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BIOMEDICAL RESEARCH ETHICS COMMITTEE (BREC)
STANDARD OPERATING PROCEDURES

These Standard Operating Procedures (SOPs) outline how BREC will conduct its activities as mandated by the current BREC Terms of Reference.

1. BREC MEETINGS

- Meetings will be held on the second Tuesday of every month, excluding January. Members will be notified annually of the scheduled dates no later than the second week of January.
- The minutes of meetings and the agenda will be circulated to members at least 7 days prior to the meeting.
- A special meeting may be called at any time by the Chairperson.

2. COMPOSITION

The composition of BREC will be in accordance with the provisions of the Department of Health *Ethics in health research: Principles, processes and structures* (2015) and *South African good clinical practice guidelines* (2020 or later). These include:

- Members of BREC should collectively have the qualifications, experience and expertise to review and evaluate the scientific, medical, legal, psychosocial and ethical aspects of research proposals.
- Appointment to the Committee will be by nomination and co-option. The total number of Committee members must be no less than 14.
- The Chair of BREC is appointed by the Deputy Vice Chancellor of Research for a renewable term of three years.
- The Chair of BREC reports to the University Dean of Research.
- Any unanticipated problems involving risks to participants or others or any serious or continuing non-compliance with this document or the requirements or determinations of BREC and any suspensions of BREC approval will be reported to the Dean of Research by the BREC Chair.
- Changes in BREC Standard Operating Procedures and membership may be approved by a quorate BREC meeting and will be reported to the SA National Health Research Ethics Council (NHREC) and the US Office for Human Research Protections (OHRP).

2.1 Membership

The committee shall:

(i) Be representative of the communities it serves and, increasingly, reflect the demographic profile of the population of South Africa;

(ii) Include members of both genders, although not more than 70% should be either male or female;

(iii) Have at least 14 members, with a simple majority constituting a quorum

(iv) Have a chairperson;

(v) Elect a vice-chairperson (or persons) from the members of the committee, who shall be a member of the staff of the University;

(vi) Include at least one lay person who has no affiliation to the institution, is not currently involved in medical, scientific or legal work and is preferably from the community in which the research is to take place;

(vii) Include at least one member with knowledge of, and current experience in, areas of research that are likely to be regularly considered by BREC;

(viii) Include at least one member with knowledge of, and current experience in, the professional care, counselling or treatment of people. Such a member might be, for example, a medical practitioner, psychologist, social worker or nurse);

(ix) Include at least one member who has professional training in both qualitative and quantitative research methodologies;

(x) Include at least one member who is legally trained;

(xi) Ensure that the membership is equipped to address all relevant considerations arising from the categories of research likely to be submitted to it;

(xii) Ensure that it is adequately informed on all aspects of a research protocol, including its scientific and statistical validity, that are relevant to deciding whether the protocol is both acceptable on ethical grounds and conforms to the principles of this document;

(xiii) Members not attending 2 consecutive meetings without a valid written reason, and without submitting their reviews, risk termination of their membership of BREC;

(xiv) BREC members will serve for a term of 3 years, renewable;

(xv) BREC members will be required to have continuous personal development in research ethics. Members must have current certificates of evaluated research ethics training and GCP training and lodge these certificates with the BREC office. Such certificates are generally valid for 3 years unless otherwise stated;

(xvi) BREC may co-opt expert members and other representatives as voting members as required by particular protocols. Voting status is to be confirmed by BREC in advance on a case by case basis;

(xvii) On invitation or request, BREC meetings may be attended by *bona fide* students, researchers and other interested parties as non-voting observers, subject to the signing of a confidentiality undertaking and subject also to being excluded from certain agenda items as determined by the Chair.

2.2 Conflict of Interest

BREC members shall declare any prior interest and/or involvement in any matter being discussed by BREC to avoid conflict of interest in BREC decision-making, including reviewing of protocols. In convened BREC meetings, the Chair shall determine whether the member be recused for items of discussion, or be allowed to remain and address questions when asked to do so, but not vote or participate in final decision-making on the matter in question.

2.3 Confidentiality

"Confidential Information" shall mean certain proprietary, personal, clinical or protocol-specific information. Such information includes all protocols relating to research with human participants and associated documentation. The Confidential Information may be written, graphic, oral or physical including (but not limited to) scientific knowledge, skills, processes, inventions, techniques, formulae, products, business operations, patient requirements, biological materials, designs, sketches, photographs, drawings, specifications, reports, studies, findings, data, plans or other records, and/or software. All BREC members and support staff shall sign a standard confidentiality agreement on appointment to BREC (see Appendix C).

2.4 Quorum / Voting:

The Committee will make its decisions at scheduled or extraordinary meetings at which a quorum of members is present. A quorum is a simple majority of members. Minutes of inquorate meetings must be tabled for approval at a subsequent quorate meeting. Decisions will be determined by consensus (general agreement). Where general agreement does not exist, consensus will be undermined and the decision will be arrived at by vote. Minutes taken at BREC meetings will be of sufficient detail to show attendance at the meetings; actions taken by BREC; if applicable, the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of disputed issues and their resolution.

2.5 Compliance

The Biomedical Research Ethics Committee functions in compliance with, but not limited to, the following documents and guidelines:

- The SA Department of Health *Ethics in health research: Principles, processes and structures* (2015), and *South African good clinical practice guidelines* (2020 or later).
- Declaration of Helsinki (Current version)
- The Belmont Report,
- The US Office of Human Research Protections 45 CFR 46 (for non-exempt research with human participants conducted or supported by the HHS), 21 CFR 50, 21 CFR 56,
- CIOMS (Current version),
- ICH-GCP-E6 Sections 1-4 and,
- The International Conference on Harmonisation and Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH Tripartite).
- UKZN Research Policy V: Research Ethics (Current version)
- UKZN Plagiarism Policy (Current version)

When strict compliance with the letter of a particular requirement of these declarations and codes is not possible, BREC will ensure that the proposed research is nonetheless in keeping with the spirit of the declarations and codes.

