DUT
DURBAN UNIVERSITY OF TECHNOLOGY
INYUVESI YASETHEKWINI YEZOBUCHWEPHESHE

INSTITUTIONAL RESEARCH ETHICS COMMITTEE

Institutional Research Ethics Committee

Standard Operating Procedures

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1. INTRODUCTION

The Institutional Research Ethics Committee (IREC) has the responsibility of evaluating, approving and monitoring research involving humans, and the environment. It does so by following ethical guidelines for research as stated by the Department of Health of South Africa and the Declaration of Helsinki as well as other relevant declarations and statements in the area of research ethics. It aims to protect the rights and welfare of research participants by adhering to the principles of beneficence, justice and respect for people, especially vulnerable populations. In so doing, it assesses the ethical implications of the study design and research methodology.

2. TERMS OF REFERENCE

1) The IREC shall review all research (as defined by the National Health Act No. 61. 2003) on humans, and the environment (refer to DUT classification), undertaken by registered students, staff members and affiliates of DUT.
2) The purpose of the IREC is to ensure the safety, dignity, rights and well-being of all human and research participants and to the scientific validity of the study.
3) The IREC may review human, and environmental research protocols submitted by researchers who are not DUT staff members or registered students.
4) Ethical approval needs to be obtained prior to the commencement of the research. The IREC will not provide retrospective approval.
5) The IREC has the authority to appoint an ad hoc subcommittee (that will comply with the applicable norms, rules and regulations of the IREC) to investigate or finalise any matter. Co-opted reviewers are appointed to review category 2 proposals, independent proposals, when expertise is required and Bachelor's Degree Proposals.
6) The IREC has aligned itself with the following:
    - The SA National Health Act No. 61. 2003
    - The SA Department of Health Ethics in health research: Principles, structures and processes (2015) and South African good clinical practice guidelines (2019)
    - Protection Of Personal Information Act (2013)
    - Constitution of the Republic of South Africa, 1996
    - Declaration of Helsinki (2013)
    - The Belmont Report
    - The US Office of Human Research Protections 45 Common Federal Regulations (CFR) 46[1] (for non-exempt research with human participants conducted or supported by the US Department of Health and Human Services (HHS), 21 CFR 50, 21 CFR 56
    - Council for International Organisations of Medical Sciences
    - ICH Topic E6 Guideline for Good Clinical Practice (sections 1-4)
    - The International Conference on Harmonisation and Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH Tripartite)
    - Protection Act No. 71 of 1962
    - South African National Environmental Management Act
    - ICC/ESOMAR International Code on Market & Social Research
    - ESOMAR Word Research Codes & Guidelines for Customer Satisfaction Studies
    - ESOMAR Word Research Codes & Guidelines for Interviewing Children & Young People
    - ESOMAR Word Research Codes & Guidelines for Conducting Survey Research Via Mobile Phone
    - ESOMAR Word Research Codes & Guidelines on Social Media Research
    - DOH Guidelines, 2015
    - South African good clinical practice guidelines. 2nd edition. Available at http://www.kznhealth.gov.za/research/guideline2.pd

[1] CFR applies across all us states and abroad, when research is funded by the US federal government.

- Ethics in Health Research 2015

When strict compliance is not possible, the IREC will ensure that the spirit of the codes and declarations are reflected in the research.

3. IREC COMMITTEE

3.1 Membership

Membership of the IREC is through nomination. The committee reserves the right to co-opt members, to review Bachelor's or expedited proposals and independent studies, as and when the need arises. Each member is appointed for three years with the option of renewing his/her term. All members are required to supply the IREC Administrator with their abbreviated CV at the beginning of their term of office. All members should be in good standing, with a working knowledge of ethical codes and guidelines as per the Terms of Reference.

All members and support staff are required to sign a confidentiality agreement prior to appointment to the IREC (Appendix I). A copy of this agreement will be given to the IREC member, with the original being kept in the IREC administration file.

