An Integrated Consent-Centred Ethical Framework for Human Tissue Research in South Africa

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Preface

This study, entitled "An Integrated Consent-Centred Ethical Framework for Human Tissue Research in South Africa", is a qualitative study on human tissue research which involved an investigation of ethical values, processes, guideline documents and regulatory frameworks from the perspectives of various respondents that included anatomists and human tissue researchers from national and international contexts as well as members of Human Research Ethics Committees (HRECs) and human biobank managers in South Africa.

The study was conducted under the supervision of Dr P. Pillay and Dr B.Z. De Gama from the Discipline of Clinical Anatomy in the School of Medicine, College of Health Sciences at the University of KwaZulu-Natal, Westville Campus.

Declaration

I, Ms Seonaid Moonega, declare as follows:

1. That the work described in this thesis has not been submitted to the UKZN or any other tertiary institution to obtain an academic qualification, whether by me or any other party. Moreover, where use was made of the work published by others, it has been duly acknowledged in the text.

2. That my contribution to the project was as follows:

- Conceptualisation and design of the research idea, methodology and protocol.
- Execution of research methodology.
- Acquisition, analysis and interpretation of the data.
- Formulation and write-up of all manuscripts and final thesis.

3. That the contributions of others to the project were as follows:

Dr P Pillay (Supervisor), Dr BZ De Gama (Co-Supervisor)

- Assisted with conceptualisation and refinement of the research design and methodology.
- Critical review, editing and approval of the thesis and all manuscripts before submission.

Signed (Candidate) 

Date __4 February 2026_____

Signed (Supervisor) 

Date __4 February 2026_____

Signed (co- supervisor) 

Date __4 February 2026_____

AI Declaration

I used generative artificial intelligence (GenAI) in this thesis in the following areas: visualisation, reference management, conceptual framework ideation, and language editing. In all instances, the content generated by artificial intelligence (AI) was fully interrogated by myself for applicability, content accuracy, and plagiarism.

This use of AI complies with the University of KwaZulu-Natal's guidelines on responsible use of AI in academic work (Principles and Guidelines on the Use of Generative Artificial Intelligence Tools in Academic Work found at https://ukzn.ac.za/wp-content/uploads/2025/01/UKZN-AI-Academic-Guidelines-SL-01-0312-24-protected.pdf).

Signed: _____

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List of Acronyms

3D	Three-dimensional
AAA	American Association for Anatomy
AI	Artificial Intelligence
ASSA	Anatomical Society of Southern Africa
BREC	Biomedical Research Ethics Committee
CIOMS	Council for International Organisations of Medical Sciences
DNA	Deoxyribonucleic acid
DoH	Department of Health
HREC(s)	Human Research Ethics Committee(s)
ICEF	Integrated Consent-centred Ethical Framework
IFAA	International Federation of Associations of Anatomists
IRB(s)	Institutional Review Board(s)
MTA(s)	Material Transfer Agreement(s)
NHA	National Health Act
NHRA	National Heritage Resources Act
NHREC	National Health Research Ethics Council
OECD	Organisation for Economic Co-operation and Development
POPIA	Protection of Personal Information Act
SA	South Africa
SATiBA	South African Tissue Bank Association
SMTA	Standard Material Transfer Agreement
UK	United Kingdom
UNESCO	United Nations Educational, Scientific and Cultural Organisation
USA	United States of America
WHO	World Health Organisation

ABSTRACT

Human tissue research is essential to medical advancement; however, it raises complex ethical, legal, and regulatory challenges, particularly regarding consent, ownership, privacy, commercialisation, and emerging contemporary uses. In South Africa, these challenges are exacerbated by fragmented oversight and regulatory inconsistencies, underscoring the need for ethically coherent and contextually responsive governance. The purpose of this study was to investigate and document the ethical values underpinning human tissue research, examine the processes and regulatory frameworks governing human tissue research and human biobanks, identify gaps within existing national and international guidelines, and develop a comprehensive ethical framework to guide ethically responsible human tissue research in South Africa. This study employed a qualitative, exploratory design within a constructivist paradigm, combining empirical investigation and ethical analysis. Data were collected through semi-structured interviews with twenty-four (24) anatomists and human tissue researchers from national and international settings, fifteen (15) Human Research Ethics Committee (HREC) members from two South African universities, and nine (9) human biobank managers across South Africa. Interview data were anonymised, transcribed, and thematically analysed using NVivo, and findings were corroborated with national and international literature and validated through expert consultation.

Findings from Chapter 2 revealed that anatomists and researchers perceived research involving living participants and deceased donors as ethically different, requiring differentiated consent models and regulatory approaches. While broad consent was generally supported for living participants, fully informed consent was favoured for cadaveric research. Significant governance gaps were identified relating to legacy and unconsented collections, foetal tissue research, commercialisation, the public display of human remains, and contemporary secondary uses of human tissue. Chapter 3 demonstrated that HRECs and human biobanks operate within fragmented governance environments, characterised by unclear legislative guidance, limited oversight, and the absence of a national ethics authority or human biobanking governance framework. Participants highlighted ethical challenges related to vulnerable populations, high-risk research contexts, and emerging technologies, particularly artificial intelligence (AI)-driven research.

Following the synthesis of the findings from Chapter 2 and 3, the study developed an Integrated Consent-Centred Ethical Framework (ICEF) for human tissue research presented in Chapter 4. This five-layer framework positions consent as the ethical anchor and integrates five domains: 1) Foundational Consent Ethics; 2) Governance of Legacy and Unconsented Collections; 3) Sensitive Consent Contexts; 4) Biobank, Commercialisation, and Secondary Research Governance; and 5) Ethical Adaptation for Emerging Technologies, supported by continuous Governance and Regulatory Oversight. This framework could make a significant contribution to science since it provides (i) contextually grounded ethical guidance for South African researchers and (ii) practical tools, viz.

structured consent form checklists, thus strengthening ethical governance, protecting human dignity, and promoting public trust in human tissue research.

Overall, this thesis established a consent-centred ethical framework that strengthens governance, promotes social justice, and supports ethically responsible human tissue research in South Africa amid evolving scientific and technological change.

Keywords: human tissue research, ethics, biobank, consent, governance, South Africa, framework development.

CHAPTER 1: INTRODUCTION

1.1 Chapter Overview

This chapter critically examines the ethical aspects of human tissue research in South Africa, situated against relevant international regulatory and normative legislation. It underscores the ethical principles of autonomy, dignity, transparency, accountability, and social justice as foundational to the governance of human tissue research, human biobanking, and the operation of Human Research Ethics Committees (HRECs). Two key terms are defined at the outset, i.e., “human tissue” and “human tissue research”.

The definition of "human tissue" adopted in this study is that provided in the South African National Health Act 61 of 2003, namely, any organ, fragment of a human body, or material removed from a human body (National Health Act, 2003). This definition includes the whole human body, including internal organs, glands, flesh, bone, and body fluids, except for blood and gametes. This definition also extends to any device or object implanted into a person’s body before death (National Health Act, 2003).

In this study, “human tissue research” is defined as including the scientific study, analysis, or use of human tissue derived from the human body for educational or research purposes. This definition includes research involving both living and deceased donors (obtained through body donation programmes), including biobanking, anatomical and genetic research, foetal tissue research, and the development of biomedical technologies (Bledsoe and Grizzle, 2022).

1.2 Background

Human tissue research is crucial to advancing medical science and healthcare innovation, underpinning developments in disease diagnosis, therapeutic interventions, and biomedical research (Allen et al., 2010). In recent decades, the scope of human tissue research has expanded beyond traditional anatomical, pharmacological, and genetic applications to incorporate advanced technologies and practices, including three-dimensional (3D) imaging and printing, plastination, commercialisation, public display of human tissue specimens, artificial intelligence (AI)-driven research, and biobanking (Allen et al., 2010). This expansion has intensified ethical complexity and placed increasing strain on existing regulatory frameworks.

Despite national and international efforts to strengthen ethical oversight, human tissue research continues to be characterised by regulatory fragmentation and ethical uncertainty (Page and

Nyeboer, 2017; Comer, 2022; Billings et al., 2024; Kramer, 2024; Meiring et al., 2024). Persistent challenges include inconsistent use of consent models, inadequate regulation of cadaveric research and biobanking, and uncertainty regarding ownership, secondary use, and long-term governance of human tissue. Furthermore, distinguishing what is *lawful* from what is *ethical* remains a challenge, particularly in relation to legacy skeletal collections and the historical use of unclaimed bodies for anatomical research (Gibbon et al., 2023; Kramer, 2024; Baliso et al., 2025). Although many South African institutions have transitioned to voluntary body donation programmes (Billings et al., 2024), unresolved ethical concerns remain regarding provenance, consent, and the continued use of unconsented or unidentified human remains. These ethical concerns reveal a clear gap between existing governance mechanisms and the ethical demands of contemporary human tissue research, underscoring the need for a coherent ethical framework that addresses both historical injustices and emerging research practices.

While organisations such as the International Federation of Associations of Anatomists (IFAA) and the American Association for Anatomy (AAA) have issued ethical guidance on the respectful acquisition, handling, use, and display of human remains and tissue for education and research purposes (IFAA, 2012; Balta et al., 2025), these instruments lack legal force and remain inconsistently implemented, particularly in relation to consent acquisition, data management, commercialisation, and centralised oversight (Grizzle et al., 2011). These gaps can have serious consequences, so ethical considerations must be taken into account. Firstly, the donors' autonomy and dignity may be at risk due to unclear or inconsistent consent processes. Secondly, legacy and unconsented collections and bodies continue to be used without standardised provenance review or ethical oversight. Further, the rise of new technologies has rendered existing legal and ethical guidance obsolete, due to the additional gaps that are evident in the governance of emerging technologies and contemporary practices, including AI-driven research, human biobanking, digital imaging and virtual anatomy platforms, genetic analysis, cross-border data and tissue sharing, and the secondary and commercial use of stored human tissue (Grizzle et al., 2011). In addition, the differences between lawful and ethical practices, particularly concerning the use of unclaimed bodies, highlight historical injustices and ongoing risks of exploitation (Billings et al., 2024; Kramer, 2024).

As a result, the ethical governance of human tissue research is frequently devolved to institutional stakeholders, most notably Human Research Ethics Committees (HRECs) and human biobanks, who are required to interpret and apply fragmented legislation, and to provide professional guidance on ethical principles in the absence of coherent national oversight. This institutional burden exposes further ethical gaps since HRECs and human biobanks often operate without

standardised national guidance, clear legislative mandates, or specialised frameworks for emerging technologies (Xu et al., 2020; Alkhatib and Gaede, 2024).

1.3 Problem Statement

Human tissue research in South Africa is governed by a combination of legislation, ethical guidelines, institutional policies and professional practices; however, these sources do not provide a single, coherent governance structure that adequately addresses the full range of ethical challenges associated with the acquisition, use, storage, transfer, secondary use and commercialisation of human tissue. Existing governance mechanisms provide important protections concerning consent, autonomy, dignity, and research oversight, but uncertainty remains when human tissue is reused for purposes not foreseeable at the time of collection, when historical or unconsented collections are involved, or when tissue is incorporated into biobanking, commercialisation, or emerging technologies. The problem is further complicated by differences between research involving living participants and deceased donors, uncertainty concerning appropriate consent models for future and secondary research, and limited guidance regarding sensitive contexts such as foetal tissue, vulnerable populations and genetic research. Contemporary technologies, including digital imaging, three-dimensional reconstruction, artificial intelligence and genetic analysis, introduce additional questions concerning consent, privacy, dignity, representation and future use. At the institutional level, Human Research Ethics Committees and human biobanks may therefore be required to interpret ethical and regulatory requirements in circumstances where national guidance is incomplete, fragmented, or insufficiently tissue specific. This may contribute to variation in ethical review, consent practices and governance procedures between institutions.

The central problem addressed by this study is consequently the absence of an integrated, consent-centred governance approach capable of connecting established ethical principles with the specific and evolving circumstances of human tissue research in South Africa. This problem is particularly significant because human tissue may retain ethical significance beyond the point of collection and may subsequently be stored, transferred, reused, commercialised or technologically transformed in ways that raise new ethical questions.

1.4 Aim/Purpose of the Study

This study aimed to investigate, explore, and document the ethical values underpinning human tissue research, the processes and regulations surrounding research on human tissue and human biobanks, and identify existing legislation and guidelines that have been implemented internationally to regulate ethical research on human tissue, whilst identifying gaps that exist in the existing guidelines. Additionally, it aimed to develop a comprehensive ethical framework for human tissue research, guided by the ethical principles of autonomy, dignity, transparency, accountability, and justice. The study qualitatively explored how anatomists, human tissue researchers, members of Human Research Ethics Committees (HRECs), and representatives of South African human biobanks perceive and navigate ethical challenges related to consent, governance, and regulatory oversight.

1.5 Research Questions

The study addressed the following key research questions:

1. What are the central ethical values, principles, and consent practices underpinning human tissue research internationally and within South Africa?
2. How do stakeholders, including anatomists, human tissue researchers, South African HREC members, and South African human biobanks, identify and address ethical challenges in human tissue research and biobanking?
3. What gaps exist in current legislation, guidelines, and governance systems regulating human tissue research in South Africa?
4. How can an empirically validated ethical framework be developed to guide the moral and lawful conduct of human tissue research in South Africa?

1.6 Research Objectives

The objectives of the study included:

1) Evaluating stakeholders' views internationally and nationally (anatomists and researchers) concerning human tissue research, focusing on consent.
2) Qualitatively investigating and exploring the ethical views of South African human research ethics committee members and human biobanks on ethical concerns, consent preferences, and policy gaps in human tissue research and biobanking governance.
3) Developing a comprehensive ethical framework for research on human tissue in South Africa.

1.7 Theoretical Framework

This study employed a constructivist grounded research paradigm, which aims to understand people's interpretations of their experiences (Adom et al., 2016). The participants were interviewed, and their views, observations, and experiences were critically analysed to understand the phenomenon and common points of view from the perspective of those experiencing it, thereby informing the formulation of an ethical framework for research on human tissue.

In the context of this study, constructivism recognises that ethical values, consent practices, and regulatory interpretations in human tissue research are socially constructed and shaped by context, professional experience, and interaction (Mann and MacLeod, 2015). Guided by this perspective, the doctoral candidate used qualitative methods to explore how key stakeholders interpret and apply ethical principles such as autonomy, dignity, justice, transparency, and accountability in practice. Data were analysed thematically, allowing for the identification of shared meanings and context-specific ethical considerations. This constructivist and qualitative alignment supported the development of the framework, ensuring that it is grounded in stakeholder perspectives and regulatory realities within the South African context.

1.8 Literature Review

This section critically examines the core ethical values underpinning human tissue research, with particular emphasis on transparency and accountability, autonomy and dignity, and justice. Drawing on international and South African literature, legislation, regulations, and ethical guidelines, the section explores how these values have been conceptualised, standardised, and disputed in the governance of human tissue research, including cadaveric research, human biobanking, and emerging digital and technological applications. Attention is given to consent models, regulatory fragmentation, the role of Human Research Ethics Committees (HRECs), and the ethical challenges posed by historical practices, legacy collections, and contemporary research applications. By synthesising these bodies of literature, this section identifies key ethical gaps and tensions that inform the rationale for developing an integrated, consent-centred ethical framework suited to the South African context.

1.8.1 The Evolution of Human Tissue Research

Human tissue research has developed within a complex historical relationship between scientific advancement, human dignity and the protection of individuals whose bodies or tissues become

objects of study. Early anatomical and medical research frequently involved the acquisition and use of human remains without the knowledge or consent of individuals or their families (Ghosh, 2015; Brenna, 2021). Anatomical specimens were sometimes obtained from socially marginalised populations, unclaimed bodies, and other sources in circumstances that did not meet contemporary standards of consent, dignity, or accountability (Ghosh, 2015; Brenna, 2021). These practices demonstrate that the ethical governance of human tissue is historically connected to questions of power, ownership, respect for the dead and the authority of scientific institutions.

During the twentieth century, major abuses in human research further demonstrated the consequences of conducting research without adequate ethical safeguards. The atrocities associated with Nazi experimentation during the Second World War contributed to the development of the Nuremberg Code (1947) and the subsequent emergence of international research-ethics principles emphasising voluntary consent and protection of research participants (Brawley, 1998; Skloot, 2010; Khuroo and Sofi, 2020). Later developments, including the Declaration of Helsinki (World Medical Association, 1964; and subsequent revisions), progressively strengthened the principles of informed consent, respect for persons, beneficence, non-maleficence and justice. This historical transition represented a movement from largely unregulated or paternalistic research practices towards formal ethical oversight and consent-centred research governance (Jones, 2019; Comer, 2022; Ghosh and Walocha, 2022; Billings et al., 2024).

The development of formal research ethics, however, did not resolve all ethical questions concerning human tissue. Unlike many conventional research interactions, tissue may remain in institutional collections for decades and may be separated from the circumstances in which it was originally obtained. Historical collections may therefore contain specimens for which consent documentation is incomplete, unavailable or inconsistent with contemporary standards (Ghosh and Walocha, 2022; Billings et al., 2024; Dziedzic et al., 2024; Natale and Fornai, 2024). In addition, tissue may be transferred between institutions, incorporated into new research projects, linked with personal or genomic information, or used in ways that were not foreseeable when it was initially acquired. Consequently, the ethical significance of historical acquisition practices extends beyond the question of whether new research obtains prospective consent.

The historical trajectory is therefore relevant to the present study not merely as background, but because past acquisition practices continue to shape contemporary ethical questions concerning legacy collections, unidentified or unclaimed bodies, provenance, consent, dignity, repatriation and institutional accountability (Jones, 2019; Comer, 2022; Ghosh and Walocha, 2022; Billings

et al., 2024). The contemporary challenge is consequently not only to regulate new research technologies but also to determine how historical human tissue can be ethically governed when the original conditions of acquisition may not satisfy current standards of consent and dignity.

These historical developments provide an important foundation for understanding the contemporary governance challenges examined in this study. The progression from unconsented acquisition towards consent-based ethical governance demonstrates why consent remains central to the ethical use of human tissue, while the persistence of legacy collections demonstrates why consent cannot be considered only at the point of initial tissue acquisition. The contemporary governance of human tissue therefore requires consideration of both how tissue was originally obtained and how it is subsequently stored, governed and used (World Medical Association, 2024).

1.8.2. Ethical Values underpinning Human Tissue Research

The core values underpinning ethical principles related to human tissue research include (i) transparency and accountability, (ii) autonomy and dignity, and (iii) justice. These principles ensure that research is conducted responsibly to protect the rights and well-being of the individuals whose tissue is used and provide the moral foundation for the development of an ethical framework (Kapp, 2006; Ghosh and Walocha, 2024).

1.8.2.1 Transparency and Accountability

Transparency and accountability are core bioethical values, essential for building trust, promoting accountability, and fostering ethical decision-making in human tissue research (Nicholls et al., 2016). These bioethical values encompass the legislation, regulations, and guidelines that govern research on human tissue, as reflected in Figure 1 below (Beauchamp and Childress, 2019).

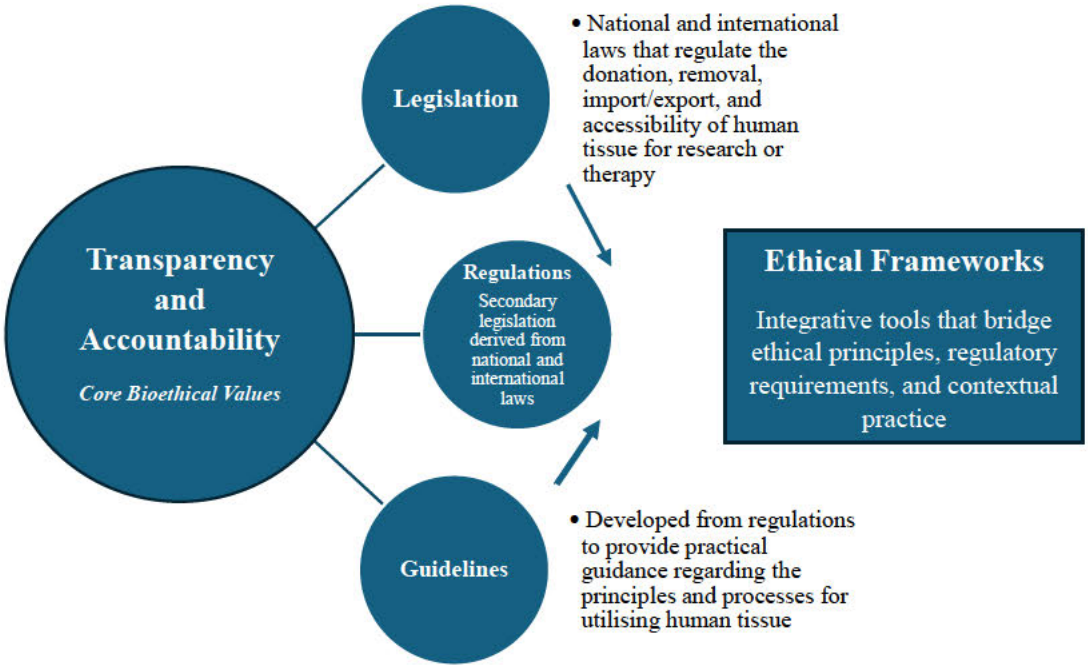

Figure 1: Reflecting the relationship between legislation, regulations, guidelines, and ethical frameworks.

Ethical frameworks, as reflected in Figure 1, play a distinct yet complementary role to legislation, regulations, and guidelines. Unlike laws and regulations, which are legally binding, and guidelines, which provide practical direction, ethical frameworks serve as integrative tools that bridge ethical principles, regulatory requirements, and contextual practice (Nicholls et al., 2016). Frameworks assist researchers, human research ethics committees, and institutions in navigating ethical uncertainties, regulatory gaps, and emerging scientific practices by providing structured ethical reasoning and decision-making support. In the context of human tissue research, such frameworks enhance transparency and accountability by promoting consistent interpretation of ethical obligations across diverse research settings, without displacing existing legal or regulatory authority (Beauchamp and Childress, 2019).

1.8.2.1.1 Legislation, Regulations, and Guidelines Related to Human Tissue Research

Human tissue research legislation was developed nationally and internationally to address ethical concerns, particularly those related to consent, autonomy, and the prevention of exploitation. This legislation aimed to achieve several key objectives, including addressing issues related to historical misuse, a lack of clear consent protocols, and evolving public expectations. Below is a tabulation of key international and national legislative and guideline developments (Table 1), focusing primarily on the guidelines established in the United Kingdom (UK) and Europe, which are major reference points in this field and form the basis for current human tissue regulation.

Table 1 summarises the development of key international and national legislation and ethical guidelines governing human tissue research.

Table 1. Key legislative and guideline developments for human tissue and their link to the current study's aim and objectives

Year	Country	Legislation/Guideline	Major Ethical Guidelines/Principles	Link to Study Aim and Objectives
1832	United Kingdom (UK)	Anatomy Act	Legalised the use of unclaimed and donated bodies for human tissue research and sought to curb grave robbing and the illicit trade of human tissue.	It highlights the early legal but ethically limited governance of human tissue use, which lacked informed consent. Informs the study's first objective (stakeholder perspectives on consent) and explains historical influences on South African practices regarding unclaimed and legacy collections.
1947	Germany	Nuremberg Code	Established that voluntary and informed consent is essential and that research must minimise harm and maximise benefit.	Provides the ethical foundation for autonomy and dignity, aligning directly with the study's aim to document the ethical values underpinning human tissue research. It informs objectives 1 and 2 of the study, guiding the analysis of stakeholders' consent practices and ethical views.
1964 (last updated in 2024)	Finland (World Medical Association)	Declaration of Helsinki	Reinforced the Nuremberg Code principles and mandated scientific validity, independent ethical review, and prioritisation of participant safety.	Informs the second objective, emphasising the role of HRECs in upholding transparency, accountability, and independent review. Provides an ethical guide for developing governance and oversight components within the proposed framework.
1979	United States of America (USA)	Belmont Report	Introduced three core principles: *Respect for persons, beneficence,* and *justice,* creating a unifying ethical framework for human tissue research.	Aligns with the study's guiding ethical principles, autonomy and dignity, transparency and accountability, and justice. Supports objective 3 of the study by providing a conceptual foundation for developing the ethical framework.
2003	South Africa	National Health Act (NHA) 61 of 2003	Defines "human tissue" and regulates its removal, storage, and use for research.	Forms the legal foundation of the study's South African context. Directly supports objectives 2 and 3 by informing the

			Prohibits the sale and commercialisation of tissue and mandates approval for export.	analysis of local ethical gaps and guiding the development of a framework aligned with national law.
2004	United Kingdom (UK)	Human Tissue Act	This Act consolidated and reformed earlier UK human tissue legislation by repealing and replacing previous Human Tissue Acts, while reaffirming consent as the foundational legal and ethical basis for the use of human tissue from living or deceased persons. These earlier Acts informed subsequent international human tissue regulatory models, including those adopted in South Africa, which were later incorporated into the National Health Act.	Provides a coherent comparative model for this study and informs its central aim by addressing ethical and regulatory gaps in consent, governance, and accountability in South Africa. Provides a comparative model for the framework's components.
2012	International	International Federation of Associations of Anatomists (IFAA) Guidelines	Promotes respect, transparency, and accountability in the use of human bodies and tissues, and outlines standards for donor consent, image use, and public display of human tissue for educational purposes.	Reinforces objective 3, providing international reference points for ethical use of cadaveric human tissue and digital materials.
2024	South Africa	Department of Health (2024), *Ethics in Health Research: Principles, Processes and Structures*, 3rd edition	Established principles for human tissue research, including consent, risk-benefit analysis, justice, confidentiality, and data protection. Aids as a general guide to human biobank research.	Strengthens the study's national ethical foundation, informs objective 2 (HREC and biobank perspectives), and supports objective three by aligning the developed framework with current national ethics standards.

These guidelines were reviewed and enacted by recognised international ethics authorities and national regulatory bodies, including the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, the World Medical Association, and South African governance institutions, because modern regulatory frameworks are heavily influenced by these key pieces of legislation (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979; The Nuremberg Code, 1996; World Medical Association, 2024; National Health Act, 2003; Human Tissue Act, 2004; Fischer, 2006; Human Tissue Regulations, 2007; IFAA, 2012; Jones, 2019; Aaron et al., 2021). Additionally, these developments illustrate the shift from early legal regulation, such as the Anatomy Act of 1832, to comprehensive ethical governance frameworks, including the Nuremberg Code (1947), the Declaration of Helsinki (1964, revised in 2024), and the Belmont Report (1979). In South Africa, the National Health Act (2003, revised in 2018) and the Department of Health Ethics in Health Research: Principles, Processes and Structures, 3rd edition (2024) established the legal and ethical framework for human tissue research. These landmarks align with the study's objectives by highlighting historical progress, identifying ethical gaps, and informing the development of a national ethical framework for human tissue research.

A) International Legislation and Guidelines

Although key international research ethics legislation and guidelines, such as the Nuremberg Code and the Declaration of Helsinki, have been established to protect human participants and regulate the use of human tissue, these guidelines primarily address the use of human subjects (Scarpulla et al., 2023). They do not adequately address the more complex tissue-specific ethical considerations and questions, such as consent for the use of unclaimed bodies, secondary use, the commercialisation of human tissue, and digital replication. Moreover, these guidelines do not adequately address contemporary research applications involving human tissue, such as 3D printing, digital imaging, and plastination. Additionally, the issue of obtaining 'consent' for research involving human tissue is not fully addressed in these guidelines (Allen et al., 2010; Bach, 2016; Cornwall et al., 2024b).

These shortcomings exist because these early laws, frameworks and guidelines were not primarily concerned with ethics; they were pragmatic, utilitarian solutions aimed at stopping crime while ensuring a steady supply of bodies for medical training (Fischer, 2006). They also focused on living subjects first, allowing a residual legal category of the deceased or unclaimed bodies to remain ethically under-scrutinised due to the presumption of utilitarian benefit (advancing medical science) outweighing a voice that could not speak (the deceased).

Literature reinforces the ethical transformation of human tissue research from exploitative historical practices to ethically governed scientific disciplines. Earlier analyses detail the shift from grave robbing to donation-based systems (Brawley, 1998; Tward and Patterson, 2002), while newer studies highlight how modern technological capabilities and global governance frameworks require continual ethical recalibration (Mitchell et al., 2011; Harris et al., 2022; Jones and Van den Heever, 2025). Harris et al. (2022) and Jones & Van den Heever (2025) argue that the rapid development of contemporary human tissue research, such as stem cell research, challenges traditional ethical boundaries and necessitates the development of renewed frameworks to protect donors and ensure responsible innovation. These developments underscore the enduring importance of the ethical lessons of the past in navigating the emerging frontier of human tissue research.

Taken together, international ethical instruments provide an important foundation for human tissue research, particularly through principles such as respect for persons, autonomy, informed consent, beneficence, justice, transparency and protection of participants. Instruments such as the Declaration of Helsinki (World Medical Association, 2024) and the CIOMS International Ethical Guidelines for Health-related Research Involving Humans (CIOMS, 2016), therefore, establish important principles against which human tissue research can be ethically assessed. However, these instruments are predominantly principles-based and human research-oriented, rather than providing a single, integrated governance model specifically designed for the full lifespan of human tissue (World Medical Association, 2024; CIOMS, 2016).

This distinction is important because the ethical governance of human tissue extends beyond the initial interaction between researcher and living participant. Tissue may be obtained from living donors, deceased individuals or legacy collections; it may subsequently be stored, transferred, linked with personal or genomic data, reused for secondary research, commercialised, exported, digitised or incorporated into emerging technologies. Although international guidance provides principles applicable to these situations, the literature demonstrates that these principles are not always integrated into a single tissue-specific governance pathway that addresses the transition from initial consent to long-term storage, secondary use, and emerging applications (Knoppers, 2014; Harris et al., 2022). The resulting gap is therefore not necessarily an absence of ethical principles, but an insufficient integration of those principles across the different stages and forms of human tissue research**.**

This creates a tension between the generality of principles-based guidance and the specificity required for human tissue governance. Broad principles may promote flexibility and international

consistency, but they may provide limited operational direction when researchers and ethics committees must determine whether a particular secondary use is compatible with the original consent, how legacy or unconsented collections should be governed, or how consent should respond to technologies that were not foreseeable when tissue was obtained (Caulfield et al., 2008; Kaye et al., 2015). The literature similarly indicates that contemporary applications such as digital imaging, three-dimensional printing, plastination, and other forms of digital representation raise ethical questions that were not central to earlier research ethics instruments (Caulfield et al., 2008; Kaye et al., 2015).

B) National Legislation and Guidelines

In South Africa, the repealed Human Tissue Act 65 of 1983 established regulations for the use of tissue samples in research. This included guidelines for the donation and access to human bodies and tissues for research or therapy, the removal of tissue from living individuals, and the regulations regarding the import and export of human tissue (Human Tissue Act, 1983). Additionally, the National Health Act 61 of 2003 and its regulations (amended in 2018) address medical research in Section 8. It outlines regulations for the use of blood, blood products, tissue, and gametes in humans, the removal and use of human tissue from living individuals, transplantation of human tissue in hospitals or authorised institutions, the donation of human bodies and tissues, as well as the roles of regional and national ethics committees and informed consent (National Health Act, 2003). However, the NHA and its regulations do not account for modern advancements in human tissue research, such as digital imaging, 3D printing, plastination, and the commercialisation of human tissue (Jones, 2016).

In the South African context, research institutions are legally required to have a material transfer agreement (MTA) when sharing human biological material and associated data for health research. An MTA is a written agreement between two research institutions, in which one provides the human biological material and the other agrees to use it for research purposes (Dhai et al., 2019). This agreement regulates the transfer of tangible research materials (Dhai et al., 2019; Thaldar et al., 2020). Several prominent organisations have established standardised MTAs, such as the World Health Organisation (WHO), which employs the Standard Material Transfer Agreement 2 (SMTA 2) for sharing human biological materials with other institutions. A significant challenge to improving cross-border sharing is the existence of contradictory legal and ethical frameworks (Chalwe et al., 2025). What is legally required and considered ethical in one country can be viewed very differently in another. For example, broad consent for the future use and international sharing of human tissue is legally permissible and widely accepted in many high-income countries, including the United States and several European Union member states

(Knoppers, 2014; Grady et al., 2015). In contrast, in many low- and middle-income countries, including parts of Africa, human research ethics committees often require more specific, tiered, or re-consent models due to concerns about participant exploitation, benefit sharing, and historical inequities in global research collaborations (Tindana et al., 2015; de Vries et al., 2017). Consequently, material transfer agreements that are legally compliant in one country or region may be deemed ethically insufficient or non-compliant in another, thereby complicating international collaboration and cross-border sharing of human tissue.

However, over the last five years, considerable progress has been made in national and institutional governance frameworks. Dhai (2024) noted that South Africa's revised ethics guidelines for health research now explicitly require stronger data stewardship, accountability mechanisms, and oversight of ethical review for research involving human biological materials.

The unresolved issue for South Africa is therefore not whether international ethical principles should apply, but how they should be translated into a coherent governance architecture that addresses the historical, legal, institutional and socio-cultural circumstances of human tissue research in the country. This is especially important where South African law and ethical guidance do not always provide a unified approach to consent, secondary use, biobanking, cross-border transfer and emerging technologies (Department of Health, 2024; National Health Act 61 of 2003; Protection of Personal Information Act 4 of 2013). The literature consequently supports the need for a framework that does not replace established principles but integrates them with tissue-specific governance requirements and the South African regulatory environment.

C) International and National Legislation on Human Biobanking

Most countries rely on general law to govern human biobanking, supplemented by more specific codes of practice from national bodies (Kaye et al., 2016). However, the reviewed literature suggests a lack of laws, regulations, or guidelines governing human tissue biobanking (Table 2). This regulatory insufficiency creates significant governance challenges, including legal uncertainty regarding ownership and control of stored tissue, variability in consent requirements for future and secondary use, and difficulties in ensuring long-term accountability and oversight of biobank activities (Rynning, 2009). In low- and middle-income settings, particularly in Sub-Saharan Africa, these challenges are compounded by limited regulatory capacity, resource constraints, weak institutional oversight, and reliance on ethics committees to interpret fragmented legal and ethical guidance (Staunton and Moodley, 2013).

The countries presented in Table 2 represent a purposively selected, illustrative comparison rather than an exhaustive survey of all countries with biobank governance arrangements. The countries were selected to demonstrate variation in regulatory approaches, including dedicated biobank legislation, reliance on general health or research legislation, data-protection regulation, professional or ethical guidance, and fragmented combinations of these mechanisms. The comparison is therefore intended to identify contrasting governance models and lessons relevant to the South African context rather than to provide a comprehensive international account of biobank legislation.

Table 2. Selected International Approaches to the Legal and Regulatory Governance of Human Biobanks

Country	**Biobank Law or Regulation**
South Africa	There is no single, comprehensive national legislation governing biobanks. The current system is fragmented and disjointed. While the NHA of 2003 broadly governs the use of human tissue, and the Protection of Personal Information Act (POPIA) applies to associated data, a recognised gap exists in specific legislation governing research biobanks (Dhai, 2013; Mahomed, 2021).
Brazil	*The National Health Council (Resolution 347) of 2005* regulates the storage and use of biological material. However, discussions are underway to develop new national guidelines for biobanks of human biological material intended for research, which would clearly distinguish between storage and donation (Garrafa, 2010).
Finland	*Biobank Act 2013:* Legal framework for collecting, storing, and processing samples. This Act contains more specific rules for tissue banks than the general rules outlined in the Personal Data Act (Kaye et al., 2016).
France	The existing legislation does not explicitly refer to biobanks, but rather to the collection of biological samples (*The Bioethics Law, The Law on Biomedical Research, and the law regarding data protection)*. *The Public Health Code* describes the collection of samples for biobanking (Kaye et al., 2016).
Germany	No biobank-specific laws exist (in 2015, a biobank law was drafted, but it remains only a proposal). Other laws regulating biobanks are followed, including the Act on Medical Devices, the Fifth Amendment to *the Act on Pharmaceutical Products, and the Code of Deontology.* (Kaye et al., 2016).
Netherlands	No specific regulation for biobanks. Instead, it follows a general *Code of Conduct* for medical research (Kaye et al., 2016)

Norway	*Health Research Act:* contains specific provisions related to research biobanks (Kaye et al., 2016).
United Kingdom	There is no single regulatory framework for biomedical research or biobanking. The *Human Tissue Act 2004* is general legislation governing the removal, storage, use, and disposal of human tissue (Kaye et al., 2016; Mahomed, 2021).
European Union	The European Union does not have a single, unified biobank-specific regulation. Instead, biobanking is governed through a fragmented legal framework comprising EU-level instruments and national laws, such as the General Data Protection Regulation (GDPR), Clinical Trials Regulation, and the Tissues and Cells Directive (Çami et al., 2023)

The comparative literature demonstrates that there is no single international instrument for governing human biobanks. Countries have adopted different combinations of general health legislation, dedicated biobank legislation, ethical guidance, data protection law, and institutional governance. These approaches reflect different balances among regulatory specificity, flexibility, administrative feasibility, and the protection of donor interests (Knoppers, 2014).

General legislation offers an established legal foundation without creating a separate regulatory structure for each emerging research practice. It may also allow governance systems to adapt as scientific practices change. However, general legislation may lack the specificity required for long-term storage, secondary use, ownership and control, cross-border sharing and governance of future research uses (Caulfield et al., 2014). Dedicated biobank legislation, by contrast, can provide clearer requirements concerning collection, storage, access, consent and accountability. Finland's Biobank Act illustrates the potential value of a specific statutory framework for establishing clearer procedural requirements (Kaye et al., 2016).

Dedicated legislation is not without limitations. Strict statutory frameworks may be slower to adapt to technological developments and may create administrative burdens for researchers and institutions (Hansson et al., 2006). The international comparison also demonstrates that the absence of dedicated biobank legislation does not necessarily imply a lack of governance. Countries such as Germany and the Netherlands rely more heavily on broader legal instruments, professional standards, and codes of conduct, while the United Kingdom uses general human tissue legislation to regulate activities, including biobanking (Kaye et al., 2016; Mahomed, 2021).

Ethics guidance provides another layer of governance by allowing ethical principles to be interpreted in relation to research contexts. Its flexibility can be advantageous where scientific

practices develop rapidly. However, guidance may lack the enforceability and consistency of legislation and may place significant responsibility on HRECs and institutions (CIOMS, 2016; World Medical Association, 2024). Institutional governance can address this gap through standard operating procedures, consent requirements, and local oversight, but excessive institutional discretion may lead to inconsistent practices across institutions (Hansson et al., 2006).

Taken together, these regulations reveal a broader governance tension between flexibility and specificity. General law offers adaptability but may leave important tissue-specific questions unresolved; dedicated legislation provides greater certainty but may become rigid; ethical guidance offers interpretive flexibility but may lack equivalent legal force; and institutional governance permits contextual adaptation but may produce variation across institutions. No single mechanism, therefore, appears sufficient on its own (Knoppers, 2014).

This issue is particularly significant in South Africa. The literature identifies the absence of a single comprehensive national law governing human biobanks, with governance distributed among the National Health Act 61 of 2003, the Protection of Personal Information Act 4 of 2013 (POPIA), the Department of Health's (2024) ethical guidance, and institutional mechanisms. This fragmentation creates uncertainty concerning ownership and control, future and secondary use, accountability and long-term oversight (Moodley & Singh, 2016; Staunton et al., 2019; Maseme, Gardner and Mahomed, 2024). The unresolved question for South Africa is consequently not simply whether dedicated biobank legislation should be introduced. Rather, it is about how general law, ethical guidance, institutional governance, and any future biobank-specific regulation can be integrated so that consent, privacy, secondary use, accountability, and scientific utility are governed coherently.

