HREC (2012 - MEDICAL)

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

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

This application <u>MUST BE TYPED</u> in Capitals & lower case. Handwritten forms are <u>NOT</u> accepted. 23 sets of application form plus attachments and 4 copies of protocol must be submitted.
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 complete application. Read the PLEASE NOTE section at the end of the application form for help.

SECTION 1

PRINCIPAL INVESTIGATOR PER SITE (graduate or student)

NAME: _____(Prof/Dr/Mr/Miss/Ms)

PROFESSIONAL STATUS OR STUDENT YEAR OF STUDY AND DEGREE

UNIVERSITY DEPARTMENT / DIVISION

NON-WITS SITE / INSTITUTION ***(if no association of any type with the University)***

DETAILS OF WHERE STUDY WILL BE DONE

HOSPITAL/INSTITUTION WHERE EMPLOYED (if applicable)

FULL-TIME OR PART-TIME EMPLOYEE: **HPCSA NO:**

SECTION 2

CONTACT PERSON'S DETAILS FOR ALL CORRESPONDENCE:

NAME:

TELEPHONE NO: **FAX NO:**

CELL: **EMAIL:**

CO-INVESTIGATORS' NAMES

ONLY FOR INVESTIGATOR-INITIATED CLINICAL TRIALS – GOOD CLINICAL PRACTICE (GCP) TRAINING: DATE AND NAME of GCP Course attended (dd/mm/year) for all investigators. ***(Note: investigators' meetings do not qualify as GCP training*****)**

Full Name:_____

GCP Course Name: _____

Date of GCP course: day/month/year: _____

SECTION 3

3. TITLE OF RESEARCH PROJECT: ***(Use no abbreviations*****)**

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

All the following sections must be completed [3]. **Please tick all relevant boxes.**

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, (*Do not say see attached!*):

SECTION 4

4. REQUIREMENTS

4.1 Is this project a secondary analysis of data in an established database? Yes ☐ No ☐
Note: written consent to access a database from the database gatekeeper plus a list of the data to be recorded (see 6.1) must accompany this application.
Is this documentation attached? Yes ☐ No ☐

4.2 Is this project a retrospective patient record review? Yes ☐ No ☐

What is the initial date for the patient records? _____

What is the final date for the patient records? _____

Note: the following must accompany this application - written permission from the hospital or clinic CEO to do the study, written permission from the clinical entity in which the patients are based, how the patients will be selected, what records will be examined, a list of the data to be recorded (see 6.1). Is this documentation attached? Yes ☐ No ☐

4.3 Is this project a prospective patient record review? Yes ☐ No ☐

What is the initial date for the patient records? _____

What is the final date for the patient records? _____

Note: the following must accompany this application - written permission from the hospital or clinic CEO to do the study, written permission from the clinical entity in which the patients are

based, how the patients will be selected, what records will be examined, a list of the data to be recorded (see 6.1). Is this documentation attached? **Yes** ☐ No ☐

4.4 **If this project involves 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 ☐
(If not, this application cannot be considered)

4.5 **If radiation or isotopes are to be used, written approval must be obtained from the Director, Radiation and 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***

Is this attached? If not, the application cannot be considered. Yes ☐ No ☐

4.6 **Is a Participant Information Sheet attached? (For written and verbal consent)**
Yes ☐ No ☐

Informed Consent Form is attached. (For written consent). Yes ☐ No ☐
For guidance please refer to the Wits Informed Consent Form Template at www.wits.ac.za/research/ethics and adjust this for your needs

If informed consent will be verbal – explain why.

If informed consent is not considered necessary – explain why not.

4.7 **If a questionnaire or interview is to be used in the research, it must be attached.**
Is it attached? (*If not, this application cannot be considered).* Yes ☐ No ☐

SECTION 5

5. STUDY PARTICIPANTS
5.1 **If patients are being studied, state where and how they are selected:**

5.2. **Where the participants are not patients,**
Will they be invited to volunteer? ☐ **Will they be selected?** ☐
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:

5.3 **Will control 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?**

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

If participants are minors, is an Assent Document provided? Yes☐ No☐

5.5 **Sex: Male** ☐ **Female** ☐

5.6 **Number of patients _____; non-patient participants_____ controls _____**

5.7 **Will the research benefit the participants in any direct way?** Yes ☐ No ☐

5.8 If yes, explain in what way.

Will participants receive any remuneration? Yes☐ No☐

If yes, explain what the remuneration is for and how much will be paid. _____

5.9 Will participation, non-participation or withdrawal from the study disadvantage persons in any way? Yes ☐ No ☐

If yes, explain in what way:

SECTION 6

6. PROCEDURES

6.1 Mark research procedure(s) that will be used and attached what is required:

☐ **Record review (attach a list of data to be recorded)**

☐ **Interview form / questionnaire (must be attached)**

☐ **Self-administered questionnaire (must be attached)**

☐ **Focus group (questions to be used must be attached. Note: there is no confidentiality in a focus group, participants must be told this)**

