

**EXPLORING KNOWLEDGE AND ETHICAL ISSUES ASSOCIATED WITH  
STEM CELL RESEARCH AMONG HEALTH WORKERS AND  
RESEARCHERS IN AMPATH, KENYA.**

**BY**

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**DECLARATION**

**Declaration by the candidate**

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## **DEDICATION**

To the relentless pursuit of medical advancements that can improve the quality of life for those afflicted by chronic diseases and ailments. To the researchers tirelessly striving to unravel the complexities of these conditions and find effective treatments, your unwavering commitment is a beacon of hope for countless individuals and their loved ones.

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You all contribute to my success!

**God bless you all.**

**LIST OF ABBREVIATIONS AND ACRONYMS**

|                  |  |
|------------------|--|
| <b>AMPATH</b>    | Academic Model Providing Access to Healthcare                |
| <b>CHS</b>       | Centre for Health Solutions                                  |
| <b>ES cells</b>  | Embryonic Stem Cells   |
| <b>HES cells</b> | Human Embryonic Stem Cells                                   |
| <b>IPS cells</b> | Induced Pluripotent Stem Cells                               |
| <b>IREC</b>      | Institution Research Ethics Committee                        |
| <b>IVF</b>       | In-vitro Fertilization                                       |
| <b>KAVI-ICR</b>  | Kenya AIDS Vaccine Initiative Institute of Clinical Research |
| <b>KEMRI</b>     | Kenya Medical Research Institute                             |
| <b>KIIs</b>      | Key In-depth Interviews                                      |
| <b>MTRH</b>      | Moi Teaching and Referral Hospital                           |
| <b>MUCHS</b>     | Moi University College of Health Sciences                    |
| <b>SCR</b>       | Stem Cell Research   |
| <b>SSA</b>       | Sub-Saharan Africa.  |

## OPERATIONAL DEFINITION OF TERMS

**Embryo Protection:** This ethical issue includes discussing the use of embryos in stem cell research, examining the embryo's moral status, the rights of potential future persons, and the ethical consequences of using or damaging embryos for scientific experiments.

**Human embryonic stem cell:** Human pluripotent stem cells are also known as human embryonic stem cells. These cells, produced from human embryos or human fetal tissue, have the ability to replicate themselves and are capable of developing into cells and tissues of the three basic germ layers.

**Induced pluripotent stem (iPS) cells:** These cells are created in the laboratory by transforming tissue-specific cells, such as skin cells, into cells that exhibit the characteristics of embryonic stem cells. Induced pluripotent stem (IPS) cells play a crucial role in facilitating scientists' understanding of normal development, as well as the initiation and advancement of diseases. Additionally, they are valuable for the advancement and experimentation of novel pharmaceuticals and treatments.

**Informed Consent:** This essentially means that people should be fully aware of all the potential risks and benefits of using stem cells as research material and should freely consent to participate without any coercion or undue influence.

**Pluripotent stem cells (PSCs):** They consist of Induced pluripotent stem cells (iPSCs) and embryonic stem cells (ESCs). These cells possess the capacity for perpetual self-renewal and can transform into nearly any type of cell when subjected to the appropriate milieu.

**Stem cell:** This is a pluripotent cell that has the ability to develop into certain cell types or undergo division to generate progeny cells.

**Tissue-specific stem cells:** Somatic or adult stem cells, also known as tissue-specific stem cells, are more differentiated or specialized compared to embryonic stem cells. Usually, these stem cells have the ability to produce several types of cells that are particular to the tissue or organ they reside in.

## ABSTRACT

**Background:** Stem cell research (SCR) holds immense transformative potential for regenerative medicine, yet its responsible progression is critically dependent on healthcare professionals' knowledge and the resolution of complex ethical issues. In Kenya, where SCR is nascent and a formal regulatory framework is under development, understanding of perspectives on SCR among frontline health workers is imperative. This study explored the level of knowledge and the ethical concerns regarding SCR among health workers at AMPATH, Kenya.

**Methods:** An exploratory, cross-sectional mixed-methods design was employed, guided by the Theory of Planned Behavior (TPB). The quantitative sample included **161** health workers (doctors and nurses) selected via stratified random sampling from Academic Model Providing Access to Healthcare (AMPATH) Moi Teaching and Referral Hospital (MTRH) and the College of Health Sciences (CHS). A purposive sample of **15 experts** (medical scientists, social scientists, and IREC members) participated in in-depth interviews. Quantitative data were analyzed using descriptive and inferential statistics (chi tests), and qualitative data underwent thematic analysis.

**Results:** The study revealed significant knowledge gaps. Only 28.6% (46/161) of participants demonstrated good knowledge of SCR, while 49.1% (79/161) had moderate knowledge, and 22.3% (36/161) had poor knowledge. Knowledge level was significantly associated with professional cadre ( $p < 0.001$ ), age ( $p < 0.001$ ), and education level ( $p = 0.004$ ). Nurses constituted the largest group (46.6%) of respondents. Qualitative analysis uncovered profound ethical concerns, crystallizing around three themes: (1) strong opposition to human embryo use, rooted in the belief that life begins at conception; (2) concerns about social justice and exploitation of vulnerable donors; and (3) critiques of current informed consent practices in biobanking.

**Conclusion and Recommendations:** There is a critical knowledge deficit regarding SCR among AMPATH, MTRH and CHS health workers, particularly among junior staff, which could impede informed patient counseling and ethical protocol development. Ethical concerns, especially regarding embryonic sources and consent, are deep-seated and reflect a complex interplay between professional role and religious beliefs. To advance SCR responsibly, we recommend: (1) implementing targeted, cadre-specific educational programs; (2) facilitating inclusive multi-stakeholder dialogues to address ethical conflicts; and (3) urgently enacting a comprehensive legal framework to govern SCR and ensure ethical compliance in Kenya.

**Keywords:** Stem cell research, Knowledge, Ethical issues, Health workers, Theory of Planned Behavior, Kenya.

**Key Words:** Stem cell research, Knowledge, Ethical issues, stem cells

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## CHAPTER ONE

### 1.0 INTRODUCTION

#### 1.1 Background of the study

Stem cell research (SCR) stands at the forefront of regenerative medicine, heralding a paradigm shift in the understanding and treatment of degenerative diseases, genetic disorders, and traumatic injuries. Globally, it represents a frontier of scientific innovation with the potential to redefine therapeutic landscapes. However, its translation from laboratory bench to clinical bedside is intricately woven with complex ethical, legal, and social issues. This study seeks to navigate this complex terrain by exploring the knowledge and ethical issues associated with SCR among doctors, nurses, and researchers in Eldoret, Kenya, a critical step towards its responsible integration into the Kenyan healthcare system.

#### 1.1 Background of the Study

Globally, it is well-established that stem cells, with their unique properties of self-renewal and differentiation, offer unprecedented opportunities for understanding disease pathogenesis and developing novel cell-based therapies (Blau & Daley, 2019; Yamanaka, 2020). The therapeutic potential spans a range of conditions from Parkinson's disease and diabetes to spinal cord injuries and hematological malignancies (Barreca et al., 2020; Omole & Fakoya, 2018).

Concurrently, the ethical debates surrounding SCR, particularly the use of human embryonic stem cells (hESCs), are deeply entrenched. The central conflict pits the imperative to alleviate human suffering against the moral status of the human embryo, a debate influenced by diverse religious, philosophical, and cultural perspectives (Anioke, 2020; Sivaraman & Noor, 2016). Studies from various countries, including

Malaysia, have demonstrated that healthcare professionals often possess moderate to low knowledge about SCR, and their attitudes are significantly shaped by their religious and ethical beliefs (Lye et al., 2015; Tork, 2017).

The stem cell research landscape in Kenya is evolving rapidly. While a 2014 report indicated no documented SCR in the country (KEMRI Bioethics Review, 2014), a pivotal shift occurred in 2023 with the announcement of the establishment of a dedicated stem cell research laboratory at the Kenya Medical Research Institute (KEMRI), described as the first of its kind in sub-Saharan Africa (Ombogo, 2023). This demonstrates a significant national investment in this frontier technology. Although AMPATH has established extensive research infrastructure and conducts a wide range of biomedical and clinical studies, there is currently no publicly documented or formally established stem cell research program within AMPATH, with most related activities remaining limited to exploratory, laboratory-based, or externally collaborative initiatives. However, this rapid infrastructural development has outpaced the understanding of the knowledge and ethical perspectives of the key professionals who will be central to its operation, creating a critical research gap this study aims to fill.

## **1.2 Problem Statement**

Despite these advancements, a significant chasm exists between the rapid pace of scientific introduction and the understanding and preparedness of the key stakeholders who will be central to its implementation healthcare professionals and researchers. The specific nuances of knowledge, attitudes, and ethical concerns among Kenyan doctors, nurses, and researchers remain largely unmapped. Critical questions are unanswered: What is the actual level of knowledge about SCR sources, applications,

and limitations among the Kenyan medical fraternity?· How do deeply held religious beliefs (e.g., the constitutional view that life begins at conception) and cultural values influence the acceptance of different stem cell sources, especially embryos?· What are the specific ethical apprehensions regarding informed consent, bio-banking, and equitable access in the Kenyan socio-economic context?

The absence of this localized evidence creates a "knowledge-to-practice" vacuum. Without understanding the perspectives of these front-line actors, the rollout of SCR in Kenya risks being met with resistance, misapplication, or ethical missteps that could undermine public trust and hinder scientific progress.

### **1.3 Justification**

It is necessary to conduct this research to generate empirical, context-specific data that can inform the responsible development of SCR in Kenya. Relying on data from other regions is insufficient, as ethical perceptions and knowledge bases are not universally transferable. The findings will provide crucial evidence to policymakers at institutions like NACOSTI and the Ministry of Health, enabling them to draft robust, culturally sensitive ethical guidelines and legal frameworks that are not merely imported but are rooted in the realities of Kenyan stakeholder concerns. To Guide Education and Capacity Building by Identifying knowledge gaps allowing the design of targeted educational programs and continuous professional development curricula for healthcare workers. This empowers them to become informed practitioners and reliable sources of information for patients, thereby bridging the current knowledge deficit. To Ensure Ethical and Equitable Translation by foregrounding the ethical concerns of local professionals, this study provides an early warning system for potential social injustices, such as the exploitation of vulnerable populations or the creation of therapies only accessible to the wealthy. It ensures that the discourse on

SCR in Kenya is not only about scientific possibility but also about social justice and ethical integrity.

In summary, as Kenya strides into the era of regenerative medicine, this study moves beyond merely documenting awareness. It seeks to actively shape the ethical and intellectual foundation upon which stem cell research will be built in the country, ensuring that its advancement is both scientifically sound and socially responsible.

## **1.4 Objectives**

### **1.4.1 Main Objective**

The study aimed to explore knowledge and ethical concerns surrounding stem cell research among health workers in AMPATH, MTRH and CHS in Eldoret town.

### **1.4.2 Specific Objectives**

1. To describe level of knowledge on stem cell research among health workers in AMPATH, MTRH and CHS in Eldoret town.
2. To examine the factors influencing knowledge levels and attitudes on stem cell research among doctors, nurses and researchers in AMPATH, MTRH and CHS in Eldoret town
3. To explore ethical concerns on stem cell research among health workers in AMPATH, MTRH and CHS in Eldoret town.

## **1.5. Research hypothesis**

This study was guided by the overarching hypothesis that: "Among health workers at AMPATH, Kenya, a higher level of knowledge about stem cell research is a significant predictor of more permissive attitudes towards its ethical acceptance, but this relationship is moderated by strong religious beliefs and specific professional roles."

The theory can be tested using regression analysis, where ethical acceptance is the dependent variable, and knowledge level, religious beliefs, and professional role are independent variables. It specifies the direction ("higher knowledge" leads to "more permissive attitudes") and introduces key moderating variables ("religious beliefs," "professional roles"). It integrates the conceptual framework by linking the "KNOWLEDGE" and "DEMOGRAPHICS" (religion, cadre) boxes to the "ETHICAL ISSUES" box and it acknowledges that knowledge alone may not be enough to overcome deeply held religious or role-based convictions, which is a classic social science insight.

### **1.6 Significance of the Study**

The significance of this research is reframed from merely assessing general knowledge to critically examining the ethical landscape that will determine the legitimate and equitable integration of stem cell research (SCR) into Kenya's health system. While understanding knowledge levels is important, this study's primary contribution lies in its timely investigation of the profound ethical dilemmas that precede and will ultimately govern clinical application. Its significance is threefold, speaking directly to policy, professional practice, and social justice.