1.8.2.2 Autonomy and Dignity

This principle applies to tissue obtained from both living and deceased individuals in human tissue research, emphasising respect for persons. It includes protecting the privacy and confidentiality of participants by treating individuals with respect and sensitivity, recognising the value and worth of each person, even after death (Garrafa, 2010). The foundational ethical principle governing the use of human tissue, grounded in respect for autonomy and dignity, is the requirement of informed consent before using any part of a person’s body for research purposes. This ensures that participants understand the research purpose, procedures, potential risks, and benefits, and are free to decide whether to participate (Garrafa, 2010).

According to Doyal (1998), informed consent is the legal foundation for removing, using, and storing human tissue, provided by a donor who is fully informed, free, and on a voluntary basis (Doyal, 1998). Beauchamp and Childress (2019) outline the three key components of informed consent: (i) Relevant information must be provided to a competent individual, who must make a voluntary decision; (ii) Participants should receive information clearly and, in a language, they can understand; (iii) Participants can choose whether to participate or not (Beauchamp and Childress, 2019).

The lack of uniformity in obtaining and managing consent represents the most significant ethical hurdle in human tissue research, directly necessitating the creation of standardised guidelines and an ethical framework. Consent ambiguity affects the utilisation of cadaveric and living tissue for research, biobanking practices, and the governance of emerging technologies (Grady et al., 2015).

1.8.2.2.1 Consent Models in Human Tissue Research

The central tension in consent models for human tissue research is balancing the donor's right to autonomy with the practicality required for maximising the use of tissue samples for research (beneficence) (Grady et al., 2015). In the South African context, this tension is intensified by historical exploitation, structural inequalities, and ongoing concerns regarding trust in human tissue research, particularly among vulnerable and marginalised populations (Merz et al., 1999). Variation in appropriate consent models has led to confusion about what research is permissible, resulting in unintended limitations on future studies and in instances of research proceeding without proper consent. Additionally, uncertainty surrounding consent can lead to decisions not to utilise certain specimens for research, resulting in a loss of potential public benefits from that research (Bledsoe and Grizzle, 2022). Several informed consent models exist for human tissue research (Gefenas et al., 2011). These include:

1) General or Blanket Consent: donors consent once for the current study and all future research involving the general use of their samples and information within a specific field.

2) Broad Consent: donors consent once for the current study and all future research within a broad field.

2.1 *Two-Part Consent*: a type of broad consent where informed consent is obtained from the individual before death for the defined project, alongside broad consent from either the deceased or, if they did not give consent, from their closest relatives.

3) Tiered Consent: donors consent once for the current study and can then select one or more specific broad fields of research where their samples can be used.

4) Re-consent: donors' consent for the current study and each future research project involving their samples and information.

5) Presumed Consent: consent is assumed to be given unless donors actively opt out of allowing their samples to be used for all research.

6) Third-Party Oversight: donors' consent to a general or broad model, but an ethics board must approve the study before any research using their stored samples can begin.

7) Dynamic Consent: a digital approach that allows participants to grant and manage permission for their tissue and data for specific uses over time through a continuous, interactive process.

Steinsbekk (2013) argued that the dynamic consent model provides participants with better information than the broad consent model. Informing research participants about the specific research purposes for which their tissue will be used is essential in all consent processes. This information helps donors make fully informed decisions about how they would like their bodies to be used in research. This issue has been central to the debate around the legitimacy of broad consent. While broad consent offers a practical solution for current research practices and those that may arise in the future, it arguably fails to fulfil the principles of fully informed consent outlined in the Declaration of Helsinki of the World Medical Association. In contrast, dynamic consent provides research participants with more information than is typically offered in the initial broad consent process for today's human tissue research studies.

However, in a study by Masiye et al. (2023) on appropriate consent models for the future use of human tissue samples, participants (research ethics committee members, policymakers, and research participants) provided several reasons for favouring a combination of broad and tiered consent, including: (1) the high costs associated with collecting biological samples under specific consent, (2) the requirement to destroy leftover samples after the study concludes, and (3) the benefit of retaining samples indefinitely for future research. The study highlighted that tiered consent empowers participants by allowing them to decide whether their samples can be stored for future research purposes. This consent model also allows participants to specify how their samples may be used in future research.

Accordingly, this study proceeds from the position that while broad consent may be practically necessary for human tissue research and biobanking in South Africa, it is ethically defensible only

when situated within robust, transparent governance frameworks and sustained ethical oversight that meaningfully protect donor autonomy, dignity, and trust.

Taken together, the literature does not identify a single universally appropriate consent model for human tissue research. Specific consent provides a strong connection between the donor's decision and a defined research purpose, thereby supporting autonomy and informed choice; however, its application becomes difficult where tissue is stored for long periods or where future research uses cannot reasonably be predicted (Beauchamp and Childress, 2019; Wendler, 2006). Broad consent addresses this practical problem by permitting future research within defined parameters but raises questions about whether participants can be considered sufficiently informed when future uses are unknown (Grady et al., 2015; Caulfield et al., 2012). Tiered consent attempts to reconcile these positions by allowing participants to express preferences regarding categories of future research, while dynamic consent extends the relationship by permitting ongoing communication and modification of preferences (Kaye et al., 2015). This creates a fundamental tension between individual autonomy and research utility. A consent model that maximises specificity may provide stronger immediate protection of individual choice but may restrict the scientific value of stored tissue and require repeated re-consent (Wendler, 2006).

The debate, therefore, cannot be resolved simply by identifying the "best" consent model. The more significant question is what governance conditions must accompany each model to maintain ethical legitimacy over time. This is particularly important because human tissue research increasingly involves secondary use, long-term storage, linkage with data, international sharing and applications that may not have been foreseeable when the original consent was obtained (Knoppers, 2014).

The South African context intensifies this problem because the literature identifies uncertainty regarding the interaction between the Department of Health's ethical guidance, the National Health Act 61 of 2003, and the Protection of Personal Information Act 4 of 2013 (Moodley & Singh, 2016; Staunton et al., 2019). The thesis literature identifies uncertainty concerning broad consent, purpose specification and the governance of secondary use. Thus, the unresolved issue is not merely which consent model should be adopted, but how consent can remain ethically meaningful when tissue moves across research purposes, institutions, time and regulatory jurisdictions.

1.8.2.2.2 Consent Models for Human Biobanking

Consent concerning human biobanking is also a dominant ethical issue due to the potential for exploitation, the long-term and often unpredictable uses of tissue samples, and the complexities surrounding data and tissue ownership and control. Proper consent procedures are crucial to ensure respect for individual autonomy, transparency, and ethical research practices (Salvaterra et al., 2008). Human biobanking employs two primary consent models, namely specific and broad consent. Specific consent refers to a donor consenting to have their tissue used for specific types of research, specifying the types of tissue they wish to donate. Broad consent refers to the use of tissue for various projects, including storage and future use (Laurie, 2008; Salvaterra et al., 2008).

Various opposing views on the appropriate consent model for biobank research exist globally (Knoppers, 2005; Caulfield, 2007; Salvaterra et al., 2008; Master et al., 2015; Solberg and Steinsbekk, 2015; Domaradzki & Pawlikowski, 2019); however, most scientists desire a general or broad consent approach, as broad consent is true to the nature of biobanks since it provides authorisation for future use of stored tissue (Knoppers, 2005; Master et al., 2015; Domaradzki & Pawlikowski, 2019). Recent work by Thompson et al. (2025) reveals that participants view biobank consent as an evolving relationship rather than a singular act, preferring communication and transparency in governance over one-time authorisation. This supports earlier advocacy for broad consent models (Grady et al., 2015) but emphasises the ethical need for periodic updates and participant engagement throughout the research life cycle.

The relationship between the consent requirements under the Protection of Personal Information Act 4 of 2013 (POPIA) and the consent models used in health-related research, including biobanking, remains a subject of ongoing legal and ethical debate. POPIA establishes requirements governing the lawful processing of personal information, including requirements relating to processing limitation, purpose specification, further processing and consent (Protection of Personal Information Act 4, 2013). However, these provisions should not be interpreted in isolation from the research-specific ethical and regulatory framework applicable to health research in South Africa. The Department of Health's Ethics in Health Research: Principles, Processes and Structures, 3rd edition (2024), provides the current national ethical guidance for research involving human participants and addresses consent, the use of biological materials, data governance, secondary research and research ethics review (National Department of Health, 2024).

The interpretation of POPIA regarding broad consent is not uniform. Some legal scholarship has argued that POPIA's requirements regarding specific, explicitly defined purposes may pose difficulties for broad consent, particularly when biological samples and associated personal information are retained for future research (Thaldar & Townsend, 2021). Conversely, other scholarship has argued that POPIA should be interpreted within the broader health-research regulatory environment and that its research-related provisions may permit future processing under appropriately governed circumstances (Maseme, Gardner & Mohamed, 2024). Accordingly, it would be overly categorical to conclude that POPIA necessarily prohibits broad consent in all health-research or biobanking contexts. The legal position is more appropriately understood as involving an interaction between POPIA's requirements for the processing of personal information, the National Health Act 61 of 2003 and its regulatory framework, the 2024 Department of Health Ethics Guidelines, and the governance safeguards applied by research ethics committees and biobanks. In particular, the further-processing provisions of POPIA create an important part of the legal context in which the use of existing personal information for research must be considered.

The ethical defensibility of broad or tiered consent, therefore, depends not simply on the scope of the initial consent but also on the safeguards governing subsequent use. These may include independent ethics review, clearly articulated categories for future research, appropriate data access controls, confidentiality and security measures, transparency regarding future use, mechanisms for withdrawal where practicable, and institutional accountability. Broad consent may consequently be understood as prospective authorisation for defined categories of future research rather than as an unrestricted waiver of a participant's interests or rights (Maseme, Gardner & Mohamed, 2024). The unresolved issue for South Africa is therefore not simply whether specific or broad consent should prevail. Rather, it is about how different consent models can be reconciled with applicable data-protection law and research-ethics requirements while preserving autonomy, dignity, privacy, and public trust, and enabling ethically responsible secondary research.

Consent in biobanking cannot be reduced to a choice between specific and broad consent. Specific consent best reflects individual autonomy but is often impractical because future research uses are unknown, and repeated re-consent may limit research utility (Grady et al., 2015; Master et al., 2015). Broad consent is widely used for biobanks where future uses cannot be fully specified. It is not unlimited consent but a prospective authorisation within defined governance, transparency and ethics oversight structures (Grady et al., 2015). In South Africa, it is recognised in ethics guidelines, although its compatibility with POPIA’s purpose-specification requirement remains

contested (National Department of Health, 2024; Maseme, Gardner & Mahomed, 2024). Maseme et al. (2024) argue that this tension should be resolved through clearer regulation and stronger safeguards rather than excluding broad consent. Tiered consent offers a middle ground by allowing participants to choose categories of future use, increasing control while avoiding repeated consent. However, it remains complex to implement and may not fully anticipate evolving research needs (Kaye et al., 2015; Steinsbekk et al., 2013).

Overall, the literature highlights a tension between autonomy and research utility. Specific consent maximises control but limits flexibility, broad consent enables research but reduces specificity, and tiered consent balances both but adds complexity. The adequacy of any model, therefore, depends not only on the type of consent but also on governance measures such as ethics review, data protection, access controls, withdrawal options, and accountability mechanisms (National Department of Health, 2024; Maseme et al., 2024). In South Africa, the key issue is not choosing one model over another, but integrating consent approaches with POPIA, ethics requirements, and governance systems.

African research contexts further emphasise the need to integrate communal and cultural values into ethical practice (Amoakoh-Coleman et al., 2023). Such work highlights how collective notions of dignity and respect differ from Western individualism, demanding culturally sensitive tissue donation and use governance. This contextualisation is vital for South African and broader Global South frameworks, where historical inequalities intersect with present-day biobank operations.

1.8.2.2.3 Emerging Consent Challenges

This section examines emerging consent challenges specific to anatomical human tissue research. Anatomical research traditionally involves the study of donated human bodies and tissues for education, training, and scientific investigation, including dissection, skeletal analysis, imaging, and long-term preservation (Jones, 2019). While historically grounded in teaching, contemporary anatomical human tissue research increasingly incorporates advanced technologies such as 3D imaging and printing, digital archiving, artificial intelligence (AI), and the secondary use of human tissue (Jones, 2019; Bledsoe and Grizzle, 2022). These developments raise complex ethical concerns regarding the scope, validity, and duration of consent obtained from donors, particularly when tissues are used in ways not envisioned at the time of donation (Bledsoe and Grizzle, 2022)

Consent for contemporary uses, such as 3D printing, digital imaging, and artificial intelligence (AI) in human tissue research, raises critical ethical concerns (Jones, 2019; Briers and Dempers, 2017; Astromskė et al., 2021). Ethical issues also arise regarding the nature of consent provided by body donors for these activities, the commercialisation of the resulting digital prints, the use of 3D-printed images derived from unidentified persons, and the use of AI algorithms in human tissue research (Jones, 2019; Briers and Dempers, 2017; Astromskė et al., 2021). Harris et al. (2022) and Jones & Van den Heever (2025) highlight that consent frameworks must evolve for digital and contemporary tissue uses, including AI representations and machine-learning training sets. Additionally, Yu et al. (2024) emphasise the importance of transparency and accountability in the use of AI in human tissue research, warning that algorithmic decision-making can obscure ethical responsibility and exacerbate biases unless properly regulated. Ethical guidelines must be implemented proactively, prioritising transparency, autonomy, and data governance models that are as adaptable as the digital and AI technologies (Jones, 2019; Yu et al., 2024).

One of the significant gaps in consent and use of deceased human tissue for research in the context of South Africa is the use of skeletal or legacy collections and unidentified or unclaimed bodies, for which consent is unknown (L'Abbé et al., 2021; Jones, 2023; Cornwall et al., 2024a; Gibbon et al., 2024). Although current legislation permits the use of historical specimens and unidentified bodies, the ethics of utilising such unconsented human tissue remain a recurring concern (Gibbon et al., 2024). Thus, the provenance review process must be a mandatory initial element of the ethical framework promoting restorative justice, since legacy collections are often associated with historical human rights violations (racism, poverty, and colonialism) (Jones, 2023; Cornwall et al., 2024a).

Studies also suggest that it is unethical to continue using such unconsented collections for research; however, disposing of the tissue is neither a viable nor an ethical option (Gibbon et al., 2023). Instead, efforts should be made to determine their source, and the skeletal tissue should undergo restitution. This restitution and redress process contributes to restorative justice, reconciliation, and healing while confronting a traumatic historical moment (Gibbon et al., 2023). This view promotes autonomy and respect for persons, allowing individuals who were once exhumed as specimens to be reburied as people.

In contrast to this view, specific studies in South Africa (L'Abbé et al., 2021; Meiring et al., 2024; Baliso et al., 2025) argue that although consent may not have been obtained for these specimens, the individuals to whom they belong are also unable to state how they wish their remains to be disposed of as well. Hence, they should not be destroyed; instead, efforts should be made to determine their provenance before using such tissue for continued research. Baliso (2025) agrees

and stated that this would thereby provide clearer historical and cultural contexts, maintain ethical integrity, and enhance the research value of these individuals.

Kramer (2024) advocated for the legal prohibition of the use of unidentified bodies in research and education to protect autonomy, dignity, and social justice, and to prevent the exploitation of vulnerable populations. This position is ethically supported by Satyapal (2012), which affirmed that dignity persists after death and demonstrated how the historical use of unclaimed bodies has disproportionately burdened marginalised communities. Although Satyapal (2012) does not call for prohibition, the study exposed the ethical insufficiency of legality without consent. Kramer (2024) therefore favoured prohibition over regulated use, as attempts to locate next of kin are often inconsistent, resource-intensive, and difficult to standardise, thereby risking the continuation of structural injustice.

El-Haddad and Pather (2025) highlighted pivotal consent issues in repositories that precede modern ethical regulation of human foetal and embryological collections in Australia. They found that stakeholders emphasised the importance of consent, with thematic analysis revealing consent as a primary concern across macro, meso, and micro ethical levels. Macro-themes encompassed informed consent, equity and fairness, and consideration of genetic provenance. Meso-themes included respect, privacy, and institutional or legal frameworks. Micro-themes related to the emotional and educational value for donors and institutions. This study highlights the need for consent in human tissue research to extend beyond legal compliance to encompass broader ethical values, such as transparency, donor autonomy, and fairness, which are closely aligned with the present study's focus on consent models for living and deceased human tissue research (El-Haddad and Pather, 2025).

The issue of ownership of cadaveric human tissue for forensic research and whether consent should be inclusive of 'ownership' of a donor's tissue following death is lacking in international and national legislation and guidelines (Mahomed et al., 2017). Many bioethicists view leftover human tissue as "abandoned" by patients, concluding that patients have relinquished any property rights over these tissues (Allen et al., 2010). This perspective is based on the idea that donors have no continuing property interest in leftover tissue, especially if it is diseased or no longer necessary for human functions. Even if donors do not retain property rights, it is crucial to establish ethical guidelines governing the ownership and use of discarded tissue for research purposes (Mahomed et al., 2017).

1.8.2.3 Social Justice

This principle ensures that the benefits and burdens of human tissue research are distributed fairly, and that vulnerable populations are not disproportionately targeted or excluded (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). It ensures that researchers select participants equitably, that research results are accessible to all who may benefit from them, and that research is conducted ethically and fairly (Kapp, 2006). Recent literature extends the principle of justice to encompass benefit-sharing, equitable participation, and restitution for historically marginalised groups. Amoakoh-Coleman et al. (2023) and Gibbon et al. (2023) emphasise that justice must encompass socio-cultural restoration, including the restitution of legacy collections and transparency in the handling of historical specimens. These ethical imperatives underscore the need for procedural fairness in research governance and distributive justice in access to research benefits.

1.8.2.3.1 Role of Human Research Ethics Committees in South Africa (HRECs)

A Human Research Ethics Committee (HREC) ensures that research is conducted ethically and fairly. It protects the rights, safety, and well-being of participants and researchers while upholding ethical principles (Guillemin et al., 2012). The committee independently reviews research proposals involving human participants, thereby validating and enhancing the ethical credibility of the research findings (Lindorff, 2010; Guillemin et al., 2012). Most countries have established local and national human research ethics committees (HRECs) that perform their functions in numerous ways (Hemminki, 2016). HRECs also ensure independence to avoid conflict of interest; hence, a degree of ethical and scientific knowledge is required to review protocols (Klitzman, 2011). National regulations and ethical principles are used as a guide for ethics committees. The National Health Act of South Africa requires proposals for conducting human tissue research to undergo an independent ethics review before the research commences. Research Ethics review must be conducted by an independent REC registered with the National Health Research Ethics Council (NHREC). Approximately 44 RECs operate in South Africa (NHREC, 2024). According to the Department of Health (2015), the ethical review process entails an independent and impartial assessment of the research's significance and impact on study participants.

The differences in views and perspectives among HREC members regarding consent stem from the fact that each institution or University follows its own set of Standard Operating Procedures (SOPs) and is answerable to its own ethics research committee. Each research ethics committee develops and adheres to internal institutional guidelines during the research ethics review process. Each HREC also categorises the research study's complexity and risk level based on the specific

population being researched, according to different criteria, which leads to variations in members' views on the assessment of consent for a particular study (Xu et al., 2020). Because different research institutions or universities within the same country may have different research ethics guidelines for review and assessment, human tissue research across a country can lack uniformity in the research review process.

1.8.3 Synthesis of the Literature and Research Gap

The literature shows that human tissue research is underpinned by strong ethical principles, legal instruments, and professional guidance, but these do not constitute a fully integrated governance system throughout the entire tissue lifecycle. While international frameworks establish key principles such as autonomy, consent, dignity, justice and privacy (World Medical Association, 2024; CIOMS, 2016; UNESCO, 2005), they provide limited tissue-specific direction for issues such as long-term storage, secondary use, legacy collections, commercialisation, cross-border transfer and emerging technologies. The main gap is therefore not a lack of principles, but their insufficient integration across the full scope of human tissue governance.

Consent literature reflects a similar unresolved tension between protecting autonomy and enabling research. Specific consent strongly links donor choice to a defined purpose but is difficult to sustain for long-term or unforeseen research uses (Beauchamp & Childress, 2019; Wendler, 2006). Broad consent improves feasibility but raises concerns about meaningful participant understanding (Grady et al., 2015). Tiered and dynamic consent offer more flexible alternatives but require greater governance and infrastructure (Kaye et al., 2015; Budin-Ljøsne et al., 2017). The key issue, therefore, shifts from identifying the “best” consent model to determining the governance conditions needed to maintain ethical validity over time.

Biobanking further illustrates this governance gap. Internationally, approaches range from dedicated legislation to general law, ethical guidance and institutional governance, each with strengths and limitations. General law may lack specificity, dedicated legislation may be rigid, ethical guidance may lack enforceability, and institutional governance may create inconsistency (Knoppers, 2014). In South Africa, overlapping instruments such as the National Health Act, POPIA, and ethical guidelines create uncertainty due to the absence of a single, coherent framework for consent, secondary use, data governance, and biobank oversight (Department of Health, 2024; Staunton & Moodley, 2013). These challenges are intensified by South Africa’s historical and socio-legal context, including inequalities, cultural diversity, and issues of trust between communities and research institutions (Moodley & Singh, 2016; Staunton et al., 2018).

As a result, international ethical principles cannot simply be transferred but must be adapted to local realities, including fragmented regulation and institutional variation.

Overall, the literature reveals five key tensions: autonomy vs research utility; consent vs future use; legal compliance vs ethical legitimacy; innovation vs dignity; and institutional autonomy vs national consistency. These demonstrate that isolated developments in consent, legislation or governance are insufficient, and that an integrated approach is required. The research gap is therefore threefold. First, there is limited empirical evidence on how anatomists and researchers understand consent and ethical challenges in human tissue research. Second, there is insufficient evidence from South Africa on how HRECs and biobanks experience and manage governance and consent issues. Third, there is no integrated, consent-centred framework that synthesises ethical principles, empirical insights and South African regulatory requirements into a coherent system. Accordingly, this study addresses these gaps by developing the Integrated Consent-Centred Ethical Framework (ICEF), which positions consent as the central ethical anchor and links it to biobanking, secondary use, emerging technologies, and governance oversight within the South African context.

1.9 Methodology

1.9.1 Researcher Reflexivity Statement

Ms Seonaid Moonega (SM) holds a Bachelor's, Honours, and a master's degree in medical science (Anatomy). Her research focus to date has been on human body donations and research ethics. This academic background fostered an informed understanding of the processes involved in collecting, storing, and utilising human tissue, as well as an appreciation for their value in advancing scientific and medical knowledge. The body of work contained in this thesis is part of her Doctor of Philosophy; thus, it is essential to acknowledge that there may have been a confirmation bias that was introduced. To minimise this impact, the researcher adopted a reflexive stance throughout the study, critically examining how personal beliefs, disciplinary training, and professional values might shape the research process and outcomes (Finlay, 2002). Credibility was further enhanced through member checking, which allowed participants to clarify, expand on, or correct their responses at the end of each interview. This process reduced interviewer-led bias and ensured that participants' perspectives were accurately represented (Birt et al., 2016). Participants were also explicitly informed that there were no right or wrong answers, encouraging open and reliable engagement.

The researcher's positionality was relevant throughout the study because her disciplinary training and prior scholarly engagement with anatomy, human body donation and research ethics provided both subject-matter expertise and pre-existing assumptions about the ethical significance of consent, dignity and human remains. This positioning was treated as a potential source of interpretive influence rather than of neutrality. Reflexivity, therefore, involved repeatedly examining whether emerging interpretations were supported by participants' accounts or reflected the researcher's prior expectations. During interviews, open-ended questions and opportunities for participants to clarify or challenge interpretations were used to reduce interviewer-led framing. During analysis, coding, and theme development were repeatedly compared with the underlying transcripts, and co-coding/member verification and an audit trail were used where applicable. During framework development, empirical findings were explicitly distinguished from subsequent normative and regulatory interpretation. This distinction was important because the ICEF represents an interpretive synthesis of stakeholder evidence, ethical principles, and governance requirements.

1.9.2 Study Design

The study employed an in-depth, qualitative, exploratory study design to collect data from research participants (Charmaz, 2014; Patton, 2015; Cresswell and Poth, 2018). Both deductive and inductive approaches were used. The qualitative study approach enabled the researcher to derive in-depth information from participants. The research study was divided into three work packages (Figure 2 below), each with its own set of interview questions.

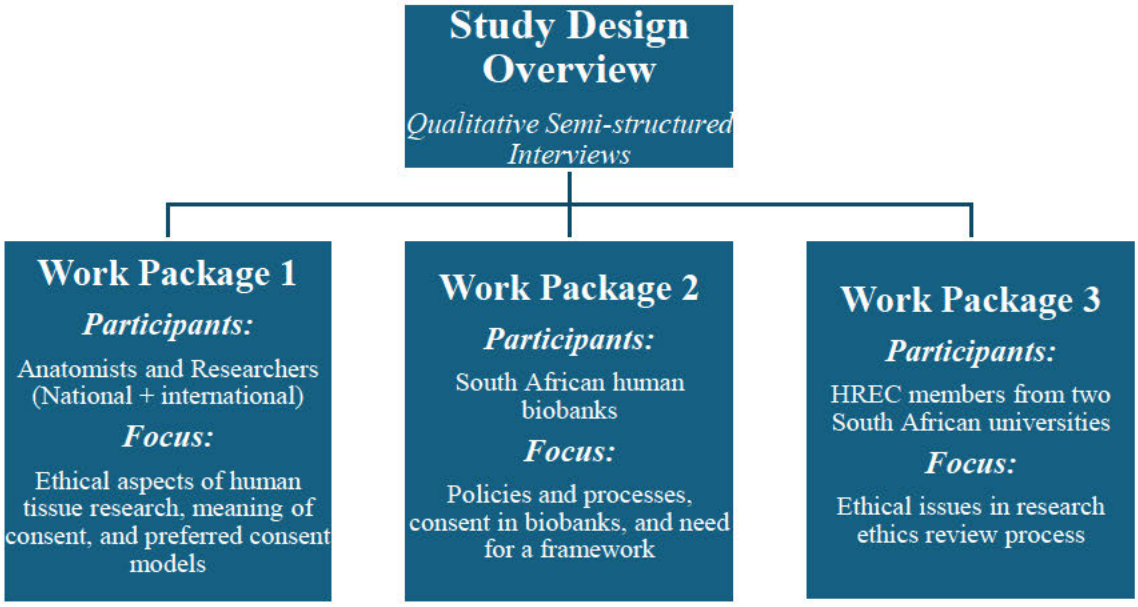

Figure 2. Study design overview.

Work Package 1 consisted of qualitative, semi-structured interviews with anatomists and researchers from both international and national contexts to gather their views and perspectives on the ethical aspects of human tissue research and to clarify further the concept of 'consent' in human tissue research, as well as their preferred consent model.

Work Package 2 consisted of qualitative, semi-structured interviews with existing human biobanks in South Africa to identify their policies and processes, the concept of 'consent' in human biobank research, and the need for an ethical framework.

Work package 3 consisted of qualitative semi-structured interviews with HREC members from two South African universities to document their opinions and understanding of the ethical issues identified in the research ethics review process.

The data obtained from one work package did not inform the interview guides for the next package. However, data collected from all three work packages were linked and related to each other and used to develop the ethical framework for human tissue research. This is because all stakeholders recruited for each work package are directly involved in the research or review process for the human tissue studies.

1.9.3 Sampling Strategy, Sampling Frame, and Sample Size

Sampling across the three work packages was purposive and information-rich rather than probability-based. Participants were selected based on their professional or institutional relevance to the research questions and their direct experience of human tissue research, anatomical practice, human research ethics review, or human biobanking. The sampling approach was therefore designed to obtain perspectives from stakeholders with relevant knowledge and experience rather than to produce a statistically representative sample of the broader populations of anatomists, researchers, HREC members, or human biobank managers.

For Work Package 1, the sampling frame comprised anatomists and researchers with professional involvement in human tissue research who were accessible through the Anatomical Society of Southern Africa (ASSA) and the International Federation of Associations of Anatomists (IFAA), which served as professional gatekeeper routes for recruitment. The inclusion of both South African and international participants was intended to provide variation in professional and geographical perspectives on the ethical governance of human tissue research. This international component enabled the study to identify ethical concerns that may extend beyond the South African context while retaining relevance to the development of a framework specifically situated within South Africa.

For Work Package 2, the sampling frame comprised South African human biobank managers or representatives with direct experience of the governance, storage, consent, reuse and/or management of human biological materials. Recruitment was undertaken through the institutional and professional gatekeeper routes described in the study protocol and participant information materials.

For Work Package 3, the sampling frame comprised members of South African Human Research Ethics Committees (HRECs) with experience relevant to the ethical review and governance of human tissue research. Recruitment was facilitated through the institutional gatekeeper route documented in the study protocol. The inclusion of HREC members was intended to provide perspectives from individuals directly involved in the ethical review and oversight of research involving human participants and human biological materials.

The eligibility criteria for each work package were those specified in the approved study protocol and associated participant information materials. These criteria were applied during recruitment and are reported in the individual manuscript Methods sections. No additional eligibility criteria were introduced retrospectively for the purpose of this thesis.

Sample size was determined through purposive recruitment and assessment of information sufficiency within the qualitative design rather than through statistical power calculations. Recruitment was undertaken to obtain information-rich accounts from participants with relevant expertise and experience. Data collection and analysis proceeded iteratively, allowing emerging issues and the sufficiency of the information obtained to inform subsequent recruitment. The final sample sizes should therefore be understood in relation to the depth and relevance of the data generated rather than as numerically representative samples of the respective stakeholder populations. The intended diversity across the work packages concerned professional role, institutional experience and, for Work Package 1, geographical context. This variation was important because ethical and governance challenges may be experienced differently by researchers, anatomists, HREC members and biobank managers. Bringing these perspectives together strengthened the analytical basis for identifying recurring ethical concerns and governance gaps that informed development of the Integrated Consent-Centred Ethical Framework (ICEF).

Accordingly, the findings are not presented as statistically generalisable to all anatomists, researchers, HREC members or human biobank managers. Rather, the contribution of the qualitative samples lies in the depth of participant accounts, variation in stakeholder perspectives

and identification of ethical and governance issues that may be analytically informative and potentially transferable to comparable human tissue research settings.

1.10 Layout of the Thesis (Thesis Structure)

Chapter	Chapter Title	Research Objective Addressed	Focus and Contribution	Journal/ Publication Status
1	Introduction	Contextual Framing of Thesis	Introduces the conceptual, historical, ethical, and regulatory foundations of human tissue research, situates the study within the South African and international settings, and defines the research problem, aims, and objectives.	N/A
2	Human Tissue Research Ethics and Consent Models: Global Reflections in Anatomical Sciences	Research Objective 1: To evaluate national and international stakeholders' views on human tissue research, with a specific focus on consent.	Presents an empirical analysis of anatomists' and researchers' perspectives across diverse international and national settings. Examines informed consent models, ethical challenges, and governance gaps, including issues related to contemporary human tissue research, commercialisation, foetal tissue, unconsented skeletal collections, and unidentified bodies. Identifies inconsistencies between ethical principles, regulatory requirements, and research practice, providing an empirical foundation for the consent-centred ethical framework.	*Annals of Anatomy* (Published; Ref: AANAT_152774)
3	Exploring Human Tissue Research Ethics in South Africa: A Qualitative Study of Research Ethics Committee and	Research Objective 2: To qualitatively investigate and explore the ethical views of South African HREC members and human biobanks on ethical concerns, consent	Explores ethical concerns, consent preferences, governance practices, and policy gaps within South African human tissue research and biobanking. Examines how consent, oversight, and human tissue management are interpreted and implemented at institutional and national levels, highlighting inconsistencies in ethics review and governance mechanisms. Provides context-specific evidence to ensure the framework's national relevance and practical applicability.	*Research Ethics* (Submitted; Manuscript ID RE-25-0167)

	Human Biobank Perspectives	preferences, and policy gaps in human tissue research and biobanking governance		
4	A Proposed Integrated Consent-Centred Ethical Framework for Human Tissue Research in South Africa	Research Objective 3: To develop a comprehensive ethical framework for human tissue research in South Africa.	Synthesises empirical findings from Chapters 2 and 3 with international and South African policy analysis and ethical principles. Develops a comprehensive, contextually relevant ethical framework offering practical guidance on consent processes, governance mechanisms, and ethical oversight to harmonise research practices and strengthen national governance.	*Anatomical Sciences Education Journal* (Submitted: Manuscript ID ASE-26-0059)
5	Synthesis	General discussion/synthesis	Demonstrates the logical thread that runs across the various manuscripts, indicating how each chapter addresses the objectives, and provides a conclusion and recommendations.	N/A

Interlinking Page

Chapter 1 established the ethical, historical, legal and regulatory foundations of the study and identified a key problem: existing frameworks do not provide an integrated approach to the acquisition, consent, storage, use and governance of human tissue. The literature highlighted ongoing tensions around consent, legacy collections, cadaveric tissue, biobanking, secondary use, commercialisation and emerging technologies, forming the basis for the empirical work.

Chapter 2 addresses *Research Objective 1* i.e., evaluating stakeholders' views, both nationally and internationally, on human tissue research, with a specific focus on informed consent. It explores how anatomists and researchers understand consent models, distinguish between living and cadaveric tissue, and perceive ethical challenges related to legacy collections, unidentified bodies, foetal tissue, commercialisation and emerging uses of human tissue.

The chapter identifies key stakeholder-level ethical and consent tensions, showing that consent is context-dependent and cannot be treated as purely procedural. It also reveals gaps between ethical principles, regulation and practice, supporting the need for a consent-centred approach. The chapter's findings identify recurring inconsistencies among ethical principles, regulatory requirements, and research practice, thereby generating empirically grounded perceptions that directly inform the fundamental components of the proposed ethical framework developed in subsequent chapters. The chapter also establishes the empirical foundation for the framework's consent-centred structure, governance considerations, and practical recommendations.

This chapter is presented in a manuscript format and is published in the *Annals of Anatomy-Anatomischer Anzeiger* journal (Reference: AANAT_152774; Appendix 1).

CHAPTER 2: FIRST MANUSCRIPT

Human Tissue Research Ethics and Consent Models: Global Reflections in Anatomical Sciences

Abstract

Background

Human tissue research has evolved to incorporate three-dimensional (3D) printing, genetic research, digital imaging of human tissue, plastination, and the public display of human specimens. This has raised several concerns regarding the ethical acquisition, storage, and use of human tissue, particularly in relation to informed consent. This empirical study gathered the perspectives and viewpoints of anatomists and researchers from five countries on the ethical aspects of human tissue research.

Methods

Thirty in-depth Zoom interviews were conducted with participants from South Africa, the United States of America (USA), New Zealand, Germany, and France. Participants shared their perspectives and viewpoints on informed consent models, ethical challenges surrounding human tissue research, and existing gaps in policy guidelines. The data was analysed using thematic and content analysis.

Results

Participants (57%) indicated that human tissue research on both living and deceased individuals is ethically distinct; hence, it requires separate policy guidelines and regulations. There was a clear preference for 'broad consent' and 'fully informed consent' when conducting research on living humans and using cadaveric tissue, respectively. Key ethical challenges and policy gaps were identified, including contemporary human tissue research, commercialisation of human tissue, consent for foetal tissue, and the use of unconsented skeletal collections and unidentified bodies for human tissue research.

Conclusions

This study highlights the moral complexity of contemporary human tissue research. It underscores the necessity for context-specific consent models and regulatory alignment for commercialisation and contemporary research uses of human tissue. Additionally, recommendations are provided to

address the policy gaps highlighted in consent models and to address the ethical challenges in human tissue research.

Keywords: Anatomists, Researchers, Human Tissue, Informed Consent, Ethics, Legislation

1. Introduction

Although human tissue research and ethics encompass diverse conceptual spheres, they are complementary and essential to bioethical questions regarding human life in research and clinical practice. Human tissue research has evolved to a multifaceted contemporary approach encompassing three-dimensional (3D) printing, genetic research, digital imaging of human tissue, plastination, and the public display of human tissue (Halkoaho et al., 2012). This evolution raises ethical concerns regarding the acquisition, storage, and use of human tissue, particularly in relation to informed consent. As a result, ethics plays a fundamental role in the study of human tissue. Previous studies have investigated appropriate consent models related to the ethics of living and cadaveric tissue research (Ballantyne et al., 2020; Ciliberti et al., 2021; Furness, 2003; Grady et al., 2015; Knoppers, 2005; Meiring et al., 2024; Wendler, 2013). These studies highlighted a significant shortfall in legislation, regulations, and policy guidelines for cadaveric tissue research as compared to research on living human tissue (Aaron et al., 2021; Bach, 2016; Champney, 2011; Gefenas et al., 2011). Bach (2016) alluded to the higher level of risk associated with research on living human tissue compared to cadaveric tissue. It was suggested that more regulations and policy guidelines should be implemented on the ethics of research on cadaveric tissue, considering the ever-advancing field of anatomy and the broad spectrum of what research on cadaveric tissue now encompasses (Bach, 2016; Champney, 2011; Ciliberti et al., 2021).

Several types of consent are used to acquire human tissue for present and future research, viz, broad, blanket, specific fully informed, and re-consent. “Broad consent” enables individuals to donate their tissue or body for unspecified future research, subject to specific consent and/or procedural restrictions. “Blanket consent,” on the other hand, allows individuals to donate their tissues or bodies without any limits. Conversely, “specific, fully informed consent” refers to individuals who agree to a clearly defined study based on a clear understanding of the study’s purpose, risks, and benefits. “Re-consent” refers to the renewal of consent from a research participant for future studies or when significant changes occur during the study (Grady et al., 2015). The variation in consent models has created uncertainty about what research is permitted, inadvertently limiting future research and sometimes resulting in research proceeding without consent (Wendler, 2013). Several studies have obtained opinions and perspectives from

researchers, patients, potential body donors, and ethics committee members on the most suitable consent models for living and cadaveric tissue research (Ballantyne et al., 2020; Grady et al., 2015; Masiye et al., 2023; Moodley et al., 2014). Conflicting views regarding consent models for research on cadaveric human tissue have been documented (Grady et al., 2015; Masiye et al., 2023; Wendler, 2013). Some stakeholders argued that Body Donation forms should include informed "blanket" consent for research conducted on body donors, as future anatomical research is unpredictable, and any restrictions placed on cadaveric tissue would limit and eventually terminate research altogether (Knoppers, 2005; Masiye et al., 2023; Wendler, 2013). Masiye et al. (2023) added that when an individual donates their body to 'science,' it is done to 'science' as a whole. However, some stakeholders were more inclined towards a more "specific" consent approach, where body donation forms should explicitly allow donors to choose how they would or would not like their tissue to be used to ensure that future research is conducted according to the wishes of the donor (Ciliberti et al., 2021; Moodley et al., 2014).

However, policy guidelines and human tissue legislation do not mention the most appropriate consent models recommended by regulatory ethics bodies for research on living and cadaveric tissue. To address these issues, scholars have suggested further study to provide evidence for policymakers to develop policy guidelines and make informed decisions on acceptable consent models in biomedical research (Comer, 2022). Therefore, this qualitative study explored the perspectives of anatomists and researchers from five countries on appropriate informed consent models, the ethical challenges surrounding human tissue research, and the gaps in existing policy guidelines to inform the development of guidelines towards an ethical framework for cadaveric tissue research in South Africa.

