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**PROTOCOL NUMBER:**

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*For office use only*

**BIOMEDICAL RESEARCH ETHICS COMMITTEE**

**APPLICATION FORM[[1]](#footnote-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](mailto:ngwenyap@ukzn.ac.za) ; Website: <http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx>

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| **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: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 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 | | | | | | | | | | | | MHIV | | | | | | PhD | | |
| 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: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Title of the research project:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Name and qualifications of Supervisor:  e-mail address: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Name and qualifications of Co-supervisor:  e-mail address: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| If not for degree purposes, state other (example, self-initiated research): | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | 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 name and number of Co-investigators in project:[[2]](#footnote-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: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Name: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Faculty: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Department: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| \*Gender: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| \*Race: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Role: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| e-mail address: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 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 | | | | | |  | | | | |
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| 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 aga | | | | | | 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 | | | |  | | | |
| **TYPE OF RESEARCH** *(please tick)* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Expedited | | | |  | | | | | Full review | | | | | | | | |  | | | | | |  | | | | | | | | |  | | | | | | | | | | | | |
| **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*](http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

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| **SECTION B:** | | | | | | | | | |
| **NATURE OF STUDY** | | | | | | | | | |
| **Quantitative** | | | | | | | | | |
| Type of Study:  *(please tick)* | Epidemiological | Observational clinical study | Experimental | | Clinical Trial | | | Observational | |
| Retrospective Chart Review | Prospective Chart Review | Laboratory study on stored samples | | Other:(Specify) | | | | |
| **Qualitative** | | | | | | | | | |
|  | | | | | | | | | |
| **1. THE PROTOCOL FOR STUDY** | | | | | | | | | |
| 1.1 Full title of research project: *(Please DO NOT use abbreviations or acronyms)* | | | | | | | | | |
| 1.2 Aims (what you hope to achieve) and Objectives (how you will achieve your aims) of study:  *(please list)* | | | | | | | | | |
| 1.3 Hypothesis to be tested, or Research Question to be answered: | | | | | | | | | |
| 1.4 Summary of the proposed research methodology (restrict to 100 words) | | | | | | | | | |
| 1.5 Keywords (for database): | | | | | | | | | |
| 1.6 Background and Literature Review (maximum 1 page): | | | | | | | | | |
| 1.7 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 your data collection methods for the research project in detail | | | | | | | | | |
| **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: | | | | | | | | | |
| 3.4 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.* | | | | | | | | | |
| 3.5 For *qualitative* studies: What is the analytic paradigm to be used for analysis of the data? | | | | | | | | | |

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| **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 | | | | | | | | | Animals | | | | | | | |
| 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 | | | | |  |  |
| 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 | | | | |  |  |
| 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 | | | | |  |  |
| 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 | | | | |  |  |
| 4.12 List in detail the inclusion and exclusion criteria. | | | | | | | | | | | | | | | | | | | | | | | |

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| **5. CLINICAL TRIALS** | | | | | | | | | | | | | | | | | | | | | | | | |
| 5.1 Has Medicines Control Council (MCC) approval been applied for? | | Yes | | |  | | | | No | |  | | | N/A | | | | |  | | |  | | |
| 5.2 Indicate current status of MCC approval application: | | | | | | | | | | | | | | | | | | | | | | | | |
| 5.3 Has this clinical trial been registered with the SA National Clinical Trials Register? | Yes | | |  | | No | | | | | |  | | | | N/A | | | | |  | | |  |
| 5.4 If “yes” to (5.3), please provide SANCTR registration number: | | | | | | | | | | | | | | | | | | | | | | | | |
| 5.5 If “no” to (5.3), PI hereby undertakes to register the trial with SANCTR after final ethics and MCC approval  N/A  No  Yes | | | | | | | | | | | | | | | | | | | | | | | | |
| 5.6 Please provide the names of all members of the Data Safety and Monitoring Board (DSMB) (CLINICAL TRIALS ONLY) | | | | | | | | | | | | | | | | | | | | | | | | |
| 5.7 The PI hereby undertakes to ensure that all DSMB reports are forwarded to BREC for comment as soon as possible.  No  Yes  N/A | | | | | | | | | | | | | | | | | | | | | | | | |
| 5.8 Are any of the intended research participants in other research studies and/ or trials? (*If yes, describe in detail*) | | | Yes | | | | |  | | No | | | | | | |  |  | | | | | | |
| 5.9 Is the PI presently involved in other research and/or clinical trial activities? (*If yes, please provide details and % time allocated to each)* | | | Yes | | | | |  | | No | | | | | | |  |  | | | | | | |
| 5.10 Has the funder imposed any restrictions on PI regarding publication of study results?  If **Yes**, give details: | | | Yes | | | | |  | | No | | | | | | |  |  | | | | | | |
| **6. Potential risks or discomfort** | | | | | | | | | | | | | | | | | | | | | | | | |
| 6.1 Can the project have any potential risks or discomfort on participants, members of the public, researchers, field staff or the physical environment? | | | | | | | Yes | | | | | |  | | No | | | | |  | | |  | |
| 6.2 If “yes” to (6.1) indicate, for each study group/arm, the potential additional risks as follows:  6.2.1 Biological risks  6.2.2 Psychological risks  6.2.3 Social Risks  6.2.4 Legal risks  6.2.5 Financial risks  6.2.6 Other risks  6.3 Please detail steps that will be taken to minimise the risks indicated above:  6.3.1 Biological risks  6.3.2 Psychological risks  6.3.3 Social Risks  6.3.4 Legal risks  6.3.5 Financial risks  6.3.6 Other risks | | | | | | | | | | | | | | | | | | | | | | | | |

