

Ethics clearance procedure for research in the Faculty of Health Sciences 2013

- The Human Research Ethics Committee (Medical) is the committee to deal with. Wits policy is outlined on the Wits website (www.wits.ac.za under research resources). In brief ethics clearance is required for all health related research involving humans:
 - By Wits students, staff or affiliated staff
 - In the name of Wits, using Wits resources or property
- The research includes
 - Therapeutic or diagnostic research with patients
 - Research with healthy people
 - Physical research, questionnaires or examination of records

All studies involving human participants in any way require a full application x 25 copies (see requirements at www.wits.ac.za under research resources). No research may begin before ethics clearance, no retrospective approval for research already done is ever granted. Applications and amendments are in hard copy submitted to the ethics secretariat in the Wits Research Office (Medical School 011-717-2700 or Senate House East Campus 011-717-1252)

There are some circumstances in which the usual full application and approval method is simplified:

Case study

For presentation either as oral / poster or write-up for publication (normally not more than 5 cases; more require a full application):

- Two completed application forms with a covering letter indicating that no identifying details will be used particularly when using photographs.
- If a patient is lost to follow up there no need for consent but if the patient in the case study is still coming for medical care signed informed consent is required.

A waiver from ethics approval may be granted under the following circumstances:

For an *in vitro* laboratory study for non-degree purposes:

- (if applicable) and head of department (or designated deputy) indicating what will be done (e.g. use of cell lines, bacterial cultures, or whatever) will be used and confirming that no humans, human data or human tissues will be used.

For an *in vitro* laboratory study for MSc or PhD students, not part of a project that already has ethics approval:

- A motivation letter, signed by the applicant and research supervisor. Two completed application forms signed by the applicant, research supervisor and head of department (or designated deputy) indicating what will be done (e.g. use of cell lines, bacterial cultures, or whatever) and confirming that no humans, human data or human tissues will be used plus two protocol copies.

For an *in vitro* laboratory study for MSc or PhD students within a bigger study for which an ethics waiver has already been obtained by a principal investigator:

- A motivation letter, signed by the applicant, research supervisor and PI of the approved study. Two completed application forms signed by the applicant, research supervisor, head of department (or designated deputy) and principal investigator (who has the ethics clearance) indicating what will be done (e.g. use of cell lines, bacterial cultures, or whatever) and confirming that no humans, human data or human tissues will be used plus two protocol copies.

For an *in vitro* laboratory study for MSc or PhD students within a bigger study for which an ethics waiver has already been obtained by a principal investigator and which has stored human specimens:

- A motivation letter, signed by the applicant, research supervisor and PI of the approved study. Two complete application forms signed by the applicant, research supervisor, head of department (or designated deputy) and principal investigator (who has the ethics clearance) indicating what will be done, what human specimens are stored (with human participant consent) and confirming that no new specimens will be collected plus two protocol copies.

Sub-study processes in already approved projects above do not cover:

1. Studies where new data will be collected
2. Studies where new specimens will be collected
3. Studies where there is any use of human data e.g. secondary data analysis

For these situations a full application plus 25 copies (as per new study) is required.

Also, if an application for a waiver is not considered suitable for a waiver, a full application will be required.

RETROSPECTIVE ETHICS APPROVAL – I.E. AFTER DATA COLLECTION HAS ALREADY STARTED, WILL NOT BE GIVEN UNDER ANY CIRCUMSTANCES.

This includes the situation where an ethics application is submitted, changes are requested and those changes are not submitted to the ethics committee so final approval is not given.