health
Department:
Health
PROVINCE OF KWAZULU-NATAL

UMGUNGUNDLOVU HEALTH ETHICS REVIEW BOARD (UHERB) REC-051010-026

APPLICATION FOR ETHICS APPROVAL

INSTRUCTIONS:

- *Ensure that the current version of the application form on the UHERB web page is used:* http://portal.kznhealth.gov.za/components/sps/hrkm/UHERB
- *Ensure that the application is completed and signed.*
- *Complete checklist on page 15 prior to submission.*
- *This application form must be self-sufficient. Indicating "see protocol" or "see information sheet" in responses are unacceptable and will be returned.*
- *Other documents that are required with submission of the application are:* electronic copies of the protocol, current CV/s, evidence of current GCP / research ethics training, study questionnaires, informed consent forms, and study participant information leaflet.

SECTION 1: ADMINISTRATIVE DETAILS

1.1. PRINCIPAL INVESTIGATOR – TITLE, NAME, SURNAME	
1.2. PROFESSIONAL STATUS (IF STUDENT, YEAR OF STUDY)	
1.3. HOSPITAL / INSTITUTION WHERE EMPLOYED	
1.4. FULL POSTAL ADDRESS:	
1.5. TELEPHONE (OFFICE):	
1.6. MOBILE NUMBER:	
1.7. EMAIL ADDRESS:	

1.8. CURRENT HPCSA NUMBER *(OR EQUIVALENT STATUTORY HEALTH COUNCIL REGISTRATION NO. IF APPLICABLE) – IF REGISTRATION IS PENDING, SUBMIT PROOF OF APPLICATION.*	
1.9. CO-INVESTIGATOR - TITLE, NAME, SURNAME	
1.10. PROFESSIONAL STATUS (IF STUDENT, YEAR OF STUDY)	
1.11. HOSPITAL / INSTITUTION WHERE EMPLOYED	
1.12. FULL POSTAL ADDRESS	
1.13. TELEPHONE (OFFICE):	
1.14. MOBILE NUMBER:	
1.15. EMAIL ADDRESS:	
1.16. CURRENT HPCSA NUMBER *(OR EQUIVALENT STATUTORY HEALTH COUNCIL REGISTRATION NO. IF APPLICABLE) – IF REGISTRATION IS PENDING, SUBMIT PROOF OF APPLICATION)*	

1.17. EXACT ROLE/S OF PRINCIPAL INVESTIGATOR/CO-INVESTIGATOR/S IN THE STUDY:

Name	Institution	Department	Role	Signature

SECTION 2: APPLICATION TYPE

2.1. Please select the type of application review being sought	○ Full ○ Expedited ○ Exempt
2.2. Please specify the level of risk associated with the proposed research.[1]	○ Low ○ Medium ○ High
Please explain the research risk and justify the need for the proposed research.	

SECTION 3: STUDY DETAILS

3.1.	**TITLE OF PROJECT IN FULL:** (do not abbreviate)
3.2.	**WHERE WILL THE RESEARCH STUDY BE CARRIED OUT?** (Please furnish the name of hospital/institution and department)

[1] Research risk refers to the probability and magnitude of harms participants may experience as a result of the proposed research methods and/or type of data to be collected. Examples include research procedures or collection of data relating to clinical diagnoses or side effects; cognitive or emotional factors such as stress or anxiety during data collection; and socio-economic or legal consequences of research such as stigma, loss of employment, deportation, or criminal investigation.

SECTION 4: FUNDING

4.1.	Has funding been secured?	◯ Yes ◯ No
4.2.	Amount:	R
4.3.	Name of funder (full details):	
4.4.	Can this project proceed without funding?	◯ Yes ◯ No
4.5.	Provide a brief explanation:	
4.6.	Has an application for funds been made to other sources to support this project?	◯ Yes ◯ No
4.7.	If yes, state: Name/s of funding agency and Amount requested	
FAILURE TO MAKE FULL FINANCIAL DISCLOSURES WILL DELAY ETHICS APPROVAL		

SECTION 5: DISCLOSURES

5.1.	Has this study been, or is it likely to be, submitted to any other Research Ethics Committe?	◯ Yes ◯ No
5.2.	If yes, Name of the committee(s):	
5.3.	Provide the outcome – ***IF APPROVED, ATTACH APPROVAL LETTER***	☐ Approved ☐ Rejected ☐ Pending ☐ Not applicable
5.4.	Has the principal investigator or any of the co-investigators been previously/or are presently being investigated for alleged research misconduct?	◯ Yes ◯ No
5.5.	If yes, please provide details and dates:	

