

**AN EXPLORATION OF BIOBANKING ETHICAL ISSUES AMONG CANCER  
PATIENTS AND HEALTH CARE PROFESSIONALS AT BUGANDO MEDICAL  
CENTRE, MWANZA**

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**An Exploration of Biobanking Ethical Issues among Cancer Patients and Health Care  
Professionals at Bugando Medical Centre, Mwanza**

**By**

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**A Dissertation Submitted in (Partial) Fulfillment of the Requirements for the  
Degree of Master of Bioethics of  
Muhimbili University of Health and Allied Sciences**

**October 2021**

## **CERTIFICATION**

The undersigned certify that they have read and here by recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled “**An Exploration of Biobanking Ethical Issues among Cancer Patient and Health Care Professionals at Bugando Medical Centre, Mwanza**”, in (Partial) fulfillment of the requirements for the degree of Master of Bioethics in Muhimbili University of Health and Allied Sciences.

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(Co-Supervisor)

Date: \_\_\_\_\_

**DECLARATION AND COPYRIGHT**

I, **Ibrahim William Mgoo** declare that this **Dissertation** is my own original work and that it has not been presented and will not be presented to any other University for a similar or any other degree award.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

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## **DEDICATION**

I dedicate this **dissertation** to my beloved parents; **Mrs. Helena Daudi Mgoo** and **Mr. William Satu Mgoo (R.I.P)** for raising me with unconditional love. Live long, my mother.

## **ABSTRACT**

### **Background**

Biobanking studies enhance the discoveries in Medicine to improve human health challenges through targeted individualized diagnosis, prevention, and therapy to cancer patients. But biobanking ethical issues remain indispensable in the field of medicine. Therefore, this study informs about the biobanking ethical issues among cancer patients and health care professionals.

### **Aim of the study**

To explore biobanking ethical issues among Cancer patients and Health Care Professionals at Bugando Medical Centre, Mwanza, Tanzania

### **Methodology**

The study used the exploratory study design involving Cancer Patients and Health Care Professionals. The participants were selected purposively from Bugando Medical Centre. Data were collected using In-depth interviews and the conversations were audio-recorded. The audios were then transcribed verbatim and the transcriptions were analyzed using content analysis with the help of NVivo 10 software to identify relevant themes and tracing of quotations.

### **Findings**

The findings in this study were inductively led to the formation of four main themes which are the perception of Cancer patients and health care professionals in decision making on biobanking; perception of cancer patients and health care professionals on privacy in biobanking; perception of cancer patients and health care professionals on ownership of stored biospecimens; and perception of cancer patients and health care professionals on commercialism in biobanking.

### **Conclusion**

Comprehensive information which covers the expected future procedures of the study, its purpose, and related benefits are necessary before the commencement of research in health care settings to address biobanking ethical issues among the participants of the research. This will enhance decision-making among biobanking partners.

**Key words:** Biobanking, Biospecimens, Informed consent, Perception, Privacy

**ACRONYMS AND ABBREVIATION**

BMC	Bugando Medical Centre
DNA	Deoxyribonucleic acid
MUHAS	Muhimbili University of Health and Allied Sciences
IARC	International Agency for Research on Cancer
IC	Informed Consent
IDI	In-depth Interview
IRB	Institute of Review Board
CAQDAS	Computer- Assisted Qualitative Data Analysis Software
HCP	Health Care Professionals
MBE	Master of Bioethics
PI	Principal Investigator



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## OPERATIONAL DEFINITIONS

**Biobanking** refers to the process by which samples of bodily fluid or tissue are collected for research use to improve understanding of health and disease.

**Biospecimens** are any natural material from the human body, tissue, blood, and urine that are obtained during a diagnostic test or a procedure, such as surgery.

**Cancer patients** are persons diagnosed with, and receiving medical treatment for a malignant growth or tumor

**Custodianship** is the process of planning, implementing, and making policies to assure the long-term stability of biospecimens and the handling of specimens and data.

**Decision making** refers to the act of the patients who have the capacity to make decisions about their care and are permitted to do so voluntarily when having all relevant information regarding their condition and alternative treatments, including possible benefits, risks, costs, other consequences, and significant uncertainties around any of the information.

**Health care professionals** refer to any members of medical, dental, nursing, or pharmacy or any other persons, who in the course of their professional activities may prescribe, recommend, administer a pharmaceutical product, or promote health.

**Informed consent** means the moral contract between researchers and the study participants and setting the framework for the allowable use of biospecimens and data.

**Perception** refers to the way in which something is regarded, understood, or interpreted based on available knowledge, experiences, and thoughts.

**Privacy** is a state in which one is not observed or disturbed by other people without a prior permit.

**Refusal of Informed Consent** refers to the situation where a person has refused a recommended medical treatment or any investigation procedure based upon the understanding of the facts and implications of not consenting and not being intellectually disabled or mentally ill and without impairment of judgment at the time of refusing.

## CHAPTER ONE

### 1.0 INTRODUCTION

#### 1.1 Background

Cancer and other non-communicable diseases continue to be the leading causes of deaths globally and data show mortality, incidence and disabilities increase every year(1), while personalized medicine carries headlines among scientists' debates. Research on biobanking to enhance personalized medicine was encouraged to alleviate the problem(2,3). The success in research using stored biospecimens and debates over the appropriate use of archived biospecimens, the interests of the research participants in seeing productive use of their blood or tissues should be considered in addressing concerns about potential risks and lack of specific consent. This depends much on the public's trust in the research institutions and the willingness of individuals to contribute biospecimens for research and cooperative spirit, in turn, will be more affected by the policies and practices we use in collecting, processing, maintaining, and distributing these biospecimens for research to encourage contributions and processes(4).

Many research initiatives globally present special attention for studies involving biospecimens analysis through biobanking. Although there was a rise of best practices of collections, transporting, storing, and analyzing biospecimens, but there is little international coordination of biospecimen standards, both from the operational and ethical issues to address them. And at the same time, as a result, investigators share samples and collaborate across borders which must be taken care of in quality standards and observe ethics established before specimen collection(5,6). It should be considered that, in this era of new science and technology, biobanking research is important for advancing knowledge and improving human health challenges through new targeted diagnostic, preventive, and therapeutic research. Not at rest situations, in recent years, the numbers of scientists have struggled with a number of ethical and legal conflicts related to the collection and use of bio specimens in research where the ethical issues range from expanded legal battles over who owns stored biological materials as tangible property to charges of improper informed consent and subsequent in appropriate research use of

contributed biospecimens, how the donors involved and especially when samples were collected for diagnostic purposes(4,6,7).

The individualized care of cancer patients was a focus of many physicians and researchers globally since it is well known that the molecular signatures of disease can be confounded by the signatures of biospecimen biological stress, with the potential to affect clinical and research outcomes through an incorrect diagnosis of disease, improper use of a given therapy, misinterpretation of artifacts as biomarkers. Understanding of biospecimen stress-related effects is critical to make advances in translational research through biobank research to represent the kind of bricks that provides a solid scientific foundation for future advances that will directly help patients(2). Biobanking is the world's demand for medical scientists to answer the question of individualized care to cancer patients(8). With no doubt, research participants, regardless of the site of care, ethnicity, or socioeconomic status, are willing to provide a biological sample for research purposes. This allows the investigators to determine the research to be done without re-contacting after provision of individual simplified broad informed consent with a one-time binary choice whether to provide biological samples for future research in regarding power of the subject to withdraw and the privacy of the information generated(9).

The situation in Africa and Tanzania included on the practice of biobanking is not in place(8) and ethical issues surrounding the use of biobanking for future research among donors, health care professionals, and researchers were not known as the studies on biobanking were lacking. Considering that, racial and ethnic groups differed concerning several factors that can be obstacles for participation, e.g., medical mistrust, lack of benefit, usage of biospecimen for unspecified research, suspicion of exploitation by corporate entities, and privacy disclosure. But some studies in cross-cultural regional analysis show participants uniformly reported general interest and willingness to participate in biobanking for altruistic purposes, particularly to benefit future generations. The interest of donors was framed with a strong warning that donations should be accompanied by transparency about study ownership, use of biospecimens, and study information that fit participants' backgrounds and experiences(7,10). The cross-cultural regional analysis especially among cancer patients as a target for individualized

medicine is needed to offer significant insights about the similarities and variations in opinions and perceptions on biobanking ethical issues for future research.

## **1.2 Problem Statement**

People participating in research need to safeguard their rights, safety, dignity, and well-being(11). Biobanking ethical issues endure unresolved topics in health care settings which would assist decision making(12). Biobanking studies aim at individualized treatment to cancer patients to reduce mortality incidence and disability which is the burden to health care systems(9,13,14). And there reported inequitable translation of research findings to all global population subgroups in clinical research, including clinical trials that relate to identified low participation rates of minorities in biobanking research and clinical trial(15). This contributes to inequities in access to appropriate cancer care and treatments offered in clinical trials and routine medical care(16).

Transparency in decision making, privacy, and ownership contributes as the motivational factor to participation in biobanking studies(17). Another study noted individual benefits and societal benefits as the pulling factors to participate in biobanking research(18). Also, other findings inform the challenge of ethnic group leaders to discourage community members to participate in research because they fear the possible discrimination or stigmatization(7,19). But, there are efforts to encourage biobank studies among community members to be willing to donate biospecimens for biobanking studies as in medical diagnosis(20).

However, the biobanking ethical issues concerning perceptions of cancer patients and health care professionals on biospecimen donation for future research are unidentified. Notably, little research has examined the biobanking ethical issues under which people would consent to donate biological samples for research(17). Despite the presence of laws and regulations in DNA analysis(21), the perception of cancer patients and health care professionals on decision making, privacy, and ownership on biobanking research is missing in Tanzania where collected biospecimens for diagnosis are used for research. Therefore, it makes the necessity of this study to explore biobanking ethical issues among cancer patients and health care professionals.



### **1.3 Rationale of the Study**

The findings will add knowledge to the researchers on biobanking research, bioethics on stored biospecimens, and create awareness to the cancer patients and HCP to participate in different studies on ethical issues adherence in Tanzania.

