

***HREC (MEDICAL) Application form for 2023***

***UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG***

***APPLICATION TO THE HUMAN RESEARCH ETHICS COMMITTEE: (MEDICAL) FOR CLEARANCE OF RESEARCH***

***Please read the APPENDIX section at the end of this application form before completing this application form. Also please note that no data may be collected before issue of an ethics clearance. In no circumstance will ethics clearance be issued retrospectively***.

* Category 1 and 2 applications (see below) are subject to monthly closing dates, which may be viewed at <https://www.wits.ac.za/research/researcher-support/research-ethics/ethics-committees/>, chose HREC (Med), see “Downloads”
* Categories 1 and 2 are submitted online at <https://www.witsethics.co.za/Login.aspx>
* Categories 3, 4 and 5 below are not yet online and one completed hard copy of this form may be submitted to the Ethics Office at any time
* Category 6 is not yet online and one completed hard copy of the form referenced below may be submitted to the Ethics Office at any time

Please *complete ALL sections of this application form; the Committee needs the information to make a decision. If this is not done, clearance is unlikely - you may have to resubmit a fully completed**application.*

**Categories** (please tick the applicable one)**:**

1. New Application:

2. Resubmission – state protocol no.

3. Case Report

4. Sub-study

5. Lab study

6. Waivers – not this form. Please refer to <https://www.wits.ac.za/research/researcher-support/research-ethics/ethics-committees/> chose HREC (Med), see “Downloads”

**SECTION 1**

**PRINCIPAL INVESTIGATOR/S**

**TITLE:** (Prof/Dr/Mr/Mrs/Miss/Ms/Other) **FIRST NAME:** **SURNAME**:

**WITS STAFF NUMBER:**

**WITS STUDENT NUMBER:**

**PROFESSIONAL STATUS, OR STUDENT YEAR OF STUDY AND DEGREE:**

**UNIVERSITY SCHOOL/ DEPARTMENT/DIVISION:**

**NON-WITS SITE/ INSTITUTION:**

**WHERE THE RESEARCH WILL BE CARRIED OUT (**Please furnish hospital/institution and department**):**

**HOSPITAL/INSTITUTION WHERE EMPLOYED:**

**FULL-TIME OR PART-TIME EMPLOYEE:**

**OTHER PROFESSIONAL REGISTRATION DETAILS:**

**SECTION 2**

**CONTACT PERSON DETAILS:**

**TITLE:** (Prof/Dr/Mr/Mrs/Miss/Ms/Other) **FIRST NAME:** **SURNAME**:

**TELEPHONE NO:** **CELL NO**: **E-MAIL**:

**SUPERVISOR DETAILS:**

**TITLE:** (Prof/Dr/Mr/Mrs/Miss/Ms/Other) **FIRST NAME:** **SURNAME**:

**TELEPHONE NO:** **CELL NO**: **E-MAIL**:

**CO-INVESTIGATOR(S) DETAILS:**

**TITLE:** (Prof/Dr/Mr/Mrs/Miss/Ms/Other) **FIRST NAME:** **SURNAME**:

**TRAINING**

**ETHICS TRAINING:**

Ethics training is a compulsory requirement for consideration of this application. This applies to the applicant, any co-applicants and the supervisor(s), where there is one (or more). If you do not already have ethics training, one easy way to get it is to go to https://elearning.trree.org/course/index.php?categoryid=1 and complete at least the Introductory Module, which costs nothing and will generate a certificate. Please attach copies of the training certificates of all investigators and supervisors every time.

**ONLY FOR INVESTIGATOR-INITIATED CLINICAL TRIALS:**

GOOD CLINICAL PRACTICE (GCP) TRAINING DETAILS FOR ALL INVESTIGATORS

(Please note that investigators’ meetings do not qualify as GCP training and GCP training often includes no ethics component)

**SECTION 3**

**3. TITLE OF RESEARCH PROJECT:**

**3.1 Purpose of the research :**

Postgraduate Degree/Diploma (state which):

Undergraduate Degree/Diploma: (state which):

Not for Degree Purposes:

**3.2 Objectives of the research:** (please list: *Do not say “see attached“*):

**3.3 Summary of the research:** (give a brief outline of the research plan such that reviewers can understand what is to be done. (*Do not say “see attached“***):**

**3.4 Scientific approval:**

Has the protocol been approved a scientific committee, *e.g.* Wits Post Graduate Assessors’ Committee?

