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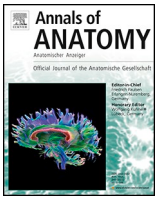

# Human tissue research ethics and consent models: Global reflections in anatomical sciences

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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)

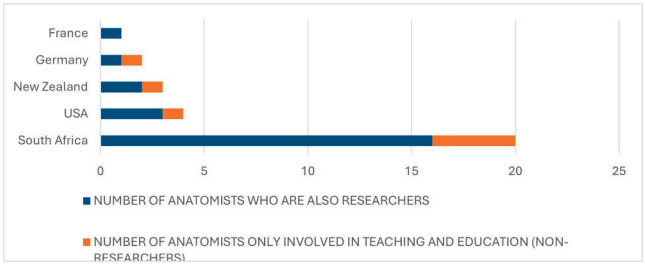


**Fig. 1.** Category of Stakeholders recruited by country.

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_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 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-

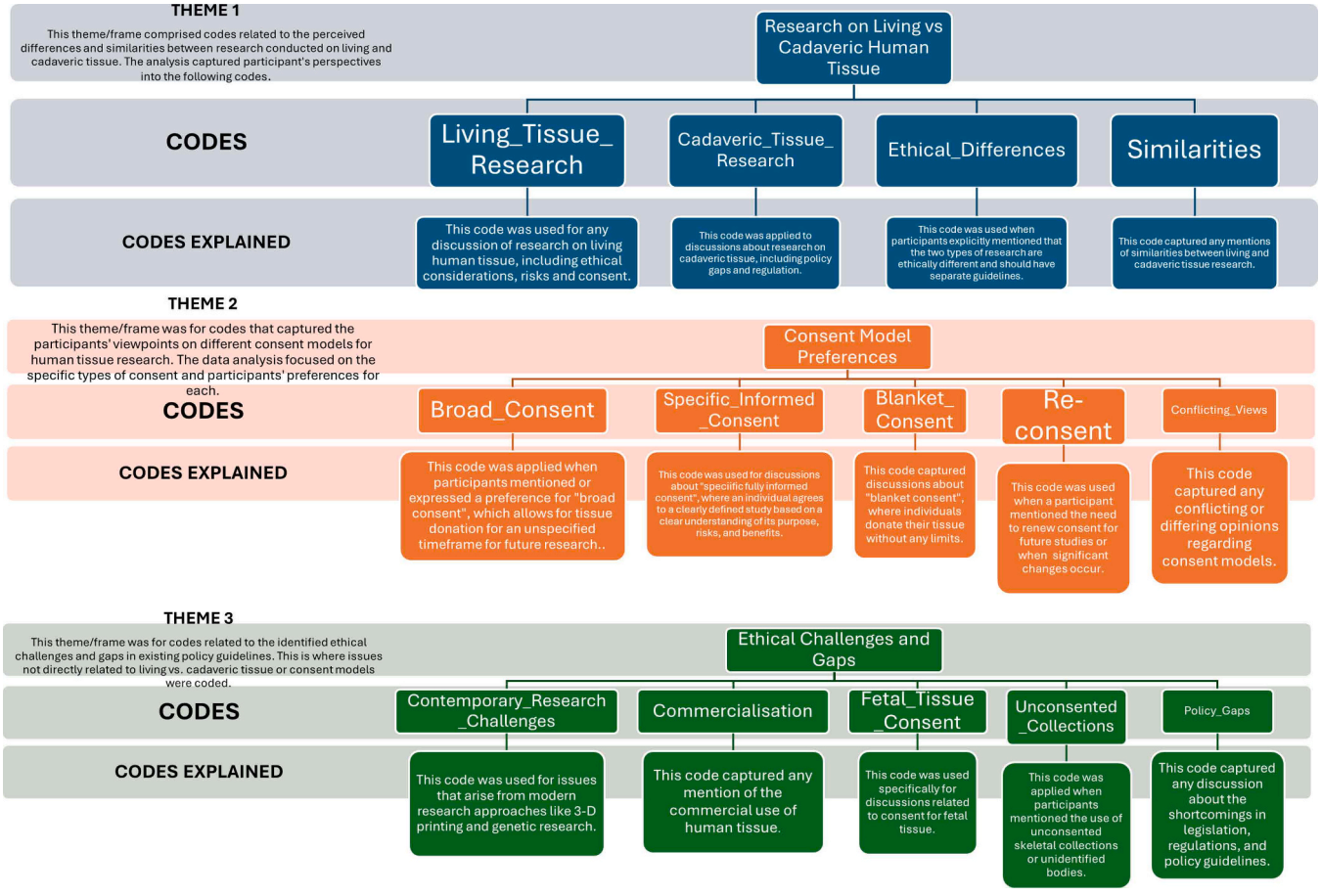


**Fig. 2.** Hierarchal coding frame from the analysed data.

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*

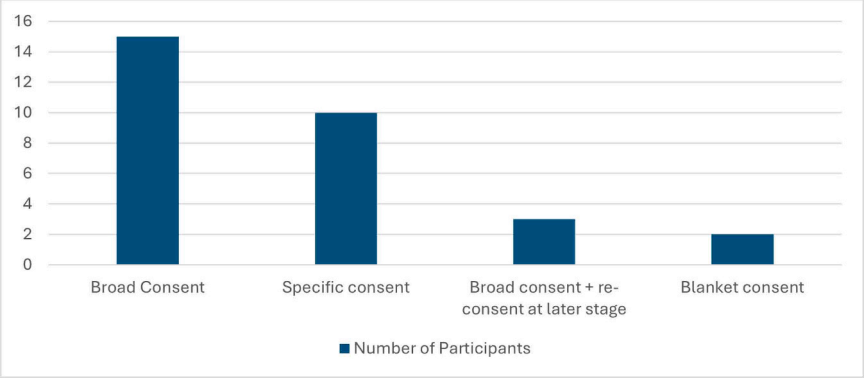


