BIOLOGICAL MATERIALS, DATABASES, REGISTRIES & REPOSITORIES, OCTOBER 2023, V1

Research Ethics Committee

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1	Developed and published for implementation	October 2023
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1. DEFINITIONS

- **Human Biological Material** means refers to material from a human being, including but not limited to Deoxyribonucleic Acid (DNA), Ribonucleic Acid (RNA), blastomeres, polar bodies, cultured cells, embryos, gametes, progenitor stem cells, tissues and growth factors and any modifications or derivatives thereof.
- **Genetics** - refers to the study of genes (human DNA), heredity and variation as well as how they affect inheritance of traits and conditions between generations of people, especially regarding human health and disease.
- **Genomics research** - refers to the study of all of a person's genes (the genome) and how they interact with each other and with the person's environment.
- **Participant** means the person participating in the clinical trial / study and/or receiving treatment, including receiving blood or blood products, or using a health facility or establishment, as a result of participation in the clinical trial / study. The words **research participant or participant** may be used interchangeably, where applicable.
- **Patient** is defined as a participant with a clinical condition.

2. INTRODUCTION

Human Biological Material - refers to material from a human being, including but not limitedto Deoxyribonucleic Acid (DNA), Ribonucleic Acid (RNA), blastomeres, polar bodies, cultured cells, embryos, gametes, progenitor stem cells, tissues and growth factors and any modifications or derivatives thereof.

According to the National Health Act 2003 Regulation Relating to the Use of Human Biological Materials, Section 2 which deals with the Removal of Human Biological Material states

(b): Biological material for genetic testing, genetic training, genetic health research or therapeutic purposes may only be removed in -

(i) an authorised institution;

(ii) prescribed institution; and

(iii) a research institution prescribed in terms of the National Heritage Resources Act, 1999 (Act No. 25 of 1999}, for ancestry analysis.

3. BIOLOGICAL MATERIALS

3.1. Collection of biological materials and data

Biological materials and data are collected in a variety of ways namely:

- specifically for research purposes;
- incidentally to diagnostic or therapeutic procedures; and
- for a combination of purposes, including the intention of possible future research use.

The Regulations permit for the collection of biological materials from both living and deceased donors provided that ethical approval and informed consent has been obtained.

Biological material data may be used secondarily. Secondary use means use in research of materials or data originally collected for other purposes. In such instances, a written agreement must be established to ensure that researchers do not receive identifiers.

3.2. Genetic/ genomic research

Genetics - refers to the study of genes (human DNA), heredity and variation as well as how they affect inheritance of traits and conditions between generations of people, especially regarding human health and disease.

Genomics research - refers to the study of all of a person's genes (the genome) and how they interact with each other and with the person's environment.

When conducting genetic/genomic research, special consideration will be given to the following:

- The social value of the proposed research.
- The effect of the research on families, communities and other groups including stigmatisation or discrimination.
- The effect of the findings on the individual when data or samples are identifiable.

Potential social, psychological, legal, or economic risks that a study may pose on a participant, his family, or his community.

3.3. Research using commercially available cell lines

Biosafety and ethical issues may arise from use of commercially available cell lines depending on the nature of the planned research work. For example, if cells are to be infected, biosafety and hence also ethical issues, arise for researchers rather than participants. If cells will undergo genetic modification, there may also be ethical implications.

Whether Research Ethics Committee (REC) review is required, depends on whether institutions have properly functioning Research Review and Biosafety infrastructures. Where these do not yet exist, RECs should be part of the process to ensure biosafety and ethical standards are maintained.

> ***Note*** *that 'blanket approval' for use of commercially available cell lines is not permitted. At minimum, a researcher is expected to liaise with the REC about the biosafety and ethical implications of the planned work. RECs should draw up a SOP and query template to assist establishing the implications.*

3.4. Informed consent

Prior to collecting any biological material, informed consent is required. The collection of consent will must be distinguished between living and deceased donors.

- In living donors, consent must be obtained from the donor or in some cases (i.e., minors or mentally ill persons), Ministerial permission is required.

- In deceased donors however, consent must be obtained from the deceased's Will or from the spouse, partner, major child, parent, guardian, major brother, or major sister of that person (donor) in the specific order mentioned.

There are different forms of consent:

Narrow consent	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 necessitates new consent if further use is desirable.
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. Permission may be sought to re-contact the person if intended future use is outside the scope of the current consent

In research using secondary biological material data new informed consent is required if the scope of the new research is outside of that which the original consent. New consent is however not required if the samples/data are anonymous, or the research team does not have access to identifying data and the result place no social, psychological, legal, or economic risk on the individual, family, or community.

3.5. Ethical Considerations/ SAMAREC Considerations

Prior to the collection of biological materials, ethical clearance is required. Submissions to SAMAREC must detail the following:

- A detailed description of the biological material including the purpose for collecting it.
- An overview of the process of collecting the biological material including who will remove the biological material.
- A detailed description of the informed consent process including who will provide consent.
- A detailed description of how biological material and data will be managed including how privacy and confidentiality will be upheld.
- How biological materials will be stored, transported, and disposed. (Please refer to the SAMAREC SOP Annextures for the Material Transfer Agreement).
- In the case of secondary usage, a written agreement between the researchers and person/s who hold the link to the identifying data.

4. DATABASES, REGISTIRES AND REPOSITORIES

Databases, registries, and repositories are a valuable research resource that allows researchers to pursue questions that were not anticipated at the time of collection of either data or material.

Noted, Accepted and Approved

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Database	a collection of information including images (data) arranged to facilitate swift search and retrieval. It may be electronic, or paper based
Registry	a collection of information (data) from multiple sources, maintained over time with controlled access through a gatekeeper organizer.
Repository	a collection, storage, and distribution system for human biological materials for research purposes including blood, urine, faeces, bone marrow, cell aspirates, diagnostic specimens, pathology specimens and so on. Usually demographic and medical information about the donors is included in the repository as are codes that link the material to the donors.

Databases, registries, and repositories should maintain the appropriate facilities as well as policies and procedures to ensure the safe storage of information. All databases, registries and repositories used for research should have prospective ethical approval.

5. REFERENCES

National Health Research Ethics Council (2024) ***South African Ethics in Health Research Guidelines: Principles, Processes and Structures***, 3rd ed. National Department of Health of the Republic of South Africa. Pretoria: NDoH. 137p. ISBN 978-0-621-52027-9.

Approved by:

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SAMAREC Chairperson

25 October 2023

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Signed: 10 October 2024