Currently, Kenya operates in a significant regulatory vacuum regarding SCR. While the Health Act, 2017 and its subsequent amendments provide general guidance on biomedical research and ethical oversight, they do not specifically regulate stem cell research, underscoring the need for context-specific regulatory frameworks in Kenya. This study provides the indispensable empirical evidence needed to move from abstract policy discussion to concrete, context-sensitive regulation. By documenting the specific ethical concerns of Kenyan doctors, nurses, and researchers the very

individuals who will oversee and implement these technologies this research offers a critical evidence base. It answers urgent questions: What are the red lines for Kenyan medical professionals regarding embryo use? What consent models are deemed trustworthy for bio-banking? The findings will empower regulatory bodies like NACOSTI and the Ministry of Health to craft policies that are not only scientifically sound but also ethically legitimate and socially acceptable within the Kenyan context, thereby building essential public and professional trust.

As SCR transitions from research to potential therapy, healthcare professionals will become the primary interface for patient inquiries and decision-making. This study shifts the focus from their role as mere conduits of technical information to their crucial function as ethical navigators. The findings reveal the specific ethical tensions (e.g., the conflict between the potential to alleviate suffering and the moral status of the embryo) that clinicians themselves grapple with. By bringing these conflicts to the fore, the study underscores the urgent need for targeted ethics training and support systems. It will inform the development of continuing education programs that equip doctors and nurses not just with facts about SCR, but with the ethical reasoning skills needed to guide patients through complex choices, uphold informed consent in its truest sense, and advocate for their patients' best interests within a morally contested field.

A key ethical finding of this study is the palpable concern among participants that SCR could become a tool of inequity, benefiting only the affluent while exploiting vulnerable donors. This preemptive identification of a social justice risk is one of the study's most critical contributions. By highlighting these concerns before SCR becomes widespread, the study provides a vital opportunity to "bake in" equity from

the very beginning. It serves as a stark warning to policymakers, researchers, and health institutions to proactively address issues of fair access, community engagement, and benefit-sharing. It argues that the ethical evaluation of SCR in Kenya is incomplete without considering its potential to exacerbate existing health disparities. Therefore, this research is significant for ensuring that the advancement of this cutting-edge science in Kenya is guided by a commitment to justice, protecting against the commodification of human biological materials and ensuring that the benefits of scientific progress are distributed fairly across society.

In conclusion, this study's significance transcends the assessment of knowledge gaps. It positions itself as an essential, foundational inquiry into the ethical soul of a nascent medical technology in Kenya. By giving voice to the ethical apprehensions and values of key stakeholders, it provides the necessary compass to navigate the complex moral terrain of SCR, ensuring that its development in Kenya is not only technologically advanced but also ethically responsible, culturally resonant, and fundamentally just.

## CHAPTER TWO

### 2.0 LITERATURE REVIEW

#### 2.1 Definition of stem cells

Stem cells are uniquely identified cells that can form all the different cell types that makeup tissues in the human body. These tissues consist of highly specialized cells that emerged from the stem cell pool that formed soon after the fertilization process, as Hassani et al. (2019) pointed out. At each stage of human development, stem cells are used to repair tissue damage and replace cells that are lost through normal daily wear and tear, such as skin cells, hair, blood, and the lining of our intestines. According to Odibaa et al. (2019), stem cells have the property of self-rollback, i.e., the ability to divide and create other stem cells, as well as the ability to change and create human organs and body tissues.

##### 2.1.1 Tissue specific stem cells

Tissue-specific, or adult stem cells, are the undifferentiated cells of tissue origin in the body. However, unlike pluripotent stem cells, they have limited differentiation potential as they produce only cell types of the tissue or organ of origin. These cells therefore have the overall responsibility of regulating and repairing the tissue, including a role in homeostasis. For instance, multipotent stem cells in the bone marrow differentiate into different kinds of blood cells, and neural stem cells in the brain generate neurons and glial cells. Adult tissue-specific stem cells are essential in disease treatments as they help with tissue repair and regeneration issues without the drawbacks of embryonic stem cells (Barreca et al., 2020).

### **2.1.2 Embryonic stem cells**

Embryonic stem cells have been obtained from various species, including humans, and are characterized as "pluripotent," indicating their ability to produce all the diverse cell types found in the body. Embryonic stem cells can be derived from the blastocyst, an early developmental stage characterized by a mostly hollow sphere of around 150-200 cells, which is scarcely discernible without magnification. Currently, there are no organs or blood present. Only a "inner cell mass" exists, which can be used to derive embryonic stem cells. Human embryonic stem cells are primarily obtained from surplus blastocysts generated during in-vitro fertilization (IVF) for assisted reproduction (Anioke, 2020). The fertilized egg and the cells that quickly form in the first few divisions exhibit totipotency. Under optimal circumstances, these cells have the capability to produce a functional embryo, complete with supportive structures like the placenta. However, these cells undergo a transformation to become pluripotent within a few days. The embryonic stem cell lines now under study lack the ability to independently produce a viable embryo. Instead, they possess pluripotency, meaning they can differentiate into several cell types but cannot form a whole organism. (Anioke, 2020).

Embryonic stem cells possess the capacity to produce all cell types present in the body, unlike tissue-specific (adult) stem cells. Equally significant, these cells have the capability to be cultivated and multiplied indefinitely in their unspecialized or "undifferentiated" form, given the appropriate circumstances. Holm, S. (2017) argues that stem cells have the advantage of providing insights into early human developmental processes that are otherwise inaccessible. This knowledge can enhance the field's ability to study diseases and develop strategies for therapies aimed at replacing or restoring damaged tissues.

### **2.1.3 Induced pluripotent stem cells**

An area of stem cell research that is currently of great importance and fascination is the investigation of induced pluripotent stem cells (iPS cells). These cells, such as skin cells, are modified or "reprogrammed" to acquire pluripotency, meaning they can function like embryonic stem cells. Although iPS cells possess numerous similarities to embryonic stem cells, such as the capacity to differentiate into all cell types in the body, it is crucial to recognize that they are not completely identical. The initial induced pluripotent stem (iPS) cells were generated using the viral-mediated introduction of three to four specific genes that are recognized as crucial in embryonic stem cells, into the specialized cell (Omole & Fakoya, 2018). The mechanism by which these three to four "reprogramming" genes generate pluripotency is still not fully comprehended, and continuing research is dedicated to addressing this subject. Furthermore, current research has prioritized exploring alternate approaches to reprogram cells, employing techniques that are deemed to be safer for practical application.

An important benefit of iPS cells, which attracts researchers, is their ability to generate disease-specific or patient-specific pluripotent stem cell lines. Disease-specific stem cells are highly effective instruments for investigating the etiology of a certain disease and then evaluating pharmaceuticals or uncovering alternative methodologies to manage or eradicate such sickness. The generation of patient-specific stem cells holds great appeal for cell therapy due to their origin from the patient themselves, which may mitigate the significant complications of rejection and immunosuppression that can arise from transplants using unrelated donors (Omole & Fakoya, 2018).

## **2.2 Application of Stem Cells**

### **2.2.1 Potential therapies**

Although other stem cell treatments show promise, they are still in the nascent stages of experimentation. For instance, the mesenchymal stem cell, which is present in various parts of the body including the bone marrow, has the ability to differentiate into bone, cartilage, fat, and maybe muscle (Barreca et al., 2020). These cells possess a limited capacity to alter immunological activities in specific experimental scenarios. The remarkable capabilities of mesenchymal stem cells have sparked significant enthusiasm for their potential applications in the treatment of various musculoskeletal disorders, heart ailments, and certain immunological abnormalities including graft-versus-host disease that may occur after bone marrow transplantation (Li et al., 2022).

Future investigations into human embryonic stem cells (hES cells) will primarily contribute to the advancement of cell-based treatments for certain disorders. These therapeutic applications serve as the foundation of the entire field of regenerative medicine. There is a significant disparity between the demand for organs and tissue for transplantation and the supply available. Therefore, the production of specialized cells from the nucleus of a skin cell extracted from the same patient will significantly aid the population requiring transplants (Scholer, 2016). Recent studies have conducted early research on mice and other animals to investigate the potential of adult stem cells to undergo trans-differentiation into different types of tissues. Can bone marrow stem cells produce cardiac muscle cells, for instance? Stem cells from the bone marrow of mice were implanted into a heart that had been injured, and they eventually developed into muscle cells of the heart, replenishing the damaged heart tissue. Subsequent research has shown comparable achievements when working with hES cells and adult stem cells in a controlled environment.

Before employing cell-based treatments for illness treatment, it is imperative for scientists to possess the ability to effectively distinguish, transfer, and integrate the human embryonic stem (hES) cells. Every individual cell must possess the capability to undergo rapid and effective reproduction, resulting in the generation of abundant amounts of tissue. Human embryonic stem cells must possess the capability to undergo differentiation into the specific cell type under consideration, as well as exhibit viability within the recipient's body following transplantation (Eguizabal et al., 2019). Subsequently, the cells must possess the capability to assimilate into the tissue's surroundings and operate effectively for the entirety of the patient's life. Ultimately, but of utmost significance, it is crucial that the transplanted cells do not cause any harm to the patient. Once these criteria are fulfilled, cell-based therapies can be employed to treat a range of disorders that rely on the employment of replacement cells for treatment.

Furthermore, conducting HES studies will contribute to a comprehensive comprehension of human development. It is necessary to determine the process by which undifferentiated stem cells transform into differentiated cells. Current research suggests that this transition is attributed to alterations in gene expression; yet, the precise mechanism behind this process remains unidentified. Through comprehending the intricacies of human development, scientists can deduce remedies for birth abnormalities and cancer that result from anomalous cell division and differentiation. Moreover, understanding the specific genes that control the growth and differentiation of stem cells can potentially disrupt and rectify conditions like type 1 diabetes (Wan et al., 2022) and neurological problems (McKinney, 2017).

Human embryonic stem cells can also be employed to assess the toxicity and effectiveness of novel medications. Similar to the utilization of cancer cell lines for evaluating the effectiveness of anti-tumour medications, pluripotent ES cell lines can be employed for in vitro drug testing before proceeding to in vivo experiments. The stem cells will undergo differentiation to become a specific type of cell that is wanted, and subsequently, the medicine was subjected to testing using these differentiated cells (Shi et al., 2017).

The conviction is that eventually, human pluripotent stem cells will discover remedies and assist in the improved management of illnesses. Through the examination of the processes involved in cell differentiation in people, it is anticipated that any abnormalities can be identified and effectively addressed. Furthermore, it is hypothesized that through the examination of pluripotent stem cells, scientists would be able to discern the genes responsible for decision-making and the potential indicators that activate or deactivate them. Omole & Fakoya (2018) conduct a comprehensive analysis of multiple studies that illustrate the process of stem cell specialization and its significance in enhancing researchers' comprehension of diseases like cancer and birth abnormalities such as Down syndrome.

The utilization of pluripotent stem cells in "cell transplantation therapies" holds great potential, however it remains a long-term prospect. There is a significant disparity between the demand for organ and tissue transplantation and the limited supply that is currently available. Therefore, both adult and embryonic stem cells have the potential to differentiate into specific cells and serve as substitutes for impaired or sick cells. For instance, in the context of Parkinson's disease, specific nerve cells that produce dopamine can be surgically inserted into the patient. Subsequently, these cells will

reconfigure the neural connections in the brain and restore the appropriate cognitive processes. Furthermore, the advancement and examination of drug safety could significantly broaden through additional investigation and isolation of pluripotent stem cells. This would enable the testing of medications specifically within the available cell lines. If successful, the drugs may then be tested on humans, thus minimizing the harmful impacts they may have on living beings.

### **2.3 The Trajectory of Stem Cell Research**

This section delineates the evolution of SCR, tracing its path from established global scientific and ethical paradigms to its nascent yet strategically emerging status within the Kenyan context. This transition highlights both the potential for knowledge transfer and the critical need for context-specific adaptation.

#### **2.3.1 Global Advancements and Evolving Ethical Frameworks**

Globally, SCR has moved beyond foundational science into an era of advanced clinical application and sophisticated ethical governance. The field has been revolutionized by the refinement of Induced Pluripotent Stem Cells (iPSCs), which continue to offer a promising alternative to embryonic sources by mitigating ethical concerns while enabling disease modeling and personalized drug screening (Shi et al., 2017; Omole & Fakoya, 2018). In regenerative medicine, clinical trials using mesenchymal stem cells (MSCs) have shown tangible success in treating conditions like graft-versus-host disease and are being actively explored for musculoskeletal and cardiac repair (Li et al., 2022).

Concurrently, the global ethical framework has matured. The initial intense debate over human embryonic stem cells (hESCs) has evolved into a more nuanced discourse that emphasizes robust informed consent processes, the governance of biobanking,

and a pressing concern for global equity and justice in the distribution of emerging therapies (Sivaraman, 2019; Choudhury et al., 2021). This mature global landscape is characterized by a synergy between cutting-edge science and well-defined, albeit continually debated, ethical and regulatory structures.

