## INTRODUCTION
1. COLLECTIONS OF HUMAN BIOLOGICAL MATERIALS (HBMs)
2. IDENTIFIABILITY OF HBMs
3. STORAGE OF HBMs
4. BIOBANKS
5. INFORMED CONSENT FOR COLLECTION AND STORAGE OF HBMs
6. SECONDARY USE OF HBMs
7. GENETIC RESEARCH ON HBMs
   7.1 Genetic Counseling
8. MATERIAL TRANSFER AGREEMENT
USE OF HUMAN BIOLOGICAL MATERIALS, BIOBANKING, GENETIC TESTING AND MATERIAL TRANSFER

INTRODUCTION

In terms of the National Health Act (ss 55 and 62) human biological material may be removed from living and deceased persons for diagnostic, therapeutic and health research purposes [NHA s 64(1)]. Biological material and data are collected in a variety of ways:

- Specifically for research purposes
- Incidentally to diagnostic or research purposes
- For a combination of purposes, including the intention of possible future research use

1. COLLECTIONS OF HUMAN BIOLOGICAL MATERIALS (HBMs)

HBMs are materials collected from human beings and include, blood, DNA, RNA, blastomeres, polar bodies, cultured cells, embryos, gametes, progenitor stem cells, tissues and growth factors from tissues. Where HBMs are to be used in research, researchers and the committee must be satisfied that the research proposal conforms to the following principles of ethical conduct and the prescribed regulations of the National Health Act 61 of 2003:

- Approval must be obtained from the committee for collecting biological samples for research.
- New approval must be obtained for all research on biological samples not specifically mentioned when approval was originally obtained.
- A full description must be provided of any specimens that will be collected (blood, body fluids and tissue biopsies).
- Plans to obtain consent and clearance from participants and the committee for long-term storage, export and future research must be specified.
- The arrangement for disposal of human tissue must be specified.
- Information about transport and storage arrangements must be supplied, including the period of time for which specimens will be stored.
2. IDENTIFIABILITY OF HBMs

Pharma-Ethics will assess the extent to which HBMs can be used to identify a donor. Materials with direct identifiers can directly identify a donor whereas coded material may identify a donor if security and confidentiality measures are not adequate. Anonymised materials without any linkage to donors are unlikely to identify an individual donor. However, genetic markers may make it possible to identify groups even if the materials are anonymised.

Informed consent documents for the use of HBMs in health research will be carefully scrutinised by the committee to ensure that the proposed approach and its implications are adequately disclosed and explained.

3. STORAGE OF HBMs

If HBMs are to be stored for future analysis, it must be stored at a facility agreed with Pharma-Ethics.

Samples may only be released once the proposal has been approved by Pharma-Ethics.

For sample storage outside South Africa, Pharma-Ethics requires justification from the sponsor why samples cannot be stored in South Africa.

4. BIOBANKS

(Segments taken from the Principles and Policy on Biobanks compiled by the Biobanks Ethics Committee of the University of Witwatersrand HREC)

Biobanks are repositories where organised collections of HBMs and associated data from large number of individuals are collected, stored and distributed for the purpose of health research.

All biobanks associated with research being reviewed by Pharma-Ethics must be approved by Pharma-Ethics and adhere to the following criteria:

- Human rights and freedoms must be respected and the rights and well-being of participants should prevail over the research.
• Information on the scientific rationale underlying the biobank must be provided to Pharma-Ethics.
• Evidence of stakeholder consultation must be provided to Pharma-Ethics.
• Results of research conducted using the biobank’s resources must be made publicly available.
• Communities and Ethics Committees must have access to updated information about the types of research carried out.
• Communities and Ethics Committees must be provided with information about commercial products that may arise from the research using their resources and any benefit they may receive.
• Collection of HBMs and associated data must adhere to the ethical and legal requirements for informed consent.
• The privacy and confidentiality of participants, their families and potentially identifiable populations must be protected and secured.
• The biobank must benefit donor participants and communities and have benefit sharing strategies in place.

5. INFORMED CONSENT FOR COLLECTION AND STORAGE OF HBMs

Written Informed Consent is required prior to removal of biological material from a living donor. In the case of a deceased person, consent for removal or use of biological materials may be provided by ‘the spouse, partner, major child, parent, guardian, major brother or sister’ of that person in the specific order mentioned.

HBMs may be collected for diagnostic, therapeutic or health research purposes and the nature of the planned usage must be explained adequately in the informed consent documents.

The following forms of consent can be used:

• **Narrow (restrictive):** The donor permits use of the biological specimen for single use only; no storage of leftover specimen and no sharing of data or specimen. This form requires new consent if further use is considered.

