UNIVERSITY OF THE WESTERN CAPE

THE BIOMEDICAL RESEARCH ETHICS COMMITTEE (BMREC)

PRINCIPLES AND POLICY ON BIOBANKS
Biobanks are repositories where organised collections of human biological materials (HBMs) and associated data from large numbers of individuals are collected, stored and distributed for the purpose of health research. Data includes health, environment and lifestyle information and often individuals are followed over long periods of time. These repositories range from large national biobanks which cater for research into a range of conditions to smaller ones within institutions. The latter are used for research into a limited number of diseases or for disease-specific conditions. Biobanks are further distinguished into being either public or private in nature. Public biobanks are often called population biobanks. HBMs and associated data from public biobanks are used for the promotion of the health of the population. Hence, biobanks may be any of the following, or a combination thereof: cross-sectional, longitudinal, large scale, disease-specific, or population-based and they provide platforms for international collaborations on a scale not previously achieved. (Dhai and Mahomed, 2013)

The BMREC has established the Biobanks Ethics Committee (BEC) to:

1. Develop principles, policy and guidelines for the review and approval of applications for the establishment of biobanks;
2. To review all applications for the establishment of biobanks and to make recommendations to the BMREC; and
3. To review all research using tissue samples and/or associated data from approved biobanks and make recommendations to the BMREC.

**Preamble**

All biobanks associated with the University must be approved by the BMREC. These biobanks or any biobank being accessed by researchers submitting protocols for review to the BMREC, will be required to adhere to the following criteria, adapted from the *OECD Guidelines on Human Biobanks and Genetic Research Databases (2009)*:

- Human rights and freedoms must be respected and the rights and well-being of the participants should prevail over the research and other interests of the owners and users of biobanks in accordance with the Bill of Rights of the Constitution of South Africa and any other pertinent South African law.
- There is growing consensus for harmonization of governance of biobanks and broad use of HBMs.
- Biobank resources must be embedded within health systems with researchers, policy makers, health care providers and other key roleplayers being involved early in the process.
- Information on the scientific rationale underlying the biobank and on its scientific and business uncertainties and risks, must be made available to the BMREC.

**Objectives**

- The objective of the biobank must be to foster research.
- Data and materials must be made rapidly and widely available to researchers in order to advance knowledge and understanding.
Stakeholder Consultation and Ongoing Information Sharing

- Stakeholder consultation and involvement are very necessary to the success of biobanking.
- Evidence of stakeholder consultation and dialogue must be presented to the BMREC.
- Aggregate and general results of research conducted using the biobank’s resources, regardless of outcome, must be made publicly available.
- Public trust in biobanking must be promoted and maintained to encourage participation.
- Communication strategies must take into consideration the different needs of the participants.
- Participating communities and RECs must have access to regularly updated information about the type of research being carried out with the human biological materials and data contained within the biobank.
- Participating communities and RECs must be provided with information about commercial products that may arise from research conducted using their resources and the benefits, if any, they may receive.

Informed Consent and Withdrawal

- Collection of HBMs and associated data must take into consideration and adhere to the ethical and legal requirements for informed consent.
- Explicit information must be provided to participants on whether and under what circumstances the biobank may be legally obliged to provide their human biological materials and data, to third parties (e.g. law enforcement agencies) for non-research purposes.
- Participants must be informed of their right to withdraw their samples and information, and the implications of and limits to exercising that right.
- Where participants are minors, clearly articulated policy must be formulated on whether, when and how the minor’s assent will be obtained, in accordance with applicable law and what steps will be taken once such participants become legally competent to consent.
Privacy and Risk

- Participants’ privacy and the confidentiality of their data and information must be protected and secured.
- Risks to participants, their families and potentially identifiable populations or groups whose specimens and data are included in the biobank, must be minimised.
- Measures must be taken to avoid discrimination against or stigmatisation of a person, family or group, whether or not they have contributed to the biobank.

Benefits

- The biobank must benefit donor participants and communities.
- Benefit sharing strategies must be clearly outlined.