Yes (please attach the one page Faculty approval letter – this is mandatory; the assessors’ comments are not required) 

Not applicable 

**3.5 Select study design:**

Retrospective Record Review 

Prospective Record review 

Qualitative 

Quantitative 

Cross-sectional 

Trial:

Randomized control 

Single-Blind 

Double Blind

Other (please give brief details)

**3.6 Will the study involve human materials**?

Yes No 

If yes, please select:

Human Data 

Human Material: Blood Sperm Sputum Tissue Other genetic materials

Other (please give brief details)

**3.7 Is the study intended to inform improved clinical or therapeutic practice?**

Yes No 

**SECTION 4**

**4.1 Documentation requirements:**

**4.1.1 Is this project a secondary data analysis of data in an established database?**

Yes No 

Notes:

If “yes”, written consent to access a database from the database gatekeeper, plus a list of the data to be recorded (refer to general section) must accompany this application; omit all identifiers on the data collection sheet – name, address, contact details, date of birth, etc; use a study number to identify individuals where necessary

**4.1.2 Is this a sub-study, using data from an already-approved primary study?**

Yes No 

If so, please provide, as appropriate:

* + Written permission to use data from the Principal Investigator of the primary study, to include the Ethics Clearance Certificate Number
	+ Copies of informed consent documents from primary study, agreeing to sharing data for future research
* a list of the data to be recorded (refer to general section) must accompany this application; omit all identifiers on the data collection sheet – name, address, contact details, date of birth, etc; use a study number to identify individuals where necessary

Is this documentation attached? Yes No 

Please note: If the applicant is gathering new data, interviewing participants, analysing new samples, etc, this does not meet the HREC (Med) definition of a sub-study

**4.2 Is this study a retrospective patient record review?**

***Note:*** *for a retrospective review the date of the ethics committee meeting at which the application is considered sets the final date for the patient records. If the initial and / or final data is after the meeting date, the study is prospective and 4.3 below applies. Patient records include all data collected on patients including blood results and radiographs etc.*

**What is the initial date for the patient records?**

(DD/MM/YYYY)

**What is the final date for the patient records?**

(DD/MM/YYYY)

**Note:** the following must accompany this application:

1. written proof of approval from the hospital or clinic CEO to do the study
2. written permission from the Head of the clinical entity in which the patients in which patients records are based
3. how the patients will be selected
4. what type of records will be examined
5. a list of the variables to be extracted – a data collection sheet, without identifiers, *e.g.* name, address, contact details, date of birth, etc; use a study number to identify individuals where necessary

**Is this documentation attached?** Yes No 

**4.3 Is this study a prospective patient record review??**

***Patient records include all data collected on patients including blood results and radiographs, etc.***

**What is the initial date for the patient records?**

(DD/MM/YYYY)

**What is the final date for the patient records?**

(DD/MM/YYYY)

Note: the following must accompany this application:

1. written proof of approval from the hospital or clinic CEO to do the study
2. written permission from the Head of the clinical entity in which the patients in which patients records are based
3. how the patients will be selected
4. what type of records will be examined
5. a list of the variables to be extracted – a data collection sheet, without identifiers, *e.g.* name, address, contact details, date of birth, etc; use a study number to identify individuals where necessary
6. a participant Information Sheet and a Consent Sheet

**Is this documentation attached?** Yes No 

**4.4 If this project involves prospective studies with drugs at a teaching hospital associated with this University, approval must first be obtained from the Hospital’s relevant Committee.**

Has application been made? Yes No  Not applicable 

(If not, this application cannot be considered)

**4.5 If radiation or isotopes are to be used in prospective studies, written approval must be obtained from the Director of the Health Physics Unit** (James.Larkin@wits.ac.za**/**011-717 6931).

***Note:*** *for patients these are radiation dosages over and above those for standard diagnosis/ therapy*

**4.6 Is a Participant Information Sheet attached? (For written consent)**

(see guidance at <http://www.wits.ac.za/research/researcher-support/research-ethics/ethics-committees/> chose HREC (Med), see “Downloads”

Yes No 

If informed consent will be verbal, or if informed consent is not considered necessary, a written motivation and justification should be attached

**4.7 If a questionnaire or interview is to be used in the research, it must be attached. (If not, this application cannot be considered).**

Is this attached? Yes  No  Not applicable 

**SECTION 5**

**5. STUDY POPULATION**

**5.1 If patients/patient records are being studied, state where and how they are selected:**

**5.2 Where the participants are not patients:**

Will they be invited to volunteer?