5.6.	Are any of your intended research participants in other research studies and/or trials?	◯ Yes ◯ No
5.7.	If yes, please provide details	
5.8.	Are you presently involved in other research and/or clinical trial activities?	◯ Yes ◯ No
5.9.	If yes, please provide details and % time allocated to each:	
5.10.	Will any of the following be stored for purposes of the study?	☐ Human tissues (Blood, blood products, gamete, gonads, oocyte, organs, flesh, bone, gland, skin, bone marrow or body fluids) ☐ Microbial isolates ☐ Human genetic material (DNA, RNA)
5.11.	If yes, provide details of storage facilities (name, location, conditions and duration of storage)	

5.12.	Will human tissues, genetic materials and or microbial isolates be exported?	◯Yes ◯No
5.13.	If yes, please attach current copies of export and import permits and international aviation clearance certificates and a materials transfer agreement (see template on the UHERB website).	
	IT IS ILLEGAL TO EXPORT HUMAN TISSUES AND BIOLOGICAL MATERIALS WITHOUT A PERMIT (NATIONAL HEALTH ACT, 2003).	
5.14.	Please provide a rationale for export of biological materials:	

SECTION 6: CONFLICT OF INTEREST

Investigators should not have undisclosed conflict of interest with their study collaborators, sponsors or participants. Conflicts can arise, for example, when a commercial or other sponsor may not wish research results detrimental to their corporate image / interest to be disclosed, especially when the investigator is being remunerated by the sponsor for the research in question; when research subjects are being rewarded for their participation in the research; or when an investigator has a vested interest in, or is an employee / shareholder / director in the sponsor's corporate entity. Investigators should note that the duty to disclose a conflict of interest to the ethics review committee begins during application for ethical approval and continues until the research in question is complete and the research results are submitted to the sponsor / published (if applicable).

IF THE INVESTIGATOR(S) HAS/HAVE/FORESEES ANY SUCH CONFLICT OF INTEREST, PLEASE PROVIDE DETAILS HERE:

SECTION 7: PROTOCOL DETAILS

7.1. TYPE OF STUDY

☐ Epidemiological ☐ Observational Study ☐ Clinical Study ☐ Experimental
☐ Retrospective Chart Review ☐ Prospective Chart Review ☐ Laboratory study on stored samples
☐ Other - (Specify):

7.2. PROJECT DETAILS:

7.2.1. Aims /Objectives of the study – please list

7.2.2. Hypothesis to be tested

7.2.3. Summary of the proposed research (restrict to 100 words)

7.2.4. Keywords (for database):

7.2.5. Background and Literature:

7.2.6. Key References: (Give approximately 5 key references)

7.3. DESIGN AND/OR EXPERIMENTAL PROCEDURES:			
7.3.1. RESEARCH DESIGN: ☐ Qualitative ☐ Quantitative ☐ Mixed methods (Quantitative & Qualitative) ☐ Action research ☐ Other:			
7.3.2. Is this a retrospective chart review with no human contact?	◯ Yes	◯ No	◯ N/A
7.3.3. Is this a study of stored tissue?	◯ Yes	◯ No	◯ N/A
7.3.4. Are host genetic factors being studied?	◯ Yes	◯ No	◯ N/A
7.3.5. LIST THE DATA COLLECTION TOOLS THAT WILL BE USED FOR THE STUDY:			

7.4. STATISTICAL PLANNING:

Has this project been discussed with either of the following:

☐ A professional statistician ☐ A person with a statistical background

If yes, *(a) Name of statistician:*

(b) Give details - outline statistical considerations such as randomisation, size of groups, exclusions etc.

If no, *specify why statistical consultation was not obtained and motivate the design adopted.*

7.5. PARTICIPANTS:

Clinical data: Please indicate the **source, age and number** of the participants to be studied:

7.5.1. Source:

☐ Inpatients ☐ Outpatients ☐ Volunteers ☐ Animals

7.5.2. Age (Humans):

☐ Neonates (<28 days) ☐ Infants (1-11 month) ☐ Children (1-12 yrs) ☐ Adolescents (13-17 yrs) ☐ Adults (>18 yrs)

7.5.3. Numbers: Indicate the number of participants in each of the above study-groups.

☐ Inpatients: ☐ Outpatients: ☐ Volunteers: ☐ Animals:

