UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

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

## POLICY

**SOP-IEC -012** *(VERSION 6)* **REVIEWED: JANUARY 2023**

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| **SUBJECT** | **Policy regarding WITS IEC:**<br>♦ **Request to add additional tests on stored biological specimens** |
| **DIVISION / SCOPE:** | **Wits Human Research Ethics Committee: (Medical) (Wits Independent Ethics Committee)** |
| **REVISION:** | IEC Secretariat |
| **PURPOSE:** | This statement aims to provide policy regarding approval and/or non-approval of request to add additional tests on stored biological specimens. Applies to specimens already approved for storage. It is an expedited review process by the Chair(s) |
| **PREVIOUS VERSIONS / *(REASON FOR REVISION)*** | **SOP-IEC-012v5**<br>Updated Guidelines: Department of Health, 2020. South African Good Clinical Practice: Clinical Trial Guidelines. Third Edition (SA GCP 2020) |
| **CONTENT:**<br><br>**ATTACHEMENTS:** | **1. INDEX**<br>**DEFINITIONS AND ABBREVIATION** **2**<br>**2. REFERENCES**<br>♦ FDA Guidelines – OHRP (Office of the Human Rights Protection<br>♦ ICH GCP guidelines<br>♦ Declaration of Helsinki 2013<br>♦ Department of Health, 2020. South African Good Clinical Practice: Clinical Trial Guidelines. Third Edition (SA GCP 2020) **2**<br>♦ Ethics in Health Research: Principles, Processes and Structures, Department of Health 2015, Second Edition<br>♦ National Health Act No: 61 of 2003<br>**3. OVERALL POLICY STATEMENT**<br>3.1 Request to add additional tests on stored biological specimens **2**<br>3.2 Requirements for Approval of Storage Amendment **2**<br>**POST SCRIPT** **3**<br>**EXTRACT FROM HREC MINUTES**<br><br>Attachments:<br>1 Storage Amendment Application Form - Template |
| **APPROVALS:** | **Signature of Chairperson / Deputy Chairperson of IEC:** **Date:**<br>*Prof C Penny / Dr N Naran* |

## 1. Definitions and Abbreviations

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|---|---|
| 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 |
| 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 Request to increase tests on stored biological specimens

This SOP is for additional tests on stored specimens. Applies to specimens already approved for storage. It is an expedited review process by the Chair(s). A standard application form (Amendment Application Form) which lists the tests to be done, to be submitted along with a letter of motivation.

### 3.2 Requirements for Approval of Storage Amendment

- Complete Storage Amendment Application form
- Identify tests to be done on stored specimens
- Provide a letter of motivational

**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 29 JULY 2011***

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

*A committee member appealed to the committee that the current restrictions being placed on the way the committee is approving the use of samples for future as yet unspecified testing is placing collaborations at risk.*

*The following was suggested at the meeting:*
*- An SOP and standard/template application form for additional tests on stored specimens be created. Applies to specimens already approved for storage. It will be an expedited review process by the Chair(s). A standard application form which lists the tests to be done to be submitted along with a motivation.*

**ATTACHMENTS:**

1. Storage Amendment Application Form – Template