

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



POLICY

SOP-IEC -012(VERSION 2)

IMPLEMENTATION DATE: JANUARY 2010

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| SUBJECT | Policy regarding WITS IEC: <ul style="list-style-type: none"> ◆ 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) | Version 1. Nov 2008 Administrative changes and updates |
| CONTENT: | INDEX DEFINITIONS AND ABBREVIATION 2 2. REFERENCES <ul style="list-style-type: none"> ◆ FDA Guidelines – OHRP (Office of the Human Rights Protection) ◆ ICH GCP guidelines 2 ◆ Declaration of Helsinki 2008 ◆ SA GCP Guidelines 2006 Second Edition ◆ National Health Act No: 61 of 2003 3. OVERALL POLICY STATEMENT 2 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 3 3.4 Genetic Testing 4 3.5 Storage of Specimens 3.6 Restriction on the Storage Of Samples |
| ATTACHEMENTS: | POST SCRIPT 3 EXTRACT FROM HREC MINUTES 4 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: <i>Prof P Cleaton-Jones / Prof M Vorster</i> Date: |



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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 Conference on Harmonisation |
| IRB | Institutional Review Boards (USA term for IEC) |
| IEC | Independent Ethics Committee (ICH GCP term) |
| SAGCP | Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa (2006) |
| MCC | Medicine Control Council (RSA) |
| 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/>
- ◆ International Conference on Harmonisation (ICH) Good Clinical Practices (GCP) Guideline (October 2008)
 - Declaration of Helsinki 2008
 - <http://www.wma.net/e/ethicsunit/helsinki.htm>
 - <http://www.wma.net/e/policy/b3.htm>
- ◆ South African Guidelines for Good Clinical Practice Guidelines 2006 Second Edition
 - http://www.doh.gov.za/docs/policy/trials/trials_02.html
- ◆ 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.



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- 3.3 Transport and Storage of Blood and Tissue Samples in South Africa:**
If blood specimens are to be stored for future analysis and 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 IRB, with release of sub-samples only once projects have been approved by the local Research Ethics Committee applicable to where the analysis will be done as well as by the Wits Human Research Ethics Committee: (Medical).
- 3.3 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.
- 3.5 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.
- 3.6 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'

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
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**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

