**BREC Application**

# 1. Key Information

**Is this for degree or any other qualification purposes?**

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**Purpose of Research**

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**Type of ethics review**

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**System ID Number**

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**Protocol Referece Number**

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**Is this application for an individual or is it for a Group?**

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**Is this a sub study of a previously approved study?**

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## Link this application to a related ethics approval

**Is this a re-submission of a previous study that was not approved by the Research Ethics Committee?**

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## Principal Investigators

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| **Name** | **Organisation** | **Current qualification** | **Proposed qualification** | **HPCSA/Other** |
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**Is the PI currently involved in other research and/or clinical trial activities?**

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## Co-Investigators

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| **Name** | **Organisation** | **Current qualification** | **Proposed qualification** | **HPCSA/Other** |
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**Has the Principal Investigator or any of the co-investigators been previously/ or are presently being investigated for alleged research misconduct?**

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## Supervisor(s)

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| **Name** | **Organisation** | **Current qualification** | **Proposed qualification** | **HPCSA/Other** |
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**Has this study been, or is it likely to be, submitted to any other Research Ethics Committee?**

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# 2. Funding

**Has funding been secured?**

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**Funding amount in Rands**

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**Funder Name**

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**Is the project funded from a US DHHS funding source?**

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**Can this project proceed without funding?**

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**Brief Explanation**

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**Has an application been made to other sources to support this project?**

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**Has the funder imposed any restrictions on PI regarding publications of study results?**

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**Please indicate whether a BREC review fee is applicable for this study? (N/A for students) See fee schedule on BREC website**

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## 3. Study Nature of Study

**Type of study**

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## Protocol

**Full title of research project (No abbreviations to be used)**

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**Aim/s (what you hope to achieve) and Objective/s (how you will achieve your aim/s) of study. Please list:**

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**Research Questions**

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**Summary of the proposed research methodology**

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## Keywords

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**If the keywords you are looking for cannot be found using search, please enter them here**

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**Background and literature review.**

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**Key references - list five**

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## Plan of investigation for study

**Is this a retrospective chart review with no human contact?**

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**Is this a study of stored tissue?**

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**Are host genetic factors being studied?**

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**How many hours per week will the PI devote to this project?**

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**Describe your data collection methods for the research project in detail**

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## Statistical planning and data analysis

**Has this project been approved by a professional statistician?**

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**If yes, provide the name of the statistician**

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**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 anticiapted 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*

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**For qualitative studies: What is the analytic paradigm to be used for analysis of data?**

## 4. Participants Participants in the study

**Is this a multinational study?**

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**If multinational add collaborating countries**

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**List all sites in which the project will be carried out i.e. geographic location (e.g. KwaZulu-Natal) and type of place (e.g. name of hospital, clinic, schools, community, animal research facility, conservation areas etc).**

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## Source of participants

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|  | **Inpatients** | **Outpatients** | **Volunteers** | **Animals** |
| **Sample Size / No. of participants** |  |  |  |  |

## Age group(s) of participants

*Input the number of participants per age group. Neonates (<28 days) Infants (1-11 months) Children*

*(1-12 year) Adolescent (13-17 years)*

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|  | **Neonates** | **Infants** | **Children** | **Adolescents** | **Adults** |
| **No. of Participants** |  |  |  |  |  |

**Is there a control group?**

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## Demographics of participants

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| **Gender** | Female: |  | Male: |  |

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| **Population** | Black | Coloured | Indian | White |
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## Specify language groups

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**List any languages not found above**

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## Recruitment

**Describe the recruitment process in detail for all groups**

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**Will incentives be offered to facilitate recruitment?**

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**Will participants be reimbursed in some way for participation?**

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**Will reimbursements for participants and investigators be in accordance with:**

1. *Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South*

 *Africa: Department of Health (2006)*

1. *Ethics in Health Research: Principles, Structures and Processes: (2015)*
2. *Current SA DoH Guidance on reimbursement (See BREC website)*

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**Will participants be insured against research related injury? (mandatory for clinical**

**trials)**

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**List in detail the inclusion and exclusion criteria.**

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## Potential risk or discomfort

**Can the project have any potentials risks or discomfort on participants, members of the public, researchers, field staff, or the physical environment?**

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**Please detail steps that will be taken to minimize the risks indicated above:**

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## Biological samples

**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?**

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**Will human tissues, genetic materials, and/or microbial isolates be exported?**

*If required, please attach a Materials and Data 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).*

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**Please provide rationale for export of biological materials (i.e. why the work cannot be done locally why local capacity cannot be upgraded).**

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# 5. Clinical trials

**Has South African Health Products and Regulatory Authority (SAHPRA) approval been applied for?**

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**Has this clinical trial been registered with the SA National Clinical Trials Register?**

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**Please provide the names of all members of the Data Safety and Monitoring Board (DSMB)**

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**The PI hereby undertakes to ensure all DSMB reports are forwarded to BREC for comment as soon as possible.**

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**Are any of the intended research participants in other research studies and/or trials?**

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# 6. General

**Indicate, for each study group, the likely additional, i.e., over and above standard of care:**

1. *Duration of hospital stays (days):*
2. *Outpatient attendances (number):*
3. *Laboratory services used, including those appointed by the sponsor (name and location):*
4. *Type of samples and volumes to be drawn:*
5. *Which laboratory services will be used?*

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**Has a preliminary agreement been reached with laboratory service providers? If yes, attach letter of confirmation on the attachments tab.**

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**Has the nursing team who will be involved in the study been informed of the study and the nursing involvement that will be required?**

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**If no, please explain, otherwise specify**

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**In the case the participants drawn from patient populations, indicate, in respect of each sub-group, how management differs from that usually offered to patients with similar conditions.**

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**In the case of community based studies, explain what consultation is planned within the community at the following stages:**

1. *Duration of hospital stays (days):*
2. *Outpatient attendances (number):*
3. *Laboratory services used, including those appointed by the sponsor (name and location):*
4. *Type of samples and volumes to be drawn:*
5. *Which laboratory services will be used?*

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**State the expected benefits arising from this study under the following headings:**

*Possible direct benefits to study participants*

*Clinical care*

*Public Health*

*Financial*

*Prospects of tested intervention being available to the study population if proven effective: Cost Effectiveness*

*Possible indirect benefits arising from the study Other (specify)*

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**Describe the intended strategy for dissemination of study results**

*To the scientific community*

*To research participants*

*To the general public (if applicable) Other: Specify:*

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**Please explain where and how the data/samples will be stored and how long they will be stored for?**

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**Will data/samples be destroyed after analyses?**

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**NB: When filling in the online application form in the RIG system, please ensure that all relevant documents are attached onto the Attachments section of the application form before submitting your application. The preferred file format is PDF.**