3. REVIEW PROCESS

3.1 All researchers submitting protocols for ethics review should be registered with the Health Professions Council of South Africa (HPCSA) or other South African statutory body as appropriate. If not registered with HPCSA or other statutory body, the committee shall, based on the applicant's CV and other documentary submissions, satisfy itself that the applicant is competent to undertake the roles described in the protocol, subject to legal requirements. For non-South African citizens, proof of registration with an equivalent body in their home country and in South Africa will be necessary. Where this is not available,

then a motivation and/or other supporting documents from a locally registered person or appropriate authority should accompany the application as evidence of competence.

3.2 All international collaborative research will have a local Principal Investigator.

3.3 Studies that have a substantial clinical component, where the Principal Investigator is not a clinician, should appoint an HPCSA-registered clinician as a Co-Principal Investigator to the study.

3.4 The Committee will obtain the following document/s from the researcher:

- Current Biomedical Research Ethics Committee application form(s)
- Trial/study protocol(s)
- Written informed consent form(s)
- Information sheets
- Participant recruitment procedures (e.g. advertisements)
- Written information to be provided to participants
- Investigator's brochure (IB)
- Safety information
- Information about payments to participants
- Information on compensation for research related injury (insurance) for participants Details, where applicable, of Data Safety Monitoring Boards (DSMB) or other monitoring structures and processes.
- Research team's current curriculum vitae and, if relevant,
- Other documentation evidencing qualifications, and
- Evidence of recent research ethics and/or GCP training. GCP training is compulsory for key clinical trial personnel.
- For studies supported by funding from the US HHS, copies of the HHS grant application must accompany the application for review by BREC.
- Any other documents that BREC may need to fulfil its responsibilities.

3.5 The Committee will review all applications within a reasonable time. All protocols for full review must be submitted to the BREC offices during the first 10 days of each month and will be discussed at a full BREC meeting which will be held on the first Tuesday of the following month.

- **The full (non-expedited) review process will be as follows:** • 1 week for the administrative process
- 2 weeks for committee review.
- Each protocol will be discussed at a convened quorate BREC meeting at which a majority of the members of BREC are present, including at least one member whose primary concerns are in non-scientific areas.
- For all non-expedited reviews, all committee members will receive copies of the BREC application form and the protocol.
- Each non-expedited application and protocol will be reviewed in advance of a convened BREC meeting by all BREC members. A primary and secondary reviewer, and where necessary, an expert reviewer will be allocated to review each such application.
- The primary reviewer will, at the BREC meeting give a synopsis of the study together with the positive and negative aspects of the proposed research.
- The secondary reviewer will also report on their evaluation of the proposed research.
- A protocol that is ethically and scientifically sound will have a review time of 30 days.
- Where a non-expedited protocol is not approved at a convened BREC meeting and the revisions or modifications required are substantive, BREC may require that the

modifications and investigator responses are deferred to a further convened meeting of BREC. This is mandatory for all non-exempt US DHHS funded studies as per 45 CFR 46.111.

3.6 BREC's review of a protocol will lead to written confirmation to the applicant of either:
- final approval
- provisional approval conditional to modifications required by the Committee
- rejection

Reasons for provisional approval and rejection are to be furnished to the researcher in writing.

3.7 BREC must document its views in writing, clearly identifying the study, the documents reviewed, and the dates for the following:
- approval;
- modifications required prior to resubmission for approval;
- rejection; and
- termination or suspension of any prior approval.

The Chair will inform the researcher in writing of the BREC decision.

4. RECERTIFICATION OR CONTINUING REVIEW

4.1 Recertification of Non-Expedited Studies

BREC will conduct continuing review of each ongoing study at intervals appropriate to the degree of risk to human participants, but at least once per year. In special circumstances, such as heightened risk or participant vulnerability (See Appendix A) as determined by BREC as a condition of approval, more frequent reports may be called for. The procedures for continuing review by BREC may include a primary reviewer system. In conducting continuing review of research not eligible for expedited review, all BREC members should at least receive and review a BREC recertification application form containing essential study information including a protocol summary and status report on the progress of the research that includes:

- the number of participants accrued;
- a summary of any unanticipated problems and available information regarding adverse events (in many cases, such a summary could be a simple brief statement that there have been no unanticipated problems and that adverse events that have occurred and been previously reported to BREC are at the expected frequency and level of severity as documented in the research protocol, the informed consent document, and any investigator brochure);
- a summary of any withdrawal of participants from the research since the last BREC review;
- a summary of any complaints about the research since the last IRB review;
- a summary of any recent literature that may be relevant to the research;
- a list of any BREC approved amendments or modifications to the research since the last BREC review;
- any relevant multi-centre trial reports;
- any other relevant information, especially information about risks associated with the research;
- a copy of the current informed consent document and any newly proposed consent document/s.

When reviewing the current informed consent documents the following should be ensured:

- that the currently approved or proposed informed consent document is still accurate and complete;

- that any significant new findings which may relate to participants' willingness to continue participation are provided to the participant.
- review of currently approved or newly proposed consent documents must occur during the scheduled recertification review of research by the BREC, but informed consent documents should be reviewed whenever new information becomes available that would require modification of information in the informed consent document.
- recertification requests for approved studies may require information from sources other than the investigator to verify that no unapproved changes have occurred since approval or previous recertification. Such information may be required:
- for complex studies with unusual or high levels of risk
- for studies conducted by investigators who previously failed to comply with approved BREC or other conditions
- for studies about which complaints have been received from participants or other sources
- for studies with unusual or unexpected rates of adverse events or other reports
- or randomly as part of BREC's monitoring obligation.

At least one member of BREC (i.e. a primary reviewer) should also receive a copy of the complete protocol including any modifications previously approved by BREC. Furthermore, upon request, all BREC members also should have access to the complete BREC protocol file and relevant BREC minutes prior to or during the convened BREC meeting.

The minutes of BREC meetings should document separate deliberations, actions, decisions and votes, if applicable, for each non-expedited protocol undergoing continuing review by a quorate meeting of BREC.