2. Methods

2.1 Study Design

This study examined stakeholder perspectives on the ethical aspects of human tissue research, as well as the current and preferred consent models. In this study, stakeholders were defined as anatomists and researchers involved in the study, teaching and research of the human body and its associated tissues. A qualitative, exploratory design was employed, incorporating both deductive and inductive approaches to gather data from research participants. This enabled the researcher to derive in-depth information concerning the ethics of human tissue research from study participants. This study was guided by a constructivist research paradigm, which suggests that reality is socially constructed through individual experiences, interpretations and

perspectives. This approach allowed the researcher to explore the subjective meanings that participants attach to their experiences and perspectives, rather than testing a pre-defined hypothesis (Kelly and Bunniss, 2010; Charmaz, 2014; Patton, 2015). Participants were interviewed, and their views, observations, and experiences were critically analysed to understand a phenomenon, common points of view, and emerging themes from the perspective of those experiencing it, so that ethical guidelines for research on human tissue can be formulated (Azungah, 2018). While the broad research questions and objectives were set (deductive), the analysis allowed new themes and patterns to emerge from the data (inductive).

2.2 Ethics Statement

Ethical approval for this study was obtained from the Biomedical Research Ethics Committee prior to data collection (BREC/00005587/2023) (Appendix 2). Informed consent was obtained from all the interviewees.

2.3 Data Collection Methods

Semi-structured interviews were conducted with international and national anatomists and researchers to gather their perspectives on the ethical aspects and their preferred consent models surrounding human tissue research. These interviews were conducted online in English and recorded via Zoom to produce data; each interview took approximately 20 minutes. The interview question guide (Appendix 3) was created by examining existing literature on the subject and identifying essential themes and concepts from the literature, consisting of open-ended questions, which allowed the principal investigator to add follow-up questions (Karatsareas, 2022). This data collection method was employed due to the flexibility of the approach, since semi-structured interviews can bring to light current information, new topics, or new dimensions to established knowledge (Karatsareas, 2022). Before administering the questionnaire to participants, a pilot test was conducted with a small sample of anatomists from the author's affiliated university to increase the reliability and validity of the results.

2.4 Recruitment of Participants and Sampling Strategy

A purposive sampling method was used to recruit participants, targeting key stakeholders to gain expert insights into human tissue research (Tajik et al., 2024). Given differences in national policy guidelines, stakeholders included anatomists and researchers from various countries. The

researcher approached the heads/gatekeepers of the Anatomical Society of Southern Africa (ASSA) and the International Federation of Associations of Anatomists (IFAA) and specifically requested assistance in reaching anatomists and researchers with professional involvement relevant to human tissue research. The study invitation was subsequently distributed through these professional networks. A total of 87 individuals were invited to participate. Because the researcher was not provided with a nationality-stratified list of all individuals to whom the invitation was distributed, the nationality of each invited individual cannot be retrospectively established from the study records. Nationality was not used as an inclusion, exclusion or selection criterion. The nationality distribution reported in this study, therefore, refers only to participants who ultimately consented and for whom demographic information was collected. ASSA was selected for its inclusion of anatomists in South African universities, while IFAA was chosen for its global reach. Upon receiving permission and the participant lists, the principal investigator emailed an invitation to potential participants, along with the participant information sheet (Appendix 4) and the informed consent form (Appendix 4), requesting a signed response from those willing to participate in the study.

The use of both ASSA and IFAA recruitment routes was intended to provide variation in professional and geographical perspectives. South African participants provided perspectives directly relevant to the national ethical and regulatory context, while international participants provided comparative professional perspectives on ethical practices and governance challenges in human tissue research. The international component was therefore not intended to provide a statistically representative international sample, but to broaden the range of professional experiences informing the analysis.

Recruitment was conducted through the established professional gatekeeper routes, with prospective participants receiving information regarding the study and the voluntary nature of participation. Eligibility was determined according to the criteria specified in the approved study protocol and participant information documentation. No additional eligibility criteria were introduced retrospectively.

Of the eighty-seven (87) invited individuals, thirty (30) agreed to participate in Zoom interviews, which were audio-recorded for analysis and subsequent review. Before the interviews, personal data such as name, institutional affiliation, and job title were recorded but anonymised in reporting. The 30 participants included twenty (20) from South Africa, four (4) from the USA, three (3) from New Zealand, two (2) from Germany, and one (1) from France (Figure 1). The final sample size was determined through purposive recruitment and consideration of information

sufficiency within the qualitative design rather than statistical representativeness. Data collection and analysis were iterative, with emerging findings informing assessment of whether further interviews were required to address the research questions and develop the emerging categories and themes.

The sample was therefore designed to provide information-rich perspectives from individuals with relevant professional experience rather than to estimate the prevalence of ethical views within the wider anatomy or research community. The findings should consequently be interpreted as analytically informative and potentially transferable to comparable human tissue research settings, rather than statistically generalisable to all anatomists or researchers.

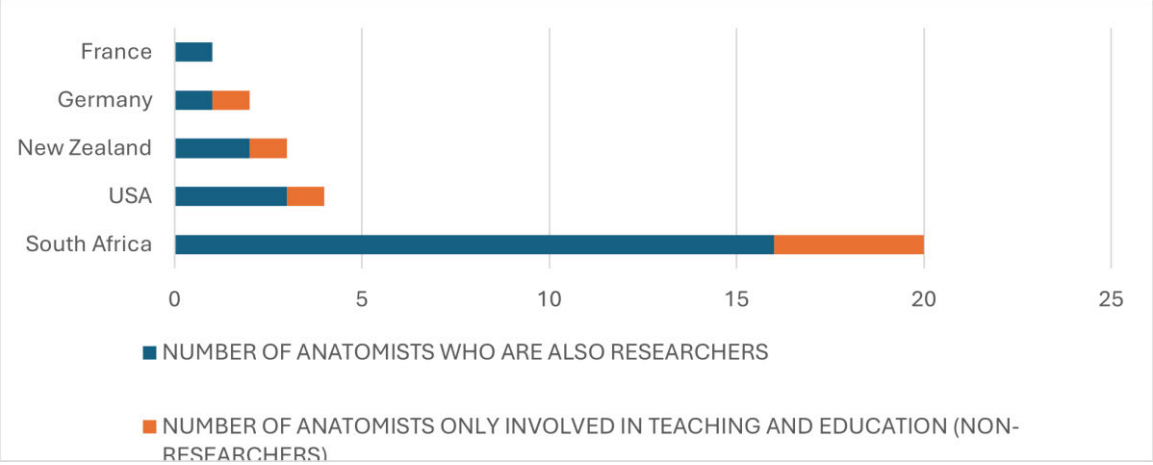

Figure 1. Category of Stakeholders Recruited by Country.

Additionally, a prevalence of anatomists who were also researchers ($^{23}/_{30,}$ 77%) in various research fields, such as imaging and radiology, human tissue ethics, biological and forensic anthropology, cell biology, gross anatomy, and neuroanatomy, was noted.

2.5 Data Analysis

All interview recordings were transcribed using NVivo and coded according to participant type and country, reflecting the study's three components, e.g., SA_ANAT_01 for a South African anatomist, USA_ANATRES_01 for a U.S. anatomist-researcher.

The authors repeatedly engaged with the data to identify, analyse, and report patterns using a step-by-step approach, which allowed for the refinement of findings and ensured that conclusions were sound. Hence, data analysis was ongoing, using thematic analysis (Naeem et al., 2023). The iterative process involved the following steps: (1) Familiarisation of the data by reviewing

transcribed interview recordings; (2) Building a coding frame by developing a system of codes to apply to the data; (3) Defining and grouping codes to create broader categories. This step involved going back to the data to determine how well the codes fit and adjusting as needed; (4) Identifying patterns and emergent themes by further examining each code group; (5) Selecting quotes from the interviews that supported the identified themes; and (6) Reviewing themes by comparing them to existing literature. This contributed to the transferability of the data collected, allowing for the extrapolation of the research findings to other similar settings (Kekeya, 2016). A co-coder was used, and themes were identified independently and then compared and agreed upon. Member verification was also conducted to ensure that the collected data accurately reflected the participants' statements on human tissue research ethics practices. Rigour was maintained through a clear audit trail, and the final interviews reached data saturation.

3. Results and Discussion

The hierarchical coding frame of the analysed data led to the creation of the following overarching themes, which formed the results and findings of this study (Figure 2). The findings are presented and discussed according to the final three themes deduced from the overall analysis of the data: *(i) Research on Living vs Cadaveric Tissue: how different or similar are they? (ii) Consent Model Preferences: Living and Cadaveric Tissue, and (iii) Ethical Challenges and Gaps in Human Tissue Research.*

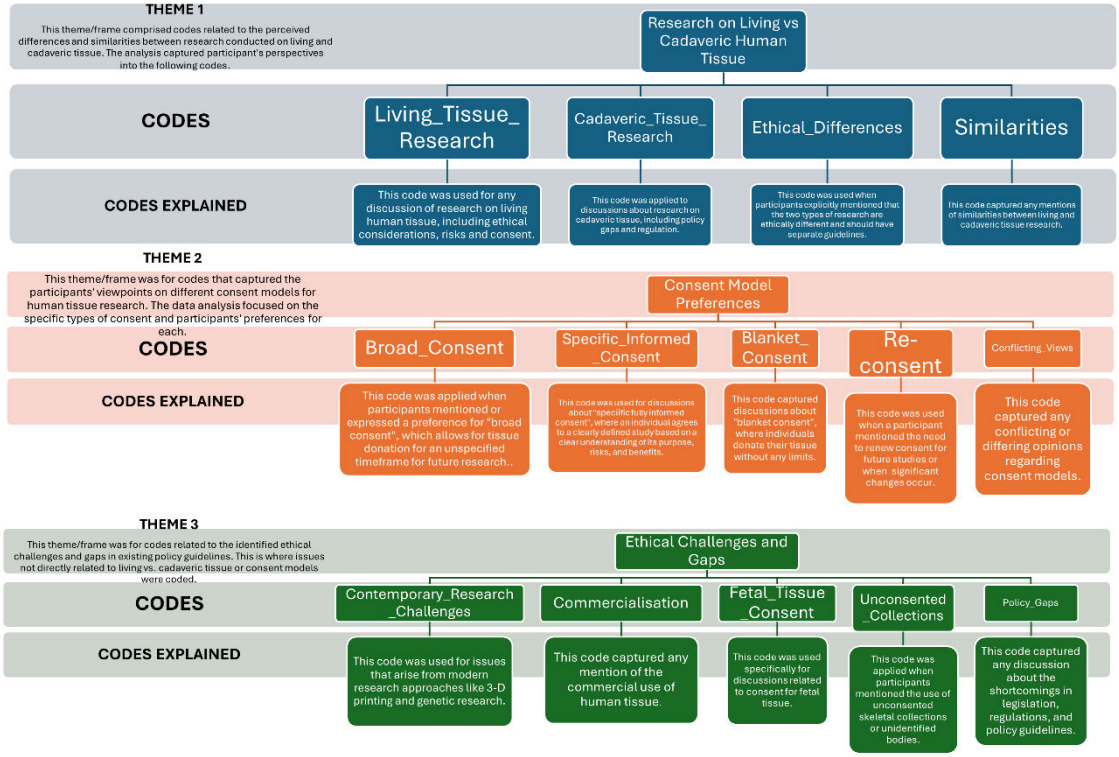

Figure 2. Hierarchical Coding Frame from the Analysed Data.

3.1 Research on Living vs Cadaveric Tissue: How different or similar are they?

Seventeen participants ($^{17}/_{30}$) indicated that research on living and cadaveric tissue differs significantly, with distinct consent and levels of risk; therefore, they require separate policy guidelines and regulations.

"…They are almost two different subjects. They are, of course, separated by death, yes. Moreover, death is viewed differently from life. The most substantial similarity is that both are tissues, and then everything changes…like you know, with deceased human tissue, consent is already acquired, most often voluntarily, whereas with living human tissue, you have to acquire consent from the Department of Health, from hospitals or sometimes from patients directly for radiographs". (SA_ANATRES_03)

They also stated that the process of recruiting and maintaining living participants for research and the acquisition of consent is time-consuming and complicated compared to research on the deceased. Participants also advocated that both divides should be clearly defined and regulated through separate legislation and policy guidelines. This aligns with Knoppers (2005), who noted

that when using tissue samples removed during routine medical care for research in university hospitals in Canada, general consent is typically obtained upon hospital admission, and participants have the right to withdraw from participating in such research at any time (Knoppers, 2005). As stated by Thasler et al. (2002), living participants can advocate for themselves, whereas the deceased cannot; hence, it is easier to access and utilise tissue from the deceased for a broad range of research than from the living (Thasler et al., 2002). Consequently, more barriers to access exist for research on the living compared to research on the deceased.

Participants mentioned that the level of risk is significantly higher for research on the living, especially research on vulnerable groups and children, compared to research on the deceased. This view supported the Belmont Report, which highlights possible harms, viz., risks of psychological harm, physical harm, legal harm, social harm, and economic harm, and the corresponding benefits of executing a research study that is ethically sound and just (Nagai et al., 2022). Further, it also supports Matisonn and Maude (2023) who emphasised moral status (or human dignity), which uses Metz's and Chemhuru's moral theories to highlight that dead human bodies lack moral status because they do not have goal-directed behaviour or cannot be made better or worse off, as in research on the living (Matisonn and Maude, 2023).

Thirteen participants ($^{13}/_{30}$) mentioned more similarities than differences between human tissue research on living and deceased individuals. They described a continuum from the living human to the deceased human, stating that cadaveric tissue should not be treated as an 'object' after death, but should be offered the same dignity and respect, treated in the same manner, and regulated with equal protection.

"…So, I think that there are not as many differences as other people do. I talk about a continuum from the living human to the deceased. So, both should be given the same considerations, the same respect…maybe they are different in a legal context, but when you say ethically…yes, ethically they are the same." (USA_ANATRES_02)

This view contrasts with the Metz and Chemhuru theories but aligns with Jones (2007), who asserts that a cadaver possesses both intrinsic and influential values (Jones, 2007). He argues that "the intrinsic value of a living person is conferred upon his/her cadaver at death and when a person and his/her body are inseparable." As a result, how the living behave affects how they treat the dead and contributes to the idea that a corpse deserves respect and "decent" care, as reflected in Jones' (2007) words, "To desecrate a corpse is … to desecrate a person".

3.2 Consent Model Preferences: Living and Cadaveric Tissue

3.2.1 Consent Model Preferences for Living Human Tissue

Half of the study participants ($^{15}/_{30}$) preferred 'broad consent' to specific informed consent for research on living human tissue or biological specimens (Figure 3).

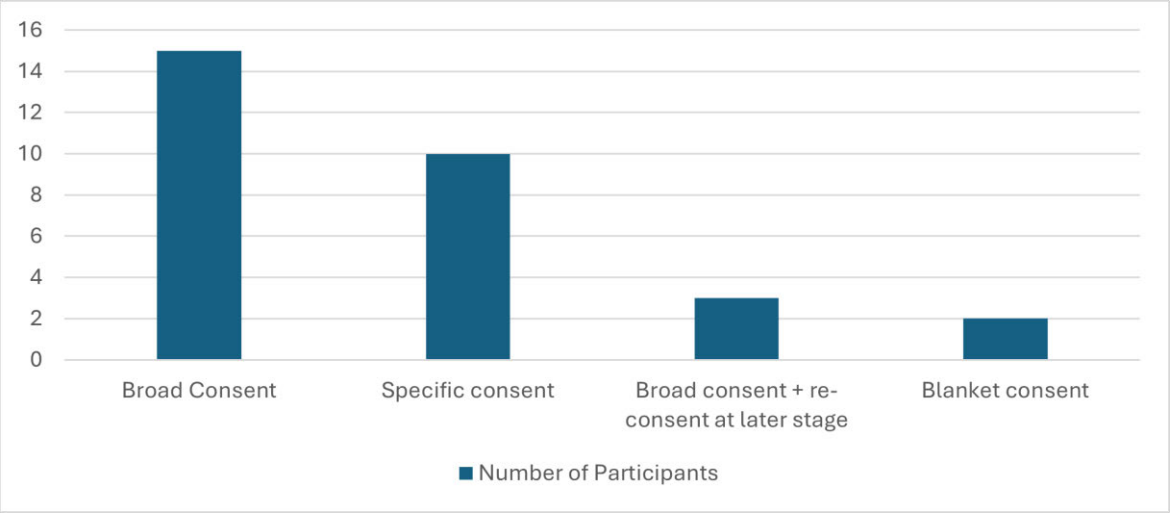

Figure 3. Participants' Consent Model Preferences for Research on Living Human Tissue.

Advocating for broad consent, its practicality from a researcher's perspective was emphasised.

"…I would say broad consent is more appropriate and suitable from the point of a researcher, especially… it is expensive, you know, to use tissue for a specific study and then to destroy it afterwards, and it is also time-consuming… so broad consent works because it allows you to do future research without wastage and getting consent again". (SA_ANATRES_01)

The primary reason for broad consent was that it is not feasible to collect tissue specimens using specific consent continually, as this would also mean destroying leftover tissue samples after each study, thereby wasting precious biological tissue. Most participants favoured this consent model since it allows for the reuse of samples within the scope of the original permission, offering flexibility and efficiency.

The Common Rule is a US Policy for the Protection of Human Subjects that was initially introduced in 1979 and offers a modern ethical and regulatory framework for research involving human subjects and is based on the three ethical principles of the Belmont Report: beneficence, justice, and respect for persons to protect research participants (Aaron et al., 2021). Supporting the finding in this study, the 2018 amendment to the Common Rule (effective in January 2019) introduced broad consent as a legal option. It states that broad consent can only be used to get study participants' permission to store, maintain, and use identifiable biological samples or private

information for secondary research (Masiye et al., 2023). Broad consent is considered ethical and optimal since it eliminates the potential strain on researchers of requesting participants to decide for every new study, and gives them control over whether their samples are used for research (Grady et al., 2015; Wendler, 2013). However, Gefenas (2011) and Wendler (2013) argued that broad consent should contain a requirement that mentions that future research can only be performed if an independent body determines that the proposed study is morally acceptable and presents no more than minimal risk (Wendler, 2013; Gefenas et al., 2011).

In contrast, some participants ($^{10}/_{30}$) preferred specific informed consent to broad consent, stating that individuals would not fully understand the nature of future studies at the time of providing consent, and it is not easy to know what types of research may develop in the future and whether individuals would have consented to such a study. This consent model also ensured that researchers do not misuse biological samples in future studies and offered more protection and respect for participants.

"*…it is not ethical for participants to consent to a broad range of research when it is uncertain what type of research the future holds, and it may not be something that the participant would consent to…so I would say in terms of ethics, specific consent is the most ethical and ensures protection of the participant." (FR_ANATRES_01)*

This preference aligns with a survey by Tosoni (2022), in which most patients favoured being informed, educated, and given a choice about potential research uses, favouring a specific informed consent approach that prioritises clarity and transparency. However, Tosoni (2022) mentions that this model has limitations, such as difficulty in tracking participants, resulting in the disposal and wastage of tissue specimens, which limits opportunities for valuable future human tissue research (Tosoni et al., 2022).

A small cohort of participants ($^{3}/_{30}$) favoured a broad consent approach with the option to acquire proxy or re-consent at a later stage from the individual when the use of the tissue changes with advances in human tissue research. They mentioned that this could prevent the destruction of human tissue once a specific research project is completed, thereby protecting the participant and respecting their wishes.

"…And so, one of them that I will mention is proxy consent or re-consent. And that being said, allowing for the need to provide further consent when we believe that the request falls so far outside of the original consent that we do not feel comfortable, or a participant may not feel comfortable, right? We can go to the individual or the proxy for re-consent...this protects and respects them, and biospecimens will not go to waste, right?" (USA_ANAT_01)

Resnik (2009) states that broad consent with re-consent may be suitable when the original consent was invalid, or there has been a significant change to the research or the participant's condition since the original consent; however, a more appropriate approach is hypothesised to be reaffirmation. This approach is suitable when a substantial amount of time has passed, allowing participants to reconsider their participation, and does not require participants to sign a new consent document (Resnik, 2009).

Only two participants ($^{2}/_{30}$) preferred blanket consent, citing that it allowed human tissue samples to be used in any research without limitations. They mentioned that when individuals donate human tissue samples to science, they relinquish their rights to the samples. Hence, the specimens can be used in future research without any restrictions. As one participant expressed:

"…When someone donates their body or tissue samples to science, they donate them to different types of research in science as a whole…Hence, I feel consent should be taken from the donor as an umbrella or blanket consent for all types of human tissue research. It should not be restricted or limited in any way…the more we limit this, eventually research will cease to exist." (SA_ANAT_04)

In contrast with this view, Masiye et al. (2023) argued that blanket consent is not informed consent at all since participants are not fully informed about the type of future use of biological samples, and it is considered unethical as participants cannot agree to something they do not know (Masiye et al., 2023).

3.2.2 Consent Model Preferences for Cadaveric Tissue

Most participants ($^{17}/_{30}$) favoured a specific fully informed consent approach for research on cadaveric tissue. They stated that body donation forms should be as detailed as possible, allowing donors to select the types of research they would permit their body and tissues to be used for, as well as the types of research they would not be in favour of. (Figure 4)

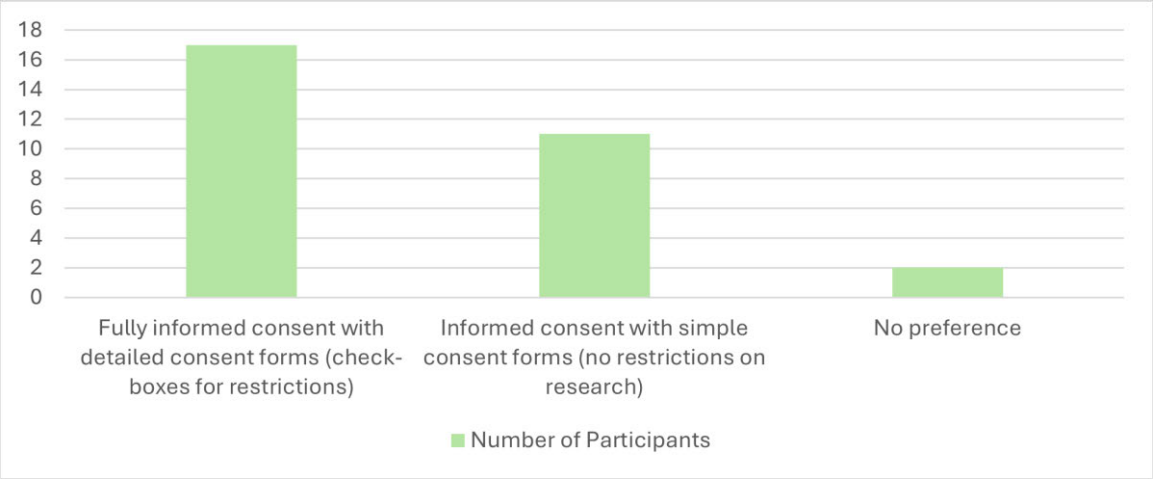

Figure 4. Participants' Consent Preferences for Body Donors (Cadaveric Tissue Research).

The reasons provided by participants were that the donor has the right to be fully aware and informed about how their body and tissues will be used for research and has the right to stipulate what they will permit and what they will not. Participants mentioned that consent forms should inform participants that the type of research uses will change and whether they consent to this.

"…So I am in favour of a more detailed consent where the individual who is going to donate would have a check box that could say yes you could do this and no you cannot do that you know and mention the different research uses and allow them to choose…because they may sign off, they may consent, but do we really know that a future research use is something that they would have been comfortable with? Would they have approved of this?" (USA_ANATRES_02)

Conversely, some participants ($^{11}/_{30}$) favoured simpler consent forms that asked the donor whether they consented or not to their body and tissues being used for research in general, with no detailed checkboxes restricting research in any way. One of the reasons stated for this was that when donors consent to donate their bodies for human tissue research, the consent includes all types of research; otherwise, the purpose of the study is defeated. Another participant mentioned that consent forms are a historical document, and it is impossible to predict how anatomy and research will advance; hence, blanket consent should apply to all research on cadaveric tissue. As one participant noted:

"…But, you know, I have always asked the question, if I donated my body previously to science. So, science is widely defined, and therefore, you know, it, it doesn't have to be an explicit specific permission, for every type of scientific research…consent should encompass and include all of that… it is all science after all." (SA_ANATRES_11)

Two participants expressed no preference for any consent model, emphasising that their choice would depend on the information provided. They would select the type of consent in which sufficient information about the study is supplied to prospective research participants.

"…researchers are required to follow research guidelines of the country in which they live…so I do not think a researcher can prefer a consent model…we just have to follow the research regulations in our country and what it says about consent." (USA_ANATRES_03)

When asked about waivers of consent, participants reported instances where institutions approved research without direct consent, particularly in studies involving skeletal collections or cadavers. An entire bone collection was sometimes approved for multiple research projects via an institutional waiver.

"…So, if we find something and we want to do research in that aspect, we normally ask the collections committee of the school, because they are the holder of that waiver, and we send them a full protocol as to what we are going to do. And they will notify the ethics committee of the different projects which have fallen under the waiver." (SA_ANATRES_03)

These findings are particularly relevant to South Africa, where donor consent forms are typically straightforward, simply asking the donor whether they consent to the use of their body for research. This finding is consistent with Meiring (2024), who mentions that specific and detailed research uses are not mentioned in most donor consent forms in South Africa, and since informed consent is grounded on the principle of autonomy, in the absence of fully informed, detailed consent, a donor is thus deprived of their independence and, in turn, their dignity (Meiring et al., 2024).

In New Zealand, participants reported that donor consent forms clearly specify the type of research for which the donor's body and tissues will be used, enabling donors to make a fully informed decision.

In the USA, Anatomists and researchers believe that donor consent forms tend to prioritise legalities over the ethical aspects of human tissue research. This is congruent with the findings of Zealley et al. (2022), who states that although the donor consent forms in most American States differ, the recurring finding was that additional information needs to be included in donor consent forms to better inform donors and their families about the donation process, the specific types of research for which their bodies and tissues will be utilised, and the final disposal of the bodies once studies are completed. Although the donation forms indicated that a body may be used for education and/or research, only 2% of the forms provided examples of the types of research (Zealley et al., 2022).

One participant from Germany mentioned an interesting approach to body donor consent, following a "3-type donor" model, which allows donors to choose between being a 24-hour donor, a 1-year donor, or a lifetime donor. A 24-hour donor consent would allow the University to harvest as much tissue as possible in 24 hours and then suture the body back together and return to the family for last rites; a 1-year donor consent allows for the use of the donor's body for 1 year only, and thereafter the remains are cremated and returned to the family. Lifetime donor consent allows the unrestricted and unlimited use of the donor's body for human tissue research. This practical and ethical approach allows the donors to make informed choices about the extent and duration to which they would like their bodies to be used for research.

3.3 Ethical Challenges and Gaps in Human Tissue Research

The ethical issues and gaps in human tissue research mentioned by participants are reflected in Figure 5.

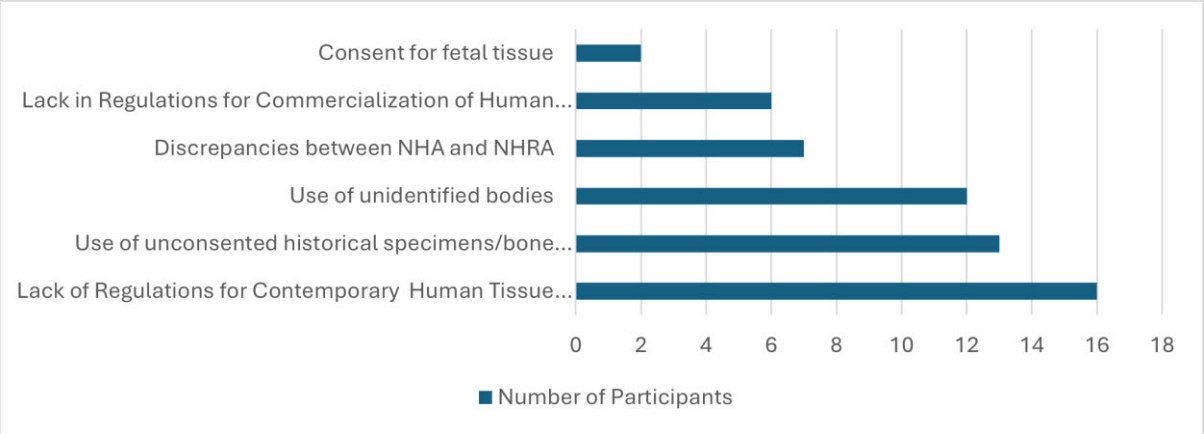

Figure 5. Ethical Challenges and Gaps in Human Tissue Research Mentioned by Participants.

3.3.1 Lack of Regulations for Contemporary Human Tissue Research

Sixteen participants ($^{16}/_{30}$) identified the main ethical gap as being the lack of regulations for contemporary human tissue research (advancements or developments in anatomical and human tissue research), such as 3D printing of the human body, digital imaging (used for publications and teaching, plastination of specimens, genetic analyses, and the public display of specimens (museums and conference exhibitions).

"…Should we just be able to perform a genomic analysis on a donor when there are ramifications for relatives and cultures? Should we be able to undertake 3D printing and then move those prints internationally? Whether it be the acquisition of images, photographs,

printing, plastination, genomic analyses, or international transfer, it is not an ethical right." (NZ_ANATRES_01)

Most participants agreed that 3D prints, digital images, and plastinated human body specimens should still be regarded as human tissue, treated with the same dignity and respect as the cadaver itself, and regulated appropriately by policy guidelines. It was repeatedly mentioned that using and circulating images in unethical ways can undermine the relationship with local communities and potential body donors. Thus, these contemporary uses of human tissue must be appropriately managed and controlled. Participants also stated that the same regulations that apply to genetic analyses on living individuals should also apply to the deceased. This view aligns with the IFAA Recommendations for the Ethical Use of Anatomical Images (Cornwall et al., 2024). One of the main recommendations mentioned by the IFAA is that the use of images should be covered by informed, specific consent of the body donor at the time of consent. Consent forms should indicate whether donors agree to these modern applications, allowing ethically sound practices to proceed with donor autonomy (Cornwall et al., 2024). This recommendation would permit the contemporary use of human tissue to proceed without any ethical consideration, as it is known that the donor explicitly consented to this use at the time of donation. Thus affirming, Jones (2019) stated that retaining the humanity of anatomy is paramount and obtaining 3D-printed images from unidentified persons is unacceptable. 3D imaging represents a move away from the human body or person. Therefore, recommendations and guidelines must be implemented to prevent the dominance of such depersonalisation in human tissue research (Jones, 2019).

However, some anatomists in this study stated that plastinated specimens are not entirely 'human biological tissue' since they contain a significant amount of plastic. Although they represent the human body or tissues, they are not human tissue. Proper policy guidelines must then be implemented to regulate the plastination of specimens and how these hybrid models (part human and part plastic) should be treated. This affirms Jones (2002) in that although plastinated models (Anatomy Art) are merely representations of the human body and/or tissues, they still contain a 'human' element regardless. Hence, such 'hybrid' models should be treated equally as human tissue (Bin et al., 2016).

3.3.2 Use of Unconsented Skeletal Collections and Unidentified/Unclaimed Bodies in South Africa

A recurring challenge mentioned by participants was differentiating between the legality and ethics of human tissue research encompassing the use of unconsented historical specimens or bone collections ($^{13}/_{30}$), as well as unidentified or unclaimed bodies ($^{12}/_{30}$). Only participants from

South Africa identified this as a challenge to research in their country since the use of unidentified bodies is still permitted and utilised in certain Universities in the country. Participants from the USA, Germany, New Zealand, and France mentioned using unidentified bodies as a general concern for human tissue research, but not specifically in their countries, since most universities only utilise bodies from Body Donation Programmes for research. To fully understand this ethical challenge, it is essential to realise that Human skeletal collections were used in South Africa for medical education and research as early as 1919, following the introduction of Departments of Anatomy in various universities. Once gross anatomy dissection was completed, the bodies were further macerated and processed into skeletons, then catalogued into the Raymond A. Dart Skeletal Collection, which now contains approximately 2022 individuals, of whom the majority are Black South African males (Dayal et al., 2009). The ethical dilemma, however, arises concerning what should be done presently about these legacy skeletal collections and unclaimed bodies for which consent is unknown. Should these collections and bodies be reviewed to understand their origin, should they be returned, or should they be disposed of? This ethical dilemma must be balanced with the reality that if the origin of these skeletal collections or unclaimed bodies is not determined or investigated, these individuals or collections could remain in storage indefinitely or be destroyed (L'Abbé et al., 2021).

Although the use of such human tissue is regarded as legal in terms of legislation and regulations in South Africa (SA), some participants in this study deem their use as unethical and state that it does not respect the integrity and autonomy of the deceased individuals to whom they belonged, since no consent has been knowingly obtained for such human tissue specimens or bodies. Therefore, they suggest that such historical tissue should be legally prohibited from being used for research and disposed of.

"…I think about those institutions that use unclaimed bodies or use unidentified bodies. Well, those individuals obviously never consented. And if they are used in teaching, research, or any other process, they are being used without their consent, right? And therefore, my view is we should not even be using unclaimed or unidentified bodies. Legal prohibitions should be made against its use" (SA_ANATRES_03)

This finding is consistent with other studies in South Africa, which state that due to ethical concerns, some medical schools in the country are no longer utilising unclaimed persons for research and education and mentions that no clarity has been provided within the research community in South Africa as to how to address the ethics of unclaimed bodies and skeletal collections that are currently being used for education and research (Baliso et al., 2025; Gibbon et al., 2024; L'Abbé et al., 2021; Meiring et al., 2024). From a global perspective, Jones and

Whitaker (2012) also note that the use of unidentified bodies for research has raised ethical concerns regarding the inclusion of historical or unidentified image data in public exhibitions worldwide (Jones and Whitaker, 2012). The IFAA suggests that in the case of unidentified or historical image data, an indication of the consent status of the person (unknown, unconsented, or consented) should be provided together with the image upon display or publication; however, where possible, images from historical collections and unidentified persons should be replaced with images from consented persons (Cornwall et al., 2024).

In contrast, a few anatomists from South Africa in the field of biological anthropology argued that if the use of unidentified bodies for human tissue research is deemed unethical and if laws are implemented to prohibit its use, then the study of biological anthropology of the population of South Africa will not be inclusive of all racial groups within the South African population.

"...So, I think that racial categorisation is the main issue for human tissue research in SA. We are so focused on ethics sometimes that we cannot help the racial groups that need help. Body donors are majority of white race group here and we cannot study the anthropology of other races because of the ethics of using unclaimed bodies...we need to understand that we are not comparing people or races we are comparing traits." (SA_ANAT_02)

These anatomists stated that, presently, almost all donated bodies at their institutions belong to the White population group, and the balance of the bodies are from unidentified persons. Although Awareness Campaigns exist to promote body donation among other racial groups in South Africa, body donors from the different population groups in South Africa are still limited. Thus, they added that it is essential to understand that anthropological research is not a form of "race science" and that comparisons are not being drawn between people and races; instead, it involves comparing traits and human variation. This opinion starkly contrasts with much of the available literature on South Africa (Chia and Oyeniran, 2020; Gibbon et al., 2023; Habicht et al., 2018; Kramer, 2024; Walters and Jansen, 2022). The dominant view emerging from all these studies, as mentioned precisely by Walters and Jansen (2022), is that unidentified bodies belong to individuals who may have died in public places and who are from impoverished communities. Their class, race, and health statuses are a result of systemic discrimination imposed on them during apartheid. Hence, the continued use of these bodies is unethical, and anthropological research should proceed through the proper channels of body donation and public awareness rather than relying on unidentified bodies (Walters and Jansen, 2022).

Anatomists ($^{5}/_{30}$) also stated that, although these historical specimens may not have been obtained with consent, they should not be discarded, as this would be a waste of precious human tissue. Baliso et al. (2025) agree that, instead, its origin should be conceptualised and used as a lesson

for the future acquisition of consent for skeletal collections and body donors to maintain ethical integrity while enhancing these individuals' research value (Baliso et al., 2025). They argued that although consent may not have been obtained for these specimens, the individuals to whom they belonged have also not consented to how they wish their remains to be disposed of. Hence, the conventional means of disposing of their human remains would also be deemed unethical.

"…So, again, the problem for me is the fact that our collections are old, the…bone collection is old and not consented for use, but does that mean we should discard it completely? We cannot discard it but rather learn from it for future collections…we cannot simply destroy historical data because we feel it has been obtained unethically." (SA_ANATRES_01)

3.3.3 Discrepancies between the National Health Act (NHA) and the National Heritage Resources Act (NHRA) in South Africa

Another issue raised by participants from South Africa ($^{7}/_{30}$) is that discrepancies exist in policy guidelines between the National Health Act, which regulates human tissue research in general, and the National Heritage Resources Act, which governs research on archaeological remains, in South Africa.

"…So, there is tension between the Heritage Resources Act and the National Health Act, in terms of who it belongs to, you know? So, under the Heritage Act, human body tissue is considered artefacts or objects, not people and persons. Whereas in the National Health Act, they are seen as people and persons, and not objects. So, there is a discordance in that area." (SA_ANATRES_04)

In line with L'Abbé et al. (2021), participants in this study noted that the NHA is vague and lacks sufficient information on cadaveric material. In contrast, the NHRA does not specify who the legal authority is to consent to the use of skeletal remains for research (L'Abbé et al., 2021). Stakeholders in this study also noted an inconsistency between the two Acts, whereby the NHA refers to human tissue as 'people/persons.' In contrast, the NHRA refers to human tissue or skeletal remains as 'artefacts/objects.' Some participants argued that skeletal remains used in legacy bone collections for research should not be referred to as 'artefacts/objects' as they once belonged to a human being and are, hence, derivatives of human tissue. They agreed that these Acts should correlate, and guidelines should refer to heritage resources and material as 'human tissue'.

On the other hand, other participants believed that skeletal remains are no longer human tissue, and it is appropriate to refer to them as 'objects/artefacts. This discrepancy and argument can be resolved using Stutz's (2023) model of liminality for human remains, where human remains are

viewed as existing on a continuum between being objects of science and lived lives. This model is proposed to capture the range of how human heritage remains are perceived, classified, and handled, on one end of the spectrum, from the view of the remains as being a relative or an ancestor, to the other end of the spectrum, which is a view represented by science, as objects to be studied (Stutz, 2023). The flexibility of this liminal positioning of the classification of human remains aids in better understanding how human remains should be treated during research and consent requirements (Stutz, 2023).

3.3.4 Commercialisation of Human Tissue

Another gap in human tissue research included the need for proper regulations controlling the commercialisation of human tissue ($^{6}/_{30}$), including body brokering and the trade of human tissue.

"…So here in the United States, the gap is, mostly in the legal realm, where, basically, there are no prohibitions against trade with dead human tissues. There are body brokering companies handling body donations, but they really are for-profit organisations…So we need a law specifically addressing the prohibition of for-profit marketing of dead human bodies, which essentially prey on the indigent." (USA_ANATRES_01)

Although participants from varying countries in the study identified the commercialisation of human tissue as a concern for human tissue research ethics, participants from the USA specifically regarded using human tissue for profit as a key gap in human tissue policy guidelines. They mentioned that there are no prohibitions on the use of cadaveric tissue for trade, and, in some instances, there are body brokering companies dealing with body donations, but they are for-profit organisations. This finding is consistent with Champney et al. (2019), who state that these companies advertise for donors, pay for cremation and other fees for the donor, distribute the bodies or body parts nationally and internationally, and charge their users for access to the body or body parts to generate profits (Champney et al., 2019). Some anatomists and researchers also mentioned that, in some instances, the public display of human tissue specimens in exhibitions and anatomy conferences is also considered a form of commercialisation and commodification of human tissue. Hence, such issues need to be appropriately regulated in ethical policy guidelines. Considering this perspective, IFAA Recommendations for the Ethical Use of Anatomical Images and IFAA Recommendations for Good Practice for the Donation and Study of Human Bodies and Tissue for Anatomical Examination state that human tissue images should not be commodified or yield monetary gain, meaning they should not be bought, sold, or traded for profit (Cornwall et al., 2024; IFAA, 2012). This finding is also congruent with Bin (2016), who mentions that when donors consent to donate their bodies and tissues, they do so for the better good and the primary purpose of advancing research and science. The public display of bodies, tissues, and plastinated

specimens in exhibitions, museums, and conferences should be conducted solely for research and educational purposes, rather than for commercial gain, entertainment, or recognition (Bin et al., 2016).