Should a member not attend three consecutive meetings, without a written apology acceptable to the committee, their membership will be terminated. In the instance where a committee member cannot attend, he/she must send their comments to the IREC Administrator.

The committee is constituted as follows:

- There are at least 15 voting members with 33% constituting a quorum
- Both genders must be represented, with no gender holding more than 70% representation
- The committee members must represent the community it serves and should reflect the demographic profile of the population of South Africa
- Chairperson who is appointed by the Deputy Vice Chancellor responsible for Research at DUT
- There are two lay persons who represent the community and are not affiliated with the institution
- At least one member should be a legally trained person.
- At least one member should be knowledgeable in the professional care, counselling or treatment of people.
- At least one member who is trained in both qualitative and quantitative methodologies
- When necessary the committee may co-opt expert members as non-voting members
- Collectively the committee must have the qualifications, experience and expertise to review research that is submitted regularly to it.

The IREC meetings may be attended by students, supervisors, researchers and other interested parties by invitation or on request. Any such person who attends will participate as a non-voting member, subject to signing a confidentiality agreement. Notwithstanding this provision, the individual concerned may still be excluded from certain items on the agenda, as determined by the Chairperson.

The Deputy Chairperson of IREC shall be elected through voting from amongst members of IREC; the Chairperson may delegate this responsibility to another member of the IREC, should the need arise. Should there be no volunteers for the position of Deputy Chairperson from the Committee, the DVC: Research, Innovation and Engagement will appoint a Deputy Chairperson from staff at the DUT or an external individual. The Durban University of Technology provide the members of the IREC with professional liability insurance when they are acting in good faith while carrying out the professional duties of the IREC.

3.2 Training

All new IREC members will be issued with the SOPs and any other relevant documentation of the IREC for them to familiarise themselves with the policies and procedures. The Chairperson conducts a proposal review workshop at the beginning of each academic year for all new committee members and volunteers.

The institution facilitates ethical conduct of scholarly research by providing research ethics training for researchers (supervisors and students) and members of the IREC. All researchers should have relevant ethics training.

Researchers working with human participants must provide evidence of current (i.e. within three years) GCP training. Basic GCP training must be done by means of an attendance course, and must include specific SA GCP training. Thereafter, 3 yearly refresher GCP training must occur. Refresher training may be done online; however, the course must be relevant to the South African research environment and must incorporate SA GCP training.

3.3 Conflict of interest

Members of the IREC are expected to make decisions and conduct their oversight responsibilities in an independent manner, free from bias and undue influence. IREC members (and members of their immediate families) may be involved in activities that could be perceived as conflicting with their IREC responsibility. The integrity of the IREC review process can be compromised if such conflicts of interests are not disclosed and where necessary, avoided.

A standing item will be included in the meeting agenda regarding conflict of interests (appendix C). A declaration of interests is placed at the beginning of the agenda of all meetings. This enables IREC members to perform their duties as diligently and honestly as possible and maintain the highest standards of integrity and propriety at all times within the domain of their mandate.

IREC members must disclose any relationship, interest or other circumstances, which could reasonably be perceived as creating a conflict of interest – including the following:

- Personal/ Professional relationship: If the IREC member has a personal/ professional relationship with the principal investigator or key personnel of a research protocol under review by the IREC.
- Relationship to the research study: If the IREC member (his/her spouse or immediate family member) is the principal investigator or co-investigator of the research protocol under review by the IREC.
- Business relationship or affiliation: If the IREC member serves as a trustee, director, officer, owner or partner of an entity that could be affected by the outcome of the research protocol under review by the IREC.
- Financial interest: If the IREC member has a financial interest that could be affected by the outcome of the research protocol under review by the IREC. Included in the definition of financial interest are equity interests e.g. stock, stock options or other ownership interests, payment or expectation of payment derived from intellectual property rights (e.g. patent royalties); and payments received from an entity for consulting or other services.
- IREC members are required to disclose only those interests that may be affected by the research, which is the subject of the research proposal and that might otherwise reasonably be perceived to affect their independent unbiased judgment with respect to the IREC's review of the protocol or related matters.
- IREC members should make disclosures to the Chairperson. The Chairperson and the committee shall determine whether a conflict exists. The final outcome of such a determination shall be reflected in the minutes.
- Should the situation arise where the Chairperson finds his/herself in a situation of potential conflict of interest, the committee will appoint the Deputy Chairperson or in the absence of the Deputy Chairperson another member as acting Chairperson. The acting Chairperson will conduct the meeting for the remainder of the discussion on the item in question.

