

The legal position on the classification of human tissue in South Africa: Can tissues be owned?

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The ownership of tissue samples donated for medical research is an ongoing subject of dispute. Some advocates assert that patients have ongoing ownership rights in their tissues, including an unfettered right to determine what happens to their tissue sample. Researchers argue that giving patients property rights in their samples will turn the human body and body parts into a commodity and bring research to a halt. The question of the human body as property involves complex and philosophical dimensions. The law displays an uneasiness in making sense of the human body in the context of ownership and property, as the notion of owning oneself (and one's tissues) implies that persons are able to objectify their selves, and in the process become susceptible to objectification by others. The creation of commercial products from human tissue has generated very difficult legal and ethical questions that have no clear, universally accepted answers.

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Recent advancements in medicine, ranging from transplant surgery to *in vitro* fertilisation, nanotechnology and neuroscience, have drastically changed the way in which human bodies are perceived. There are abundant examples in law showing the law's uneasiness in making sense of the human body in the context of ownership and property, as the notion of owning oneself (and one's tissues) implies that persons are able to objectify their selves, and in the process become susceptible to objectification by others. The question of the human body as property involves complex and philosophical dimensions which cannot be comprehensively discussed in the scope of this article.

The human body and its parts are traditionally classified as *res extra commercium* (things outside the commercial sphere). Separated bodily materials present another problematical category, as the law has traditionally regarded separated bodily materials as *res nullius*, belonging to no one, until brought under the control of the first person who obtains possession of the separated human tissue.^[1] The universal legal prohibition on the sale or trade of human tissue, embodied globally, and various statutory regulations on the use of human tissue are equally ambiguous, as these statutory prohibitions paradoxically reinforce a construction of the human body as a commodity (property), subject to regulation.^[1]

This prompts the question as to how, in view of the common law position that no man is *dominus membrorum suorum* (master of his own bodily members) and the universal notion that the human body is *res extra commercium* (a thing outside the commercial sphere),^[2] legislation in South Africa addresses the issue of human tissue as property, and, if it does hold this view, what the consequences of this classification are. What rights do individuals have over their own tissues, if any? As South Africa is becoming an increasingly litigious environment, a legal analysis of the classification of human tissue is extremely relevant.

National Health Act 61 of 2003 and relevant regulations

The National Health Act (NHA)^[3] defines *tissue* as '*...human tissue, and includes flesh, bone, a gland, an organ, skin, bone marrow or body fluid, but excludes blood or a gamete*'. The 2012 Regulations Relating to the Use of Human Biological Material^[4] define *biological material* as '*... material from a human being including DNA, RNA, blastomeres, polar bodies, cultured cells, embryos, gametes, progenitor stem cells, small tissue biopsies and growth factors from the same*'. Furthermore, the 2012 Regulations Relating to Tissue Banks^[5] define *tissue* as '*... a functional group of cells. The term is used collectively in Regulations to indicate both cells and tissue*'. Finally, the Regulations Relating to the Import and Export of Human Tissue, Blood, Blood products, Cultured Cells, Stem Cells, Embryos, Foetal Tissue, Zygotes and Gametes^[6] define a *substance* as '*... tissue, blood, blood product or gamete*'. The Regulations Regarding Rendering of Clinical Forensic Medicine Services^[7] define a *body specimen* as '*...anybody [sic] sample which can be tested to determine the presence or absence of HIV infection*'.

The contradictions between the definitions are evident, and as they currently stand the definitions result in ambiguity. The NHA definition of tissues exclude gametes, while the definition of biological material in the Regulations Relating to the Use of Human Biological Material includes material from a human being (which includes tissues) and gametes. However, the definition as per the Regulations Relating to Tissue Banks indicates that 'tissue' is used collectively to indicate both cells and tissues. In addition to the obvious contradictions, the definitions in the NHA and the Regulations thereto do not provide for a legal classification of human tissue. This leaves questions about the classification of human tissue open-ended.

Regulations 2(a) and 2(b) of the Regulations Relating to the Use of Human Biological Material allow for the removal of biological material

(including tissues) for genetic testing, genetic training, genetic health research or therapeutic purposes by a competent person and at an authorised, prescribed institution. The definition of a competent person describes who may be authorised to remove certain tissues for specific processes. Furthermore, these Regulations^[4] specify that human biological material, may be removed or withdrawn from living persons for the following medical and dental purposes:

- DNA, RNA and chromosome-based genetic testing
- health research referred to in section 69(3) of the NHA
- training referred to in section 64(1)(a) of the NHA
- studies of archaeological, medical or heritage value on DNA obtained from human genetic material, conducted in terms of the National Heritage Resources Act.

