UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

WITS HUMAN RESEARCH ETHICS COMMITTEE: (MEDICAL) (WITS INDEPENDENT ETHICS COMMITTEE)

POLICY

SOP-IEC -012*(VERSION 9)* **REVIEWED: JANUARY 2023**

SUBJECT	**Policy regarding WITS IEC:** ♦ **Transport and Storage of Blood Samples/Specimens;** ♦ **Tissue Samples and** ♦ **Genetic Testing**
DIVISION / SCOPE:	**Wits Human Research Ethics Committee: (Medical) (Wits Independent Ethics Committee)**
REVISION:	IEC Secretariat
PURPOSE:	This statement aims to provide current policy regarding approval and/or non-approval of the transport and Storage of Blood Samples / Specimens, Tissue Samples and Genetic testing, with regard to clinical trials to be conducted and requiring the Wits Human Research Ethics Committee approval at Wits Medical Facilities and/or Private Institutions
PREVIOUS VERSIONS / *(REASON FOR REVISION)*	SOP-IEC-012 v1 - 8 Updated Guidelines: Department of Health, 2020. South African Good Clinical Practice: Clinical Trial Guidelines. Third Edition (SA GCP 2020)
CONTENT: **ATTACHEMENTS:**	**INDEX** **DEFINITIONS AND ABBREVIATION** **2. REFERENCES** ♦ FDA Guidelines – OHRP (Office of the Human Rights Protection ♦ ICH GCP guidelines ♦ Declaration of Helsinki 2013 ♦ Department of Health, 2020. South African Good Clinical Practice: Clinical Trial Guidelines. Third Edition (SA GCP 2020) ♦ Ethics in Health Research: Principles, Processes and Structures, Department of Health 2015, Second Edition ♦ National Health Act No: 61 of 2003 **3. OVERALL POLICY STATEMENT** 3.1 Transport and Storage of Blood Samples 3.2 Avoid Delays in the Approval Process 3.3 Transport and Storage of Blood and Tissue Samples in South Africa 3.4 Transport and Storage of Blood and Tissue Samples Outside South Africa 3.5 Histological Diagnostic Specimens 3.6 Genetic Testing 3.7 Capacity Building in South Africa 3.8 Restriction on the Storage of Samples 3.9 Consent for retention of stored samples from participants who withdraw from a study **POST SCRIPT** **EXTRACT FROM HREC MINUTES** Attachments: 1 Material Transfer Guidelines 2 Materials Transfer Agreement – Template 3 National Health Act No: 61 of 2003 4 Letter for circulation on Storage of Blood and Genetic Testing
APPROVALS:	**Signature of Chairperson / Deputy Chairperson of IEC:** **Date:** *Prof C Penny / Dr N Naran*

1. Definitions and Abbreviations

ADR	Adverse Drug Reaction
CFR	Code of Federal Regulations (USA)
Clinical Investigation	Means any experiment 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 IEC policies and procedures.
FDA	Food and Drug Administration (USA)
GCP	Good Clinical Practices
ICH	International Council for Harmonisation
IRB	Institutional Review Boards (USA term for IEC)
IEC	Independent Ethics Committee (ICH GCP term)
SAGCP	Department of Health, 2020. South African Good Clinical Practice: Clinical Trial Guidelines. Third Edition (SA GCP 2020)
SAHPRA	South African Health Products Regulatory Authority
REC	Research Ethics Committee
SAE's	Serious Adverse Events
SOPs	Standard Operating Procedures
WHC	Wits Health Consortium
WITS	Witwatersrand

2. References

- FDA Guidelines – OHRP (Office of the Human Rights Protection, applicable FDA requirements for Institutional Review Boards
  - http://www.hhs.gov/ohrp/policy/
- ICH Harmonised Guideline – Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH – E6(R2) – Current Step 4 version dated 9 November 2016
- Declaration of Helsinki 2013
  - http://www.wma.net/en/30publications/10policies/b3/index.html
- Department of Health, 2020. South African Good Clinical Practice: Clinical Trial Guidelines. Third Edition (SA GCP 2020)
- Ethics in Health Research: Principles, Processes and Structures, Department of Health 2015, Second Edition'
- 21 Code of Federal Regulations Part 56 – Institutional Review Boards
- 21 Code of Federal Regulations Part 50 – Protection of Human Participants
- MRC Guidelines on Ethics for Medical Research, Revised Edition, 1993
- National Health Act No: 61 of 2003

3. Overall Policy Statement

3.1 Transport and Storage Of Blood Samples/Specimens And Genetic Testing

It has been noted that numerous studies and amendment documents submitted for Wits Human Research Ethics Committee approval contain genetic research, biomarker studies, transport and the storage of blood. We request your attention to the items listed below that have been and will be included in every approval letter.