### **2.3.2 The Nascent Kenyan Landscape: A Focus on Foundational Steps and Contextual Challenges**

In stark contrast to the established global environment, Kenya's SCR landscape is in its foundational phase, characterized by pioneering institutional efforts and a significant regulatory lag. The country has recently taken a monumental step with the establishment of its first stem cell research laboratory at the Kenya Medical Research Institute (KEMRI) in 2023, a move explicitly aimed at addressing the burden of non-communicable diseases and building local research capacity (Ombogo, 2023). This development signifies a direct intent to localize global scientific advancements.

Prior to this, SCR activities in Kenya were limited and collaborative. Early work involved using stem cell technology for wound and burn treatment at Kenyatta National Hospital in partnership with the University of Nairobi (Omondi et al., 2016). Furthermore, studies on the feasibility of sources like umbilical cord blood have been conducted, indicating a growing research interest in the necessary infrastructure for SCR (Murei, 2021).

However, these scientific advancements occur within a significant regulatory and ethical vacuum. While the Kenya Health Bill (2015) proposed regulations for stem cell facilities, specific, actionable guidelines remain underdeveloped. This gap is part of a broader regional challenge in Sub-Saharan Africa, where governance frameworks for modern biotechnologies often lag behind scientific capacity, raising risks related

to informed consent, exploitation, and inequitable benefit sharing (de Vries et al., 2017; Tindana & de Vries, 2020). The constitutional view that life begins at conception (Kramon & Posner, 2011) adds a layer of legal and ethical complexity to any future research involving human embryos, creating a potential fault line between scientific ambition and socio-legal norms.

Bio banking in Kenya and Africa lacks rules, despite the presence of numerous research organizations in the region. These organizations should be held responsible for their social, ethical, technological, and scientific obligations in biomedical research. The African Bank 4.0 Summit provided a vital forum that expanded my understanding of bio banking through the delivery of presentations and the generation of debates. In addition, the participants from different locations discussed their experiences and knowledge on bio banking, which emphasized diverse effective methods to adopt and obstacles to overcome (de Vries et al., 2017).

The trajectory from global to local thus reveals a critical disconnect. Kenya is actively importing the scientific infrastructure for SCR, as evidenced by the new KEMRI lab. However, the parallel importation or development of the necessary ethical and social scaffolding the nuanced understanding of local stakeholder perspectives, the culturally-grounded consent models, and the specific regulatory guidelines has not kept pace. This creates a precarious situation where technology risks advancing without the essential social license to operate. Therefore, this study directly addresses this gap by exploring the knowledge and, more critically, the ethical issues as perceived by Kenyan doctors, nurses, and researchers, whose buy-in is essential for the legitimate and sustainable integration of SCR into the national health agenda.

## 2.4 Stem Cell Ethics

Controversies have emerged over the utilization of human embryonic stem cells (hES cells) in scientific study since their discovery and isolation. In the past six years, a multitude of experiments have showcased the immense capacity of human embryonic stem (hES) cells in treating degenerative disorders, spinal cord injuries, and cultivating organs for transplantation. Utilizing embryonic stem (ES) cells for life-saving purposes necessitates the destruction of embryos, as these cells are often produced from the inner cell mass of a blastocyst originating from a fertilized egg (Anioke, 2020; Hassani et al., 2019). Therefore, the crux of the stem cell controversy revolves around three crucial inquiries: Does the medical advantage of eliminating a human embryo outweigh the possibilities for its future existence? Are there alternative sources of embryonic stem cells that do not need the destruction of an embryo? Can adult stem cells serve as a medicinal substitute for embryonic stem cells?

In order to address these inquiries, we shall examine the ethical status of human embryos by taking into account perspectives from both scientific and theological domains.

The ethical position regarding human embryos encompasses two fundamental principles: the imperative to both avoid and alleviate suffering, and to uphold the sanctity of human life. Stem cell research will offer a variety of treatments for debilitating diseases, thereby fulfilling the initial moral criterion (Omole & Fakoya, 2018). Human embryonic stem cell research inevitably results in the destruction of a human embryo, thereby limiting the potential for the formation of a new human life (Anioke, 2020). Therefore, it is impossible to fulfil both moral principles.

The longstanding controversy surrounding stem cell research in the United States is mostly rooted in moral convictions and can be evaluated and challenged using ethical standards. Nevertheless, it is imperative to examine the distinction between morality and ethics. Morality is the concept that involves the ability to differentiate between actions or behaviours that are considered good or wicked. The variation in beliefs is subjective, differing not only among individuals but also across different religious systems. Ethics, on the other hand, refers to a system of principles that dictate proper behaviour based on moral standards. Ethics govern the social policies formulated throughout society.

## **2.5 Debates on Stem Cell Research**

There is currently a widespread and intense discussion surrounding stem cell research. The issue revolves around the selection of specific cell types for stem cell research and treatment, as well as the question of whether the outcomes of this research should be eligible for patenting.

### **2.5.1 The Embryo is a Human Being and Should, Therefore Not Be Used for Research.**

The Catholic church and religion, in general, have disseminated the moral apprehensions regarding stem cell research, as evidenced by Sivaraman (2019) and Charitos et al. (2021). The Catholic Church has expressed a strong stance on this matter, asserting that the embryo, albeit not completely grown, is a human being and should not be subjected to destruction for the purposes of study or medical treatment. According to the Sacred Congregation for the Doctrine of the Faith, as cited in Anioke (2020, p. 183), human embryos created by in vitro fertilization are considered human beings and should be recognized as individuals with rights. It is crucial to

preserve their dignity and their right to life from the very beginning of their existence. It is unethical to create human embryos with the intention of using them as disposable 'biological material'. Their stance is that if stem cell research is necessary, alternative sources such as adult stem cells or umbilical cord cells from a newborn infant can be utilized. The Catholic Church does not oppose research that utilizes these sources of stem cells. According to their argument, because these alternative sources are highly effective and yield high-quality stem cells, it is unnecessary to employ human embryos as a source for stem cells in research or treatment.

From conception, we are biologically alive. We are genetically human, distinct, and sexually distinct.” A disabled woman at a Congressional hearing in the United States said this, “I want to see again. Dance again? Hear like I once did? I do not want those things at the cost of any living person and I consider live embryos to be people.” (Rayfield, 2000, p. 88). It is contended that although significant benefits may arise from such study, the desired outcome does not morally justify the methods employed. Anioke (2020) concludes that while embryonic stem cells therapies have potentially significant benefits for individuals with diseases and the society in general, the infringement of the rights to life and dignity of embryos as human does not justify the use of the technologies.

### **2.5.2 The Embryo is Not a Human Being and Should, therefore be Used in Research**

On the other side of the debate, the most significant ethical contribution is the concept of the soul, with religious underpinnings. In this view, as extensively pronounced in Poston and Disney (2010), Judaism and Islam and other theological philosophies that follow argue that the soul only enters the body after the significant parts, that is “seat of the soul is formed.” Here, philosophical inquiry such as, Irmak (2016), as well as,

Richardson and Goldberg (2018), have located the formation of the soul further into the development of the foetus. The significance of this is that, while these arguments do not relate directly to the scientific evidence of start of life, they project the ideological backings of the Westernized moral reasoning that is hinged in religious traditions. However, the implication of these philosophical underpinnings is enumerated in Sivaraman and Noor (2016).

First, for Islamic professing individuals, early extraction and research on hES is acceptable until the 40<sup>th</sup> day, when ensoulment has not yet occurred (Fadel, 2012; Sivaraman & Noor, 2016). Coupled with other considerations and principles, such as greater good, or the Buddhist concept of “enforced donation” (Sivaraman & Noor, 2016), stem cell research on hES that are less than 40 days for Islam and Judaism, 5 days for Buddhism and Hindu is acceptable. Furthering the argument, Sivaraman (2019) points out that at issue is not really when the ensoulment occurs, but rather the principles of “do no harm” and “intension to save lives.” From this perspective, the moral reasoning of the researcher should be individualized, based on factors such as the religious values explained in Poston and Disney (2010), whereby, if the researcher does not believe they are not doing harm to the embryo as a human, with their intention being to alleviate the suffering of others, they should be allowed to conduct the research.

From a different, and more objective perspective is the argument presented by scholars such as Huidu (2019), who take the subjective concept of ensoulment, and confines it into scientific inquiry. From this perspective, the argument is that, when the cells are still in the stage of development where capacity for differentiation is still high, the embryo cannot be considered with life as the cells can still take any shape

and form (Huidu, 2019). Similar to the ensoulment stage argument from religious and philosophical points of view (Poston & Disney, 2010; Sivaraman & Noor, 2016; Sivaraman, 2019), there is a time limit for extracting hES for research. However, in this perspective, as Huidu (2019) the cells are simply considered “medicinal” objects and not human beings towards whom ethical philosophies such as “an end in themselves” do not apply.

In the Kenyan context, this has legal ramifications. First, the constitutional conceptualization of humans is that life begins at conception (Condic, M. L. 2013), which means that applying Sivaraman’s (2019) “do no harm” principle, would make stem cell research illegal. However, as Russa (2019) among others argue (see especially Kidha’s 2020 “Principlism” argument), have supported promotion of the research since the existing arguments are religious and subjective notions on when life begins, instead of evaluation of the potential to save millions of actual human lives.

## **2.6 Theoretical Framework**

The analysis of the study's findings regarding the ethical acceptance of Stem Cell Research (SCR) can be profoundly enriched by grounding the interpretation within the three proposed theoretical frameworks: The Theory of Planned Behavior (TPB), the Social Cognitive Theory (SCT), and the Diffusion of Innovations (DOI) Theory. These models move the discussion beyond mere description, providing a predictive and explanatory structure for the complex interplay between knowledge, moral conviction, and professional context.

### **2.6.1 The Theory of Planned Behavior (TPB) and Ethical Stance**

The Theory of Planned Behavior (TPB) is the central framework because it directly models the process by which an individual's intention in this case, their ethical stance or willingness to accept/support SCR is formed (Ajzen, 1991). The study's hypothesis is perfectly tested against the three core TPB constructs:

The TPB suggests that a favorable attitude arises from positive behavioral beliefs about an action's outcomes. In the study, the health worker's knowledge level serves as the primary source of these beliefs. Higher knowledge (e.g., understanding the life-saving potential of SCR) generally forms a more favorable attitude toward the therapeutic potential ("I think is good for finding solutions to health problems..."). However, the study confirms that knowledge is a double-edged sword: increased knowledge also brought awareness of the negative outcomes (e.g., "SCR requires destroying embryos," "risk of exploitation"), leading to nuanced concerns rather than blanket acceptance. This nuanced understanding shows that while knowledge is necessary for attitude formation, it is insufficient to predict acceptance when the behavior is morally charged.

Subjective Norms refer to the perceived social pressure to perform or not perform a behavior. This is powerfully represented by the variable of religious beliefs. The findings showed that strong religious conviction often acted as an ethical veto, demonstrating that subjective norms can override a positive attitude formed by knowledge. For example, a clinician might possess a high level of knowledge about the benefits of adult stem cells, but their religious community's condemnation of embryonic stem cells (ESCs) acts as a powerful normative belief, leading to a strong, negative ethical stance on all SCR ("Life begins at conception hence it is a human... There is no justification"). This is a clear demonstration of how social pressure

(normative beliefs) acts as the primary moderator of the attitude-intention relationship in a morally contested field (Anioke, 2020).

Perceived Behavioral Control (PBC) is the perceived ease of performing the behavior, often reflecting authority and resources. This is operationalized by the professional role. Consultants and Registrars (high PBC) likely feel they possess the authority, knowledge, and resources to engage with, regulate, or utilize SCR. This high sense of control facilitates their willingness to accept and lead research. Conversely, Nurses or Junior Medical Officers (low PBC) may view SCR as beyond their influence or authority, leading to lower acceptance or engagement. This perception of control influences their intention to support or promote the therapy, explaining why high-cadre individuals are not just more knowledgeable but also more ethically engaged with the complexities of justice and consent—issues over which they feel they have greater control (Gathura, 2017).

### **2.6.2 Social Cognitive Theory (SCT) and Self-Efficacy**

The Social Cognitive Theory (SCT) (Bandura, 1986) complements the TPB by focusing on the internal mechanisms influencing the professional's capacity to act. SCT posits that self-efficacy the belief in one's ability to successfully execute a behavior is a key determinant of action. In this study, the knowledge level directly impacts professional self-efficacy. Low knowledge among Nurses and Junior Medical Officers translates into low self-efficacy regarding their ability to: Educate patients accurately about SCR, leading to avoidance or generalized fear and Critically appraise research protocols or media claims, reducing their engagement with ethical dilemmas (Fung et al., 2017). Conversely, the high self-efficacy of senior staff, rooted in advanced knowledge, drives their willingness to engage with complex ethical issues

like bio-banking consent and distributive justice, over which they feel capable of exercising influence.

SCT also emphasizes observational learning. The ethical stance of junior staff is often formed by observing the behaviors and stated values of senior colleagues and institutional bodies (IREC). If senior leaders model a cautious, process-driven approach to SCR, this behavior is observed and integrated, subtly reinforcing the institutional Subjective Norms that favor safety and ethical caution (Ezekiel et al., 2019). This explains the homogeneity of the ethical concerns regarding exploitation and regulation across different cadres.

