THE HUMAN RESEARCH ETHICS COMMITTEE MEDICAL (HREC)
PRINCIPLES AND POLICY ON BIOBANKS
UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
SOUTH AFRICA

A Biobank is an organised collection of human biological material (HBM) and associated data from different individuals, which are usually kept for an unlimited period of time, for the purposes of health research. Storage of HBMs in departments[1] for specific projects for defined purposes is not covered by this Policy document.

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

1. develop principles, policy and guidelines for the review and approval of applications to establish biobanks;
2. to review all applications to establish biobanks and to make recommendations to the HREC; and
3. to review all research using HBMs and / or associated data from approved biobanks and make recommendations to the HREC.

All biobanks associated with the University must be approved by the HREC (Medical). These biobanks, or any biobank being accessed by researchers submitting protocols for review to the HREC, will be required to adhere to the principles and criteria[2] below.

[1] The term "departments" is used broadly to include Centres, Units and other entities.

[2] Adapted from: OECD Guidelines on Human Biobanks and Genetic Research Databases. (2009) www.oecd.org/publishing/corrigenda. Accessed on 22/11/2012

PREAMBLE

- 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 both nationally and internationally for harmonization of governance of biobanks and broad use of HBMs.
- Biobank resources must be embedded within health systems and researchers, policy makers, health care providers and other key roleplayers must be 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 HREC.

OBJECTIVES

The objectives of the biobank must be:

- to foster research that generates new science with the intention of benefiting human wellbeing and health;
- to make data and materials accessible to researchers in order to advance knowledge and understanding; and
- to ensure the integrity of samples in perpetuity.

PRINCIPLES

Stakeholder[3] 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 HREC.
- 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.

[3] Stakeholders include but are not limited to: donor communities, researchers, policy makers and institutions.

- Communication strategies must take into consideration the different needs of the participants.
- Participating donors, donor 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.* as instructed by a Court Order) 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

- Reasonable steps must be taken to ensure that participants' privacy and the confidentiality of their data and information is 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 persozn, family or group, whether or not they have contributed to the biobank.

BENEFITS

- The biobank must benefit donor participants and donor communities to the extent that there are benefits.

- 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 obtain Good Clinical Laboratory Practice (GCLP) Accreditation.
- Relevant staff in the biobank must be certified with the International Aviation and Transport Authority (IATA).
- 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 HREC approved biobanks.
- All transfers must be approved by the HREC.
- Each collaborative project must have a Material Transfer Agreement.
- 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 (NHREC):
    - establishment documents of biobank,
    - governance of biobank,
    - management of biobank,
    - operation of biobank,
    - access to biobank,
    - use of the biobank and its protocols and processes for research activities,
    - oversight mechanisms of biobank,
    - strategies for ensuring long term sustainability of biobank which also address the event that funding is terminated or its nature changed,
    - stakeholder consultation (including the general public) of biobank,

- criteria for sampling and participant selection of biobank,
- benefit sharing strategies of biobank,
- quality management protocols of the biobank,
- risk management protocols of the biobank,
- biobank protocols in the event of short and long term power outages,
- safety and security measures

MANAGEMENT

- 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[4].

CLOSURE

- Should the biobank dissolve, wind-up or cease to continue operating for any reason whatsoever, the entire net asset value together with any stored HBMs and data, must be distributed in whole or in part, after obtaining HREC approval, 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. These recipient organisations will be bound by this policy document.

REGULATORY COMPLIANCE

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

[4] Adapted from Regulation 7 of the Regulations Relating to Blood and Blood Products.

- The Bill of Rights of the Constitution of South Africa.
- National Health Act 61 of 2003.
- Proclamation No 11 *Government Gazette* 35081 of 27 February 2012
  Government Gazette 35099 of 2 March 2012 (See Annexure page 8 for some pertinent aspects of the regulations):
  1. Regulations relating to Blood and Blood Products;
  2. Regulations relating to Stem Cell Banks;
  3. Regulations relating to the General Control of Human Bodies, Tissue, Blood, Blood Products and Gametes;
  4. Regulations relating to the Import and Export of Human Tissue, Blood, Blood Cultured Cells, Stem Cells, Embryos, Foetal Tissue, Zygotes and Gametes;
  5. Regulations relating to the Use of Human Biological Material and;
  6. Regulations relating to Tissue Banks.
- Companies Act 71 of 2008
- Health Professions Council of South Africa: Guidelines for Good Practice in the Health Care Professions : General Ethical Guidelines for Health Researchers[5]
- World Medical Association Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects (Version 2013)[6]

DEFINITIONS

- **Biobank:** an organised collection of human biological material (HBM) and associated data from different individuals, which are usually kept for an unlimited period of time, 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.

[5] http://www.hpcsa.co.za

[6] http://www.wma.net/en/20activities/10ethics/10helsinki/

- **Institution:** in the case of donated HBMs is: a hospital; a university; or any other entity authorized by the Minister of Health to store HBMs.

- **Material Transfer Agreement (MTA):** a contract governing the transfer of materials between 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 requirements, regulatory guidelines or policies.

ANNEXURE

Removal of biological material from deceased persons
(ref: 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.

Disposal of unclaimed bodies of deceased persons
(ref: 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 by 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.

Handing over of bodies to certain institutions
(ref: 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.

Bodies to be preserved for certain period before use

(ref: 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.

Human Biological Material Registers
(ref: 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.

Use of stem cells
(ref: 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
   i. is authorised with the Department;
   ii. conducts any activity referred to in (1) (a) or (b), as the case may be, in accordance with the provisions of these regulations;

iii. has obtained informed written consent of the donor even in the case of residual tissue, blood or blood products; and

iv. 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.

Import and Export Permits
(REF: 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. **(ref: 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. **(ref: 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)**