obtaining blood samples is a significant challenge.

"As I have mentioned, for sample storage sometimes…. Well, in our country, what challenges us is the thing related to blood. People don't like to give blood samples. That is an issue in Ethiopia. When they are told that the blood samples will be stored and kept for long, usually misunderstanding happens." (R3)

Lack of capacity to monitor shared samples: One of the respondents explained the challenges that arise in the handling and exchange of specimens with other countries. The Ethiopian research guidelines outline the requirements for the Material Transfer Agreement (MTA), including the host country's right to access and receive updates on shared samples, as well as the sharing of benefits.

However, there is a lack of capacity to effectively follow up and track their use(5). Once specimens are exchanged, the local country loses control over them. This raises concerns about the misuse of specimens. He also stated that institutions have a responsibility to safeguard and protect the specimens, but there is no follow-up on the use of specimens after they have been exchanged due to incapability to oversee shared sample.

"Perhaps one problem I can mention here is in relation to exchanging specimens with collaborators within the country and also outside. Of course, when specimens are stored and exchanged there is the governing procedure, there is material transfer agreement and so on. But once it is gone somewhere else you have no more control. On the other end there is a problem of follow up, and we have no capacity to follow. So, that is a bit problematic." (R11)

6.7.Recommendations

Consent recommendations: areas of improvements proposed by the researchers specific to the informed consent approach were developing a standardized model for informed consents that will be used for genetics and biorepository-based studies, using comprehensible words and terminologies on the information sheet as well as while explaining to participants during consent process.

"There should be a standardized consent model. Even the words, words that patients can easily comprehend should be evaluated and selected. The consent document can be flexible, in a sense that the PI can write his research title, purpose, and other information related to his research project, but the words used should be the standardized ones." (R1)

One of the respondents proposes conducting research and analysis on how informed consent is obtained, communicated, and documented in different communities and among various stakeholders. By doing so, researchers can identify the strengths and weaknesses of current consent models and develop strategies to improve them. It is also recommended to conduct context-specific studies to determine what type of consent model would work best for different studies.

Governance and Policy: Respondents emphasized the need for institutions to engage in the development of policies and guidelines that guide biobanking practices to ensure accountability and also promote ethical practices in research. Governance system is essential for biobanking as it can help manage the limitations of the informed consent approach being utilized and ensure that stored

samples and data are appropriately managed and that ethical issues are addressed. One researcher expresses his concern by saying:

"But my main concern is with the institutions, they really have to engage with this issue and develop policy, to help the researchers and also the IRBs to perform properly. So, without a policy in place it becomes problematic, because nobody is accountable for that. Particularly now that we don't have any laws governing research, there is no research act. Anything that goes wrong, you know, nobody will be accounted for. So, each institution needs to develop its own policy, especially for biobanking." (R11)

Community sensitization and engagement: When considering conducting a study, the respondents suggested that researchers must provide clear and sufficient information to the community and community representatives before initiating and recruiting participants. Creating awareness about the study should not only be done during the study but also before it, to ensure that participants have an adequate understanding of the research. They also explained that without proper awareness and information, misunderstandings and ethical issues could arise, and it may be difficult to ensure that participants are willing and fully understand the study. Raising awareness and educating the community about research is crucial to ensure that participants have an informed decision about their participation in studies.

"...I think it's crucial to increase awareness about research within the community. Specifically, we should concentrate on raising awareness about genetic studies within the entire community, reaching both educated and uneducated individuals." (R6)

Another researcher shared his views about engaging the community by saying:

"... It is also a good idea to involve the community in the drafting of informed consent, to ensure they fully understand and to avoid any potential issues." (R13)

Other recommendations suggested by some respondents are capacity building for researchers, providing training and support to enhance the capabilities of researchers and data collectors to effectively communicate the necessary information to sample donors clearly and concisely, and providing capacity building for research ethics committees so that they can scrutinize research proposals effectively and evaluate the ethical implications of the research.

7. Discussion

The study revealed that various types of informed consent are utilized in biorepository-based studies in Ethiopia, including broad consent, specific consent, tiered consent, and blanket consent. However, using broad consent, employing other consent models. The research found that the informed consent approach used by researchers provides detailed information to participants, including the study's purpose, potential benefits, possible risks, and overall societal impact. However, researchers have highlighted concerns about the informed consent process, such as the challenge of providing sufficient information to participants in a way they can understand and ensuring participants' comprehension. There are also concerns about the quality of the informed consent delivery process and the potential for participants not to return due to physical barriers or time constraints. Furthermore, the study discovered the lack of a standardized template for informed consent and the challenges in translating consent documents into local languages.