Regulation 3 of the Regulations relating to the Use of Human Biological Material provides that a competent person may not remove any biological material from the body of another living person for the purpose of genetic testing, genetic training, genetic health research or therapeutics unless it is done:

- with the written informed consent of the person from whom such biological material shall be removed
- with the written informed consent of a child over the age of 12 years, provided that child has sufficient maturity and the mental capacity to understand the benefits, risks and social implications of the procedure (should the child not possess sufficient maturity or understanding, the written informed consent of the parent or guardian will be necessary)
- with the written informed consent of a parent, guardian or caregiver where the child is younger than 12 years
- consent by the head of a health establishment in the case of an emergency
- consent by the Minister, if the parent, guardian or caregiver of the child unreasonably refuses or is incapable of giving consent, cannot be readily traced or is deceased
- with the written informed consent of a mentally ill person if that person is capable of giving consent; or a curator, spouse, next of kin, a parent, guardian, major child, brother or sister, partner or associate, if such mentally ill person is incapable of giving consent; and the head of a health establishment in the case of an emergency.

Regulations 4(1) and 4(2) of the Regulations Relating to the Use of Human Biological Material provide that any organisation, institution or person that intends to use tissue from a deceased person for purposes of genetic testing, health research and therapeutics, where no consent has been given by the deceased person before his or her death and where there is no evidence that the removal of the tissue or cells would be contrary to a direction given by the deceased before his or her death, must take steps to locate the spouse, partner, major child, parent, guardian, major brother or major sister of a deceased person, in the specific order mentioned, in order to obtain consent.

A foreign case which is currently dealing with the removal of tissue from deceased persons without informed consent is that of the Ivano-Frankovsk regional morgue in western Ukraine, where it is alleged that parts from 56 human corpses were improperly fed into the international tissue market.^[8] In 2012, charges were filed

against the morgue's deputy director, three coroners and a nurse alleging that they deceived families into signing consent forms and that they did not get proper permission before tissue was obtained from corpses.^[8] These latest criminal charges in Ukraine follow an investigation published in July by the International Consortium of Investigative Journalists (ICIJ). The ICIJ probe revealed legal, ethical and medical concerns surrounding the growing for-profit human tissue industry. Families told the ICIJ that their relatives' cadavers were harvested without informed consent.

The case in Ivano-Frankovsk is one of five cases in which questions have been raised about whether Ukrainian morgues that supplied tissue to the international market were taking tissue without consent. Prosecutors indicated that the defendants face up to 7 years in prison if found guilty.^[8]

Although South African legislation seems to adequately deal with the issue of informed consent for the removal of human biological material from living and deceased persons for research/study purposes, informed consent relating to the participation in the research/study should be distinguished from specific consent relating to the future use of human biological material. This is an issue that is often overlooked.

Despite the existence of international research ethics documents and conventions governing the future use of human biological material,^[9-12] as Nienaber^[13] points out, South Africa's framework does not address informed consent for the future use of human biological material, unlike other African countries like Nigeria and Kenya. The question then arises as to what the fate is of human tissue after it has been procured for research purposes. Does it become the property of the institution to which it has been given? Does the research institution own the research subject's tissues?

Ownership of human tissue

The ownership of tissue samples donated for medical research is an ongoing subject of dispute. Some advocates assert that patients have ongoing ownership rights in their tissues, including an unfettered right to determine what happens to their tissue sample.^[14] Researchers argue that giving patients property rights in their samples will turn the human body and body parts into a commodity and bring research to a halt.^[14] One thing is certain: the creation of commercial products from human tissue has generated very difficult legal and ethical questions that have no clear, universally accepted answers. When those questions have come up in litigation, the courts have struggled to adapt the tradition and precedent of the law to the challenges arising from the biotechnology era. The case of *Washington University v. Catalonia* is the most recent instance of a court seeking to resolve this dilemma.^[14]

The case involves a former Washington University surgeon, William Catalonia, MD, who was engaged in research using the prostate cancer repository. Dr Catalonia had argued unsuccessfully in the lower courts that research participants who donated tissue and blood samples to the university for prostate cancer research could require the university to transfer their tissues to him at his new place of employment.^[15] The Court upheld a unanimous 2007 ruling by the Eighth US Circuit Court of Appeals that stated prostate tissue and serum samples donated to Washington University may continue to be used by the institution for cancer research.