3.3.5 Consent for Foetal Tissue

A minority of participants ($^{2}/_{30}$) expressed concern for research on foetal tissue, specifically consent surrounding foetal tissue research.

"…The foetal specimens are a bit older. So, I do not think there was necessarily a tick box to say, I consent…I think the biggest ethical issue that you can probably talk up, sort of for hours upon hours, is the use of and consent for foetal samples, either embalmed or fresh, and partly because of how they are perceived by hospitals." (SA_ANATRES_01)

Anatomists in this study stated that it is difficult to determine whether consent was provided by parents or mothers for the use of foetal tissue for research, especially since the termination of pregnancy consent and body donor consent forms do not stipulate or provide for this research use. To address this issue, Barker et al. (2022) suggested that consent for termination of pregnancy should be separated from consent for the potential use of foetal material so that the donating woman can understand that the termination and possible research use of the foetal tissue are separate voluntary consents and that the consent can be withdrawn at any time up to the point of tissue collection. He also suggested that the woman be fully informed about the potential research uses of the foetal tissue, research funding, potential benefits, whether the research is approved, additional tests that may occur before the donation to determine any infections, and the implications of these tests. She should then be allowed to ask questions or raise concerns (Barker et al., 2022).

4. Key Findings and Recommendations

This study revealed essential insights from anatomists and researchers across multiple countries regarding the ethical dimensions and policy needs in human tissue research:

1) Ethical Considerations: Most study participants indicated that human tissue research on the living and deceased is ethically vastly different, as they are entirely different subjects and hence require separate policy guidelines and regulations.
2) Broad Consent Choice: Most anatomists and researchers preferred 'broad consent' for research on living human tissue because of its flexibility and practicality

3) Body Donor Forms: Detailed body donation consent forms, thus allowing potential donors to select the types of research they would permit their body and tissues to be used for and the kinds of research they would not consent to. This would enhance autonomy.
4) Regulation: Updating policy guidelines to regulate and control contemporary human tissue research uses, such as 3D printing, digital imaging, and public display of specimens. Guidelines should also include recommendations on how to deal with 'hybrid models' or plastinated specimens.
5) Legacy Collections: As consent is unknown, most anatomists and researchers deem it unethical to research skeletal collections and unidentified bodies. The provenance of legacy collections requires investigation before their continued use, and the use of unidentified bodies should be legally prohibited for human tissue research.
6) Legal inconsistencies: Discrepancies between the National Health Act and the National Heritage Resources Act regarding the referral of human heritage remains and tissue as 'people/persons' and 'artefacts/objects' need to be addressed.
7) Prohibit Commercialisation: Further recommendations should be implemented to prohibit using human tissue for commercialisation, trade/body brokering, and public display of human specimens for profit.
8) Foetal tissue consent: Consent acquired for termination of pregnancy should be separated from consent for the potential use of foetal material so that the donating woman can understand that the termination and research use of the foetal tissue are separate consents.

5. Conclusion

The findings of this study provide some evidence to support policies on consent and inform the development of new policy guidelines and recommendations. Additionally, they inform current discussions on appropriate consent models to be used for the future use of biological samples. A balance between conducting research and treating living and cadaveric tissue ethically is emphasised, requiring clear policy guidelines, community engagement, and adherence to ethical, legal, and cultural concerns. Furthermore, the ethical challenges posed by consent, autonomy, the ethical use of human tissue, and the respectful treatment of both the living and the deceased require ongoing consideration and attention. Hence, a clear ethical framework is necessary to address the aforementioned ethical challenges/gaps in human tissue research, as identified by key stakeholders.

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7. Author Contributions

S Singh, B.Z. De Gama and P. Pillay collaborated to conceive the study. S Singh was responsible for the conceptualisation, data curation, and analysis and drafted the manuscript. P Pillay and BZ De Gama supervised, analysed, reviewed and edited the manuscript. All authors read and approved the final manuscript.

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9. Data Availability Statement

The data supporting this study's findings are available from the corresponding author upon reasonable request from bona fide researchers.

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Chapter 2 examined international and national perspectives of anatomists and researchers on informed consent and the ethical challenges in human tissue research, and identified key ethical and consent-related tensions, showing that no single consent model is sufficient. Stakeholders distinguished between living and cadaveric tissue, with broad consent considered appropriate for the future use of living tissue, while fully informed consent was emphasised for cadaveric tissue. The chapter also highlighted unresolved issues in legacy collections, unidentified bodies, foetal tissue, commercialisation, and emerging technologies, revealing a gap between ethical principles, regulation, and practice. This raised the question of how these tensions are managed within South African governance structures, particularly in HRECs and biobanks.

Chapter 3, therefore, addresses *Research Objective 2, i.e.* qualitatively investigating and exploring the ethical views of South African Human Research Ethics Committee (HREC) members and human biobank managers on ethical concerns, consent preferences, and policy gaps in human tissue research and biobanking governance. It explores how consent is interpreted for storage and secondary use, and how legislation and policy shape institutional practice. Building on the ethical and policy gaps identified in Chapter 2, this chapter examines how ethical review processes are implemented, how consent, governance, and human tissue management are interpreted and implemented at institutional and national levels, and where inconsistencies and gaps persist within oversight mechanisms. In doing so, Chapter 3 shifts the focus from identifying ethical tensions to analysing how they are governed in the South African context, providing the empirical basis for the development of the Integrated Consent-Centred Ethical Framework (ICEF).

The findings are presented in a manuscript format and have been submitted to the *Research Ethics* journal (Appendix 1) (Manuscript ID RE-25-0167).

CHAPTER 3: SECOND MANUSCRIPT

Exploring Perspectives on Ethical Concerns and Challenges from Human Research Ethics Committee and Human Biobanks in South Africa: A Qualitative Study

Abstract

Human Research Ethics Committees (HRECs) play a central role in ensuring the ethical conduct and scientific merit of research involving human participants. Human biobanks facilitate the collection, storage, and distribution of biological materials for research, advancing scientific discovery, improving healthcare outcomes, and ensuring the responsible use of human tissue in accordance with ethical and legal standards. This qualitative study explored the perspectives of HREC members and human biobank representatives in South Africa to identify ethical concerns and challenges in the human tissue research review process and biobanking, as well as policy gaps and consent preferences for human biobanking. Twenty-four in-depth interviews were conducted online with fifteen HREC members from two South African Institutions and nine representatives from human biobanks. Data were analysed using the NVivo software and thematic and content analysis. The themes identified for HRECs were: 1) Review Process Concerns, and 2) Challenges for Ethical Consideration. The themes for human biobanks were: 1) Consent Model Preferences, and 2) Ethical Challenges in Human Biobanking. HREC members (60%) identified interventional studies, particularly clinical trials involving pregnant women, children, or foetal tissue, as posing significant ethical challenges during review. Additionally, the absence of a national ethics oversight structure was a significant issue reported by most HREC members (73%), as existing HRECs operate independently across institutions. HREC members (70%) supported broad consent for future tissue use and raised emerging concerns about the role of artificial intelligence (AI) in research ethics. Similarly, most biobank representatives (67%) preferred a broad consent model for secondary research. Biobank managers highlighted the lack of specific legislation, national policy, and oversight mechanisms for biobanking, as well as challenges in sharing tissue and data, and maintaining confidentiality. The findings underscore the need for a national ethics platform and a dedicated biobanking policy framework/regulatory authority to harmonise review processes, promote consistent ethical standards, strengthen ethical governance, enhance transparency, and ensure responsible stewardship of human tissue in South Africa.

Keywords

HREC members, human biobanks, consent, ethics, human tissue

1. Introduction

“Human tissue research” refers to the scientific study, analysis, or use of biological materials derived from the human body for educational or research purposes. It encompasses research involving both living and deceased donors (through body donation programmes), including human biobanking, anatomical study, genetic analysis, and the development of biomedical technologies (Bledsoe and Grizzle, 2022). In the context of this study, Human Research Ethics Committees (HRECs) are defined as independent, multidisciplinary bodies established within research institutions to safeguard the rights, dignity, and well-being of human research participants or donors. Their primary role is to review, approve, and monitor human tissue research involving human participants or human biological tissue, ensuring that studies comply with ethical principles, legal requirements, and accepted standards of scientific integrity (NHREC, 2024; Beauchamp and Childress, 2019). Human biobanks are structured institutions that serve as custodians of donated human tissue, systematically collecting, processing, storing, and managing human biological samples for current and future research purposes (Kaye et al., 2016).

Human Research Ethics Committees (HRECs) and human biobanks together form the foundation of ethical oversight and scientific progress in research involving human tissue. HRECs safeguard the ethical and scientific integrity of studies by ensuring that research respects the principles of autonomy, beneficence, non-maleficence, and justice (Beauchamp and Childress, 2019). Currently, approximately 44 HRECs are operating in South Africa (NHREC, 2024). The National Health Act of South Africa requires that proposals involving human tissue research undergo an independent ethics review before commencing the research. Human biobanks, on the other hand, implement these ethical principles in practice by facilitating the collection, storage, and distribution of biological materials to advance health innovation while protecting donors' rights and maintaining public trust (Department of Health, 2024). The interdependence of HRECs and human biobanks is thus crucial, as one governs ethical approval and oversight, while the other governs the ethical management and long-term oversight of human tissue (Singh and Moodley, 2021).

From a principle-based approach (Beauchamp and Childress, 2019), South Africa’s HREC and human biobanking systems demonstrate an imbalance between autonomy and beneficence, with the latter often prioritised to facilitate research efficiency. A justice-oriented bioethical approach, emphasising equity, transparency, and regulatory governance, is needed to restore this balance.

Ethical frameworks must therefore move beyond legal compliance to represent a transformative moral vision that integrates contextual sensitivity, cultural respect, and social responsibility.

Persistent ethical inconsistencies in HREC review processes and human biobanking governance reflect a tension between international ethical principles and social realities. While international ethical frameworks, such as the Declaration of Helsinki (1964, revised in 2024) and the Council for International Organisations of Medical Sciences (CIOMS, 2016; World Medical Association, 2024), prescribe uniform standards for consent, autonomy, and participant protection, these principles often require adaptation to local cultural and socio-legal contexts. In South Africa, where colonial legacies and social inequalities continue to influence body donation and tissue sourcing, the principle of justice becomes particularly important (Gibbon et al., 2024). Differences in power between researchers, institutions, and communities exacerbate ethical vulnerability, leading to the unfair application of consent standards and varying degrees of participant protection (Amoakoh-Coleman et al., 2023; Gibbon et al., 2024).

International comparisons, particularly with frameworks established in countries such as the United Kingdom, the United States, Finland, and Australia, are essential to this discussion because they highlight global precedents for ethical governance while exposing context-specific challenges unique to South Africa. For instance, in countries with comprehensive human biobank legislation, like Finland's Biobank Act 2013, clear procedural guidance ensures transparency and donor protection (Kaye et al., 2016). In contrast, South Africa's fragmented framework, governed by the National Health Act 61 of 2003, the Protection of Personal Information Act (POPIA), and the Department of Health Ethics Guidelines (2024), lacks a unified policy that aligns consent, data protection, and secondary use (National Health Act, 2003; POPIA, 2013; Department of Health, 2024). These inconsistencies stem not only from legal omissions but also from deeper structural issues, including differing cultural conceptions of autonomy, historical injustices in the treatment of the deceased, and institutional power dynamics that prioritise research progress over donor rights (Dhai 2013; Singh and Moodley, 2021).

Despite the creation of ethical codes, consent remains the most controversial and inconsistently applied principle**.** Studies highlight disagreement over whether donors should re-consent for secondary use, whether dynamic consent models are feasible, and how autonomy can be protected when human biobank samples are anonymised (Ballantyne et al., 2020; Colledge et al., 2019). Within South Africa, the conflict between the Department of Health's (DOH) permitted broad consent and POPIA's specific consent requirement demonstrates the regulatory conflict that undermines both ethical integrity and research efficiency (Maseme et al., 2024). These

inconsistencies point to a broader theoretical gap, the dominance of procedural ethics (focusing on compliance) over substantive ethics (focusing on moral reasoning and personal accountability).

1.1 Problem Statement and Purpose

There is a lack of empirical evidence from South Africa examining how HRECs and Human Biobank representatives navigate ethical and consent-related challenges in human tissue research. The absence of standardised guidance and the conflicting regulatory contexts create uncertainty for ethics committees and researchers. Therefore, this study explored the ethical concerns, consent model preferences, and perceived policy gaps among HREC members and Human Biobank representatives in South Africa. It sought to identify the main areas of ethical concern in the review of human tissue research, examine stakeholders' perspectives on suitable consent models for biobank-based research, assess the inadequacy of existing legislation and regulations guiding HREC review processes, and provide recommendations for developing a more coherent ethical framework for human tissue research in South Africa. By addressing these objectives, this study strengthens the ethical governance of human tissue research and human biobanks in South Africa. It advances global discussions on harmonising consent and oversight models in human research ethics.

2. Methods

2.1 Research Paradigm

This study qualitatively explored the perspectives of HREC members and human biobanks in South Africa on the challenges associated with human tissue research in the country. It specifically focused on gaps in policies regulating HRECs and human tissue biobanks, challenges encountered in the research ethics review process and human tissue biobanking, and preferred consent models for human biobanking. A qualitative, exploratory design was employed, incorporating both deductive and inductive approaches to gather data from research participants. This enabled the researcher to derive in-depth information from study participants. This study was guided by a constructivist research paradigm and a phenomenological qualitative approach, both of which emphasise understanding human experience through interpretation and meaning-making. A phenomenological approach was employed to explore how HREC members and human biobanks perceive and interpret these ethical challenges in practice. Phenomenology seeks to uncover the essence of lived experiences (Van Manen, 2016), allowing this study to capture

the depth and complexity of participants' views on consent, governance, and ethical review (Kelly and Bunniss, 2010).

2.2 Researcher Reflexivity Statement

SM holds a Bachelor's, Honours and a master's degree in medical science (Anatomy), and her research focus to date has been on human body donations and research ethics. This body of work is part of her doctoral research. This academic background fostered an informed understanding of the processes involved in collecting, storing, and using human biological materials, as well as an appreciation of their value in advancing scientific and medical knowledge. It is important to acknowledge that, given this work contributes to SM's Doctor of Philosophy, there may have been confirmation bias carried over. To minimise this impact, the researcher adopted a reflexive stance throughout the study, critically examining how personal beliefs, disciplinary training, and professional values might shape the research process and outcomes. Participants could clarify and expand on their responses at the end of each interview, reducing interviewer bias. Participants were also informed that no right or wrong answers were sought after.

2.3 Sampling Strategy

A purposive sampling approach was employed to recruit participants with direct experience in the ethical oversight and management of human tissue research in South Africa (Tajik et al., 2024). Human Research Ethics Committee (HREC) Chairs from two South African universities were contacted via email to obtain gatekeeper permission to invite their members (Appendix 2). These institutions were selected for their access to and relevance to the research questions within the approved study design. The purpose was not to obtain a statistically representative sample of all South African universities, but to obtain detailed perspectives from individuals directly involved in the ethical review of human tissue research. The inclusion of two institutional settings enabled comparison of experiences across separate HREC environments while remaining feasible within the qualitative design and approved recruitment procedures. The findings are therefore interpreted as analytically informative and potentially transferable to comparable institutional settings rather than statistically representative of all South African universities.

At the same time, managers of selected Human Biobanks/Biorepository facilities were similarly approached for voluntary participation. 15 South African human biobank or biorepository facilities/institutional units identified through relevant institutional and professional networks were approached for participation. The sampling strategy was purposive, with the researcher seeking information-rich biobanks that had direct professional involvement in the management,

governance, storage and/or use of human biological material. Participation was voluntary, and nine human biobank managers or representatives ultimately participated in the study, representing nine participating biobanks. The recruitment process, therefore, resulted in participation from 60% of the facilities approached. The 15 facilities approached constituted the accessible recruitment pool for this study and should not be interpreted as a comprehensive national sampling frame of all potentially eligible South African biobanks. The purpose of the sampling was to obtain detailed stakeholder perspectives relevant to the research questions rather than to achieve statistical representativeness. This sample was selected to ensure a diverse range of expert perspectives from individuals directly involved in the ethical oversight and management of human tissue research in South Africa.

Combining these two stakeholder groups enabled the study to examine the intersection of human ethical review and biobank practice, providing a comprehensive understanding of current challenges and opportunities for improving ethical governance in human tissue research.

Following approval from the HREC Chairs and receipt of participant lists, invitation emails, participant information sheets (Appendix 3), and informed consent forms (Appendix 3), the documents were distributed. Of the forty-five (45) individuals invited, twenty-four (24) participated in the study, comprising fifteen (15) HREC members and nine (9) Human Biobank managers from South Africa. Sampling continued until thematic saturation was reached, defined as the point at which no new codes, themes, or perspectives emerged from subsequent interviews (Guest et al., 2006; Saunders et al., 2018). The researcher assessed saturation iteratively by reviewing transcripts and comparing emerging codes after each interview. Data collection ceased after three consecutive interviews yielded no new insights, confirming that the data were sufficiently deep and rich to address the study's research questions.

2.4 Sampling Frame, Recruitment, and Sample Size

For Work Packages 2 and 3, purposive sampling was used to recruit participants with direct experience of human biobanking and institutional ethical review of human tissue research in South Africa. The sampling frame was therefore defined by institutional and professional relevance to the research questions rather than by the intention to achieve statistical representativeness.

For Work Package 2, the sampling frame comprised South African human biobank managers or representatives involved in the management and governance of human biological materials.

Recruitment was undertaken through the institutional gatekeeper route documented in the approved study protocol and participant information materials. Participants were selected because their professional roles provided direct experience with issues including consent, storage, secondary use, data governance, and the sharing and/or export of human biological materials.

For Work Package 3, the sampling frame comprised members of South African Human Research Ethics Committees (HRECs) with relevant experience in the ethical review and governance of research involving human tissue. Recruitment was conducted through the institutional gatekeeper process documented in the approved study protocol. The inclusion of HREC members enabled the study to examine ethical review processes and governance concerns from the perspective of individuals directly involved in institutional oversight of research ethics.

The final sample sizes were determined through purposive recruitment and consideration of information sufficiency within the qualitative design. The objective was to obtain detailed and relevant accounts from participants with direct experience of the research phenomena rather than to generate statistically representative estimates. The samples were therefore interpreted in relation to the depth, relevance, and diversity of participants' experiences. Findings from Work Packages 2 and 3 are consequently presented as analytically informative and contextually relevant to South African human tissue research governance, with potential transferability to comparable institutional and research settings.

Sampling in this study was purposive and information-rich. Participants were selected for their direct professional involvement in human tissue research, ethical review, anatomical practice, or human biobanking. The sampling frame was therefore defined by professional and institutional relevance to the research questions rather than by an intention to produce a statistically representative sample of all anatomists, researchers, HREC members or human biobank managers in South Africa. Consequently, the findings are not presented as statistically generalisable to the South African population of professionals concerned with human tissue research. Their value lies instead in the depth of stakeholder perspectives, variation in professional experience and the analytical insight they provide into ethical and governance challenges. The findings may be transferable to comparable human tissue research and governance settings where similar institutional, ethical or regulatory conditions exist.

2.5 Ethics Statement

Ethical approval for this study was obtained from the Biomedical Research Ethics Committee prior to data collection (BREC/00005587/2023). Informed consent was obtained from all the interviewees.

2.6 Data Collection Methods

Semi-structured interviews were conducted with HREC members and Human Biobank managers in South Africa to explore their perspectives on the ethical concerns in human tissue research review and human biobanking, preferred consent models for biobanking, and policy gaps in human tissue research review and human biobanking governance. During data collection, participants' responses were contextualised by considering their professional and institutional settings. The interviews generated qualitative data through audio recordings and verbatim transcripts. Data collection took place between March and October 2024, with transcription and preliminary analysis conducted concurrently to facilitate iterative refinement of the interview process.

Interviews were conducted in English, online via Zoom, and lasted approximately 20–30 minutes each. An interview guide for HREC members (Appendix 4) and human biobanks (Appendix 5) was developed based on a review of relevant literature and policy frameworks, with a focus on key themes such as consent models, ethical challenges, regulatory alignment, and governance practices. The guide included open-ended questions encouraging participants to elaborate on their experiences and opinions. As data collection progressed, minor adjustments were made to the phrasing and sequencing of questions to probe emerging themes and clarify issues identified in earlier interviews, reflecting the iterative and adaptive nature of qualitative inquiry. Participant identifiers, including names, institutional affiliations, and job titles, were collected for recordkeeping but anonymised in all reporting to ensure confidentiality.

During data analysis, interview transcripts were analysed together with field notes captured via Zoom Notes. These field notes documented contextual observations and non-verbal cues, which were used to corroborate and elaborate emerging codes and themes. This process constituted methodological triangulation by integrating multiple data sources into the analysis to enhance the credibility of the findings.

2.7 Data Processing and Analysis

All interview recordings were transcribed verbatim and imported into NVivo (version 14) for systematic management and analysis. Each transcript was coded by participant group and institutional affiliation to remove identifiable information (e.g., HREC_1_01 for a member of University 1, *HREC_2_01* for a member of University 2, and *HTB_01–HTB_09* for Human Biobank managers). Transcripts were cross-checked against audio recordings to ensure data integrity for accuracy before analysis. All files were password-protected, stored on an encrypted device, and anonymised to safeguard participant confidentiality.

Data analysis was conducted concurrently with data collection, employing a thematic and content analysis approach (Kekeya, 2016). This iterative process involved repeated reading of transcripts, the development of a coding framework, and grouping related codes into categories and themes. Emerging patterns and themes were refined through constant comparison and review, considering existing literature to enhance credibility and transferability. A co-coder independently verified the coding scheme and thematic structure, while member verification ensured interpretive accuracy. Rigour was maintained through an audit trail that documented analytic decisions, reflexive journaling to account for researcher influence, and ongoing peer debriefing with supervisors.

2.8 Methodological Limitations

The use of purposive sampling from specialised professional populations may have limited the range of perspectives available within each work package. Although stakeholder diversity was intentionally sought, professional homogeneity may have influenced when information sufficiency was considered achieved. This limitation is addressed by interpreting the findings in terms of analytical relevance and transferability rather than statistical representativeness.

3. Findings and Discussion

3.1 Participant Demographics

The fifteen HREC participants represented diverse professional backgrounds, including academia, research, clinical practice, psychology, and bioethics. Human biobank managers oversaw facilities that collected, stored, and distributed various human tissues, including blood,

plasma, cadaveric material, musculoskeletal tissue, and organs used for research and, in some cases, transplantation. Of the nine human biobanks interviewed, six stored tissue exclusively for research purposes, two stored tissue for both research and transplantation, and one stored tissue for transplantation purposes only.

3.2 Themes and sub-themes

Qualitative thematic analysis of interviews with HREC members and human biobanks identified two main themes, summarised in Table 1.

Table 1. Main themes and related sub-themes identified during qualitative analysis

Stakeholder	Themes	Sub-themes
HRECs	Review Process Ethical Concerns	• Interventional human research studies • Research on pregnant women, children, and foetal tissue
	Challenges for Ethical Consideration	• Independent institutional HRECs • Consent for storage, re-use, and export of human tissue for secondary research • Issues with ethics applications, review process, and supporting documents • Lack of ethical guidance on research involving artificial intelligence (AI) and human genetics
Human Biobanks	Consent Model Preferences	• Broad consent • Tiered consent Specific consent
	Ethical Challenges in Human Biobanking/Policy Gaps	• Limited specificity for biobanking and secondary use of tissue • Tissue sample/data sharing, export and commercialisation

3.2.1 Human Research Ethics Committees (HRECs)

3.2.1.1 Review Process Ethical Concerns

This theme raises the question of the extent to which the current ethical review process in South Africa provides a balanced, transparent, and equitable assessment of research risk (Bernabe et al., 2012).

Most HREC members ($^{9}/_{15}$) reflected that interventional human research studies, particularly clinical trials, pose significant ethical challenges during the review process. They also specifically mentioned that research involving pregnant women, children, foetal tissue, and certain racial groups presents the most concerns.

> "*…I think interventional studies present the most ethical challenges, so studies where you are testing a new product or a new behavioural intervention, such as one trying to help young pregnant women or children. These are vulnerable target groups…so they present more ethical challenges and require a thorough ethical review compared to research on the deceased". (HREC_2_07).*

> *"…One area of human research I would say that can raise many ethical concerns during review is research conducted on foetuses or foetal tissue. Here, consent for foetal tissue research is important and comes into play. We must find out what level of risk is imposed on the foetus during the research study, so the review process must be extensive, and we must, you know, be stringent with our feedback". (HREC_1_06).*

Affirming this study's findings, McKiever et al. (2020) emphasise that interventional studies involving living participants, particularly clinical trials, research with pregnant women or children, foetal tissue research, and studies targeting specific racial or ethnic groups, are categorised as high-risk and therefore warrant full ethical review. Pregnant women and children are recognised as vulnerable populations requiring heightened ethical safeguards, as pregnancy-related physiological changes can alter drug metabolism and toxicity, while the children's developing physiology may result in unpredictable responses to medical interventions. These factors necessitate a careful balancing of potential social or scientific value against potential harms to participants (McKiever et al., 2020). Extending this understanding, McLinton et al. (2024) argue that the research risk is not static but dynamic, continually reshaped by emerging technologies, methodologies, and participant contexts. This perspective aligns with participants' concerns in this study regarding the limitations of expedited review pathways for complex or evolving research. Together, these insights underscore the importance of adaptive, risk-sensitive ethics review processes, supported by ongoing capacity-building and heightened ethical awareness among researchers and HREC members. The standardisation and regular revision of HREC application and screening procedures, incorporating robust risk-based criteria across institutions, has therefore been identified as essential to promoting consistency, thoroughness, and participant protection in ethical risk assessment (Bernabe et al., 2012).

3.2.1.2 Challenges for Ethical Consideration

This section's theme focuses on the reported challenges commonly encountered in the research ethics review process, as mentioned by HREC members from both universities.

The primary challenge raised by the majority of HREC members ($^{11}/_{15}$) is that each University in the country has its own independent HREC, to which researchers from that Institution must submit their ethics applications. Participants noted that this process can be cumbersome and problematic, particularly when researchers need data or human tissue from multiple institutions and must submit separate ethics applications to each relevant institutional HREC. This situation slows down the research process.

> *"…You know, every institution or university in South Africa has its own HREC for researchers to submit ethics applications. This can make research complicated and lengthy because sometimes researchers may require human tissue from many different universities and will have to apply to each one. I think it is best if there is one national framework or ethics authority system that researchers from all institutions submit their ethics applications to. This will help the ethics review process and save time for both of us as reviewers and researchers." (HREC_2_01).*

This challenge echoes findings from other studies (Page and Nyeboer, 2017; Mahomed and Labuschaigne, 2019; Owusu et al., 2022; Rani et al., 2024), which highlight the ethical and procedural inconsistencies arising from independently governed institutional HRECs. Each committee follows its own principles and procedures, leading to divergent ethical standards for reviewing human tissue research nationwide (Rani et al., 2024). Such fragmentation complicates multi-site studies, as researchers must obtain separate approvals from multiple HRECs, leading to delays, higher administrative costs, and reduced collaboration (Owusu et al., 2022). Moreover, discrepancies in committee practices may foster perceptions of certain HRECs as more "lenient" or "stringent," undermining fairness and credibility in ethical oversight (Ballantyne and Moore, 2018).

In response, both the current study and prior empirical work advocate for a national digital ethics review platform to harmonise the process (Owusu et al., 2022; Rani et al., 2024; Page and Nyeboer, 2017). Such a system would ensure consistent and rigorous ethical standards, reduce administrative burden through standardised applications, enable a national knowledge-sharing registry, and streamline multi-site submissions via unified templates and checklists (Rani et al.,

2024). Importantly, this shift would move South Africa toward a more coordinated, transparent, and equitable research ethics system capable of supporting scientific innovation and ethical integrity in human tissue research.

HREC members ($^{10}/_{15}$) also expressed that, in some instances, researchers do not request participants' consent in the informed consent forms to store, reuse, or export their tissue for future research.

> "*...So in my opinion I think we need to have guidelines on when is consent required because sometimes we notice in informed consent forms that researchers may want to use the human tissue for future research but they are not seeking consent from the participant for the storage and reuse for future research and in some cases they want to export tissue for research in other countries but they are not actively asking participants permission for this. I think a broad consent should be taken initially to cover all future research, or we need to determine if re-consent is viable." (HREC_1_03).*

Some HREC members ($^{6}/_{15}$) raised the issue of the criteria for determining whether it is ethical, feasible, and viable for researchers to obtain re-consent from participants for secondary research, or whether broad consent is more suitable before a research study begins.

> *"...So, in my opinion, I think we need to have guidelines on when consent is required because the issue of getting re-consent from patients for every study on stored samples is not feasible and intrusive to the patient. Broad consent is the best way." (HREC_1_06).*

Most HREC members ($^{11}/_{15}$) in this study favoured broad consent, obtained at the outset, as the most ethically defensible type of consent for the storage, re-use, and export of human tissue for secondary research. However, international studies reveal divided perspectives. In New Zealand and Switzerland, researchers often adopt a consequentialist stance, viewing re-consent as impractical and potentially distressing, while ethics committee members, guided by deontological reasoning, emphasise autonomy and prefer specific, detailed "checkbox" consent (Ballantyne et al., 2020; Colledge et al., 2018; Ballantyne and Moore, 2018). Studies from Asia advocate for tiered consent, allowing participants to specify restrictions on the future use of their samples in research (Matsui et al., 2009).

Similar ethical tensions have also been reported across Africa and several non-Western countries, including Kenya, Malawi, China, Egypt, India, Japan, and Korea (Langat, 2005; Tindana et al.,

2014; Masiye et al., 2023). Langat (2005) noted that researchers frequently fail to adequately inform participants about how their tissue may be stored, reused, or exported, as well as the associated cultural and ethical implications. Consequently, HREC members remain deeply concerned about the adequacy of informed consent**,** the protection and traceability of exported tissue, and the long-term governance of stored samples (Tindana et al., 2014). Reusing human tissue without explicit consent, especially across borders, risks undermining participant rights and personal integrity.

However, once human tissue crosses national borders, the oversight of HRECs becomes limited. While compliance with Material Transfer Agreements (MTAs) can help mitigate ethical breaches, effective monitoring requires specialised expertise in cross-jurisdictional governance frameworks (Mahomed et al., 2016). As global demand for human tissue research continues to expand, this study proposes establishing a unified national platform for human tissue ethics applications, with dedicated expertise in the ethics of storage, reuse, and international transfer (Angell et al., 2009). Such reform could strengthen accountability and restore public trust in the governance of human tissue research.

Another ethical challenge, as reported by ($^{5}/_{15}$) HREC members, is the issue of ethics applications and the supporting documents provided by researchers. The specific concerns raised include: 1) the use of the term 'subjects' to refer to participants; 2) informed consent forms being submitted alongside questionnaires, which can act as identifiers; 3) incomplete ethics applications or insufficient supporting documents; 4) inadequate scientific rationale for data collection instruments; 5) failure to consult a statistician; and 6) participant information sheets and consent forms written in language or jargon that participants may not understand, particularly concerning the needs of children or vulnerable groups. Some HREC members expressed their thoughts regarding these issues.

> *"...So, probably the three most common problems are calling things subjects instead of participants. That is a lack of respect. The second thing is identifiers on questionnaires; the consent form must be separate from the questionnaire, and also, the data collection instruments are not scientifically rational, inappropriate, or ill-defined sometimes, or a statistician is not consulted before the ethics application is submitted." (HREC_2_04).*

> *"...Um, you know, we also need to address the issue in consent forms and participant information sheets. Sometimes, this is written in very technical words or even in a language that the participant does not understand, so this issue is also a common one. It*

should be simple and, in a language they understand, make provisions for obtaining consent from children or vulnerable groups like the blind or disabled instead of just excluding them." (HREC_2_06).

This challenge has previously been reflected in the poor quality and lack of preparedness of ethics applications in local and international studies (Brindley et al., 2020; Wilkinson, 2021; McLinton et al., 2024). Many researchers enter the review process with a limited understanding of ethical procedures, and applications are often submitted without adequate supervisory scrutiny. As McLinton et al. (2024) note, principal investigators must familiarise themselves with review requirements, while supervisors should rigorously evaluate consent forms, participant information sheets, and protocols before submission to avoid unnecessary delays. Consultation with bioethicists could further enhance ethical reasoning and the quality of application.

However, accountability does not rest solely with researchers. The ethics review process involves multiple stakeholders, investigators, supervisors, administrators, reviewers, and decision-makers, each playing a critical role in the efficiency and integrity of ethical oversight (Halkoaho et al., 2012; Page and Nyeboer, 2017; Owusu et al., 2022). Delays and inefficiencies emerge when any link in this chain falters or submissions fail to meet expected ethical standards (Page and Nyeboer, 2017; Wilkinson, 2021). To strengthen the system, post-approval monitoring**,** standardisation of review practices, and enhanced training for HREC members are recommended, all of which can improve ethical rigour, promote consistency, and elevate the overall quality of research (Halkoaho et al., 2012; Wilkinson, 2021; Owusu et al., 2022).

Participants ($^{7}/_{15}$) also identified a gap in the ethics review of human tissue research, particularly regarding the contemporary use of artificial intelligence (AI) in human and genetic research studies.

"...From a genetic standpoint, also quite concerning, especially with the issues that are raised from whole genome sequencing and clinical trials... There are also new up-and-coming challenges, like we need to have guidance related to artificial intelligence, human genetics, 3D printing, scanning and commercialisation of tissue." (HREC_2_08).

The emergence of AI in health research introduces a new layer of ethical complexity for HRECs, particularly in studies involving genetic data and human tissue. Findings from this study revealed that HREC members perceive a widening gap in regulatory and ethical guidance for the review of such research. This concern aligns with Shaw's (2024) assertion that health data serves as the backbone of AI development, underscoring the need for ethical governance in the responsible

integration of AI into biomedical research. Shaw (2024) argues that without strong ethical oversight of how health data is collected, shared, and repurposed, AI systems risk reinforcing existing biases, undermining privacy, and eroding public trust in scientific institutions.

Given the accelerating adoption of AI in medical research, HRECs must evolve beyond traditional review frameworks to address ethical risks, such as algorithmic bias, data ownership, consent for the use of secondary data, and cross-border data transfers. The absence of specific regulatory mechanisms for AI-driven genetic and tissue research creates uncertainty about how to balance innovation and participant protection. One potential way forward is to introduce AI impact assessments into the ethics review process. This step would enable committees to systematically evaluate the potential social, cultural, and individual implications of AI deployment (Shaw, 2024). Such assessments could help researchers to identify and mitigate potential harms at the design stage, rather than retroactively.

By embedding these evaluative tools into standard review procedures, HRECs could enhance the ethical robustness of AI-related health research and help develop a national framework for AI ethics in human tissue and genetic research. This approach would position ethics committees as active agents in shaping responsible AI governance, a crucial step toward safeguarding autonomy, equity, and justice in the era of data-driven biomedical innovation.

3.2.2 Human Biobanks

3.2.2.1 Consent Model Preferences

This theme raises the question of how South Africa can ethically harmonise human biobanking consent practices to protect participants while enabling responsible, future-oriented biobank research.

Most of the interviewed human biobanks ($^{6}/_{9}$) preferred a broad consent model for obtaining human tissue from donors for research purposes. They explained that this approach ensures that research is not limited and that human tissue is not wasted. Some biobanks ($^{4}/_{9}$) suggested tiered consent as a suitable approach for secondary research, ensuring ethical research and respect for donors' wishes.

> *"...So, we would prefer a broader consent approach where a donor's tissue samples, such as blood, DNA, serum or urine, can be stored and used for a wide range of research purposes. However, if the primary study is complete, then maybe tiered consent should*

be obtained from the living donor for the secondary use of their tissue to make sure it is something they would have wanted and to adhere to ethical standards." (HTB_08).

Biobank participants argued that broad consent aligns with the long-term, evolving nature of biobanking, allowing tissue samples, such as blood, Deoxyribonucleic Acid (DNA), or serum, to be used across a wide range of research contexts. This finding mirrors international studies where broad consent is viewed as most consistent with the operational realities of biobanks, which are inherently future-oriented and reliant on flexible governance mechanisms (Knoppers, 2004; Elger et al., 2009; Wendler, 2013; Master et al., 2015; Kaye et al., 2016; Domaradzki and Pawlikowski, 2019). For instance, the UK Biobank employs a broad consent framework intended to endure over time, reinforcing its feasibility and ethical legitimacy (Elger et al., 2009; Kaye et al., 2016). The suggestion for a tiered consent approach for secondary human tissue research reflects the growing international advocacy for tiered consent, which allows participants to select the types of research for which their samples may be used and thereby mitigates ethical concerns surrounding autonomy and informed choice (Matsui et al., 2009; Tindana et al., 2014; Masiye et al., 2023).

A few biobanks ($^{3}/_{9}$) preferred a specific consent approach when acquiring donor tissue for storage and research, stating that it allows donors to choose which tissues they are willing to donate for different types of research.

"...So, we prefer a more specific consent approach when acquiring donor tissue. In our consent forms, we usually list tissues so the donor can choose what tissues they would like to donate and which they will not, and for what type of research they would like their tissue to be stored for. So, using this approach, consent is very ethical and respectful of the donor's wishes." (HTB_03).

The preference for specific consent emphasises its ethical clarity and respect for participant choice; however, participants acknowledged its impracticality given the logistical and administrative demands of re-consenting for each new study. This tension between respecting autonomy and ensuring scientific progress underscores a global ethical dilemma in biobanking (Wendler, 2013; Master et al., 2015).

Within the South African context, regulatory ambiguity and policy gaps further complicate this debate. Although the National Health Act and the Department of Health's Ethical Guidelines permit broad consent, Section 13(1) of the Protection of Personal Information Act (POPIA) prohibits it and requires specific consent for data collection and processing (POPIA, 2013;

Maseme et al., 2024). This legal inconsistency creates uncertainty for biobanks, as strict adherence to specific consent would effectively inhibit secondary use of biological materials and lead to the wastage of valuable human tissue (Tindana et al., 2014; Singh and Moodley, 2021; Masiye et al., 2023). Furthermore, the inherently future-oriented nature of biobanking makes it impossible to anticipate all potential research uses at the point of collection (Singh and Moodley, 2021). This regulatory misalignment illustrates the urgent need for harmonised governance that balances respect for individual autonomy with the collective advancement of human tissue research in South Africa.

To reconcile these ethical and legal tensions, this study's findings support adopting a tiered consent model as a pragmatic and ethically sound solution. This model would integrate the flexibility of broad consent with the transparency and autonomy safeguards of specific consent (Masiye et al., 2023). It would allow donors to express preferences regarding secondary use while facilitating the sharing of data and samples essential for scientific advancement. Such an approach would also align with South Africa's broader ethical principles of respect, beneficence, and justice, fostering greater public trust in biobank governance and promoting responsible, future-oriented research practices (Singh and Moodley, 2021).