3.2 Avoid Any Unnecessary Delays In The Approval Process

Attention be made to all documentation containing any of the items below

- Identify what the specimens will be used for (BE SPECIFIC)
- Be explicit about transport and storage arrangements
- For what period of time will the specimens be stored
- Confirmation that no open ended genetic testing to be clearly indicated
- Separate consent for specimen storage

Future submissions and amendment documentation containing any of the items listed below would unfortunately delay the approval of your documentation following these decisions, also made at the Academic Ethics Chairs Meeting.

The Wits Human Research Ethics Committee's decisions on transport / storage of blood and genetic testing:
(Meetings Dated – 27 February 2004; 26 March 2004), and included in **all** Ethics Approval Letters.

3.3 Transport and Storage of Blood and Tissue Samples in South Africa:

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

3.4 Transport and Storage of Blood and Tissue Samples Outside South Africa:

If blood and specimens are to be stored for future analysis, and it is planned that such analysis is done outside South Africa, it is strongly recommended that the blood and tissues are stored at a facility in SA. 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 SA, motivation for such storage, together with comprehensive information on the storage facility and the Material Transfer Agreement must be submitted to the HREC.

3.5 Histological Diagnostic Specimens

Should a study require a portion or slides of histological diagnostic specimens to be sent away for testing, the anatomical pathologist who has custody of the specimen block must agree to this in writing.

3.6 Genetic Testing

The Wits Human Research Ethics Committee: Medical; will not approve open-ended genetic testing as this does not fit the Human Research Ethics Committee criteria.

3.7 Capacity Building in South Africa

For many years Sponsors have insisted that research specimens must be stored outside South Africa. The time has come to include an element of capacity building for South African researchers in testing specimens. The Wits HREC expects clarification of a sponsor’s view of this principle for each application involving specimen storage outside South Africa.

3.8 Restriction on the Storage Of Samples:

There are two possible scenarios with regards to Sample Storage if approved by Wits HREC:

Scenario One:
The Human Research Ethics Committee's recommends that the Sponsor insert the following suggested statement / paragraph into the Informed Consents should permission be required for **'storage or future testing':**

1. Consent Forms are required to include a statement that confirms that no future testing will be done without approval of the University of the Witwatersrand Human Research Ethics Committee: (Medical).

Scenario Two:
Restriction on the Storage of Samples.
The Human Research Ethics Committee's recommends that the Sponsor insert the following suggested statement / paragraph into the Informed Consents should permission be required for as yet **'ill-defined analysis':**

2. 'We would like permission to store samples, at the moment we cannot provide details of what will be looked at, as this is not yet known, but we give assurance that no research will be done on the specimens from Wits Entities without the approval of the Wits Human Research Ethics Committee as well as the applicable Research Ethics Committees (REC) at the analysis sites'

3.9 Consent for retention of stored samples from participants who withdraw from a study

Participants who withdraw from a study may give written consent, or not, for their specimens to be retained for future research.

POSTSCRIPT:
Ref: IRB Details – www.witshealth.co.za –Select Ethics (top left) Doc 170 Item 6.
The Wits Human Research Ethics Committee is registered as an institutional review board (IRB) with the Office for Human Research Protections (OHRP) of the USA Dept of Health and Human Services;

- ***IRB Organisation Identifier:*** ***IRB000011223***
- ***The W HREC unique Federal Assurance Number is*** ***FWA00000715***
- ***The unique Organisation Number is*** ***IORG0000862***

EXTRACT FROM MINUTES HELD BY THE
HUMAN RESEARCH ETHICS COMMITTEE MEETING
HELD ON 10 SEPTEMBER 2004

Venue: PPS Boardroom, Faculty of Health Sciences, Medical School,
University of the Witwatersrand

'The Academic Ethics Chairs will not allow storage of specimens for ill-defined purposes. The word polymorphism is very broad and cannot be used as a term to define specific genetic use. National Health Act regulations state that tissues may not be exported without a license.

It was agreed that it is acceptable to store tissues within professional laboratories at each institution. Specimens for blood banks though may not require consent if the agreement to donate includes agreement to unused blood being used for research anonymously.

At the local blood bank there is a form signed by people to give consent for leftover blood to be used for research. It was suggested that should samples be required to be sent outside the country, an official certificate should be signed stating they will not be used for future research.'

ATTACHMENTS:

1. Material Transfer Guidelines
2. Materials Transfer Agreement – Template
3. National Health Act No: 61 of 2003
4. Letter for circulation on Storage of Blood and Genetic Testing