Different researchers documented the use of stored biospecimens in considerations of all the ethical principles. And the central reconciliation of disputes over biorepository ownership, donors' privacy, and the decision-making process will allow the researchers to exploit the full potential of biobanking in promoting health practice. It will also suggest improving the policy on bioethical issues obedience in secondary research and data use.

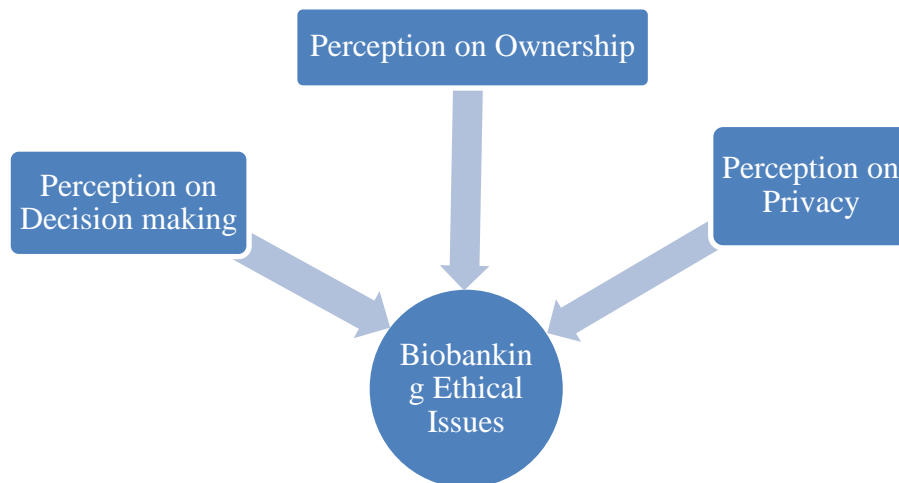
Furthermore, the results of this study will influence the policy on how to deal with research subjects and biospecimens collected for diagnostic purposes, immediate research, or future research. It will create an approach to biobanking through refinement of the informed consent for specimens in medical examinations by incorporating the biobanking ethical issues in guidelines for future research in Tanzania.

### **1.4 Conceptual Framework**

This study applies the concept of Aristotle's theory of four causes to explore perceptions of cancer patients and health care professionals on biobanking ethical issues at Bugando Medical Centre in Mwanza, Tanzania. Four causes theory talk about the material cause tells us what a thing is made of, the formal cause tells us about its form, the efficient cause tells how it came to be what it is, and the final cause tells us what a thing is made for (Aristotle and Skinner, 2014). Therefore these four causes are necessary for us to have a complete idea about things or procedures through our perceptions(22).

Learning about perceptions towards biobanking is not only more complicated but also of more interest. Its translation might be based on individual or community beliefs, cultures and traditions, norms and values, and prior knowledge of a group on biobanking. Therefore, an exploration of Biobanking ethical issues is not merely a matter of translating the terms, but also considering how people perceive the practical proceedings.

Aristotle's theory of four causes outlines the steps to describe new concepts. That's to say when an individual is faced with something new, strange, or unfamiliar, the first response is to know the thing, to know the origin of, which is its form, and what is its purpose. Therefore, this study will apply the four causes to explore the perceptions of cancer patients and health care professionals where, the material cause, the matter from which the thing is made from, denotes decision making e.g. the wood for chair; efficient cause, the agent that brings something about, denoted by ownership e.g. the carpenter; formal cause, the kind of thing that something is, represented by privacy e.g. the shape of; and final cause, the goal or purpose that a thing is made for, denotes biobanking ethical issues e.g. sitting on (Meinung B et al, 2019).



**Figure 1: Conceptual framework illustration.**

(Adapted and modified: key concepts in biobank development(23))

## 1.5 Research Questions

### 1.5.1 Broad Research Question

What are the biobanking ethical issues among Cancer Patients and Health Care Professionals at Bugando Medical Centre?

### 1.5.2 Specific Research Questions

1. What is the perception of Cancer Patients and Health Care Professionals on decision-making for a donation of biospecimens for future research?

2. What is the perception of Cancer Patients and Health Care Professionals on privacy in biobanking research?
3. What is the perception of Cancer Patients and Health Care Professionals on ownership of biospecimens collected for biobanking research?

## **1.6 Research Objectives**

### **1.6.1 Broad Objective**

To explore biobanking ethical issues among Cancer Patients and Health Care Professionals at Bugando Medical Centre.

### **1.6.2 Specific Objectives**

1. To explore the perception of Cancer Patients and Health Care Professionals on decision-making for a donation of biospecimens for future research.
2. To explore the perception of Cancer Patients and Health Care Professionals concerning privacy in biobanking research.
3. To explore the perception of Cancer Patients and Health Care Professionals on ownership of biospecimens collected for biobanking research.

## **CHAPTER TWO**

### **2.0 LITERATURE REVIEW**

#### **2.1 Perception on Decision making**

Ethical challenges in making decisions differ with the groups involved in the research. Consider that in developed countries, decision making based on the autonomy of the individual, with a written description of the studies proposed and consent was documented by the signature of the participant, the situation is different in developing countries, where the initial decision-making for informed consent is normally governed by the community rather than the individual(24).

This raised the need for the involvement of different groups in research to benefit the process of decision-making in medical research. With good and an important approach to address inclusion and equity tensions was the engagement of ethnic and minority community participants in the research and advocacy process to give them the opportunity to participate in research. The use of a certain Community will represent an ideal orientation respectfully and thoughtfully engagement of diverse members of the community in the research process. Thus, this optimizes the opportunities to address social justice issues within research. Furthermore, there is a need for community-level agreement in a specific community in approaching consent to participate in biobank research(25). This was since, willingness to donate biospecimen is affected by group differences such as racial and ethnic groups which differed with regard to a number of factors that are obstacles for participation, e.g., continuing medical mistrust, lack of benefit apprehension about the physical toll of donating, usage of biospecimen for research and suspicion of exploitation by corporate entities (26).

Different approaches in assessing willingness and asking individuals if will agree that their samples may be used for currently not defined research, the majority among the participants were willing with some concerns like benefiting the community and advancing medicines. On plan for establishing a Dermatology Research Biobank, more than 82% of participants were willing to donate blood samples and 52% were willing to donate skin samples but the willingness was associated with the level of education and exposure to the medical care(27). The research conducted on donors' beliefs about participation in biospecimen research, among various groups, has reported an unwillingness to decide to participate in future unspecified research for fear that research results would stigmatize their community. For example, some ethnic group leaders have discouraged their community members from participating in genetics research because they fear the possible discrimination or stigmatization(19)

Even though the acceptability of the decision-making process to allow future research in many developed countries, the practice was different in developing countries(28), particularly Tanzania where research can be conducted following national laws and regulations regarding permission obtained from respective authority(24), where according to laws regulating research involving DNA analysis, the studies which similar to research for individualized medicine for

cancer treatment, researchers in Tanzania are required to be granted permission from the regulator(17). To allow studies in individualized medicine, the decision-making process including a ‘broad informed consent form was necessary for developing countries including Tanzania to enable maximum potentials in research.

However, according to the research on parental attitudes and willingness to donate children’s biospecimens for congenital heart disease research: a cross-sectional study in Shanghai, China participants with higher education levels and those whose children had a previous history of hospitalization are more likely to be willing to donate their children’s biospecimens for research, where hospitalization adds knowledge on health information (17). Regarding the consultation to any action taken against donated samples, a good understanding of health issues among the population was a key element to the donation of specimens for health, a notion like “Others may benefit”, “I would like to help sick people”, and “it feels good to help” were some of the statements which measure knowledge of an individual towards research especially when asked to donate biospecimens to be used for research. Awareness to help medical researchers learn about the disease, help improve patient care, and help medical researchers develop new diagnoses or treatments come only with better knowledge(30).

Despite the demand for technology to expand individualized care, the perception of Cancer patients and Health Care Professionals on decision-making for future research to allow biobanking research is not known in Tanzania.

## **2.2 Perception on Privacy**

Biospecimen donation for research was more affected by the personal aspect of the practice. People with a family disease history and a previous donation were more likely to participate in biobanking research(31). Participants who were willing to donate their children’s biospecimens for research were doing so because will benefit their children’s future treatment and others believe the donation will contribute to medical developments. Whereas some participants were not willing to donate their children’s biospecimens, because doing so might cause physical discomfort to their children and disclose family information(17).

A community perception to participate in biobanking is a desire to benefit society, benefit family members, advance science, and find cures. Participants also feel that their participation in biobanking could contribute toward advancing science and finding cures for diseases. But, biobanking for future research show several barriers to include lack of knowledge about medical research and biobanking, specifically, the information on what donating biospecimens entails lack of communication about the results, distrust of the medical system or providers due to past medical encounters, and fear of pain from needles or Harm from contracting diseases(32).

However, privacy leakage is a major concern among the majority of participants as a primary reason affecting willingness, or indecisiveness to get involved in biobanking research. But researchers and research institutions have minimized this perception by building trust in the community through research protocols about the privacy of the respondents(31). Studying ethical perceptions on privacy matters among Cancer patients and health care professionals will help to address the knowledge gap on ethical issues in biobanking.

### **2.3. Perception on Biobanking ownership**

Participation in biobanking research is uniformly reported with general interest and willingness to participate in biobanking for altruistic purposes, particularly to benefit future generations. This interest is framed with a strong warning that donations should be accompanied by transparency about ownership, distribution, and use of biospecimens, and study information that fit participants' backgrounds and experiences(4,6,7). According to the study assessed the knowledge about biobanking among healthcare students and their willingness to donate biospecimens, despite their strong willingness to donate biospecimens, students exhibited a notable lack of knowledge about Biobanking and questioning on ownership of the specimens collected. To accelerate the transition towards biobanking research and therefore educational and awareness programs to bring into the light Biobanking technologies demanded to the scope of research and clinical applications(33).