3.2.2.2 Ethical Challenges in Human Biobanking

Participants noted that the primary challenge in biobanking was the lack of human biobank legislation and a national policy or framework specifically regulating human biobanking. The National Health Act (NHA) and the South African Tissue Bank Association (SATiBA) provide guidance and support for regulating tissue banking in South Africa; however, these guidelines offer limited specificity for human biobanking (Labuschaigne and Mahomed, 2019; Singh and Moodley, 2021).

> *"…We have a policy on donor eligibility and guidelines from the NHA and SATiBA. Apart from that, on a national level, we do not have a policy or framework on Biobanking, and that is a frustration and a freedom all in one. We try to follow guidelines from the European Association for Biobanking and the WHO." (HTB_05).*

From these findings, the fragmented and limited regulation of human biobanks in South Africa remains a pressing concern from both ethical and governance perspectives. As Chapter 8 of the National Health Act (NHA) does not mention biobanks, researchers often rely on tissue bank regulations. This limited proxy fails to capture the unique complexities of biobank research. The

existing laws overlap with domains such as data protection, clinical trials, and tissue regulation, but none specifically address the governance, consent, or data-sharing imperatives of human biobanking (Singh and Moodley, 2021).

This regulatory ambiguity has created interpretive loopholes and inconsistent practices across institutions. Given South Africa's history of human rights violations in medical research, this lack of standardisation heightens the ethical stakes, calling for stronger, more precise, and more transparent oversight mechanisms (Labuschaigne and Mahomed, 2019). Biobank managers interviewed in this study echoed this sentiment, emphasising the urgent need for a national framework to unify ethical standards and operational practices across provinces, ensuring fairness, accountability, and trust in human tissue research.

The South African experience mirrors challenges faced internationally. In Europe, human biobank regulation remains inconsistent across jurisdictions, leading to varied consent processes and uneven protections for research participants (Kaye et al., 2016). Conversely, Finland's Biobank Act of 2013 offers a model for reform, establishing a cohesive national legal structure that standardises sample collection, storage, and consent requirements, thereby enhancing ethical compliance and scientific collaboration (Kaye et al., 2016).

Similar reform in South Africa could bridge regulatory gaps and promote harmonisation. The establishment of a national biobank authority to coordinate oversight, streamline compliance, and foster collaboration among biobank institutions would move the country from a fragmented system toward a coherent, forward-looking governance framework capable of supporting ethically sound, high-quality biobank research (Dhai, 2013; Labuschaigne and Mahomed, 2019; Singh and Moodley, 2021).

Another common issue raised by biobanks is the challenge of sharing tissue samples and data, as well as exporting stored tissues. Biobank managers indicated that tissue exports are sometimes conducted for purposes beyond their initial use, such as research or transplantation. In some instances, stored human tissue samples may be exported for commercialisation or sale rather than used for research. This situation was viewed as an ethical concern within biobanking and requires appropriate regulation.

> "*…Some of the things we pick up, samples are stored in biobanks in SA, and then they send them out to the US or other countries and then research, which was intended for that tissue, is not what is being conducted. Sometimes they are sold for profit, so storage, analysis and research we feel should be done in the same tissue bank and country…it*

should not be exported for research to avoid ethical problems and commercialisation." (HTB_03).

Commercialising human biological materials emerged as a significant ethical concern among South African biobank managers, echoing international debates on the moral boundaries of tissue exchange. The UK Medical Research Council and the British Association of Tissue Banks assert that selling human tissues is ethically indefensible and should be legally prohibited, emphasising that donated tissues represent an altruistic "gift," not a tradable commodity (Bauer et al., 2004). When tissues are diverted from research or clinical use toward commercial ends, this violates the donor's intent and undermines the dignity and intrinsic value of human life. Countries such as the United Kingdom, Belgium, and Spain have implemented stringent national policies that explicitly prohibit the commercial trade of human tissues (Bauer et al., 2004; Kaye et al., 2016).

Participants in this study highlighted that, although the NHA explicitly prohibits the commercialisation of human body parts and blood products. The South African Material Transfer Agreement (Labuschaigne et al., 2019) offers procedural guidance for tissue transfer; however, neither framework adequately addresses the ethical implications of tissue commercialisation (Singh and Moodley, 2021; Thaldar, 2020). The result is a fragmented governance landscape that leaves space for exploitation, particularly in cross-border collaborations.

This concern is not hypothetical. The Wellcome Sanger Institute case, involving allegations of unauthorised use and attempted commercialisation of South African DNA samples exported from Stellenbosch University, starkly illustrates the potential for ethical breaches under the guise of international research (Singh and Moodley, 2021; Moodley et al., 2014). Such incidents amplify mistrust, threaten the credibility of South African biobanking, and expose the absence of enforceable mechanisms to ensure benefit-sharing and ethical accountability once samples are removed from the country.

4. Key Findings and Recommendations

The main findings of this study, from the perspectives of HREC members and Human Biobanks in South Africa, were:

1) Inconsistent Ethical Review: HREC members reported variability in assessing ethics applications across institutions, revealing a need for harmonised national review standards and a unified National Digital Ethics Platform.
2) Emerging Research Gaps: Lack of clear regulatory guidance for AI and human genetics research poses new ethical challenges in human tissue ethics applications.
3) Re-consent for Secondary Research: Most HREC members favoured broad consent, obtained at the outset, as the most ethically defensible type of consent for the storage, re-use, and export of human tissue for secondary research.
4) Broad Consent Preference and Tiered Consent solution: Most biobank representatives supported broad consent to prevent research limitations and tissue waste, aligning with global trends; however, a tiered consent model was viewed as a balanced alternative that respects donor autonomy while enabling secondary research use.
5) Fragmented Regulation: Human biobanks operate under partial and inconsistent governance, with inadequate oversight from existing ethical frameworks.
6) Call for National Framework: Participants recommended establishing a National Biobank Authority to standardise ethical practices and promote collaboration.
7) Concerns Over Export and Commercialisation: Exporting tissues for profit contradicts donation's "gift" principles and raises serious ethical and legal concerns.

Building on these findings, this study recommends the creation of a National Digital Ethics Platform for Biobanking. Institutionally, the proposed National Digital Ethics Platform would be mandated by the National Department of Health and governed through the National Health Research Ethics Council (NHREC), ensuring alignment with existing statutory ethics oversight mechanisms under the National Health Act. While HRECs would retain autonomous decision-making authority, the platform would function as a national digital governance infrastructure, facilitating real-time coordination, compliance monitoring, and ethical traceability across institutions. It would also track all exported samples, associated research outcomes, and benefit-sharing agreements. Multi-stakeholder oversight involving the Department of Health and biobanking representatives would further safeguard ethical independence, data protection, and public accountability. Mandating transparency and traceability would not only prevent the commodification of human biological materials but also reaffirm the ethical foundation of

biobank participation, one grounded in altruism, trust, and shared scientific advancement. To address these gaps, this study proposes establishing a National Biobank Oversight and Compliance Office within the Department of Health. This independent body would reinstate the Inspector of Anatomy's functions and extend its mandate to include oversight of tissue handling, anonymisation standards, data linkage practices, and negligence investigations. By introducing mandatory audits, accrediting biobank personnel, and establishing a national incident reporting system, the Office could institutionalise accountability and promote ethical consistency across all biobanking activities.

Overall, the findings of this study directly advance the overarching aim of identifying the ethical concerns and challenges in the human tissue research review process and human biobanking, as well as policy gaps and consent model preferences for human biobanking. The evidence gathered from Human Research Ethics Committees and biobank managers reveals discrepancies in ethical review processes, fragmented oversight structures, uncertainty regarding consent models, and the absence of a unified biobanking policy framework. Collectively, these findings demonstrate the need for an integrated ethical framework grounded in the principles of autonomy, dignity, transparency, accountability, and justice. By bringing together empirical insights from key institutional stakeholders, this study contributes to the development of a relevant, ethically robust, and practical governance model that can strengthen ethical integrity, harmonise consent practices, and promote responsible oversight of human tissue research in South Africa.

5. Conclusion

This study aimed to identify the ethical concerns and practical challenges encountered in human tissue research and biobanking in South Africa, and to examine gaps in existing policy and legislation. By foregrounding the lived experiences and perspectives of HREC members and human biobank stakeholders, the study provides empirical insight into how these aims manifest in practice. The findings reveal persistent ethical challenges in interpreting consent, secondary use of samples, data governance, and inconsistencies in ethical review processes across institutions, highlighting the complexity of regulating human tissue research within a fragmented policy landscape.

In addressing policy gaps, the study demonstrates a lack of coherent and harmonised national guidance governing consent models, biobank oversight, and cross-institutional data sharing. These regulatory ambiguities place a significant burden on HRECs and biobanks, often leading

to variable decision-making and uncertainty in the ethical review process. The exploration of consent preferences further underscores tension between broad, tiered, and dynamic consent models, with participants emphasising the need for consent approaches that are both ethically robust and responsive to evolving research practices, including AI-driven analyses and cross-border transfers.

As South Africa continues to advance in biomedical innovation, the study highlights the need for a unified national framework and a digitally enabled ethics and biobanking platform to address identified ethical concerns, close policy gaps, and align consent practices across institutions. Ultimately, achieving ethical stewardship in human tissue research requires balancing scientific innovation with respect for human dignity, thereby transforming ethical principles, policy intentions, and regulatory mechanisms into practical applications that sustain public confidence and trust.

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Interlinking Page

Chapters 2 and 3 collectively established the empirical foundation for developing the Integrated Consent-Centred Ethical Framework (ICEF). Chapter 2 identified stakeholder-level ethical and consent tensions across national and international human tissue research, while Chapter 3 demonstrated how these tensions are experienced within South African HREC and human biobank governance.

The findings from Chapter 2 established the need for a clear and context-sensitive approach to consent. The lack of uniformity in consent expectations across living tissue, cadaveric tissue and biobanking, together with concerns regarding donor comprehension, voluntariness and ongoing consent, informed *Domain 1: Foundational Consent Ethics*. The continued use and ethical uncertainty surrounding legacy and unconsented collections, as well as unidentified or unclaimed bodies, informed *Domain 2: Governance of Legacy and Unconsented Collections*. Concerns regarding foetal tissue research and other circumstances in which consent is particularly sensitive informed *Domain 3: Sensitive Consent Contexts*. The findings concerning three-dimensional printing, digital imaging, genetic research, plastination and artificial intelligence informed *Domain 5: Ethical Adaptation for Emerging Technologies*. Chapter 3 added the South African governance dimension. Findings concerning uncertainty surrounding consent for storage, reuse, and export, limited transparency regarding commercialisation, and the governance of secondary research informed *Domain 4: Governance of Biobank, Commercialisation, and Secondary Research Governance*. Findings concerning variation between institutional HRECs and the absence of a dedicated national human biobanking regulatory authority informed the *Governance and Regulatory Oversight* outer layer of the ICEF. Accordingly, the ICEF was not developed independently of the empirical findings. Rather, each domain represents the integration of an identified empirical concern with relevant ethical principles, national and international regulatory requirements, and normative analysis. Chapter 4, therefore, addresses *Research Objective 3*, i.e., developing a comprehensive ethical framework for research on human tissue in South Africa and translating the study's findings into practical guidance for consent processes, governance mechanisms, and ethical oversight in human tissue research practices.

The framework and accompanying discussion further validate the scholarly and practical contribution of this chapter, which is presented in a manuscript format and submitted to the *Anatomical Sciences Education* journal (Manuscript ID ASE-26-0059) (Appendix 1).

CHAPTER 4: THIRD MANUSCRIPT

A Proposed Integrated Consent-Centred Ethical Framework for Human Tissue Research in South Africa

Abstract

Background

Human tissue research in South Africa is experiencing rapid growth, driven by advancements in biobanking, genomics, artificial intelligence (AI), and international collaboration. Although these advances open exciting opportunities for medical science and innovation, they also raise difficult questions about consent, ownership, privacy, and how the benefits of research should be shared fairly. Ensuring that research remains ethical, transparent, and socially responsible has never been more important. An ethical framework guides anatomists, researchers, Human Research Ethics Committees (HRECs), and human biobanks to navigate these challenges. This study proposes a consent-centred ethical framework for human tissue research in South Africa, informed by the perspectives from anatomists, Human Research Ethics Committees, and human biobanks.

Methods

The proposed developed Integrated Consent-centred Ethical Framework (ICEF) was informed by a comprehensive review of existing literature and integrated with empirical findings from qualitative investigations, drawing on the practical experiences and perspectives of researchers, anatomists, Human Research Ethics Committee (HREC) members, and human biobank representatives. The framework was subsequently refined through expert consensus/independent review to ensure alignment with national regulations, ethical principles, and best practices in human tissue research.

Results

The framework identifies consent as the ethical and legal foundation for all dimensions of human tissue research, including acquisition, reuse, storage, commercialisation, and emerging technological applications. It regards consent as a dynamic continuum that evolves in relation to the nature, purpose, and context of the research. It integrates ethical reasoning, regulatory alignment, and social awareness through five interlinked domains, forming a five-layered circular conceptual model that responds to the challenges identified in empirical data and policy reviews. The five domains surrounding consent are: 1) Foundational Consent Ethics; 2) Governance of Legacy and Unconsented Collections/Bodies; 3) Sensitive Consent Contexts; 4) Governance of

Biobank, Commercialisation, and Secondary Research Consent; and 5) Ethical Adaptation for Emerging Technologies. The outer ring comprises Governance and Regulatory Oversight, representing continuous legal management and control.

Conclusion

This framework offers a practical guide to protecting donors, enhancing accountability, and promoting fairness in the use of human tissue for research. The framework is designed to support national policy development, enhance institutional review, and build an ethical foundation for future research in South Africa.

Keywords: human tissue research, ethics, biobanks, consent, governance, South Africa

1. Background

Research involving human tissue, or information derived from human tissue, is a cornerstone of anatomical and medical research and knowledge. It expands beyond traditional anatomy to include fields such as genomics, three-dimensional (3D) printing, digital imaging, plastination, artificial intelligence (AI), and the potential commercialisation of human (Aaron et al., 2021). This raises complex ethical and legal questions concerning consent, ownership, and the responsible use of biological material (Al Diffalha, 2019). Therefore, human tissue research legislation and policy must evolve to keep pace with scientific progress (Bach, 2016).

The ethical acquisition, storage, and use of human tissue are crucial to maintaining public trust and research integrity. Consent remains the legal and ethical cornerstone of human tissue research, underscoring the need to ensure that human tissue is obtained only with full, informed, and voluntary donor consent; that samples are handled with respect and dignity; that transparency between researchers and donors is maintained; and that stored tissue is used solely for its authorised purposes (Lensink et al., 2022).

In South Africa, Human Research Ethics Committees (HRECs) play a crucial role in ensuring that human tissue research is conducted ethically (Ballantyne et al., 2020; McLinton et al., 2024). The National Health Research Ethics Council (NHREC), established under the National Health Act 61 of 2003, provides national oversight and guidelines for ethical research governance (Esselaar et al., 2024). Despite this, variations in institutional Standard Operating Procedures (SOPs) and internal ethics review processes across universities have led to inconsistent ethical review outcomes (Xu et al., 2020). HREC members have identified challenges, including differing interpretations of consent for the sharing, export, and reuse of human tissue. These differences hinder multi-site research efforts by requiring multiple ethics submissions, leading to delays, increased administrative burdens, and a lack of uniformity in ethical oversight (Xu et al., 2020).

Similarly, the governance of human biobanks in South Africa presents ethical and regulatory complexities. Key ethical issues persist in biobank practice, including the export and potential commercialisation of human tissue, confidentiality, informed consent, and the absence of a central regulatory authority (Maseme et al., 2024). Although the Department of Health's (DoH) Ethics Guidelines permit broad consent for biobanking, this approach conflicts with the Protection of Personal Information Act (POPIA), which requires that data be collected for a specific, defined purpose (Maseme et al., 2024). This inconsistency limits the reuse of human tissue samples and data for future research, reflecting broader gaps and ambiguities in South Africa's regulatory landscape.

As the scope of human tissue research continues to evolve, South African legislation and policy frameworks often lag behind the realities of current scientific innovation. Hence, researchers are forced to conduct research without clear and appropriate legal and regulatory guidance. These ongoing challenges underscore the need for a coherent ethical framework that aligns national governance, institutional practices, and global standards. Therefore, this paper proposes an integrated consent-centred ethical framework for human tissue research in South Africa, informed by empirical evidence to guide researchers, biobanks, and HRECs. This framework seeks to ensure that human tissue research in South Africa remains ethically sound, legally compliant, and socially responsible in a rapidly advancing scientific era.

Definitions

In this framework, specific terms defined by the National Health Act 61 of 2003 (National Health Act, 2003) are used. “Human tissue” refers to any organ, fragment of a human body, or material removed from a human body. This definition encompasses whole cadaveric human bodies, internal organs, glands, flesh, bone, or body fluids (both from deceased or living persons), except blood and gametes. It also includes any device or object a medical practitioner or dentist implants into a person's body before death. Human tissue specimens can be used for transplantation or research purposes. These tissues can be obtained from living donors, during post-mortem examinations, or from cadaveric donors. The term “human research ethics committee (HREC)” refers to any committee registered in terms of section 73 that is responsible for reviewing research proposals and ensuring that research is conducted ethically (National Health Act, 2003; NHREC, 2024). The term “human tissue research” encompasses any study that involves investigating the structure, function, or behaviour of human tissue to understand diseases, develop new treatments, and advance biomedical knowledge. In this framework, the term “human biobank” refers to biorepositories or facilities that collect, store, and distribute human tissue samples for research purposes (Bauer et al., 2004). In many cases, the tissue donated to such biobanks is donated for research purposes, without any restrictions on the research uses to which it may be applied.

2. Methods

2.1 Research Paradigm and Context

This study was situated within the South African context of human tissue research, where rapid scientific advancement and evolving governance structures necessitate the development of ethically responsive, contextually appropriate regulatory tools. The study's methodological orientation was to develop a consent-centred ethical framework to guide human tissue research

governance in South Africa. A constructivist paradigm informed the framework development process, recognising that ethical norms, regulatory interpretations, and governance practices are shaped through social, institutional, and legal contexts. The primary purpose of adopting a constructivist grounded theory approach was to generate an ethically and contextually grounded consent-centred framework for human tissue research in South Africa (Chun Tie et al., 2019). This process enabled the development of a framework that reflects lived experiences, accommodates institutional involvement, and provides practical guidance for ethically robust human tissue research governance within the South African context.

2.2 Design

The proposed ethical framework for human tissue research in South Africa was developed through an iterative process based on empirical evidence, stakeholder input, and normative analysis. The framework was informed and developed from themes identified in interviews with anatomists, researchers, HREC members, and representatives of human biobanks from two previous components of a doctoral study by the prime author. These themes reflected key ethical challenges and policy gaps, particularly concerning consent in human tissue research, and were further refined through a review of national and international guidelines, including the DoH Ethics Guidelines, National Health Act, and the POPIA (National Health Act, 2003; NHREC, 2024), and international biobanking ethics frameworks.

A summary of the key themes and ethical gaps from the previous qualitative investigations of the doctoral study, along with their impact on the framework design model, is presented in Table 1.

Table 1. Key Themes from Empirical Evidence and how they informed the Framework Design

Theme (*group of participants derived from*)	**Key Issues Identified**	**How the Theme Informed the Framework Design Model**
General Consent *(anatomists, researchers, and human biobanks)*	• Lack of clarity and uniformity in consent models for cadaveric tissue, living tissue, and biobanking. • Challenges in balancing simplicity of information with comprehensiveness of disclosure. • Need for ongoing consent processes for living donors.	Informed the "Foundational Consent Ethics" domain, which establishes guidelines for full, free, and informed consent, donor comprehension, voluntariness, and respect for autonomy.
Consent, Legacy Collections, and Unidentified Bodies *(anatomists and researchers)*	• Ethical and legal uncertainty regarding using legacy tissue or skeletal collections. • Some researchers view the use of unidentified/unclaimed bodies as unethical. • Absence of national policy governing these practices.	Led to the "Governance of Legacy and Unconsented Collections/Bodies" domain, promoting transparent provenance review, historical accountability, and development of national ethical policies for legacy tissue and unclaimed bodies.
Consent and Foetal Tissue Research *(anatomists and researchers)*	• Ambiguity in obtaining separate consent for research use versus termination of pregnancy. • Lack of clear consent procedures for foetal tissue obtained through therapy or diagnosis.	Informed the "Sensitive Consent Contexts" domain, providing ethical and procedural guidelines for specific and voluntary consent processes in sensitive circumstances such as foetal tissue research.
Consent for Storage, Reuse, Export and Commercialisation *(human biobanks)*	• Uncertainty concerning consent for reuse and export of tissue for secondary research. • Lack of transparency regarding potential commercial gain from donated tissue.	Informed the "Governance of Biobank, Commercialisation and Secondary Research Consent" domain, addressing accountability, donor rights, and transparency in reuse, export and commercialisation while maintaining the principle of altruistic donation.
Consent for Contemporary Human Tissue Research Uses *(anatomists and researchers)*	• Emerging uses (3-D printing, digital imaging, genetic research, plastination, AI uses) not covered by traditional consent forms. • Ethical tension between innovation and donor dignity. • Risk of depersonalisation through digital representation.	Informed the "Ethical Adaptation for Emerging Technologies" domain, ensuring updated consent forms, respect for dignity, and ethical guidelines for new research technologies and representations of human tissue.
Independent Institutional HRECs *(HREC members)*	• Each University has an independent HREC for researchers to submit ethics applications. • Creates challenges when researchers need human tissue from multiple institutions. • Undermines fairness and credibility in ethical oversight.	Informed the "Governance and Regulatory Oversight" outer ring, including developing a national ethics platform.
Lack of a human biobanking regulatory authority *(human biobanks)*	• Creates loopholes and inconsistent biobanking practices across institutions	Informed the "Governance and Regulatory Oversight" outer ring, proposing the development of a national statutory or regulatory authority for human biobanking.

2.3 Framework Development

Framework development occurred through a structured process of analytical integration that translated empirical findings and normative sources into a coherent model. Figure 1 illustrates the framework development process through which empirical findings, ethical principles, and regulatory sources were iteratively translated into the consent-centred ethical framework. The circular structure emphasises reflexive movement among analysis, normative calibration, and expert refinement, demonstrating that framework development was a continuous, empirically anchored process.

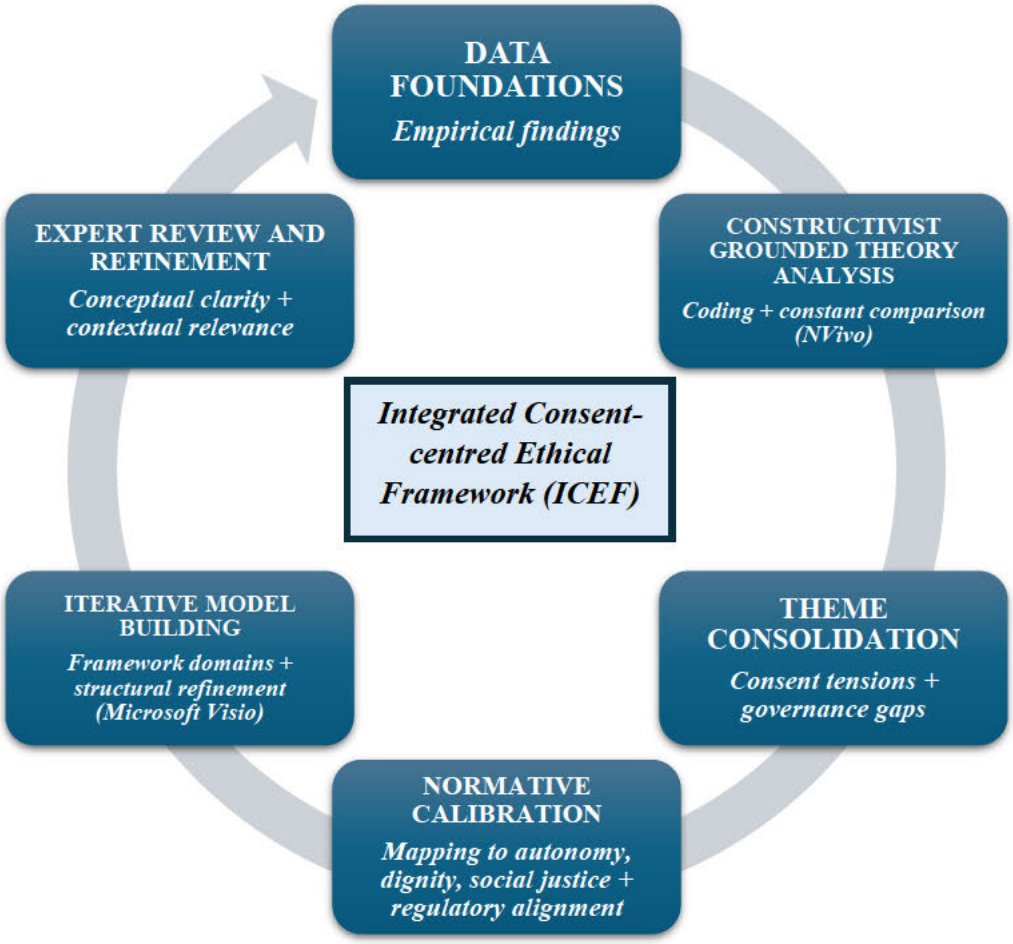

Figure 1. Integrated Consent-centred Ethical Framework (ICEF) development process.

First, themes generated through constructivist grounded theory analysis were combined into higher-order ethical categories representing recurring governance gaps, consent tensions, and stakeholder priorities. Coding and theme organisation were supported using NVivo qualitative data analysis software, which enabled methodical comparison across datasets and enhanced verifiability of analytic decisions.

Second, each empirical category was systematically mapped against established ethical principles (autonomy, dignity, and social justice) and cross-referenced with relevant national and international regulatory provisions. This mapping was conducted using a thematic framework matrix adapted from qualitative framework analysis, allowing systematic comparison of empirical themes and categories against ethical principles and regulatory standards, ensuring transparency and consistency in the development process (Rosen et al., 2023).

Third, an iterative model-building phase translated these calibrated categories into functional governance domains. During this stage, relationships between consent practices, institutional oversight, technological change, and historical inequities were diagrammed and repeatedly refined using visual modelling software (Microsoft Visio). The framework structure emerged through constant comparison between empirical data, ethical theory, and regulatory expectations, with framework domains retained only if they demonstrated coherence and practical applicability across stakeholder contexts (Charmaz, 2014). Coherence was assessed by examining whether domains consistently accounted for patterns observed across datasets and aligned with core ethical principles, while practical applicability was evaluated in terms of clarity, relevance to real governance challenges, and feasibility of implementation within existing institutional structures. These criteria ensured that retained domains were both theoretically valid and functionally meaningful.

2.3.1 Framework Refinement

The final stage of framework development comprised external expert review and refinement. This stage was undertaken to assess the clarity, completeness, accuracy, practical usefulness and contextual appropriateness of the provisional Integrated Consent-Centred Ethical Framework (ICEF). Its purpose was to obtain structured external feedback from individuals with relevant expertise and to use it to identify areas requiring clarification, addition, modification, or further justification. This refinement phase involved national-level consultations conducted via email with experts in research ethics, law, and human tissue research, as well as feedback from key stakeholder groups, including anatomists, researchers, members of the Human Research Ethics Committee (HREC), and representatives from human biobanks.

A structured feedback questionnaire was developed for this purpose and is provided in Appendix 2. The questionnaire addressed six principal domains: (1) clarity and structure; (2) completeness and content; (3) accuracy; (4) robustness of the proposed consent processes; (5) practical usefulness; and (6) alignment with South African legal, ethical and regulatory standards. These

domains were selected to assess both the conceptual coherence of the framework and its potential applicability to human tissue research governance in South Africa.

A total of five external expert reviewers participated in the review stage. Reviewers were identified based on documented professional or scholarly expertise relevant to the framework, including research ethics, law, human tissue research, anatomical sciences, and/or related governance areas. Reviewers were provided with the provisional ICEF and the structured feedback questionnaire and invited to submit written comments on the specified domains. Written feedback was reviewed systematically and organised according to the substantive issues raised. Responses were examined for recurring concerns, suggested omissions, conceptual ambiguity, practical feasibility issues and areas requiring clarification. Where feedback related directly to a particular ICEF domain, consent mechanism or governance provision, the concern was mapped to that component of the framework. The review process was therefore iterative. Where reviewers identified ambiguity, omission, insufficient explanation or practical feasibility concerns, the relevant component of the framework was reconsidered and, where appropriate, revised. Changes included refinement of the wording of framework domains, clarification of consent-related processes, strengthening of governance provisions and further specification of implementation considerations. Where a recommendation was not incorporated, the decision was considered in relation to the empirical findings, the ethical principles underpinning the framework, applicable legal and regulatory requirements, and the scope of the research.

The external review stage, therefore, served as a mechanism of expert-informed refinement. It enhanced the credibility, clarity, contextual relevance, and practical applicability of the ICEF by exposing the provisional framework to perspectives beyond those of the primary researcher and the participant dataset. However, expert review did not establish statistical validity or demonstrate that the ICEF was the only or universally applicable ethical framework for human tissue research. The outcome is more appropriately described as an expert-reviewed, empirically anchored and normatively constructed framework.

The relationship between empirical findings, normative analysis and expert refinement can therefore be represented as an iterative process:

Empirical findings → ethical and regulatory analysis → provisional ICEF → external expert review → identification of concerns and recommendations → framework refinement → final ICEF.

This process is consistent with the study's constructivist orientation because the framework represents an interpreted and progressively refined response to the ethical and governance issues identified through the research's empirical components. The resulting model is therefore a layered integration in which empirical data, ethical principles, governance requirements, and expert review mutually shaped the framework's final structure.

2.4 Researcher Reflexivity and Positionality

The development of the Integrated Consent-Centred Ethical Framework (ICEF) was guided by a constructivist approach and therefore involved interpretation rather than the discovery of a pre-existing framework. The researcher's background in Anatomy and human tissue research ethics provided valuable contextual insight, but also raised the possibility that prior assumptions could influence interpretation. Reflexivity was therefore maintained throughout the framework-development process.

Key ethical principles, autonomy, dignity, accountability, and social justice, were used as interpretive lenses rather than as neutral categories. These informed the analysis of empirical findings and governance gaps and the translation of these into framework domains, consistent with the study's aim of developing an applied ethical response rather than merely describing stakeholder views. Participant perspectives were not treated as automatically normative but were considered alongside ethical principles and legal requirements, particularly in contested areas such as consent models, secondary use and commercialisation. The researcher distinguished between empirical findings, regulatory positions and normative recommendations.

Reflexivity was supported through iterative coding, comparison across stakeholder groups, mapping to ethical principles, and independent expert review. These measures enhanced transparency but did not remove interpretation; rather, they made it explicit and open to scrutiny.

The ICEF should therefore be understood as an empirically anchored and normatively constructed framework**,** shaped by stakeholder input, ethical reasoning and regulatory analysis, with expert review strengthening its coherence and relevance.

2.5 Ethics Statement

Ethical approval for this study was obtained from the Biomedical Research Ethics Committee prior to data collection (BREC/00005587/2023). Informed consent was obtained from all the interviewees.

3. Results

3.1 The Ethical Framework

The Integrated Consent-Centred Ethical Framework aims to provide a unified ethical governance structure for human tissue research in South Africa. It recognises consent as the ethical anchor and foundation for all aspects of human tissue research. This framework model positions consent as a dynamic continuum that evolves in response to the research's nature, purpose, and context. It integrates ethical reasoning, regulatory alignment, and social awareness through five interlinked domains, forming a five-layered circular conceptual model that responds to the challenges identified in empirical data and policy reviews.

At the heart of the framework are the principles of beneficence, non-maleficence, justice, and respect for the human body, since the primary ethical consideration in acquiring and researching any living human tissue is the donor's health, welfare, and safety. The human body and its remains must be treated with respect. This framework promotes the idea that these principles must extend beyond the individual donor to encompass public trust, institutional responsibility, and stewardship.

The five domains surrounding consent are: 1) Foundational Consent Ethics (includes the major principles and baseline standards); 2) Governance of Legacy and Unconsented Collections/Bodies (recognises historical and institutional responsibilities); 3) Sensitive Consent Contexts (addresses the ethical differences in special populations); 4) Governance of Biobank, Commercialisation, and Secondary Research Consent (balances innovation with fairness); and 5) Ethical Adaptation for Emerging Technologies (ensures continued relevance in an evolving research environment). The outer ring comprises Governance and Regulatory Oversight, representing continuous legal management and control. The framework model symbolises an ethical ecosystem, where each layer/domain informs and supports the others, maintaining balance between innovation, law, and respect for human dignity.

Figure 2 provides a model of the integrated consent-centred ethical framework.

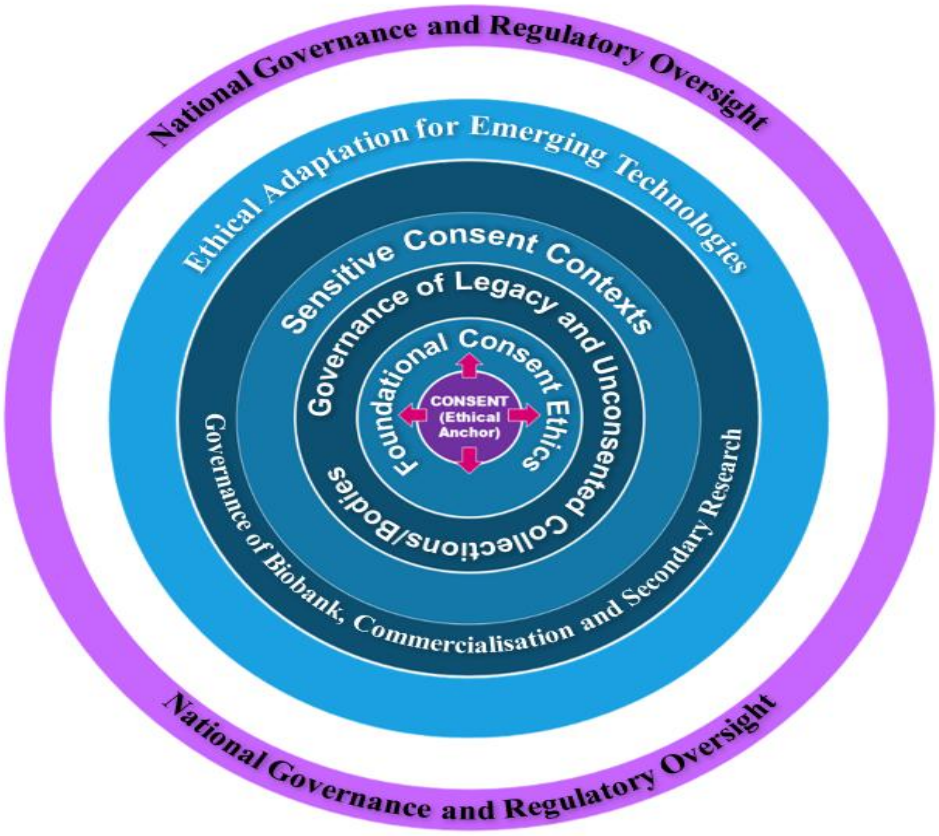

Figure 2. Integrated Consent-Centred Ethical Framework (ICEF) Model.

Table 2 explains the purpose and focus, as well as the guiding actions, of the five interconnected domains and the outer oversight structure of the Integrated Consent-Centred Ethical Framework, each representing a fundamental ethical aspect of human tissue research. The framework progresses from establishing foundational consent ethics to addressing complex issues, including legacy collections, vulnerable populations, biobank governance, and emerging technologies. Each domain provides tailored strategies and guiding actions to promote transparency, accountability, and the continuous ethical evolution of consent practices in South African human tissue research.

Table 2. The Five Domains and Outer Oversight Structure of the Integrated Consent-Centred Ethical Framework

Domain	Purpose and Focus	Strategies and Guiding Actions
Foundational Consent Ethics	Establishes a unified national standard for obtaining full, free, and informed consent for all human tissue research areas, and recommends appropriate consent models for living and cadaveric human tissue research.	Development of consent form compliance checklists; suggests a 3-type body donor system and ongoing consent review for living donors through a dynamic consent system.
Governance of Legacy and Unconsented Collections/Bodies	Ensures historical accountability and ethical future use of legacy collections and unidentified bodies.	Provenance determination, transparency reports, and national policy for legacy collections.
Sensitive Consent Contexts	Addresses circumstances where consent requires layered or proxy authorisation, particularly in cases involving foetal tissue, vulnerable populations, and genetic research.	Separation of consent processes, independent oversight, and withdrawal rights.
Governance of Biobank, Commercialisation, and Secondary Research Consent	Promotes ethical management of stored human tissue and its future use, ensuring transparency and benefit-sharing.	Tiered consent options, clear communication of potential commercial use, and ethical export review panels.
Ethical Adaptation for Emerging Technologies	3D printing, genetic analyses, digital imaging, and public display of human tissue.	Inclusion of digital and visual consent clauses, guidelines for respectful representation, and regular policy review for emerging technologies.
Governance and Regulatory Oversight: Establishes governance structures for HRECs and human biobanks by proposing the development of a national ethics platform for ethics applications and a national regulatory body/authority for biobanks.		

3.2 Comparison of the ICEF with Existing International Ethical Frameworks

The Integrated Consent-Centred Ethical Framework (ICEF) should be understood as complementary to, rather than a replacement for, established international ethical instruments. The *International Ethical Guidelines for Health-related Research Involving Humans*, developed by the Council for International Organisations of Medical Sciences (CIOMS) in collaboration with the World Health Organisation (WHO), provide a comprehensive framework for the ethical conduct of health-related research involving human participants. The Guidelines address, inter alia, scientific and social value, informed consent, vulnerability, equitable distribution of risks and benefits, ethical review, and the collection, storage and use of biological materials and associated data. CIOMS Guidelines recognise the ethical requirements associated with the future use of biological materials and data and permit specific or broad informed consent subject to appropriate governance (CIOMS, 2023). The CIOMS framework, therefore, provides an important international foundation for considering consent, biological materials, data governance and research oversight within health-related research.

UNESCO's *Universal Declaration on Bioethics and Human Rights* (2017), in contrast, provides a broader normative and human-rights foundation for bioethical decision-making. The Declaration places human dignity, human rights, and fundamental freedoms at the centre of bioethics and articulates principles, including autonomy and individual responsibility, informed consent, privacy and confidentiality, equality and non-discrimination, respect for cultural diversity, solidarity, social responsibility, and the sharing of benefits (UNESCO, 2017). Its significance for the present study lies particularly in its recognition that ethical governance of developments in medicine, life sciences and associated technologies must be situated within a broader framework of human dignity, rights and social responsibility.

The ICEF builds upon these established ethical foundations but addresses a different analytical and practical problem. While CIOMS provides broad guidance for health-related research involving humans, including the governance of biological materials, and UNESCO establishes overarching bioethical and human-rights principles, the ICEF brings these principles together within a human-tissue-specific and South Africa-specific governance structure. Its distinctive feature is therefore not the introduction of wholly new ethical principles, but the deliberate organisation and integration of established principles around consent as the ethical anchor of human tissue research. The framework consequently moves beyond considering consent as a discrete procedural requirement and conceptualises it as a continuing governance mechanism that

must remain responsive to the origin, nature, storage, subsequent use, and technological transformation of human tissue.