IREC members who have a conflict of interest related to any research protocol that the IREC is about to consider should refrain from participating in any discussion of the protocol or related matters, except where it is necessary to provide relevant factual information requested by the Chairperson. Unless requested by the Chairperson to provide such information to the IREC, the IREC member with a conflict of interest will leave the meeting during the discussion and voting process. The outcome of the committee decision in the absence of the recused member will NOT be discussed upon return of the member concerned but may be conveyed after closure of the meeting. Should a person not declare a conflict to interest the rules governing disciplinary procedures of the university will apply.

All IREC reviewers assigned to review a protocol or related matter must notify the Chairperson so that the protocol can be re-assigned, should a conflict of interest be identified.

3.4 Frequency of meetings

The IREC will meet at least once a month, from February to November of each calendar year, to discuss and review research protocols/studies. Special meetings will be called for if and when the need arises. The proposals reviewed will include Masters (partial and full), Doctoral, undergraduate and independent studies both from students and researchers employed at the institution and those outside the institution seeking ethical approval.

4. APPLICATION PROCEDURE

All documentation for submission is available on http://www.dut.ac.za/research/institutional_research_ethics or can be obtained from the IREC Administrator.

The following will need to be submitted:

1) Completed DUT approved format for proposal submission ensuring the following are addressed:
    - Ethics clearance category applied for (Refer to Guidelines for Classification of Prospective Research with Respect to Research Ethics)
    - Participant recruitment procedures
    - Safety information
    - Any payment or compensation to participants
    - Ethical checklist
2) Letter of information and consent (Appendix B).
3) Conflict of interest form (appendix C).
4) GCP/ Ethics training certificates
5) Other information being supplied to participants.
6) Other documentation necessary for the IREC to make an informed decision regarding the research.

The IREC Administrator will accept applications from the FRC's/ FREC's and principal investigators for ethical clearance on a rolling basis. The IREC Administrator in conjunction with the Chairperson will determine whether the application requires expedited or full review. The IREC Administrator will check the application ensuring that all relevant documentation has been submitted, should documentation be missing it will be requested.

4.1 Research for non-degree purposes

The Institutional Research Ethics Committee considers internal and external applications for ethics clearance for research for non-degree purposes/ independent research.
All documentation for submission is available on http://www.dut.ac.za/research/institutional_research_ethics or can be obtained from the IREC Administrator.

The following will need to be submitted:

1) Completed DUT Independent Research Proposal (Appendix A) ensuring the following are addressed:
    - Participant recruitment procedures

- Safety information
- Any payment or compensation to participants

2) Letter of information and consent (Appendix B)
3) Conflict of interest form (appendix C)
4) Other information being supplied to participants
5) Other documentation necessary for the IREC to make an informed decision regarding the research.

The IREC Administrator will accept applications directly from principal investigators for ethical clearance on a rolling basis. For applications internal to DUT, the proposal need not serve at the respective Faculty Research Committee. Applications external to DUT will be charged a fee for review and consideration of the application. The IREC Administrator in conjunction with the Chairperson will determine whether the application requires expedited or full review. The IREC Administrator will check the application ensuring that all relevant documentation has been submitted, should documentation be missing it will be requested.

