**Ethics Clearance Procedures for Medical Research at the University of the Witwatersrand**

# INTRODUCTION

The Human Research Ethics (Medical) Committee (HREC (Med)) is an independent committee within Wits structures, which is registered with the National Health Research Ethics Council (NHREC) of the South African Department of Health. One of the primary purposes of the HREC (Med) is to assess applications in which medical research on human participants is proposed against accepted national and international standards.

HREC (Med) clearance is required before any medical or health-related research study involving human participants can begin. The HREC (Med) will not entertain any application involving human participants in respect of a study which has already begun. Clearance is required whether the research is conducted by Wits students, staff members, or any other persons using Wits resources or Wits staff or students as the participants. Applications for studies being conducted by Wits staff or students, or those of any other public university in South Africa will be processed free of charge. Applicants who are entirely external to this cohort will be charged a fee, details of which may be obtained from the Medical Ethics Office. Under the jurisdiction of the HREC (Med) is all research related to (a) therapeutic or diagnostic work involving patients who may or may not be ill at the time, (b) human tissue, genetic material, fluids, or organs, (c) human cadavers, (d) questionnaires related to therapeutic or diagnostic work and other medically related subjects and (e) examination of patient records.

Any study which proposes to involve Wits staff or students must also be cleared by the university’s Deputy Registrar (Nicoleen.Potgieter@wits.ac.za ), after ethical clearance is granted, before it may begin.

# PROCESS TO REQUEST ETHICAL CLEARANCE

Apart from the study types listed below under the heading *Exceptions*, Principal Investigators (PIs) should apply for ethics clearance using the online system at <http://www.witsethics.co.za/login.aspx>. Meetings are held monthly (January to November), usually on the last Friday of the month and the closing date for applications is usually the 7th day of that month. Applications received after that date will be held over to the following month. Closing and meeting dates are listed at <https://www.wits.ac.za/research/researcher-support/research-ethics/ethics-committees/> - select the HREC (Medical) option, under “Downloads”. The Medical Ethics Office endeavours to provide feedback to applicants within 28 working days of the meeting. Applicants normally have up to 3 months to respond to the feedback.

# EXCEPTIONS

Studies fitting the descriptions below are not catered for on the online system and applications may be lodged by bringing or sending 1 hard copy of the application into the Medical Ethics Office, which is located on the 3rd Floor of the PV Tobias Building (corner of St Andrews and York Roads in Parktown). The Medical Ethics Office endeavours to provide feedback to applicants within two weeks of receipt.

Standard exceptions to the online process include waivers, sub-studies, case reports and lab studies, each of which has its own application, which may be downloaded from <https://www.wits.ac.za/research/researcher-support/research-ethics/ethics-committees/>

# POST-CLEARANCE STUDY AMENDMENTS

The range of study amendments and reasons for them is considerable and thus there can be no “one-size-fits-all” application form.

A letter (1 copy) with appropriate supporting documentation should be submitted to the Medical Ethics Office. A further copy of the study protocol would only be required if the amendments are extensive and difficult to comprehend out of this context. If the applicant is a student, it often helps to have evidence of supervisor support.

--oo0oo--