The study findings indicate that broad consent is used by majority of the institutions, broad consent is a comprehensive and flexible type of consent that allows participants to provide consent for a wide range of future research uses of their specimens and data(55). The latest edition of the Ethiopian national research ethics guideline, the H3Africa program, and the ethical rules of most African countries support the use of a broad consent approach(43). Due to the difficulty and impracticability of re-contacting each participant for re-permission, the majority of researchers and other stakeholders in biobank research, both in high-income and low-income countries, preferred the use of broad consent (8,30). Respondents on this study also stated that broad consent gave them the flexibility to conduct further studies without the need for additional consent; however, it is important to strike a balance between the flexibility provided by broad consent and the need to respect participant autonomy and protect their rights. Researchers and institutions should carefully consider the implications and requirements of implementing broad consent in biorepositories, taking into account respect for autonomy, maintaining confidentiality, building trust, and active communication (28).

This study found out that most informed consent documents used by researchers provide all necessary information, and also gives study participants options to choose what happens in the future; these two findings are very important dimension in quality of consent form. The informed consent document should provide participants with adequate and comprehensive information about the purpose of the research, how their samples will be used, and any potential risks or benefits associated with

participation. This includes information on issues such as data sharing, potential identifiability, privacy protections, and the possibility of incidental findings (55).

The findings regarding the challenges of ensuring that study participants understand the terms used in the informed consent process, as demonstrated in this study, are consistent with several other studies such as; a comprehensive systematic review study done on informed consent comprehension in African research settings showed that, comprehension of key concepts of informed consent is poor among study participants across Africa (56); a systematic review study done on Participants' Understanding of Informed Consent for Biobanking which also indicated that elements of informed consent unique to biobanking were poorly understood (12).

It is crucial to ensure that participants comprehend the information provided. Researchers or biorepository staff may use various methods to assess participants' understanding, such as asking questions, or providing additional resources for clarification(57). A study conducted on 60 Clinical and Translational Science Award (CTSA) hubs to better understand the strategies and challenges encountered in biobanking consent process revealed a major shift in biorepository model, specimen-acquisition and consent process from a combination of investigator-initiated and institutional protocols to an enterprise-serving strategy. CTSA hubs were well equipped to leverage established capacities and expertise to rapidly respond to the scientific needs through support of institutional approaches in biorepository management (58).

Although respondents of this study have stressed their concerns for participants poor comprehension, it has been identified that respondents had never experienced an instance where potential participants denied consenting to participate in a study or have withdrawn from a study. In contrast to this finding, in a systematic review done on willingness to participate in biomedical research, lack of knowledge and poor comprehension were one of the main barriers for not participating(59). This divergence between our finding and previous studies could be because people in Ethiopia consents to participate in a study not because they fully understand about the study, but due to the fact that they trust the researchers and the research institute.

Building trust was found to be easier in Ethiopia, according to most of the respondents in this study, however it needs to be maintained and strengthened. One effective method of gaining the trust of

study participants, as mentioned by respondents in this study, is to approach them through a respected member of the community and in familiar locations, such as health centers. This approach was supported by a study conducted in the Wolaita zone, Ethiopia, were researchers and field workers recommended engaging potential participants for a genetic study through a well-known and respected local intermediary (18).

Lack of standardized consent form specifically for genetics and biobanking was the other challenge revealed. This may be attributed to the newness of biobanking practices in Ethiopia and the early stage of genetics or genomics studies in the country. Another key issue uncovered in this study is the lack of informed consent for storing leftover samples from routine clinical practices, highlighting the need for further investigation. Future studies should explore the potential ethical implications of storing leftover samples without proper consent and explore alternative methods for obtaining informed consent in clinical settings.

Similar with the recommendations provided by responders on this study, some of the ways to address comprehension challenges are using plain language, providing adequate time for participants to understand and consider their decisions, addressing cultural and linguistic barriers by providing well translated consent forms and employing trained interpreters (60,61). Raising awareness and educating the community about research is also crucial to ensure that participants provide valid consent for their participation in studies, based on full comprehension(60,62).

The strength of this qualitive study lies in the gradual selection of study participants based on the intensity of their experience. This method was employed to optimize the quality and richness of the data collected, ensuring a comprehensive and detailed representation of the participants' perspectives and experiences. Limitations of the study is, given that this is the first qualitative study that aimed to explore perspectives of researchers in three different research institutions, a wide range of concerns and crucial information was raised in this study, which requires a study of its own. However, we only addressed issues directly related to the primary research question. This could be considered as the limitation of this study. Future studies could delve deeper into specific topics raised in this research.