### **2.6.3 Diffusion of Innovations (DOI) Theory and Compatibility**

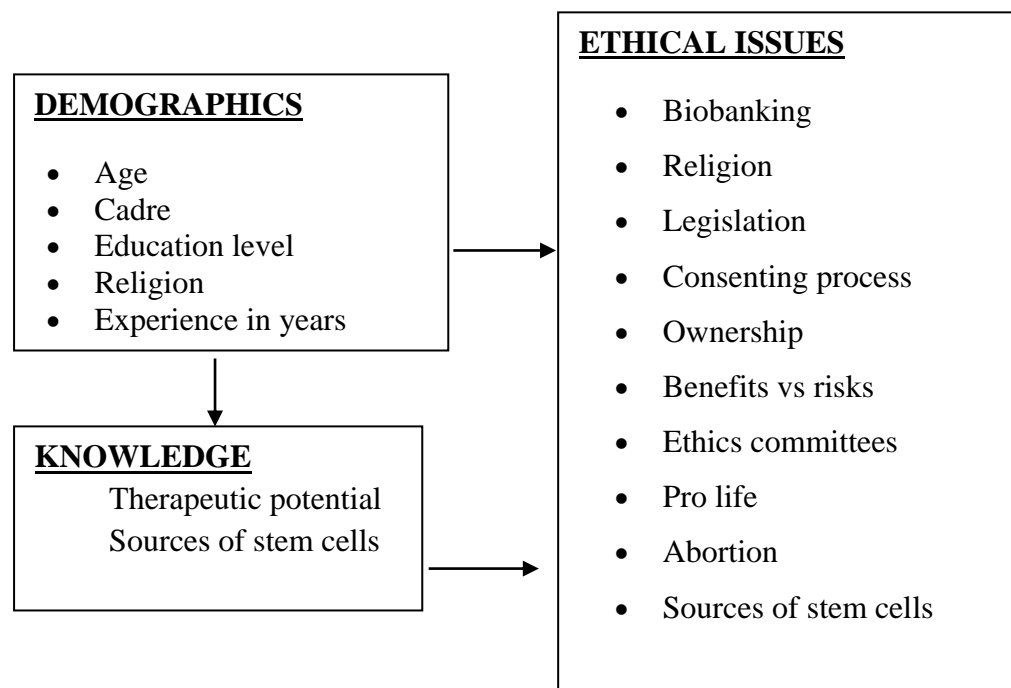
The Diffusion of Innovations (DOI) Theory (Rogers, 2003) contextualizes the study by explaining why the acceptance of SCR is slow and unevenly distributed across the professional system (AMPATH). DOI analyzes the acceptance of an innovation based on its five characteristics. For SCR in Kenya, three are particularly relevant: Complexity: The inherent biological and regulatory complexity of SCR slows knowledge acquisition and adoption across the workforce. The clear, life-changing outcomes of successful SCR (e.g., transplants) increase positive attitudes, driving the support for therapeutic potential. Compatibility: This is the most crucial characteristic. The opposition to ESCR demonstrates that the innovation (SCR) has low compatibility with the dominant moral and religious values (Subjective Norms) of the social system. The DOI model predicts that innovations with low compatibility will either be rejected outright (the "Embryo Veto") or face significantly prolonged diffusion times, forcing the system to seek ethically compatible alternatives like adult or iPSCs (Rogers, 2003; Anioke, 2020).

The unanimous demand for a robust legal framework is a call for a formal mechanism to decrease the perceived risk of the innovation. In DOI terms, the regulatory vacuum acts as a severe inhibitor, increasing perceived risk and complexity. Establishing a national legal framework would stabilize the environment, making the innovation less risky and thus more acceptable to potential adopters (Consultants, Researchers, and the public), thereby facilitating its ethical diffusion.

The TPB, SCT, and DOI collectively confirm that the ethical acceptance of SCR in Kenya is a multi-layered process. It is a function of not just an individual's knowledge (TPB Attitude), but also their religious obedience (TPB Subjective Norms), their professional capacity to act (TPB PBC and SCT Self-Efficacy), and the innovation's lack of moral fit within the local culture (DOI Compatibility). The complex interplay confirms the hypothesis: knowledge is necessary but is ultimately moderated by religious beliefs (Subjective Norms) and professional roles (PBC/Self-Efficacy), underscoring those educational efforts must be paired with legislative action to resolve the ethical incompatibility of the technology.

## 2.9 Conceptual Framework

The study aims to explore knowledge and ethical concerns about stem cell research among doctors and nurses and researchers in MTRH and CHS in Eldoret town. Doctors and nurses and researchers may attribute their knowledge on stem cell research to their level of education and years of experience. All these attributes gravitate towards ethical issues surrounding stem cell research. This relationship is illustrated in figure 1 below:



**Figure 2.1. Conceptual Framework**

Note. A graphical representation of the conceptual framework that would be employed in exploring the research question

## CHAPTER THREE

### 3.0 RESEARCH METHODOLOGY

#### 3.1 Introduction

This chapter outlines the research methods that was used to accomplish the study's objectives. This chapter will include a detailed description of the study's design, research field, population of interest, sampling strategy, size of the sample, data collection tools, validity as well as reliability testing, data collection procedures, data analysis, and ethical considerations.

#### 3.2 Study Site

The study site included Moi Teaching and Referral hospital (MTRH) and Moi University College of Health Sciences) located in the town of Eldoret, 320kms northwest of Nairobi, KENYA. MTRH is one of the largest hospitals in the Rift valley region. It is located at e 0° 30' 44" North, 35° 16' 50" East. AMPATH, situated in Eldoret, is a collaboration between Moi University, Moi Teaching and Referral Hospital, North American universities spearheaded by Indiana University, and the Kenyan Government (AMPATH, 2018). Collectively, it collaborates to establish comprehensive and enduring well-being in Kenya and globally. The College of Health Sciences, Moi University is situated in Eldoret town, adjacent to and inside the premises of the Moi Teaching and Referral Hospital. The institution comprises four schools: Medicine, Public Health, Dentistry, and Nursing. With these upcoming medical practitioners, it made it a good study site for the study to be conducted to give a better picture on the aspect of stem cell research.

### **3.3 Study Design**

This study employed a concurrent mixed-method, cross-sectional design, combining quantitative surveys and qualitative in-depth interviews. The concurrent approach allowed data triangulation, enhancing the rigor, breadth, richness, and depth of the findings. The quantitative survey provided a snapshot of participants' knowledge, while the qualitative interviews offered detailed insights into their ethical concerns regarding stem cell research. This design was appropriate as it enabled both confirmation and cross-validation of findings, ensuring a comprehensive understanding of healthcare providers' perspectives at a single point in time.

### **3.4 Target Population**

The target population were healthcare workers and researchers associated with MTRH, MUCHS and AMPATH. Participants included medical doctors, nurses, social science researchers, medical science researchers and IREC committee members within the aforementioned institutions.

### **3.5 Study Population**

Study participants included medical doctors, nurses, social science researchers, medical science researchers, and IREC committee members working at MTRH, MUCHS, and AMPATH. To minimize bias, participants were selected using purposive and stratified approaches. Each professional group was represented to ensure a diversity of perspectives rather than over-reliance on a single cadre. Inclusion criteria were based on professional role and current involvement in clinical care, research, or ethical review processes at the study sites. No preference was given to participants based on gender, seniority, or departmental affiliation. This approach

ensured that all relevant stakeholder groups were adequately represented, reducing the likelihood of selection bias and enhancing the validity of the findings.

### **3.6 Eligibility Criteria**

The eligibility criteria were meticulously defined to ensure the selection of a homogeneous and information-rich sample, thereby enhancing the credibility and validity of the study's findings regarding professional perspectives on Stem Cell Research (SCR).

#### **3.6.1 Inclusion Criteria**

The study included participants who met the following criteria:

- i. Were employed as medical doctors, nurses, medical science researchers, or social science researchers at MTRH, MUCHS, or AMPATH.
- ii. Held a minimum of a bachelor's degree (to ensure a baseline level of academic training necessary to comprehend the complex scientific and ethical concepts in the study).
- iii. Had a minimum of one year of work experience at the institution (to ensure they were sufficiently integrated into the institutional culture and had exposure to its research and clinical environment).
- iv. For the qualitative component, were purposively selected as members of the Institutional Research Ethics Committee (IREC) due to their expert role in overseeing ethical compliance.

### 3.6.2 Exclusion Criteria

Individuals who met the above inclusion criteria were excluded from the study if they:

- i. Had less than one year of professional experience in total: This ensures participants have moved beyond their initial novice orientation period and possess a foundational professional perspective.
- ii. Were on temporary, contract, or internship positions: This excludes individuals who may not be fully immersed in the long-term institutional culture and research environment, ensuring the sample represents established staff with more stable perspectives.
- iii. Declined to provide written informed consent: Upholding the ethical principle of voluntary participation is non-negotiable.
- iv. Were unable to communicate effectively in English: As the data collection tools (questionnaires and interview guides) were administered in English, lack of proficiency would compromise the validity of their responses and the ethical principle of informed consent.

The exclusion criteria were established to ensure a homogeneous and information-rich sample. The one-year professional experience minimum ensured participants had sufficient exposure to the clinical and research milieu of the institutions. Excluding temporary staff was necessary to capture the views of fully integrated healthcare professionals, thereby increasing the credibility and transferability of the findings. The language and consent criteria are fundamental ethical requirements to ensure voluntary participation and data quality.

### 3.7 Sampling Technique and Procedure

#### a. Sampling for the quantitative dimension of the study

Stratified sampling is employed when the aggregate area of interest is large. In this type of sampling, the entire population is divided into smaller subdivisions called strata. Then, a random selection of these strata is made to be included in the overall sample. Stratification was used to select 161 participants among 365 doctors and nurses who had bachelor's degrees and above from the selected study sites. The population had four strata comprising of 365 doctors and nurses, as reported by MTHR HR office and AMPATH's HR office which was categorized as nurses, medical officers, registrars and consultants. Simple random sampling was then be used to select participants from each group.

#### Sample Size calculation

The sample size for the quantitative survey was determined using Yamane's formula (1967):

$$n = N / (1 + N(e^2))$$

Where:

- n = sample size
- N = population size
- e = level of precision (0.05)

The total number of eligible doctors and nurses with at least a bachelor's degree at MTRH and AMPATH was 365, as obtained from the HR offices. Substituting these values into the formula:

$$n = 365 / (1 + 365(0.05^2)) = 365 / (1 + 365(0.0025)) = 365 / 1.9125 \approx 161$$

Thus, the required sample size was 161 participants.

To ensure representativeness, stratified sampling was employed. The population was divided into four strata: nurses, medical officers, registrars, and consultants.

Participants were then selected proportionately from each stratum using simple random sampling.

In addition, for the qualitative component, a purposive sample of medical scientists, social scientists, and IREC members was included in in-depth interviews. These groups were not subjected to the Yamane calculation since their participation was based on their expertise and their ability to provide insights into ethical concerns regarding stem cell research.

#### **b. Sampling for the qualitative dimension of the study**

Purposive sampling was employed for the qualitative dimension of the study. In addition to the 161 participants selected through stratified random sampling for the quantitative survey, a total of 15 participants were purposively chosen for in-depth interviews. These participants were drawn from key categories that could provide expert insights and strengthen the survey findings, namely medical science researchers, social science researchers, and IREC committee members. This approach allowed for a deeper understanding of both knowledge and ethical concerns surrounding stem cell research from multiple perspectives.

An optimal number of respondents for a qualitative study is one that sufficiently addresses the research question. The 15 participants purposively selected in this study were considered adequate to provide the necessary breadth and depth of perspectives on the subject matter.

| <b>Level of knowledge</b>   | <b>Frequency</b> | <b>Percentage (%)</b> |
|-----------------------------|------------------|-----------------------|
| Medical science researchers | 5                | 28.6                  |
| Social science researchers  | 5                | 49.1                  |
| IREC committee members      | 5                | 22.3                  |
| <b>Total</b>                | <b>15</b>        | <b>100</b>            |

### **3.8 Data Collection Tools**

This study utilized a concurrent approach where two tools were used; a self-administered structured questionnaire (appendix I) that took 15 minutes. The structured questionnaire facilitated gathering of information on knowledge and attitude issues associated with stem cell research. The semi-structured questionnaire had two sections; Section A that collected socio-demographics characteristics and section B knowledge on stem cells. The self-administered questionnaire was available to medical doctors, and nurses with bachelor's degree and above. It also used Key in-depth interviews where the PI conducted interviews using an in-depth interview guide (Appendix II). The participants interviewed included medical and social science researchers and IREC committee members. They were purposefully selected for the study because of their knowledge in medical and social science research. The guide included sections in demographic characteristics of participants, ethical and legal issues associated with stem cell research. The data collection tools, qualitative and quantitative, were administered to all consenting study participants.