7.5.4. Will you have control groups? ◯ Yes ◯ No

7.5.5. Details of inclusion and exclusion criteria:

7.5.6. Describe recruitment process for all groups:

7.6. THE ENVIRONMENT:	
7.6.1. Is this a multi-national study?	◯ Yes ◯ No
If yes, state collaborating countries.	
7.6.2. List all sites in South Africa in which the project will be carried out	
7.6.3. Can the project have any negative consequences on participants, members of the public, researchers, field staff or the physical environment (incl. the laboratory)?	◯ Yes ◯ No
If yes, please give details.	
7.6.4. How many hours/week will the PI devote to this project? *Timetable the project in terms of the resources and time available.*	
7.6.5. Storage:	
a. Please explain where the data is stored and how long it will be stored?	
b. Will data be destroyed after analyses?	◯ Yes ◯ No

If no, please explain:	
7.7. ETHICAL ASPECTS:	
(a) Responsibility: *In respect of any litigation which may result from this research*:	
7.7.1. Will participants be insured by sponsors against research related injury?	◯ Yes ◯ No
If yes, please provide details:	
If no, please provide rationale:	
7.7.2. Have you ensured that reimbursement for participants and investigators is in accordance with 1) *Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa* – Department of Health (2006) – *and 2) Ethics in Health Research: Principles, Structures and Processes* – (2004)?	◯ Yes ◯ No
If no, please explain.	
7.7.3. If this project is to be conducted at another institution, is additional ethics approval required?	◯ Yes ◯ No ◯ N/A
If yes, Name the Institutions:	
If no, please explain.	

(b) Incentives / Reimbursement		
7.7.4.	List any incentives, explicit and implicit, that have or will be offered to study participants, either to recruit or to retain within the study	
7.7.5.	List (include value or formula) reimbursement / compensation for participation in the study (e.g. travel costs, out of pocket expenses, etc.).	
(c) Potential risks or discomfort:		
7.7.6.	Compared to persons or patients with similar conditions, please indicate, for each study group/arm, the potential additional risks as follows:	
i.	Biological risks	
ii.	Psychological risks	
iii.	Social Risks	
iv.	Legal risks	
v.	Financial risks	
vi.	Other risks	
(d) Risk Minimisation:		
7.7.7.	Please detail steps that will be taken to minimise the risks indicated above:	
i.	Biological risks	
ii.	Psychological risks	
iii.	Social Risks	
iv.	Legal risks	
v.	Financial risks	
vi.	Other risks	

(d) Public Health Service Utilisation:		
7.7.8.	Compared with persons or participants with similar conditions indicate, for each study group, the likely additional:	
I.	Duration of hospital stay (days):	
II.	Outpatient attendances(no.):	
III.	Laboratory services used, including those appointed by the sponsor (name and location):	
IV.	Type of samples and volumes to be drawn:	
V.	Extent of nursing involvement:	
VI.	Has the nursing team who will be involved in the study been informed of the study and the nursing involvement which will be required? ◯ Yes ◯ No	
If no, please explain.		
Other (specify):		
(e) Management: *In the case of participants drawn from patient populations, indicate, in respect of each sub-group, how management differs from that usually offered to patients with similar conditions.*		
(f) Community Consultation: *In the case of community based studies, explain what consultation is planned within the community at the following stages:*		
I. Preparation		
II. Implementation of the study		

III. Dissemination of the results	
(g) State the expected benefits arising from this study under the following headings: Possible direct benefits to study participants	
I. Clinical care	
II. Public health	
III. Financial	
IV. Prospects of tested intervention being available to the study population if proven effective.	
V. Other (Specify)	
Indirect benefits (Specify):	
(h) Describe the intended strategy for dissemination of study results	
1) To the scientific community	
2) To research participants	
3) To the general public (if applicable)	

SECTION 8: INFORMATION GIVEN TO PARTICIPANTS

See SAMPLE INFORMATION SHEET AND CONSENT FORM ON DOH UHERB WEBSITE

Other consent forms are acceptable provided that they contain at least the essential elements outlined in the current UHERB Terms of Reference (ToR) and Standard Operating Procedures (SoP)

If necessary, consent forms, after ethics approval of the English form, must be translated into appropriate local languages and submitted to UHERB for further approval prior to implementation, with a copy of the translator's certificate. Copies of back translations are also acceptable.