8. Conclusion

The findings of this study provide valuable insights into the perspectives and experiences of researchers regarding informed consent for biorepository-based studies in Ethiopia. While researchers acknowledged that most informed consent papers provide all necessary information and give participants options for future use, they also expressed concerns about whether participants fully understand and make decisions based on complete comprehension. Additionally, the study sheds light on the limitations of existing consent models, including the absence of standardized approaches and challenges in terminology translation. Addressing these limitations is crucial for ensuring the ethical conduct of biorepository-based studies in Ethiopia. Moving forward, it is imperative for stakeholders in biorepository-based research to take into account the perspectives delineated in this study and work towards refining the informed consent practices in Ethiopia to align with ethical and participant-centric standards. Future studies should aim to explore IRB's perspectives regarding informed consents and their experiences in reviewing protocols for genetics/genomics and biorepository-based studies in Ethiopia.

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10. Annexes

Annex 1: Information Sheet and Consent Form (English Version)

Information Sheet

Introduction

Greetings, my name is Siham Mohammed, and I am a graduate student enrolled in the Johns Hopkins University- Addis Ababa University Research Ethics Training Program (JHU- AAU RETP). I am conducting research entitled "Exploring the Views and Experiences of Researchers regarding Informed Consent for Biorepositories in Ethiopia: A Qualitative Study." to partially fulfill the degree of Masters of Public Health in Health Research Ethics. You are kindly invited to participate in this study.

Purpose of the Research

The type of informed consent that can be considered ethically acceptable for genomic and biobank related research is a topic that has sparked much controversy and debate. Studies have shown that stakeholders in genetic/genomic and biobank research have different views and opinions about informed consent. Understanding the views and experiences of researchers, research ethics committees, and sample donors toward informed consent in biobank research is essential to developing evidence-based policy and guidelines that consider stakeholders' opinionsin genomic and biobank research in Ethiopia. The purpose of this study is to explore the views and experiences of researchers with respect to informed consent for biorepositories in Ethiopia.

Participant Selection

You are invited to participate in this study because of your experience in genetic/genomic and other biomedical research that involves collecting and storing human biological samples. And because of your affiliation with one of the institutes I have considered as my potential study setting.

Study Procedure

Face-to-face and virtual in-depth interviews will be used to conduct the study. It will take placeat the participant's office or a convenient location of choice. It is likely to take around 30 to 50 minutes to complete the interview. The interview will be audio-recorded. After the research is over, audio recordings will be deleted. Your name or other personal identifying information will not be recorded during the interview.

Confidentiality

The information recorded will be kept confidential by assigning codes, and no personal identifier will be used to document them. The data will not be shared with or given to anyone except the research team. The PI will keep interview transcriptions, audio records, and notes in a password-secured file.

Risks and Benefits

There are no foreseeable risks that you will encounter by participating in this study, except for the time spent in participating. The interview guide does not involve any sensitive or embarrassing topics. You may decline to answer any questions that you find uncomfortable. And you do not have to give any reason for not responding to the questions.

There will be no direct benefit to you for your participation in this study. However, this study's findings will help policymakers develop evidence-based guidelines and regulations for consent process and governance in biobank research.

Voluntary Participation

Your participation in this research is voluntary. It is your choice whether or not to take part in this study. If you decide to participate in this study, you will be asked to sign a consent form. You can change your mind and withdraw from participating anytime, even after signing the consent form.If you decide not to participate or withdraw later in the study, there will be no consequences or loss of benefits. If you decide to stop in the middle of the interview, we might ask your permissionto analyze the recorded information. If you don't want us to do so, we will not include the data, and it will be deleted.

Contact Information

Investigator: Siham Mohammed Email: sihamty1998@gmail.com Phone number: +251913811501

Advisor: Dr. Ayele Belachew Email: kalayeleb@gmail.com Contact number: +251913306792

Addis Ababa University, College of Health Sciences Institutional Review Board (IRB):

Phone: +251 11896 1396 Email: chs.irb@aau.edu.et

Consent Form

I have read and understand the provided information. I have had the opportunity to ask questions about it, and any questions I have been asked have been answered satisfactorily. I understand that my participation is voluntary and that I can withdraw at any time without giving a reason and without cost. I voluntarily agree to take part in this study.