This distinction is particularly important in the South African context, as evidenced by the empirical findings of this thesis. The findings demonstrate that ethical challenges do not arise solely at the point at which tissue is initially obtained. They may persist or emerge subsequently in relation to legacy collections for which provenance or consent is uncertain; the use of foetal tissue; the governance of biobanks; secondary research; commercialisation; public display; unidentified human remains; and emerging technologies. The ICEF, therefore, seeks to provide an integrated structure through which these interconnected circumstances can be considered rather than treating them as isolated ethical questions. In this respect, the framework translates general international principles into a contextually grounded approach that responds to the ethical, legal, institutional and historical circumstances identified within South African human tissue research.

The originality of the ICEF should therefore not be understood as a claim that the framework introduces new ethical principles that are absent from international bioethics. Rather, its contribution lies in the synthesis, contextualisation and operationalisation of established ethical principles within the specific domain of human tissue research in South Africa. The empirical findings of this study identified a recurring disconnection between ethical principles, regulatory requirements and their practical application across different forms and stages of human tissue research. The ICEF responds to this disconnection by providing a single, consent-centred architecture through which the ethical governance of living and cadaveric tissue, legacy collections, biobanking, secondary use, commercialisation, sensitive consent contexts, and emerging technological applications can be considered within a single integrated framework.

Accordingly, the ICEF occupies a complementary position in relation to CIOMS and UNESCO. CIOMS provides internationally recognised guidance for the ethical conduct of health-related research, including the collection, storage, and future use of biological materials and related data, while UNESCO establishes a broader human rights-based normative foundation for bioethical governance (UNESCO, 2017; CIOMS, 2023). The ICEF draws upon these foundations but reconfigures them for a more complex governance problem: how consent, dignity, autonomy, provenance, oversight and responsible use can be coherently governed across the changing life cycle of human tissue within the South African legal and institutional environment. Its contribution is consequently one of integration and application-linking internationally recognised ethical principles with empirically identified South African governance gaps and translating them

into a structured framework intended to guide researchers, biobanks, Human Research Ethics Committees and policymakers.

4. Discussion

The Integrated Consent-Centred Ethical Framework for human tissue research was developed to address ethical gaps within South Africa's advancing biomedical and anatomical research environment. This framework is considered advanced because it is grounded in ethical theory and systematically describes stakeholders' views, drawing on two prior components of the doctoral study by the prime author. Thus, it can provide guidance and is applicable in real-life policy and practice. It builds upon the foundational principles of the South African National Health Act 61 of 2003, and the Department of Health's 2024 Ethics Guidelines (National Health Act, 2003; Department of Health, 2024). While these documents collectively emphasise autonomy, beneficence, and respect for persons, they do not adequately address the complex challenges surrounding consent, legacy collections, commercialisation, and the incorporation of new technologies. This framework model extends these principles, providing a flexible and ethically sound continuum centred on consent.

4.1 Domain/Layer 1: Foundational Consent Ethics and Checklists

The *Foundational Consent Ethics* domain represents the ethical and legal foundation of the Integrated Consent-Centred Ethical Framework. It outlines the standard ethical guidelines governing all human tissue research, ensuring that the principle of autonomy is upheld through voluntary, informed consent. Within this domain, the framework distinguishes between living and cadaveric human tissue research, recognising the distinct consent processes for each.

4.1.1 Living Human Tissue Research

Ethically sound human tissue research involving living donors begins by ensuring that full, free, and informed consent is obtained from a donor before any tissue is procured or accepted. Researchers must ensure prospective donors understand the purpose of the research study, methods, risks, benefits, and alternatives before deciding to participate (National Health Act, 2003). This process reinforces transparency, comprehension, and trust, which are fundamental to ethical research.

The choice of consent model must align with the research's scope. Specific, fully informed consent remains ideal for research with a clear, defined purpose at the time of collection, as it directly links the donor's consent to a specific research objective. In contrast, broad consent is appropriate for human biobanks that support future or unspecified research. This approach informs donors that their tissue may be used for future studies and allows them to agree to a broad spectrum of unspecified studies rather than a single research project (Maseme et al., 2024). In recognition of the evolving ethical expectations in biobanking, this framework model supports the implementation of a dynamic consent model where feasible. This model utilises digital tools, such as secure electronic donor databases, to maintain ongoing communication with donors. Dynamic consent systems enable donors to update or modify their consent preferences over time, ensuring that their participation accurately reflects their current values and personal choices. This approach strengthens ethical accountability and legal compliance, particularly under frameworks such as South Africa's Protection of Personal Information Act (POPIA, 2013).

Another key ethical aspect of this domain is distinguishing consent for therapeutic use from consent for research use. When tissue is collected during a clinical procedure, researchers must explicitly separate the consent for therapeutic use from the consent for research on the tissue. Donors/patients must understand that their participation in research is optional and will not affect the quality of their medical care or treatment. Furthermore, surplus clinical tissue (tissue remaining after diagnostic or therapeutic procedures) must be handled with explicit consent. It must not be assumed that surplus tissue can be used for research without obtaining the appropriate consent from patients. Some individuals may wish their surplus tissue to be discarded rather than reused, and ethical practice requires that such preferences be respected.

Donors must also be informed of their right to withdraw consent at any stage, without fear, penalty or disadvantage. Withdrawal procedures should be clearly explained, and biobanks must have mechanisms to remove samples and data upon request. This reinforces participant control over their tissue and strengthens public trust in research governance.

To ensure adherence to national and international ethical standards, the Integrated Consent-centred Ethical Framework includes the development of a detailed Consent Form Compliance Checklist for Living Participants/Human Tissue Research (Table 3). This checklist provides a structured guide for researchers and institutions to verify that all essential ethical components, including voluntariness, comprehension, disclosure, withdrawal rights, and privacy protection, are met before tissue collection from living participants for research.

The Consent Form Compliance Checklists are not intended to replace an informed consent form or to constitute a new consent form. Rather, it is a structured quality-assurance instrument designed to assist researchers, institutions and Human Research Ethics Committees (HRECs) in determining whether a proposed consent process adequately addresses the ethical requirements specific to human tissue research.

Several checklist elements overlap with conventional informed consent requirements, including competence, voluntariness, study purpose, procedures, risks, benefits and confidentiality. The distinctive contribution of the checklist lies in its integration of these general requirements with tissue-specific and future-use considerations. These include the distinction between therapeutic and research consent; explicit consent for foetal tissue research, where applicable; storage and future reuse; donor preferences regarding secondary use; commercialisation; image and media use; emerging technological applications; and other circumstances in which tissue may acquire additional uses after the original collection.

The checklist, therefore, functions as an audit and decision-support mechanism rather than as a substitute for the informed consent process. Its purpose is to improve consistency and completeness by enabling researchers and HRECs to identify omissions in consent documentation before tissue is collected, stored, transferred or reused.

Table 3. Consent Form Compliance Checklist for Living Participants/Human Tissue Research

Checklist Component	#	Description and Recommendation:	✓
Preparatory Steps			
Competence and Voluntariness	1	Ensure that the donor or their legally authorised representative is competent to decide, is of legal age, and is not under coercion.	
Enhanced Clarity and Readability	2	Present information in clear, comprehensible language, avoiding technical jargon, and ideally write it at a lower grade reading level to ensure comprehension.	
Information to be Provided in the Consent Form			
Study Purpose	3	• Explain that tissue collection is for research purposes and clearly outline the study's specific purpose and objectives. • Clearly explain that the consent for therapeutic use differs from the consent for research on the tissue (including foetal tissue). • Explicitly state that consent for foetal tissue research is separate from consent for the termination of pregnancy when acquiring consent from pregnant women for foetal tissue research.	
Procedures	4	Describe the exact procedures for tissue collection and processing.	
Tissue Storage and Handling	5	State where the tissue will be stored, how long it will be kept (e.g., in a biobank), and whether it might be used for future research.	
Comprehensive Risk and Benefit Disclosure	6	• Disclose any reasonably foreseeable risks, discomforts, and potential benefits to the donor, with more robust review procedures for studies involving more than minimal risk. • Ensure consent covers the risks associated with Artificial Intelligence (AI) applications. Explain the risk that AI algorithms (if applicable) could perpetuate.	
Future Use/Reuse of Tissue	7	• Clearly state if anonymised or de-identified tissue or data will be retained and used for additional research studies in the future. • Provide donors with options in the form of checkboxes to define how their body/tissue(s) may be used to allow them to clearly specify their preferences for how they permit their body/tissue(s) to be used and the applications they do not consent to. • Clearly disclose whether the donor's body/tissue(s) will be used for commercial purposes or by for-profit companies and allow the donor to specify consent for such use.	
Image and Media Rights	8	Acquire specific consent from the participant/donor to use images or body parts in educational materials or public displays, with assurance that the donor will not be personally identifiable.	

Transfer/Export of Tissue	9	Acquire explicit consent from the participant/donor for the program/institution to transfer/export the tissue(s) to other medical schools or research institutions nationally or internationally.	
Anonymity and Confidentiality	10	Clearly explain the extent to which the participant/donor's identity will be protected, the measures taken to protect their identity, and the confidentiality of records, including any publications, articles, or presentations resulting from the research. For tissue samples used in genomic research, ensure appropriate protections are in place.	
Transparency on Incidental Findings	11	Include details on how the research team will handle and disclose any unexpected medical findings that may be discovered during the study.	
Protection for Vulnerable Populations	12	Ensure that special protection and proxy consent from authorised representatives are obtained for studies involving tissue from children, cognitively impaired individuals, or other vulnerable groups.	
Regulatory Information	13	Include ethical approval and contact information for the Institutional Review Board (IRB) or Research Ethics Committee (REC).	
Right to Withdraw	14	Explicitly state that participation is voluntary and that the participant/donor can withdraw their consent without penalty. Clarify what will happen to the collected tissue if they withdraw.	
Final Disposal of Tissue	15	Acquire the participant's consent if tissue samples will be disposed of after research use.	
Signatures	16	Include signature lines for the participant/donor, their authorised representative, and the person acquiring consent.	
Enquiries Contact Details	17	Include an offer to answer any enquiries concerning research procedures, the participant/donor's rights, and who to contact in the event of a research-related injury. For student research, the supervisor must be the primary contact listed for enquiries.	
Additional Considerations			
Review and Update	18	Regularly review consent forms to reflect current ethical guidelines and legal requirements.	
Transparency and Communication	19	When obtaining consent, ensure clear and consistent communication with participants to foster trust and promptly address any questions or concerns they may have.	
Digital Options	20	Encourage the use of electronic consent forms/consent processes to securely store data, ensuring data completeness, legibility, and accuracy, while also enhancing efficiency. This allows donors to stay engaged with the type of research for which their tissue is used and manage their consent preferences over time. Researchers and Body/Tissue Donation Programs/Institutions must verify donor identity and ensure comprehension.	

4.1.2 Cadaveric Human Tissue Research

The ICEF extends its *Foundational Consent Ethics* domain to research involving cadaveric donations, recognising that consent for body donation after death demands both dignity and clarity. Ethical cadaveric research must begin with comprehensive body donor consent forms that include detailed information about the scope of current use, potential future uses, image and media rights, the export of tissue to other institutions, and the disposition of their remains. Donors should be allowed to opt into or out of different types of research and clearly select how they would allow their body to be used and what they would not permit, thereby exercising autonomy even in death.

A practical and ethically responsive mechanism proposed within the framework is the "three-type" body donor consent system, adapted from existing tiered cadaveric donation models described by international stakeholders in another component of the previously mentioned doctoral study, and contextualised for application within the South African human tissue research environment. This system allows donors to stipulate the extent and duration of their bodies' use for research. Under this model, a 24-hour donor permits immediate short-term use before return to the family for burial rites, a one-year donor allows use of the body for up to one year before respectful cremation and repatriation of remains, and a lifetime donor consents to unrestricted and unlimited use of the donor's body for human tissue research. This practical and ethical tiered system respects individual values and family considerations while enhancing transparency and ethical accountability in cadaveric donation.

Together, these components form the ethical foundation for the Integrated Consent-Centred Ethical Framework. This domain establishes a unified ethical standard that promotes respect, autonomy, and trust in all forms of human tissue research, living or cadaveric. This domain aligns closely with South Africa's National Health Act 61 of 2003 (National Health Act, 2003), which stipulates that no human tissue may be removed or used for research without valid informed consent, as well as with the Department of Health's 2024 Ethics in Health Research Guidelines (Department of Health, 2024), which emphasise participant autonomy and continuous consent review. Internationally, this framework complements the Organisation for Economic Co-operation and Development (OECD) Guidelines on Human Biobanks and Genetic Research Databases (2017) and the H3Africa Ethics Framework (2018), both of which support relevant consent processes, transparency, and community trust in biobanking. By harmonising national legislation with evolving international standards, the framework provides a contingent yet proactive foundation for ethical human tissue research in South Africa.

To promote alignment with both national and international ethical requirements, the ICEF incorporates a comprehensive Consent Form Compliance Checklist for Body and Tissue Donors (Table 4). This checklist serves as a systematic tool to assist researchers and institutions in confirming that key ethical elements, such as voluntariness, comprehension, full disclosure, the right to withdraw, and privacy protection, are addressed prior to cadaveric body or tissue donation. By standardising consent review

practices, the checklist enhances consistency, transparency, and ethical rigour throughout the consent process.

Table 4. Consent Form Compliance Checklist for Body and Tissue Donors

Checklist Component	#	Description and Recommendation:	✓
Preparatory Steps			
Voluntary Decision	1	Ensure that the body/tissue donor makes a voluntary decision to donate, without coercion.	
Eligibility	2	Confirm that the body/tissue donor is of legal age and mentally competent when signing.	
Family Notification	3	Ensure that the body/tissue donor informs their family of their decision to donate and to honour their wishes after death.	
Documentation	4	Ensure all necessary forms are completed, that supporting documents are submitted to the designated program coordinator, and that copies of the records are kept.	
Information to be Provided in the Consent Form			
Purpose	5	Clearly outline whether the donated body/ tissue(s) will be used solely for teaching anatomy, general research, specific research projects, plastination, or all mentioned uses.	
3-type Body Donor Consent	6	Provide the option for body donors to choose between 24-hour, 1-year, or lifetime donation.	
Scope of Use	7	• Provide donors with options in the form of checkboxes to define how their body/tissue(s) may be used to allow them to clearly specify their preferences for how they permit their body/tissue(s) to be used and the applications they do not consent to. • Inform donors that research uses will likely evolve with the introduction of contemporary research and modern technological advancements and allow them to specify whether they consent to such unknown future uses of their body/tissue(s). • Clearly disclose whether the donor's body/tissue(s) will be used for commercial purposes or by for-profit companies and allow the donor to specify consent for such use.	
Image and Media Rights	8	Obtain specific consent from the donor to use images or body parts in educational materials or public displays, ensuring the donor's identity is not personally identifiable.	
Transfer/Export of Tissue	9	Acquire explicit consent from the donor for the program/institution to transfer/export the body/tissue(s) to other medical schools or research institutions nationally or internationally.	
Exclusion Criteria	10	Outline any conditions that might lead to a body/tissue being rejected by the donation program/institution, such as certain communicable diseases or trauma.	

Next-of-kin Rights	11	• Ensure that the form specifies the role and rights of the next-of-kin, including whether they have a say in the donation and how they will be notified. • Ensure donors specify who has the legal right to consent if a deceased person was not a registered donor.	
Duration	12	Clearly state the length of time the body/tissue(s) may be used and retained.	
Anonymity and Confidentiality	13	Clearly explain the extent to which the donor's identity will be protected and how it will be protected, including in any publications, articles, or presentations that result from the research.	
Role of Artificial Intelligence (AI)	14	• Clearly explain the AI's function concerning the donation, using plain language rather than technical jargon. • Explicitly acquire the donor's consent to future, unspecified uses of their body/tissue(s) and their associated data by AI, or if they wish to place limitations. • Clearly acknowledge that ethical scrutiny is an ongoing process that will adapt as AI technology evolves.	
No Financial Benefit	15	Inform donors and their families that they will not receive any financial compensation from the donation, regardless of whether commercial products are developed from the donated tissue.	
Tissue Retention and Final Disposal of Tissue	16	• Provide clear information on the specific tissues and/or skeletal tissue that may be retained for long-term storage, the duration of retention, and the purpose for such retention. • Describe the procedures and institutional responsibility for the final disposition of all bodily material, including soft tissue and skeletal remains, specifying whether skeletal remains may be curated for ongoing research, teaching, or storage purposes, or whether they will be cremated or otherwise respectfully disposed of. • Indicate whether cremated remains or residual skeletal material will be returned to the family, disposed of in accordance with donor preferences, or managed according to institutional and legal requirements.	
Witnesses	17	Acquire the signatures of two competent witnesses to the donor's signature.	
Program Contact	18	Provide contact information for the Body/Tissue Donation Program coordinator for questions.	
Additional Considerations			
Review and Update	19	Review body/tissue donation consent forms regularly to reflect current ethical guidelines and legal requirements.	
Transparency and Communication	20	Ensure clear, consistent communication with potential donors and their families to foster trust and address any questions or concerns.	
Digital Options	21	Encourage the use of electronic consent forms/consent processes to securely store data, ensuring data completeness, legibility, accuracy, and efficiency. Researchers and Body/Tissue Donation Programs/Institutions must verify donor identity and ensure comprehension.	

4.2 Domain/Layer 2: Governance of Legacy and Unconsented Collections/Bodies

Legacy tissue and skeletal collections are essential to South Africa's scientific and educational heritage, representing decades of anatomical and anthropological research. However, many of these collections were established in historical periods when ethical standards, consent processes, and donor rights were poorly defined or absent (Bach, 2016). The *Governance of Legacy and Unconsented Collections/Bodies* domain of the framework recognises that although the continued use of such collections holds scientific value, it must occur within a contemporary ethical and legal framework that upholds principles of respect, accountability, and transparency (Department of Health, 2024).

The continued use of such legacy collections should be permitted under strict ethical oversight, acknowledging that they were assembled and acquired under different ethical conditions. However, the provenance of these collections, including their origins, acquisition methods, and historical background, should still be thoroughly investigated before continued use. Provenance checks provide a means to assess the ethical validity and historical accountability of collections, ensuring that the reuse of legacy collections does not perpetuate past injustices or compromise donor autonomy (UNESCO, 2017). Where the provenance of legacy collections cannot be adequately established, their continued use should be subject to heightened ethical scrutiny and, where appropriate, restriction or suspension. Human Research Ethics Committees should require documented efforts to determine provenance, a formal risk-benefit assessment, and clear justification for any proposed use, particularly where there is a possibility of non-consensual or exploitative acquisition (UNESCO, 2017).

To address inconsistencies in current practice, a national policy should be implemented to govern access to and use of legacy tissue and skeletal collections in South Africa. Such a policy may require legislative intervention to clarify ownership, consent, and repatriation issues (National Health Act, 2003). It should also distinguish between research on unconsented legacy collections (which requires special ethical review and restricted use) and research involving sufficiently consented tissue (which should follow standard ethical processes and oversight mechanisms) to ensure that research involving legacy tissue aligns with ethical standards and international best practices.

Moreover, the continued use of unidentified bodies/unclaimed bodies for teaching or research is unethical and should be explicitly prohibited by national legislation. Human tissue and anthropological research should proceed through the proper channels for body donation and public awareness, rather than relying on unidentified bodies.

Through these measures, the ICEF model promotes the ethical governance of human tissue collections, maintaining the scientific and educational value of legacy collections while promoting respect, justice, and human dignity in all research practices.

4.3 Domain/Layer 3: Sensitive Consent Contexts

This Integrated Consent-Centred Ethical Framework domain recognises that obtaining valid, ethically sound consent becomes increasingly complex in sensitive research settings, particularly when participants are vulnerable or when research involves foetal tissue or genetic data. In such instances, consent must extend beyond practical requirements to embody principles of autonomy, comprehension, voluntariness, and respect for persons (CIOMS, 2023).

A significant ethical distinction must be made between consent for the termination of pregnancy and consent for the use of foetal tissue for research. These separate, voluntary consents should never be merged (Department of Health, 2024). This is vital so that the donating woman can understand that the termination and possible use of the foetal tissue for research are separate voluntary consents and that the consent can be withdrawn at any time up to the point of tissue collection. Consent for the termination of pregnancy or collection of foetal tissue for therapy or diagnosis should be obtained by the pregnant woman's physician. Subsequently, and as a separate matter, the responsibility for obtaining consent for the foetal tissue for research purposes should rest with the researcher or research team receiving the donation and utilising the foetal tissue for research.

Similarly, research involving vulnerable populations, such as children, prisoners, and individuals with cognitive impairment, requires heightened ethical scrutiny. Researchers must ensure that such participants are protected from exploitation by enhanced verbal consent measures, proxy consent (where appropriate), and constant consent procedures. HRECs and researchers should implement *maximal protection and minimal intrusion* in these circumstances, ensuring that participation is voluntary, understandable, and appropriate (CIOMS, 2023).

4.4 Domain/Layer 4: Governance of Biobank, Commercialisation and Secondary Research Consent

Within the proposed ICEF model, this domain underscores that the governance of human biobanks is a key component of ethical human tissue research, ensuring that human tissue collection, storage, reuse, and export are conducted transparently, responsibly, and with full respect for donor autonomy. Since regulatory frameworks for biobanking are still developing in South Africa, aligning governance practices with international ethical standards, such as those established by the OECD (2017) and H3Africa (2018), is crucial.

A key requirement is that donors be fully informed about the potential export or secondary use of their tissue. Explicit consent should be obtained to explain whether stored tissue may be exported for research purposes, ensuring that participants are aware of the geographical and institutional boundaries of tissue use (World Health Organisation, 2021). Biobanks must also ensure that any transferred tissue was

ethically and legally obtained, and that receiving institutions adhere to ethical standards and data protection measures.

Furthermore, all biobank activities must operate under a clear tissue management plan that specifies how samples will be collected, stored, distributed, reused, shared, and disposed of. Such plans ensure continuity, accountability, and traceability throughout the research, preventing misuse of human tissue samples. Maintaining a verifiable provenance check also helps safeguard public trust and institutional integrity.

Accountability processes form another essential aspect of biobank governance. Clear lines of responsibility must be established for handling tissue, protecting donor data, and addressing ethical concerns. Researchers, HRECs, and biobanks must all be held accountable for ensuring compliance with ethical and legal norms. This aligns with the National Health Act 61 (2003) and the Protection of Personal Information Act (POPIA, 2013), which require the protection of donor privacy and the prevention of data misuse. A Research Ethics Committee may consider waiving consent for secondary research on existing tissue samples if re-contacting donors is impractical, the risk is minimal, and the research is of significant public value. However, the committee must assess all risks, including privacy breaches.

Ethical governance also extends to the commercialisation of human tissue research. This framework model prohibits direct financial gain from human tissue donations. Donors should not be offered financial incentives for tissue donation beyond reimbursement for reasonable expenses. This preserves the altruistic nature of tissue donation and prevents potential exploitation, particularly in low-income or vulnerable communities (CIOMS, 2023).

Researchers have an ethical duty to disclose any potential commercial interests related to the research to donors before obtaining their consent. This includes clear communication regarding intellectual property rights and profits that may arise from research involving the donated tissue. Transparent disclosure emphasises the ethical principle of respect for persons and allows donors to make fully informed decisions (Bledsoe and Grizzle, 2022).

Ownership of human tissue is one of the most contentious ethical and legal issues in human tissue research and biobanking. It is fundamentally linked to how tissue is managed, stored, reused, and commercialised (Moodley et al., 2014). Within the proposed framework, ownership is conceptualised as a governance issue rather than a property right, aligning with the principle that donated tissue is an altruistic contribution to science rather than a commodity (Moodley et al., 2014). Human tissue donations should only be accepted if the donor waives all ownership rights and claims to the tissue in question. Donations should be accepted only if they are given as gifts, without any expectation of personal benefit to the donor. Donation should not be accepted if a donor refuses to comply with these terms. However, although the donor relinquishes ownership rights to their tissue once it is donated, they

still retain rights to privacy and autonomy. This approach prevents the commercialisation of human tissue, aligns with the ethical principle of altruism, and ensures that donated tissue is managed in accordance with the donor's specified intent (National Health Act, 2003).

Finally, the proposed ICEF model promotes equitable benefit-sharing agreements, especially when research involves communities with limited access to healthcare resources. Within the framework, benefit-sharing is implemented through formal agreements that are reviewed as part of ethics approval and institutional governance. Researchers must specify measurable commitments in advance, such as capacity-building, improved healthcare infrastructure, or improved access to resulting innovations. Implementation is reinforced by linking these commitments to ethics approval conditions, contractual agreements, and periodic oversight by institutions and HRECs. Community involvement in discussing priorities helps ensure that benefits address locally identified needs. In this way, benefit-sharing becomes an enforceable accountability mechanism that promotes social justice in human tissue and biobank research (Bauer et al., 2004).

Implementing a national biobank registry would facilitate tracking of all exported samples, associated research outcomes, and benefit-sharing arrangements. Mandating transparency and traceability would not only prevent the commercialisation of human tissue but also reaffirm the ethical foundation of biobank participation, one grounded in altruism, trust, and shared scientific advancement.

Collectively, these mechanisms (ethical export controls, transparent governance structures, responsible commercialisation, ownership rights, and fair benefit-sharing) form the ethical structure of the *Governance of Biobank, Commercialisation, and Secondary Research Domain.* This ensures that biobanking in South Africa advances scientific progress while upholding respect and accountability at every stage of research (Bauer et al., 2004).

4.5 Domain/Layer 5: Ethical Adaptation for Emerging Technologies

Technology's rapid advancement has transformed how human tissue is studied, displayed, and shared. The *Ethical Adaptation for Emerging Technologies* domain recognises that advances such as digital imaging, artificial intelligence (AI), plastination, and public display of human specimens introduce new ethical challenges that require updated governance.

Under the proposed ICEF model, digital imaging of cadaveric material must only occur when prior consent has been explicitly obtained. The digitisation of human tissue, including 3D scans or holographic reconstructions, transforms it into digital biobank data, thereby extending the ethical responsibilities of data protection and privacy (World Health Organisation, 2021). Institutions must ensure that digital files are securely stored and that researchers adhere to the same ethical standards that govern the handling of physical specimens.

Within this framework, this domain proposes that AI-driven research must ensure donors are informed of the potential for algorithms to use their biological data. Researchers and human biobanks must implement transparent data governance systems and conduct ethical impact assessments within the ethics review process to identify and mitigate potential biases or harms arising from the use of AI (Cornwall et al., 2024). Such assessments could help researchers to identify and mitigate potential harms at the design stage, rather than retroactively (Shaw, 2024).

The ICEF model proposes the principle of "dignity in perpetuity", ensuring that, whether tissue is displayed, digitised, or algorithmically analysed, it remains treated as a representation of human life deserving of continual respect. This domain underscores the importance of continuous ethical oversight, prompting institutions to anticipate emerging ethical challenges and adjust their governance systems accordingly. It mandates the introduction and explanation of emerging technological uses in informed consent forms, thereby allowing donors to choose whether to consent to such research. The developed Compliance Checklists for living human tissue and body donors include recommendations for emerging technologies (Tables 3 and 4). In this way, the framework ensures that technological advancement does not degrade ethical integrity but enhances it, aligning modernisation with respect, transparency, and social responsibility (Cornwall et al., 2024).

4.6 Surrounding Layer: Governance and Regulatory Oversight

The effectiveness of the proposed framework model depends on robust, transparent, and well-organised governance structures that ensure consistent ethical review, compliance, and accountability across all domains of human tissue research. *Governance and Regulatory Oversight*, as the outermost ring of the model, provides continuous ethical guidance and reinforces national standards across institutions.

A foundational principle of this component is the mandate for independent ethical review. All human tissue research must be reviewed and approved by an independent Human Research Ethics Committee (HREC) or Institutional Review Board (IRB) to minimise conflicts of interest and protect participants and donors (Department of Health, 2024). The independence, integrity, and transparency of these committees are vital. Any conflict of interest must be rigorously avoided. The appointment of such ethics committees or IRBs should also be transparent (NHREC, 2024).

To enhance national consistency, the ICEF model proposes the establishment of a National Ethics Platform, a centralised electronic system through which all human tissue research applications would be submitted, reviewed, and tracked, rather than submitting to independent institutional HRECs within the country. This platform would standardise review specifications across institutions, reduce administrative workload, and ensure uniform review and approval processes nationally. It would also streamline multi-site research approvals using standardised checklists and application forms, improving efficiency while maintaining thorough oversight.

Complementary to HREC oversight, human biobanks play a fundamental role in the governance of human tissue research. Each biobank should operate under a robust internal governance framework, guided by transparent and appropriate systems, standards, policies and procedures for sample acquisition, storage, use, and disposal. This should include securing the necessary licenses and obtaining ethical approval for their biobank activities (Singh and Moodley, 2021).

To strengthen accountability at a national level, all human biobanks in South Africa should fall under the authority of a National Statutory/Regulatory Body sanctioned to license, oversee, and ensure compliance with the ethical and legal requirements for biobanking. Biobanking should be prohibited without a license from this regulatory body. This Body should have the legal mandate to provide oversight, issue directives, and ensure ongoing ethical alignment with national laws and international best practices.

Protecting donor privacy and confidentiality is another continuous regulatory obligation of human tissue research (POPIA, 2013). It is a key aspect of *Governance and Regulatory Oversight* because it represents an ongoing ethical responsibility that protects donor trust across all domains of the framework model. To reduce the risk of breaches, researchers should de-identify tissue samples by removing unnecessary personal identifiers. The level of de-identification required for different types of research should be clearly defined and documented. Strict protocols and robust data security should also be established to protect against unauthorised re-identification. This is essential since advances in genetic sequencing make re-identification increasingly possible (Bauer et al., 2004). This framework proposes using a coding system to manage data while maintaining traceability to minimise the risk of a confidentiality breach. Such practices strike a balance between scientific value and donor confidentiality, aligning with the requirements of the POPIA in South Africa (POPIA, 2013).

The ICEF model recommends that a tiered access system governs access to human tissue to protect highly sensitive data, such as whole-genome sequences. Access to research data requires more gradation to ensure the protection of donors. This system balances the need for researchers to access human tissue and its associated data, protecting the privacy and confidentiality of the individuals who donated the tissue. This system operates on the principle of least privilege, ensuring that researchers have access to only the minimum amount of tissue or data necessary for their specific research. This helps to mitigate the risk of misuse of human tissue.

Collectively, these measures create a multi-tiered governance ecosystem, where independent HRECs maintain ethical decision-making at the institutional level, and a centralised national authority for research applications and biobanking ensures consistency, transparency, privacy, confidentiality, and accountability across the broader research landscape. This model strengthens public trust and ensures that every component and domain of the framework model, from consent to emerging technologies,

operates within a secure, ethically governed environment that protects the privacy and confidentiality of donors and participants.

4.7 Operationalisation and Pathways to Policy and Legal Adoption

The ICEF is intended as an ethical and governance framework. Its implementation, therefore, requires translation through institutional, policy, and, where necessary, regulatory and legislative mechanisms. The study's findings highlight fragmented governance, inconsistent HREC practices, and uncertainty around consent, secondary use, and biobanking, underscoring the need for clearer operational pathways.

ICEF implementation is proposed across three levels: (1) institutional, (2) national policy/guideline, and (3) legislative/regulatory. These levels are sequential but interconnected. Institutional implementation allows initial testing and refinement, national policy promotes consistency, and legislative reform is considered only where existing law is insufficient. ICEF has no legal force unless formally adopted through these processes.

4.7.1 Institutional implementation

At the institutional level, ICEF can be integrated into existing HREC and biobank systems through consent checklists, Standard Operating Procedures (SOPs), and decision pathways. These tools would standardise documentation of key consent elements such as storage, secondary use, tissue sharing, commercialisation, and emerging technologies, without replacing HREC review.

For legacy collections, institutions should conduct a provenance review that documents acquisition history, consent status, and ethical concerns, with HRECs recording decisions on continued use or restrictions when uncertainty exists. For secondary use and biobanking, governance procedures should require evidence that the use aligns with the original consent or has received additional ethical approval. Documentation should also cover data protection, transfer, and export requirements. Institutions should further develop standardised HREC decision pathways for recurring complex cases (e.g., legacy samples, cross-border research, commercialisation, and emerging technologies) to improve consistency and transparency.

4.7.2 National policy/guideline implementation

At the national level, ICEF principles could inform updates to NHREC and Department of Health guidance, including standardised consent templates, biobanking standards, and requirements for provenance review, secondary use, and export governance. This is particularly important given the current variation in institutional practices.

ICEF may also support the development of national biobanking standards, as South Africa currently lacks a single dedicated legislative framework for research biobanks. Proposed governance structures, such as a National Digital Ethics Platform and a Biobank Oversight Office, could support implementation, subject to further feasibility and consultation.

4.7.3 Legislative and regulatory implementation

ICEF does not create legal obligations but may identify areas requiring legal reform, including legacy collections, biobank governance, ownership of tissue and data, secondary use, commercialisation, export, and emerging technologies. Any legal change would depend on formal governmental and legislative processes. The framework, therefore, serves as an evidence base for identifying regulatory gaps rather than a substitute for law.

4.7.4 Implementation pathway

ICEF is intended to be implemented iteratively (Table 5):

Evidence → expert refinement → institutional pilot → national consultation → policy/guideline adoption → regulatory/legal review (if required) → monitoring and revision.

Table 5. Proposed Pathway for Operationalisation and Policy Adoption of the ICEF

Stage	Key Activity	Responsible/Participating Stakeholders	Expected Output
1. Evidence	Integrate empirical findings, ethical principles, legislation and international guidance	Researchers, ethics scholars, and legal experts	Evidence base for ICEF
2. Expert Refinement	Review framework content, feasibility and ethical coherence	Human tissue experts, HREC members, biobank representatives, legal and ethics experts	Refined ICEF
3. Institutional Pilot	Pilot consent checklists, SOPs, provenance review and HREC decision pathways	Universities, HRECs, researchers, biobanks	Implementation evidence and identified gaps

4. National Consultation	Consult on feasibility, consistency, legality, social acceptability and resource implications	Department of Health, NHREC, HRECs, biobanks, researchers, legal experts, public/community representatives	Stakeholder-reviewed implementation proposals
5. Policy/guideline Adoption	Consider the incorporation of relevant ICEF principles into ethics guidance, biobanking standards and model consent templates	Department of Health, NHREC and relevant national stakeholders	National ethical guidance/standards
6. Regulatory/legal Review	Determine whether identified gaps require regulatory amendment or legislative intervention	Relevant government departments, legal experts and regulatory authorities	Proposed regulatory or legislative reforms where justified
7. Monitoring and Revision	Assess implementation using defined indicators. Review framework in response to evidence, technological developments and emerging ethical concerns	Institutions, HRECs, biobanks and national oversight structures	Compliance and implementation data. Updated and adaptive governance guidance

This staged approach ensures feasibility testing, stakeholder input, and adaptability to evolving technologies such as AI, genomics, and digital tissue applications. Implementation requires consultation with the Department of Health, NHREC, HRECs, biobanks, researchers, legal and ethics experts, data protection specialists, and public/community representatives, particularly where culturally sensitive materials or legacy collections are involved. This ensures ethical, legal, and social acceptability.

Implementation should be supported by indicators such as compliance with consent checklists, completion of provenance reviews, adoption of SOPs, consistency of HREC decisions, and documentation of secondary-use approvals. At the national level, monitoring may include uptake of guidelines and reporting of governance issues. Regular review is essential to ensure responsiveness to emerging technologies and evolving ethical challenges.

5. Conclusion

An Integrated Consent-Centred Ethical Framework is proposed as a comprehensive and appropriate model to strengthen ethical governance in human tissue research in South Africa. Centred on consent as the ethical anchor, the framework integrates foundational ethics, legacy collections and unidentified bodies, sensitive consent contexts, biobank and commercialisation governance, and emerging technologies within a five-domain model of continuous governance and regulatory oversight. The framework links ethical principles with the practical applications of human tissue research, promoting transparency, accountability, and respect for human dignity. The framework ensures that human tissue research aligns with national and international ethical standards by guiding researchers, HRECs, and human biobanks toward fair and responsible practices. The national adoption and institutional integration of this framework is recommended across all research institutions that conduct human tissue research in South Africa. To ensure consistent application and effective implementation, the national Department of Health should play a coordinating and oversight role by incorporating the framework within national policy guidance, ethics review standards, and institutional compliance mechanisms. Additionally, the framework should be subject to periodic review, stakeholder consultation, and policy refinement to maintain its relevance amid evolving scientific and technological developments. This will ensure that the ethical governance of human tissue remains dynamic, fair, and aligned with the principles of justice, beneficence, and respect for persons, providing an ethically sound future for human tissue research in South Africa.

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CHAPTER 5: SYNTHESIS

This study aimed to explore and address the ethical challenges underlying human tissue research in South Africa, an area that interconnects biomedical innovation, legal governance, and ethical responsibility. This study also aimed to advance the conversation on research ethics by extending traditional Western bioethical frameworks to include South African and Global South perspectives grounded in contextual realities such as historical injustices, public values, and socio-economic differences. While prior studies (Doyal et al., 1998; Knoppers, 2005; Caulfield, 2007; Allen et al., 2010; Garrafa, 2010; Gefenas et al., 2011; Kaye et al., 2016; Domaradzki and Pawlikowski, 2019; Amoakoh-Coleman et al., 2023; Billings et al., 2024; Gibbon et al., 2024) have examined specific ethical areas, such as consent or biobank regulation, this study uniquely investigated and synthesised multiple stakeholder perspectives to develop a complete model informed by both South African experiences and international best practices. It thereby sought to extend existing global frameworks that emphasise personal autonomy and social justice by incorporating historical sensitivities (Amoakoh-Coleman et al., 2023).

Integrative Overview of the Thesis

The three empirical and conceptual components of this thesis are cumulative rather than independent. Chapter 1 established the ethical, historical, legal and regulatory problems and identified the need for a more integrated approach to human tissue research governance. Chapter 2 addressed Research Objective 1 by establishing the perspectives of anatomists and human tissue researchers regarding consent and ethical challenges across national and international settings. The findings identified important tensions concerning consent models, living versus cadaveric tissue, legacy and unconsented collections, commercialisation, and emerging uses of human tissue. Chapter 3 addressed Research Objective 2 by examining how these ethical and consent tensions are experienced within the South African HREC and human biobank environment. The findings demonstrated fragmented governance, legislative and policy uncertainty, inconsistencies in ethics review, uncertainty surrounding secondary use and biobanking, and the need for stronger national coordination and oversight. Chapter 4 addressed Research Objective 3 by synthesising the empirical findings from Chapters 2 and 3 with established ethical principles and analyses of South African and international regulations to develop the Integrated Consent-Centred Ethical Framework (ICEF). The framework positions consent as the ethical anchor and integrates five domains: Foundational Consent Ethics; Governance of Legacy and Unconsented Collections; Sensitive Consent Contexts; Governance of Biobank, Commercialisation and Secondary Research; and Ethical Adaptation for Emerging Technologies, supported by an outer layer of Governance and Regulatory Oversight.

The present chapter, therefore, does not treat the individual manuscripts as independent studies. Instead, it synthesises how the three stages collectively address the research questions and establishes the thesis's contribution. The progression is consequently:

Chapter 1: Literature, ethical and regulatory gap → Chapter 2: Stakeholder-level empirical evidence → Chapter 3: South African institutional and governance evidence → Chapter 4: Framework integration and development → Chapter 5: Overall synthesis, contribution, implications and recommendations.

Each ICEF domain can therefore be traced to a combination of empirical evidence, normative reasoning and regulatory analysis. The framework is consequently not an independent conceptual proposal introduced after the empirical work; it represents the cumulative outcome of the study design and the integration of findings across the three work packages.

Research Objective 1: To evaluate stakeholders' views internationally and nationally (anatomists and researchers) concerning human tissue research, focusing on consent.