Although, Biobanks have emerged as a significant research tool, gaining support from both the scientific community and regional, national and international research funding agencies,

developing and maintaining these projects was expensive(34). Different cultures and traditions are concerned with commercialization in biobanks where human bodily substances such as tissues and blood to be used as a capital resource. In some parts of the world, there was a possibility of using body parts or other human tissues as a capital resource while others prohibit. This makes it necessary for commercialization in biobanking to be considered with different ethical values. This lead to particularity for the best possible use of collected biobank materials for the benefit of the patient(35). According to the study conducted by mark Hall et al concluded that; Allowing commercial use of donated samples was controversial in some Asian countries(36). But challenges of sustainability about how to maintain biobanks in the long term should be addressed based on how to deal with the voluntarily, altruistic relationship between biobanks and the donors' differences(37).

In the world of researchers, biospecimens were rare and valuable resources, and it is not surprising that their ownership has been the focus of recent controversy and debate. From the vantage point of the Bioethicists decisions about ownership or custodianship of biospecimens collected for research should be guided by a discrete set of principles and as it was judged in the case of Washington University versus Dr. William Catalona et al that individual research participants retained control over their specimen(3). The level of Literacy on health matters is the reason for participation in health-related research. People with high-level knowledge on health have a higher chance associated with their willingness to participate in research including the donation of their sample specimen for biobanking research after clear information about the ownership (20).

Despite the presence of laws and authorities(21,29) regulating access to archived bio-specimens, the perceptions of health care professionals and donors on ownership and commercialization status of the donated samples are not known in Tanzania.

## **CHAPTER THREE**

### **3.0 MATERIALS AND METHODS**

#### **3.1 Study Design**

An exploratory study design was used to answer the research questions and address the aim of the study. The aim was to explore biobanking ethical issues among Cancer patients and Health care professionals at Bugando Medical Centre in Mwanza. Due to the limited understanding of the aim of the study, an explorative study design was suitable for investigating a problem that is understudied(38). The design was expected to yield maximal information on many different aspects of a problem. It is also considered the most appropriate and efficient design in qualitative research(39). The design was aimed at providing explicitly streamlining and integration from data collection to data analysis in a manner that obtain responses to research questions(40). The design employed the In-depth interview which was found appropriate help to a better understanding of the existing ethical issues in biobanking. A number of open-ended questions were used to guide the researcher to explore more information from the participants. And this study was conducted for three (3) consecutive months.

#### **3.2 Study Area**

This study was conducted at Bugando Medical Centre (BMC) which is a Teaching and Consultant Hospital in Lake Zone located in Mwanza, Tanzania. It is the second-largest health institution in Tanzania with 1000 beds capacity(41–43). The selection of the institution is purposefully based on the fact that it is one of the institutions which has the burden to save the life of people suffering from cancer diseases particularly in the lake zone(44). And also, at BMC some of the biospecimens collected for clinical care and research are archived and later on are used for secondary research by obtaining permission from Hospital Director General.

#### **3.3 Study population**

The study populations were Cancer Patients and Health Care Professionals who have been involved in biospecimens collections and analysis for medical diagnosis and or research at Bugando Medical Centre. The population was purposefully selected because was eligible and



qualified to provide the necessary information based on their experience in medical care and research to address the study objectives(45).

### **3.4 Inclusion criteria**

Cancer Patients who were stable and had been attending Oncology services for at least three (3) months and Health Care Professionals who were involved in collection and processing biospecimens for clinical care or research were invited to participate in the study because they were able to address research questions.

### **3.5 Sample Size**

Informants of this study were purposively select to suit the study design. They were categorized into two groups based on the designed tools for In-depth Interviews. In-depth interview conducted to four (4) cancer patients and ten (10) health care professionals regarding their involvement in biospecimens collections and analysis for medical diagnosis and, or research at Bugando Medical Centre. This makes a total of fourteen (14) respondents. The sample size of participants was determined by the information provided (46,47). Therefore, this sample size of Cancer patients and health care professionals was able to give information that satisfied the aim of the study using the concept of “power of information” as a way of determining the sample size in qualitative studies(48,49).

### **3.6 Sampling Techniques**

The study used the purposive sampling method to properly choose and approach eligible participants who fit the profile of the research-specific objectives. The cancer patients were purposefully selected among cancer patients who were attending the oncology clinic in the oncology department at Bugando Medical Centre and were interviewed based on the research objectives. health care professionals were purposefully selected based on their working stations, two (2) were from Research and community health services department, three (3) were from the Laboratory department, two (2) from Emergency Medicine Department, one (1) from the Internal medicine department, and two (2) were from Oncology department.

Cancer patients were interviewed in a convenient room at the oncology department where they were comfortable to respond to the questions posed by the principal investigator. But health care professionals were comfortable being interviewed in their respective working stations at side rooms. To all respondents, their informed consent was obtained orally and in written form by signing the informed consent form.

### **3.7 Thematic areas**

Using open-ended questions directed by the principal investigator, the information of participants about perception on biobanking ethical issues lead to the development of four main themes which are the perception of cancer patients and health care professionals in decision making on biobanking; perception of cancer patients and health care professional on privacy in biobanking; perception of cancer patients and health care professionals on ownership of stored biospecimens; and perception of cancer patients and health care professionals on commercialism in biobanking.

### **3.8 Data collection Procedure**

An in-depth interview (IDI) was conducted to the participants using an interview guide with a semi-structured interview guide written in Kiswahili language (Tanzania native language) tailored to answer study specific objectives. After obtaining permission from the study participants, each interview between a researcher and a study participant was audio recorded using an audio recorder. Each respondent was given a unique identification number for anonymity and also to identify response by the type of informant.

### **3.9 Pretesting of study tools**

The main purpose of a pretesting of study tools was to strengthen the quality of methodology by identifying the problems in advance before the main study(40,45). These problems are identified by assessing the accuracy of the tools selected for the qualitative study. Before the main fieldwork, the instruments were pre-tested to one Cancer patient and one health care

professional who had similar characteristics to the targeted population. The tools were pretested at Bugando Medical Centre and respondents were purposively selected. The pretesting helped to assess estimates time required for each interview and aimed at modifying questions, where no modification was necessary based on outcomes.

The pretesting was also used as part of quality control that helped the researcher to test the validity and reliability of the data collection tool before the main study. The pretesting of the investigation tools was necessary to ensure clarity, suitability, and flow of the questions. It was used to uncover any doubt or ambiguity in questions(40).

### **3.10 Data management**

The informants' information which was recorded in an audio recorder was kept in a confidential place. Informants' names were not addressed in the study findings. Confidentiality of collected data was maintained by using identifiers to protect participants' identification. The audio files from the interview sessions were also renamed using codes to make them anonymous. Data collected in form of audio and the transcriptions were stored in a computer(50). The computer was secured with a password that was limited to the principal investigator.

### **3.11 Trustworthiness**

The trustworthiness of this study is based on the comprehensive flow of the entire study. The credibility and dependability, conformability, transferability, and authenticity of the study findings were achieved by accurate transcription of audio recorded from the experience of the study participants based on trustworthiness definitions as outlined by Cope DG(51).

Credibility refers to the truth of the information from the participants, interpretation, and representation by the researcher. The credibility in this study was archived by ensuring data saturation was reached through recognizing participants are sharing the same information and constantly verifying the source of my data and their interpretation

Dependability is therefore defined as the consistency of data over similar conditions. This was achieved through an audit trail of the data collected.

Conformability ensures that data and interpretations represent the responses of the participants and not the Researcher's biases. This was achieved by providing rich quotes from the participants that depicted respective themes.

Transferability means the results which can be applied to other locations. Through providing sufficient information on the participants and the research context enable the reader to assess the findings' as being acceptable and therefore the transferability was archived.

Lastly, authenticity which refers to the ability to which the researcher expresses the feelings and emotions of the participants'' experience in a faithful manner was achieved by reporting the essential experience of participants through the quotations.

### **3.12 Data analysis procedure**

The audio-recorded interviews were first transcribed verbatim and then translated from Kiswahili to English except for one transcript which was interviewed in English. The interviews transcripts were analyzed using qualitative content analysis with the help of computer software. The qualitative content analysis offers development of themes from the text data inductively as from concrete and specific to general where themes are formed. The inductive derivation of themes is important in capturing the experiences of the participants by coding them where different sub-themes were developed then condensed to main themes(38).

The method is used to analyze data by identifying and organizing relevant themes and sub-themes. The method was beneficial in this research study due to its flexibility. Five steps were used during data analysis with the assistance of NVivo 10 software to identify the themes as adopted from iterative phases of thematic analysis(52,53).

- a) Getting used to the collected data. The transcribed findings were read and read to get an in-depth understanding of what the participants were talking about.
- b) Generating initial codes. The transcripts were read line by line to ensure clarity and commented on the phrases to produce meaningful codes.
- c) Searching for themes. The codes were then combined to come up with general themes. Where some codes were combined to produce sub-themes of the main theme.

- d) Reviewing themes. Themes were reviewed with the assistance of my supervisors. This was done through renaming, merging, and removing some themes. This was done to ensure the quality of the themes. The theme developed was Perception of Cancer patients and Health care professionals in decision making on Biobanking, and sub-themes were; Impact of socio-cultural beliefs and traditions on Biobanking decision making, and Comprehensive information to research participants of Biobanking
- e) Defining and naming themes. The reviewed themes were then modified to enhance clarity for readers to comprehend.

An inductive approach of reasoning was used in data analysis because of the exploratory nature of the study design to assist in identifying emerging themes(50,54).

### **3.13 Ethical Considerations**

Ethical clearance was obtained from the Research and Publication Committee at Muhimbili University of Health and Allied Sciences (MUHAS). Permission to research at Bugando Medical Centre was obtained from the Director General. Written informed consent outlining the purpose of the study, benefits, and risks, voluntariness to or not to participate in a study was obtained directly from each participant.

The vulnerability of cancer patients was taken care of where their participation or refusal to participate was not unduly influenced by the expectation(s), whether justified or not, of benefits associated with participation, or of a reprisal response in the case of refusal to participate. Seriously ill patients were excluded from this study to offer their time for clinical care. For those who were able to participate, confidentiality and privacy were observed during interviews and no names were associated with the data. All Interviews took place in a room with the interviewer and interviewee where the conversations between interviewer and interviewee were not heard by third parties and not in a busy clinic place.