The correct contact details for the Umgungundlovu Health Ethics Review Board (UHERB) should be in the information sheets and consent forms as follows:

Umgungundlovu Health Ethics Review Board (UHERB) Secretariat
Natalia Building (South Tower 10th floor, Room 102)
330 Langalibalele Street
Private Bag X9051
Pietermaritzburg 3200
Tel: 033 395 2046/ 3123 / 3189 / 2805 – Fax: 033 394 3782
Email: hrkm@kznhealth.gov.za

SECTION 9: QUESTIONNAIRES:

Provide copies of all questionnaires, interview guides, data collection sheets etc.

List all such attachments here:

SECTION 10: DECLARATION

Conflict of Interest:

I declare that all potential conflicts of interest regarding my application for ethics approval to conduct this study have been declared in accordance with UKZN and UHERB Terms of Reference and Standard Operating Procedures.

Oversight of study: Will this study be overseen by a professional Clinical Research Organisation or study sponsor?

◯ Yes ◯ No

Please give details:

Undertaking:

I understand and accept that I will be required to submit a yearly recertification application, failing which authorisation to continue the study lapses. Progress reports may be required more frequently depending on level of risk and other factors – this will be detailed in the UHERB approval letter.

◯ Yes ◯ No ◯ N/A

I undertake to request permission for any changes/amendments to the study from UHERB in advance of implementing any such changes, unless they are emergencies required to prevent harm or save life. In such cases UHERB must be notified urgently.

◯ Yes ◯ No ◯ N/A

I agree to provide monitoring data if and when required

◯ Yes ◯ No ◯ N/A

I expect the project to be completed by (Date): _____

I agree to abide by the guidance contained in the SA Department of Health (2004) *Ethics in Health Research: Principles, structures and processes* and the (2006) *South African Good Clinical Practice Guidelines* and the current Umgungundlovu Health Ethics Review Board Terms of Reference and Standard Operating Procedures.

◯ Yes ◯ No ◯ N/A

I understand and accept that all information pertaining to this application is a true reflection of the project proposed and I take full responsibility should there be any transgression.

◯ Yes ◯ No ◯ N/A

SIGNED		**DATE**	
FULL NAME			

SECTION 11: DECLARATION AND APPROVAL BY INSTITUTIONAL HEAD

(Must include verification of interdepartmental agreements and co-operation)

Remarks:

SIGNED		**DATE**	
FULL NAME		**DESIGNATION:**	

PART 2 – SUGGESTED CURRICULUM VITAE FORMAT

CURRICULUM VITAE (of Principal Investigator and all Co-Investigators)
(CVs to be completed and signed for each member of the research team)

Full name:	
Date of birth:	
Male/Female:	
Telephone (Home):	
Telephone (Business):	
Cell:	
Fax No:	
E-mail Address:	
Current HPCSA No: (or equivalent statutory health council registration No. as appropriate)	
Present position:	
Institution:	
Department/Section:	
Nationality/Permanent residency:	
Previous positions held (last 10 years):	
Qualifications:	
University where obtained/year:	

Area of study:	
Publication list over the past 3 years:	
Details of all other research studies presently being conducted:	
Certificate of recent (past 3 years) research ethics and/or GCP training (GCP required for clinical trials):	

PART 3 – UHERB SUBMISSION CHECKLIST

1	Proof of PI and Co–PI current HPCSA (or equivalent) registration	Yes No N/A
2	Permission from hospital manager/clinics submitted	Yes No N/A
3	For degree purposes	Yes No N/A
4	Roles of PI & co-investigators given	Yes No N/A
5	CV of PI submitted	Yes No N/A
6	CV's of co-investigators submitted	Yes No N/A
7	GCP/ethics training certificate of PI	Yes No N/A
8	GCP/ethics training certificates of co-investigators	Yes No N/A
9	Funding amount specified	Yes No N/A
10	Funder specified	Yes No N/A
11	Other ethics committees' involvement specified	Yes No N/A
12	If YES to above - Have approval letters been submitted?	Yes No N/A
13	Protocol submitted	Yes No N/A
14	UHERB details on Information Sheet updated/checked	Yes No N/A
15	Statistics addressed	Yes No N/A
16	Information to participants submitted	Yes No N/A
17	Informed consent documents submitted	Yes No N/A
18	Signature of PI	Yes No N/A
19	Signature of HOD	Yes No N/A
20	Signatures of co-investigators	Yes No N/A
21	Questionnaires submitted	Yes No N/A
22	Translation of documents certified	Yes No N/A
23	Will genetic studies be performed? If yes, provide consent form	Yes No N/A
24	Export certificate for tissue storage/transportation	Yes No N/A
25	Permission from Department of Health/Province	Yes No N/A
26	Proof of payment of UHERB review fee if externally funded	Yes No N/A