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| **7. BIOLOGICAL SAMPLES** | | | | | | | | | | | | | | | |
| 7.1 Will human tissues (blood, blood products, gamete, gonads, oocyte, organs, flesh, bone, gland, skin, bone marrow or body fluids, waste materials such as urine and stools), microbial isolates and human genetic materials (DNA, RNA) be stored? | | Yes | | | |  | | | No | |  | | | |  |
| 7.2 If “yes” to (6.1), give details of storage facilities (name, location, conditions and duration of storage). | | | | | | | | | | | | | | | |
| 7.2 Will human tissues, genetic materials and or microbial isolates be exported? | | Yes | | | |  | | | No | |  | | | |  |
| 7.3 If “yes” to (7.2), please attach current copies of export and import permits and International Aviation Clearance Certificates and a Materials Transfer Agreement (*see template on BREC website).* It is illegal to export human tissues and biological materials without an export permit (National Health Act, 2003). | | | | | | | | | | | | | | | |
| 7.4 Please provide a rationale for export of biological materials (i.e. why the work cannot be done locally why local capacity cannot be upgraded) | | | | | | | | | | | | | | | |
| 7.5 Conflict of Interest:  Investigators should have no 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; or when an investigator has a vested interest in, or is an employee/shareholder/director in the sponsor’s corporate entity. Conflicts of interest can also arise when an academic supervisor is also a co-investigator on a study with a student. Investigators should note that the duty to disclose a conflict of interest to BREC 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: | | | | | | | | | | | | | | | |
| **8. GENERAL** | | | | | | | | | | | | | | | |
| 8.1 Indicate, for each study group, the likely additional, i.e., over and above standard of care:  8.1.1 Duration of hospital stay (days):  8.1.2 Outpatient attendances (number):  8.1.3 Laboratory services used, including those appointed by the sponsor (name and location):  8.1.4 Type of samples and volumes to be drawn:  8.1.5 Which laboratory services will be used?  8.1.5.1 Has a preliminary agreement been reached with laboratory service providers?     |  |  |  |  | | --- | --- | --- | --- | | Yes |  | No |  |   If Yes, attach letter of confirmation. | | | | | | | | | | | | | | | |
| 8.2 Has the nursing team who will be involved in the study been informed of the study and the nursing involvement which will be required?  *(If no, please explain; other, please specify)* | Yes | | |  | | | No | | |  | | |  | | |
| 8.3 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. | | | | | | | | | | | | | | | |
| 8.4 In the case of community based studies, explain what consultation is planned within the community at the following stages:  8.4.1 Preparation   * + 1. Implementation of the study and     2. Dissemination of the results thereafter | | | | | | | | | | | | | | | |
| * 1. State the expected benefits arising from this study under the following headings:      1. Possible direct benefits to study participants         1. Clinical care         2. Public health         3. Financial   8.5.1.4 Prospects of tested intervention being available to the study population if proven effective   * + - 1. Other (Specify)   8.5.2 Specify the Indirect benefits arising from this study | | | | | | | | | | | | | | | |
| * 1. 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)      4. Other: Specify: | | | | | | | | | | | | | | | |
| **9. RESEARCH DATA/SAMPLES** | | | | | | | | | | | | | | | |
| 9.1 Please explain where the data/samples will be stored and how long they will be stored for? | | | | | | | | | | | | | | | |
| 9.2 Will data/samples be destroyed after analyses?  *(If no, please explain)* | | | Yes | |  | | | No | | | |  | |  | |
| **10. 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*](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 a15  *[http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx](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](mailto:ngwenyap@ukzn.ac.za) | | | | | | | | | | | | | | | |
| **11. QUESTIONNAIRES: GIVEN TO PARTICIPANTS** | | | | | | | | | | | | | | | |
| Provide 25 copies of all questionnaires, interview guides, data collection sheets etc.  List all such attachments here: | | | | | | | | | | | | | | | |

|  |
| --- |
| **12. 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.    Oversight of study: Will this study be overseen by a professional Clinical Research Organisation or study sponsor?     |  |  |  |  | | --- | --- | --- | --- | | Yes |  | No |  |   If Yes, 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 BREC approval letter. Where applicable, all reports from the Data Safety Monitoring Boards (or similar committees) will be provided to the Biomedical Research Ethics Committee within 7 days.    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*](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**………………………………………..   |  | | --- | | **13. 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.** |
| **14. 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 AND 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 4769 / 2486 Email:** [**BREC@ukzn.ac.za**](mailto: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.**