## CHAPTER FOUR

### 4.0 FINDINGS

This chapter presents the findings obtained during the in-depth interview conducted at Bugando Medical Centre, Mwanza. The participants were the cancer patients and health care professionals who were purposively selected to fit the study objectives. However, the chapter will begin by enlisting the demographic characteristics of the participants to allow the reader to know the population of whom the findings were generated. Where HCP and Pt represent health care professionals and cancer patients respectively.

#### 4.1 Socio-demographic characteristics of the study participants

Identifier	Gender	Age	Tribe	Religion	Education
HCP #1	F	30s	Msukuma	RC	Bachelor level
HCP#2	M	30s	Mnyaturu	Christian	Bachelor level
HCP#3	M	54yo	Msukuma	Christian	Master level
HCP#4	F	35yo	Msukuma	RC	Bachelor level
HCP#5	M	58yo	Mkurya	RC	Master level
HCP#6	F	53yo	Mhaya	RC	Master level
HCP#7	F	40yo	Mchaga	Christian	Master level
HCP#8	M	40yo	Msukuma	AICT	Master level
HCP#9	M	60yo	Msukuma	Christian	PhD level
HCP#10	M	44yo	Makonde	Christian	Master level
Pt#1	F	56yo	Mhangaza	PAG	Primary Education
Pt#2	F	45yo	Msukuma	Muslim	Primary Education
Pt#3	M	77yo	Mruri	SDA	Primary Education
Pt#4	F	55yo	Mhangaza	Muslim	Secondary Education

#### 4.2 A table showing developed themes and sub-themes

Themes	Main themes	Sub-themes
#1	Perception of cancer patients and health care professionals in decision making on biobanking	Decision making in cancer patients and health care professionals to donate biospecimen for future research
		Impact of sociocultural beliefs and traditions on biobanking decision making
#2	Perception of cancer patients and health care professionals on privacy in biobanking.	Trust in medical and research ethics in health care research for biobanking
		Comprehensive information to research participants of biobanking
#3	Perception of cancer patients and health care professionals on ownership of stored biospecimens.	Existence of an institution to store and maintain the quality of biospecimens
		The role of the institution is to provide non-profitable biobanking related services to the community
#4	Perception of cancer patients and health care professionals on commercialism in biobanking.	Health benefits related to biobanking
		Compensations in donating biospecimens for future research
		Income generation in biobanking



### **4.3 Perception of Cancer Patients and Health Care Professionals on Biobanking decision making**

#### **4.3.1 Decision making in Cancer patients and Health care professionals to donate biospecimen for future research**

Decision-making in biobanking needs satisfactory information to the research subjects. Research subjects also may have their preferences which need to be considered by researchers before the commencement of the study. However, as part of advancement in technology, biobanking is viewed as a solution for current and future health challenges. This is what the participant said when asked about biobanking; *“This issue I see for myself is a good and fundamental one in our society. ... when we store those human samples, it becomes easier if there is research to happen, it becomes easier to help, ...but through research can be re-diagnosed with another problem other than the one they found and get help. ....so those stored samples can be helpful”* (HCP#1).

Before proceeding to the bioethical issues, the researcher also was interested in the kind of biobanking practices in the study area. When asked at all if there is a kind of biobanking practice, the respondent who works in a medical laboratory at a storage unit agreed that there is a time when researchers do come and ask for stored samples for their research. The quotation below validates the statement; *“Yes, I can say, there are those who have come..., they are many because here there is a college; there are many students who come to do those studies.”* (HCP#3). When asked about the procedures to obtain the permission to use stored specimens, the response was; *“they follow the procedure set for the person doing the research; he gets clearance from college, comes to the institution he gets permission from Director General for him to do it by being given guidance, .... Comes to the laboratory where they are kept....”* (HCP#3).

The inquiry on the importance of biobanking among the participants was done where some participants commented based on health care. The idea of storing biospecimen for research in the future seems very important to solve health challenges in the future. Their perception is based on the fact that full analysis of the stored samples may help respective donors or members

of the community who might suffer the same condition through the discoveries of medications. To certify the statement above, one respondent said; *“because in case it has been found that the sample has been kept for four years, then, found a problem, the donor to should be traced and tell the new results from the sample, if there a cure, to be given; but if not, or maybe someone has died, then others to benefit”* (HCP#7).

When responding to the question of whether they would be willing to have their body specimens being collected and stored for research, cancer patients and health care professionals were willing to participate by donating biospecimens as they perceive to be a good thing. One respondent among the cancer patients said; *“I am ready to participate in the program as long as they take the tissue that does not cause me problems”* (Pt#3). Another patient committed by saying; *“I could approve because I know that, when they do that research even future generations will be helped”* (Pt#4). The results show that Health Care Professionals were ready to participate too. For example, one of the participants, despite conditions to be considered before donating, but the participant showed a willingness by seeking the assurance, saying; *“When I am invited, I can accept but after getting a satisfactory explanation. For example, maybe the sample taken, I should know its limits of use, because you can give the sample and the purpose changed to bad use. But it is better for the person involved there to be informed and to be able to personally analyze the pros and cons”* (HCP#6).

When asked if they can consent for their children who are under 18 years old as they were not eligible for informed consent, the findings show that they were ready to give consent on behalf of their child. And the findings were similar to all groups of participants from cancer patients to health care professionals. But the selections of children to participate in such studies should be followed by complete information as one respondent said; *“as I said at the beginning if I could get in, and I could let my son in, but I must first know what the research is all about, what the privacy is, how my secrets will be kept and what other things will be used later for what use, once I know that, then I will be sure that things will be fine, it will not harm me, then I can participate without a problem”* (HCP#2).

For purpose of improving the procedures for future studies using biospecimens that are collected for diagnostic purposes, it was suggested that the decision-making process for sample collections be modified to respond to the demand of using stored biospecimen as far as biobanking is of concern. The quotation of the participant below strengthens the statement; *“ahaa, my view was to make improvements, eeh, that even if a patient is taken for a diagnosis of the disease he has brought with him, maybe we would go one step further to ensure that s/he is told that, this sample can be used for testing a disease that s/he seems to have brought right now, the second way is that we can go farther and save for future use; so it is an improvement of informed consent so that one can make a choice”* (HCP#10).

#### **4.3.2 Impact of socio-cultural beliefs and traditions on biobanking decision making**

Findings in this sub-theme showed that there were no barriers to participating in the collection of biospecimens that were to be stored for future research. Participants from different religions and tribes were interviewed to assess any biobanking-related barriers. Most of the participants didn't show any barrier for them to participate in biobanking studies. Those who agree with the biobanking activities mentioned helping others with the expected discoveries.

On other hand, some participants had different thoughts on biological samples which are stored and get used for research. Their worries were based on the kinds of trials that might be performed using their biological materials. And here the fact of their point of view is the development of science and technology advancement that probably can remote someone regardless of a physical connection. This is what one participant said concerning the use of biological samples for research; *“The implication is that you may be there for example if your sample is used as a tool then your life is going in-directional, random. Eeh, you are only used you don't know maybe you are used, you are changed, so because science has an uncertainty of use and implications”* (Pt#1).

The findings of this study revealed that most participants whose faith is based on Christianity and Islamic religion are ready to decide to participant in biobanking studies as their contributions to medical science discoveries.

#### **4.4 Perception of Cancer Patients and Health Care Professional on Privacy in Biobanking**

In analyzing findings to address privacy in biobanking, this main theme was divided into two sub-themes which were: Medical trust in a health care setting for biobanking; and comprehensive information to research participants of biobanking.

##### **4.4.1 Trust in medical and research ethics in health care research for biobanking**

The outcomes of this study showed that Cancer patients and Health care professionals trust decisions made by researchers in the medical field. Their responses showed that they don't think if the researcher can do something different from what was supposed to do. For example, one respondent insisted that keeping a medical oath is the solution for researchers to keep their promises not to disclose personal information which is not permissive unless indicated. On responding to the probing question of whether there was any worry related to information disclosure by researchers, responded *"when it comes to ethics, as a caregiver, always have an oath, either a nurse, a doctor, or a pharmacist; we all live under oath. Keeping the patient's secrets, 'I will not give either by force or commanding the patient's secret', so the secret is still kept, you do genetics, you have found that this and this as long as no one came to say that this is my father, or this is my mother, did not ask so there is no need for you to give him answers that will bring him negativity on the journey. We still live as providers live on the oath"* (HCP#7).

The trust to the researchers as stated by cancer patients and health care professionals were, researchers are known to what they are doing, therefore, most of the information was safe. In addressing important issues which are considered for privacy. Participants mentioned that names and other identifiable characters should be kept confidential. But one said; *"but we are confident that when they take them, they will take good care of them, the secrets of customers who have donated samples"* (HCP#8). *"No, I wouldn't worry about that, so far so good a good researcher will not mention the name of the particular a person who donated, even if there is a just a location or just name, I think they won't mention and I won't be worried about that"* (HCP#5).

#### **4.4.2 Comprehensive information to research participants of Biobanking**

Comprehensive information to participants appeared to be an important issue to clear all doubts of disclosure of private information of research participants for biobanking. Participants need to be given complete information at the beginning of the study, that's before donating samples.

This study's findings show that comprehensive information includes knowing the purpose of the study, the procedure of the research, security of personal information collected during data collection, and biological information as part of data analysis. The participants think that if someone was given enough information about what can be done with the sample and likely expected outcomes of later research prepares mindsets to minimize the felt related stigma and discrimination.

When respondents asked what things, which cover comprehensive information are, expressed by protecting the autonomy of the individuals, saying; *“Enough information. I want to know because part of my body will be used. I want to know exactly the aim and what is going to happen, is it beneficial or not, because I may be donating blood for good but found doing something different”*. Continued by saying, *“For example, you are donating to someone doing research but does it have direct benefit either to me or to the community in which I live”* (HCP#6). The participant went further by giving detail on what enough information means and its contribution to removing bias on biobanking research. *“But also, to its use, because you may find someone taking perhaps human organs for doing something different, things that are not ethical and alike. If the information comes out and you have fully understood that I'm participating in research, maybe a trial of the drug, or if a society is involved in something beneficial to the society and me in person as well”* (HCP#6).

