**UKZN BIOMEDICAL RESEARCH ETHICS COMMITTEE (BREC)**

**APPLICATION FOR ETHICS APPROVAL**

**For research with human participants (Biomedical)**

Please Note:

1) Research for non-degree purposes: Complete this form and submit to the BREC offices at the Research Office, Govan Mbeki Centre, Westville Campus. A separate proposal and supporting documentation must accompany the application (see p. 13). All non-degree applications must submit the complete number of hard copies required (see p. 13).

2) Applications for postgraduate degrees must be submitted, on this form, to the applicable school Postgraduate and Research Office in the College of Health Sciences. All postgraduate studies will undergo scientific and ethics review in parallel.

3) This proposal may need to be sent to other scientific review or Research Ethics Committees for comment/review.

4) Please ensure that BREC review fees are paid in advance on all grant-supported or funded studies.

5) Note that applications on outdated BREC application forms will be rejected. The most recent versions are always on the BREC website at <http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx>



**RESEARCH OFFICE**

**Biomedical Research Ethics Administration**

#  **Westville Campus, Govan Mbeki Building**

**Private Bag X 54001
Durban
4000**

**KwaZulu-Natal, SOUTH AFRICA**

**Tel: 27 31 2604769 - Fax: 27 31 2604609**

**Email:** **BREC@ukzn.ac.za**

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

**BIOMEDICAL RESEARCH ETHICS COMMITTEE**

**APPLICATION FOR ETHICS APPROVAL**

**For research on human participants (Biomedical)**

**PART 1 (Provide 24 copies)**

**IMPORTANT: COMPLETE CHECKLIST ON PAGES 12-13 PRIOR TO SUBMISSION**

RESEARCH MAY NOT COMMENCE WITHOUT ETHICS APPROVAL

This application form must be self-sufficient. Sections indicating e.g., “see protocol” or “see information sheet” are unacceptable and will be returned. The application must be typewritten.

**SECTION 1: ADMINISTRATIVE DETAILS**

|  |  |
| --- | --- |
| **NAME: PI - Prof/Dr/Mr/Mrs/Miss/Ms**  |   |
| **Gender:\*** |  |
| **Race:\*** |  |
| **NAME: Co-investigator- Prof/Dr/Mr/Mrs/Miss/Ms**  |   |
| **Professional status (if student, year of study)**  |   |
| **UKZN Faculty:** |  |
| **UKZN Department**  |   |
| **Hospital / Institution where employed**  |   |
| **Full Postal address**  |   |
| **Contact telephone and fax numbers**  |   |
| **Email Address**  |   |
| **Full time/part time employment**  |   |
| **Current HPCSA Number (or equivalent statutory health council registration no. as appropriate) – if registration is pending, submit proof of application.**  |   |

|  |
| --- |
| **1.1 TITLE OF PROJECT in full:** (do not abbreviate)     |

|  |
| --- |
| **1.2** WHERE **WILL THE RESEARCH BE CARRIED OUT?** *(interaction with participants)*  |
| (Please furnish the name of hospital/institution and department.)    |

**1.3 PURPOSE OF RESEARCH:**

For Postgraduate Degree: *(circle applicable:)* **Masters or PhD*?***

**PhD MMedSc MMed MPH MFamMed MHIV MSc**

**OTHER (PLEASE INDICATE) DEGREE:**

**(If for postgraduate degree, please confirm that application has been reviewed and approved by your school’s Postgraduate Committee: Y/N. If Y, provide approval date and attach approval letter).**

If not for degree purposes, state other:

* 1. **Student number if applicable:**

**1.5 PRINCIPAL INVESTIGATOR/CO-INVESTIGATOR/S (state exact role/s in the study):**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Name**  | **Faculty** | **Department** | **Gender\*** | **Race\*** | **Role**  | **Signature**  |
|  |  |  |  |  |  |  |
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|  |  |  |  |  |  |  |

\* For UKZN statistical reporting purposes.

**1.5 FUNDING**

Has funding been secured? **Yes:** **No:**

Amount: R

Name of Funder (full details):

Is this project funded from a US DHHS funding source?

 If yes, name Federal funding agency:

Can this project proceed without funding? Yes: No:

 Give a brief explanation:

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. Included?

|  |  |  |
| --- | --- | --- |
| **YES**  | **NO**  | **N/A**  |

Please indicate whether BREC review fees have been paid for this project?

|  |  |  |
| --- | --- | --- |
| **YES**  | **NO**  | **N/A**  |

Please note that any contractual undertaking that involves the Faculty of Health Sciences must be processed through UKZN Innovation (Pty) Ltd – contact Ms K Reinerstsen, Tel: 031-260 4360 - e-mail reinertsen@ukzn.ac.za

Contracts from other Faculties should be routed through Ms M Mokotedi, Legal Services– Tel: 031-260 3564 – mokotedim@ukzn.ac.za

 **FAILURE TO MAKE FULL FINANCIAL DISCLOSURES WILL DELAY ETHICS APPROVAL.**

 **1.6 EXPEDITED OR FULL REVIEW?**

|  |  |
| --- | --- |
| Expedited: | Full review: |

Note that 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>

 **1.7 CLINICAL TRIALS: (Mark N/A below if the study is not a clinical trial)**

1. Has Medicines Control Council approval been applied for?

|  |  |  |
| --- | --- | --- |
| **YES**  | **NO**  | **N/A**  |

Indicate current status of MCC approval application:

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

|  |  |  |
| --- | --- | --- |
| **YES**  | **NO**  | **N/A**  |

2.1If Yes, please provide SANCTR registration number: ……………….