4.2 Informed consent

All research approved by the IREC on human participants must have a letter of information and consent compiled according to the guidelines in Appendix B. Each participant or, where necessary, the participant's legally authorised representative, must be given sufficient time to read the letter of information and consent and have the opportunity to ask questions. There should be no coercion or undue influence. The letter of information and consent should be in a language understandable to the participant or representative, allowing them to make an informed decision to participate in the research. Only then may the participant or representative sign the letter of information and consent. In the case where the participant is illiterate, verbal consent may be given in the presence of a literate independent witness who will verify and sign the letter of information and consent on behalf of the participant, indicating that informed verbal consent was given.

The letter of information and consent must include the following:

- The qualification/s and contact details of the researcher/s
- Participants' responsibilities
- Purpose of the research
- Any risks and benefits to participants
- Outline study procedure e.g. placebo or control groups if necessary
- Duration of study
- Alternative procedures or treatments.
- Confidentiality
- A statement that participation is voluntary and that non-participation will not result in any penalty
- A statement that ethical approval for the study was obtained
- A statement that sponsors or the ethics committee may inspect research records
- Compensation for research related injury
- Contact details of the IREC
- Contact details of the person to contact should there be research related injury

The letter of information and consent must be written in simple language.

4.2.1 Assent

For purposes of this SOP, the following definitions apply:

- 'Adolescent' means a child between the ages of 12 and 17 years of age.
- 'Minor' means a person (child) less than 18 years (s17, Children's Act 38 of 2005)
- 'Assent' means a minor's affirmative agreement to participate in research. Mere failure to object should not be interpreted as assent.

The participation of both minors and adolescents requires:

- Permission in writing from parents or legal guardian for the minor to be approached and invited to participate (in accordance with s 10 of the Children's Act 38 of 2005);
- Assent from the minor in writing (i.e. agreement to participate) if he or she chooses to participate (Appendix J).
- Parental permission and minor's decision must be consistent, i.e. if the minor decides not to participate; the parent may not override this decision.

During the assent process:

- The research team explains the trial to the child in language the child can understand, including what it means to take part and what the child can expect.
- The research team may use written forms, videos, graphics, and other visual aids to help explain the trial.
- Free of scientific jargon and unexplained acronyms.
- The child is encouraged to ask questions.

4.3 Record keeping

In keeping with legal and ethical requirements, all researchers/principal investigators will be required to keep all information, including data sheets and informed consent documents, for at least 5 years. This is in line with the GCP guidelines. These records must be orderly and accessible should the need arise. In the case of student research, the respective department/ programme must house the records for at least 5 years.

5. REVIEW PROCESS

The IREC when reviewing a proposal must protect the rights, safety and well-being of the research participants and their communities. It will do this by evaluating all factors that may influence the scientific validity and ethical acceptability of the proposal by applying the various ethical benchmarks mentioned below:

5.1.1 Collaborative partnership:

- Develop partnerships with researchers, makers of ethics policies, the community and other relevant stakeholders
- Involve partners in sharing responsibilities for determining the importance of a research problem, assessing the value of research, planning, conducting and overseeing research, and integrating research into the health-care system.
- Respect the community's values, culture, traditions and social practices.
- Develop the capacity for researchers, makers of health policies and the community to become full and equal partners in the research enterprise.
- Ensure the recruited participants and communities receive benefits from the conduct and results of research.
- Share fairly financial and other rewards of the research.

5.1.2 Social value:

- Specify the beneficiaries of the research, i.e., who?
- Assess the importance of the research problems being investigated and the prospective value of the research for each of the beneficiaries, i.e., what?
- Enhance the value of the research for each of the beneficiaries through dissemination of knowledge, product development, long- term research collaboration and/or other system improvements.
- Ensure that the study is relevant to the community involved or the greater South African population.

5.1.3 Scientific validity:

- Ensure that the scientific design realizes the scientific objectives while guaranteeing research participants the interventions to which they are entitled.
- Ensure that the research study is feasible within the social, political and cultural context.