#### **4.5 Perception of Cancer Patients and Health Care Professionals on Ownership of Stored Biospecimens**

Biospecimens stored for future research, here referred to as biobanking were proposed to be the property of the institution which stores them. The majority of the approached participants in both groups, that's Cancer patients and health care professionals agreed with the notion that it was a right of the institution to own biospecimen collected for medical purposes, or the aim of

current and future research. Several reasons were mentioned to qualify the institution to be the right owner which is outlined as sub-themes from this main theme as here discussed.

#### **4.5.1 Existence of an institution to store and maintain quality of biospecimens**

Since the institution, lasts long in contrary to individuals, the collected samples which are stored for future research should remain the property of the institution. To justify the statement above, here the participant's quotation stated to express the custodianship during the interview; *“that is, because the institution exists, and will continue to exist, while people will always change. So, the researcher may change, with the one who donated those samples may change, I think the property should remain under the institution”* (HCP#6).

In the findings of this study, the results show that participants are more comfortable if the collected samples will remain the hospital property rather than the individuals, neither donor nor the particular researcher.

#### **4.5.2 The role of the institution to provide non-profitable biobanking related services to the Community**

Most of the medical institutions were perceived as non-profit Centres which offer non-profitable services to the community. Therefore, it is good for them to continue owning the stored specimens. The quotation here justifies the statement where, confidently the respondent said; *“It belongs to the institution. As long as the institution will use it for a public interest, not for profit, will continue to be the property of the respective institute”* (HCP#10). When asked how the donor could benefit from the donated sample, the response was; *“no. because he was exhausted, he had already given enough permission and received services”* (HCP#10).

#### **4.5.3 Functionless of the departed part of the body for biobanking to the individual donor**

Some viewed the donated sample as valueless to their life. Since it is no longer a part of their body, therefore, recommend for no more follow-ups be made by donors. The quotation below certifies the truthiness of the statement when the participant was asked if there was a need for re-contact after donating, then stated that; *“for what purpose that tissue to me?”* (Pt#2), as the follow-up question tells the real owner of the sample, the answer was directly open; *“asset for*

*institute*” (Pt#2). When asked if there could be any concern if the institution raises income from the samples, the respondent said; *“It's just ok, that the institute saved and already I have gained the benefit from the tissue”* (Pt#2).

#### **4.6 Perception of Cancer Patients and Health Care Professionals on Commercialism in Biobanking**

This main theme of Commercialism in biobanking was divided into three sub-themes which were: health benefits related to biobanking; compensations in donating biospecimens for future research; and Income generation in biobanking.

##### **4.6.1 Health benefits related to biobanking**

Biobanking studies are viewed as beneficial to individual health, family, community, and national in whole in present health conditions and future generations. Participants think that, if the researchers will discover the drugs through samples they donated, was satisfactory benefits to them, whether directly to the donor themselves or come to benefit the future generation. When participants were asked if there were issues that motivate them to donate samples for future research, they said for benefit of their coming offspring.

Furthermore, the participants view the improvement of services as one of the benefits to them. In responding to issues motivated to donate samples for future studies, one said that; *“eeeh, it benefits, it benefits because the services will be better improved in the community, eeeh, will benefit and for research to be done it depends on whether the services within the community can be better improved. More people should be healthy to work their development within families, communities and countries in general”* (HCP#8).

##### **4.6.2 Compensations in donating biospecimens for future research**

The findings show that there was no way to compensate someone who donates for research. This should be viewed similar to those who donate to helpless sick people who need a transfusion. Some said that their giving was much more important than being compensated with anything. As the quote of one of the participants said; *“It has value beyond money because if I donate my blood, let say 1 ml, even if you give me money, blood value is more than the monetary*

*value because it is not exchanged for money. ... so, there is no way to say that I will get compensation for the donation. ....So, based on the money, I don't think there is any compensation that one can get help” (HCP#6).*

Biological donations for research that purposely aim to improve medical care are valued in the community. People consider the idea of helping each other as necessary rather than individual benefits that cannot last long. Here is the real example is given by the participant dialogue of payment in biobanking research. *“For example, people who going to donate blood, in the past they were given money but now when you get there you will be given maybe soda but they know you can't compensate someone for using his blood, you paid for it with money” (HCP#6).*

#### **4.6.3 Income generation in biobanking**

Many viewed that, researchers or the institution generating income through stored samples was not a good thing. The notion was perceived as a kind of exploiting innocent people who donated their samples for free. To validate this statement, the quotation below of cancer patients is applied. *“It's wrong, they make mistakes, for example like those who donate blood, I say it for comparison, those who donate blood to be given to patients are doing a good thing, but if that sample is traded or sold for income generation, no, that is not good because even the word of God says “we are given free and give for free”” (Pt#1).*

But on other hand, when asked if they can accept money generated from biobanking activities as partnership gain. They found the idea to be good for both to benefit, that's sample donor and the institution which stores biospecimen.

Unlike cancer patients, health care professionals found no problem for the institution to earn money from the stored biospecimens where the reasons were based on the running costs in storing these biospecimen. This statement can be cemented by the quotation of the participant who said; *“It is a good thing; I see it is not even a bad issue. It is normal for me, to give an example here, there are samples stored but someone who needs it maybe from abroad needs to study on some kind of tissues and it was given. Because the institution can't give it to him for free, because they take care of it. .... remember those people take care of them for certain people.*



*I allow. If someone wants to use them, the institute must charge the related cost to use them and return them for others to use (HCP#1).*

## **CHAPTER FIVE**

### **5.0 DISCUSSION**

This was an exploratory qualitative study aimed to explore biobanking ethical issues among Cancer patients and Health care professionals at Bugando Medical Centre in Mwanza, Tanzania. From this study, we found that biobanking ethical issues were nested within a broad range of issues revealed by Cancer patients and Health care professionals at Bugando Medical Centre in Mwanza, Tanzania.

#### **5.1 Perception of Cancer Patients and Health Care Professionals on Biobanking decision making**

The concept of donating biospecimens for future research rather than clinical or diagnostic purposes was an unfamiliar topic to some participants. But after brief explanations of what does biobanking means, participants understood the concepts of using bodily samples which include blood and tissues for future research to discover medicines and find new ways of treatments.

The findings of this study are in line with studies conducted by Erwin et al in 2013 and Julie H.T. Dang, 2014 which found the awareness of the term biobanking was low among the approached participants. They also in such studies they found that participants failed to understand the concept of biobanking and using genetic materials such as biological samples of blood or tumors for epidemiological research(7,55). The findings show that; when participants receive the information on the aim of storing biospecimens for future research, they showed interest to participate in biobanking.

When discussing the willingness of Cancer Patients and Health Care Professionals to donate biospecimen for future research, most of the participants in this study widely liked the idea. Participants were ready to participate to donate biological samples for future research. Similarly, another study found that the research participants need to be informed about the study in which they may participate and give their consent before they engage(55).

In this study, participants suggested that to reach the decision-making to participate, they should be provided with detailed information on future possible uses of their biospecimens. And there

should be an option to agree or disagree to donate for diagnostic purposes and future research, or donating for diagnosis only but not for future research.

It is widely known worldwide and Tanzania included, that anyone under the age of independent decision making, where in Tanzania is before the age of 18 years old is not mandated to give informed consent to participate in research without legal guardian permission. The findings in this study show that participants can consent for their children to participate in studies involving donating biospecimens for future research. That mean legal guardian can decide on behalf of their children below the age of legal capacity to decide.

However, this study agrees with another study in 2007 that participants such as children, adults with impaired decision-making capacity, and some critically ill patients, cannot decide on their own. This is because they are not old enough to understand the information being conveyed or because they have lost their ability to understand but their legal caretakers can consent on behalf of the study found crucially necessary(56).

Willingness to participate in donating samples for future research was widely discussed within the context of biobanking ethical issues. The goal was to ensure that competent individuals decide whether to participate in a research program or not to participate after receiving appropriate information from the researcher. And this comprehensive information should entail the informed consent to be signed by the subject.

Findings of this study show without doubt that the majority of cancer patients and health care professionals are comfortable donating their biospecimens. The reason behind this is to contribute knowledge to the possible future studies in which their biospecimens will be used. The studies agree with these findings that people participate in biobanking to improve current and future scientific progress. It includes the treatment of people with serious illnesses by making the most efficient use of biospecimens. The other studies conquer these findings as they suggest that biobanks and medical institutions should encourage biospecimen donation for future use in research using a broadly informed consent model in decision making for biobanking use(14,18).

The study also strongly support insurance of the individual's decision to be effectively informed and adaptation of "broad consent" model, which is the agreement for utilization of sample for current, or future studies within a specified framework without the need for re-contacting the patient(12). Therefore, these findings support the use of wide decision-making through broad informed consent to store and use biological samples in future research. And this should be only when the decision of the individual is well informed to his or her capacity of understanding as part of respecting person's autonomy.

Most of the participants show no barriers related to socio-cultural beliefs and tradition on their contributions to biobanking for future studies. Based on bioethics concepts, any decision should be individually based. One of the participants expressed the fear of being used as an object unknowingly and getting changed by science outcomes. This notion is similar to the study by Julie in 2014 where several Hmong participants expressed the idea that the leftover stored tissue can be a mechanism for someone to cause them ill will(7).

Based on these findings, this study shows that biobanking is part of science development and medical advancement; the researchers should consider everyone's perception on biobanking especially in matters of religious beliefs, cultures, and traditions to support everyone in decision making.

## **5.2 Perception of Cancer Patients and Health Care Professional on Privacy in Biobanking**

Biobanking is not only for the individual providing samples but also, communities, the public, and scientists. The goal of biobanking is to collect, store, and disseminate specimens and related data for medical research to improve health care. The processes involved from collection to storage, utilization of samples to the dissemination of findings should be carried out following standard procedures to protect and respect donors' privacy and confidentiality(12). In this study, we found that individuals are more concerned with the security of their information provided during participation and their information following the analysis and dissemination.

Findings in this study show that participants are contented with the care of health care providers and researchers. Participants believe that they cannot misuse the stored biospecimens out of the

stated purposes during collection. And this trust was based on the pledge made by medical graduates during their graduation ceremony, so it is hard for them to deny their oath.