Participant's signature_____Date _____

Interviewer's signature_____Date _____

Annex 2: Information Sheet and Consent Form (Amharic Version)

የመረጃ ገፅ

የጥናቱ ርዕስ: በኢትዮጵያ ለባዮሬፖዚቶሪዎች በመረጃ ላይ የተመሰረተ ስምምነት በተመለከተ
የተመራማሪዎችን እይታ እና ልምድ ማሰስ

መግቢያ

ሰላም, ስሜ እባላለሁ። “በኢትዮጵያ ለባዮሬፖዚቶሪ ወይም ለባዮባንክ በመረጃ የተደገፈ የስምምነት ሞዴሎችን በተመለከተ የተመራማሪዎችን አስተያየት እና ልምድ ማሰስ” በሚል ርዕስ የማስተርስ የምርምር ፕሮጀክት አባል ነኝ። ይህ ጥናት የሚካሄደው በአዲስ አበባ ዩኒቨርስቲ ጤና ሳይንስ ኮሌጅ የማስተርስ ኦፍ ፐብሊክ ሄልዝ በ ሄልዝ ሪሰርች ኤቲክስ ዘርፍ በመማር ላይ የምትገኝ ተማሪ በ ሲሃም መሃመድ ነው። በዚህ ጥናት ላይ አነድትሳተፉ በትህትና እጠይቃለሁ።

የዚህ ጥናት አላማ

በመረጃ ላይ የተመሰረተ የስምምነት አቀራረብ በ ባዮባንክ ጥናት ውስጥ ካሉ አከራካሪ እና ከባድ ከሀኑ ጉዳይዎች ውስጥ አንዱ ነው።ጥናቶች እንደሚያሳዩት ከባዮባንክ ጋር የተገናኙ የምርምር ባለድርሻ አካላት በመረጃ ላይ የተመሰረተ ስምምነት ላይ የተለያዩ አመለካከቶች እና አስተያየቶች አሏቸው። ለባዮባንክ ጥናትና ምርምር በመረጃ ላይ የተመሰረተ ስምምነት ላይ የናሙና ለጋሾችን፣ ተመራማሪዎችን እና የምርምር የሥነ ምግባር ኮሚቴዎችን አመለካከት እና ልምድ መረዳት በኢትዮጵያ የባዮባንክ ጥናት ባለድርሻ አካላትን አመለካከት እና አስተያየት ያካተተ በማስረጃ ላይ የተመሰረቱ ፖሊሲዎችን እና መመሪያዎችን ለማዘጋጀት ወሳኝ ነው። የዚህ ጥናት ዋነኛው አላማ የተመራማሪዎችን በመረጃ ላይ የተመሠረተ የስምምነት አቀራረብ ሞዴሎችን በኢትዮጵያ ላይ በ ባዮሬፖዚቶሪ ላይ ያላቸውን ተሞክሮ እና ግንዛቤ ለማሰስ እና ለመረዳት ነው።

የተሳታፊዎች አመራረጥ

በዚህ ጥናት ውስጥ እንድትሳተፍ/ፊ የተመረጡበት ምክንያት በጄኔቲክ እና ጂኖሚክ እንዲሁም በሌሎች ባዮሜዲካል ዘርፍ ላይ የሰዎች ባዮሎጂካል ናሙናዎችን መሰብሰብ እና ማከማቸትን በውስጡ ያጠቃለለ ጥናቶች ላይ በቂ ልምድ አና ተሞክሮ ስላለዎት ነው።አንዲሁም ሌላኛው ምክንያት ለጥናቴ የመረጥኪቸው ተቋሞች ውስጥ ስለምትሰሩ ነው።

የጥናቱ አፈፃፀም

በዓካል ተገናኝተን የምናካሄደው ሰፊ ቃለመጠይቅ ወይም ኢንተርቪው ይኖራል። የቃለመጠይቁ ቦታ የተሳታፊው ቢሮ ውስጥ ወይንም ለተሳታፊው የሚመች ሌላ ቦታ ሊሆን ይችላለል።ቃለመጠይቁ ሊወስድ የሚችለው ግዜ ከ30 እስከ 50 ደቂቃ ተብሎ ሊገመት ይችላል።ቃለ መጠይቁ በድምፅ ይቀዳል።ጥናቱ በመጨረሻ ላይ ሲጠናቀቅ የተቀዳው የድምፅ መረጃ ይሰረዛል። በቃለ መጠይቁ ወቅት፣ የእርስዎ ስም ወይም ሌላ የግል መለያ መረጃ አይመዘገብም።

ሚስጥራዊነት

ኮዶችን በመመደብ የተቀዳው መረጃ በሚስጥር ይጠበቃል፣ እና ምንም የግል መለያ እነሱን ለመመዝገብ ጥቅም ላይ አይውልም።መረጃው ከተመራማሪው ቡድን በስተቀር ለማንም አይጋራም ወይም አይሰጥም።የቃለ መጠይቅ ግልባጮች፣ የድምጽ መዝገቦች እና ማስታወሻዎች በዋናው ተመራማሪ በይለፍ ቃል በተረጋገጠ ፋይል ውስጥ ይቀመጣሉ።