This objective aimed to advance scholarly understanding of human tissue research ethics by demonstrating that consent serves as a dynamic ethical paradigm at the intersection of law, professional practice, and moral philosophy, rather than a static regulatory requirement. This objective was addressed through an empirical investigation of anatomists' and researchers' perspectives on human tissue research and consent practices in Chapter 2, revealing a persistent structural disconnection between the ethical principles underpinning consent and their translation into research practice. Participants' perspectives revealed a clear ethical and regulatory divide between research involving living participants and that involving cadaveric tissue. By analysing stakeholder views on consent practices in human tissue research, the study identified the major consent models currently in use (i.e. broad, tiered, and dynamic consent) and their ethical strengths and limitations. While "broad consent" emerged as the preferred model due to its practicality for future use of human tissue, participants also underscored the importance of maintaining donor autonomy and that research uses remain ethically justified (Grady et al., 2015; Masiye et al., 2023). The chapter highlighted persistent ethical challenges, including the continued use of unconsented legacy skeletal collections, the commercialisation of human tissue, and inadequate regulation of contemporary research uses such as 3D printing, plastination, and digital imaging (Cornwall et al., 2024b). These challenges highlighted a recurring disconnect between ethical principles and research practice, particularly where legality was relied upon as a substitute for ethical reasoning. Through the lens of autonomy and dignity, the study demonstrated that consent remains ethically central even when regulatory frameworks permit alternative practices. Social justice and

accountability further emerged as critical considerations, especially in relation to historically marginalised populations whose contributions have disproportionately advanced scientific knowledge.

The chapter contributed to the field of science by reconceptualising consent as an ongoing ethical relationship grounded in respect for autonomy, dignity, and social justice (Beauchamp and Childress, 2019). It demonstrated that ethical authenticity in human tissue research cannot be guaranteed solely through legal approval but requires ongoing moral validation, particularly in contexts shaped by historical inequities and power imbalances (Gibbon et al., 2023). For researchers, this reframing carries significant implications: it necessitates a shift from minimal regulatory adherence toward reflexive ethical governance that foregrounds accountability, transparency, and proactive engagement with emerging technologies. By empirically demonstrating the gap between ethical principles and operating procedures, Chapter 2 provided a rigorous foundation for developing a consent-centred framework capable of responding to evolving scientific settings. In doing so, it extended existing literature by positioning consent not as an administrative endpoint but as the central organising principle of ethically viable human tissue research (Harris et al., 2022; Kramer, 2024).

Research Objective 2: To qualitatively investigate and explore the ethical views of South African human research ethics committee (HREC) members and human biobanks on ethical concerns, consent preferences, and policy gaps in human tissue research and biobanking governance.

This objective was addressed through an in-depth qualitative exploration of the experiences of South African HREC members and human biobank managers regarding ethical review, consent governance, and regulatory oversight. This objective advances the field by indicating that governance weaknesses in South African human tissue research are not simply organisational inadequacies but ethically significant shortcomings that directly affect the protection of autonomy, dignity, and social justice (Beauchamp and Childress, 2019; Mahomed and Labuschaigne, 2019). The qualitative findings revealed that fragmented oversight and legislative inconsistency undermine the ability of research ethics committees and human biobanks to safeguard meaningful consent, equitable benefit sharing, and respect for persons (National Health Act, 2003; POPIA, 2013). Participants described how these legislative discrepancies create uncertainty surrounding the use, storage, and secondary use of human tissue, particularly in human biobanking research (Maseme et al., 2024). Additionally, the absence of a unified regulatory authority or a centralised oversight body for biobanks was identified as a critical gap, leading to inconsistencies in the management of consent, data protection, and benefit sharing. This matters to researchers because it shows that ethical responsibility cannot be entirely delegated to compliance structures. Instead, the findings call for a systemic shift toward harmonised national governance that integrates ethical values consistently across institutions (Rani et al., 2024). The rapid emergence of AI, genomics, digital replication, and large-scale data linkage further intensifies this

urgency. The consequence is a widening gap between technological capability and ethical oversight, where the protection of dignity and social justice becomes conditional rather than guaranteed.

What must change, therefore, is not only regulatory coherence but the adoption of ethically anchored governance that explicitly centres autonomy, dignity, and social justice as operational principles rather than aspirational standards. By empirically demonstrating how governance fragmentation gives rise to ethical weakness, Chapter 3 provided a compelling mandate for integrated restructuring. It established that viable human tissue research requires coordinated oversight, national standardisation, and reflexive ethical governance that evolves alongside scientific innovation (Mahomed and Labuschaigne, 2019; Dhai, 2024).

Research Objective 3: To develop a comprehensive ethical framework for research on human tissue in South Africa.

This objective was addressed by synthesising empirical findings from Objectives 1 and 2 with established ethical principles and legislative analysis, culminating in the development of the Integrated Consent-Centred Ethical Framework (ICEF) for human tissue research in South Africa. This section addressed the gap between regulation and ethical principles. The framework represents the study's primary scholarly and original contribution and is explicitly grounded in the ethical principles of autonomy, dignity, transparency, accountability, and social justice. By positioning consent as the ethical anchor, the framework directly responded to regulatory fragmentation and ethical uncertainty by translating ethical principles into practical governance tools. It addressed the gap between what is lawful and what is ethically defensible by recognising that legal permissibility does not eradicate ethical responsibility, particularly in contexts involving cadaveric research, legacy collections, biobanking, and the secondary use of human tissue and data. The ICEF provides structured guidance for consent processes, ethics committee review, and institutional accountability, thereby promoting transparency and procedural fairness. Importantly, the ICEF engages with the ethical complications arising from the rapid expansion of AI, digital imaging, and biotechnological innovation (Yu et al., 2024). By incorporating adaptive consent strategies, enhanced oversight mechanisms, and ongoing governance review, the framework enables ethical responsiveness to evolving research practices while safeguarding dignity and public trust. It further proposes mechanisms for restitution, provenance review, and culturally sensitive governance of legacy collections, aligning social justice with socio-historical realities in South Africa (Gibbon et al., 2023; Baliso et al., 2025). Through its integrative design, the framework harmonises consent models, strengthens the governance of biobanking and human tissue research, clarifies responsibilities for secondary use and ownership, and supports consistent ethical decision-making across institutions. In doing so, it offers a rational response to the study's central

research question by demonstrating how an empirically validated, consent-centred ethical framework can guide the ethical and lawful conduct of human tissue research in South Africa.

Limitations of the study

Despite its contributions, the study acknowledges certain limitations. Although the qualitative approach provided depth and richness, it limits generalisation across all institutions. Participant representation was restricted to anatomists, researchers, HREC members, and human biobank managers, excluding policymakers, body donors, and community representatives who could enhance future analysis. Additionally, the study's focus on South Africa does not fully capture regional variations across Sub-Saharan Africa. Future research should therefore expand stakeholder inclusion to include donors and the public and empirically test the implementation of the proposed framework across various institutional settings. Comparative research between South Africa and other African countries could further refine the understanding of ethical harmonisation and cross-border governance.

The purposive sampling strategy used across the three work packages was appropriate for the qualitative and constructivist orientation of the study, but limits the extent to which the findings can be generalised statistically to all anatomists, researchers, HREC members or human biobank managers. The samples were intentionally selected for their professional relevance and information richness. The findings should therefore be understood in terms of analytical relevance, contextual applicability and potential transferability, rather than statistical generalisability. Transferability is supported where readers or institutions operating in comparable human tissue research environments can identify similarities between the contexts described in this study and their own settings. The detailed description of the sampling frames, participant groups and research context is intended to assist such assessment.

The study also did not include all stakeholder groups who may be affected by human tissue governance. Policymakers, body donors, and representatives of the broader community were not included among the primary participant groups. Their perspectives would be valuable in future research, particularly regarding public expectations, cultural considerations, benefit-sharing, and the social acceptability of governance arrangements. This limitation is acknowledged when interpreting the proposed ICEF and its potential implementation.

Another limitation of this study is the researcher's positionality influence on the development of the ICEF. The researcher's background in Anatomy and prior work in human body donation and research ethics provided valuable insight but may also have shaped the interpretation of empirical findings, particularly regarding consent, autonomy, dignity, and ethical governance. Although reflexive practice, iterative analysis, member checking, and expert review were used to enhance transparency, the

researcher's interpretation could not be fully eliminated. This is important because the ICEF was not derived purely inductively, but constructed through the interaction of empirical data, ethical principles, and regulatory analysis. As such, decisions about the ethical significance of findings and their translation into framework domains involved interpretation. The ICEF should therefore be understood as an empirically anchored and normatively constructed framework, rather than the only possible interpretation of the data. Future research should broaden stakeholder engagement and test the ICEF in different institutional contexts to further refine its assumptions and practical application.

Conclusion

The study's findings have significant implications for policy, education, and research. The proposed framework provides a foundation for establishing a National Biobank Authority and creating a National Digital Ethics Platform, developments that would enhance ethical oversight, accountability, and transparency. It also offers practical guidance for aligning HREC review processes and harmonising ethical standards across South African research institutions through the proposed checklists. Furthermore, the framework promotes international collaboration based on fair data sharing and equitable benefit distribution, addressing global ethical concerns regarding exploitation and the distribution of benefits.

In conclusion, this study bridges the gap between ethical theory, empirical stakeholder experience, and regulatory practice for human tissue research in South Africa. By aligning ethical principles with governance mechanisms and emerging technologies, it proposes a consent-centred ethical framework for human tissue research in South Africa that balances scientific innovation with respect for human dignity, autonomy, and social justice. The study provides a foundation for policy development and institutional harmonisation, contributing meaningfully to both South African and global ethics discussions.

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Appendices

Chapter 2

Appendix 1: Published Manuscript

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Human tissue research ethics and consent models: Global reflections in anatomical sciences

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Legislation

ABSTRACT

Background: Human tissue research has evolved to include three-dimensional (3-D) printing, genetic research, digital imaging of human tissue, plastination, and the public display of human tissue. This has resulted in several concerns about ethical acquisition, storage, and use of human tissue, particularly informed consent. This empirical study obtained the perspectives and viewpoints of anatomists and researchers across five countries on the ethical components of human tissue research.
Methods: Thirty in-depth Zoom interviews were conducted with participants from South Africa, the United States of America (USA), New Zealand, Germany, and France. Participants shared their perspectives and viewpoints on informed consent models, ethical challenges surrounding human tissue research, and existing gaps in policy guidelines. The data was analysed using thematic and content analysis.
Results: Participants (57 %) indicated that human tissue research on the living and deceased is ethically different; hence, requires separate policy guidelines and regulations. There was a clear preference for 'broad consent' and 'fully informed consent' when conducting research on living humans and using cadaveric tissue, respectively. Key ethical challenges and policy gaps were identified as contemporary human tissue research, commercialising human tissue, consent for foetal tissue, and using unconsented skeletal collections and unidentified bodies for human tissue research.
Conclusions: This study highlights the moral complexity of contemporary human tissue research. It underscores the necessity for context-specific consent models and regulatory alignment for commercialisation and contemporary research uses of human tissue. Additionally, recommendations are provided to fill the policy gaps highlighted on consent models and ethical challenges in human tissue research.

1. Introduction

Although human tissue research and ethics encompass diverse conceptual spheres, they are complementary and essential to bioethical questions regarding human life in research and clinical practice. Human tissue research has evolved to a multi-faceted contemporary approach encompassing three-dimensional (3-D) printing, genetic research, digital imaging of human tissue, plastination, and the public display of human tissue (Halkoaho et al., 2012). This evolution raises ethical concerns regarding the acquisition, storage, and use of human tissue, particularly concerning informed consent. As a result, ethics plays a fundamental role in studying human tissue. Previous studies have investigated appropriate consent models related to the ethics of living and cadaveric tissue research (Ballantyne et al., 2020; Ciliberti et al., 2021; Furness, 2003; Grady et al., 2015; Knoppers, 2005; Meiring et al., 2024; Wendler, 2013). These studies highlighted a significant shortfall in legislation, regulations, and policy guidelines for cadaveric tissue research as compared to research on living human tissue (Aaron et al., 2021; Bach, 2016; Champney, 2011; Gefenas et al., 2011). Bach (2016) alluded to the higher level of risk in research on living human tissue than cadaveric tissue. It was suggested that more regulations and policy guidelines should be implemented on the ethics of research on cadaveric tissue, considering the ever-advancing field of anatomy and the broad spectrum of what research on cadaveric tissue now encompasses (Bach,

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2016; Champney, 2011; Ciliberti et al., 2021).

Several types of consent are used to acquire human tissue for present and future research, viz, broad, specific, fully informed, blanket consent, and re-consent. "Broad consent" allows individuals to donate their tissue or body for an unspecified timeframe for future research, subject to a few consent and/or process restrictions. "Blanket consent," on the other hand, allows individuals to donate their tissues or bodies without any limits. Conversely, "specific, fully informed consent" refers to individuals who agree to a clearly defined study based on a clear understanding of the study's purpose, risks, and benefits. "Re-consent" requires the renewal of consent from a research participant for future studies or when significant changes occur during the study (Grady et al., 2015). The variation in consent models has created uncertainty about what research is permitted, inadvertently limiting future research and sometimes resulting in research proceeding without consent (Wendler, 2013). Several studies obtained opinions and perspectives from researchers, patients, potential body donors, and ethics committee members on the most suitable consent models for living and cadaveric tissue research (Ballantyne et al., 2020; Grady et al., 2015; Masiye et al., 2023; Moodley et al., 2014; Wendler, 2013).

Conflicting views regarding consent models for research on cadaveric human tissue have been documented (Grady et al., 2015; Masiye et al., 2023; Wendler, 2013). Some stakeholders argued that Body Donation forms should include informed "blanket" consent for research conducted on body donors, as future anatomical research is unpredictable, and any restrictions placed on cadaveric tissue would limit and eventually terminate research altogether (Knoppers, 2005; Masiye et al., 2023; Wendler, 2013). Masiye et al., 2023 added that when an individual donates their body to 'science,' it is done to 'science' as a whole. However, some stakeholders were more inclined towards a more "specific" consent approach, where Body Donation forms should explicitly allow donors to choose how they would or would not like their tissue to be used to ensure that future research is conducted according to the wishes of the donor (Ciliberti et al., 2021; Moodley et al., 2014).

However, policy guidelines and human tissue legislation do not mention the most appropriate consent models recommended by regulatory ethics bodies for research on living and cadaveric tissue. To address these issues, scholars have suggested further study to provide evidence for policymakers to develop policy guidelines and make informed decisions on acceptable consent models in biomedical research (Comer, 2022). Therefore, this qualitative study explored the perspectives of anatomists and researchers from five countries on appropriate informed consent models, the ethical challenges surrounding human tissue research, and the gaps in existing policy guidelines to assist in developing guidelines towards an ethical framework for cadaveric tissue research in South Africa.

2. Methods

2.1. Study design

This study explored stakeholder perspectives on ethical aspects of human tissue research and current and preferred consent models. In this study, stakeholders were defined as anatomists and researchers involved in the study, teaching and research of the human body and its associated tissues. A qualitative, exploratory design was used, incorporating deductive and inductive approaches to produce data from research participants. This enabled the researcher to derive in-depth information concerning the ethics of human tissue research from study participants. This study was guided by a constructivist research paradigm, which suggests that reality is socially constructed through individual experiences, interpretations and perspectives. This approach allowed the researcher to explore the subjective meanings that participants attach to their experiences and perspectives, rather than testing a pre-defined hypothesis (Kelly and Bunniss, 2010). Participants were interviewed, and their views, observations, and experiences were critically analysed to understand a phenomenon, common points of view, and emerging themes from the perspective of those experiencing it, so that ethical guidelines for research on human tissue can be formulated (Azungah, 2018). While the broad research questions and objectives were set (deductive), the analysis allowed new themes and patterns to emerge from the data (inductive).

2.2. Ethics statement

Ethical approval was obtained for this study from the Biomedical Research Ethics Committee before data collection (BREC/00005587/2023). Informed consent was obtained from all the interviewees.

2.3. Data collection methods

Semi-structured interviews with international and national anatomists and researchers were conducted to obtain their perspectives on the ethical aspects and their preferred consent model surrounding human tissue research. These interviews were conducted online in English and recorded via Zoom to produce data; each interview took approximately 20 min. The interview question guide (Appendix 1) was created by examining existing literature on the subject and identifying essential themes and concepts from the literature, consisting of open-ended questions, which allowed the principal investigator to add follow-up questions (Karatsareas, 2022). This data collection method was employed due to the flexibility of the approach, since semi-structured interviews can bring to light current information, new topics, or new dimensions to established knowledge (Karatsareas, 2022). Before administering the questionnaire to participants, a pilot test was conducted with a small sample of anatomists from the author's affiliated university to increase the reliability and validity of the results.

2.4. Recruitment and enrolment of participants

A purposive sampling method was used to recruit participants, targeting key stakeholders to gain expert insights into human tissue research (Omid et al., 2024). Given differences in national policy guidelines, stakeholders included anatomists and researchers from various countries. Heads of the Anatomical Society of Southern Africa (ASSA) and the International Federation of Associations of Anatomists (IFAA) were contacted for gatekeeper permission to interview members. ASSA was selected for its inclusion of South African university anatomists, while IFAA was chosen for its global reach. Upon receiving permission and participant lists, the principal investigator emailed potential participants an invitation, the participant information sheet (Appendix 2), and the informed consent form (Appendix 2), requesting a signed response from those willing to participate in the study.

Of eighty-seven (87) individuals invited, thirty (30) agreed to participate in Zoom interviews, which were audio recorded for analysis. Before the interviews, personal data such as name, institutional affiliation, and job title were recorded but anonymised in reporting. The 30 participants included twenty (20) from South Africa, four (4) from the USA, three (3) from New Zealand, two (2) from Germany, and one (1)

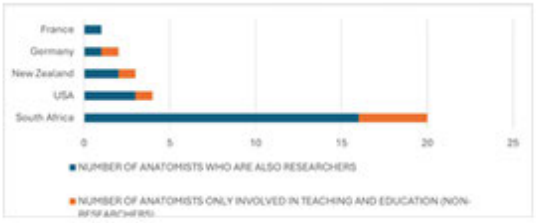

Fig. 1. Category of Stakeholders recruited by country.

from France (Fig. 1).

Additionally, a prevalence of anatomists who were also researchers ($^{23}/_{30}$, 77 %) in various research fields such as imaging and radiology, human tissue ethics, biological and forensic anthropology, cell biology, gross anatomy and neuroanatomy was noted.

2.5. Data analysis

All interview recordings were transcribed using NVivo and coded according to participant type and country, reflecting the study's three components, e.g., SA_ANAT_01 for a South African anatomist, USA_A-NATRES_01 for a U.S. anatomist-researcher.

The authors repeatedly engaged with the data to identify, analyse and report patterns using a step-by-step approach, which allowed refinement of findings and ensured that conclusions were sound. Hence, data analysis was ongoing, using thematic analysis (Naeem et al., 2023). The iterative process involved the following steps: (1) Familiarisation of the data by reviewing transcribed interview recordings; (2) Building a coding frame by developing a system of codes to apply to the data; (3) Defining and grouping codes to create broader categories. This step involved going back to the data to determine how well the codes fit and adjusting as needed; (4) Identifying patterns and emergent themes by further examining each code group; (5) Selecting quotes from the interviews that supported the identified themes; and (6) Reviewing themes by comparing them to existing literature. This contributed to the transferability of the data collected and allowed for the extrapolation of the research findings to other similar settings (Kekeya, 2016). A co-coder was used, and themes were identified independently and then compared and agreed upon. Member verification was also conducted to ensure that the collected data was a true reflection of the participants' statements on human tissue research ethics practice. Rigour was maintained through a clear audit trail, and the final interviews reached data saturation.

3. Results and discussion

The hierarchical coding frame of the analysed data led to the creation of the following overarching themes, which formed the results and findings of this study (Fig. 2). The findings are presented and discussed according to the final three themes deduced from the overall analysis of the data: *(i) Research on Living vs Cadaveric Tissue: how different or similar are they? (ii) Consent Model Preferences: Living and Cadaveric Tissue, and (iii) Ethical Challenges and Gaps in Human Tissue Research.*

3.1. Research on living vs cadaveric tissue: how different or similar are they?

Seventeen participants ($^{17}/_{30}$) indicated that research on living and cadaveric tissue differs significantly, with distinct consent and levels of risk; therefore, they require separate policy guidelines and regulations.

> *"…They are almost two different subjects. They are, of course, separated by death, yes. Moreover, death is viewed differently from life. The most substantial similarity is that both are tissues, and then everything changes…like you know, with deceased human tissue, consent is already acquired, most often voluntarily, whereas with living human tissue, you have to acquire consent from the Department of Health, from hospitals or sometimes from patients directly for radiographs". (SA_ANATRES_03)*

They also stated that the process of recruiting and maintaining living participants for research and the acquisition of consent is time-

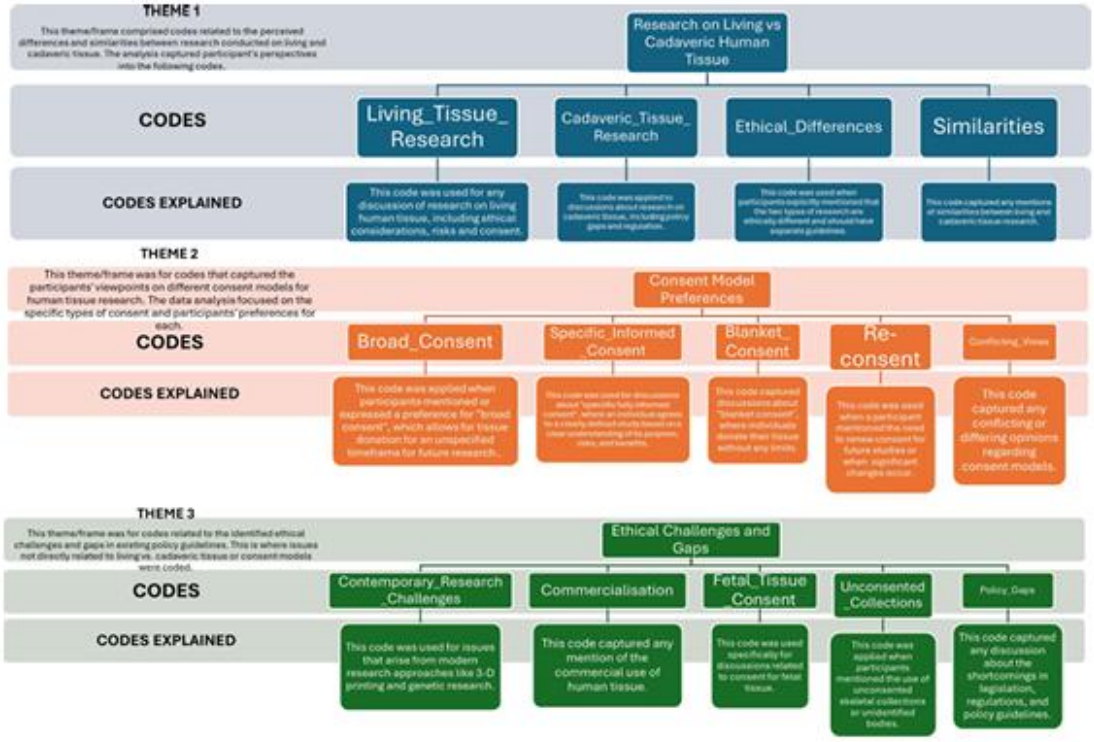

Fig. 2. Hierarchal coding frame from the analysed data.

consuming and complicated compared to research on the deceased. Participants also advocated that both divides should be clear and regulated using separate legislation and policy guidelines. This aligns with Knoppers (2005), who mentioned that when using tissue samples removed during routine medical care for research in university hospitals in Canada, general consent is usually signed upon hospital admission, and participants have the right to withdraw from participating in such research whenever they choose to (Knoppers, 2005). As stated by Thasler et al. (2002), living participants can advocate for themselves, whereas the deceased cannot; hence, it is easier to access and utilise tissue from the deceased for a broad range of research than from the living (Thasler et al., 2002). Consequently, more barriers for access exist for research on the living compared to research on the deceased.

Participants mentioned that the level of risk is significantly higher for research on the living, especially research on vulnerable groups and children, compared to research on the deceased. This view supported the Belmont Report, which highlights possible harms, viz., risks of psychological harm, physical harm, legal harm, social harm, and economic harm, and the corresponding benefits of executing a research study that is ethically sound and just (Nagai et al., 2022). Further, it also supports Matisonn and Muade (2023) who emphasised moral status (or human dignity), which uses Metz's and Chemhuru's moral theories to highlight that dead human bodies lack moral status because they do not have goal-directed behaviour or cannot be made better or worse off, as in research on the living (Matisonn and Muade, 2023).

Thirteen participants ($^{13}/_{30}$) mentioned more similarities than differences between human tissue research on the living and deceased. They described a continuum from the living human to the deceased human, stating that cadaveric tissue should not be treated as an 'object' after death but should be offered the same dignity and respect, be treated in the same manner, and be regulated with equal protection.

> *"…So, I think that there are not as many differences as other people do. I talk about a continuum from the living human to the deceased. So, both should be given the same considerations, the same respect…maybe they're different in a legal context, but when you say ethically…yes, ethically they are the same." (USA_ANATRES_02)*

This view contrasts with the Metz and Chemhuru theories but aligns with Jones (2007), who asserts that a cadaver possesses both intrinsic and influential values (Jones, 2007). He argues that "the intrinsic value of a living person is conferred upon his/her cadaver at death and when a person and his/her body are inseparable." As a result, how the living behave affects how they treat the dead and contributes to the idea that a corpse deserves respect and "decent" care, as reflected in Jones (2007) words "To desecrate a corpse is … to desecrate a person".

3.2. Consent MOdel preferences: living and cadaveric tissue

3.2.1. Consent model preferences for living human tissue

Half of the study participants ($^{15}/_{30}$) preferred 'broad consent' to specific informed consent for research on living human tissue/biological specimens (Fig. 3).

Advocating for broad consent, its practicality from a researcher's perspective was emphasised.

> *"…I would say broad consent is more appropriate and suitable from the point of a researcher, especially…it's expensive you know to use tissue for a specific study and then to destroy it afterward and it's also time-consuming…so broad consent works because it allows you to do future research without wastage and getting consent again". (SA_ANATRES_01)*

The main reasons for broad consent were that it is not feasible to collect tissue specimens using specific consent continually, as this would also mean destroying leftover tissue samples after a particular study, wasting precious biological tissue. Most participants favoured this consent model since it allows for the reuse of samples within the scope of the original permission, offering flexibility and efficiency.

The Common Rule is a US Policy for the Protection of Human Subjects that was initially introduced in 1979 and offers a modern ethical and regulatory framework for research involving human subjects and is based on the three ethical principles of the Belmont Report: beneficence, justice, and respect for persons to protect research participants (Aaron et al., 2021). Supporting the finding in this study, the 2018 amendment to the Common Rule (effective) in January 2019 introduced broad consent as a legal option. It states that broad consent can only be used to get study participants' permission to store, maintain, and use identifiable biological samples or private information for secondary research (Masiye et al., 2023). Broad consent is considered ethical and optimal since it eliminates the potential strain on researchers of requesting participants to decide for every new study, and gives them control over whether their samples are used for research (Grady et al., 2015; Wendler, 2013). However, Gefenas (2011) and Wendler (2013) argued that broad consent should contain a requirement that mentions that future research can only be performed if an independent body determines that the proposed study is morally acceptable and presents no more than minimal risk (Wendler, 2013; Gefenas et al., 2011).

In contrast, some participants ($^{10}/_{30}$) preferred specific informed consent to broad consent, stating that individuals would not fully understand the nature of future studies at the time of providing consent, and it is not easy to know what types of research may develop in the future and whether individuals would have consented to such a study. This consent model also ensured that researchers do not misuse biological samples in future studies and offered more protection and respect for participants.

> *"…it is not ethical for participants to consent to a broad range of research when it is uncertain what type of research the future holds, and it may not*

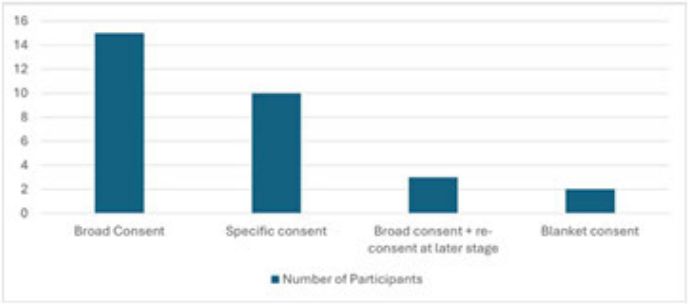

Fig. 3. Participants' Consent Model Preferences for Research on Living Human Tissue.

be something that the participant would consent to…so I would say in terms of ethics-specific consent is the most ethical and ensures protection of the participant." (FR_ANATRES_01)

This preference aligns with a survey by Tosoni (2022), where most patients favoured being informed, educated, and given a choice about potential research uses, favouring a specific informed consent approach prioritising clarity and transparency. However, Tosoni (2022) mentions that this model has limitations, such as difficulty in tracking participants, resulting in the disposal and wastage of tissue specimens, which limits opportunities for valuable future human tissue research (Tosoni et al., 2022).

A small cohort of participants ($^{3}/_{30}$) favoured a broad consent approach with the option to acquire proxy or re-consent at a later stage from the individual when the use of the tissue changes with advances in human tissue research. They mentioned that this could prevent destroying human tissue once a specific research project is completed, allowing the participant to be protected and respecting their wishes.

"…And so, one of them that I'll mention is proxy consent or re-consent. And that being, allowing for the need to provide further consent when we believe that the request falls so far outside of the original consent that we don't feel comfortable, or a participant may not feel comfortable, right? We can go to the individual or the proxy for re-consent…this protects and respects them and biospecimens won't go to waste, right?" (USA_ANAT_01)

Resnik (2009) states that broad consent with re-consent may be suitable when the original consent was invalid or there has been a significant change to the research or the participant's condition since the original consent; however, a more appropriate approach is hypothesised to be reaffirmation. This approach is suitable when substantial time has passed, such that participants may have changed their minds about participation and does not require participants to sign a new consent document (Resnik, 2009).

Only two participants ($^{2}/_{30}$) preferred blanket consent, citing that it allowed human tissue samples to be used in any research without limitations. They mentioned that once individuals donate human tissue samples to science, they give up their rights to the samples. Hence, the specimens can be used in future research without any restrictions. As one participant expressed:

"…When someone donates their body or tissue samples to science, they donate them to different types of research in science as a whole…Hence, I feel consent should be taken from the donor as an umbrella or blanket consent for all types of human tissue research. It shouldn't be restricted or limited in any way…the more we limit this, eventually research will cease to exist." (SA_ANAT_04)

In contrast with this view, Masiye et al. (2023) argue that blanket consent is not informed consent at all since participants are not fully informed about the type of future use of biological samples, and it is considered unethical as participants cannot agree to something they do not know (Masiye et al., 2023).

3.2.2. Consent model preferences for cadaveric tissue

Most participants ($^{17}/_{30}$) favoured a specific fully informed consent approach for research on cadaveric tissue. They stated that body donation forms should be as detailed as possible and allow donors to select the types of research they would permit their body and tissues to be used for and the types of research they would not be in favour of. (Fig. 4)

The reasons provided by participants were that the donor has the right to be fully aware and informed about how their body and tissues will be used for research and has the right to stipulate what they will permit and what they will not. Participants mentioned that consent forms should inform participants that the type of research uses will change and whether they consent to this.

"…So I'm in favour of a more detailed consent where the individual who's going to donate would have a check box that could say yes you could do this and no you can't do that you know and mention the different research uses and allow them to choose…because they may sign off, they may consent, but do we really know that a future research use is something that they would have been comfortable with? Would they have approved of this?" (USA_ANATRES_02)

Conversely, some participants ($^{11}/_{30}$) favoured simpler consent forms asking the donor whether they consent or not for their body and tissues to be used for research in general, with no detailed checkboxes restricting research in any way. One of the reasons stated for this was that when donors consent to donate their bodies for human tissue research, the consent includes all types of research; otherwise, the purpose of the study is defeated. Another participant mentioned that consent forms are a historical document, and it is impossible to predict how anatomy and research will advance; hence, blanket consent should apply to all research on cadaveric tissue. As one participant noted:

"…But, you know, I've, always asked the question, if I donated my body previously to science. So, science is widely defined, and therefore, you know, it, it doesn't have to be an explicit specific permission, for every type of scientific research…consent should encompass and include all of that… it's all science after all." (SA_ANATRES_11)

Two participants expressed no preference for any consent model, emphasising that their choice would depend on the information provided. They would select the type of consent in which sufficient information about the study is supplied to prospective research participants.

"…researchers are required to follow research guidelines of the country in which they live…so I don't think a researcher can prefer a consent model…we just have to follow the research regulations in our country and what it says about consent." (USA_ANATRES_03)

When asked about waivers of consent, participants reported instances where institutions approved research without direct consent,

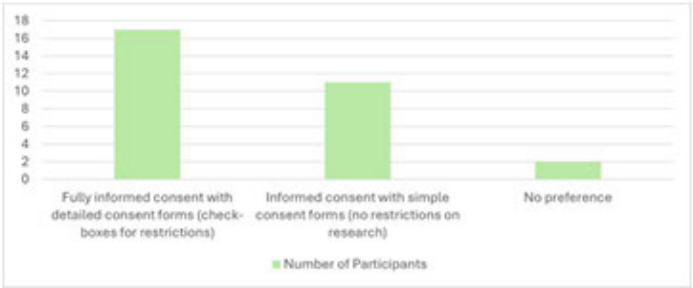

Fig. 4. Participants' Consent Preferences for Body Donors (cadaveric tissue research).

particularly in studies involving skeletal collections or cadavers. An entire bone collection was sometimes approved for multiple research projects via an institutional waiver.

> *"…So, if we find something and we want to do research in that aspect, we normally ask the collections committee of the school, because they're the holder of that waiver, and we send them a full protocol as to what we're going to do. And they will notify the ethics committee of the different projects which have fallen under the waiver." (SA_ANATRES_03)*

These findings intimately relate to South Africa, where donor consent forms are usually basic, simply asking the donor whether they consent to using their body for research. This finding is consistent with Meiring (2024), who mentions that specific and detailed research uses are not mentioned in most donor consent forms in South Africa and since informed consent is grounded on the principle of autonomy, in the absence of fully informed, detailed consent, a donor is thus deprived of their independence and, in turn, their dignity (Meiring et al., 2024).

In New Zealand, participants indicated that donor consent forms specify what type of research the donor's body and tissues will be used for, to allow donors to make a fully informed decision.

In the USA, Anatomists and researchers believe that donor consent forms are more inclined toward legalities than ethical aspects of human tissue research. This is congruent with the findings of Zealley et al. (2022), who states that although the donor consent forms in most US States differ, the recurring finding was that additional information needs to be included in donor consent forms to better inform donors and their families about the donation process, the specific types of research for which their bodies and tissues will be utilised, and the final disposal of the bodies once studies are completed. Although the donation forms indicated that a body may be used for education and/or research, only 2 % of the forms provided examples of the types of research (Zealley et al., 2022).

One participant from Germany mentioned an interesting body donor consent approach following a "3-type donor" consent approach, allowing donors to choose between being a 24-hour donor, 1-year donor, or lifetime donor. A 24-hour donor consent would allow the University to harvest as much tissue as possible in 24 h and then suture the body back together and return to the family for last rites; a 1-year donor consent allows for the use of the donor's body for 1 year only and thereafter the remains are cremated and returned to the family, and lifetime donor consent allows the unrestricted and unlimited use of the donor's body for human tissue research. This practical and ethical approach allows the donors to make informed choices about the extent and duration to which they would like their bodies to be used for research.

3.3. Ethical challenges and gaps in human tissue research

The ethical issues and gaps in human tissue research mentioned by participants are reflected in Fig. 5.

3.3.1. Lack of regulations for contemporary human tissue research

Sixteen participants ($\frac{16}{30}$) identified the main ethical gap as being the lack of regulations for contemporary human tissue research (advancements or developments in anatomical and human tissue research), such as 3-D printing of the human body, digital imaging (used for publications and teaching, plastination of specimens, genetic analyses, and the public display of specimens (museums and conference exhibitions).

> *"…Should we just be able to perform a genomic analysis on a donor when there are ramifications for relatives and cultures? Should we be able to undertake 3D printing and then move those prints internationally? Whether it be the acquisition of images, photographs, printing, plastination, genomic analyses, or international transfer, it's not an ethical right." (NZ_ANATRES_01)*

Most participants agreed that 3-D prints, digital images, and plastinated human body specimens should still be regarded as human tissue, treated with the same dignity and respect as the cadaver itself, and regulated appropriately by policy guidelines. It was repeatedly mentioned that using and circulating images in unethical ways can undermine the relationship with local communities and potential body donors. Thus, these contemporary uses of human tissue must be appropriately managed and controlled. Participants also stated that the same regulations that apply to genetic analyses on the living should also apply to the deceased individual. This view aligns with the IFAA Recommendations for the Ethical Use of Anatomical Images (Cornwall et al., 2024). One of the main recommendations mentioned by the IFAA is that the use of images should be covered by informed, specific consent of the body donor at the time of consent. Consent forms should indicate whether donors agree to these modern applications, allowing ethically sound practices to proceed with donor autonomy (Cornwall et al., 2024). This recommendation would allow the contemporary use of human tissue to proceed without any ethical consideration, as it is known that the donor consented explicitly to this use at the time of donation. Thus affirming, Jones (2019) states that retaining the humanity of anatomy is paramount and obtaining 3D-printed images from unidentified persons is unacceptable. 3-D imaging represents a move away from the human body or person. Therefore, recommendations and guidelines must be implemented to prevent the dominance of such depersonalisation in human tissue research (Jones, 2019).

However, some anatomists in this study stated that plastinated specimens are not entirely 'human biological tissue' since they are part plastic. Although they represent the human body or tissues, they are not human tissue. Proper policy guidelines must then be implemented to regulate the plastination of specimens and how these hybrid models (part human and part plastic) should be treated. This affirms Jones (2002) in that although plastinated models (Anatomy Art) are merely representations of the human body and/or tissues, they still contain a 'human' element regardless. Hence, such 'hybrid' models should be treated equally as human tissue (Bin et al., 2016).

Fig. 5. Ethical Challenges and Gaps in Human Tissue Research mentioned by Participants.

3.3.2. Use of Unconsented Skeletal Collections and Unidentified/Unclaimed Bodies in South Africa

A recurring challenge mentioned by participants was differentiating between the legality and ethics of human tissue research encompassing the use of unconsented historical specimens or bone collections ($\frac{13}{30}$), as well as unidentified/unclaimed bodies ($\frac{12}{30}$). Only participants from South Africa identified this as a challenge to research in their country since the use of unidentified bodies is still permitted and utilised in certain Universities in the country. Participants from the USA, Germany, New Zealand, and France mentioned using unidentified bodies as a general concern for human tissue research, but not specifically in their countries, since most universities only utilise bodies from Body Donation Programmes for research. To fully understand this ethical challenge, it is essential to realise that Human skeletal collections were used in South Africa for medical education and research as early as 1919 due to the introduction of Departments of Anatomy in various universities. Once gross anatomy dissection was completed, the bodies were further macerated and processed into skeletons, then catalogued into the Raymond A. Dart Skeletal Collection, which now contains approximately 2022 individuals, of whom the majority are Black South African males (Dayal et al., 2009). The ethical dilemma, however, arises concerning what should be done presently about these legacy skeletal collections and unclaimed bodies for which consent is unknown. Should these collections and bodies be reviewed to understand their origin, should they be returned, or should they be disposed of? This ethical dilemma must be balanced with the reality that if the origin of these skeletal collections or unclaimed bodies is not determined or investigated, these individuals or collections could remain in storage indefinitely or be destroyed (L'Abbé et al. 2021).