4.2 Recertification of Expedited Studies

This is limited to specific research categories and to the review of minor changes in previously approved research during the period (of one year or less) for which approval is authorised.

An expedited review procedure may be used for the continuing review of research previously approved by the convened BREC where:

- the study was originally approved through an expedited review process, or
- the research is permanently closed to the enrolment of new participants;
- all participants have completed all research related interventions; and
- the research remains active only for the long-term follow-up of the participants, or,
- where no participants have been enrolled and no additional risks have been identified, or
- where the remaining research activities are limited to data analysis.

When reviewing research under an expedited review procedure, the BREC Chair (or designated BREC member(s)) should receive and review the BREC Recertification form with the required attached information.

4.3 Dating of Recertification (Continuing Review)

BREC should decide the frequency of continuing review for each study protocol necessary to ensure the continued protection of the rights and welfare of research participants, to be done either on a bi-annual or annual basis.

4.4 Should changes in circumstances make it necessary, BREC may at any time withdraw approval of a protocol previously approved.

4.5 Where applicable, BREC Sub-Committee decisions may be implemented from the date of the Sub-Committee review. All Sub-Committee decisions will be reported to a monthly BREC meeting for ratification.

5. SCIENTIFIC VALIDITY OF PROPOSED RESEARCH

BREC must ensure that the proposed research is scientifically valid. (Patients and volunteers may not, ethically, be exposed to potential risks and burdens where the project will not generate the intended knowledge). This requirement includes ensuring that the researchers are suitably qualified to undertake the research.

6. ETHICAL ACCEPTABILITY OF PROPOSED RESEARCH

BREC, in reviewing a protocol, must consider any and all factors that may influence the ethical acceptability of the protocol.

(a) In order to approve research covered by this policy, BREC shall determine that all of the following requirements are satisfied:

- Risks to participants are minimised:
  - (i) Using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk, and
  - (ii) Whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.
- Risks to participants must be reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, BREC shall consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies participants would receive even if not participating in the research). BREC shall not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among the research risks that fall within the purview of its responsibility.
- Selection of participants is equitable. In making this assessment BREC shall take into account the purposes of the research and the setting in which the research will be conducted and shall be particularly cognisant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons (see Appendix A).
- Informed consent will be sought from each prospective participant or the participant's legally authorized representative, in accordance with, and as required by Sections 7.1 and 7.2.
- Informed consent will be appropriately documented, in accordance with, and as required by Section 7.3.
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.
- There are adequate provisions to protect the privacy of participants and to maintain the confidentiality and security of data.

(b) When some or all of the participants are likely to be vulnerable to undue influence or coercion, such as children, prisoners, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these participants (see Appendix A).

7. INFORMED CONSENT PROCEDURES AND DOCUMENTATION

7.1 General requirements for informed consent:

Except as provided elsewhere in this document, no investigator may involve a human being as a participant in research covered by this policy unless the investigator has obtained the legally effective informed consent of the participant or the participant's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective participant or their representative with sufficient opportunity to consider whether or not to participate and that minimise the possibility of undue influence or coercion. The information that is given to the participant or the representative shall be in language and a language level understandable to the participant or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the participant or their representative is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent.

Except as provided in paragraph (c) of this section, in seeking informed consent the following information shall be provided to each participant:

- a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the participant's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- a description of any reasonably foreseeable risks or discomforts to the participant;
- a description of any benefits to the participant or to others which may reasonably be expected from the research;
- a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;
- a statement describing the extent to which confidentiality of records identifying the participant will be maintained;
- for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- an explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of research-related injury to the participant; and
- a statement that participation is voluntary and that refusal to participate will involve no penalty or loss of benefits or reduction in the level of care to which the participant is otherwise entitled.
- a statement that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

(b) Additional elements of informed consent.

When appropriate, one or more of the following elements of information shall also be provided to each participant:

- a statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or foetus, if the participant is or may become pregnant) which are currently unforeseeable;
- anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent;

- any additional costs to the participant that may result from participation in the research;
- the consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant;
- a statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided to the participant;
- the approximate number of participants involved in the study, and
- a statement as to whether the research is part of a degree requirement.

(c) Variations of Consent Procedures:

BREC may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided BREC finds and documents that:

- the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, audit, evaluate, or otherwise examine:
  - (i) public benefit or service programs;
  - (ii) procedures for obtaining benefits or services under those programs;
  - (iii) possible changes in or alternatives to those programs or procedures; or
  - (iv) possible changes in methods or levels of payment for benefits or services under those programs; and
- the research could not practicably be carried out without the waiver or alteration.

BREC may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided BREC finds and documents that:

- the research involves no more than minimal risk to the participants;
- the waiver or alteration will not adversely affect the rights and welfare of the participants;
- the research could not practicably be carried out without the waiver or alteration; and
- whenever appropriate, the participants will be provided with additional pertinent information after participation.

Informed consent is not required for use of information in the public domain, although guidance may be needed concerning definition of what type of information about citizens is regarded as public.

(d) The informed consent requirements in this SOP are not intended to pre-empt any applicable governmental or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(e) Nothing in this policy is intended to limit the authority of a registered health professional to provide emergency medical care, to the extent the registered health professional is permitted, under applicable governmental or local law.

(f) The participant must, having been fully informed, be asked to give his/her free and voluntary consent to inclusion in the study. Where a relationship of dependence exists between participant and researcher (e.g., service provider/service recipient), consent should ideally be obtained by an independent person.

7.2 Documentation of informed consent:

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by BREC and signed by the participant or the participant's legally authorized representative. A copy shall be given to the person signing the form.

(b)Except as provided in paragraph (c) of this section, the consent form may be either of the following:

- A written consent document that embodies the elements of informed consent required by Section 7.1. This form may be read to the participant or the participant's legally authorized representative, but in any event, the investigator shall give either the participant or the representative adequate opportunity to read it before it is signed; or
- A short form written consent document stating that the elements of informed consent required by Section 7.1 have been presented orally to the participant or the participant's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. In addition, BREC must approve a written summary of what is to be said to the participant or the representative. Only the short form itself is to be signed by the participant or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the participant or the representative, in addition to a copy of the short form.