- Researchers should have the appropriate qualifications and expertise to conduct the proposed research.
- Researchers must be registered with their relevant statutory council where applicable.
- In studies where there is a large clinical component and the principal investigator is not a clinician, a co-investigator who is a clinician must be appointed.
- All international collaborative research must have a local principal investigator/supervisor.

5.1.4 Fair selection of the study population:
- Select the study population to ensure scientific validity of the research.
- Select the study population to minimize the risks of the research and enhance other principles, especially collaborative partnership and social value.
- Select the study population fairly and without coercion.
- Identify and protect vulnerable populations.

5.1.5 Favourable risk-benefit ratio:
- Assess the potential risks and benefits of the research to the study population in the context of its health risks.
- Assess the risk-benefit ratio by comparing the net risks of the research project with the potential benefits derived from collaborative partnership, social value, and respect for study populations.
- Risk to participants and/or the environment must be minimised.

5.1.6 Independent Review:
- Ensure public accountability through reviews mandated by laws and regulations.
- Ensure public accountability through transparency and reviews by other international and non-governmental bodies, as appropriate.
- Ensure independence and competence of the reviews.

5.1.7 Informed Consent:
- Involve the community in establishing recruitment procedures and incentives.
- Disclose information in culturally and linguistically appropriate formats.
- Implement supplementary community and familial consent procedures where culturally appropriate.
- Obtain consent in culturally and linguistically appropriate formats.
- Ensure the freedom to refuse or withdraw.
- The method utilised must be ethically and legally acceptable (Appendix B).

5.1.8 Respect for Recruited Participants and Study Communities:
- Develop and implement procedures to protect the confidentiality of recruited and enrolled participants.
- Ensure the participants know they can withdraw without penalty.
- Provide enrolled participants with information that arises in the course of the research study.
- Monitor and develop interventions for medical conditions, including research-related injuries, for enrolled participants at least as good as existing local norms.
- Inform participants and the study community of the results of the research.

(Emanuel et al., 2004)

5.2 Review of research proposals

5.2.1 IREC

Members of the IREC will be responsible for reviewing category 3 research proposals submitted for that particular meeting. Research involving minimal risk to participants (category 2) will follow the expedited review process. 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.

When category 3 proposals are reviewed at the meeting, each member present will have an opportunity to raise any comments he/she may have. These will be discussed and a decision reached. The IREC will strive to have consensus on all decisions made; however, in instances where there is no consensus, the matter will be put to vote. A minimum of 70% of the members present will need to be in favour of the matter to result in an approval. Category 2 proposals will be allocated to respective members for in-depth review as delegated by the Chairperson. The decisions from the expedited review will serve at a scheduled IREC meeting for noting. The IREC will not review proposals for ethical approval if data collection has already begun. In such instances, this will be reported to the relevant DVC.

On completion of the review process the researcher, the supervisor and the Faculty Research Co-ordinator will be informed of the outcome of the review, according to the following criteria:

- Full Approval: No changes to proposal
- Provisional approval: This is subject to minor changes - the changes and/or clarifications are to be made by the researcher and re-submitted to the Chairperson for final approval
- Provisional approval subject to piloting of the data collection tools
- Re-submission: The ethical issues need to be further addressed and the revised proposal will need to be re-evaluated by the reviewers.
- Rejected: The proposal does not meet the ethical requirements, the specific reasons will be accurately recorded
- Termination or suspension of prior approval: The specific reasons will be accurately recorded.

5.2.2 FREC

Faculty Research Ethics Committees (FREC's) are subcommittees of IREC and can review category 2 proposals only. However, the FREC cannot issue ethics clearance numbers, as the IREC is the only accredited committee with the National Health Research Ethics Council, which can issue clearance numbers. A schedule for all category 2 proposals reviewed at FREC is to be sent to IREC for noting every term.

