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| **BIOMEDICAL RESEARCH ETHICS COMMITTEE** **Application for Database Class Approval** |



**PROTOCOL NUMBER:**

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*For office use only*

**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; Fax: +27 31 2604609; Email: BREC@ukzn.ac.za ;

Website: <http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx>

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| **SECTION A:** |
| **DATABASE ADMINISTRATOR / CONTROLLER:**  *\* 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 |  |

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| **Please provide details of co-administrators who will collaborate on the design and maintenance of the database. If additional space is required for more administrators, please add at the end of the application** |

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| **CO-ADMINISTRATOR/S ROLE IN DATABASE DESIGN AND MAINTENANCE** *\* For UKZN statistical reporting purposes* |
| Name: |
| Faculty: |
| Department: |
| \*Gender: |
| \*Race: |
| Role: |
| Signature of Co-Administrator: |
| Has the principal administrator or any of the co-administrators been previously/or are presently being investigated for alleged research misconduct? *(If yes, please provide details and dates)* | Yes |  | No |  |
| **SECTION B:** |
| **DETAILS OF THE DATABASE** |
| * 1. Full title of the Database:
 |
| * 1. Purpose of Database:
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| * 1. Are the data already collected routinely? : Yes/No
 |
| * 1. If you answered ‘No’ above, state who will collect the additional (non-routine) data:
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| * 1. How long will the database be maintained?
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| * 1. Please note, gatekeeper permission to extract data from the original source (e.g. hospital records, laboratory data records etc.) must be obtained following provisional BREC approval. Copies of gatekeeper permission must be provided to BREC before final approval is granted.

 Provide details of gatekeeper(s) here: |
| * 1. Does anyone claim intellectual rights to the construction of the database?
 |
| * 1. If the person in 1.7 is not an administrator or included in the list of co-administrators, have property rights been ceded or has permission been granted to use the database? Please provide supporting documentation.
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| * 1. State the plan in place for continuation of the database should the primary administrator be no longer available.
 |
| 1.10 List possible research questions for which the data could be interrogated: |
| 1.11 List possible quality control and assurance benefits of the database: |
| 1.12 How will patient anonymity be secured? |
| 1.13 Where will the database be kept? |
| 1.14 How will data security be ensured? |
| 1.15 In the case of computer storage of data, is the computer protected from remote internet access, and how?  |
| 1.16 In the case of a web-based database (e.g. Redcap™ ) Please supply a copy of the contract with the **third party host** detailing: * Company name
* Address and contact details for the company
* Contact details of the responsible support officer daily contactable around the clock
* Details of the data protection provided within the company
* A letter providing the details of the level of security provided against unauthorized external access
 |
| 1.17 **DATA ACCESS.** Who will be permitted to interrogate the data (via the administrators/ co-administrators listed in A) |
| 1.18 Please provide a copy of the data collection sheet and / or top row containing data headings of software–based database file. Also a copy of the contract with third party hosts of web-based systems. |

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| **DECLARATION OF PRINCIPAL ADMINISTRATOR** |
| Conflict of Interest: I declare that all potential conflicts of interest regarding my application for ethics approval to keep this database have been declared in accordance with UKZN and BREC Terms of Reference and Standard Operating Procedures. Note: The database administrator/s will not unreasonably withhold researchers access to the content of the database for appropriate research, and may not demand co-authorship on resulting papers unless the person fulfils the criteria for authorship of the ICMJE, namely: •Substantial contributions to: the conception or design of the work (individual study); OR the acquisition, analysis, OR interpretation of data for the work; AND •Drafting the work or revising it critically for important intellectual content (comment during writing the paper); AND •Final approval of the version to be published (email approval acceptable); AND •Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.Contributions not substantial for authorship will gain an "Acknowledgement" at the end of the paper detailing the contribution of the other staff. **Undertaking:**  * I understand and accept that I will be required to submit a yearly recertification application, failing which authorisation to expand the database will lapse.
* I undertake to request permission for any changes/amendments to the database from BREC in advance of implementation.
* I agree to provide monitoring data if and when required.
* I agree to submit any publications emanating from this database to BREC for record keeping on an annual basis.

 * 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*](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 database proposed and I take full responsibility should there be any transgression.

 **SIGNATURE OF PRINCIPAL ADMINISTRATOR**……………………………………**FULL NAME OF PRINCIPAL ADMINISTRATOR**……………………………………**DATE**……………………………………….. |

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| **DECLARATION AND APPROVAL OF LINE MANAGER***(Must include verification of interdepartmental agreements and co-operation)*  |
| Remarks:    **SIGNATURE OF LINE MANAGER** ……………………………………**FULL NAME OF 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 Administrator and all Co-Administrators)**

***(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, Govan Mbeki Building, University Road, Westville Campus, Tel: 031-260 4769 / 2486 Email:** **BREC@ukzn.ac.za**

**Note:**

**PLEASE NOTE THAT THREE COPIES OF APPLICATION AND SUPPORTING DOCUMENTS NEED BE SUBMITTED**

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

**For all Class Approval for databAses review applications:**

1. • **3 TYPEWRITTEN COPIES** OF APPLICATION (Back-to-back (double-sided) copies preferred)
2. • **3 COPIES** OF CURRENT CV/s **(**abbreviated max 4 PAGES)
3. • **3 COPIES** OFEVIDENCE OF CURRENT GCP / RESEARCH ETHICS TRAINING
4. • HAVE YOU FAMILIARISED YOURSELF WITH THE BREC TERMS OF REFERENCE? (See <http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx> )
5. • DETAILS OF ALL FUNDING SUPPORT?
6. • ALL PERSONAL INFORMATION?
7. • ANSWERED ALL QUESTIONS?
8. • DELETED UNNECESSARY BLANK SPACES IN THE DOCUMENT?
9. • **IS DECLARATION PAGE SIGNED BY ALL REQUESTED?**