There were 20 related statements as shown in Table 3, which were designed in order from the most obvious to the most advanced to identify knowledge level and its relationship with various socio-demographic factors shown in Table 2.

### **3.9 Data Collection Procedure**

Informed written consent was obtained from each study participant to participate in the study; using a voluntary, non-coercive approach. The research team ensured confidentiality of all data collected by not divulging the names of the study participants in the reports.

### **3.9.1 Open-ended Interviews**

The PI conducted face-to-face interviews in English, these interviews took 30 minutes. Interviews were conducted in a private location identified by the PI. The interviews were tape-recorded and notes taken with the participant's permission.

### **3.9.2 Self-administered Questionnaires**

The structured questionnaires were self-administered by study participants after the principal investigator obtained informed consent. These survey questions had been tested and validated by a previous study on knowledge among healthcare providers on stem cell research (Tork et al., 2017). The study that tested the survey questions was based in the United States. The questions were true and measured using a Likert scale of 5.

### **3.10 Data Management, Analysis and Presentation**

All filled self-administered questionnaires were checked for completeness. The quantitative data were cleaned, coded, entered, and analyzed using SPSS version 20. Descriptive statistics including frequencies, percentages, means, and standard deviations were used to summarize the socio-demographic characteristics and general knowledge levels of the participants.

In addition to descriptive statistics, inferential statistical tests were employed to test the study's hypotheses. The knowledge score was classified into three categories (good, moderate, poor) for analysis. Chi-square tests were used to assess the associations between categorical variables, such as between professional cadre and knowledge level, and between religious affiliation and specific ethical stances (e.g., opposition to embryonic research).

To test the overarching hypothesis and understand the combined influence of variables, a binomial logistic regression was performed. The dependent variable was participants' acceptance or non-acceptance of the use of human embryos in research. The independent variables included knowledge level (categorical), religious affiliation (categorical), and professional cadre (categorical). This model allowed for the examination of the effect of knowledge on ethical acceptance while controlling for the effects of religion and profession, thereby testing for moderating relationships. The model's goodness-of-fit was assessed using the Hosmer-Lemeshow test, and the odds ratios (OR) with 95% confidence intervals (CI) were reported for each predictor variable.

Qualitative data underwent coding and categorization through theme analysis as described by Braun and Clarke (2006), the in-depth interview data from 15 participants was examined. Thematic analysis is the process of summarizing and analysing qualitative data by using longer phrases and sentences instead of shorter codes, as defined by Saldana (2009). "A theme captures something important about the data in relation to the research question, and represents some level of *patterned* response or meaning within the data set" (Braun & Clarke, 2006, p. 82). Specifically, the act of encoding and classifying results in a specific result (Saldana, 2009). The data was classified based on the frequency of occurrences (Ryan & Bernard, 2003) and recurring patterns (Green & Thorogood, 2009). Key analytic findings were linked to ethical and legal issues associated with SCR and biobanks.

### **3.11 Ethical Considerations**

The study methodology addresses study goals while protecting individual autonomy, minimizing harm and ensuring voluntary participation. Ethical clearance and approval to conduct the study was obtained from Moi University Institutional Research Ethics Committee (IREC) (Appendix 4). Informed written consent was obtained from each study participant to participate in the study; using a voluntary, non-coercive approach. The research team ensured confidentiality of all data collected by not divulging the names of the study participants in the reports.

## **CHAPTER FOUR: RESULTS**

### **4.1 Participant's Characteristics**

This chapter presents the summary of findings according to the research objectives which include to describe level of knowledge on stem cell research among doctors and nurses and researchers in MTRH and CHS in Eldoret town and to explore ethical concerns on stem cell research among doctors and nurses and researchers in MTRH and CHS in Eldoret town. The demographic characteristics are described to provide contextual information on the study respondents.

### **4.2 Knowledge of Stem Cell Research**

#### **4.2.1 Overall Knowledge Levels**

The study assessed knowledge using a 20-item instrument. The overall knowledge score was categorized as Good ( $\geq 70\%$  correct), Moderate (50-69%), and Poor ( $< 50\%$ ). As presented in Table 4, only 28.6% (46/161) of participants demonstrated good knowledge, while nearly half (49.1%, 79/161) had moderate knowledge, and 22.3% (36/161) had poor knowledge. This indicates a significant knowledge gap among a substantial portion of the health workers.

#### **4.2.2 Factors Associated with Knowledge Levels**

The analysis of factors influencing knowledge about stem cell therapies revealed significant associations with age and professional experience, professional cadre, and education level. These findings are highly consistent with scholarly literature concerning knowledge dissemination and acquisition in specialized medical fields, underscoring systemic patterns in how healthcare professionals engage with emerging science.

The data clearly indicated that age (30 years and above) ( $\chi^2=15.8, p<0.001$ ) and experience (over 10 years) ( $\chi^2=9.4, p=0.002$ ) are positively correlated with superior knowledge scores. This relationship is often attributed to increased exposure to continuous professional development (CPD) opportunities and specialized conferences over a longer career span. Senior and more experienced practitioners are typically expected to keep abreast of rapidly evolving therapeutic modalities, such as those within regenerative medicine, through formal training and self-directed learning. This tenure provides greater opportunity to encounter, evaluate, and integrate novel clinical data, contrasting with younger professionals who may have only received foundational instruction that quickly becomes outdated in this fast-moving field.

A striking disparity was observed across professional roles, with consultants (84.6%) and Registrars (74.2%) demonstrating significantly higher advanced knowledge than Nurses (48.2%) and Medical Officers ( $\chi^2=22.1, p<0.001$ ). This difference reflects the scope of practice and clinical responsibility within the healthcare hierarchy. Consultants and Registrars operate at the tertiary level, often specializing in fields like hematology or oncology where stem cell transplantation is a standard therapeutic tool. Their roles mandate a deep, detailed understanding of the underlying science, indications, and complex delivery protocols. Conversely, while Nurses and general Medical Officers are crucial to care delivery, their primary focus remains on broader patient management and supportive care. However, because these frontline staff are critical for patient education and counseling, particularly in managing patient expectations regarding a technology often sensationalized in media, the observed knowledge gap presents a potential risk for suboptimal patient communication and care.

The positive association between higher education levels (Master's degree or higher) and increased awareness of the range of treatable diseases (73% vs. 52% for Bachelor's degree only;  $\chi^2=8.5$ ,  $p=0.004$ ) highlights the value of formal academic depth. Advanced degrees typically incorporate research methodology training and demand a critical appraisal of scientific literature. This scholarly exposure equips professionals to better understand the translational potential and the full spectrum of investigational and approved applications for emerging therapies. This suggests that the foundational training provided during entry-level programs may be insufficient to maintain currency in highly specialized areas, making advanced study or robust, research-informed CPD a necessary component for comprehensive knowledge.

**Table 4.1: Factors Associated with Good Knowledge of Stem Cell Research**

| Factor                    | Category        | % with Good Knowledge | p-value |
|---------------------------|-----------------|-----------------------|---------|
| <b>Age Group</b>          | < 30 years      | 15%                   | < 0.001 |
|                           | ≥ 30 years      | 35%                   |         |
| <b>Professional Cadre</b> | Nurse           | 20%                   | < 0.001 |
|                           | Medical Officer | 25%                   |         |
|                           | Registrar       | 40%                   |         |
|                           | Consultant      | 55%                   |         |
| <b>Education</b>          | Bachelor's      | 24%                   | 0.004   |
|                           | Master's+       | 42%                   |         |

#### 4.2.3 Inferential Analysis of Factors Influencing Knowledge and Ethics

The Chi-square tests revealed significant associations between knowledge level and key demographic variables. Participants aged 30 and above were significantly more likely to possess good knowledge compared to those under 30 ( $\chi^2 = 15.84$ ,  $p < 0.001$ ). Furthermore, a significant association was found between professional cadre and knowledge level ( $\chi^2 = 22.15$ ,  $p < 0.001$ ), with consultants and registrars disproportionately represented in the 'good knowledge' category.

The logistic regression model predicting acceptance of human embryo use was statistically significant,  $\chi^2(5) = 34.72$ ,  $p < 0.001$ . The model explained 38.6% of the variance (Nagelkerke  $R^2$ ) and correctly classified 76.4% of cases. As hypothesized, knowledge level was a significant predictor. Participants with good knowledge had 3.2 times the odds of accepting embryonic research compared to those with poor knowledge (OR = 3.20, 95% CI [1.45, 7.08],  $p = 0.004$ ). However, religious affiliation was a more powerful predictor. Participants identifying with conservative Christian faiths had significantly lower odds of acceptance (OR = 0.28, 95% CI [0.14, 0.58],  $p = 0.001$ ), indicating that the effect of knowledge was moderated by this variable. Professional cadre was not a significant independent predictor in the final model ( $p = 0.187$ ).

#### **4.2.4 Qualitative Elucidation of Knowledge Gaps**

The qualitative data provided serves as a vivid, on-the-ground validation of the quantitative findings that pointed toward widespread moderate-to-poor knowledge regarding Stem Cell Research (SCR). The narrative responses effectively translate the statistical deficiency into a recognized functional knowledge gap, highlighting deficits in both conceptual understanding and contextual awareness among key stakeholders.

The core issue illuminated by the qualitative data is the vagueness and incompleteness of participants' definitions of SCR. This lack of precision suggests that the knowledge deficit is not merely a matter of lacking specialized detail, but often a failure to grasp the fundamental conceptual boundaries of the field. When basic definitions are shaky, it becomes impossible to engage in informed critical appraisal of complex research protocols, ethical considerations, or policy implications. This observation aligns with literature suggesting that healthcare professionals, particularly those outside specialized research fields, frequently possess fragmented knowledge derived from

media or preliminary training, which often fails the test of detailed inquiry (Lau et al., 2018).

The candid statement from the Social Science researcher, "I do not know much about the real details about stem cell research particularly here in Kenya," is highly revealing. It highlights a critical distinction between abstract scientific knowledge and contextualized operational knowledge. While a professional might understand the basic biology of stem cells, a lack of awareness regarding the research landscape particularly within their jurisdiction (e.g., Kenya) renders that knowledge functionally limited.

A lack of local contextual knowledge directly impedes the ability of researchers, policy makers, and ethics committees to effectively govern or participate in the field, as decisions must be grounded in the existing national framework (Ezekiel et al., 2019).

Perhaps the most critical qualitative finding is the admission by the IRB member: "My understanding of it is not full, I have very little knowledge on SCR." Institutional Review Board (IRB) members are the gatekeepers of research ethics and participant safety. Their role involves the nuanced review of complex scientific proposals, including assessing scientific merit, risk-benefit ratios, and informed consent procedures for clinical trials involving stem cells. A self-declared "very little knowledge" within this cadre poses a significant risk to the integrity of research governance.

This specific qualitative finding is a powerful indicator that the knowledge gaps observed quantitatively are translating directly into structural weaknesses in the ethical infrastructure designed to protect research subjects.

In synthesis, the qualitative statements serve as a critical call to action. They transform the abstract statistical findings into personal admissions of professional deficiency, validating the need for targeted educational interventions identified in the preceding quantitative analysis. Any future educational strategy must therefore not only address the scientific fundamentals of SCR but also specifically integrate training on local regulatory requirements, ethical frameworks, and effective communication strategies to manage patient expectations, especially for high-leverage roles like IRB membership and policy advocacy (Koplin et al., 2020).

### **4.3 Ethical and Attitudinal Perspectives**

The exploration of ethical and attitudinal perspectives reveals a complex, nuanced landscape where strong support for the therapeutic promise of Stem Cell Research (SCR) is rigorously tempered by profound moral reservations and concerns over social justice and regulatory weakness. This dual nature of acceptance conditional support versus deeply rooted ethical caution is a common feature in public and professional discourse surrounding transformative biomedical technologies (Hyun, 2016).

The general attitude toward SCR, as evidenced by the qualitative data, is fundamentally supportive of its therapeutic potential. This endorsement is rooted in the utilitarian desire to find "solutions to health problems" and its usefulness "in transplant" as articulated by a medical researcher. This perspective positions SCR as a powerful tool in the arsenal of regenerative medicine, capable of addressing currently incurable diseases and significantly improving patient outcomes through tissue repair, regeneration, or replacement (National Academies of Sciences, Engineering, and

Medicine, 2017). The optimistic view focuses squarely on the societal benefits and clinical advancements that stem from cellular therapies.

Crucially, this support is rarely unconditional. The attitudes demonstrate a high degree of ethical sensitivity, acting as a moral filter through which scientific advancement is evaluated. While the ends curing disease are widely accepted, the means the specific source of the stem cells introduce significant ethical tension. The willingness to accept SCR is immediately curtailed by the perceived moral status of the biological material used, indicating that the ethical principles of respect for persons and non-maleficence hold significant sway over the principle of beneficence (Beauchamp & Childress, 2013). This sets the stage for the most significant ethical challenge: the status of the human embryo.