(c) BREC may waive the requirement for the investigator to obtain a signed consent form for some or all participants if it finds either:

- That the only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern; or
- That the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context. In cases in which the documentation requirement is waived, BREC may require the investigator to provide participants with a written statement regarding the research.

8. WITHOUT WRITTEN CONSENT

Where the protocol indicates that prior consent of the study participant or the participant's legally acceptable representative is not possible, BREC must determine that the proposed protocol and/or other document(s) adequately address/es relevant ethical concerns and meets applicable regulatory requirements for such studies.

9. DETERMINING ACCEPTABLE RISKS

The Committee must be fully informed regarding the degree of risk and/or discomfort that patients/volunteers will undergo.

9.1 BREC must ensure that, where a research protocol involves greater than minimal risk or discomfort to participants, no feasible alternative exists that could provide the answer sought and that the investigator will take all possible steps to minimise such risk or discomfort. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

9.2 BREC must satisfy itself that there is an acceptable balance between the risk/discomfort that the participant is asked to undergo, and the benefit that is expected to result from the research.

9.3 BREC must ensure that patients are not deprived of recognised benefits as a result of being included in the placebo arm of a trial.

9.4 BREC must be informed of the benefits that may be expected to result from the research, including
- potential benefits to participating participants
- anticipated benefit to categories of individuals (e.g. sufferers from particular diseases) - anticipated benefit to society and/or particular communities.

10. COMPENSATION / FINANCIAL BENEFITS

BREC must review the amount and method of payment to participants to ensure that neither presents a problem of undue influence for the study participants. Payment to participants must be prorated and not wholly contingent on completion of the study by participants. Payment should be in accordance with relevant DoH (2012) on payment to research participants and, where relevant, with SAHPRA guidance for compensation of clinical study participants in South Africa: GUIDANCE DOCUMENT: (sahpra.org.za)

10.1 BREC must ensure that information regarding payment to participants, including the methods, amounts and schedule of payment to study participants, is included in the written informed consent form and any other written information that is provided to participants. The way in which payment will be prorated must be specified.

10.2 BREC must satisfy itself that, where substantial expenditure of public funds will be incurred, the importance and potential benefit of the research will be proportionate.

11. CONFIDENTIALITY

BREC must ensure that confidentiality regarding the identity of participants of research is maintained at all stages of the research, particularly in regard to published results of research. In some cases the identity of communities or institutions may also need to be protected to prevent stigmatisation or discrimination.

12. RESEARCH INVOLVING CHILDREN

12.1 A “Child” is defined as someone younger than 18 years in the Bill of Rights of the Constitution of South Africa.

12.2 Research with children should comply with the South African DoH (2015) Ethics Guidelines (Section 3.2.2) and be undertaken only when the research cannot be carried out equally well with adults, and the research question will not be answered using adult participants. The purpose of the research must be to obtain knowledge relevant to the health needs of children.

12.3 Research involving children must be in conformity with ethical guidelines and the law.

12.4 Unless contrary to South African laws and regulations, research involving children should be determined by BREC as falling into one of the following categories:

- Research not involving greater than minimal risk to the children
- Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual child participants involved in the research
- Research involving greater than minimal risk and no prospect of direct benefit to the individual child participants involved in the research, but likely to yield generalisable knowledge about the participant's disorder or condition provided that the risk represents a minor increase over minimal risk
- Research that BREC believes does not meet the conditions above but finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children.

12.5 Adequate provision should be made for obtaining assent of the children and consent from their parents or legal guardians.

12.6 Where parents and legal guardians are not available, BREC shall be guided by applicable laws and guidelines, the merits of the study and expert opinion on legal and technical points concerning the proposed study.

12.7 US DHHS funded research with children must comply with US 45 CFR 46.404-407 in addition to relevant South African legislation and regulations.

13. COMMUNITY / PRISON BASED STUDIES

The Committee must ensure that, particularly with regard to research involving communities, those communities' traditions and values are respected, particularly with regard to obtaining consent to participate in the research. However, permission given by a community's leaders does not absolve the researcher from also obtaining the fully informed consent of each individual participant.

13.1 When reviewing non-expedited studies involving prisoners, BREC must ensure that:

- at least one member of BREC shall be a prisoners' representative (e.g., prisoner, ex prisoner, prisoner or ex-prisoner service provider or member of an NGO representing prisoners) with appropriate background or experience and a voting member of BREC, unless the study has also been reviewed by another accredited REC on which a prisoner representative was present,
- at least one member present shall be a non-scientist,
- the majority of BREC members, other than the member described above, shall have no association with the prison(s) involved, apart from their membership of BREC,
- the Investigator has complied with the conditions specified in the South African DoH (2015) Ethical Guidelines (Section 3.2.8),
- Studies on prisoners should only be conducted on prisoners if the researcher satisfies BREC that the research cannot be carried out equally well on non-prisoners and the research question cannot be answered with non-prisoners. The purpose of the research must be to obtain knowledge relevant to the health needs of prisoners.
- US HHS-funded studies with prisoners must comply with 45 CFR 46.301 to 45 CFR 46.306 in addition to relevant South African legislation and regulations.

14. RESPONSIBILITIES TO STUDY STAFF

BREC must ensure that all related professionals who are actively involved in the care of participants of research, particularly nurses, are fully informed of the demands, nature and purpose of the research.

15. TRANSLATIONS OF INFORMATION/CONSENT DOCUMENTS

- The investigator must ensure that such documents are translated into the relevant languages on receipt of provisional approval from BREC.
- Translations must be carried out by accredited translators and certification to this effect produced (with the translated and back-translated documents for BREC approval where requested).