Yes No 

Will they be selected?

Yes No 

**State who is invited to volunteer, or how the participants are selected:**

**Are the participants subordinate to the person doing the recruiting?**

Yes No 

If “yes”, justify the selection of subordinate participants:

* 1. **Will control patients/participants be used?**

Yes No 

If “yes”, explain who they are and how they will be recruited

**5.4 What is the age range of participants in the study?**

Show age range here:

If participants are minors (under 18 years), from whom will consent be obtained?

If participants are in the age range 7-17, at least one age-appropriate Information Sheet and a Consent Sheet must be attached

**5.5 Gender of study participants**

Male  Female  Both 

* 1. **Number of patients/participants: Number of controls:**
	2. **Will the research benefit the patients/participants in any direct way?**

Yes No 

If so, please explain in what way:

**5.8 Will participants receive any remuneration?**

Yes No 

If so, explain what the remuneration is for and how much will be paid

**5.9 Will participation, non-participation or withdrawal from the study disadvantage**

**patients/participants in any way?**

Yes No 

If so, please explain in what way:

**SECTION 6**

**6. PROCEDURES** (**Throughout Section 6, “Procedures” refers to** **STUDY, not clinical, procedures, so “Not Applicable” would rarely be an appropriate answer)**

**6.1 Please mark research procedure(s) that will be used and attach what is required: (see notes section regarding storage of supplies)**

* Record review:
* Interview form/questionnaire:

 Self-administered questionnaire:

* Focus group (questions to be used must be attached; Note: there can be no guarantee of confidentiality in a focus group and participants must be told this in the Information Sheet):
* Examination (state nature and frequency of examination):

 Drug or other substance administration (state drug name, dose and frequency of administration):

* Radiographs:
* Blood sampling: venous  ; arterial 

(State amount to be collected and the frequency of sampling)

**Will a biobank be used in the study?**

Yes No 

*(See Appendix to this form regarding biobanks)*

Biopsy:

Explain:

Other procedures:

Explain:

Use this space to elaborate on procedures marked above:

**6.2 Is/are the research procedure/(s) as described above:**

routine for: diagnosis/management 

specific to this research 

Identify which of the procedures at 6.1 above are routine for diagnosis and management of patients; and identify those procedures specific to the research.

**6.3 Who will carry out the research procedure(s) as described above?**

**6.4 When will the research project commence after obtaining ethics clearance, and over what approximate time period will the research be done?**

**DATA COLLECTION START DATE:** (DD/MM/YYYY)

**ESTIMATED STUDY END DATE:**  (DD/MM/YYYY)

**6.5 For studies being done outside the Gauteng Academic Hospitals, please list the number of studies currently being done by the Principal Investigator, the number of patients per study and where they are being done:**

**For applications outside the Gauteng Academic Hospitals: Is the investigator involved in a clinical Part-Tim/Full-Time capacity at the study site?**

Yes Part-time  Full-time  No 

If so, please explain in what way:

**SECTION 7**

**7. RISKS OF THE STUDY PROCEDURE(S):**

**7.1 Please consult the risk table at** <https://www.wits.ac.za/research/researcher-support/research-ethics/ethics-committees/> chose HREC (Med), see “Downloads” **CHECK** 9999 **and indicate the level of risk to:**

**Patients/Participants:**

None  Minimum  Low  Medium  High 

**Research team members:**

None  Minimum  Low  Medium  High 

**All other persons:**

None  Minimum  Low  Medium  High 

**7.2 Please indicate whether the patients/participants will be exposed to any levels of:**

Physical discomfort 

Pain 

Possible complications 

Side effects from agents used 

Breach of confidentiality 

Possible stigmatization 

Psychological stress 

If you have checked any of the above, please provide details:

**SECTION 8**

**8. GENERAL**

**8.1 For any study, has permission from relevant authority/ies been obtained to do the study?**

Yes No 

If “yes,“ please state name of authority/ies and provide written proof of approval; evidence of application serves no purpose, it is the response which is required

**8.2 Has this study been submitted to other Ethics Committees? If yes, why and what is the status of the application?**

**8.3 How will confidentiality be maintained so that participants are not identifiable to persons not involved in the research? Please answer the questions below:**

Will data be anonymous? How?

(Please attach SOP on period of keeping data, back up, destruction of data/samples and

sharing of data for future research with third parties.)

Will identifiable data be coded and the links kept separate? How?

Who will have access to the raw data?