The qualitative data unequivocally identifies strong opposition to the use of human embryos as the most prominent ethical theme. This opposition is not driven by scientific scepticism regarding the utility of embryonic stem cells (ESCs), but by a deeply held moral stance that life begins at conception. The assertion by a Social Science Researcher, "I disagree with using the human embryos because it is taking science too far," encapsulates the view that the creation or destruction of human embryos for research crosses an immutable moral boundary, irrespective of potential medical gains.

The stark pronouncement, "Life begins at conception hence it is a human... There is no justification," directly employs the personhood argument. This perspective grants the embryo full moral status equivalent to a human being from the moment of conception. Within this framework, the destruction of an embryo for scientific purposes is viewed as the unjustifiable taking of a human life, establishing a moral

prohibition against Embryonic Stem Cell Research (ESCR) that cannot be overridden by therapeutic utility (President's Council on Bioethics, 2004). This issue is often particularly pronounced in settings where cultural or religious convictions strongly influence ethical perspectives, leading to an almost universal moral rejection of ESCR compared to the more ethically flexible use of adult or induced pluripotent stem cells (iPSCs).

This moral conflict is the oldest and most persistent ethical challenge in regenerative medicine, sparking significant legislative and public debate globally. The intensity of this opposition, even among professionals and researchers, underscores the difficulty of establishing universally accepted ethical guidelines for SCR, highlighting a fundamental tension between scientific liberty and moral inviolability (Holm, 2016).

Beyond the debate over the embryo, participants raised critical concerns regarding social justice and equitable access. The fear is not merely that SCR will be expensive, but that it will actively exacerbate existing inequalities. The Social scientist's concern "those who can afford can get an embryo from a poor person and use it to support the richer person" articulates the fear of exploitation of the vulnerable. This highlights a risk associated with global biomedical tourism and commercialization, where economic disparities could turn biological material (e.g., oocytes, discarded embryos, or even somatic cells) into a commodity traded from the poor to the wealthy (Baviskar & Petropanagos, 2018). The ethical principle of Justice requires that the benefits and burdens of research be distributed fairly, and the perception that SCR could become a tool for wealth-based biological transfer is a severe ethical drawback.

A second major concern addressed the ethics of bio-banking and the concept of "broad consent." Bio-banking involves storing biological samples (including stem

cells or tissues) for future, often unspecified, research. The participant's worry that a sample consented "for breast cancer then another person comes in and wants to look for diabetes, when the consent was done these things were not mentioned" illustrates the tension between the scientific efficiency of bio-banking and the donor's right to informed consent and autonomy.

For consent to be valid, it must be informed meaning the donor fully understands the purpose, risks, and benefits of the research. Broad consent, which seeks permission for any future, unspecified research, challenges the very definition of "informed" (Taye et al., 2021). This concern fundamentally relates to the stewardship of biological material. Once a sample is banked, the donor loses control over its use, which participants view as a potential violation of their autonomy and an avenue for exploitation beyond the original agreement. Clear, tiered consent mechanisms are required to address this ethical challenge.

Participants universally identified the absence of a robust legal framework as a critical impediment and a source of profound ethical anxiety. The sentiment, "It has to have some legal framework. There should be a clear-cut legal framework," from IREC Committee Members, reflects the professional community's recognition that science has outpaced governance. In the absence of specific, comprehensive laws:

Institutional ethics committees (like IREC) and bodies like NACOSTI can establish guidelines, but these lack the binding force of law. Guidelines can be disregarded or subject to varied interpretation, failing to provide the predictability and enforcement necessary to ensure public trust and protect vulnerable populations.

A regulatory vacuum creates fertile ground for the growth of unregulated stem cell clinics, which often exploit the hopes of patients by offering unproven, potentially

dangerous, and extremely costly therapies (Knoepfler, 2018). The identification of this legal vacuum as a critical barrier signifies that, from the perspective of research and ethics professionals, the immediate focus should shift from merely discussing ethical issues to implementing effective legal and policy tools to govern the responsible conduct of SCR.

## **CHAPTER FIVE: DISCUSSION**

### **5.1 INTRODUCTION**

This chapter interprets the study findings in light of the research objectives, methodological approach, and prior scholarship. The study employed a mixed-methods design within the context of Moi Teaching and Referral Hospital (MTRH) and Moi University College of Health Sciences (CHS) institutions that represent major training and healthcare facilities in Western Kenya. These settings are especially relevant because stem cell research (SCR) in Kenya is nascent, and health workers knowledge and ethical perspectives will heavily shape institutional readiness for future SCR activities.

The mixed-methods design quantitative surveys among 161 clinicians and nurses and qualitative interviews with 15 experts strengthened the interpretation of results by providing both measurable trends and contextualized reasoning. The following discussion synthesizes these findings within the broader literature and Kenya's emerging bioethical landscape.

### **5.2 Interpretation of Key Findings Through the Theoretical Framework**

The theoretical framework guiding this study proposes that knowledge, beliefs, and contextual norms influence attitudes and ethical judgments among healthcare workers. The findings align with this model. Respondents with higher knowledge levels demonstrated more nuanced ethical reflections, while those with limited knowledge relied more heavily on absolute moral beliefs. This supports the framework's assertion that adequate knowledge is necessary but not sufficient to shape ethical reasoning; deeply rooted religious, cultural, and moral norms also strongly influence attitudes toward SCR.

For example, strong moral objections to embryonic stem cell use persisted even among knowledgeable participants, demonstrating how normative beliefs can override scientific understanding. This confirms the framework's position that attitudes toward complex biomedical issues are a product of both factual knowledge and ethical, cultural, or religious schemas.

The study's findings regarding the relationship between knowledge, ethical stance, and professional context are best understood through the lens of the Theory of Planned Behaviour (TPB) (Ajzen, 1991). The TPB postulates that an individual's ethical acceptance (Intention) is mediated by three core constructs, each strongly supported by our empirical data.

The association between knowledge level and ethical disposition directly tests the TPB's Attitude toward the Behaviour. Our results show that while higher knowledge is associated with a more nuanced ethical position, it does not necessarily translate into blanket acceptance. Knowledge informs the clinician's behavioural beliefs; those with higher knowledge are aware of the immense therapeutic promise of SCR, fostering a favourable attitude toward its potential (beneficence). Critically, this increased knowledge also includes awareness of the negative outcomes namely, the required destruction of the human embryo and the risk of exploitation. This duality explains why knowledge often leads to nuanced concern rather than straightforward endorsement, demonstrating that for morally charged behaviours, attitude formation is a complex calculus of perceived benefits versus moral costs.

The variable of religious beliefs functioned as the primary expression of Subjective Norms within the TPB model. Our regression analysis confirmed that strong religious conviction was the most potent moderator of ethical acceptance, often overriding a

scientifically informed attitude. This demonstrates the power of normative beliefs in a system where the perceived social and moral pressure from religious authority dictates an absolute "pro-life" stance. The strong opposition to Embryonic Stem Cell Research (ESCR), regardless of therapeutic potential, is the empirical validation of the TPB's Subjective Norms at work, where the desire to conform to the prevailing moral expectations of the community outweighs personal scientific conviction (Anioke, 2020).

The influence of the professional role on the type of ethical concern raised maps precisely onto Perceived Behavioural Control (PBC). Senior staff (Consultants and Registrars) demonstrated a higher degree of ethical engagement with systemic issues like distributive justice and informed consent protocols. This suggests a higher PBC they perceive themselves as possessing the authority and resources to influence research governance and institutional policy (Gathura, 2017). Conversely, junior staff (Nurses and Medical Officers), who exhibited lower PBC, focused more on fundamental moral principles (the embryo veto), issues over which they feel less capable of exerting control. This indicates that a professional's intention to support or lead SCR initiatives is profoundly conditioned by their perceived capacity to manage the associated ethical risks.

### **5.2.1 Analysing Professional Capacity and Learning via Social Cognitive Theory (SCT)**

Complementing the TPB, the Social Cognitive Theory (SCT) (Bandura, 1986) provides an essential framework for interpreting the stratified knowledge gap and the formation of professional confidence.

The low knowledge observed among Nurses and Junior Medical Officers is best interpreted as evidence of low Self-Efficacy in the domain of advanced biomedical science. SCT posits that knowledge is a prerequisite for self-efficacy. Low self-efficacy translates into avoidance behaviours, reducing their confidence to accurately educate patients about SCR or critically appraise research protocols (Fung et al., 2017). Conversely, the high knowledge of consultants creates high self-efficacy, driving their willingness to engage with complex ethical debates and lead new research initiatives. This reinforces that educational strategies must target not just knowledge retention, but also the internal confidence (self-efficacy) required to act as informed professionals.

SCT's concept of observational learning explains the homogeneity of ethical concerns across different professional cadres. The ethical stance of junior staff is often formed by observing the behaviours and values of senior colleagues and institutional bodies (IREC). When institutional leadership models a cautious, process-driven approach, this behaviour is observed and integrated, subtly reinforcing the institutional Subjective Norms that favor safety and ethical caution. This mechanism explains why concerns regarding exploitation and the need for legal frameworks are universal, as these are issues being actively addressed and debated by the highest professional cadres (Ezekiel et al., 2019).

### **5.2.2 Contextualizing Acceptance via Diffusion of Innovations (DOI) Theory**

The slow and uneven acceptance of SCR among AMPATH health workers, despite its clear therapeutic benefits, must be contextualized using the Diffusion of Innovations (DOI) Theory (Rogers, 2003).

DOI analyses innovation acceptance based on its characteristics. For SCR in Kenya, the critical limiting factor is Compatibility. The overwhelming opposition to ESCR confirms that the innovation has low compatibility with the dominant moral and religious values of the professional and social system. As the DOI model predicts, an innovation with low compatibility will face either outright rejection or a significantly prolonged diffusion time, forcing the system to seek ethically compatible alternatives like adult stem cells (ASCs) or induced pluripotent stem cells (iPSCs) that do not compromise core moral tenets (Anioke, 2020).

The unanimous demand for a robust legal framework is a systemic response aimed at reducing the innovation's perceived risk and complexity. In DOI terms, the current regulatory vacuum acts as a severe Inhibitor to diffusion. Establishing clear laws would stabilize the ethical environment, making the innovation less complex and more legitimate for potential adopters. This required legal structure is viewed by professionals as a necessary precursor to achieving ethical acceptance and public trust, essential for the responsible diffusion of SCR technology.

### **5.3 Knowledge Levels On Stem Cell Research and Influencing Factors**

The finding that only 28.6% of health workers had good knowledge of SCR finds resonance with studies from Greece (Tork, 2017) and the Middle East (Khalil & Sharshor, 2016), which also reported significant knowledge gaps. However, this comparison requires nuance. The study in Greece focused specifically on knowledge of umbilical cord blood donation, a narrower and clinically established topic, whereas our study assessed broader SCR knowledge, including contentious embryonic and induced pluripotent stem cells. Unlike in settings where SCR is established, Kenyan healthcare professionals have had limited exposure to integrated SCR education,

clinical trials, or mainstream therapeutic applications. This finding aligns with studies in other emerging contexts, where knowledge deficits among health workers are common (Tork, 2017). However, our finding that knowledge was significantly higher among senior, more educated, and experienced professionals (see Table 4) suggests that the ecosystem is building from the top down. As predicted by the global-local model, the initial beneficiaries of knowledge transfer are the academic and clinical elites, creating an internal capacity gap that must be addressed to ensure equitable and informed practice across the entire health system. Therefore, the insufficient knowledge seen among Kenyan health workers reflects not only individual factors but also system-level educational and policy gaps.

The findings validate the study's justification: that without strong foundational knowledge among frontline professionals, Kenya risks misinformation, poor patient counselling, and ethical missteps as SCR expands.

This substantial knowledge deficit is not merely an academic concern; it poses a direct practical challenge. These professionals are the frontline educators responsible for informed consent, the practitioners overseeing patient safety, and the ethical gatekeepers who shape local research culture. A failure here risks jeopardizing patient trust and facilitating the growth of unregulated, dangerous stem cell tourism (Knoepfler, 2018).

### **5.3.1 Interpretation of Inferential (Bivariate) Statistics**

The inferential analysis revealed statistically significant associations between knowledge level and several demographic and professional variables, including age, professional cadre, years of experience, and educational level ( $p < 0.05$ ). These findings indicate that knowledge of SCR is not evenly distributed among healthcare

professionals. Senior cadres particularly consultants and registrars demonstrated substantially higher knowledge levels, whereas nurses and early-career clinicians exhibited the lowest scores. This gradient likely reflects the differences in training pathways, involvement in research, and frequency of exposure to emerging biomedical technologies within these groups.