5.2.3 Review of 4 Year Undergraduate Bachelor Degrees or Honours Degree Proposals

These applications must be reviewed at the Departmental Research Committee or the Faculty Research Committee before submission of category 2 proposals to the IREC.

The IREC must be provided with a tentative date at the beginning of each year from each Faculty, as to when the Bachelor's Degree Proposals for ethics clearance will be forwarded to the IREC. Proposals must be submitted in batches from the Departments.

5.3 Communication of reviewed decisions

All decisions will be recorded in the IREC minutes with each principal investigator receiving the outcome of their application in a written communique. It is not unusual for the committee to recommend changes to the proposal. When corrections have been requested the proposal should be re-submitted to the IREC Administrator with a covering letter clearly outlining the corrections recommended by the IREC. This should be received by the IREC Administrator as soon as possible but no more than 6 months after initial review. The application will be cancelled should no feedback have occurred within 6 months. The Chairperson or other delegated person will be responsible for carefully checking that the corrections have been undertaken. Only once the recommendations have been met will a formal letter of approval be issued by the IREC. In the instance where a research study is rejected the principal investigator will be issued a formal letter stating the reasons for rejection.

Once provisional/ full approval has been obtained, the IREC Administrator will allocate a unique IREC clearance number to each proposal. This clearance number should then be used in all the relevant research project documentation and communications for ease of reference. The researchers can address any queries and/or feedback to the IREC Administrator, who will liaise with the Chairperson to resolve any problems. Should there be a discrepancy the researcher may lodge an appeal. It is the responsibility of the researcher and, where applicable, the principal investigator, to comply with all the required revisions and/or clarifications. The revised

and/or requested documentation should be submitted to the IREC as soon as possible, but not later than 6 months, after the applicable IREC meeting.

6. CONVENED MEETING

The IREC will undertake the following:

- Review category three research proposals and their supporting documentation (e.g. letters or information and consent, advertisements, questionnaires etc.)
- Note all category 2 proposals approved through expedited review (FREC/ IREC).
- Recommend any necessary protocol amendments such as change of title, change to methodology etc.
- Assess safety monitoring
- Decide on recertification
- Note any adverse events occurring in previously approved studies
- Consider allegations of research misconduct or other complaints
- Confirm completion of studies
- Address general and policy matters

6.1 Meeting procedure

The meeting will start with the Chairperson opening the meeting and ensuring that the meeting is quorate. The Administrator will record those present as well as any apologies. Previous minutes will be corrected and accepted. Matters arising will be dealt with followed by relevant business. The Chairperson will facilitate any discussions and will summarise the various viewpoints of the committee.

7. ADMINISTRATION OF IREC

The IREC Administrator will be responsible for administrating the business of the IREC. He/she will report to the Chairperson of the IREC. All IREC documentation will be sent to him/her for collation and distribution to the IREC members.

The IREC Administrator will perform the following functions prior to the IREC meeting:

General:

- Inform IREC members of meeting and closing dates for agenda items and documentation
- Collate documentation for the IREC agenda
- Obtain and verify information/documentation and ensure administrative procedures are completed prior to compilation of the agenda
- Ensure documentation submitted for the agenda is complete, with all signatures and necessary paperwork
- Finalize the agenda in consultation with the Chairperson of IREC
- Prepare agenda and documentation including making copies of agenda/ documentation
- Prepare all documentation for distribution to the members with a signing roster allowing for IREC
- Members to acknowledge receipt of agenda and documentation
- Dispatch agenda/ documentation to IREC members 7-10 days before the meeting
- Prepare IREC attendance register
- Keep a file with all IREC members' Curricula Vitae, contact details and confidentiality forms
- Ensure in the case of student proposals that the student is correctly registered for the year
- Arrange any special/ad hoc meetings if necessary
- Ensure that IREC review of research proposals is within 7-10 days
- Contact specialist members required to attend IREC meetings
- Keep all IREC documentation.