• **Tiered consent:** The donor provides consent for the primary study and chooses whether to permit storage for future use, sample and data sharing.

• **Broad consent:** The donor permits use of the specimen for current research, for storage and possible future research purposes, even though the precise nature of future research may be unclear at present. The nature of the further
usage should be described as fully as possible and should stipulate that further prior ethics review of the new study is necessary. The consent should be broad enough to allow for future and secondary uses of samples or data but need to be appropriate for the cultural contexts in which the research takes place. BROAD CONSENT WILL NOT BE ALLOWED FOR GENETIC RESEARCH on biological samples since genetic research cannot be completely anonymised from the presence of hereditary elements.

- The sponsor must insert one of the following two statements in the Informed Consent, should permission be required for ‘storage or future testing’:
  - “No future testing will be conducted on your sample without first obtaining approval from Pharma-Ethics Research Ethics Committee”;
  - or
  - “We would like permission to store some of your biological samples but cannot provide details of what will be looked at, as this is not yet known. However, we give assurance that no research will be done on the stored specimens without the approval of Pharm-Ethics Research Ethics Committee.

6. SECONDARY USE OF HBM

Secondary use means that the materials were originally collected for diagnostic or therapeutic purposes and stored for future use. Initial informed consent to obtain the materials would ordinarily not include additional use of the materials for research purposes and in the absence of broad consent to future use of material, the following must be implemented:

- If initial consent for the use of existing or archived material collected does not fall within the scope of the current proposal, new consent must be obtained.
- If samples are anonymous and the results of the research would not place any individual, family or community at social, psychological, legal or economic risk of harm, the new consent is not required.
- If the link to identifiers exists but is not provided to the research team and the results of the research would not place any individual, family or community at social, psychological, legal or economic risk of harm, new consent is not required. The person who holds the code or link should sign an explicit written agreement not to release the identifiers to the research team. The agreement must accompany the REC submission.
7. GENETIC RESEARCH ON HBM{s}

Genetics refer to the study of genes (human DNA), heredity and variation as well as how they affect the inheritance of traits and conditions between generations of people, especially regarding human health disease. Genetic information is not only specific to one individual but reveals a lot about a person’s relatives and ancestors.

In the instances where a proposal for review includes human genetic or pharmacogenetic research on HBM{s}, a sub-protocol or appendix to the main protocol, outlining the objectives and procedures to be followed must be submitted.

The committee will only allow genetic research within the scope of the protocol (study medicine toxicity, metabolism, efficacy and specific disease entity studied within the protocol). **No open-ended genetic research will be approved.**

- The following will be considered:
  - The social and cultural significance of the research.
  - The balance between the contribution of knowledge and the potential for harm to individuals or collectives.
  - The confidentiality and privacy of stored genetic information or research results relating to identified or potentially identified participants.
  - How information revealed by the genetic research will be managed.
  - The availability for genetic counseling, where required.

A separate informed consent for the specific collection of a HBM{s} for pharmacogenetic research must be submitted (Refer to “Participant informed consent for optional pharmacogenetic testing on human biological materials”, template).

This document must contain the following information:

- The genetic research will be limited to the medicine [specify name] and disease or condition [specify name] under investigation.
- No unspecified research will be conducted without prior consent from the participant and approval from the committee.
- The costs of the research will be covered by the sponsor.
- Information on privacy and confidentiality.
• Information on compensation in the event of a trial-related injury.
• If samples are to be exported to a central laboratory outside South Africa, the physical address of this laboratory must be specified.
• The period for which the samples will be stored (a maximum of 15 years).
• In the consent statement, participants must consent to their samples being shipped to a secure laboratory outside South Africa.

7.1 Genetic Counseling

If it is anticipated that participants will receive results from genetic testing, they should be counselled about the possible consequences of doing so. Reference must be made to the counselling in the consent document.

Counselling can be provided at the time of obtaining consent, or in the future, prior to providing feedback, where applicable.

8. MATERIAL TRANSFER AGREEMENT

For all human biological material leaving South Africa for purposes of health research a Material Transfer Agreement (MTA) is required. (See template entitled Material transfer agreement template).

In all cases, there must be reasonable justification for the cross-border transfer or exchange of human biological materials.

The following information must be provided in the MTA:

• The name and physical address of the provider (researcher, sponsor or CRO on behalf of the investigator)
• The name and address of the recipient (international laboratory where the samples will be analysed and stored)
• The purpose for which the samples will be used; the tests that will be conducted on the samples.
• The period for which the samples will be stored and information on the return or destruction of the samples.