በጥናት ውስጥ በመሳተፍ ሊከሰቱ የሚችሉ አደጋዎች እና የሚጠበቁ ጥቅሞች

በዚህ ጥናት ውስጥ በመሳተፍ ሊያጋጥሙዎት የሚችሉ ምንም ሊታዩ የሚችሉ አደጋዎች የሉም፣ በመሳተፍ ላይ ከሚጠፋው ጊዜ በስተቀር። የቃለ መጠይቁ መመሪያው ምንም አይነት ሚስጥራዊነት ያለው ወይም አሳፋሪ ርዕሶችን አያካትትም። የማይመቹዎትን ማንኛቸውም ጥያቄዎችን ለመመለስ እምቢ ማለት ይችላሉ። እና ለጥያቄዎቹ ምላሽ ላለመስጠት ምንም ምክንያት መስጠት የለብዎትም።በዚህ ጥናት ውስጥ ለሚያደርጉት ተሳትፎ ምንም አይነት ቀጥተኛ ጥቅም አይኖርም። ነገር ግን፣ የዚህ ጥናት ግኝቶች ፖሊሲ አውጪዎች በማስረጃ ላይ የተመሰረቱ መመሪያዎችን እና ደንቦችን በባዮባንክ ጥናት ውስጥ የስምምነት ሂደት እና አስተዳደርን እንዲያዘጋጁ ይረዳቸዋል።

በፈቃደኝነት ተሳትፎ

በዚህ ምርምር ውስጥ መሳተፍ በፈቃደኝነት ላይ የተመሰረተ ነው። በዚህ ጥናት ውስጥ መሳተፍ ወይም አለመሳተፍ የእርስዎ ምርጫ ነው። በዚህ ጥናት ለመሳተፍ ከወሰኑ፣ የስምምነት ፎርም እንዲፈርሙ ይጠየቃሉ።በዚህ ጥናት ውስጥ አልሳተፍም ማለት ይችላሉ።በማንኛውም ጊዜ ከጥናቱ ተሳትፎ ራሰን ማግለል ይችላሉ። በቃለ መጠይቁ መካከል ለማቆም ከወሰኑ፣ የተቀዳውን መረጃ ለመተንተን ፍቃድ ልንጠይቅ እንችላለን። ካልፈቀዱ ግን መረጃውን አንጨምርም። የተቀዳው መረጃ ይሰረዛል።

የመገኛ አድራሻ

ተመራማሪ: ሲሀም መሀመድ ኢሜይል: sihamty1998@gmail.com ስልክ ቁጥር: +251913811501

አማካሪ: ዶር. አየለ በላቸው ኢሜይል: kalayeleb@gmail.com ስልክ ቁጥር: +251913306792

የአዲስ አበባ ዩኒቨርሲቲ፣ ጤና ሳይንስ ኮሌጅ ተቋማዊ የሥነ ምግባር ግምገማ ቦርድ: ስልክ ቁጥር : +251 11896 1396 ኢሜይል: chs.irb@aau.edu.et

የስምምነት ቅፅ

የቀረበውን መረጃ አንብቤ ወይም ተነብቦልኝ ተረድቻለሁ። ስለ ጥናቱ ጥያቄዎችን ለመጠየቅ እድሉን አግኝቻለሁ፣ እና ለማንኛውም የጠየቅኳቸው ጥያቄዎች አጥጋቢ ምላሽ አግኝቻለሁ። የእኔ ተሳትፎ በፈቃደኝነት እንደሆነ እና በማንኛውም ጊዜ ምክንያት ሳይሰጥ እና ያለምንም ወጪ ማቋረጥ እንደምችል ተረድቻለሁ። በዚህ ጥናት ለመሳተፍ በፈቃደኝነት ተስማምቻለሁ።

የተሳታፊ ፊርማ _____ ቀን _____

የጠያቂው ፊርማ _____ ቀን _____

Annex 3: Demographic and Supplementary Questions

Exploring the Views and Experiences of Researchers regarding Informed Consent for Biorepositories in Ethiopia:
A Qualitative Study

Demographic and Supplementary Questions

1. Sex: Male ☐ Female ☐
   (ፆታ)

2. Age: _____
   (ዕድሜ)

3. Background (Area of Expertise): _____
   (የሙያ ዘርፍ /ስፔሻላይዜሽን)

4. Years of experience in research that involves biorepositories/ biobanks: _____
   (ባዮሬፖዚቶሪን /ባዮባንክን የሚያካትት ጥናቶች ላይ ምን ያህል ጊዜ ቆይተዋል?)