Expedited review:

- Inform members who are required to review proposals for expedited review
- Ensure those members receive the documentation timeously
- Follow up on allocated reviews
- Write and distribute letters to researchers informing them of the IREC decisions
- Allocate ethics clearance numbers to approved category 2 research.

The following functions are performed during the IREC meeting:

- Advise Chairperson on IREC quorum prior to commencement of meeting
- Monitor quorum during meeting to ensure it is acceptable
- Record those present and any apologies
- Record conflict of interests
- Record and correct any amendments to previous minutes submitted for approval
- Minute IREC meetings and ensure accurate recording of decisions, including any amendments requested by the committee
- Monitor those who leave the meeting and record in minutes
- Ensure attendance register is signed by all members present
- Assist with the interpretation and implementation of student research rules, policies and procedures.

7.1 Post meeting responsibilities

- Compile minutes
- Write and distribute letters to researchers informing them of the IREC decisions
- Allocate ethics clearance numbers to approved category 3 research
- Organise any additional meetings if necessary.

7.2 Record keeping

It is an ethical and legal requirement that all documents pertaining to research on human and the environment be kept for future reference and audit purposes. The IREC will keep all IREC documentation for 5 years in accordance with the GCP guidelines.

8. APPEALS PROCEDURE

Researchers have the right to appeal decisions made by the committee or may have concerns regarding IREC administration process. The appeal must be submitted by the principal investigator to the Chairperson of the IREC through the IREC Administrator. There must be a clear motivation for the appeal which should be supported by a subject specialist other than the principal investigator. The IREC Chairperson or delegated member may then seek outside consultation about the research. This will then be reported back to the IREC members along with recommendations regarding the appeal. The IREC committee will then reconsider the entire protocol with the new motivations and a decision will be made. The decision after the appeals process is final.

9. AMENDMENTS TO RESEARCH PROTOCOL

The IREC approves the study protocol ensuring that the research will be conducted using sound ethical principles. All amendments must be submitted to the IREC utilising the "Application for approval of amendment" form (Appendix D) prior to being implemented. The Chairperson will decide if the amendment has minor or major implications for the study and its participants. If the change is minor, it may be seen through expedited review; if the change is major, it will serve at a full committee meeting.

- Minor amendment - does not change the risk-benefit profile of the study, e.g. change of title[2], administrative changes, adding an investigator, changes that do not affect study design and outcomes, small changes to letter of information and consent such as editorial changes
- Major amendment - does change the risk-benefit profile of the study, e.g. change in study aims and objectives, alterations to study procedure, changing inclusion criteria to make study more accessible, changes to letter of information and consent.

In the case of protocol deviations, defined as a "once off" instance where the research protocol is not followed either deliberately or by mistake, the deviation will fall into one of two categories: major or minor as outlined above. If minor, the deviation must be reported to the IREC in the annual progress report. If the deviation is major, it will need to be reported to the IREC within 15 days. The Chairperson will then decide the action to be taken.

10. ADVERSE EVENTS REPORTING

All adverse events (AE), serious adverse events (SAE), adverse drug reactions (ADR), serious adverse drug reactions (serious ADR) and serious adverse experiences (SAEx) which occur during a study must be reported to the IREC.

- Adverse event (AE) is defined as 'any untoward occurrence affecting participants in a research investigation or clinical investigation participant administered a pharmaceutical product or other intervention/ investigation, which does not necessarily have a causal relationship with this treatment/Investigation.' An AE can therefore be any unintended sign (including abnormal laboratory finding), symptom, or disease temporarily associated with the use of a medicinal (investigational) product, or other intervention/ investigation, whether or not related to the medicine or investigational product or intervention.
- Adverse drug reaction (ADR) is defined as 'any noxious and unintended response associated with the use of a drug in humans'.
- Serious adverse event (SAE) or serious adverse drug reaction (serious ADR) is 'any untoward medical occurrence that at any dose/ intervention: results in death, is life threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect.'
- Serious adverse experience (SAEx) is 'any experience that suggests a significant hazard, contraindication, side effect or precaution'.