16. EXPEDITED REVIEW

- Definition: An expedited review procedure consists of a review of research involving human participants by one or more members of BREC allocated to the study by the BREC Chair.
- Minimal Risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
- Expedited review may thus be applied to research activities that present no more than minimal risk to human participants, and
- involve only procedures listed below:

a. Prospective collection of biological specimens for research purposes by non-invasive means
   Examples:
   - Hair and nail clippings in a non-disfiguring manner
   - Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction
   - Permanent teeth if routine patient care indicates a need for extraction
   - Excreta and external secretions (including sweat)
   - Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue
   - Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings
   - Sputum collected after saline mist nebulisation.

b. Collection of data through non-invasive procedures e.g., weighing or testing sensory acuity.
c. Research involving materials (data, documents, records, or specimens) that have been collected solely for non-research purposes (such as medical treatment or diagnosis, e.g., retrospective chart review).
d. Collection of data from voice, video, digital, or image recording made for research purposes.

- The activities listed above should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for

review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human participants.

- The expedited review procedure may not be used where identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, insurability, reputation, or be stigmatising, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- Expedited review may not lead to outright disapproval/rejection of the proposed study. An expedited proposal may only be disapproved after being referred to a convened BREC meeting.
- The standard requirement for informed consent applies regardless of the type of review (expedited or convened) utilised by the BREC.
- BREC will consider "Class approvals" for expedited review in circumstances where the usual criteria for expedited approval are met, in addition to the following:
- Where an investigator wishes to do exploratory research involving several lines of inquiry on retrospectively collected specimens or data, or
- Where an investigator needs to repeat a specified research exercise, annually for teaching or training purposes.

17. STORED TISSUE

17.1 If blood or tissue specimens are to be stored for future analysis and such analysis is planned to take place outside the University of KwaZulu-Natal (UKZN), the specimens must be stored in a repository located within UKZN (or as otherwise specified and approved by BREC) and released only with BREC approval and approval from a local Research Ethics Committee at the proposed site of the analysis (unless otherwise specified and approved by BREC).

17.2 Only BREC approved analyses may be done.

17.3 BREC must be provided with details of provisions made to protect the privacy of the donors and the maintenance of the confidentiality of the data.

17.4 Specimens may not be shared with any party unless approved by BREC in advance.

17.5 Where tissue samples are to be exported, a valid current export permit is required.

17.6 A separate consent form for storage of additional or residual samples is required.

17.7 A separate consent form for genetic testing is required.

17.8 An approved Material Transfer Agreement (MTA) should be considered and provided wherever possible.

18. MODUS OPERANDI

18.1 In addition to the research protocol and additional documentation, the researcher must complete a detailed, current BREC ethics application form to facilitate ethics evaluation of the research proposal. A separate, abridged BREC application form is used where expedited review is requested.

18.2 All researchers are required to submit annual progress reports for purposes of recertification. Recertification requests must be made on the standard current BREC recertification form.

18.3 For participants who are enrolled in studies for more than 12 months' duration, an assessment of their ongoing knowledge and willingness may need to be demonstrated in the annual recertification application.

18.4 Any proposed amendment of an approved study must be submitted to BREC for further approval using the current BREC amendment application form with supporting documents, e.g., change in protocol, key personnel/senior investigators and research site/s. Substantial clinical trial amendments and amendment of US DHHS funded studies will be reviewed at a convened BREC meeting as per review procedure described in section 3.5 above, substituting 'amendment application' for 'protocol' where applicable. A clarification memo is to be submitted for other minor notifications. BREC approval must be received prior to implementation of the modifications/changes. (**For Clinical Trials and US DHHS supported studies, see also Appendix B**).

18.5. **Reports on Suspected Unexpected Serious Adverse Reactions (SUSARs), Serious Adverse Events (SAEs), Adverse Events (AEs), Protocol Violations and Protocol Deviations.**

18.5.1 Reports on Suspected Unexpected Serious Adverse Reactions (SUSARs), Serious Adverse Events (SAEs) and Adverse Events (AEs) that, in the judgement of the PI or the sponsor, impact on participant or study personnel safety and welfare at BREC approved sites should be reported in writing to BREC within 7 working days of occurrence, or failing that, within 7 working days of PI awareness for local sites. They must also be reported to other authorities (e.g. the sponsor and regulatory authority (SAHPRA)) as required by those authorities.

Such reports for all other related South African or international sites these must be reported to BREC monthly, or as required by SAHPRA. These may be reported in a combined report format.

18.5.2 Reports on protocol violations and protocol deviations that, in the judgement of the PI or the sponsor, impact on participant or study personnel safety and welfare at BREC approved sites should be reported in writing to BREC no more than within 7 working days of occurrence, or failing that, within 7 days of PI awareness. These should also be reported to other authorities (e.g. the sponsor and regulatory authority (SAHPRA)) as required by those authorities.

Such reports for all other related South African or international sites must be reported to BREC as required by the sponsor or by the regulatory authority (SAHPRA). These may be reported in a combined report format

18.5.3 Reports on protocol violations and protocol deviations that, in the judgement of the PI or the sponsor, have no impact on participant or study personnel safety and welfare at BREC approved sites should be reported in writing to BREC within 6 months of occurrence, or failing that, within 6 months of PI awareness. These may be reported to BREC in a combined report format. These should also be reported to other authorities (e.g. the sponsor and regulatory authority (SAHPRA)) as required by those authorities.

Such reports for all other related South African or international sites must be reported to BREC as required by the sponsor or by the regulatory authority (SAHPRA). These may be reported in a combined report format

18.6 BREC may suspend or terminate approval of a study that is not being conducted in accordance with prevailing BREC or South African Department of Health Ethics guidance (or is in serious or continuing non-compliance with 45 CFR 46 for US DHHS funded studies), or that has been associated with unexpected serious harm to participants or others. The primary justification for suspension or termination of approval should be the safety of participants or others. Such suspension or termination of approval must be authorised by the BREC chair in minuted consultation with a BREC subcommittee and/or other co-opted parties as soon as possible but not more than seven days after receipt of relevant information by the chair. Such action

must be reported to BREC at the next quorate meeting. The primary justification for suspension or termination of approval should be the safety of participants or others. BREC must give detailed written reasons for such suspension or termination, and must give written notification to other appropriate parties, as soon as possible, of such actions. Parties to be notified in writing by the BREC chair include, but are not limited to, the investigator, the Dean (Research), the study sponsor or agency, the investigator's departmental head, the South African National Health Research Ethics Council and the South African Health Products Regulatory Authority (SAHPRA) (if applicable). For US HHS funded studies the OHRP should also be notified.