But, on the other hand, the participants were worried too, were expressed concerns of worries on biobanking research for the fear of being changed. These findings agree with the work done by Julie Dang in 2014 where participants were worried about being cloned(7). Trust is critical in determining whether people will participate in, and support biobanking research.

Moreover, Public trust is viewed as a complex idea that is predisposed by different factors including perceptions of donors and health care professionals involved in research to support science development(34).

The majority of the participants in this study suggested that the researchers should inform the donors when something serious is discovered in their samples that relate to their health. The study findings tell us that the donors are to be informed of proceedings on their samples. The information is necessary to reduce fear when the disclosure of their important privacy and confidential information related to their donation is required.

Transparency in biobanking is required to motivate diverse communities in biospecimen contribution for cancer disease research. As discussed by another study, the findings were similar to these research findings that communities need transparency to participate in contributions of their samples for research(26).

Based on these facts, participants in this study were concerned with having comprehensive information before the commencement of the procedures to donate biospecimens for future research. This was widely stated by most participants that they were ready to donate whatever the sample requested. This is when the sample does not affect their health after receiving complete information from the researcher that, their samples will undergo which procedures to make them comfortable. The information to be given included the purpose of the study, procedures the specimen will be likely to undergo, and how their information will be protected.

On other hand, respondents in this study suggested that there should be a limitation of information to be given to the donors following the analysis of their samples. The limitation should be to the only information which affects donors' health such as new diagnosis which can

be managed with the available treatment regimen. Furthermore, the study informs that since the donor's particulars are kept anonymous, bankers and investigators who manage specimen data and or else who have access to it, are obligated legally and ethically to protect data that are considered private information and limit disclosure to the clients.

These research findings agree with the suggestion by Yvonne and Greenspan in 2014 that suggested that the concept of providing research results to participants in studies might affect biobanks in the future(57).

### **5.3 Perception of Cancer Patients and Health Care Professionals on Ownership of Stored Biospecimens**

The discussion on ownership of biobanks is surrounded by many ethical and legal issues among all involved in biobanking. The groups of those involved are three of them, that's subject (donor), the researcher (collector), and the institution (infrastructures) that should be considered. Biobank research collects samples and data of human origin for the current research or that of third parties that termed as future research. Regardless of the absence of guidelines and laws on biobank ownership but some kinds of literature show important unsolved topics for discussion(12).

The basic dialogue on ownership is from the storage of samples to the findings. Most of the participants suggested the institutions should be the owner of the collected samples. This is because the institution store, make decisions from processing, analysis, and reporting and do transportation when needed. Generally, different reasons rose on why the institution qualifies to be the rightful owner. The reasons include the existence of an institution to store and maintain the quality of biospecimens; the role of an institution to provide non-profitable biobanking-related services to the Community; and functionless of departed part of the body to an individual donor.

But the finding does not match directly with the constitute slavery and violates article 4 of the Universal Declaration of Human Rights that 'no person can own another person(58). On the other hand, the report by Coppola et al in 2019 shows an absence of a protocol for ownership of

biological samples, and therefore, the report suggested that biobank ownership or custodianship should base on national and institutional guidelines(12). Therefore, the findings of this study support the option for the country or an institution to set its protocols for ownership of stored biological samples, however, donors may have some degree of control over biological materials as shared ownership. And it should be remembered that they have the opportunity to withdraw from respective research when opting to do so(12). Furthermore, it has been suggested that when biological materials are donated to a biobank, the biobank is anticipated to be a responsible custodian to protect the material and the data. This includes its storage, use, and access while observing the regulations(35). The suggestion is concretely agreed with findings in this study that, since the institution will be responsible for quality control of the specimen, therefore it is supposed to be the right custodian of the stored biospecimen for future research.

#### **5.4 Perception of Cancer Patients and Health Care Professionals on Commercialism in Biobanking**

Commercialization in biobanks raises ethical issues on decision making, privacy, and ownership(37), however maintaining of quality of stored biospecimens, sustainability of storage, sample processing, data management, and data sharing are conversely expensive. As revealed by this study, the costs that can be related to quality maintenance may regard consumables, software, and hardware maintenance when talking to non-human costs. Similarly, some other costs are staffing, service contracts, and expertise to the biobanks.

In this study, it was found that charging related to maintenance of quality to sustain the stored biospecimen activities is not a business, but compensation to an institution to be able to run the services. While some respondents especially health care professionals view payment for biospecimens to an institution as cost-sharing to sustainability, but other participants, more from Cancer patients define the payments as a business.

An exploration of how cancer patients and health care professionals view the benefits related to the donation of biological samples for future research; most of the respondents show that there is no problem for an institution to gain benefits. They insisted that if an institution is diagnosing diseases and discovering treatments from the stored samples, and getting other benefits from the

services it provides, it cannot be viewed as a business. However, the idea of commercialization in the medical field differs among different groups in which there is a need for a better understanding of the term as far as quality care services are concerned. The public understanding of this term is indistinct which gives the opportunities to learn more about the term commercialization in the medical field(35).

As discussing biobanking-related benefits, Cancer patients in this study opted that if they will be compensated for donating biological samples, will be helpful for their health as they can use the money obtained to buy a balanced diet including fruits. This was similar to the findings by Vaught, Kelly, and Hewi in 2009; Meijer, Molas-Gallart, and Masson in 2012; as their studies revealed that the University of hospital-based biobanks are often characterized as not being financially secured to payments but per-project funding streams can compensate and covers the costs(23,34). This shows that compensation in research is not about buying or paying for the donations but showing comfort to the subjects.

As defined earlier, Commercialization in biobanks can also refer to income generation. The income can be from biobank resources, research results derived from biobanks, or products developed from those resources; or public-funded biobanks partnering to, or receiving funds from for-profit entities like biotech companies, pharmaceutical corporations, or the medical device industry(34). However, it is reported that researchers or companies who have access to these public materials may be able to use them in developing commercial value or to claim intellectual property in such products of their research using biological stored materials(36). Erwin et al in 2013 also found that participants can make money off studies through giving biological samples like plasma(55).

As far as income generation is of concern, this study's findings revealed that the issue of financial gains from research results cannot be viewed as exploitation to donors. In one of the publications, it was shown that selling products of the research is not specifically related to the biobank domain but concerns all medical research expenses(35).

The perception of participants in this study varies based on their backgrounds. For example, health care professions regard income gain from research as not a problem, while cancer patients



need information on uses and are involved in benefit sharing. Cancer patients need to be informed before the study begins; if their donation may result in business and know the distributions of the profits.

For the development of medicine and advances in sciences, commercial interests can increase willingness to invest money into a given area of research which can greatly benefit health care and patient groups but in another way can increase the reluctance to share the access of the research materials, notably from donors and affect life-saving innovations(35). The other study suggested that “the only way to prevent such commercial uses and claims would be to permit research access to only governments or nonprofit organizations(36). This statement is concurred by this study which found that public institutions are more trusted compared to individual researchers and private institutions when comes to the security of information and benefit-sharing.

## CHAPTER SIX

### 6.0 CONCLUSION, RECOMMENDATIONS, LIMITATIONS, AND MITIGATION

#### 6.1 Conclusion

1. Comprehensive information for biobanking research includes the details about the aim of the study, the procedures of the study, related benefits, security of personal information recorded at the initial of the study, and the personal information following data analysis. These clarifications are termed as the basics on the expected use of stored biospecimen for future research to influence decision making to the participation in biobanking studies. To use the biological samples collected for diagnosis in future research, the decision-making process including filling out the informed consent forms for different procedures need to be modified to allow donors to opt whether they can allow their samples to be stored for future research or therapeutic only. The clarity of information also will attract parents to consent for their children to participate in biobanking study by considering that there should be a medical indication for sample collections from the children.
2. Public institutes are more trusted for the security of personal information compared to individual researchers and private institutions. But this is accompanied by a professional oath which plays a great role for the health care professionals to maintain professional ethics and conducts. Based on public trust, the institutions which offer nonprofit services like public hospitals and training institutions are proposed by this study to own and be responsible for storage, processing, analyzing, and transferring of biological samples for research.
3. Compensation for participation in biobanking studies is needed to make the subject comfortable and free from distress that might happen during the procedure. This is considered as generating income from stored biospecimen but it doesn't have a barrier in socio-cultural beliefs and traditions. And any financial gain should not be viewed as payments for participation which can exclude the individuals' autonomy. Also, income generated from research products is considered as not business in biobanks but

maintenance costs and motivation to experts. And this is done because biobanking studies are for the community, future benefits, and advancement of medical sciences and not merely individual benefits only.

## **6.2 Recommendation**

Adherence to biobanking ethical issues paves the way to an innovative research field that involves the storage of biospecimens for future research. The attainment will be helpful to the scientific society to extend their expertise to solve community health-related problems.

From the findings in this study, the following are recommended: -

1. An extensive study is recommended to assess the need for the Universities and health care institutions to implement biobank projects to offer the opportunity to Scientists to utilize their potentials in the medical field.
2. The Medical Centres to have a standardized decision-making process that will include options for research and diagnostic purposes. This will permit an extensive analysis of the biospecimen of research interest to advance and improve healthcare services to individuals.
3. Comprehensive information which includes the purpose of the procedure, how the procedure will be undergone, and security of privacy and confidential information generated from the biospecimen and possibility of extensive analysis should outline in a paper, that's 'informed consent form' and get interpreted to the level of individual understanding before undergoing the procedures.
4. The institution to set the protocols or policies for biospecimen collections, storage, analysis, and transfers to be familiar to the members of the institutions and their clients. This also should include the ownership plan and generation of incomes related to the use of stored biospecimen and products of the research.

### **6.3 Study Limitation and Mitigation**

1. This study was predisposed to methodological considerations that necessitate the use of the qualitative methodology in data collection. The data from in-depth interviews were subject to respondent bias from participants. With apprehension participants responded by telling their perception on whether they were ready to grant permission for their children, the question seemed to produce discomfort to participants because they were to explain their interests which might be against their children's will. To address this limitation, the participants were explained to give their perception on the question of concern only where their children have the option to give their assents.
2. To avoid unnecessary disturbance from other people within the institute, the in-depth interviews were carried out in a private room where no one who is not concerned could notice the conversations.
3. The generalization of findings from this study will be limited to the typical population represented by the sample of Cancer patients and health care professionals of different ages, experiences, and levels of education. But, the main purpose of this study was not to produce representative findings, but rich information which can answer the research questions. Some participants who faced difficulty understanding the term biobanking, their responses were influenced by scenarios to widen their understandings.
4. Moreover, there were inadequate research studies on the biobanking ethical issues topic particularly in Tanzania which were the basis for the literature review for my study. Therefore, this study lacks enough references from regional and Tanzania, however, enough references from the global perspective can satisfy the readers.

