PROTOCOL NUMBER:

……
For office use only

BIOMEDICAL RESEARCH ETHICS COMMITTEE
EXPEDITED APPLICATION FORM[1]

Application to the UKZN Research Ethics Committee for ethics review of new research projects
(For research on human participants)

RESEARCH OFFICE CONTACT DETAILS: Biomedical Research Ethics Administration, Westville Campus, Govan Mbeki Building, Private Bag X 54001, Durban, 4000, KwaZulu-Natal, South Africa; Tel: +27 31 2602486; Email: BREC@ukzn.ac.za ; Website: http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx

SECTION A:

APPLICANT/PRINCIPAL INVESTIGATOR: ** For UKZN statistical reporting purposes*

Title: Mr		Ms		Mrs		Dr		Prof		*(Select option)*

Name :			
*Gender:			
*Race:			
UKZN College:			
UKZN School/Discipline:		NA	
Hospital/Institution where employed:		NA	
Professional status:			
Postal address:			
Contact phone Numbers: Office:			
Mobile number:			
Fax number:			
Email address:			
Full/Part time Employment:			
Current HPCSA Number (or equivalent): *if registration is pending, submit proof of application			

Purpose of research: If postgraduate degree *(Please tick)*	Hons	MMedSc	MMed	MSc	MFamMed	MChB	PhD	N/A

Other degree not listed above:				
Student Number and year of study: (*if applicable)*				
If for postgraduate degree, please confirm whether the application has been reviewed and approved by your school's Academic Leader (Research):	Yes		No	
If yes, provide approval date and attach approval letter:				

[1] Note: This application must be self-sufficient. Sections marked "see protocol" are unacceptable and will be returned to the applicant.

Title of research project:						
Name and qualifications of Supervisor: e-mail address of Supervisor:						
Name and qualifications of Co-supervisor: e-mail address of co-supervisor:						
If not for degree purposes, state other (example, self-initiated research):						
Has this study been, or is it likely to be, submitted to any other Research Ethics Committee?	Yes		No		N/A	
If yes, please name the Committee/s and or institution and give outcome - i.e. approved/rejected/pending/not applicable? *(If approved, attach approval letter)*						
Please state number of Co-investigators in project:[2] **(if additional space is required for more investigators details please add to the end of application)**						
CO-INVESTIGATOR/S ROLE IN PROJECT ** For UKZN statistical reporting purposes*						
Name:						
Faculty:						
Department:						
*Gender:						
*Race:						
Role:						
e-mail address:						
Signature of Co-Investigator:						
Name:						
Faculty:						
Department:						
*Gender:						
*Race:						
Role:						
e-mail address:						
Signature of Co-Investigator:						
Name:						
Faculty:						
Department:						
*Gender:						
*Race:						
Role:						
e-mail address:						

[2] Please note that because of conflict of roles and interests that can arise, academic supervisors and co-investigators should be separate individuals.

Signature of Co-Investigator:				
Has the Principal Investigator or any of the co-investigators been previously/or are presently being investigated for alleged research misconduct? *(If yes, please provide details and dates)*	Yes		No	
FUNDING OF THE RESEARCH:				
Has funding been secured?	Yes		No	
Amount: R				
Name of funder: *(full details)*				
Is this project funded from a US DHHS funding source?	Yes		No	
If yes, name the federal funding agency:				
Can this project proceed without funding? *(give a brief explanation)*	Yes		No	
Has an application for funds been made to other sources to support this project?	Yes		No	
If yes, state name/s of funding agency and amount requested:				

Note:

For all US Federally funded studies (e.g. NIH, CDC, NIAID, DAIDS, NIMH, etc), one complete copy of the original funding application and approval must accompany the BREC ethics application.

All University contracts need to be uploaded on the Contracts Management online submission form with either the signed **Approval letter** (non-research) **or Form 1**(research related). The website link to the system is http://legalservices.ukzn.ac.za/ContractsManagement.aspx

If you require assistance with the completion of the online submission form, or with any aspect of the new system, please contact Mr Rendra Phalad on Ext 7455 for all contracts (non-research contracts), and Mr Deon Moodley on Ext 8199 (for research contracts).