The appellate court had affirmed the lower federal district court ruling that donors who gave tissue or serum samples to the university for research cannot later compel the school to transfer ownership of the samples to another research institution. The Court held that under the specific facts of the case, the men who participated had donated their tissue to the university as a gift and they could not get it back or have it sent to another researcher. However, the Eighth Circuit Court indicated that the men retained the right to stop participating in the research by:

- declining to answer any additional questions
- not donating more tissue, or
- disallowing the use of their tissue in future research.

This means that the men have the right to order the university to stop using their tissue, and the university cannot merely strip their names off it and continue to use it as they please.

Understanding ownership

The common-law description of ownership is found in South African case law, where ownership is defined in various decisions as *'the most complete real right which gives the owner the most complete and absolute entitlements to a thing. Even so, it is a right which can be limited by objective law and by the rights of others (limited real rights or creditor's rights).'*^[16] A thing is defined *'in terms of characteristics, as a corporeal or tangible object external to persons and which is, as an independent entity, subject to juridical control by a legal subject, to whom it is useful and of value.'*^[16]

Ownership is a real right that is often defined on the basis of entitlements. The following entitlements are usually distinguished: control; use; encumber (the entitlement to grant limited real rights in respect of a thing); alienate/transfer; and vindicate (the unique entitlement of the owner to claim the thing from another person).^[16]

Should an institution or organisation procure ownership of an individual's tissues, it would obtain a real right and ultimate control over that tissue. This could result in unscrupulous individuals utilising tissues of vulnerable individuals to advance the purposes of their research, without consideration of the individuals from whom the tissues were sought. Furthermore, should the research institutions 'own' tissues by a transfer of ownership rights from the research subject to the specific institution, any future uses of the tissues may occur without the research subject's consent. In this scenario, since ownership rights have been transferred to the institution, any proceeds generated from a therapy produced using the individual's tissues (directly or indirectly), may never benefit the individual in question.

In *Moore v Regents of the University of California*, the physician treating Mr Moore for hairy-cell leukaemia in 1976 removed samples of his blood, bone marrow aspirate and other tissues and fluid for examination.^[17] The physician and his research assistant knew upon taking these samples that the tissues had potential commercial and scientific value as material for medical research, but they did not disclose this information to Moore.^[17] In 1979, the University of California, Los Angeles (UCLA) Medical Center researchers established and patented a cell line from Moore's cells. The patent was assigned to the Regents of the University of California (Regents) who assisted the researchers in commercial development of the cell line and products to be developed from it. When Moore discovered that his cells had

been used in developing the patent, he took legal action against Regents and the UCLA Medical Centre researchers and doctors involved in his care.

The California Supreme Court found that Moore had a cause of action for breach of his physician's disclosure obligations and that an individual has a tangible property right in his or her own tissue.^[18] In *dicta*, however, the court explicitly stated that its decision left undecided whether the transfer of human tissue should be gift-based or market-based, and that future controversies would have to be decided on a case-by-case basis.^[18]

Recommendations and lessons learnt from these foreign case-law examples

When dealing with the issue of ownership of human tissues, there are no firm 'rules' *per se*. Each situation will have to be determined by the facts presented in that particular case. An individual may have a tangible proprietary right or interest in his or her own tissues. Any proceeds generated from the use of that individual's tissue will have to be apportioned to the individual himself. However, guidance on the exact apportionment of profits has not been explored in South African law. Therefore, the practitioner or researcher who intends to utilise an individual's tissue will have to obtain the individual's prior informed consent to do so and inform the individual of their intention to do so. This should include a very clear exposition of the intended uses of the individual's tissue, as well as possible profit that may result from the use of the tissue.

Truog *et al.*^[19] have suggested that there are three distinct obligations that an investigator who seeks access to tissue might have towards an individual whose tissues, upon removal from the body, might hold value for biomedical research. These include:

- consent
- compensation for effort and burden
- rights to revenue streams.

While the issues of consent and revenue streams have briefly been alluded to in this article, it is generally accepted that subjects are compensated for the time, effort (including travel), and co-operation that their participation requires. It has also been suggested that renewable tissues may be procured from volunteers, not for their medical benefit, but solely for the benefit of others e.g. blood and blood derivatives, oocytes, sperm, and breast milk. Truog *et al.*^[19] recommend that, in light of the Moore decision and other legal precedents that hold that individuals do not retain property ownership over removed tissues, 'a plausible rationale for justifying such payments is that they are made in exchange for the performance of a service, rather than for the transfer of property'.^[19]

The question arises however, as to whether such payment for renewable tissues is tantamount to organ or tissue trafficking. Interestingly, the definition of organ in the NHA^[3] is *'... any part of the human body adapted by its structure to perform any particular vital function, including the eye and its accessories, but does not include skin and appendages, flesh, bone, bone marrow, body fluid, blood or a gamete.'* Payment for renewable tissues such as skin, blood or gametes would therefore be excluded from organ trafficking.