Although the use of such human tissue is regarded as legal in terms of legislation and regulations in SA, some participants in this study deem their use as unethical and state that it does not respect the integrity and autonomy of the deceased individuals to whom they belonged, since no consent has been knowingly obtained for such human tissue specimens or bodies. Therefore, they suggest that such historical tissue should be legally prohibited from being used for research and disposed of.

> *"…I think about those institutions that use unclaimed bodies or use unidentified bodies. Well, those individuals obviously never consented. And if they're used in teaching or research or any sort of process, they're being used against their consent, right? And therefore, my view is we shouldn't even be using unclaimed or unidentified bodies. Legal prohibitions should be made against its use" (SA_ANATRES_03)*

This finding is consistent with other studies in South Africa, which state that due to ethical concerns, some medical schools in the country are no longer utilising unclaimed persons for research and education and mentions that no clarity has been provided within the research community in South Africa as to how to address the ethics of unclaimed bodies and skeletal collections that are currently being used for education and research (Baliso et al., 2025; Gibbon et al., 2024; L'Abbé et al. 2021; Meiring et al., 2024). From a global perspective, Jones, Whitaker (2012) also mention that using unidentified bodies for research has created an ethical issue regarding using historical or unidentified image data for public exhibitions worldwide (Jones, Whitaker, 2012). The IFAA suggests that in the case of unidentified or historical image data, an indication of the consent status of the person (unknown, unconsented, or consented) should be provided together with the image upon display or publication; however, where possible, images from historical collections and unidentified persons should be replaced with images from consented persons (Cornwall et al., 2024).

In contrast, a few anatomists from South Africa in the field of biological anthropology argued that if the use of unidentified bodies for human tissue research is deemed unethical and if laws are implemented to prohibit its use, then the study of biological anthropology of the population of South Africa will not be inclusive of all racial groups within the South African population.

> *"…So, I think that racial categorisation is the main issue for human tissue research in SA. We're so focused on ethics sometimes that we cannot help the racial groups that need help. Body donors are majority of white race group here and we cannot study the anthropology of other races because of the ethics of using unclaimed bodies…we need to understand that we are not comparing people or races we are comparing traits." (SA_ANAT_02)*

These anatomists stated that, presently, almost all donated bodies at their institutions belong to the White population group, and the balance of the bodies are from unidentified persons. Although Awareness Campaigns exist to promote body donation among other racial groups in South Africa, body donors from the different population groups in South Africa are still limited. Thus, they added that it is essential to understand that anthropological research is not a "race science" and that comparisons are not being drawn between people and races; it is rather a comparison of traits and human variation. This opinion starkly contrasts with much of the available literature on South Africa (Chia and Oyeniran, 2020; Gibbon et al., 2023; Habicht et al., 2018; Kramer, 2024; Walters, Jonathan, 2022). The dominant view emerging from all these studies, as mentioned precisely by Walters, Jonathan (2022), is that unidentified bodies belong to individuals who may have died in public places and who are from impoverished communities. Their class, race, and health statuses are a result of systemic discrimination imposed on them during apartheid. Hence, the continued use of these bodies is unethical, and anthropological research should proceed through the proper channels of body donation and public awareness rather than relying on unidentified bodies (Walters, Jonathan, 2022).

Anatomists ($\frac{5}{30}$) also stated that although these historical specimens may not have been consented to, they should not be discarded, as this would be a waste of precious human tissue. Baliso et al. (2025) agree that, instead, its origin should be conceptualised and used as a lesson for the future acquisition of consent for skeletal collections and body donors to maintain ethical integrity while enhancing these individuals' research value (Baliso et al., 2025). They argued that although consent may not have been obtained for these specimens, the individuals to whom they belonged have also not consented to how they wish their remains to be disposed of. Hence, the conventional means of disposing of their human remains would also be deemed unethical.

> *"…So, again, the problem for me is the fact that our collections are old, the…bone collection is old and not consented for use, but does that mean we should discard it completely? We cannot discard it but rather learn from it for future collections…we cannot simply destroy historical data because we feel it has been obtained unethically." (SA_ANATRES_01)*

3.3.3. Discrepancies between the NHA and NHRA in South Africa

Another issue raised by participants from South Africa ($\frac{7}{30}$) is that discrepancies exist on policy guidelines between the National Health Act, which regulates human tissue research in general, and the National Heritage Resources Act, which governs research on archaeological remains, in South Africa.

> *"…So, there's tension between the Heritage Resources Act and the National Health Act, in terms of who it belongs to, you know? So, under the Heritage Act, human body tissue is considered artefacts or objects, not people and persons. Whereas in the National Health Act, they are seen as people and persons, and not objects. So, there's a discordance in that area." (SA_ANATRES_04)*

Congruent with L'Abbé et al. (2021), participants in this study mentioned that the NHA was vague and does not include sufficient information on cadaveric material, while the NHRA does not state who the legal authority is to consent to using skeletal remains for research (L'Abbé et al. 2021). Stakeholders in this study also mentioned an inconsistency between the two Acts, whereby the NHA refers to human tissue as 'people/persons' while the NHRA refers to human tissue or

skeletal remains as 'artefacts/objects. Some participants argued that skeletal remains used in legacy bone collections for research should not be referred to as 'artefacts/objects' as they once belonged to a human being and are, hence, derivatives of human tissue. They agreed that these Acts should correlate, and guidelines should refer to heritage resources and material as 'human tissue'.

On the other hand, other participants believed that skeletal remains are no longer human tissue, and it is appropriate to refer to them as 'objects/artefacts. This discrepancy and argument can be solved using Stutz's (2023) model of liminality for human remains, where human remains are seen as moving on a continuum between being objects of science and lived lives. This model is proposed to capture the range of how human heritage remains are perceived, classified, and handled, on one end of the spectrum, from the view of the remains as being a relative or an ancestor, to the other end of the spectrum, which is a view represented by science, as objects to be studied (Nilsson Stutz, 2023). The flexibility of this liminal positioning of the classification of human remains aids in better understanding how human remains should be treated during research and consent requirements (Nilsson Stutz, 2023).

3.3.4. Commercialisation of human tissue

Another gap in human tissue research included the need for proper regulations controlling the commercialisation of human tissue ($^{6}/_{30}$), including body brokering and the trade of human tissue.

> *"…So here in the United States, the gap is, mostly in the legal realm, where, basically, there are no prohibitions against trade with dead human tissues. There are body brokering companies handling body donations, but they really are for-profit organisations…So we need a law specifically addressing the prohibition of for-profit marketing of dead human bodies, which essentially prey on the indigent." (USA_ANATRES_01)*

Although participants from varying countries in the study identified the commercialisation of human tissue as a concern to human tissue research ethics, participants from the USA specifically regarded using human tissue for profit as a key gap in human tissue policy guidelines. They mentioned that there are no prohibitions on the use of cadaveric tissue for trade, and, in some instances, there are body brokering companies dealing with body donations, but they are for-profit organisations. This finding is consistent with Champney et al. (2019), who state that these companies advertise for donors, pay for cremation and other fees for the donor, distribute the bodies or body parts nationally and internationally, and charge their users for access to the body or body parts to generate profits (Champney et al. 2019). Some anatomists and researchers also mentioned that, in some instances, the public display of human tissue specimens in exhibitions and anatomy conferences is also considered a form of commercialisation and commodification of human tissue. Hence, such issues need to be appropriately regulated in ethical policy guidelines. Considering this perspective, IFAA Recommendations for the Ethical Use of Anatomical Images and IFAA Recommendations for Good Practice for the Donation and Study of Human Bodies and Tissue for Anatomical Examination (https://ifaa.net/committees/ethics-and-medical-humanities-ficem/recommendations-for-good-practice-around-human-tissue-image-acquisition-and-use-in-anatomy-education-and-research/) state that human tissue images should not be commodified or yield monetary gain, meaning they should not be bought, sold, or traded for profit (Cornwall et al. 2024; IFAA, 2012). This finding is also congruent with Bin (2016), who mentions that when donors consent to donate their bodies and tissues, they do so for the better good and the primary purpose of advancing research and science. The public display of bodies, tissues, and plastinated specimens in exhibitions, museums, and conferences should never be done for merchandising or entertainment or even seeking recognition, but purely for research and education (Bin et al. 2016).

3.3.5. Consent for foetal tissue

A minority of participants ($^{2}/_{30}$) expressed concern for research on foetal tissue, specifically consent surrounding foetal tissue research.

> *"…The foetal specimens are a bit older. So, I don't think there was necessarily a tick box to say, I consent…I think the biggest ethical issue that you can probably talk up, sort of for hours upon hours, is the use of and consent for foetal samples, either embalmed or fresh, and partly because of how they are perceived by hospitals." (SA_ANATRES_01)*

Anatomists in this study stated that it is difficult to determine whether consent was provided by parents or mothers for the use of foetal tissue for research, especially since the termination of pregnancy consent and body donor consent forms do not stipulate or provide for this research use. To address this issue Barker et al. (2022) suggested that consent for termination of pregnancy should be separated from consent for the potential use of foetal material so that the donating woman can understand that the termination and possible research use of the foetal tissue are separate voluntary consents and that the consent can be withdrawn at any time up to the point of tissue collection. He also suggested that the woman be fully informed about the potential research uses of the foetal tissue, research funding, potential benefits, whether the research is approved, additional tests that may occur before the donation to determine any infections, and the implications of these tests. She should then be allowed to ask questions or raise concerns (Barker et al. 2022).

4. Key findings and recommendations

This study revealed essential insights from anatomists and researchers across multiple countries regarding the ethical dimensions and policy needs in human tissue research:

1) Ethical Considerations: Most study participants indicated that human tissue research on the living and deceased is ethically vastly different, as they are entirely different subjects and hence require separate policy guidelines and regulations.
2) Broad Consent Choice: Most anatomists and researchers preferred 'broad consent' for research on living human tissue because of its flexibility and practicality
3) Body Donor Forms: Detailed body donation consent forms, thus allowing potential donors to select the types of research they would permit their body and tissues to be used for and the kinds of research they would not consent to. This would enhance autonomy.
4) Regulation: Updating policy guidelines to regulate and control contemporary human tissue research uses, such as 3-D printing, digital imaging, and public display of specimens. Guidelines should also include recommendations on how to deal with 'hybrid models' or plastinated specimens.
5) Legacy Collections: As consent is unknown, most anatomists and researchers deem it unethical to research skeletal collections and unidentified bodies. The provenance of legacy collections needs to be investigated before continued use, and the use of unidentified bodies should be legally prohibited from being used for human tissue research.
6) Legal inconsistencies: Discrepancies between the National Health Act and the National Heritage Resources Act regarding the referral of human heritage remains and tissue as 'people/persons' and 'artefacts/objects' need to be addressed.
7) Prohibit Commercialisation: Further recommendations should be implemented to prohibit using human tissue for commercialisation, trade/body brokering, and public display of human specimens for profit.
8) Fetal tissue consent: Consent acquired for termination of pregnancy should be separated from consent for the potential use of foetal material so that the donating woman can understand that the termination and research use of the foetal tissue are separate consents.

9) Uniform framework: There must be consistency and uniformity in policy guidelines and legislation among all institutions and universities in South Africa conducting human tissue research.

5. Conclusion

The findings of this study provide some evidence to verify policies on consent and lead to the development of new policy guidelines and recommendations. Additionally, they inform current discussions on appropriate consent models to be used for the future use of biological samples. A balance between conducting research and treating living and cadaveric tissue ethically is emphasised, requiring clear policy guidelines, community engagement, and adherence to ethical, legal, and cultural concerns. Further, it is evident that the ethical challenges posed by consent, autonomy, ethical use of human tissue, and respectful treatment of the living and the deceased require constant consideration. Hence, a clear ethical framework regulating the mentioned ethical challenges/gaps in human tissue research is needed, as cited by key stakeholders.

Author contributions

S Singh, B.Z. De Gama and P. Pillay collaborated to conceive the study. S Singh was responsible for the conceptualisation, data curation, and analysis and drafted the manuscript. P Pillay and BZ De Gama supervised, analysed, reviewed and edited the manuscript. All authors read and approved the final manuscript.

Ethics statement

Ethical approval was obtained for this study from the Biomedical Research Ethics Committee before data collection (BREC/00005587/2023). Informed consent was obtained from all the interviewees.

CRediT authorship contribution statement

S. Singh: Writing – original draft, Methodology, Formal analysis, Conceptualization. **BZ De Gama:** Supervision, Validation, Reviewing and Editing. **P Pillay:** Supervision, Validation, Reviewing and Editing.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper. and proceed

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Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.aanat.2025.152774.

Data availability

The data supporting this study's findings are available from the corresponding author upon reasonable request from bona fide researchers.

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Appendix 2: BREC Ethics Approval

UNIVERSITY OF KWAZULU-NATAL
INYUVESI YAKWAZULU-NATALI

17 September 2025

Miss Seonaid Singh (215034091)
School of Laboratories Medicine & Medical Science Westville

Dear Miss Singh,

Protocol reference number: BREC/00005587/2023
Project title: Towards the Development of an Ethical Framework related to Research on Human Tissue Degree: PhD

RECERTIFICATION APPLICATION APPROVAL NOTICE

Approved:	**26 February 2025**
Expiration of Ethical Approval:	**25 February 2026**

I wish to advise you that your application for recertification for the above study has been **noted and approved** by a subcommittee of the Biomedical Research Ethics Committee (BREC). The start and end dates of this period are indicated above.

If any modifications or adverse events occur in the project before your next scheduled review, you must submit them to BREC for review. Except in emergency situations, no change to the protocol may be implemented until you have received written BREC approval for the change.

The committee will be notified of the above approval at its next meeting to be held on 14 October 2025.

Yours sincerely

[redacted]

.....
Ms A Marimuthu
(for) Prof S Singh
Chair: Biomedical Research Ethics Committee
Biomedical Research Ethics Committee Chair: Professor S Singh

Appendix 3: Interview Question Guide for Anatomists and Researchers

****

Country: _____

Institution: _____

Occupation/job title/what your job entails: _____

1. What field of human tissue research are you currently involved in or have been involved in in the past? (Focus areas)
2. Do you conduct research/tests on the human tissue of living or deceased patients? What would you say are the ethical differences between the two?
3. What is the ethical process/steps involved when you conduct research/tests on human tissue?
4. What are the main policies/laws/legislations do you follow when conducting research/tests on human tissue?
5. What is your view/opinion pertaining to consent in human tissue research? (Specifically, cadaveric, what type is most suitable?)
6. Were there any instances in your studies in which consent was not required for you to conduct testing/research on human tissue?
7. What are some of the ethical issues/challenges you may have encountered when you conducted human tissue research? (if any)
8. What, in your opinion, are the gaps that currently exist in human tissue research?
9. In your opinion, in what ways should current policies and legislation be adjusted and remodelled to alleviate the current ethical challenges encountered in human tissue research?

Appendix 4: Participant Information Sheet and Informed Consent Form

Informed Consent Form for Anatomists and Researchers

PARTICIPANT INFORMATION SHEET

TITLE OF THE RESEARCH PROJECT: Towards the Development of an Ethical Framework related to Research on Human Tissue

PRINCIPAL INVESTIGATOR: Miss Seonaid Singh

ADDRESS: University of KwaZulu-Natal
College of Health Sciences
School of Laboratory Medicine and Medical Sciences
Westville Durban
3269
South Africa

My name is Seonaid Singh, and I am a PhD student at the University of KwaZulu-Natal. I would like to invite you to participate in a research project that aims to develop an ethical framework for research on human tissue, helping stakeholders conduct research in an entirely ethical manner. This study will explore the views of HREC members, human biobanks, as well as those of anatomists and laboratory technicians, regarding the ethical issues they experience, and evaluate the regulations governing 'informed consent' in relation to human tissue research.

Please take a moment to review the information presented here, which outlines the details of this project. If you require further explanation or clarification on any aspect of the study, please do not hesitate to contact me. Additionally, your participation is entirely voluntary, and you are free to decline participation at any time. If you say no, it will not affect you negatively in any way. You are also free to withdraw from the study at any point, even if you do agree to take part.

This study has been approved by the Biomedical Research Ethics Committee (BREC/00005587/2023) and will be conducted in accordance with accepted and applicable National and International ethical guidelines and principles.

What is this research study all about?

The purpose of this component of my study is to explore the views of anatomists and researchers in Anatomy departments on the ethical issues they experience. This study will help in understanding perspectives on the ethical issues that anatomists typically identify in their research activities. Your participation involves taking part in a semi-structured interview. You will be asked some open-ended questions, which will help us explore these ethical issues. The questions are not personal or sensitive in any way, but you are free not to answer any specific question. Participants' details will be anonymised in all reports and publications.

Why have you been invited to participate?

You have been invited to participate because, as an anatomist who is familiar with human tissue research and the ethical research process, we would like to explore your views on human tissue

research and the ethical issues typically encountered. Your comments will help us in correlating findings with national research ethics guidelines.

What will your responsibilities be?

Your responsibilities will be to provide your opinions and responses to some open-ended questions asked during an interview.

Will you benefit from taking part in this research?

There are no direct benefits that you will receive from participation in this study. However, your participation in the study has the potential to contribute to scientific knowledge to the research being conducted.

Are there in risks involved in your taking part in this research?

Presently, there are no foreseeable risks in your participation. All data will be completely anonymised, and your name will not be recorded anywhere nor revealed in subsequent publications.

If you do not agree to take part, what alternatives do you have?

Please note that participation is voluntary and completely based on your willingness. You are not being forced to take part in this study. The choice of whether to participate or not is yours alone. If you choose not to take part, you will not be affected in any way whatsoever. If you agree to participate, you may stop participating in the research at any time. You are guaranteed that there will be no penalties or any action taken against you, and you will not be prejudiced in any way should you decide to withdraw from the study. If you choose not to take part or choose to withdraw from this study, your welfare will not be affected in any way.

BIOMEDICAL RESEARCH ETHICS ADMINISTRATION
Research Office, Westville Campus

Govan Mbeki Building

Private Bag X 54001

Durban

4000

KwaZulu-Natal, SOUTH AFRICA

Tel: 27 31 2604769 – Fax: 27 31 2604609

Email: BREC@ukzn.ac.za

If you are willing to participate in this study, please sign the attached Declaration of Consent and return it to me via email (the investigator).

Declaration by participant

By signing below, I _____agree to take part in a research study entitled **Towards the Development of an Ethical Framework related to Research on Human Tissue.**

I declare that:

- I have read the attached information leaflet, and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions, and all my questions have been adequately answered.
- I understand that taking part in this study is voluntary and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.
- I may be asked to leave the study before it has finished, if the researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

Signed at (place) .....…..……... On (date) ……...……. 2024.

Signature of participant

_____

CONSENT FOR RECORDING
I hereby agree to the audio-recording of my participation in the study.

……..

Signature of participant

Date…….

In the event of any problems or concerns/questions, you may contact the researcher at mobile number [redacted] or e-mail [redacted]; the Supervisor for the study, Dr Pamela Pillay, at e-mail soobramoneypa@ukzn.ac.za, or the UKZN Biomedical Research Ethics Committee, contact details as follows:

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4000

KwaZulu-Natal, SOUTH AFRICA

Tel: 27 31 2604769 – Fax: 27 31 2604609

Email: BREC@ukzn.ac.za

Chapter 3

Appendix 1: Manuscript Submission

Dear Mrs. Moonega:

Your manuscript entitled "Exploring Human Tissue Research Ethics in South Africa: A Qualitative Study of Research Ethics Committee and Human Biobank Perspectives" has been successfully submitted online and is presently being given full consideration for publication in Research Ethics.

Your manuscript ID is RE-25-0167.

Please mention the above manuscript ID in all future correspondence or when calling the office for questions. If there are any changes in your street address or e-mail address, please log in to ScholarOne Manuscripts at https://mc.manuscriptcentral.com/rea and edit your user information as appropriate.

You can also view the status of your manuscript at any time by checking your Author Center after logging in to https://mc.manuscriptcentral.com/rea.

As part of our commitment to ensuring an ethical, transparent and fair peer review process Sage is a supporting member of ORCID, the Open Researcher and Contributor ID (https://orcid.org/). We encourage all authors and co-authors to use ORCID iDs during the peer review process. If you already have an ORCID iD you can link this to your account in ScholarOne just by logging in and editing your account information. If you do not already have an ORCID iD you may login to your ScholarOne account to create your unique identifier and automatically add it to your profile.

Thank you for submitting your manuscript to Research Ethics.

Sincerely,
Research Ethics Editorial Office

Appendix 2: HREC Gatekeeper Permissions

UNIVERSITY OF KWAZULU-NATAL
INYUVESI YAKWAZULU-NATALI

19 February 2024

Seonaid Singh (SN 215034091)
School of Laboratory Medicine and Medical Sciences
College of Health Sciences
Westville Campus UKZN
Email: 215034091@stu.ukzn.ac.za soobramoneypa@ukzn.ac.za

Dear Seonaid

RE: PERMISSION TO CONDUCT RESEARCH

Gatekeeper's permission is hereby granted for you to conduct research at the University of KwaZulu-Natal (UKZN), towards your postgraduate degree, provided Ethical clearance has been obtained. We note the title of your research project is:

"Towards the Development of an Ethical Framework related to Research on Human Tissue."

It is noted that you will be constituting your sample by conducting interviews with department of Laboratory Medicine and Medical Science's anatomists and laboratory technicians (Zoom, Skype or telephone interviews recommended) at UKZN.

Please ensure that the following appears on your notice/questionnaire:

- Ethical clearance number;
- Research title and details of the research, the researcher and the supervisor;
- Consent form is attached to the notice/questionnaire and to be signed by user before he/she fills in questionnaire;
- gatekeepers approval by the Registrar.

You are not authorized to contact staff and students using the 'Microsoft Outlook' address book. Identity numbers and email addresses of individuals are not a matter of public record and are protected according to Section 14 of the South African Constitution, as well as the Protection of Public Information Act. For the release of such information over to yourself for research purposes, the University of KwaZulu-Natal will need express consent from the relevant data subjects. Data collected must be treated with due confidentiality and anonymity.

Yours sincerely

[redacted]

MR MA TUFTS
Director Governance & Administration

29 October 2024

Ms Seonaid Singh
University of UKZN

Dear Ms Singh

PERMISSION TO CONDUCT RESEARCH AT THE UNIVERSITY OF JOHANNESBURG

We are pleased to inform you that permission has been granted to conduct the study **Towards the Development of an Ethical Framework related to Research on Human Tissue** at the University of Johannesburg (UJ). This approval is contingent upon adherence to all ethical guidelines and university regulations.

Please note that this permission does not obligate UJ students and/or staff to participate in the study. As the principal investigator and applicant, you are responsible for engaging with potential participants and obtaining their informed consent before involving them in the research.

We wish you success in your research.

Prof Thea de Wet
[redacted] (WhatsApp only) On behalf of the UJ Registrar

Appendix 3: Participant Information Sheet and Informed Consent Form

Informed Consent Form for Human Biobanks

PARTICIPANT INFORMATION SHEET

TITLE OF THE RESEARCH PROJECT: Towards the Development of an Ethical Framework related to Research on Human Tissue

PRINCIPAL INVESTIGATOR: Miss Seonaid Singh

ADDRESS: University of KwaZulu-Natal
College of Health Sciences
School of Laboratory Medicine and Medical Sciences
Westville Durban
3269
South Africa

My name is Seonaid Singh, and I am a PhD student at the University of KwaZulu-Natal. I would like to invite you to participate in a research project that aims to develop an ethical framework for research on human tissue, helping stakeholders conduct research in an entirely ethical manner. This study will explore the views of HREC members, human biobanks, as well as those of anatomists and laboratory technicians, regarding the ethical issues they experience, and evaluate the regulations governing 'informed consent' in relation to human tissue research.

Please take a moment to review the information presented here, which outlines the details of this project. If you require further explanation or clarification on any aspect of the study, please do not hesitate to contact me. Additionally, your participation is entirely voluntary, and you are free to decline participation at any time. If you say no, it will not affect you negatively in any way. You are also free to withdraw from the study at any point, even if you do agree to take part.

This study has been approved by the Biomedical Research Ethics Committee (BREC/00005587/2023) and will be conducted in accordance with accepted and applicable National and International ethical guidelines and principles.

What is this research study all about?

The purpose of this component of my study is to explore the views of human biobanks on the ethical issues they face. This study will help in understanding perspectives on the ethical issues that biobanks typically encounter when dealing with human tissue. Your participation involves taking part in a semi-structured interview. You will be asked some open-ended questions, which will help us explore these ethical issues. The questions are not personal or sensitive in any way, but you are free not to answer any specific question. Biobank's details will be anonymised in all reports and publications.

Why have you been invited to participate?

You have been invited to participate because we would like to explore first-hand views from a human biobank on the ethical issues typically encountered when dealing with human tissue. Your comments will help us in correlating findings with national research ethics guidelines.

What will your responsibilities be?

Your responsibilities will be to provide your opinions and responses to some open-ended questions asked during an interview.

Will you benefit from taking part in this research?

There are no direct benefits that you will receive from participation in this study. However, your participation in the study has the potential to contribute to the scientific knowledge being generated in this research.

Are there in risks involved in your taking part in this research?

Presently, there are no foreseeable risks in your participation. All data will be completely anonymised, and your name will not be recorded anywhere nor revealed in subsequent publications.

If you do not agree to take part, what alternatives do you have?

Please note that participation is voluntary and completely based on your willingness. You are not being forced to take part in this study. The choice of whether to participate or not is yours alone. If you choose not to take part, you will not be affected in any way whatsoever. If you agree to participate, you may stop participating in the research at any time. You are guaranteed that there will be no penalties or any action taken against you, and you will not be prejudiced in any way should you decide to withdraw from the study. If you choose not to take part or choose to withdraw from this study, your welfare will not be affected in any way.

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KwaZulu-Natal, SOUTH AFRICA
Tel: 27 31 2604769 – Fax: 27 31 2604609

Email: BREC@ukzn.ac.za

If you are willing to participate in this study, please sign the attached Declaration of Consent and return it to me via email (the investigator).

Declaration by participant

By signing below, I ……...……. agree to take part in a research study entitled **Towards the Development of an Ethical Framework related to Research on Human Tissue.**

I declare that:

- I have read the attached information leaflet, and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions, and all my questions have been adequately answered.
- I understand that taking part in this study is voluntary and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.
- I may be asked to leave the study before it has finished, if the researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

Signed at (place) .....….....……... On (date) ……...……... 2024.

Signature of participant

_____

CONSENT FOR RECORDING
I hereby agree to the audio-recording of my participation in the study.

……..

Signature of participant

Date……...

In the event of any problems or concerns/questions, you may contact the researcher at mobile number [redacted] or e-mail [redacted]; the Supervisor for the study, Dr Pamela Pillay, at e-mail soobramoneypa@ukzn.ac.za, or the UKZN Biomedical Research Ethics Committee, contact details as follows:

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Email: BREC@ukzn.ac.za

Informed Consent Form for HREC Members

PARTICIPANT INFORMATION SHEET

TITLE OF THE RESEARCH PROJECT: Towards the Development of an Ethical Framework related to Research on Human Tissue

PRINCIPAL INVESTIGATOR: Miss Seonaid Singh

ADDRESS: University of KwaZulu-Natal
College of Health Sciences
School of Laboratory Medicine and Medical Sciences
Westville Durban
3269
South Africa

My name is Seonaid Singh, and I am a PhD student at the University of KwaZulu-Natal. I would like to invite you to participate in a research project that aims to develop an ethical framework for research on human tissue, helping stakeholders conduct research in an entirely ethical manner. This study will explore the views of HREC members, human biobanks, as well as those of anatomists and laboratory technicians, regarding the ethical issues they experience, and evaluate the regulations governing 'informed consent' in relation to human tissue research.

Please take a moment to review the information presented here, which outlines the details of this project. If you require further explanation or clarification on any aspect of the study, please do not hesitate to contact me. Additionally, your participation is entirely voluntary, and you are free to decline participation at any time. If you say no, it will not affect you negatively in any way. You are also free to withdraw from the study at any point, even if you do agree to take part.

This study has been approved by the Biomedical Research Ethics Committee (BREC/00005587/2023) and will be conducted in accordance with accepted and applicable National and International ethical guidelines and principles.

What is this research study all about?

The purpose of this component of my study is to explore the views of Human Research Ethics Committee (HREC) members who have experience with ethical issues. This study will help in understanding perspectives on the ethical issues that HRECs typically identify in their review activities. Your participation involves taking part in a structured interview. You will be asked some open-ended questions, which will help us explore these ethical issues in more detail. The questions are not personal or sensitive in any way, but you are free not to answer any specific question. The study will be conducted at your University and one other South African University. Details of both participating institutions will be anonymised in all reports and publications. A total of 15 participants will be recruited for this study.

Why have you been invited to participate?

You have been invited to participate because, as a HREC member who is familiar with the ethical review process of biomedical research studies, we would like to explore your views on the ethical issues typically raised by the two participating HRECs. Your comments will help us in correlating findings with national research ethics guidelines.

What will your responsibilities be?

Your responsibilities will be to provide your opinions and responses to some open-ended questions asked during an interview.

Will you benefit from taking part in this research?

There are no direct benefits that you will receive from participation in this study. However, your participation in the study has the potential to contribute to the scientific knowledge being generated in this research.

Are there in risks involved in your taking part in this research?

Presently, there are no foreseeable risks in your participation. All data will be completely anonymised, and your name will not be recorded anywhere nor revealed in subsequent publications.

If you do not agree to take part, what alternatives do you have?

Please note that participation is voluntary and completely based on your willingness. You are not being forced to take part in this study. The choice of whether to participate or not is yours alone. If you choose not to take part, you will not be affected in any way whatsoever. If you agree to participate, you may stop participating in the research at any time. You are guaranteed that there will be no penalties or any action taken against you, and you will not be prejudiced in any way should you decide to withdraw from the study. If you choose not to take part or choose to withdraw from this study, your welfare will not be affected in any way.

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KwaZulu-Natal, SOUTH AFRICA
Tel: 27 31 2604769 – Fax: 27 31 2604609
Email: BREC@ukzn.ac.za

If you are willing to participate in this study, please sign the attached Declaration of Consent and return it to me via email (the investigator).

Declaration by participant

By signing below, I …….……. agree to take part in a research study entitled **Towards the Development of an Ethical Framework related to Research on Human Tissue.**

I declare that:

- I have read the attached information leaflet, and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions, and all my questions have been adequately answered.
- I understand that taking part in this study is voluntary and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.
- I may be asked to leave the study before it has finished, if the researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

Signed at (place) .....….....…….... On (date) ……...……. 2024.

Signature of participant

_____

CONSENT FOR RECORDING
I hereby agree to the audio-recording of my participation in the study.

……..

Signature of participant

Date…….

In the event of any problems or concerns/questions, you may contact the researcher at mobile number [redacted] or e-mail [redacted]; the Supervisor for the study, Dr Pamela Pillay, at e-mail soobramoneypa@ukzn.ac.za, or the UKZN Biomedical Research Ethics Committee, contact details as follows:

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Email: BREC@ukzn.ac.za

Appendix 4: Interview Question Guide for Human Research Ethics Committee (HREC) members

****

Name of Human Research Ethics Committee: _____

Province: _____

Position Held: _____

1. What is the core function of your HREC?

2. What is your role/duties in your HREC?

3. In your opinion, what role does an institutional ethics committee play in the research ethics review process?

4. Explain the research ethics review process followed by your HREC.

5. Who are the stakeholders in the research ethics review process?

6. Based on your experience of reviewing research protocols, identify some common ethical issues/challenges encountered in the review process.

7. What criteria/policy guidelines does your HREC follow when reviewing research proposals?

8. In general, which research areas/fields bring about the most ethical concerns and challenges during the review process?

9. Do you feel that there are ethical issues which should be given more consideration than others during ethics review?

10. In your opinion, what are some of the new policy guidelines that should be implemented to alleviate current ethical challenges experienced by HRECs?

Appendix 5: Interview Question Guide for Human Biobanks

****

Name of Biobank: _____

1. What is human biobanking?

2. What is the purpose of human biobanking?

3. What types of biological samples/materials does your biobank store? What are these samples stored for?

4. Explain the process that your biobank follows to obtain, process and store biological samples/materials.

5. What are the policies and guidelines that your biobank follows for collecting, processing and storing biological samples?

6. How does consent work in your biobank? Who provides consent for biological materials?

7. What are the ethical challenges/issues faced by your biobank when dealing with biological samples? (if any)

8. In what ways should national policies/guidelines be adjusted to alleviate current ethical challenges encountered by human biobanks?

Chapter 4

Appendix 1: Manuscript Submission

Dear Miss Singh,

Your manuscript entitled "A Proposed Integrated Consent-Centred Ethical Framework for Human Tissue Research in South Africa" has been successfully submitted online and is presently being given full consideration for publication in Anatomical Sciences Education.

Your manuscript number is ASE-26-0059. Please mention this number in all future correspondence regarding this submission.

CRediT Taxonomy: authors' contribution(s) to the submitted manuscript are attributed as below. Submitting Authors may provide Author Contributions at original submission but MUST provide the information at revised submission. At revision submission, all authors should check the contributions carefully as if your manuscript is accepted, this information will be included in the published article:
Author Contributions:
Seonaid Moonega: Conceptualization; Writing - original draft; Investigation; Methodology; Formal analysis. Brenda Zola De Gama: Validation; Writing - review & editing; Supervision. Pamela Pillay: Funding acquisition; Writing - review & editing; Validation; Supervision.. Author Contributions:
Seonaid Moonega: Conceptualization; Writing - original draft; Investigation; Methodology; Formal analysis. Brenda Zola De Gama: Validation; Writing - review & editing; Supervision. Pamela Pillay: Funding acquisition; Writing - review & editing; Validation; Supervision.

Appendix 2: Structured Feedback Questionnaire

FRAMEWORK FEEDBACK QUESTIONNAIRE

Integrated Consent-centred Ethical Framework (ICEF) for Human Tissue Research in South Africa

Contact Email: _____

Date: _____

Section A: Personal Information

Please complete for contextual purposes; your responses will remain confidential.

Name: _____

Professional Title / Role: _____

Institution / Organisation: _____

Area(s) of Expertise: _____

Years of Experience in this Field: _____ years

Section B: Framework Review

Please review the attached draft framework and provide feedback under each area below. You may answer in brief statements or bullet points.

Focus Area	**Guiding Questions**	**Comments / Feedback**
Clarity and Structure	Is the framework clearly presented and logically structured? Are the key components easy to understand?	
Relevance and Applicability	Does the framework reflect current ethical, legal, and practical realities of human tissue research in South Africa? Are recommendations feasible?	
Completeness and Content	Are any important principles, issues, or governance mechanisms missing? Are any sections redundant?	
Accuracy and Alignment	Does the framework align with national (e.g., NHA, POPIA, DoH Guidelines)	

	and international ethical standards (e.g., CIOMS, WHO)?	
Practical Usefulness	Could the framework be realistically implemented by HRECs, biobanks, and researchers? What would improve usability?	
Strengths	What do you consider the main strengths or innovations of this framework?	
Weaknesses / Areas for Improvement	What aspects require revision or clarification?	
Overall Assessment	On a scale of 1–5, how valid and robust do you find this framework for guiding ethical human tissue research? (1 = Poor; 5 = Excellent)	☐1 ☐2 ☐3 ☐4 ☐5

Section C: Additional Comments

Please include any other remarks or suggestions for strengthening the framework.

_____

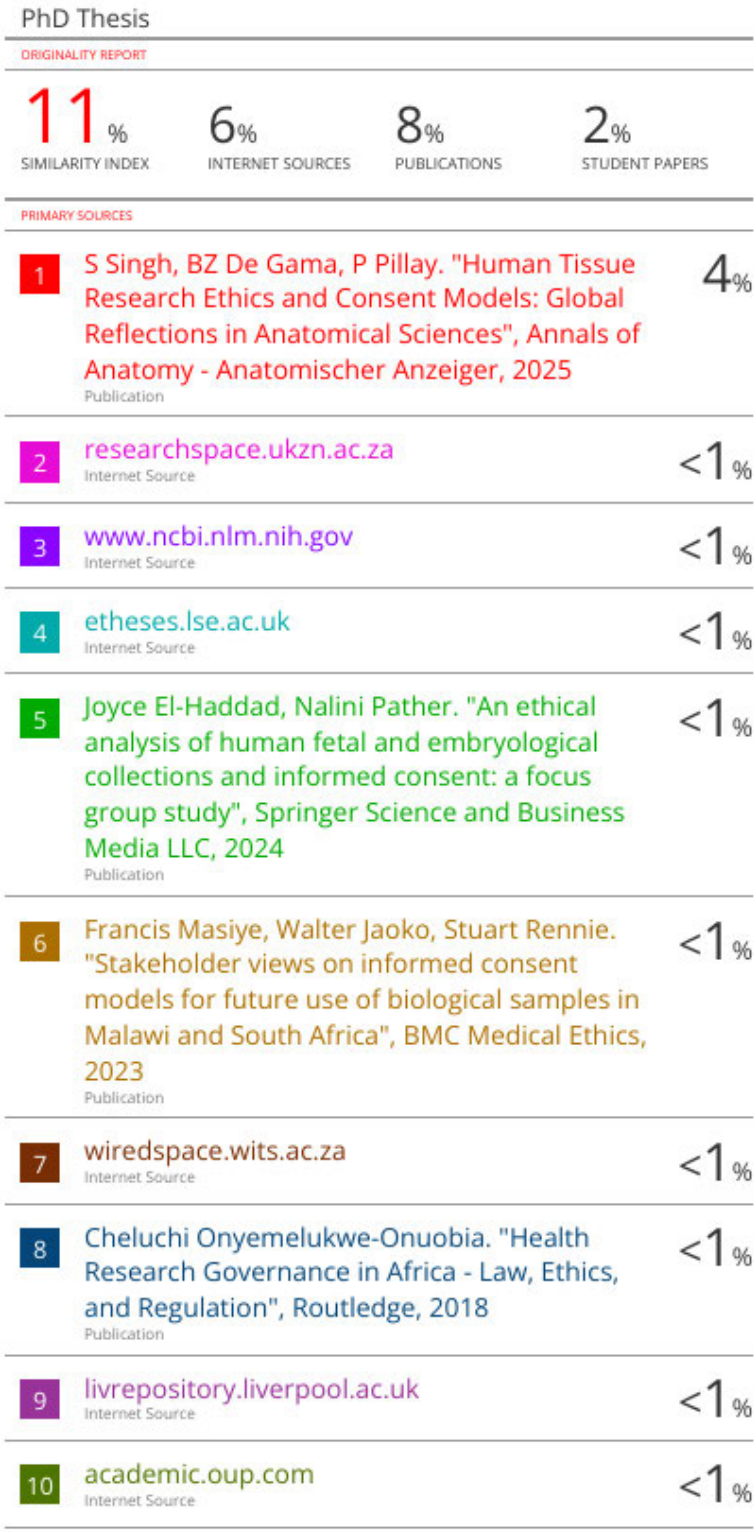
_____

Consent

By completing this form, you consent for your anonymised feedback to be included in the framework's validation process and subsequent reporting.

Signature: _____ Date: _____

Additional Appendix: Turnitin Originality Report



PhD Thesis

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Word count:	26,623
Character count:	164,913
Submission date:	26-Jan-2026 06:03PM (UTC+0200)
Submission ID:	2864189994

ABSTRACT

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