18.7 BREC or an authorised representative may observe the consent process or other aspect of a study which has been approved by BREC.

18.8 Electronic, material and other records of research are to be securely stored for a minimum of 5 years and 15 years for clinical trials.

18.9 For clinical trials, it is the investigator's responsibility to furnish proof to BREC that regulatory approval has been sought and obtained from the regulatory authority (SAHPRA) and that the trial is registered with the South African National Clinical Trials Register (SANCTR).

18.10 **Complaints:** Investigators should seek to resolve complaints with BREC procedures or decisions informally through the Chair in the first instance. If complaints remain unresolved investigators may lodge a formal complaint with the Dean (Research). If not resolved through the Dean of Research, the complaint may be escalated and reported to chair of the National Health Research Ethics Council at the National Department of Health.

18.11 **Review Fees:** BREC may, with the approval of the DVC (Research), levy a schedule of review fees fee for different types of protocols. The schedule of fees must be approved by the DVC (Research) from time to time as required and must be published on the BREC website.

19. RESEARCH MISCONDUCT

19.1 Research misconduct encompasses *inter alia*:

- Failure to submit a protocol for ethics approval in term of this document
- Fabrication, falsification, plagiarism in proposing, performing, reviewing or reporting of research
- Deviation from or failure to adhere to the approved protocol without prior formal approval from BREC
- Misrepresentation of data and/or interests and/or involvement
- Falsification of credentials
- Deception in the research proposal
- Non-approved deception in the carrying out of research
- Piracy of materials
- Failure to follow accepted procedures to exercise due care in avoiding unreasonable harm or discomfort to participants or research staff
- Failure to obtain voluntary and informed consent
- Breach of confidentiality
- Negligent management of data security.
- See also the UKZN Research Policy V: Research Ethics
- See also the UKZN Plagiarism Policy and Procedures

19.2 Incidents of research misconduct will be reported to the Dean (Research) and managed in accordance with applicable University rules and procedures.

19.3 The identity of the individual who raises awareness of research misconduct will be protected and will be made known to the Chair, DVC (Research) and BREC only. Protocol violations are to be tabled and discussed at quorate meetings of BREC.

20. A researcher may be requested to attend a convened BREC or subcommittee meeting to provide information on any aspect of the study but may not participate in the vote or decision making of the Committee.

21. BREC may consult with and/or invite non-members with expertise in special areas to convened BREC or subcommittee meetings.

22. BREC reserves the right to develop policy documents to provide for any complexity in research-related ethical issues as they develop.

23. BREC will perform its functions according to these BREC Terms of Reference and Standard Operating Procedures (SOPs) and will maintain written records of its activities and minutes of its meetings and will comply with GCP and applicable regulatory requirements.

24. This document will be reviewed and updated annually or as required.

SELECTED REFERENCES:

Council for International Organizations of Medical Sciences (CIOMS) (2016). *International ethical guidelines for biomedical research involving human subjects*. Geneva: Author

Department of Health (2020). *Guidelines for Good Practice in the conduct of clinical trials with human participants in South Africa.* (*South African good clinical practice guidelines)* Pretoria: Author.

Department of Health (2012). Payment of trial participants in South Africa: Ethical considerations for Research Ethics Committees (RECs). NHREC. http://www.nhrec.org.za/index.php/grids-preview?download=11:guidelines-for-payment

Department of Health (2015). *Ethics in health research: Principles, processes and structures.* Pretoria: Author. http://www.nhrec.org.za/index.php/grids-preview?download=14:nhrec-guidelines

Department of Health, Education, and Welfare (1979). *Belmont Report: Ethical principles and guidelines for the protection of human subjects of research. Report of the National Commission for the protection of human subjects of biomedical and behavioral research.* Washington: Author.

Medical Research Council: (2000). *Guidelines on ethics for medical research: General principles. Cape Town: Author.*

Medical research Council: (2003). *Guidelines on ethics for medical research: HIV preventive vaccine research*. Cape Town: Author.

Nuffield Council on Bioethics (2002). *The ethics of research related to healthcare in developing countries.* London: Author.

Nuffield Council on Bioethics (2005). *The ethics of research related to healthcare in developing countries. Follow-up discussion paper.* London: Author.

UK Research Integrity Office (2008). *Procedure for the investigation of misconduct in research.* London: Author.

UNAIDS (2012). *Ethical considerations in biomedical HIV prevention trials: UNAIDS/WHO guidance document*. Geneva: Author.

UNAIDS (2011). *Good participatory practice guidelines for biomedical HIV prevention trials.* Geneva: UNAIDS/AVAC.

US Federal Regulations: 45 CFR 46. Available from http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

World Health Organisation (2011). *Standards and operational guidance for ethics review of health-related research with human participants.* Geneva: Author.

World Medical Association: (2013). *World Medical Association Declaration of Helsinki: Ethical principles for medical research involving human subjects*. Geneva: Author.

APPENDIX A

1) DEFINITION: VULNERABLE COMMUNITIES - UNAIDS (2011; 2012) AND SA DoH (2015).