2.2 If No, PI hereby undertakes to register the trial after final ethics and MCC approval:

|  |  |  |
| --- | --- | --- |
| **YES**  | **NO**  | **N/A**  |

1. Please provide the names of all members of the Data Safety and Monitoring Board (DSMB).
2. The PI hereby undertakes to ensure that all DSMB reports are forwarded to BREC for comment as soon as possible.

|  |  |  |
| --- | --- | --- |
| **YES**  | **NO**  | **N/A**  |

**SECTION 2: DISCLOSURES**

1. 1. Has this study been, or is it likely to be, submitted to any other Research Ethics Committee?

|  |  |
| --- | --- |
| **YES**  | **NO**  |

1.

1. **2.** If yes, please name the Committee/s and give outcome - i.e. approved/rejected/pending/not applicable**? If approved, attach approval letter.**

|  |  |
| --- | --- |
| **YES**  | **NO**  |

1. 3. 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**  |

1. 4. Are any of your intended research participants in other research studies and/or trials? If yes, please provide details.

|  |  |
| --- | --- |
| **YES**  | **NO**  |

1. 5. Are you presently involved in other research and/or clinical trial activities? If yes, please provide details and % time allocated to each.

|  |  |
| --- | --- |
| **YES**  | **NO**  |

1. 6. Will human tissues (blood, blood products, gamete, gonads, oocyte, organs, flesh, bone, gland, skin, bone marrow or body fluids), microbial isolates and human genetic materials (DNA, RNA) be stored?

|  |  |
| --- | --- |
| **YES**  | **NO**  |

1. If yes, give details of storage facilities (name, location, conditions and duration of storage).

1. 7. Will human tissues, genetic materials and or microbial isolates be exported?

|  |  |
| --- | --- |
| **YES**  | **NO**  |

1. If yes, 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 a permit (National Health Act, 2003).

7.1 Please provide a rationale for export of biological materials:

1. 8. 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; 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 3: THE PROTOCOL**

Type of Study: Epidemiological:………. Observational clinical study:………Experimental:………

Clinical Trial:…………Observational:………… Retrospective Chart Review:……………Prospective Chart Review:………………Laboratory study on stored samples:…………Other:(Specify):……………………………

**3.1 THE PROJECT**:

1. 1. Aims (objectives of study) – please list.

1. 2. Hypothesis to be tested.

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

4. Keywords (for database):

5. Background and Literature:

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

**3.2 PLAN OF INVESTIGATION:**

**(a) Design and/or experimental procedures :**

*In the case of Higher Degrees, please state name and department of person consulted regarding the design.*

Is this a retrospective chart review with no human contact? Yes:…………No:…………

Is this a study of stored tissue? Yes:…………No:…………

Are host genetic factors being studied? Yes:…………No:…………

**(b) Statistical Planning:**

Has this project been discussed with:

 a professional statistician? Yes:…………No:…………

 a person with a statistical background? Yes:…………No:…………

***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.*

**(c) Participants:**

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

Source:

Inpatients:………Outpatients:………Volunteers:………Animals:………

Age (humans):

Neonates (<28 days):……… Infants (1-11 month)………Children (1-12 yrs)…………

Adolescent (13-17 yrs):………Adults:………

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

Inpatients:………Outpatients:………Volunteers:………Animals:………

Will you have control groups?

Detail inclusion and exclusion criteria:

Describe recruitment process for all groups:

**(d) The Environment:**

1. Is this a multi-national study? Yes / No. *If yes, state collaborating countries*.

2. List all sites in South Africa in which the project will be carried out.

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*.

4. How many hours/week will the PI devote to this project?

 *Timetable the project in terms of the resources and time available.*

5. Storage:

 Please explain where the data is stored and how long it will be stored?

 Will data be destroyed after analyses? If no, please explain:

 **3.3 ETHICAL ASPECTS:**

**(a) Responsibility:** *In respect of any litigation which may result from this research*:

1. Will participants be insured by sponsors against research related injury?

 **Yes:………. No:……… Not applicable:………**

 *If yes, please provide details:*

 *If no, please provide rationale:*

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.*

3. If this project is to be conducted at another institution, is additional ethics approval required?

 **Not Applicable:**…………..**Yes: (Name of institution)……… No:………***If no, please explain.*

**(b) Incentives / Reimbursement**

1. List any incentives, explicit and implicit, that have or will be offered to study participants, either to recruit or to retain within the study.