Governance

- Governance of a biobank from establishment to dissolution must be in accordance with the principles of accountability and transparency and must take into consideration applicable legal frameworks and ethical principles.
- Biobanks must be registered with the Department of Health as required by the Regulations of the National Health Act.
- Biobanks must be accredited through the South African National Accreditation System (SANAS).
- Biobanks must obtain Good Clinical Laboratory Practice (GCLP) Accreditation.
- Staff in the biobank must be certified with the International Aviation and Transport Authority (IATA).
- The Biobanks Ethics Committee must establish a Biospecimen Access Committee to govern requests for access to HBM and as part of its governance structure.
- Specimens and data are to be transferred to other biobanks only for specific research projects.
• In the event of temporary closure of the biobank, specimens and data are to be transferred to other biobanks.
• All transfers must be approved by the BMREC.
• Each collaborative project must have an overarching Material Transfer Agreement (MTA).
• Clearly documented operating procedures and policies for the procurement, collection, labelling, registration, processing, storage, tracking, retrieval, transfer, use and destruction of human biological materials, data and/or information must be written up and implemented.
• There must be transparency about the nature and source of the biobank’s financing/funding HBMs and information must not be sold for private gain.
• The following must be approved and annually reviewed by an independent research ethics committee registered with the National Health Ethics Research Council (NHERC):
  o Establishment documents of biobank
  o governance of biobank
  o management of biobank
  o operation of biobank
  o access to biobank
  o use of the biobank and its protocols and processes for research activities
  o oversight mechanisms of biobank
  o strategies for ensuring long term sustainability of biobank which also addresses the event that funding is terminated or its nature changed
  o stakeholder consultation (including the general public) of biobank
  o criteria for sampling and participant selection of biobank
  o benefit sharing strategies of biobank
  o quality management protocols of the biobank
  o risk management protocols of the biobank
  o biobank protocols in the event of short and long term power outages
Structure and Closure of a Biobank

- A biobank must appoint a suitably qualified practitioner as director to be in charge of and take full responsibility for its activities. Such director must at least have some experience in research and the collection of HBM’s and related matters. The director must manage the day to day activities of the biobank as well as any complications that may arise therefrom. (Adapted from National Health Act Regulations Relating to Blood and Blood Products, 2012.)

- A public biobank must be structured as a non-profit company (NPC) incorporated under Section 10 of the Companies Act 71 of 2008.

  Should the biobank dissolve, wind-up or cease to continue operating for any reason whatsoever, the entire net asset value together with any stored HBM’s and data, must be distributed in whole or in part, to one or more organisations or institutions carrying on biobank activities in South Africa or, a non-profit trust; or voluntary association having objectives similar to the biobank’s main objective. (Adapted from the Companies Act 71, 2008.)

- A private biobank must be structured as a for-profit entity, but will not trade or sell HBM’s and associated data in accordance with Section 60 of the National Health Act 61 of 2003.

  Should the private biobank dissolve, wind-up or cease to continue operating for any reason whatsoever, the entire net asset value together with any stored HBM’s and data, must be distributed in whole or in part, to one or more organisations or institutions carrying on biobank activities in South Africa, a non-profit trust or a voluntary association having objectives similar to the biobank’s main objective.
Regulatory Compliance

The following Acts, Regulations and Guidelines must be complied with at all times:

- The Bill of Rights of the Constitution of South Africa.
- National Health Act No 61 of 2003.
- Proclamation No 11 Government Gazette 35081 of 27 February 2012.
- Regulations of the National Health Act No 61 of 2003 (See Annexure A for some pertinent aspects of the regulations):
  - Regulations relating to Blood and Blood Products (2012);
  - Regulations relating to Stem Cell Banks (2012);
  - Regulations relating to the General Control of Human Bodies, Tissue, Blood, Blood Products and Gamete (2011);
  - Regulations relating to the Import and Export of Human Tissue, Blood, Blood Cultured Cells, Stem Cells, Embryos, Foetal Tissue, Zygotes and Gametes (2012);
  - Regulations relating to the Use of Human Biological Material (2011); and
  - Regulations relating to Tissue Banks (2011).
- Companies Act 71 of 2008.
Definitions

- **Biobanks**: repositories where organised collections of human biological materials (HBMs) and associated data from large numbers of individuals are collected, stored and distributed for the purpose of health research.

- **Human Biological Materials (HBMs)**: material from a human being including DNA, RNA, blastomeres, polar bodies, cultured cells, embryos, gametes, progenitor stem cells, tissues and growth factors from the same.

- **Institution**: in the case of donated HBMs, is a hospital, a university or an authorized entity.

- **Material Transfer Agreement (MTA)**: a contract governing the transfer of materials between organisations and/or institutions, which sets out what will be done with any material supplied, whether the material will be used in humans or not, the quality of the material, the terms and conditions under which the materials will be used, any modifications to the material, third party transfers, benefit sharing, intellectual property rights and other legal, regulatory guidelines or policies.

- **Private biobanks**: are established as for-profit entities. HBMs and associated data from private biobanks are used for the promotion of the specific interests of the private biobank.

- **Public/population biobanks**: are established as non-profit companies incorporated under the Companies Act 71 of 2008. HBMs and associated data from public biobanks are used for the promotion of the health of the population.
References


Acknowledgement

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1. REMOVAL OF BIOLOGICAL MATERIAL FROM DECEASED PERSONS
   (From Regulation 4 of the Regulations relating to the Use of Human Biological Material)

Any organisation or 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 her or his 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 specific 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.

The steps must include, but are not limited to, obtaining the name, address, the telephone number of the spouse, partner, major child, parent, legal guardian, major brother or major sister of the deceased person from:

(i) any person working in the relevant hospital, institution or facility where the deceased died; or
(ii) any person who visited the deceased before his or her death.