Vulnerable communities are defined as having some or all of the following characteristics:

- Limited economic development;
- Inadequate protection of human rights and discrimination on the basis of health status;
- Inadequate community or cultural experience with the understanding of scientific research;
- Limited availability of health care and treatment options;
- Limited ability of individuals in the community to provide informed consent;
- Culturally marginal groups
- Persons involved in illegal activities or livelihoods

2) **RESEARCH REQUIRING ADDITIONAL ATTENTION: (SA GCP Guidance, DoH, 2006 or later)**

Minors: Children and adolescents
Foetuses in-utero
Foetuses ex-utero
Persons with mental disabilities
Persons with substance abuse related disorders
Persons in dependent or subservient relationships (e.g., students where the investigator is directly involved in their training; employees where the investigator has line authority over them).
Prisoners
Persons highly dependent on medical care
Intensive care
Neonatal intensive care
Terminal care
Persons with impaired capacity to communicate
Unconscious persons
Specific social collectivities
Persons in indigenous medical systems
Emergency care research
Innovative therapy or intervention
HIV/AIDS clinical and epidemiological research

APPENDIX B

(In accordance with the Department of Health: (2020 or later) *South African Good Clinical Practice Guidelines*)

CLINICAL TRIAL PROTOCOLS AND PROTOCOL AMENDMENT(S)[1]

In addition to the Research Ethics Application forms, the contents of a trial protocol should generally include the following topics. However, site-specific information may be provided on separate protocol page(s), or addressed in a separate agreement, and some of the information listed below may be contained in other protocol-referenced documents, such as an Investigator's Brochure.

1. General Information

- Protocol title, protocol identifying number, and date. Any amendment(s).
- Should also bear the amendment number(s) and date(s).
- Name and address of the sponsor and monitor (if other than the sponsor).
- Name and title of the person(s) authorized to sign the protocol and the protocol amendment(s) for the sponsor.
- Name, title, address, and telephone number(s) of the sponsor's medical expert (or dentist when appropriate) for the trial.
- Name and title of the investigator(s) who is (are) responsible for conducting the trial, and the address and the address and telephone number(s) of the trial site(s)
- Name, title, address, and telephone number(s) of the qualified physician (or dentist, if applicable), who is responsible for all trial-site related medical (or dental) decisions (if other than investigator).
- Name(s) and addressees) of the clinical laboratory(ies) and other medical and/or technical department(s) and/or institutions involved in the trial.
- Written curriculum vitae of Principal Investigator (PI), Co-Principal Investigators (Co-PI), Sub-Investigators (Sub-I) and other persons designated by the principal investigator to be responsible for some aspects of the trial.

2. Background Information

- Name and description of the investigational product(s).
- A summary of findings from non-clinical studies that potentially have clinical significance and from clinical trials that are relevant to the trial.
- Summary of the known and potential risks and benefits, if any, to human participants.
- Description of and justification for the route of administration, dosage, dosage regimen, and treatment period(s).
- A statement that the trial will be conducted in compliance with the protocol, GCP and the applicable regulatory requirement(s).
- Description of the population to be studied.
- References to literature and data that are relevant to the trial and that provide background for the trial[2].

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[1] SOURCE: ICH Guidelines for Good Clinical Practice

[2] **Systematic Review**: The research protocol should demonstrate knowledge of relevant literature and wherever possible be based on prior laboratory and animal experiments. Investigators do not always take into proper account the results of existing research when planning new clinical trials. This constitutes unethical practice for several reasons. Firstly, if existing evidence is available that an active form of care is better than placebo, further placebo controlled research denies some patients effective treatment.

- Insist on a well-conducted and systematic literature review of relevant existing research as a precondition for approving new research.
- The review should provide convincing evidence that proposed research is necessary, that it will not expose patients to unacceptable risks or practices, and that it will not withhold care that is known to be effective.
- Require that investigators make available to potential trial participants a summary of the finding of the literature review before requesting their consent. Both the possible benefits and the risks of treatment should be clearly stated.
- Help to minimise bias resulting from non-publication of negative studies by
  (a) ensuring registration of clinical trials at inception and
  (b) requiring a written commitment from investigators to publish the results of trials.

3. Trial Objectives and Purpose

- A detailed description of the objectives and the purpose of the trial.

4. Trial Design

The scientific integrity of the trial and the credibility of the data from the trial depend substantially on the trial design. A description of the trial design should include:

- A specific statement of the primary endpoints and the secondary endpoints, if any, to be measured during the trial.
- A description of the type/design of trial to be conducted (e.g. double-blind, placebo controlled, parallel design) and a schematic diagram of trial design, procedures and stages.
- A description of the measures taken to minimise/avoid bias, including:
  (a) Randomization. (b)
  Blinding.
- A description of the trial treatment(s) and the dosage and dosage regimen of the investigational product(s). Also include a description of the dosage form, packaging, and labelling of the investigational product(s).
- The expected duration of participant participation, and a description of the sequence and duration of all trial periods, including follow-up, if any.
- A description of the "stopping rules" or "discontinuation criteria" for individual participants, parts of trial and entire trial.
- Accountability procedures for the investigational product(s), including the placebo(s) and comparator(s), if any.
- Maintenance of trial treatment randomization codes and procedures for breaking codes.
- The identification of any data to be recorded directly on the CRFs (i.e. no prior written or electronic record of data), and to be considered to be source data.

5. Selection and Withdrawal of Participants

- Participant inclusion criteria.
- Participant exclusion criteria.

Such research should only be considered where there is a need to evaluate additional important outcomes, including adverse effects. Secondly, failing to take into account evidence that a treatment is ineffective, or that it does more harm than good, inevitably exposes patients to inconvenience or unnecessary risk. Thirdly, conducting trials that address previously answered questions wastes limited resources.

Systematic review has evolved over the past decade as a rigorous methodology for synthesising the results of primary research. The process involves identification, appraisal and integration of the findings of published and unpublished studies, with the aim of drawing conclusions from the totality of relevant evidence. All ethics committees must therefore:

- Participant withdrawal criteria (i.e. terminating investigational product treatment/trial treatment) and procedures specifying:
  (a) When and how to withdraw participants from the trial/investigational product treatment.
  (b) The type and timing of the data to be collected for withdrawn participants.
  (c) Whether and how participants are to be replaced.
  (d) The follow-up for participants withdrawn from investigational product treatment/trial treatment.