5. What is/was your role in the most recent biorepository/biobank-related research you participated in?
   (በቅርብ በተደረገ ባዮሬፖዚቶሪ/ ባዮባንክ ተዛማጅ ጥናት ላይ የእርስዎ ሚና?)

Annex 4: Interview Guide (English Version)

Warm-up Question: Please tell me about the research projects you are currently working on.

1. What type of consent model or models does your institution use for biorepository-based research?

2. What is your view of the consent model that your institution employs for biorepository-based research?

Probing questions:

- What is your view on the consent model in relation to providing adequate information for participants?

- What do you think of the consent model regarding establishing trust between the researcher and the participant?

- What is your view on the consent model regarding allowing participants to withdraw when needed?

3. Do you think this type of consent best protects the participants' autonomy in the case of biorepository-based research?

- Please explain your reasons for saying yes or no.

4. What do you think are the strengths of the consent model used by your institution for biorepository-based research?

5. What do you think are the limitations of the consent model used by your institution for biorepository-based research?

6. What ethical challenges have you (or your data collectors) faced when obtaining informed consent from participants for biorepository-based research?

Annex 5: Interview Guide (Amharic Version)

የቃለ መጠይቅ መመሪያ:

- እባክዎን አሁን እየሰሩበት ስላለው ምርምር ወይም ፕሮጀክቶች ይንገሩኝ?

1. ከጥናት ስምምነት ሞዴሎች ውስጥ ተቋምዎ ለጂኔቲክስ እና ባዮባንክ ጥናቶች የትኛውን/ የትኛዎቹን ይጠቀማል?

2. ተቋመዎ ለጂኔቲክስ እና ባዮባንክ ጥናቶች የሚጠቀመው የስምምነት ሞዴልን በተመለከተ የርስዎ አስተያየት ምንድን ነው?

የመመርመሪያ ጥያቄዎች:

- ለተሳታፊዎች የተሟላ መረጃ ከመስጠት ጋር በተያያዘ በስምምነት ሞዴሉ ላይ የእርስዎ አስተያየት ምንድነው?

- በተመራማሪው እና በተሳታፊው መካከል መተማመንን ከመፍጠር አንፃር ስለ ስምምነት ሞዴሉ ምን ያስባሉ?

- ተሳታፊው በፈለገው ጊዜ ከጥናቱ መውጣት መፍቀድ እና ማስቻልን በተመለከተ በስምምነት ሞዴሉ ላይ የእርስዎ አስተያየት ምንድነው?

3. ይህ ሞዴል የተሳታፊውን የግል የመወሰን መብት ያከብራል ብለው ያምናሉ?

- መልስዎ አዎን ከሆነም ካልሆነም እባክዎ ምክንያተዎን ያብራሩ

4. በጂኔቲክስ እና ባዮባንክ ጥናት ወቅት ናሙና ከተሳታፊዎች ሲሰበስቡ ምን አይነት የሥነምግባር ተግዳሮቶች (Ethical challenges) አጋጥመዎታል?

5. ተቋመዎ በጂኔቲክስ እና ባዮባንክ ጥናቶች ላይ የሚጠቀመው የስምምነት ሞዴል በጎ ጎን ብለው የሚያስቧቸው የትኞቹ ናቸው።።

6. ተቋምዎ በጂኔቲክስ እና ባዮባንክ ጥናቶች ላይ የሚጠቀመው የስምምነት ሞዴል ገደቦች ምን እንደሆኑ እባክዎ ያብራሩ።።

Annex 6: COREQ Checklist

Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

Table 3: COREQ Checklist

Domain 1: Research team and reflexivity		
	Personal Characteristics	
1.	Interviewer	SM (Principal Investigator)- was a moderator for 10 interviews and the actual interviewer for the remaining 6 interviews. AT- Interviewer for 10 interviews
2.	Credentials. What were the researcher's credentials?	BSc, MPH candidate
3.	Occupation. What was their occupation at the time of the study?	MPH student
4.	Gender. Was the researcher male or female?	Female
5.	Experience and training. What experience or training did the researcher have?	Had taken three weeks of qualitative method course. Online courses of qualitative studies. Conducted a mini-qualitative study (for training purpose).
	Relationship with participants	
6.	Relationship established Was a relationship established prior to study commencement?	The P.I. (interviewer) did not have collegial relationships with the participants, and no relationship was established before conducting the study. However, two study participants taught the P.I. (interviewer) a few courses last year.
7.	Participant knowledge of the interviewer What did the participants know about the researcher?	The participants knew that the P.I. (interviewer) is currently a master's student at Addis Ababa University School of Public Health, specializing in the field of Health Research Ethics
8.	Interviewer characteristics What characteristics were reported about the interviewer/facilitator?	It has been reported that the P.I. (interviewer) is interested in the subject of informed consent and in exploring the practice and challenges in Ethiopia
Domain 2: Study design		
	Theoretical framework	
9.	Methodological orientation and Theory	Exploratory qualitative study