FAILURE TO MAKE FULL FINANCIAL DISCLOSURES WILL DELAY ETHICS APPROVAL

Please indicate whether a BREC review fee is applicable for this study? (See Fee Schedule on BREC Website)	Yes		No	
If Yes, is the study covered by your Centre/Unit's annual levy fee to BREC?	Yes		No	

Note:

* Expedited review only applies to minimal risk studies – e.g. retrospective chart reviews, studies on stored samples etc., for details see BREC ToR and SoP at *http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx*

SECTION B:

NATURE OF STUDY

Quantitative

Type of Study: *(please tick)*	Epidemiological	Observational clinical study	Experimental	Observational

	Retrospective Chart Review	Prospective Chart Review	Laboratory study on stored samples	Audit	Other:(Specify)
Qualitative					

1. THE PROTOCOL FOR STUDY					
1.1 Full title of research project: *(Please DO NOT use abbreviations or acronyms)*					
1.2 Where will the Research be carried out? (Hospital, clinic etc.).					
1.3 Aims (what you hope to achieve) and objectives (how you will achieve your aims) of study: *(please list)*					
1.4 Hypothesis to be tested, or Research Question to be answered:					
1.5 Summary of the proposed research methodology (restrict to 100 words)					
1.6 Keywords (for database):					
1.7 Background and Literature Review (maximum 1 page):					
1.8 Key References: *(Give approximately 5 key references)*					
2. PLAN OF INVESTIGATION FOR STUDY					
* In the case of Higher Degrees, please state name and School of person consulted regarding the design:					
2.1 Is this a retrospective chart review with no human contact?	Yes		No		
2.2 Is this a study of stored tissue?	Yes		No		
2.3 Are host genetic factors being studied?	Yes		No		
2.4 How many hours per week will the PI devote to this project? (Timetable the project in terms of the resources and time available)					
2.5 Describe in detail your data collection methods for the research project					
3. STATISTICAL PLANNING AND DATA ANALYSIS					
3.1 Has this project been approved by a professional statistician? If No, please justify.	Yes		No		
3.2 If answered "yes" to (3.1), provide the name of the statistician:					
3.3 Please provide a brief overview of statistical and data analytic considerations, including: *How was the number of participants determined? Please include assumptions made in any power analysis (e.g. control incidence or mean and standard deviation of primary outcome variable, desired or anticipated effect of treatment or intervention, level of statistical significance and desired power), and list all planned statistical methods to be used. For descriptive studies list statistical operations to be performed.*					
3.4 For *qualitative* studies: What is the framework/approach to be used for analysis of the data?					

4. PARTICIPANTS IN THE STUDY												
4.1 Is this a multi-national study? (*If yes, state collaborating countries)*	Yes				No							
4.2 List all sites in South Africa in which the project will be carried i.e. geographic location (e.g. KwaZulu-Natal) and type of place (e.g. hospital, clinic, schools, community etc).												
4.3 Source: *(Please indicate number per group)*	Inpatients				Outpatients				Volunteers			
4.4 Age (human studies) *(Please indicate number per group)*	Neonates (<28 days)		Infants (1-11 month)		Children (1-12 years)		Adolescent (13-17 years)		Adults			
4.5 Is there a control group(s)?	Yes				No							
4.6 Demographic profile of participants *(please tick ALL appropriate boxes below.)* 4.6.1 Gender: Female ☐ Male ☐ 4.6.2 Population Group: Black ☐ Coloured ☐ Indian ☐ White ☐ 4.6.3 Language Group/s: Specify……												
4.7 Describe the recruitment process in detail for all groups.												
4.8 Will incentives be offered to facilitate recruitment? (*If yes, describe in detail*)	Yes				No				N/A			
4.9 Will participants be reimbursed in some way for participation? (*If yes, describe in detail*) *See SA DoH Guidelines on BREC Website*	Yes				No				N/A			
4.10 Will reimbursement for participants and investigators be in accordance with: *(If no, please explain)* • Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa: Department of Health (2006) and; • Ethics in Health Research: Principles, Structures and Processes: (2015) • Current SA DoH Guidance on reimbursement (*See BREC website*)	Yes				No				N/A			
4.11 Will participants be insured against research related injury? *(If yes, please provide details; If no, please provide rationale)* *Mandatory for Clinical Trials*	Yes				No				N/A			
4.12 List in detail the inclusion and exclusion criteria.												

