UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

HUMAN RESEARCH ETHICS COMMITTEE: (MEDICAL)

STANDARD OPERATING PROCEDURE

TRANSPORT, STORAGE AND FUTURE RESEARCH

SOP-HREC-012*(VERSION 1)* **REVISED AND UPDATED: MAY 2025**

SUBJECT	**Policy regarding Wits HREC (Medical):** ♦ **Transport, Storage and Future Research on human biospecimens for future laboratory research, including genetic testing**
DIVISION / SCOPE:	**University of the Witwatersrand, Johannesburg Human Research Ethics Committee: (Medical)**
REVISION:	Ethics Secretariat
PURPOSE:	This statement aims to provide current policy regarding the transport and storage of human biospecimens for future laboratory research, including genetic testing, which may be related to the original study protocol, or future unrelated research studies.
PREVIOUS VERSIONS / ***(REASON FOR REVISION)***	SOP-IEC-012 v9 - Revised
CONTENTS:	1. Policy Statement 2. Collection of human biospecimens 3. Wits HREC (Medical) requirements 4. Transport and storage of human biospecimens in South Africa 5. Transport and storage of human biospecimens outside South Africa 6. Histological and biomarker diagnostic specimens 7. Capacity building in South Africa 8. Consent for retention of stored human biospecimens 9. Tracking of biospecimens 10. Request to increase tests on stored biospecimens Definitions and Abbreviations References Attachments
APPROVALS:	**Signature of Chair / Co-Chair of Wits HREC (Medical)** Paul Ruff **Date:** 2025/05/07

STANDARD OPERATING PROCEDURE

TRANSPORT, STORAGE AND FUTURE RESEARCH

SOP-HREC-012*(VERSION 1)* **REVISED AND UPDATED: MAY 2025**

1. Policy Statement

This statement aims to provide current policy regarding the collection, transport and storage of human biospecimens for future laboratory research, including genetic testing which may be related to the original study protocol, or future unrelated research studies.

2. Collection of Human Biospecimens

When human biospecimens are collected from research participants, the research participant will be made aware that no future testing, beyond the overall scope of the original study may be undertaken, unless the research participant specifically consents to future research using the biospecimen.

Participants may consent to the use of their biospecimens in future studies but only on the basis that the Wits HREC (Medical) will approve the research on a project specific basis.

The HREC (medical) will approve the use of these biospecimens for future research provided that the interests of the participants are protected and that the research is in the public interest.

The participants may also consent to storage of their biospecimens in a Biobank inside or outside of South Africa, with the approval of the Biobank Ethics Committee (BEC) of the Wits HREC (Medical).

3. Wits HREC (Medical) Requirements

Any applicant that applies to the Wits HREC (Medical) for purposes of conducting research on human biospecimens must:

- Identify which human biospecimens will be used for the study
- Explain the research which will be done on the human biospecimens
- Explain the transport and storage arrangements for the biospecimens including the period of time for which the biospecimens will be stored
- Demonstrate that the transport and storage arrangements conform with the terms of the informed consent agreed to by the participant
- Demonstrate that the interests of participants will be protected by the researchers
- Demonstrate that the research is in the public interest
- The Wits Human Research Ethics Committee (Medical) must approve future research which is not related to the original study

- There are three potential scenarios which should be explained to participants in the Participant Information Leaflet and Informed Consent Form (PIL/ICON):

Scenario 1: Participant consents to research on samples/data in the current study/protocol only. No future testing beyond the scope of the study/protocol will be done. This requires no further approval by the Wits HREC (Medical).

The Wits HREC (Medical) recommends that the Applicant / Investigator / Sponsor insert the following statement into the Main PIL/ICON:
"I give permission for my sample to be used in the current study only. I understand that no future testing will be done on my sample, beyond the scope of this study."

Scenario 2: Participant consents to research on samples/data for the current study/protocol, and also stored for future studies that are within the broad scope of the disease(s) being studied. Wits HREC (Medical) must approve these future studies.

The Wits HREC (Medical) recommends that the Applicant / Investigator / Sponsor insert a statement to this effect into the Main PIL/ICON:
"I give permission for my sample to be used for the current study, and also to be stored for future studies related to the disease/research area of this study. I understand that permission will be required for such future analysis, and approval for these future studies must be obtained from the Wits HREC (Medical)."

Scenario 3a) Participant consents to ***non-genetic*** *research* on samples/data for as yet 'ill-defined' future analysis not related to the current study/protocol/scope of the disease(s), but in the public's best interest. Wits HREC (Medical) must approve these future studies.

The Wits HREC (Medical) recommends that the Applicant / Investigator / Sponsor insert a statement to this effect, should permission be required for as yet 'ill-defined' future analysis, e.g. unrelated disease(s)

"I give permission to use my sample/s for the current study, and also to be stored for future studies, possibly unrelated to the disease/research question of this study, but ***not*** *including genetic studies. This future research may look at other conditions or biological processes not related to disease xxx, but will seek knowledge that is in the public's best interests. I understand that should permission be required for either defined or as-yet-undefined future analysis, ethics approval for this next study will be sought from the Wits HREC (Medical). The Wits HREC (Medical) will ensure that my interests are taken into consideration and the security of my biospecimen is protected."*

- OR

Scenario 3b) Participant consents to ***genetic research*** on samples/data for as yet 'ill-defined' future analysis not related to the current study/protocol/scope of the disease(s), but in the public's best interest. Wits HREC (Medical) must approve these future studies. In this case, the participant must have been clearly informed around genetic testing (present and future) in the PIL.