**Fig. 3.** Participants' Consent Model Preferences for Research on Living Human Tissue.

*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,

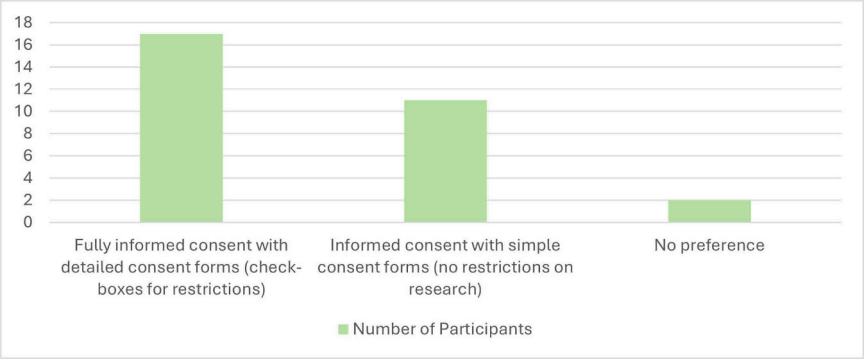


**Fig. 4.** Participants' Consent Preferences for Body Donors (cadaveric tissue research).

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).

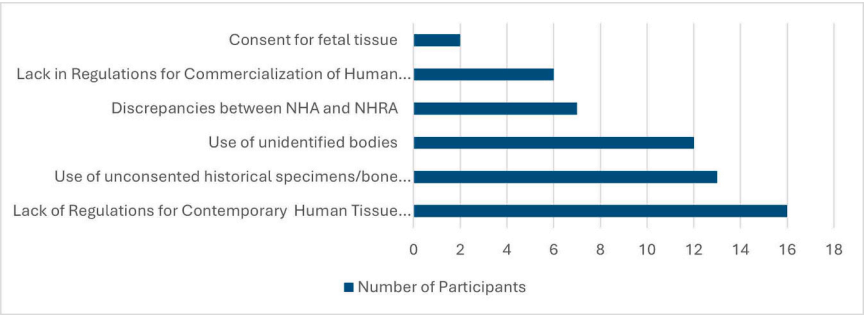


**Fig. 5.** Ethical Challenges and Gaps in Human Tissue Research mentioned by Participants.

### 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 ($^{13}/_{30}$), as well as unidentified/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 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 ($^{5}/_{30}$) 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 ($^{7}/_{30}$) 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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