**INCOMPLETE SUBMISSIONS MAY RESULT IN DELAYED REVIEW OF THE APPLICATION**

**For all non-degree, non-expedited (full) review applications:**

1. • **25** TYPEWRITTEN COPIES OF APPLICATION **(Back-to-back (double-sided) copies preferred)**
2. • **5 COPIES** OF THE PROTOCOL
3. • **5 COPIES** OF CURRENT CV/s **(abbreviated 2 PAGES)**
4. • **5 COPIES** OF **EVIDENCE OF CURRENT GCP / RESEARCH ETHICS TRAINING**
5. • **25 COPIES** OFALL QUESTIONNAIRES TO BE USED IN THE STUDY
6. • **25 COPIES** OF THE INFORMED CONSENT FORMS (See BREC templates)
7. • **25 COPIES** OF THEPATIENT INFORMATION LEAFLET (See BREC templates)
8. • HAVE YOU FAMILIARISED YOURSELF WITH THE BREC TERMS OF REFERENCE? (See <http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx> )
9. • DETAILS OF ALL FUNDING SUPPORT?
10. • ALL PERSONAL INFORMATION?
11. • ANSWERED ALL QUESTIONS?
12. • GIVEN DETAILS OF ALL RESEARCH PRESENTLY BEING UNDERTAKEN?
13. • DELETED UNNECESSARY BLANK SPACES IN THE DOCUMENT?
14. • **IS DECLARATION PAGE SIGNED BY PI AND HOS/DEAN OR SUPERVISOR?**

**In addition: FOR CLINICAL TRIALS – SUBMIT:**

1. • **5 COPIES** OF THE INVESTIGATOR’S MANUAL
2. • **5 COPIES** OF MCC APPROVAL
3. • **5 COPIES** OF THE FINANCIAL AGREEMENT

**FINAL CHECKLIST FOR FULL (Non-expedited) APPLICATIONS:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | Proof of PI and Co–PI current HPCSA registration | **YES** | **NO** | **N/A** |
| 2 | Permission from hospital manager/clinics submitted | **YES** | **NO** | **N/A** |
| 3 | For degree purposes, please attach copy of postgraduate approval letter | **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 requirements below \* | **YES** | **NO** | **N/A** |
| 8 | GCP/ethics training certificates of co-investigators \* requirements below | **YES** | **NO** | **N/A** |
| 9 | Have other REC approval letters been submitted? | **YES** | **NO** | **N/A** |
| 10 | Is applicant affiliated to BREC – e.g. BREC member? If yes, please specify | **YES** | **NO** | **N/A** |
| 11 | Clinical protocol submitted | **YES** | **NO** | **N/A** |
| 12 | BREC details on Information Sheet updated/checked | **YES** | **NO** | **N/A** |
| 13 | Statistics addressed | **YES** | **NO** | **N/A** |
| 14 | Information to participants submitted | **YES** | **NO** | **N/A** |
| 15 | Informed consent documents submitted | **YES** | **NO** | **N/A** |
| 16 | Signature of PI | **YES** | **NO** | **N/A** |
| 17 | Signed supervision agreement (if applicable) | **YES** | **NO** | **N/A** |
| 18 | Signature of ACADEMIC LEADER/HOS/DEAN or Line Manager | **YES** | **NO** | **N/A** |
| 19 | Signatures of co-investigators | **YES** | **NO** | **N/A** |
| 20 | Questionnaires submitted | **YES** | **NO** | **N/A** |
| 21 | Translation of documents certified | **YES** | **NO** | **N/A** |
| 22 | Materials Transfer Agreement (MTA) | **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 | One copy of grant funding proposal and Award notice if funded by any US DHHS source, e.g., NIH, CDC, DAIDS | **YES** | **NO** | **N/A** |
| 27 | Copy of MCC approval or application | **YES** | **NO** | **N/A** |

1. **\* 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**](http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx)**)**

1. Note: This application must be self-sufficient. Sections marked “see protocol” are unacceptable and will be returned to the applicant. [↑](#footnote-ref-1)
2. Please note that because of conflict of roles and interests that can arise, academic supervisors and co-investigators should be separate individuals. [↑](#footnote-ref-2)