In cases where none of the persons referred to above can be located, an application, including evidence that the above steps have been taken must be submitted with the request to remove such tissue, to the Director-General in terms of Section 62(3) of the National Health Act.

2. DISPOSAL OF UNCLAIMED BODIES OF DECEASED PERSONS
   (From Regulation 10(1) of the Regulations regarding the General Control of Human Bodies, Tissue, Blood, Blood Products and Gametes)

The body of a deceased person that is not buried, or claimed for burial within 30 days after the death of that person by the spouse, partner, major child, parent, guardian, major brother or major sister in the specific order mentioned or bona fide friend of the deceased, shall be at the disposal of the health officer in whose area the body is.

3. HANDING OVER OF BODIES TO CERTAIN INSTITUTIONS
   (From Regulation 12(1) of the Regulations regarding the General Control of Human Bodies, Tissue, Blood, Blood Products and Gametes)

A health officer may on receipt of a notice, by written order direct that the body concerned be handed over to a specific institution situated within the area of the health officer concerned, or such an institution nearest to where the body is.
4. BODIES TO BE PRESERVED FOR CERTAIN PERIOD BEFORE USE  
(From Regulation 13(1) of the Regulations regarding the General Control of Human Bodies, Tissue, Blood, Blood Products and Gametes)

The person in charge of an institution to which a body has been handed over shall keep and preserve that body for a period of not less than 14 days before it may be used: Provided that, if the said person deems it advisable, any tissue of such a body may be removed and preserved separately.

5. HUMAN BIOLOGICAL MATERIAL REGISTERS  
(From Regulation 12 of the Regulations relating to the Use of Human Biological Material)

An authorised institution that performs genetic research or generates embryonic stem cells, must have separate registers to record such genetic research or generation of embryonic stem cell lines. The authorised institution must submit details of the registers to the Minister by the end of March of each year.

6. USE OF STEM CELLS  
(From Regulation 2 of the Regulations relating to Stem Cell Banks)

No person. shall –

(1) (a) remove, acquire or import human stem cells from any living or deceased person; or
(b) preserve, screen, test, process, store, separate, label, pack, supply or distribute or export or in any other manner dispose of human stem cells whether in its original from or in any altered form; or
(c) release any stem cell products for therapeutic use, unless

i) these activities are authorised in terms of Section 54 of the National Health Act; and

ii) laboratory tests for the following infectious agents which may cause transplantation transmitted diseases have been completed and the results of each are available:
   - Syphilis
   - Hepatitis B
   - Hepatitis C
   - Human Immunodeficiency Virus type 1 and 2.

(2) Where stem cells are for autologous use, the tests referred to in (c) (ii) above may not be required;

(3) No person shall use stem cells or its products for therapeutic, research or educational purpose unless he or she:
   (a) is authorised with the Department;
conducts any activity referred to in (1) (a) or (b), as the case may be, in accordance with the provisions of these regulations;

(c) has obtained informed written consent of the donor even in the case of residual tissue, blood or blood products; and

(d) is sure that the donor has donated voluntarily and it documented as such. The, provisions of (1) above are not applicable to a person transporting human tissue, blood or blood products in the usual course of business as a carrier, if special transport requirements are adhered to.

7. IMPORT AND EXPORT PERMITS

(From Regulation 2 of the Regulations relating to the Import and Export of Human Tissue, Blood, Blood Products, Cultured Cells, Stem Cells, Embryos, Foetal Tissue, Zygotes and Gametes)

No person may import or export any tissue or any blood, blood product, cultured cells, gametes, stem cells or embryos without a permit.

Any person who wishes to import or export any tissue or any blood, blood product, cultured cells, stem cells, embryo, zygote or gamete, must apply in writing to the Director-General. The Director-General may on receipt of the application issue a permit to a person authorising such a person to import or export, subject to such conditions as the Director-General may determine and record on the permit, including an expiry date, any tissue or any blood, blood product, and cultured cells.

The Director-General may issue a permit authorising the applicant to export or import any tissue, blood, blood product, and cultured cells. If he or she is satisfied that the information submitted in support of an application for a permit meets specific requirements.

An applicant for an export permit must have proof in writing that the tissue or gametes for which an export permit is being applied for, was or were donated in terms of the National Health Act, and that the tissue or gametes to be exported are to be used in terms of the National Health Act, and such proof must accompany the application. (From Regulation 3 of the Regulations relating to the Import and Export of Human Tissue, Blood, Blood Products, Cultured Cells, Stem Cells, Embryos, Foetal Tissue, Zygotes and Gametes)

No import or export permit shall be issued for placenta tissue, embryonic or foetal tissue, or embryonic, foetal and umbilical stem cells, except with the written consent of the Minister and subject to any condition as the Minister may determine. (From: Regulation 4(2) of the Regulations relating to the Import and Export of Human Tissue, Blood, Blood Products, Cultured Cells, Stem Cells, Embryos, Foetal Tissue, Zygotes and Gametes).