	What methodological orientation was stated to underpin the study?	
	Participant selection	
10.	Sampling How were participants selected?	Purposive snowball sampling technique
11.	Method of approach How were participants approached?	Email and in person visit
12.	Sample size How many participants were in the study?	15 actual interview and 1 pilot study
13.	Non-participation How many people refused to participate or dropped out? Reasons?	3 non response. And 1 refusal due to the reason of recent participation in a similar study. And others due to busy work schedule. There was no drop out
14.	Setting of data collection Where was the data collected?	Interviews took place at their institution; in the office, a quite room, or a meeting hall. 3 interviews were virtual, over Zoom meeting. Interview location and time were based on the participants' preferences.
15.	Presence of non-participants Was anyone else present besides the participants and researchers?	On one of the face-to-face interviews, there was one individual present in the office, but he was not Ethiopian and doesn't understand Amharic language.
16.	Description of sample What are the important characteristics of the sample?	Participants in this study have different position (roles) in research they are currently working on. Most of them have a background of medical microbiology. Except for three participants, the rest of them are males.
	Data collection	
17.	Interview guide Were questions, prompts, guides provided by the authors? Was it pilot tested?	The interview guide is semi structured, and it was pilot tested. It also has probing questions. Further guide was given for some questions that were unclear for the responders.
18.	Repeat interviews. Were repeat interviews carried out? If yes, how many?	No
19.	Audio/visual recording. Did the research use audio or visual recording to collect the data?	Yes, audio recorder was used
20.	Field notes Were field notes made during and/or after the interview or focus group?	During the interview, field notes were taken for each.

21.	Duration. What was the duration of the interviews or focus group?	The duration of the interview's ranges from 16 to 63 minutes (mean of 33 minutes).
22.	Data saturation. Was data saturation discussed?	The concept of saturation grid was used to determine data saturation. (Further discussed on the method section)
23.	Transcripts returned. Were transcripts returned to participants for comment and/or correction?	No.
Domain 3: Analysis and findings		
	Data analysis	
24.	Number of data coders. How many data coders coded the data?	The data was coded by a single person (principal investigator). But the codes and categories were reviewed and commented by advisors.
25.	Description of the coding tree. Did authors provide a description of the coding tree?	Yes, the code book is provided in the Annex, and a summary of the identified themes and codes is displayed on Table 2.
26.	Derivation of themes. Were themes identified in advance or derived from the data?	Both. Some themes were inductively derived from the data, while some of them were derived in advance.
27.	Software. What software, if applicable, was used to manage the data?	NVivo version 20
28.	Participant checking. Did participants provide feedback on the findings?	Yes, Findings were sent to the participants and some had provided their comments and feedbacks.
	Reporting	
29.	Quotations presented. Were participant quotations presented to illustrate the themes / findings? Was each quotation identified?	Yes, quotes were presented. And each of the quotations were identified by using the assigned pseudonyms.
30.	Data and findings consistent. Was there consistency between the data presented and the findings?	Consistency with the raw data was maintained as much as possible during the interpretation and write-up.
	Were major themes clearly presented in the findings?	Yes, major themes were clearly defined and described, also presented in a table form (Table 2).
32.	Clarity of minor themes. Is there a description of diverse cases or discussion of minor themes?	Yes, the sub-themes are presented and described in detail under their main theme. (Also presented in Table 2.)

Annex 7: Code Book

Table 4: Code Book

Code book: Exploring the Views and Experiences of Researchers regarding Informed Consent for Biorepositories in Ethiopia,					
No.	**Themes**	**Categories**	**Codes**	**Description**	**Example**
1.	**Types of informed consent used**		Broad, Specific, Tiered, Both broad and specific consent, Depends on the type of research, Phone-based, Similar with broad consent, Waiver	The type of informed consent model or models utilized by the researcher for biorepository-based studies. It can either be standardized or non-standardized ones.	"… so, we obtained the participants consent for participation in the study, directly and for the future studies with a broad consent" *AAU3M* "And when the idea of putting those stored samples to use came, based on all of this awareness, our consents I think is more inclined to tiered" *AHRI1F*
2.	**Views regarding informed consent**	The consent process Contents of the consent Views on withdrawal	Positive, negative, Flawed consent process, Respects autonomy, No guideline, They may not comeback Well written, Not well written, No template, Comprehensible words, Withdraw options, Weak regulation, Poor description about withdrawal, Never experienced withdrawal, Experienced withdrawal	Their thoughts on the informed consent process in general for biorepository-based research	"...but as much as possible he is told to participate freely and only if he is willing to participate, and if he wants, he can withdraw at any time" *AAU3M* "But there is a problem on preparing a proper template for an informed consent used for biobanks, both by the institution and by the individual." *AAU1M*
3.	**Information comprehension**	Participant's comprehension	There is no guarantee of their understanding, Both educated and uneducated	Researchers' views or opinions regarding participants' or sample donors' comprehension of the information provided to them during the consent process and the	"But, until now, whether the study participants have well understood, even if we explain it to them, I cannot be sure whether they comprehend it as we do or as