**8.4 To whom will results be made available?** (*e.g.* participants, supervisor, hospital management,

etc)

**8.5 How will the results be disseminated** (*e.g.* journal article, conference presentation, departmental

 seminar, etc)

**8.6 Will there be financial costs to**:

Participants: Yes  No 

Hospital/Institution: Yes  No 

Other: Yes  No 

**Explain any box marked "Yes":**

**8.7 If no protocol is attached, please indicate:**

Budget:

How the research will be funded:

(Please give details of the source of funds)

**8.8 Any other information, which may help the Committee to evaluate this application, may be provided here:**

**Repeat Project title here:**

**8.9 SIGNATURES:**

In appending my signature below, I confirm that am aware of and agree to abide by the University’s policy on plagiarism, as referenced at paragraph 12 in the Appendix to this Application Form

Date: Applicant's Signature:

**Who will supervise the project? (Where applicable)**

Name Department:

Telephone No: Email:

Signature: Date:

**Head/Research Co-ordinator of School/Department/Entity in which the research will be**

**conducted: (Where applicable)**

Name Department:

Telephone No: Email:

Signature: Date:

**APPENDIX – PLEASE DO NOT RETURN THIS PAGE OR THE NEXT ONE WITH YOUR APPLICATION**

###### Please note that it is the responsibility of the Principal Investigator in an application to ensure that he/she has received the final HREC (Medical) Clearance before commending any research. This is signified by, and only by, the issuing of a Clearance Certificate, which will be headed as such.

###### Please indicate clearly, where correspondence should be sent; failure to do this may cause delays. Please provide the supervisor’s email address (where applicable) for sending copies of correspondence.

###### It is normally preferable that a protocol detailing the background to the research, the design of the investigation and all procedures, is submitted with the application.

###### If any doubt exists, please come into the Ethics Office (Phillip Tobias Building, 3rd Floor, Cnr York Road and Princess of Wales Terrace, Parktown) during normal office hours and ask the staff on duty there

###### Please note that written response normally takes about 15 working days after submission.

###### STORAGE OF BLOOD AND/OR TISSUE SAMPLES:

The policy of the ethics committee is:

* If, blood or tissue specimens are to be stored for future analysis and/or it is planned that analysis may be done outside Wits, then the specimens must be stored at Wits with release of sub-samples only once projects have been approved by the local Research Ethics Committee applicable to where the research will be done, as well as by the Wits Human Research Ethics Committee: (Medical);
* A separate information sheet and consent form for this is required. Please see the Standard Operating procedure at [www.witshealth.co.za/Services/Research-Ethics](http://www.witshealth.co.za/Services/Research-Ethics)
* For information on Biobanks and the Biobank Ethics Committee within the Wits Human Research Ethics Committee, please go to <https://www.wits.ac.za/research/researcher-support/research-ethics/ethics-committees/>, chose HREC (Med), see “Downloads”, see “Biobanks Ethics Committee”
* Only approved analyses may be done;
* Specimens may not be shared with anyone, unless approved by the Wits Human Research Ethics Committee (Medical); usually an inter-institutional Materials Transfer Agreement (MTA) will be pre-requisite

###### Evaluation of applications from private sites/institutions without any affiliation to Wits may be done but is at the discretion of the Wits Human Research Ethics Committee (Medical). In such instances a processing fee is payable – current cost and payment procedure available on enquiry.

###### Researchers from abroad should obtain ethics clearance before arriving at Wits, as a tight time schedule is not considered a valid reason for departing from Wits Standard Operating Procedure. A Wits collaborator may help obtain the clearance.

###### Researchers with syndicates in the Wits Health Consortium – please read the home page at [www.witshealth.co.za](http://www.witshealth.co.za) regarding the requirement that the syndicate must be based in a Wits academic department, or recognised research entity

###### Please note: No late online applications under Categories 1 and 2 on page 1 above will be accepted after the submission date listed at: <https://www.wits.ac.za/research/researcher-support/research-ethics/ethics-committees/>, chose HREC (Med), see “Downloads”. Applications received after this date will be carried forward to the following meeting; incomplete applications will not be accepted

######  No data may be collected before a clearance is issued by the HREC (Medical). In no circumstance will retrospective clearance be given.

1. **PLAGIARISM POLICY**

The University’s policy on plagiarism is set out at:

<https://intranet.wits.ac.za/exec/registrar/Policies/Policy%20-%20Plagiarism.pdf#search=plagiarism>

Applicants seeking ethics clearance are required to be familiar with this policy

January 2023