6. Treatment of Participants

- The treatment(s) to be administered, including the name(s) of all the product(s), the dose(s), the dosing schedule(s), the route/mode(s) of administration, and the treatment period(s), including the follow-up period(s) for participants for each investigational product treatment/trial treatment group/arm of the trial.
- Medication(s)/treatment(s) permitted (including rescue medication) and not permitted before and/or during the trial.
- Procedures for monitoring participant compliance.

7. Assessment of Efficacy

- Specification of the efficacy parameters.
- Methods and timing for assessing, recording, and analysing of efficacy parameters.

8. Assessment of Safety

- Specification of safety parameters.
- The methods and timing for assessing, recording, and analysing safety parameters.
- Procedures for eliciting reports of and for recording and reporting adverse event and intercurrent illnesses/infections.
- The type and duration of the follow-up of participants after adverse events.
- Procedures for unmasking the identity of treatment.

9. Statistics

- A description of the statistical methods to be employed, including timing of any planned interim analysis/analyses.
- The number of participants planned to be enrolled. In multi-centre trials, the numbers of enrolled participants projected for each trial site should be specified.
- Reason for choice of sample size, including reflections on (or calculations of) the power of the trial and clinical justification.
- The level of significance to be used.
- Criteria for the termination of the trial.
- Procedure for accounting for missing, unused, and spurious data.
- Procedures for reporting any deviation(s) from the original statistical plan (any deviation(s) from the original statistical plan should be described and justified in protocol and/or in the final report, as appropriate).
- The selection of participants to be included in the analyses (e.g. all randomized participants, all dosed participants, all eligible participants, valuable participants).

10. Direct Access to Source Data/Documents

- The sponsor should ensure that it is specified in the protocol or other written agreement that the investigator(s)/institution(s) will permit trial-related monitoring, audits, ethics committee review, and regulatory inspection(s), providing direct access to source data/documents.

11. Quality Control and Quality Assurance

- **A detailed description of the Quality control and assurance procedures that will be put in place, implemented and monitored.**

12. Ethics

- Detailed consideration of the ethical considerations relating to the trial. Stating that the trial "will be ethically reviewed by an REC" is insufficient.

13. Data Handling and Record Keeping

- **A detailed description of the data security and record keeping procedures that will be put in place, implemented and monitored.**

14. Financing and Insurance

- Financing and insurance if not addressed in a separate agreement.

15. Publication Policy

- Publication policy, if not addressed in a separate agreement.

APPENDIX C

BREC Confidentiality Agreement

[1]CONFIDENTIALITY AGREEMENT

FOR MEMBERS OF THE

UKZN BIOMEDICAL RESEARCH ETHICS COMMITTEE (BREC)

I the undersigned _____ (hereinafter referred to as "the BREC Member") with physical address at _____

_____.

HEREBY AGREE TO THE FOLLOWING:

A. The UKZN BREC is a body constituted by appropriately qualified professionals tasked with the reviewing of novel proposals for research which is to be conducted on/or with human participants and/or animals.

B. The work of the UKZN BREC is the scientific evaluation and systematic review of the ethical status of the research related actions of researchers and/or clinicians within the framework of health care.

C. The Members of the UKZN BREC, supporting Administrative staff and ad hoc attendees hereby agree to be bound by the provisions of this Agreement for the duration of their service to and on the UKZN Research Ethics Committee.

1. INTERPRETATION

Unless the context indicates the contrary:

1.1 "Confidential Information" shall mean certain proprietary or confidential information which the UKZN BREC member acknowledges to be confidential. Such information relates to all trial protocols relating either to research on human participants, and associated documentation. The Confidential Information may be conveyed in written, graphic, oral or physical form including (but not limited to) scientific knowledge, know-how, processes, inventions, techniques, formulae, products, business operations, patient requirements, designs, sketches, photographs, drawings, specifications, reports, studies, findings, data, plans or other records, biological materials, and/or software.

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1.2 “Results” shall mean all results obtained and conclusions reached during the contingency of the Project and the Main Agreement.

2. CONFIDENTIALITY

2.1 The BREC Member undertakes in favour of the others that he/she will treat as confidential all information labelled as confidential information including all results generated from any proposal and/or project, including any and all information whether of a technical or scientific nature or otherwise relating to all research proposals reviewed by the UKZN BREC as a whole or communicated to him/her hereunder or otherwise in connection with the BREC Member’s role on the UKZN BREC. The BREC member agrees that he/she will not disclose such information to any person, any legal entity, or to the media, and will not use such information other than for the purposes of this Agreement, subject to any prior specific written authorization by the other members to such disclosure or use.

2.2 Confidential information shall not include:

(a) Information which at the time of disclosure is published or otherwise generally available to the public, or later becomes generally available to the public otherwise than through any act or omission on the part of the BREC Member; or

(b) Information which the BREC Member can show by written records and to the satisfaction of the Disclosing Party, was in his/her possession at the time of disclosure and which was not acquired directly or indirectly from the Disclosing Party; or

(c) Information rightfully acquired from a *bona fide* third party who did not obtain it under pledge of secrecy to the disclosing Party; or

(d) Information which is or had been independently generated or developed by the BREC which can be shown by written records and to the satisfaction of the Disclosing Party; or

(e) Information which is required to be disclosed by law or a valid order of a court of competent jurisdiction or the request of any governmental or other regulatory authority, in which event the parties hereto shall use their best endeavours to seek confidential treatment of such information.

(f) Information released to specified parties by or after consultation with the Chair of BREC and any other relevant parties (e.g., Dean of Research, DVC (Research)).

2.3 The confidentiality obligations contained in this Agreement shall endure beyond the confines of the BREC Member’s obligations to the UKZN BREC and without limit in time.

3. GOVERNING LAW

3.1 This Agreement shall be governed by the law of the Republic of South Africa. Any disputes under this Agreement shall be resolved in a court of competent jurisdiction in Durban, South Africa.

Thus read, signed and agreed:

Signed at on the day of 20__

Full names:

_____

Signed: UKZN BREC Member