

# Human Tissue Legislation



Michael S. Pepper  
MBChB, PhD, MD



UNIVERSITEIT VAN PRETORIA  
UNIVERSITY OF PRETORIA

Institute for Cellular and Molecular Medicine

# Human tissue legislation

- Complex
  - ever-changing landscape in which advances in science and medicine need to be accommodated
  - high degree of technical expertise is required to ensure that the legislation is accurate, appropriate and unambiguous
- Generally accepted that the law has struggled to keep pace with advances in science and technology (Parker, 1986: 1028)

# Legislation

Level	Legally-binding	Human tissues
Constitution	Yes	
Policy	No	Limited
Act	Yes	Yes
Regulations	Yes	Incomplete
Guidelines Standards	No	None officially

# National Health Act 61 of 2003

- Assented to by the President on 18 July 2004
- Came into force on 02 May 2005
- Chapter 8: “Control of use of blood, blood products, tissue and gametes in humans”
  - fully enacted in 2012
- Matters pertaining to human tissues were previously legislated under the Human Tissue Act 65 of 1983
  - repealed

# Acts

- National Health Act No. 61 of 2003
- ~~Human Tissue Act No. 65 of 1983~~
- Medicines and Related Substances Control Act No. 101 of 1965 (Medicines Act)
- Children's Act No. 38 of 2005
- Inquest Act No. 58 of 1959
- Consumer Protection Act No. 68 of 2008

# Areas covered by Chapter 8 of the NHA

- Blood and blood products
- Assisted reproductive technology
- Cell-based therapy
- Transplantation
- DNA and genetic services
- Tissue banks
- Examination, allocation and disposal of human bodies and tissues

# Chapter 8

- Removal and use of human tissues
- **“tissue”** means human tissue, and includes flesh, bone, a gland, an organ, skin, bone marrow or body fluid, but excludes blood or a gamete
  - “organ” means any part of the human body adapted by its structure to perform any particular vital function, including the eye and its accessories
  - silent on DNA and genomic sovereignty

# Chapter 8

- Section 56: “Use of tissue, blood, blood products or gametes removed or withdrawn from living persons”
  - removal or withdrawal of stem cells (excluding umbilical cord progenitor cells) from a living person for medical or dental purposes requires Ministerial authorization
  - HSC transplantation
    - practiced for several decades in SA
    - need for Ministerial authorization?



# Chapter 9

- National Health Research and Information
- Section 71: “Research on or experimentation with human subjects”
  - all research conducted on minors for non-therapeutic purposes requires Ministerial authorization
  - research for therapeutic purposes: Ministerial authorization apparently not required

# Regulations published in Government Gazette no. 35099 on 02 March 2012

Regulation no.	Title	Pages
No. R. 175	Regulations relating to artificial fertilization of persons	GG 35099 pages 3-21
No. R. 176	Regulations regarding rendering of clinical forensic medicine services	GG 35099 pages 22-30
No. R. 177	Regulations relating to the use of human biological material	GG 35099 pages 31-38
No. R. 179	Regulations relating to blood and blood products	GG 35099 pages 62-74
No. R. 180	Regulations regarding the general control of human bodies, tissue, blood, blood products and gametes	GG 35099 pages 75-96
No. R. 181	Regulations relating to the import and export of human tissue, blood, blood products, cultured cells, stem cells, embryos, foetal tissue, zygotes and gametes.	GG 35099 pages 97-124
No. R. 182	Regulations relating to tissue banks	GG 35099 pages 125-141
No. R. 183	Regulations relating to stem cell banks	GG 35099 pages 142-158

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# Regulations

- Lack of regulations
  - cell-based therapy
  - biobanks
  - transplantation
- Redundancy/overlap
- Definitions
  - not harmonized
    - between regulations
    - relative to NHA

# Guidelines and Standards

- Several professional bodies have established their own guidelines
- No official guidelines
  - i.e. emanating from or recognized/endorsed by the DoH

# Professional bodies: human tissues

Area	Professional body	Guidelines
Transplantation	Southern African Transplantation Society (SATS)	Yes <a href="http://www.sats.org.za/Guidelines.asp">http://www.sats.org.za/Guidelines.asp</a>
Assisted reproductive technology	Southern African Society of Reproductive Medicine and Gynaecological Endoscopy (SASREG)	Yes <a href="http://www.fertilitysa.org.za/TreatmentGuidelines/ReproductiveMedicine.asp">http://www.fertilitysa.org.za/TreatmentGuidelines/ReproductiveMedicine.asp</a>
Blood and blood products	National Blood Committee (not in operation since 2008)	Yes SANBS and WPBTS websites & other
Cell-based therapy	South African Stem Cell Transplantation Society (SASCTS)	Yes; none on website <a href="http://www.stemcell.org.za/index.htm">http://www.stemcell.org.za/index.htm</a>
Genetic Services	Southern African Society of Human Genetics (SAHGS)	Yes <a href="http://www.sashg.org/documents.htm">http://www.sashg.org/documents.htm</a>
Tissue banks	South African Tissue Bank Association (SATiBA)	Newly formed; in progress
Forensic pathology and medicine	National Forensic Pathology Services Committee	Yes No website
	National Clinical Forensic Committee	In progress

# Cell therapy product standards

- Standards for cellular therapy product collection, processing, storage and distribution
- Does not include cell therapy per se
  - SASCTS standards
- Alignment with other bodies
  - AABB
  - FACT-JACIE
- Enforcement
  - SANAS

# Clinical trials

- Need to be registered with the Medicine's Control Council (MCC)
- Any form of therapy that is unproven or experimental in nature
- Need to be examined by an ethics committee (peer reviewed)
- Patients should not have to pay for treatments that are unproven or experimental



# Legislation - objectives

- Protect the individual from harmful and unethical practices
- Respect the individual's right to determine how to use her/his own stem cells
- Make provision for all South Africans
- Allow South Africans to benefit from the advances in medical science
- Should not be unduly restrictive so as to avoid stifling basic and clinical research and biotechnological innovation

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