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## APPENDICES

### **Appendix I: Interview Guides for Health care Professionals English Version**

#### **Perception on decision making on biospecimens for research**

1. How much do you know about biospecimens for research?

Probe: Have you ever donated bodily samples for scientific research?

Probe: If you were invited to participate in a project that includes biospecimens to be processed for studies, how would you feel?

2. How do you feel about people having their blood and other tissue collected and stored for future research? And why?

-To probe for any fear, attitude/religious beliefs.

Probe: How do you feel about the idea of your blood or tissue being stored for a long time?

3. Do you think you would be willing to have your body specimens collected and stored for research? Why or why not?

#### **Perception on Privacy in biobanking research**

4. What do you know about biobanking? **Probe questions:** What have you heard about it? Can you describe what it is? What do you think it is?

Probe: Has anyone ever asked to collect or store your blood or other human tissue for future research?

5. What things concern or worry you or make you less willing about having your blood or other tissue collected and stored for research?

-To probe if they can mention them... What do you think makes collecting blood or other samples terrifying? -If necessary, to probe also for potential concerns: fear, misuse of blood/tissue, loss of privacy, mistrust of biobanks, potential for future discrimination, and security of the data, no benefit, no information

Probe: What would make you more willing to have your blood or other tissue collected and stored for research?

Probe: Do you think it is important for blood and other tissue to be collected for research? Why or why not?

Probe for good things about having your blood and other tissue collected and stored for research?

-If necessary, probe for potential benefits: (helping other people, scientific progress, receiving results from blood tests).

6. If you have children, would you consent to having their blood collected and stored for research? Why or why not?

Probe: How do you think others in your community feel about collecting and storing blood and other tissue for research?

### **Perception on ownership of biobanking**

7. How do you think about ownership of specimens stored for long time for the purpose of research?

Probe for a right of the institution to reuse any time they wish

Also probe on re-consultation for reuse of your samples collected

8. How do you think is the right way of treating biospecimens collected for future research?

9. How do you feel for institution to use the stored biospecimens for any commercial purposes? Probe for individual commercial gaining for donating; Probe on cultural perspectives, religion bases and personal values about the business on biospecimen.

10. Is there anything we didn't discuss about biobanking that you would like to tell us or think we should know?

**Thank you for your participation**

## **Appendix II: Mwongozo wa Hojaji ya Utafiti kwa Wataalamu wa Afya kwa Kiswahili**

Mtazamo juu ya idhini ya kushiriki katika utafiti

1. Je! Unajua nini juu ya sampuli za mwili kwaajili ya utafiti?

**Hoji:** Je! Umewahi kutoa sampuli za mwili kwaajili ya utafiti wa kisayansi?

**Hoji zaidi:** Ikiwa umealikwa kushiriki katika mradi unaojumuisha ukusanyaji wa sampuli za mwili kwaajili yautafiti, ungejisikiaje?

2. Je! Unajisikiaje juu ya watu kukusanywa kwa damu yao na tishu zingine na kuhifadhiwa kwa utafiti wa baadaye? Na kwa nini?

**Hoji kuhusu:-** Kuchunguza hofu yoyote, mtazamo / imani ya kidini.

**Hoji zaidi:** Unajisikiaje juu ya wazo la damu yako au tishu kuhifadhiwa kwa muda mrefu?

3. Je! Unafikiri ungekuwa tayari kutoa sampuli za mwili wako kukusanywa na kuhifadhiwa kwa utafiti? Kwa nini au kwa nini siyo?

### **Mtazamo juu ya faragha katika tafiti za biobanking**

4. Je! Unajua nini juu ya Uhifadhi wa sampuli za mwili kwaajili ya Utafiti? **Hoji zaidi:** Je! Umesikia nini juu yake? Je! Unaweza kuelezea ni nini? Unafikiri ni nini?

**Hoji kuhusu:** Kuna mtu yeyote amewahi kukuliza kukusanya au kuhifadhi damu yako au tishu nyingine za binadamu kwaajili ya utafiti wa baadaye?

5. Ni mambo gani unayoyajali au kukupa wasiwasi au kusita juu ya kukusanywa na kuhifadhiwa kwa damu yako au tishu nyingine kwa ajili ya utafiti? **Kuchunguza ikiwa aweza kuyataja:**Je! Unafikiri ni kwanini hufanya kukusanya damu au sampuli zingine za mwili wako kukutishe? **-Ikibidi, uliza pia** kuhusu wasiwasi unaowezekana; hofu, matumizi mabaya ya damu / tishu?, kupoteza faragha yako?, kutokuaminika kwa taasisi za utafiti?, uwezekano wa unyanyapaa wa baadaye, na usalama wa taarifa zako? Kukosekana kwa taarifa sahihi?

**Hoji pia:** Ni nini kitakachokufanya uwe tayari zaidi kuwa na damu yako au tishu nyingine zikusanywe na kuhifadhiwa kwaajili ya utafiti?

**Hoji pia:** Unafikiri ni muhimu kwa damu na tishu nyingine kukusanywa kwa utafiti? Kwa nini au kwa nini siyo?

**Hoji pia** ikiwa Kuna Jambo lolote zuri juu ya kukusanywa na kuhifadhiwa kwa damu yako na tishu zingine na kuhifadhiwa kwaajili ya tafiti za baadaye. -**Ikibidi, hoji zaidi** kama ni: (kusaidia watu wengine?, maendeleo ya kisayansi?, kupokea matokeo kutoka kwa sampuli zako?)

6. Ikiwa una watoto, je! Utakubali damu yao ikusanywe na kuhifadhiwa kwaajili ya utafiti? Kwa nini au kwa nini siyo?

**Hoji:** Unafikiri wengine katika jamii yako wanahisije kuhusu kukusanya na kuhifadhi damu na tishu zingine kwaajili ya tafiti za baadaye?

### **Mtazamo juu ya umiliki wa biobanking**

7. Je! Unafikiriaje juu ya umiliki wa sampulizilizohifadhiwa kwa muda mrefu kwa lengo la utafiti? Je! unadhani ni haki ya taasisi hiyo ya utafiti kutumia tena wakati wowote wanaotaka?

**Uliza pia:** Hisia juu ya kuombwa ridhaa tena kwaajili ya utumiaji wa sampuli zake zilizohifadhiwa.

8. Je! Unadhani ni njia gani sahihi ya kushughulika nasampuli zilizokusanywa kwa utafiti wa baadaye?
9. Je! unahisi vipi kuhusu taasisi kutumia sampuli zinazohifadhiwa kibiashara? Unamtazamo gani kuhusu kujipatia fedha kutokana na kutoa sampuli kwaajili tafiti. Vipii kuhusu mila na desturi, au imani yako juu ya biashara inayohusiana na sampuli?
10. Je, kuna jambo lolote ambalo hatutajadili kuhusu biobanking ambalo ungependa kuniambia au unafikiri tungelijua?

**Ahsante kwa ushirikiano wako**

### **Appendix III: Interview guide for Cancer Patients English version**

#### **Perception on decision making in biospecimens for research**

1. How much do you know about biospecimens for research?
2. How do you feel about people having their blood and other tissue collected and stored for future research? And why?
3. Do you think you would be willing to have your body specimens collected and stored for research? Why or why not?

#### **Perception on Privacy in biobanking research**

4. What do you know about biobanking? **Probe questions:** What have you heard about it? Can you describe what it is? What do you think it is?
5. What things concern or worry you or make you less willing about having your blood or other tissue collected and stored for research?
6. If you have children, would you consent to having their blood collected and stored for research? Why or why not?

Probe: How do you think others in your community feel about collecting and storing blood and other tissue for research?

#### **Perception on ownership of biobanking**

7. How do you think about ownership of specimens stored for long time for the purpose of research?
8. How do you think is the right way of treating biospecimens collected for future research?
9. How do you feel for institution to use the stored biospecimens for any commercial purposes? Probe for individual commercial gaining for donating; Probe on cultural perspectives, religion bases and personal values about the business on biospecimen.
10. Is there anything we didn't discuss about biobanking that you would like to tell us or think we should know?

**Thank you for your participation**

## **Appendix IV: Mwongozowa Hojaji ya Utafiti kwaajili ya Wagonjwa wa Saratani kwa Kiswahili**

### **Mtazamo juu ya idhini ya kushiriki katika utafiti**

1. Je! Unajua nini juu ya sampuli za mwili kwaajili ya utafiti?
2. Je! Unajisikiaje juu ya watu kukusanywa kwa damu yao na tishu zingine na kuhifadhiwa kwa utafiti wa baadaye?
3. Je! Unafikiri ungekuwa tayari kutoa sampuli za mwili wako kukusanywa na kuhifadhiwa kwa utafiti? Kwa nini au kwa nini siyo?

### **Mtazamo juu ya faragha katika tafiti za biobanking**

4. Je! Unajua nini juu ya Uhifadhi wa sampuli za mwili kwaajili ya Utafiti?
5. Ni mambo gani unayoyajali au kukupa wasiwasi au kusita juu ya kukusanywa na kuhifadhiwa kwa damu yako au tishu nyingine kwa ajili ya utafiti?
6. Ikiwa una watoto, je! Utakubali damu yao ikusanywe na kuhifadhiwa kwaajili ya utafiti? Kwa nini au kwa nini siyo?