5. POTENTIAL RISKS OR DISCOMFORT					
5.1 Can the project have any potential risks or discomfort on participants, members of the public, researchers, field staff or the physical environment?	Yes		No		

5.2 If "yes" to (6.1) indicate, for each study group/arm, the potential additional risks as follows:
5.2.1 Biological risks
5.2.2 Psychological risks
5.2.3 Social Risks
5.2.4 Legal risks
5.2.5 Financial risks
5.2.6 Other risks

5.3 Please detail steps that will be taken to minimise the risks indicated above:
5.3.1 Biological risks
5.3.2 Psychological risks
5.3.3 Social Risks
5.3.4 Legal risks
5.3.5 Financial risks
5.3.6 Other risks

6. INFORMED CONSENT: GIVEN TO PARTICIPANTS

See SAMPLE INFORMATION SHEET AND CONSENT FORM ON UKZN BREC WEBSITE at *http://research.ukzn.ac.za/Libraries/Notices2011/BREC_Informed_consent_form_sflb.sflb.ashx*

Other consent forms are acceptable provided that they contain at least the essential elements outlined in the current UKZN BREC Terms of Reference (ToR) and Standard Operating Procedures (SoP) available at *http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx*

If necessary, information sheets and consent forms, after ethics approval of the English version, must be translated into appropriate local languages and submitted to BREC for further approval prior to implementation, with a copy of the translator's certificate, and back translations if applicable.

The correct and complete contact details for the UKZN Biomedical Research Ethics Committee should be in the information sheets and consent forms as follows:

BIOMEDICAL RESEARCH ETHICS ADMINISTRATION
Research Office, Westville Campus
Govan Mbeki Building
University of KwaZulu-Natal
Private Bag X 54001, Durban, 4000
KwaZulu-Natal, SOUTH AFRICA
Tel: 27 31 2602486 - Fax: 27 31 2604609
Email: BREC@ukzn.ac.za

7. DECLARATION OF PRINCIPAL INVESTIGATOR

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 BREC Terms of Reference and Standard Operating Procedures.

Undertaking:

I understand and accept that I will be required to submit a yearly recertification application, failing which authorisation to continue the study lapses.
I undertake to request permission for any changes/amendments to the study from BREC in advance of implementing any such changes, unless they are emergencies required to prevent harm or save life. In such cases BREC must be notified urgently.

I agree to provide monitoring data if and when required.

I expect the project to be completed by **DATE**……

I agree to abide by the guidance contained in the SA Department of Health (2015) Ethics in Health Research: Principles, structures and processes and the (2006) South African Good Clinical Practice Guidelines and the current UKZN Biomedical Research Ethics Committee Terms of Reference and Standard Operating Procedures. These are available at *http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx*

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.

SIGNATURE OF PRINCIPAL INVESTIGATOR……

FULL NAME OF PRINCIPAL INVESTIGATOR……

DATE……..

8. DECLARATION AND APPROVAL FROM SUPERVISOR AND CO-SUPERVISOR (if applicable)

(I HAVE READ AND CHECKED THE PROPOSAL AND IT IS READY FOR SUBMISSION;

Remarks:

SIGNATURE OF SUPERVISOR ……..……

FULL NAME OF SUPERVISOR…..……

DATE……..

SIGNATURE OF CO-SUPERVISOR ……..……

FULL NAME OF CO-SUPERVISOR…..……

DATE……..

If applicable, attach a signed copy of the Supervision Agreement between the student, supervisor and any co-supervisor.