The Wits HREC (Medical) recommends that the Applicant / Investigator / Sponsor insert a statement to this effect, should permission be required for as yet 'ill-defined' future analysis, e.g. unrelated disease(s)

"I give permission to use my sample/s for the current study, and also to be stored for future studies, including genetic studies, possibly unrelated to the disease/research question of this study. This future research may look at other conditions or biological processes not related to disease xxx, but will seek knowledge that is in the public's best interests. I understand that should permission be required for either defined or as-yet-undefined future analysis, ethics approval for this next study will be sought from the Wits HREC (Medical). The Wits HREC (Medical) will ensure that my interests are taken into consideration and the security of my biospecimen is protected."

4. Transport And Storage Of Human Biospecimens In South Africa

If human biospecimens are to be stored for future analysis and it is planned that such analysis will be done outside of Wits, then the biospecimens must be stored at a facility in South Africa agreed with the relevant REC(s). Samples may only be released once projects have been approved by the local REC(s) applicable to where the analysis will be done, as well as by the Wits Human Research Ethics Committee: (Medical). In addition, an MTA will be required for release of samples.

5. Transport And Storage Of Human Biospecimen Outside South Africa

If human biospecimens are to be stored for future analysis, and it is planned that such analysis is done outside South Africa, it is recommended that the biospecimens are also stored at a facility in South Africa. The HREC must approve the storage at this facility and the release of samples, together with the Material Transfer Agreement to facilities outside the country. The approval must be protocol specific. Where storage is intended to be at a facility outside South Africa, motivation for such storage, together with comprehensive information on the storage facility and the Material Transfer Agreement (MTA) must be submitted.

6. Histological and Biomarker Diagnostic Specimens

Should a study require a portion or slides of histological and/or biomarker diagnostic specimens to be sent away for testing, the anatomical pathologist who has custody of the specimen block must agree to this in writing. In addition, any such specimens from the National Health Laboratory Services (NHLS) require approval from the Academic Affairs and Research Management System (AARMS).

7. Capacity Building in South Africa

To encourage capacity building in biomedical research in South Africa, applications for storage of biospecimens outside of South Africa need to be justified to the Wits HREC (Medical).

8. Consent for Retention of Stored Human Biospecimens from Participants who Withdraw from a Study

Biospecimens from participants who withdraw completely from a study must be destroyed, although any data collected prior to the date of withdrawal can be retained*.
In exceptional circumstances biospecimens may be retained on participants withdrawing from a study but only if they give specific written consent for this to happen.

*Note that withdrawal of study consent is prospective from the date of withdrawal, and cannot be retrospective.

9. Tracking of Biospecimens

It is the responsibility of the Site/Investigator and Applicant/Sponsor must ensure that all biospecimens are appropriately tracked as to not fall into unauthorised and potentially unscrupulous hands. Any such concerns should be brought to the attention of the Biobank Ethics Committee (BEC), as well as the Wits HREC (Medical).

10. Request to Increase Tests on Stored Biospecimens

Where the Sponsor/Applicant/Investigator want to do additional study related tests on biospecimens already approved for storage, this will be done through a study amendment. A standard application form (Amendment Application Form) which lists the additional tests to be done, is to be submitted. Unrelated research testing will require a full Wits HREC (Medical) approval.

Definitions and Abbreviations

AARMS	Academic Affairs and Research Management System (AARMS)
BEC	Biobank Ethics Committee
Clinical Investigation	Means any investigation that involves a test article and one or more human participants. The terms "research", "clinical research", clinical study", clinical trial" and "clinical investigation" are considered synonymous for Wits HREC (Medical) policies and procedures.
FDA	Food and Drug Administration (USA)
GCP	Good Clinical Practice
HREC	Human Research Ethics Committee
MTA	Material Transfer Agreement
NHLS	National Health Laboratory Services
ICH	International Council for Harmonisation
SAGCP	South African Good Clinical Practice: Clinical Trial Guidelines. Third Edition (SA GCP 2020)
SOP	Standard Operating Procedure
NHREC	National Health Research Ethics Council (2024) South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 3rd Edition
SAHPRA	South African Health Products Regulatory Authority
WHC	Wits Health Consortium
WITS	University of the Witwatersrand

References

- FDA Guidelines – OHRP (Office of the Human Rights Protection, applicable FDA requirements for Institutional Review Boards
  - http://www.hhs.gov/ohrp/policy/
- ICH GCP E6(R3) 06 January 2025
- Declaration of Helsinki 2024
  - WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Participants – WMA – The World Medical Association
- Department of Health, 2020. South African Good Clinical Practice: Clinical Trial Guidelines. Third Edition (SA GCP 2020)
- National Health Research Ethics Council (2024) South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 3rd Edition
- 21 Code of Federal Regulations Part 56 – Institutional Review Boards
- 21 Code of Federal Regulations Part 50 – Protection of Human Participants
- National Health Act No: 61 of 2003, Regulation No. R.180 of 2nd of March 2012

Attachments:

1. Amendment Application Form – Template
2. HREC Material Transfer Agreement