These trends align with the theoretical framework, which suggests that knowledge acquisition and ethical attitudes are shaped by experiential learning and professional norms. Participants with extensive clinical experience were more likely to have encountered SCR concepts through continuous medical education or research engagements, enabling more informed ethical reflections. In contrast, participants with limited experience appeared to rely more heavily on entrenched religious or cultural beliefs when evaluating SCR, contributing to more rigid ethical positions.

Comparable studies from Iran, Malaysia, and South Africa similarly report that senior medical professionals exhibit better understanding of SCR than junior staff, this finding echoes the observations of Peberdy et al. (2016) underscoring the role of training and exposure in shaping knowledge patterns. Thus, the inferential findings not only reinforce global evidence but also illuminate how professional hierarchies and educational structures contribute to variations in ethical reasoning within the Kenyan context.

### **5.3.2 Comparison with Other Research Settings**

Compared to settings such as the USA and Europe, where SCR is integrated into medical and biomedical curricula (Tork et al., 2017), Kenya lacks an institutionalized training framework (Gathura, 2017). This contextual difference explains why clinicians and researchers in this study do not display high knowledge levels despite

working in a high-volume referral hospital. Studies from high-income countries consistently report higher SCR awareness due to strong policy support, funding, and academic integration.

## **5.4 Ethical Concerns Associated with Stem Cell Research**

### **5.4.1 Moral status of the embryo**

The strong opposition to human embryonic stem cell research is a defining feature of our data. This sentiment powerfully echoes the 'pro-life' argument prevalent in global bioethical debates, particularly those informed by Catholic doctrine (Anioke, 2020). However, the *strength* and *prevalence* of this view in our sample are likely amplified by the specific socio-religious context of Western Kenya. The profound ethical concerns voiced by participants demonstrate that global ethical debates are not abstract; they are deeply resonant in the local context. The moral status of the embryo, a central controversy in global bioethics (Sivaraman, 2019; Anioke, 2020), was a primary subjective norm for our participants, often grounded in religious conviction and the Kenyan constitutional view of life. This finding underscores that the ethical framework for SCR cannot be simply imported; it must be negotiated locally.

Furthermore, this study adds a critical, context-specific layer to the global equity discourse. Participants' fears that SCR would benefit the affluent while exploiting the poor ("those who can afford can get an embryo from a poor person") directly mirror concerns about "scientific colonialism" raised in the literature (Munung et al., 2021; Tindana & de Vries, 2020). This demonstrates a sophisticated local awareness of global power dynamics and a demand for justice that must be central to any SCR policy developed in Kenya.

This finding is of paramount importance because, unlike in some secularized or multicultural settings (e.g., Lye et al., 2015), this moral prohibition appears to function as an absolute veto. It signals that the advancement of SCR in Kenya cannot be a purely scientific or utilitarian endeavor; it is fundamentally an ethical negotiation. Progress must prioritize ethically less contentious avenues, such as adult stem cells (ASCs) and induced pluripotent stem cells (iPSCs), which circumvent the destruction of the embryo, thereby respecting the dominant moral framework. The findings partially supported the primary hypothesis. While a higher knowledge level was indeed a predictor of more permissive ethical views, the strong moderating effect of religion was even more powerful than anticipated, often overriding knowledge-based reasoning.

#### **5.4.2 Justice, fairness and potential exploitation**

The concerns regarding justice and exploitation are equally critical and reflect a deep-seated distrust rooted in historical and contemporary global health inequalities. The fear that SCR would become a tool for the wealthy at the expense of the poor illustrated by the anticipation of the rich obtaining materials from the vulnerable highlights a keen sensitivity to distributive justice (de Vries et al., 2017). This perspective anticipates a new form of "biomedical colonialism," where local populations bear the risks of research (donating samples or being enrolled in trials) while the benefits (expensive therapies and intellectual property) accrue disproportionately to wealthy, often external, entities. Addressing this requires robust policy measures that mandate equitable benefit-sharing and access.

The universal participant demand for a robust legal framework is perhaps the most significant finding that bridges the global-local divide. It confirms the literature's

identification of a regulatory gap in SSA (de Vries et al., 2017) and moves it from an academic observation to a pressing, on-the-ground barrier identified by practitioners themselves. This absence of governance directly impacts perceived behavioral control; without clear rules, healthcare professionals perceive significant risk and uncertainty in engaging with SCR, which stifles support and innovation. The establishment of the KEMRI lab (Ombogo, 2023) makes the resolution of this vacuum not just an academic priority but an urgent operational necessity. The lab provides the "hard" infrastructure for science, but this study identifies the desperate need for the "soft" infrastructure of ethics and regulation to make it functional and trustworthy.

#### **5.4.3 Informed consent and Bio-banking concerns**

Furthermore, the unease with broad consent in biobanking indicates a sophisticated understanding of research ethics among participants. Their insistence on the necessity of specific, ongoing permission is a direct challenge to the administrative convenience of broad consent, which allows samples to be used for future, currently unforeseen research. This challenges global biobanking practices and underscores the imperative for context-appropriate, dynamic consent models that actively engage participants and reinforce autonomy over the long term, a particularly salient ethical concern in African settings where historical exploitation in research remains a legacy issue (Taye et al., 2021; de Vries et al., 2017). The demand for granular consent is fundamentally a demand for trust and transparency.

#### **5.4.4 The Imperative for a Robust Legal Framework**

The unanimous call for a robust legal framework underscores a critical vulnerability in Kenya's research infrastructure. While this aligns with recommendations by Kenyan science journalists like Gathura (2017), it presents a stark contrast to the situation in countries like the UK or Singapore, where comprehensive frameworks for embryonic research have long been in place. Our participants' emphasis on law is not merely an academic point but a pragmatic response to a palpable regulatory vacuum. This absence of clear national guidelines places a heavier burden on local IRECs and individual conscience, a challenge less commonly faced by health workers in jurisdictions with mature regulatory systems.

Establishing a clear, comprehensive legal framework is therefore not merely a bureaucratic necessity but a foundational requirement for building and maintaining public trust. Such legislation would provide the necessary legal certainty to: 1) resolve the national stance on the moral status of the embryo; 2) mandate equitable benefit-sharing; and 3) impose enforceable penalties for exploitation and unethical conduct. This political and legal intervention is essential for institutionalizing the high ethical standards demanded by the health workers themselves.

### **5.5 Methodological and Contextual Interpretation of Findings**

#### **5.5.1 Influence of Study Design**

The mixed-methods cross-sectional design enhanced the study's robustness by integrating numerical trends with rich qualitative insights. The qualitative findings helped explain the reasoning behind quantitative patterns, providing a more comprehensive understanding of participants' knowledge and ethical positions.

### **5.5.2 Influence of the Research Setting**

The study was conducted in tertiary and academic institutions (MTRH and CHS), which provide greater exposure to research than typical county hospitals. This may explain the moderately higher awareness levels compared to some African studies. However, the lack of formal SCR training programs in Kenya limits comparability with countries such as Iran, South Korea, and the United States, where SCR is a national research priority.

### **5.6 Integration of Ethical and Knowledge findings**

A clear relationship emerged between knowledge levels and ethical positions. Participants with higher knowledge demonstrated more nuanced ethical considerations (e.g., concerns about consent, justice, and exploitation), whereas those with lower knowledge relied heavily on absolute moral objections to embryonic SCR.

This pattern is consistent with the theoretical framework, which emphasizes that while knowledge informs beliefs, beliefs ultimately shape ethical judgments. These findings underscore the need for educational programs that integrate scientific content with ethical reasoning.

### **5.7 Study Limitations**

While this study provides valuable insights into knowledge and ethical issues surrounding stem cell research among health workers in western Kenya, its findings must be interpreted in light of several methodological limitations.

The use of a cross-sectional design means that data were collected at a single point in time. As such, the study can identify associations between variables (e.g., between knowledge and ethical acceptance) but cannot establish causal relationships. It is not

possible to conclude that higher knowledge *causes* more permissive ethical views; the relationship may be bidirectional or influenced by unmeasured confounding factors.

The study was conducted within a single, advanced academic and healthcare consortium (AMPATH, MTRH, and CHS). The participants in this setting are likely to have greater exposure to research and advanced medical concepts than health workers in rural or non-academic facilities in Kenya. Therefore, the findings on knowledge levels and ethical concerns may not be fully generalizable to the broader population of Kenyan health workers.

The topic of stem cell research, particularly the use of human embryos, is sensitive and closely tied to moral and religious beliefs. During both the questionnaires and interviews, participants may have provided responses they believed to be socially desirable or professionally acceptable, rather than their fully candid opinions. This could have led to an under-reporting of support for embryonic research or an over-emphasis on certain ethical concerns.

The knowledge assessment tool, while adapted from a previous study, was a self-administered questionnaire with fixed responses. This format may not have fully captured the depth or nuance of participants' understanding. Furthermore, the classification of knowledge into "good," "moderate," and "poor" categories, while necessary for analysis, involves an arbitrary cut-off that may oversimplify the continuum of understanding.

The qualitative component, comprising 15 in-depth interviews, provided rich, detailed data. However, this sample size, while adequate for achieving thematic saturation on major issues, limits the diversity of perspectives captured, particularly

Despite these limitations, the study's mixed-methods approach allowed for triangulation of data, strengthening the validity of the core findings related to the significant knowledge gaps and the profound ethical concerns prevalent among health workers in this pioneering Kenyan institution.

## **CHAPTER SIX: CONCLUSIONS AND RECOMMENDATIONS**

### **6.1 CONCLUSIONS**

This study successfully achieved its objectives by exploring the knowledge and ethical issues associated with stem cell research (SCR) among health workers at AMPATH, Kenya. The following conclusions are drawn directly from the integrated findings:

#### **6.1.1 On the Level of Knowledge**

The study concludes there is a significant and concerning knowledge gap among the majority of the health workforce. The finding that only 28.6% possessed good knowledge, reinforced by qualitative data showing vague and incomplete understandings of SCR, signals that the majority of the workforce is not adequately prepared for the complex clinical and ethical integration of stem cell technologies. Crucially, this deficit is not uniform; it is significantly more pronounced among nurses, medical officers, and those under 30 years of age. This stratification underscores the necessity of moving beyond generalized education toward urgent, targeted intervention for these specific professional cadres and career stages.

#### **6.1.2 On Factors Influencing Knowledge and Attitudes**

The study concludes that knowledge and attitudes toward SCR are determined by a complex interplay of professional context, educational attainment, and personal conviction. While professional seniority factors, such as higher education and being a consultant or Registrar, reliably predicted better scientific knowledge, this cognitive advantage did not necessarily translate into ethical endorsement. In fact, the most powerful factor shaping overall attitudes was religious belief. This personal, deeply held conviction often functioned as an ethical veto, effectively overriding scientific

understanding and creating a profound, non-negotiable opposition to embryonic research, regardless of its potential therapeutic utility.

### **6.1.3 On Ethical Concerns**

The study concludes that the ethical landscape for SCR in this setting is dominated by three primary, interconnected, and urgent concerns:

**The Moral Status of the Embryo:** This represents the central, non-negotiable issue for a majority of participants, establishing the use of human embryonic stem cells as the most significant, principled ethical barrier to research progression.

**Distributive Justice and Fear of Exploitation:** There is widespread concern over social justice, with participants anticipating a new form of biomedical colonialism where the poor are exploited as donors of biological material while the rich disproportionately benefit, thus threatening the principle of equitable access to care.

**Informed Consent in Bio banking:** This was identified as a critical operational and trust challenge. The strong opposition to "broad consent" signifies a firm demand for a more rigorous process requiring specific, ongoing permission for the use of biological samples to uphold donor autonomy and trust.

## **6.2 Recommendations**

Based on these definitive conclusions, the following targeted and actionable recommendations are proposed to directly address the identified gaps and create a responsible environment for the development of regenerative medicine:

### **6.2.1 For Bridging the Knowledge Gap**

**Implement Tiered, Cadre-Specific Training:** It is essential to develop and mandate continuous professional development (CPD) modules on SCR. These educational interventions must be precisely tailored to professional need: for nurses and junior medical officers, the focus must be on fundamental principles and their critical role in accurate patient education; conversely, for registrars and consultants, training should concentrate on advanced therapeutic applications, rigorous trial design, and leadership in the complex ethical discourse.

### **6.2.2 For Navigating the Ethical Landscape**

**Initiate Structured Ethical Dialogues;** AMPATH and Moi University must urgently facilitate regular, multi-stakeholder forums that bring together clinicians, researchers, IREC members, religious leaders, and bioethicists. The explicit goal of these forums must be to directly confront the moral status of the embryo and determine the feasibility of strategically focusing initial national research efforts on ethically less contentious sources, such as adult and induced pluripotent stem (iPS) cells, thereby charting an ethically tenable path forward.

To address the significant trust deficit identified, all future biobanking initiatives must move decisively beyond broad consent. The findings demand the institutional development and implementation of a dynamic consent model or a tiered system where participants are actively re-contacted and asked for renewed permission for

new, unforeseen research applications, ensuring autonomy is respected throughout the life cycle of the biological sample.