9. DECLARATION AND APPROVAL OF LINE MANAGER/HOD/ACADEMIC LEADER
(Must include verification of interdepartmental agreements and co-operation)

Remarks:

SIGNATURE OF ACADEMIC LEADER/HOD OR LINE MANAGER ……

FULL NAME OF ACADEMIC LEADER/HOD OR LINE MANAGER…….

DATE……..

NB: If applicant is ACADEMIC LEADER/DEAN/HOS, the ACADEMIC LEADER'S/DEAN'S/HOS's Line Manager (DVC) must sign.

SIGNATURE OF ACADEMIC LEADER's/ HOS's/DEAN's Line Manager……

FULL NAME OF ACADEMIC LEADER's, HOS's/DEAN's Line Manager……

DATE……..

SUGGESTED CURRICULUM VITAE FORMAT

(3 COPIES MAXIMUM 4 PAGES)

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:
Number of Postgraduate theses supervised (Masters and Doctoral):
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):

Signature of PI/Co-PI:

CHECKLIST FOR BIOMEDICAL RESEARCH ETHICS APPLICATIONS

NB: DO NOT BIND SUBMISSIONS (STAPLE ONLY)

Applications to be addressed to: The Administrator, Biomedical Research Ethics Committee, Govan Mbeki Building, University Road, Westville Campus, Tel: 031-260 2486/1074 Email: BREC@ukzn.ac.za

Note to Students:

PLEASE NOTE THAT ONLY ONE COPY OF APPLICATION AND SUPPORTING DOCUMENTS NEED BE SUBMITTED IF STUDY IS FOR DEGREE PURPOSES. ALL APPLICATIONS FOR DEGREE PURPOSES MUST BE SUBMITTED VIA THE COLLEGE POST-GRADUATE OFFICE WITH AN APPROVAL LETTER ATTACHED.

IF STUDY IS FOR NON-DEGREE PURPOSES THEN 3 COPIES MUST BE SUBMITTED TO BREC.

INCOMPLETE SUBMISSIONS MAY RESULT IN DELAYED REVIEW OF THE APPLICATION

For all expedited review applications:

- **3 TYPEWRITTEN COPIES** OF APPLICATION (Back-to-back (double-sided) copies preferred)
- **3 COPIES** OF THE PROTOCOL
- **3 COPIES** OF CURRENT CV/s (abbreviated max 4 PAGES)
- **3 COPIES** OF EVIDENCE OF CURRENT GCP / RESEARCH ETHICS TRAINING *requirements below
- **3 COPIES** OF ALL QUESTIONNAIRES TO BE USED IN THE STUDY
- **3 COPIES** OF THE INFORMED CONSENT FORMS (See BREC templates)
- **3 COPIES** OF THE PATIENT INFORMATION LEAFLET (See BREC templates)
- HAVE YOU FAMILIARISED YOURSELF WITH THE BREC TERMS OF REFERENCE? (See http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx)
- DETAILS OF ALL FUNDING SUPPORT?
- ALL PERSONAL INFORMATION?
- ANSWERED ALL QUESTIONS?
- GIVEN DETAILS OF ALL RESEARCH PRESENTLY BEING UNDERTAKEN?
- DELETED UNNECESSARY BLANK SPACES IN THE DOCUMENT?
- **IS DECLARATION PAGE SIGNED BY PI/SUPERVISOR AND ACADEMIC LEADER/H**

*** Requirement for this application is as follows:**

Online TRREE Module 1 (Introduction) and then the South Africa specific TRREE module certificates are required. There is no need to do TRREE modules 2-4 unless you choose to do them as relevant to your study design or sample, or for educational purposes. Current Good Clinical Practice (GCP) certification is required for clinical trials and interventional studies. BREC reserves the right to request a GCP certificate for interventional studies that are not formal clinical trials. The NIH online module may be compulsory for PIs who are funded by US Federal Agencies (e.g. NIH, NIMH, DAIDS, etc) – this is a funder requirement. Ethics certificates expire after 3 years unless otherwise stated by the issuer of the certificate. **(Links on BREC website http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx)**