### **Mtazamo juu ya umiliki wa biobanking**

7. Je! Unafikiriaje juu ya umiliki wa sampuli zilizohifadhiwa kwa muda mrefu kwa lengo la utafiti?
8. Je! Unadhani ni njia gani sahihi ya kushughulika nasampuli zilizokusanywa kwa utafiti wa baadaye?
9. Je! unahisi vipi kuhusu taasisi kutumia sampuli zinazohifadhiwa kibiashara? Unamtazamo gani kuhusu kujipatia fedha kutokana na kutoa sampuli kwaajili tafiti. Vipii kuhusu mila na desturi, au imani yako juu ya biashara inayohusiana na sampuli?
10. Je, kuna jambo lolote ambalo hatutajadili kuhusu biobanking ambalo ungependa kuniambia au unafikiri tungelijua?

### **Ahsante kwa ushirikiano wako**

**Appendix V: Consent form English Version****Informed Consent form for Participating in a research study**

Greetings! My name is **Ibrahim William Mgoo**; I am studying Master of Bioethics (MBE), at Muhimbili University of Health and Allied Sciences (MUHAS). I am doing a study on Exploration of Biobanking Ethical Issues among Cancer Patients and Health Care Professionals at Bugando Medical Centre.

**The aim of the Study**

This study aims to explore the ethical issues among Cancer Patients and Health Care Professionals at Bugando Medical Centre which may hinder participation in biobanking research.

**Procedure**

I would like to invite you to participate in this study. You have been selected to participate because you have experience in biospecimens collections for medical and or research purposes. I hope that you will be willing to share your information with the research team. The information will be collected using interview guides, and the conversations will be recorded using digital voice recorder and some points will be noted in the note book. If you have questions about this research, please do not hesitate to ask or contact the research team at any time.

**Confidentiality**

All information and issues relating to your participation in the study will be treated confidential, no unauthorized person who will have access to your information. Note that, to protect your confidentiality, your names will not appear in the written copy of the discussion anonymous.

**Right to Refuse or Withdraw**

Your participation in this study is voluntary, but I encourage you to participate because your views have great importance in this study and for the facilitating future research at MUHAS, BMC and Tanzania at large. However, you will be allowed to withdraw at any time you wish to do so.

**Benefits**



There are no direct benefits; however, the findings of this research might benefit the community through the expected outcomes.

**Risks**

There will be no risk because your information is anonymous and confidential and there is no way of linking you with the discussion held.

**Whom to Contact**

In case of any inquiry please contact the principal investigator, **Ibrahim William Mgoo (MBE)** from MUHAS, P. O. BOX 65001, Dar - Es - Salaam, mobile number 0759-935-505. Dr. Renatha Joseph, Head, Bioethics Department, or If you ever have questions about this study you may call, the Chairperson of the Research and Publications Committee, MUHAS, P.O. Box 65001, Dar – Es- Salaam -Tanzania, Tel +2552150302-6.

I ..... have read the contents of this form and understand. My questions have been answered. I agree to participate in this study.

Signature of participant..... Date.....

Signature of researcher/research assistant .....

**Appendix VI: Fomu ya Idhini toleo la Kiswahili**

**Fomu ya idhini ya Kushiriki katika utafiti.**

Salamu Salamu!

Jina langu ni **Ibrahim William Mgoo**; ambaye ni Mwanafunzi wa Shahada ya Uzamili katika Chuo Kikuu cha Afya na Sayansi Shirikishi Muhimbili (MUHAS). Ninafanya utafiti juu ya Maswala ya Maadili kwenye matumizi ya Sampuli

### **Lengo la Utafiti**

Utafiti huu unakusudia kuchunguza maswala ya kimaadili kwa Wagonjwa wa Saratani na Wataalam wa Huduma ya Afya katika Hospitali ya Kanda Bugando ambayo yanaweza kuzuia ushiriki katika tafiti zinazotokana na Sampuli zilizohifadhiwa.

### **Utaratibu**

Ningependa

kukualika kushiriki katika utafiti huu. Wewe umechaguliwa kushiriki kwa sababu una uzoefu katika uchangiaji/uchakataji wa sampuli kwa madhumuni ya matibabu na au utafiti. Natumaini kuwa utakuwa tayari kushirikisha maoni yako kwa timu ya utafiti.

Maoni haya yatakusanywa kwa kutumia miongozo ya mahojiano, na mazungumzo yatanakiliwa kwa kutumia kinasauti na vidokezo vingine vitanakiliwa katika kijitabu cha maandishi.

Ikiwa una maswali juu ya utafiti huu, tafadhali usisite kuuliza au wasiliana na timu ya utafiti wakati wowote.

### **Usiri**

Habari na maswala yote yanayohusiana na ushiriki wako katika utafiti yatashughulikiwa kama siri, hakuna mtu asiyeidhinishwa ambaye atapata habari yako. Kumbuka kuwa, ili kulinda usiri wako, majina yako hayataonekana kwenye nakala iliyoandikwa ya majadiliano.

### **Haki ya Kukataa au Kujiandoa**

Ushiriki wako katika utafiti huu ni wa hiari, lakini ninakuhimiza kushiriki kwa sababu maoni yako yana umuhimu mkubwa katika utafiti huu na kwa kuwezesha utafiti wa siku za usoni

kwa chuo cha MUHAS, BMC na Tanzania kwa ujumla. Walakini, utaruhusiwa kujiondoa wakati wowote unapotaka kufanya hivyo.

### **Faida**

Hakuna faida za moja kwa moja, hata hivyo, matokeo ya tafiti hizi yanaweza kunufaisha jamii kupitia matokeo yanayotarajiwa.

### **Hatari**

Hakutakuwa na hatari kwa sababu habari zako ni siri na hakuna njia ya kukuunganisha na majadiliano yaliyofanyika.

### **Mawasiliano**

Tafadhali wasiliana na Mtafiti Mkuu, ambaye ni **Ibrahim William Mgoo** (MBE) kutoka wa MUHAS, P.O Box 65001, Dar - Es - Salaam, nambari ya simu ya 0759-935-505. Au Dk. Renatha Joseph, ambaye ni Mkuu wa Idara. Au ikiwa una hoja yoyote juu ya utafiti huu unaweza kupiga simu kwa Mwenyekiti wa Kamati ya Utafiti na Uchapishaji, wa MUHAS, S.L.P 65001, Dar - Es- Salaam -Tanzania, Simu + 2552150302-6.

Mimi ..... nimesoma yaliyomo katika fomu hii na kuelewa. Maswali yangu yamejibiwa. Ninakubali kushiriki katika utafiti huu.

Saini ya mshiriki

.....

Saini ya Mtafiti / Msaidizi wa utafiti .....

Ahsante sana

## Appendix VII: Ethical Clearance



**UNITED REPUBLIC OF TANZANIA**  
 MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY  
 MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES  
**OFFICE OF THE DIRECTOR - RESEARCH AND  
 PUBLICATIONS**



Ref. No.DA.282/298/01.C/

Date: 22/04/2021

MUHAS-REC-04-2021-569  
 Ibrahim William Mgoo  
 School of Public Health and Social Sciences  
 MUHAS

**RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED: AN  
 EXPLORATION OF BIOBANKING ETHICAL ISSUES AMONG CANCER  
 PATIENTS AND HEALTH CARE PROFESSIONALS AT BUGANDO  
 MEDICAL CENTRE, MWANZA**

Reference is made to the above heading.

I am pleased to inform you that the Chairman has on behalf of the University Senate, approved ethical clearance of the above-mentioned study, on recommendations of the Senate Research and Publications Committee meeting accordance with MUHAS research policy and Tanzania regulations governing human and animal subjects research.

APPROVAL DATE: 22/04/2021  
 EXPIRATION DATE OF APPROVAL: 22/04/2022

**STUDY DESCRIPTION:**

**Purpose:**

The purpose of this exploratory study is to explore ethical issues of biobanking researches among Cancer Patients and Health Care Professionals at Bugando Medical Centre, Mwanza.

The approved protocol and procedures for this study is attached and stamped with this letter, and can be found in the link provided: <https://irb.muhas.ac.tz/storage/Certificates/Certificate%20-%20487.pdf> and in the MUHAS archives.

## Appendix VIII: Introduction Letter



**UNITED REPUBLIC OF TANZANIA**  
 MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY  
 MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES  
**OFFICE OF THE DIRECTOR – POSTGRADUATE**  
**STUDIES**



Ref. No. HD/MUH/T.525/2019

22<sup>nd</sup> April, 2021

DIRECTOR GENERAL,  
 BUGANDO MEDICAL CENTRE,  
 P.O BOX 1370,  
 MWANZA.

**Re: INTRODUCTION LETTER**

The bearer of this letter is Ibrahim William Mgoo (HD/MUH/T.525/2019), a student at Muhimbili University of Health and Allied Sciences (MUHAS) pursuing Master of Bioethics.

As part of his studies he intends to do a study titled: **“An Exploration of Biobanking Ethical Issues Among Cancer Patients And Health Care Professionals At Bugando Medical Centre, Mwanza”**.

The research has been approved by the Chairman of University Senate.


Kindly provide him with the necessary assistance to facilitate the conduct of his research.

We thank you for your cooperation.

  
 Ms. *Victoria Mwanilwa*  
 For: **DIRECTOR, POSTGRADUATE STUDIES**

cc: Dean, School of Public Health and Socia Sciences, **MUHAS**  
 cc: Ibrahim William Mgoo

## Appendix IX: Permission Letter



**BUGANDO MEDICAL CENTRE**

Consultant and Teaching Hospital

*Department of:* **ADMINISTRATION**

*Our Ref:* **P/F NO. 4644/80**

*Date:* **28/04/2021**

**P.O. Box 1370**  
**Mwanza, Tanzania**  
**Telephones 2540610/5**  
**2500513**  
**Fax: 255 – 028 – 2500799**  
 E-mail: [hospbugando@gmail.com](mailto:hospbugando@gmail.com)

Ibrahim William Mgoo  
 Bugando Medical Centre  
 P.O. Box 1370  
**MWANZA**

**RE: PERMISSION TO CONDUCT RESEARCH AT  
 BUGANDO MEDICAL CENTRE**

Refer to the caption above.

This is to inform you that you have been allowed to conduct Study Titled: **'An Exploration of Biobanking Ethical Issue among Cancer Patients and Health Care Professionals at Bugando Medical Centre'**

Your are welcome,

  
 Abbas J. Malindo

**For; DIRECTOR GENERAL**



**Copy to;** Head of Department -  
**Bugando Medical Centre**