The NHA Regulations Relating to the Artificial Fertilisation of Persons^[20] attempt to provide clarity on the issue of ownership and state that:

Before artificial fertilisation, the ownership of a gamete donated for the purpose of artificial fertilisation is vested (in the case of a male gamete donor) but:

- before receipt of such gamete by the authorised institution to effect artificial fertilisation, *by the authorised institution which removed or withdrew the gamete* [our emphasis]
- after receipt of such gamete by the authorised institution that intends to effect artificial fertilisation, *in that institution*. [our emphasis]

In the case of a male gamete donor for the artificial fertilisation of his spouse, in that male gamete donor; and in the case of a female gamete donor, for the artificial fertilisation of a recipient, in that female gamete donor.

After artificial fertilisation, the ownership of a zygote or embryo effected by donation of male and female gametes is vested:

- in the case of a male gamete donor, *in the recipient* [our emphasis]
- in the case of a female donor, *in the recipient*.^[20] [our emphasis]

An embryo is defined in the NHA^[3] as ‘... a human offspring in the first 8 weeks from conception’ and in the Regulations Relating to the Import and Export of Human Tissue, Blood, Blood products, Cultured cells, Stem cells, Embryos, Foetal tissue, Zygotes and Gametes^[7] as ‘... a human offspring in the first 8 weeks of conception’. Despite these operational definitions (the latter of which is conceptually confusing i.e. ‘of conception’), our current legislation does not provide any guidance on whether an embryo may fulfil the requirements to be categorised as property. Therefore, the exact characterisation of an embryo in South African law remains unknown and will have to be dealt with on a case-by-case basis, taking into consideration all relevant factors. It is submitted that the use of the word ‘ownership’ in the NHA Regulations is problematic and that it should have been substituted with a ‘proprietary interest’, which denotes something different from the legal understanding of ownership.

Proprietary rights are property rights of an owner of proprietary information that may be protected under law.^[21] Proprietary information is information that is not public knowledge. The recipient of such information is therefore generally duty bound from making unauthorised use of such information.^[22] If human tissues are afforded a proprietary interest, they would be protected from unauthorised use. The holder of the proprietary right (i.e. the research subject) would have to consent to any use of their human tissues in the research phase and any subsequent future use thereof. This would also ensure that the proceeds of any therapy developed from the tissues would be distributed, in part, to the subject.

A mandatory agreement stipulating the terms and conditions of such distribution should be required. In this way, unscrupulous activities could be minimised and vulnerable individuals, in particular, could benefit from the use of their tissues.

In the United Kingdom, separated body parts can, under certain circumstances, if skill and labour had been applied thereto, be owned by an individual. This view was confirmed in 1998 in *R v. Kelly*.^[23] In this case, a technician who worked at the Royal College of Surgeons removed body parts and gave these to an artist who used the body parts as moulds to create sculptures. Both the technician and the artist were subsequently charged with theft. They argued that parts of corpses are not property

and could therefore not be stolen under the British Theft Act. The Court of Appeal held that parts of a corpse are capable of being stolen, if they have acquired different attributes by virtue of the application of skill. As the body parts in question had been preserved and used as specimens, they became fit for proprietary rights.

Conclusion

It is imperative that legislation in South Africa relating to the regulation of human tissue be amended to provide a clear and consistent message regarding any proprietary claims in respect of human tissue. A South African case in point is the recent spate of organ trafficking in which medical practitioners at St Augustine’s Hospital performed 109 illegal operations between 2001 and 2003, which included the removal of kidneys from five children, and admitted receiving R3.8 million from an illegal organ-trafficking syndicate.^[24]

Under the false pretense of ‘further investigations’, a medical practitioner or researcher may easily obtain an individual’s tissue without the proper required consent. Legal requirements relating to informed consent in the South African medico-legal context have been discussed extensively.^[25] In the context of medical research, specifically Section 12(2)(c) of the Constitution of the Republic of South Africa, 1996, states that everyone has the right to bodily and psychological integrity, which includes the right not to be subjected to medical research or scientific experiments without his or her informed consent.

In the present context, many academic scientists working in the field of human tissues are extremely confused regarding the meaning and practical implications of possession, custodianship, ownership, database rights and intellectual property generally.^[26] The conflicting descriptions in statute and regulations relating to the regulation of human tissues, referred to above, add to this confusion.^[27]

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