		Reasons for poor comprehension	Lack of knowledge, Information overload, Recruited in a hurry, Misconception,	reasons they believe could be for their poor comprehension.	it is in the study, it is uncertain" *EPHI1M* "When they are told that the blood samples will be stored and kept for long, usually misunderstanding happens. Because what we should see is that participants are of different kinds, and some of them may not be well educated, even the educated once may not have the scientific knowledge" *CDT1F*
4.	**Building trust**	Views regarding establishing trust Ways to build trust	Community engagement is crucial, Trust depends on the individual researcher, Trust is based on providing full information, Building trust is not a one-time process A known person and place, Institution's reputation, The consent process, Community engagement, Sharing of results & benefits, Telling participants about IRB, Active contacts with participants	Consists of all types of approaches that could be used for establishing and strengthening trust. And explains how trust can be built between the researcher and participants	"The informed consent process should base itself on trust, established through the communication and delivery of adequate, correct appropriate information to participants" *AHRI3M* "..apart from that, the opinion of the community towards the institution conducting the study also has an impact"*AAU3M* "..one is, providing clear information. If it is explained to him in a language he understands, trust will be built" *EPHI1M*

5.	**The good side of the informed consent**		-Strength of Broad consent -Options are given -Detail Information is provided	It includes what the researchers think or perceive the strength or the positive side of the informed consent utilized by them and their institution.	"The main strength is flexibility to researchers without the need for additional consent. It maximizes use of resources, shortens time avoiding delays on consent seeking. It facilitates scientific investigations at lower cost and promotes innovation with existing resources. Participant autonomy is respected where there is an option to opt-out." (AHRI3M)
6.	**Drawback of the consent form**	Limitations of the informed consent Limitations related to governance and guideline	No reference for terminology, No standardized template, Poor description about withdrawal, Translated words, Drawbacks of broad consent, Lack of I.C for sample storage from clinical visits Lack of monitoring and regulation, **No guideline**, Lack of guidance for withdrawal process, No legal form for deceased in Ethiopia, Lack of continuous communication	Explains the limitations or drawbacks of the informed consent model currently being used for studies that involve collecting and storing human specimens.	"But most of the time the consents we use does not give detailed description about the withdrawal… It is written in a similar way as others. This is a gap that we should take a look at" *CDT1F* "There is no reference for medical terminologies in the case of biobanking to be used in the consent form" *AAU1M*

7.	**Challenges faced**	Communication challenge and the reasons Comprehension challenge among sample donors Challenges unrelated to informed consent	Difficult to explain about the study, Not well informed, The word genetics is sensitive, Traditional & religious belief Comprehension challenges Drawing blood challenge, Pain, Loss to follow up, Lack of capacity to monitor shared samples, Participants ask for results	Challenges researchers have faced or their data collectors, during the informed consent process for biorepository-based studies. And explains different causes for communication gap during the consent process. It can be from the researcher side, from participant's sides, due to the study nature, or other technical reasons	"The most frequent challenge in my opinion was doing the "informing" well - appropriate communication - providing a clear picture of the study aim and explaining how they fit in there and why their participation is required.." *AHRI3M* "So, when the participant came and reads or is read to him the information sheet, does he understand it to the level intended is put to question, especially in genetics study" *AHRI1F*
8.	**Recommendations**	Consent Recommendations Governance Recommendations for IRB	Comprehensible words, Standardized model, Conducting investigations, Stop using blanket consent Governance and policy, Capacity building, Reporting results, Community engagement Post approval & site monitoring, Promote sample use, Withdrawal oversight, Focus on the ethics part only	Applies for all types of recommendations mentioned by researchers on how to improve the current informed consent models, as well as the informed consent process.	"There should be a standardized consent model. Even the words, words that patients can easily comprehend should be evaluated and selected" *AAU1M* "..for any researcher who wants to participate in this study or related studies, I think it would be good if there was a research ethics guideline that is customized for genomics and distinct from the standard research ethics guidelines." *AHRI4M*