2. 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:**

1. Compared to persons or patients with similar conditions indicate, for each study group/arm, the potential additional risks as follows:

1. Biological risks
2. Psychological risks
3. Social Risks
4. Legal risks
5. Financial risks
6. Other risks

**2. Risk Minimisation**: Please detail steps that will be taken to minimise the risks indicated above:

1. Biological risks
2. Psychological risks
3. Social Risks
4. Legal risks
5. Financial risks
6. Other risks

**(d) Public Health Service Utilisation:**

Compared with persons or participants with similar conditions indicate, for each study group, the likely additional:

 Duration of hospital stay (days):

 Outpatient attendances (number):

 Laboratory services used, including those appointed by the sponsor (name and location,):

Type of samples and volumes to be drawn:

 Extent of nursing involvement:

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:*

1. 1. Preparation

1. 2. Implementation of the study and

1. 3. Dissemination of the results thereafter

**(g) 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
	4. Prospects of tested intervention being available to the study population if proven effective.
	5. Other (Specify)
2. 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 4: INFORMATION 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](http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx%20%20%20)

If necessary, consent forms, after ethics approval of the English form, 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. Copies of back translations are also acceptable.

**The correct 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 2604769 - Fax: 27 31 2604609**

**Email:** **BREC@ukzn.ac.za**

**SECTION 5: QUESTIONNAIRES:**

Provide 22 copies of all questionnaires, interview guides, data collection sheets etc.

List all such attachments here:

**SECTION 6: 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 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? 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 (2004) *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 Names\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ DATE:\_\_\_\_\_\_\_\_\_\_\_\_\_**

**SECTION 8: DECLARATION AND APPROVAL BY HEAD OF DEPARTMENT**

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

**Remarks:**

**HOD NAME: ……………………………………………HOD SIGNATURE:……………………….**

Has the applicant consulted and informed the Head of Department if different from above?

**Yes No**

**(HOD of Applicant’s Department (if different from above))**

**Name in Block Capitals:**

**Signature:………………………………………………….** **Date:………………………………….**

**PART 2 – SUGGESTED CURRICULUM VITAE FORMAT**

**(3 COPIES)**

**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):

**CHECKLIST FOR BIOMEDICAL RESEARCH ETHICS APPLICATIONS**

**NB: DO NOT BIND SUBMISSIONS (STAPLE ONLY)**

**Applications to be addressed to: The Administrator, Biomedical Research Ethics Committee, Room N40, Govan Mbeki Building, University Road, Westville Campus, Tel: 033-260 4769 / 2486 Email:** **BREC@ukzn.ac.za**

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

1. • **24** TYPEWRITTEN COPIES OF APPLICATION **(PART 1) (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. • **24 COPIES** OFALL QUESTIONNAIRES TO BE USED IN THE STUDY
6. • **24 COPIES** OF THE INFORMED CONSENT FORMS (See BREC templates)
7. • **24 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 HOD/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
4. • **PROOF OF PAYMENT** OF BREC REVIEW FEES

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 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  | **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  | Is applicant affiliated to BREC – e.g. BREC member? If yes, please specify  | **YES**  | **NO**  | **N/A**  |
| 14  | Clinical protocol submitted  | **YES**  | **NO**  | **N/A**  |
| 15  | BREC details on Information Sheet updated/checked  | **YES**  | **NO**  | **N/A**  |
| 16  | Statistics addressed  | **YES**  | **NO**  | **N/A**  |
| 17  | Information to participants submitted  | **YES**  | **NO**  | **N/A**  |
| 18  | Informed consent documents submitted  | **YES**  | **NO**  | **N/A**  |
| 19  | Signature of PI  | **YES**  | **NO**  | **N/A**  |
| 20  | Signature of HOD  | **YES**  | **NO**  | **N/A**  |
| 21  | Signatures of co-investigators  | **YES**  | **NO**  | **N/A**  |
| 22  | Questionnaires submitted  | **YES**  | **NO**  | **N/A**  |
| 23  | Translation of documents certified | **YES**  | **NO**  | **N/A**  |
| 24 | Materials Transfer Agreement (MTA) | **YES** | **NO** | **N/A** |
| 25 | Will genetic studies be performed? If yes, provide consent form | **YES** | **NO** | **N/A** |
| 26 | Export certificate for tissue storage/transportation  | **YES**  | **NO**  | **N/A**  |
| 27 | Permission from Department of Health/Province | **YES**  | **NO**  | **N/A**  |
| 28 | One copy of grant funding proposal if funded by any US DHHS source, e.g., NIH, CDC, DAIDS | **YES** | **NO** | **N/A** |
| 29 | Proof of payment of BREC review fee if externally funded | **YES** | **NO** | **N/A** |
| 30 | Copy of MCC approval or application | **YES** | **NO** | **N/A** |