**Expedite the Development of a National SCR Framework:** The overwhelming concern for the absence of a legal framework, voiced across all professional cadres, must be immediately addressed at the national level. This study provides the empirical justification to urgently petition the Ministry of Health and NACOSTI to operationalize the relevant sections of the Kenya Health Bill (2015). This framework must explicitly regulate embryo use, enforce equitable access, and institute safeguards to protect vulnerable populations from exploitation, thereby establishing the necessary legal foundation for responsible and ethical progress in SCR in Kenya.

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## APPENDICES

### Appendix 1: Structured Questionnaires

**FOR MEDICAL DOCTORS AND NURSES ONLY.**      Participant's ID:

Date:

Name of interviewer:

#### Section A: Socio-demographic characteristics

1. Age (in years) .....
2. Sex  Male  Female
3. Nationality: \_\_\_\_\_
4. Marital status  married  single  separated  Widowed
5. Children:  Yes  No
6. Religion: \_\_\_\_\_
7. Qualification:  Degree  Masters and above
8. Occupation:  Medical Doctor  registrar  consultant  Nurse
9. Years of experience \_\_\_\_\_

#### Section B: Knowledge questions on stem cell research (SCR)

What is your opinion on stem cells according to the following statements? Tick (✓) where applicable

| Knowledge statement  | True | False | Don't Know |
|--|------|-------|------------|
| Stem cell is sample cell in the body that is able to develop into any one of various kinds of cell |      |       |            |
| One of sources of stem cells is umbilical cord blood   |      |       |            |
| Bone marrow stem cells are taken from the spine  |      |       |            |
| Sperm and eggs are a source for adult stem cells.  |      |       |            |
| Umbilical cord blood unit may be used for transplantation even after 25 years                      |      |       |            |
| Stem cells are cells that have the ability to produce other types of cells                         |      |       |            |
| We can use stem cells in treatment of diseases   |      |       |            |
| Stem cells are unspecialized.  |      |       |            |
| Stem cells can treat neurological diseases such as Alzheimer and Parkinson                         |      |       |            |
| Stem cells can treat the diabetes mellitus   |      |       |            |
| Stem cells can treat spinal cord injuries and paralysis  |      |       |            |
| Stem cells can treat heart diseases  |      |       |            |

|  |  |  |  |
|--|--|--|--|
| Stem cells can treat infertility   |  |  |  |
| Stem cells can treat tumor   |  |  |  |
| Stem cells are capable of dividing and self-renew for long periods   |  |  |  |
| Umbilical cord blood stem cells are embryonic stem cells   |  |  |  |
| Embryonic stem cells are capable of forming any cell type in the body including placenta                             |  |  |  |
| Umbilical cord blood stem cell transplantation is less efficient compared with bone marrow stem cell transplantation |  |  |  |
| Embryonic stem cell transplantation has serious disadvantages as it could result in the formation of tumor           |  |  |  |
| In order a parent to donate umbilical cord blood, the delivery has to take place in big public hospital              |  |  |  |

**Appendix 2: Guide for Open-Ended Interviews**

INTERVIEW GUIDE FOR EXPLORING KNOWLEDGE AND ETHICAL CONCERNS ON STEM CELL RESEARCH AMONG DOCTORS AND NURSES AND RESEARCHERS IN MTRH, AMPATH AND MUCHS, ELDORET.

**Section A: Socio-Demographic Characteristics**

10. Age (in years) .....

11. SEX  Male  Female

12. Nationality: \_\_\_\_\_

13. Marital status  married  single  separated  Widowed

14. Children:  Yes  No

15. Religion: \_\_\_\_\_

16. Qualification:  Degree  Masters and above

17. Cadre:  Medical researcher  Social science researcher  Ethics committee member

Years of experience? \_\_\_\_\_

**INTERVIEW GUIDE ON EXPLORING KNOWLEDGE AND ETHICAL CONCERNS ON STEM CELL RESEARCH AMONG DOCTORS AND NURSES AND RESEARCHERS IN MTRH, AMPATH AND MUCHS, ELDORET**

**STEM CELL RESEARCH**

1. What do you know about SCR? What are your thoughts and feelings about SCR?
2. What are some of the ethical issues around SCR and bio banking that you are aware of?

**Probing questions:**

- a. Do you agree with using human embryos in stem cell research?
- b. If yes, why? If not, tell me why. What are some of the ethical challenges you are thinking of with using human embryos?
  - i. If they raise the issue of “when life begins” then probe about if life begins immediately at conception/fertilization. Can the human embryo be considered to be human being? What is your opinion on this?  
[Expect many to refer to religious values versus African traditional beliefs].
- c. But what about the fact that SCR might offer promising new medical treatment?
  - i. SCR involves taking cells from human embryos that are less than 2 weeks old. They was used to grown new cells that can be used to treat diseases in any part of the body, how do you feel about this?
  - ii. What do you think about using stem cells from other parts of the body i.e., umbilical blood or bone marrow?

- d. For you, what are the moral and ethical implications, if any, of destroying human embryos in the process of conducting medical research?
  - i. One of the main ethical issues regarding SCR is the concern that harvesting human embryonic stem cells and destroying them in the process violates respect for nascent human life [Pro-choice versus pro-life debate].
3. As a **health researcher** what are your thoughts/feelings about supporting research that might lead to new treatments even when it involves use of human embryos? Probing questions:
  - a. Does your ethical and scientific viewpoint differ? Should the scientific view point should prevail?
    - i. Do you support developments of Stem cell research if it benefits people? [Deontology versus Utilitarianism].

**BIOBANKS:**

1. What do you know about biobanking? Is it being practiced here in Eldoret?  
Practiced in Kenya?
  - a. Storing of biological materials e.g., blood, tissue, etc.
  - b. Storing medical records.
2. What are some of the ethical issues with biobanking?
  - a. Is informed consent being obtained for use of samples/data? Is the consenting process being conducted in an ethical manner? Probing questions:
    - i. What does it mean to “properly inform” a participant? about risks and benefits? Withdrawing, confidentiality?

- ii. “Board” versus “narrow” consent. [Consent for biobank participation versus consent for specific research project using material from biobank]. Most biobanks are doing narrow consent for a specific intervention but using the biomaterials/data for broader medical experiments that consent was not obtained for. Should biobanks practice broad or narrow consenting process?
  1. When a scientist does research on data in a biobank, what do you think about the need for consenting, should the researcher ask for permission? Are there any special circumstances that they do not need to ask for permission?
- iii. Who owns the sample/data? Donor versus Institution (hospital or research institute). [Participants have “no property” in their samples based on the understanding that body parts, once detached, are “no one’s thing”. What do you think about this issue of “no property”? Would it hinder research? Do you think it would lead commodification of persons? Who benefits financially? Should profits be shared?
- iv. “Feedback” on incidental findings. Should biobanks have obligation to provide feedback on later incidental findings?
- v. Would you be willing to provide info about yourself to a biobank? Would you personally be concerned or reluctant about collection of any material from you? i.e blood sample, umbilical blood, tissues, medical record.

**LEGAL ISSUES/RECOMMENDATIONS**

1. Are you aware of some of the legal issues or legislation around SCR and bio banking?
  - a. What are your thoughts and feelings about SCR being done in Kenya? Is it a problem? What do you think it means for Kenya as a society?
  - b. What do you think should be the legal status of SCR in Kenya? Is there a legal framework for regulation of SCR in Kenya?
  - c. Do you think the sharing and exchange of personal data and biological materials across borders should be encouraged? Are you aware of any legal framework or regulations in Kenya to safe guard this cross-border exchange of biological materials?
2. What role(s) should be played by ethics committees/institutions in protecting donors' interest?
  - a. Biobanks will follow up participants over a long period of time and many researchers will work with industrial companies to develop new medicines from stem cells, who do you think should primarily be responsible for protecting the public interest?
    - i. What of ethics committees, universities or hospitals?
3. What are some of the recommendations that will address some of your ethical concerns?
  - a. Provision of education/training
  - b. Ethics workshops

**Thank you very much for participating.**

**END**

**Appendix 3: Informed Consent form (ICF) for Semi-Structured Questionnaires and Key Informant Interviews**

KNOWLEDGE, ATTITUDE AND AWARENESS ON STEM CELL AND STEM CELL RESEARCH AMONG DOCTORS AND NURSES AND RESEARCHERS IN MTRH AND CHS, ELDORET TOWN

CONSENT FORM

**INTRODUCTION**

You are invited to participate in a research study on “Exploring knowledge and Ethical issues on stem cell research among doctors and nurses and researchers in MTRH, AMPATH and MUCHS in Eldoret town”. You are being asked to participate in this study and if you have any questions, you may ask before agreeing to be in the study. Reuben Kiptui, a student of Moi University pursuing Master of Science in International Health Research Ethics, is conducting the study.

**STUDY PURPOSE**

The purpose of this study is to assess the knowledge, attitude and ethical concerns on stem cell research among doctors and nurses and researchers. It is intended to shade light and help in understanding the knowledge gap on stem cell research among doctors.

**PROCEDURES FOR THE STUDY**

If you agree to be in the study, you was part of 190 respondents filling a semi-structured questionnaire or part of 6 key informant interviewees (KII). The questions will ask questions about your knowledge, attitude, and ethical concerns on stem cell research. The sessions will last for approximately half an hour and for the KII, it was audio recorded.

**RISKS OF TAKING PART IN THE STUDY**

While participating in this study, the primary risk is a possible loss of confidentiality. In order to guard against this risk, all electronic information containing your name or other identifying information was kept in password-protected folder. If at one point you feel uncomfortable answering some of the questions, you can skip them. You are also free to discontinue from being part of the study at any time.

**BENEFITS OF TAKING PART IN THE STUDY**

There are no anticipated direct benefits to you from participating in this study. However, study findings. The outcome of this study will potentially help in addressing the issue of advocating doctors and nurses and researchers as well as other medical practitioners in providing the necessary information about stem cell in medical settings. The result of this study also might serve as a basis to facilitate policy makers to ensure a consistent continuous nursing education regarding stem cells and improve medical practice as a whole in Kenya.

**CONFIDENTIALITY**

Every effort was made to keep your personal information confidential. However, we cannot guarantee absolute confidentiality; your personal information may be disclosed if required by law. Your identity was held in confidence in reports in which the study may be published and databases in which results may be stored. Only the researchers conducting this study will have access to the questionnaires of this interview.

**COSTS**

You will not be responsible for any study-specific costs

**PAYMENT**

You will not receive payment for taking part in this study

**CONTACTS FOR QUESTIONS OR PROBLEMS**

For questions about the study, contact the researcher: Reuben Kiptui, +254722217381, Reubenkiptui07@gmail.com. For questions about your rights as a research participant or to discuss problems, complaints or concerns about a research study, or to obtain information, or offer input, contact the IREC, Human research subjects' office, P O Box 3-30100, Eldoret, irec@mtrh.or.ke, Tel: 0787723677

**VOLUNTARY NATURE OF STUDY**

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss. Your decision whether or not to participate in this study will not affect your current or future relations with the investigator(s).

Signed:

Participant

\_\_\_\_\_

Date

\_\_\_\_\_

Researcher

\_\_\_\_\_

Date

\_\_\_\_\_

## Appendix 4: IRB Ethics Approval



**MU/MTRH-INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)**  
 MOI TEACHING AND REFERRAL HOSPITAL  
 P.O. BOX 3  
 ELDORET  
 Tel: 334711/2/3  
 Reference: IREC/2018/171  
**Approval Number: 0003197**



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 25<sup>th</sup> January, 2019

Kiptui Reuben Kiptisia,  
 Moi University,  
 School of Medicine,  
 P.O. Box 4606-30100,  
 ELDORET-KENYA.



Dear Mr. Kiptui,

### **RE: FORMAL APPROVAL**

The MU/MTRH- Institutional Research and Ethics Committee has reviewed your research proposal titled: -

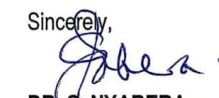
***"Exploring Knowledge and Ethics Associated with Stem Cell Research among Clinicians and Researchers in Eldoret"***.

Your proposal has been granted a Formal Approval Number: **FAN: IREC 3197** on 25<sup>th</sup> January, 2019. You are therefore permitted to begin your investigations.

Note that this approval is for 1 year; hence will expire on 24<sup>th</sup> January, 2020. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date. You will be required to submit progress report(s) on application for continuation, at the end of the study and any other times as may be recommended by the Committee.

Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. You will also be required to seek further clearance from any other regulatory body/authority that may be appropriate and applicable to the conduct of this study.

Sincerely,

  
**DR. S. NYABERA**  
 DEPUTY-CHAIRMAN  
 INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc    CEO    -    MTRH            Dean    -    SOP            Dean    -    SOM  
       Principal -    CHS            Dean    -    SON            Dean    -    SOD