☐ **Examination (state nature and frequency of examination)**

☐ **Drug or other substance administration (state name, dose, and frequency of administration)**

☐ **Radiographs**

☐ **Isotope administration (state name, dose, and frequency)**

☐ **Blood sampling;** ☐**venous;** ☐**arterial**
(State amount to be collected and the frequency of sampling)

☐ **Biopsy (explain)**

☐ **Other procedures (explain)**

Use this space to elaborate on procedures marked above:

6.2 Is/are procedure/(s) routine for: diagnosis/management? ☐
specific to this research? ☐

6.3 Who will carry out the procedure(s)?

6.4 When will the research project commence, and over what approximate time period will the research be done?

START DATE: _____END DATE: _____

RECRUITMENT START: _____ END DATE: _____

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.

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

SECTION 7

7. RISKS OF THE STUDY PROCEDURE(S):

- ☐ **No risk**
- ☐ **Physical discomfort**
- ☐ **Pain**
- ☐ **Possible complications**
- ☐ **Side effects from agents used**
- ☐ **Breach of confidentiality**
- ☐ **Possible stigmatisation**
- ☐ **Psychological stress**

If you have checked any of the above except "No risk" please provide details:

SECTION 8

8. GENERAL

8.1. Has permission of relevant authority/ies been obtained to do the study?

Yes☐ No☐ N/A☐

State name of authority/ies and provide written evidence of this

8.2 Has this study been submitted to other Ethics Committees? Yes☐ No☐ N/A☐
If yes, 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?

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

Who will have access to data?

8.4 To whom will results be made available?

8.5 Will there be financial costs to:

Participants	**Yes☐**	**No☐**
Hospital/Institution	**Yes☐**	**No☐**
Other	**Yes☐**	**No☐**

Explain any box marked "Yes":

8.6 How will the research be funded?
Please give details of the source of funds

8.7 Any other information, which may be of value to the Committee, should be provided here:

Date: **Applicant's Signature:**

WHO WILL SUPERVISE THE PROJECT? (WHERE APPLICABLE)

Name

Department:

Telephone No:

Date

Signature:

HEAD / RESEARCH COORDINATOR OF DEPARTMENT / ENTITY IN WHICH STUDY WILL BE CONDUCTED (where applicable)

Name:

Signature:

Date:

Entity:

Tel No:

Fax No:

Email:

MSWord/Iain0015/HERCMedAF

PLEASE NOTE:

1 Please indicate clearly, where correspondence should be sent; failure to do this causes delays.

2 This requirement holds even if, to assist the Committee, a protocol detailing the background to the research, the design of the investigation and all procedures, is submitted with the application.

3 If any doubt exists please contact Anisa Keshav, Wits Research Office, 10th Floor Senate House, East Campus at 011-717-1234 Fax: 011-717-1265 Email anisa.keshav@wits.ac.za

4. Please note that written clearances will not be available until approximately 10-14 working days after a Committee meeting – minutes must be checked, clearances printed and signed by the Committee Chair and only then despatched to applicants, this takes time.

5. Whether written or verbal consent is to be obtained, the HREC requires a Participant Information Sheet written in friendly language understandable to lay persons explaining what is required from a potential participant. This should include the following (a template is available to help applicants at www.wits.ac.za/research/ethics/):

(1) Participation is voluntary, and refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled:

(2) The participant may discontinue participation at any time without penalty or loss of benefits:

(3) A brief description of the research, its duration, procedures and what the participant may expect and/or be expected to do:

(4) Any foreseeable risks, discomforts, side effects or benefits, including those for placebo:

(5) Disclosure of alternatives available to the participant. If risks are involved:

(6) A professional contact name and 24 hour telephone number:

(7) Explanation whether medical treatment will be provided in the case of a complication developing:

(8) If required - compensation for clinical trial related injuries will be in accordance with the ABPI guidelines:

(9) A separate Patient Information and Informed Consent sheet for blood / tissue samples taken for future testing. The Participant Information Sheet may be incorporated into the consent form, or the consent form may be submitted separately:

Please ensure to INVITE a person to take part in the study; and remember to include a greeting and to introduce yourself.

5 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 it is planned 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);
- Only approved analyses may be done;

- Specimens may not be shared with anyone unless approved by the Wits Human Research Ethics Committee (Medical).

6. 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 management fee is payable.

7. Researchers from abroad should obtain ethics clearance BEFORE arriving at Wits, 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.

8. Researchers with syndicates in the Wits Health Consortium – please read the home page at www.witshealth.co.za regarding the requirement that the syndicate must be based in a Wits academic department or recognised research entity.

9. **Please note: No late applications will be accepted after the submission date listed at www.wits.ac.za/research.**