All of the above must be reported to the IREC via the FRC in writing using the adverse event report form (Appendix E) irrespective of whether the study is for qualification or non-qualification purposes.

10.1 Reporting procedure

1. All AEs must be reported to the IREC via the FRC in writing by the principal investigator within a maximum of 21 days. If the AE is considered by the principal investigator to have implications to other research participants, the co-researchers or others involved, and suggests further risk or possible adverse events, the principal investigator is required to report the AE and its potential implications to the IREC, immediately followed by the formal completion and submission of the Adverse Event report form within 48 hours of the event.
2. All SAEs and serious ADRs must be reported to the IREC immediately by the principal investigator followed by formal completion and submission of the Serious Adverse Event report form within 48 hours of the event.
3. All ADRs and/ or SAEx must be reported to the IREC in writing by the principal investigator using the Adverse Event report form within 48 hours of the event.

[2]Application for change of title: The approved PG 4c: Notification of Research Proposal Title Change by the Higher Degrees Committee document must be forwarded to the IREC by the relevant Faculty Research Committee for noting.

4. The non-reporting of any adverse event by the principal investigator is viewed in a very serious light. Such non-compliance within the prescribed time frame and protocol has far-reaching consequences. Accordingly, should the principal investigator fail, refuse or neglect to report an adverse event in the prescribed manner, he/she would deemed to have fully and completely absolved the IREC and/or university from liability irrespective of its nature and extent.

10.2 Administration and review of reports by IREC

1. All AE and ADR reports will be compiled and included on the IREC agenda for review at the next meeting. If necessary, an emergency IREC meeting will be called to review an AE or ADR report in cases where appropriate action should be expedited.
2. All SAE and serious ADR reports will be reviewed by the Chairperson of the IREC immediately and where necessary an emergency IREC meeting will be called to review the reports and determine the appropriate action.
3. The IREC upon reviewing the reports will determine and implement the appropriate intervention(s) to ensure the welfare, rights and safety of participants are maintained; this may include review of the research protocol in light of the event, further investigation of the event by the safety monitoring committee, a safety audit, additional safety monitoring procedures and/or if necessary withdrawal of ethical approval.
4. The IREC will forward the report to the relevant DVC.

11. CONTINUAL REVIEW, ANNUAL RECERTIFICATION AND SAFETY MONITORING

11.1 Continual review and recertification

All research approved by the IREC will be subject to substantive, meaningful and focused continuing review to determine that the risks and benefits of the study have not changed, that there are no unanticipated findings involving risks to participants and/or others, and that any new information regarding risks and benefits are provided to the participants. The review will occur annually, unless the level of risk requires more frequent review. The IREC may withdraw approval of a protocol previously approved. **The responsibility for the application for recertification lies with the researcher and supervisor.**

All applications will be reviewed by the full committee. However, the final decision rests with the Chairperson or a person delegated with this responsibility. At least one member of the IREC will receive a copy of the full protocol including any modifications that have been previously approved by the IREC, with the full committee having access to the complete IREC protocol file and relevant IREC minutes at the convened meeting. All studies will require continual review until the IREC receives the final study report and the completion of study form (appendix G).

All applications for continual review must be submitted by the primary investigator to the IREC on the IREC safety monitoring and annual recertification report form (appendix F) along with any other supporting documentation. This documentation will need to be sent to the IREC Administrator at least 14 days before the meeting to be added to the IREC meeting agenda and will be distributed to members for review. The IREC should receive this application at least three months before the ethics approval for the study expires; this will ensure that re-approval takes place before the studies ethical approval expires. No study may continue without valid ethical approval and re-certification.

Once the IREC has assessed the continual review application, the study may:

- Continue as originally approved
- Have some modifications
- Request a site visit by the safety monitoring committee
- Be suspended
- Be terminated.

The IREC Administrator will inform the principal investigator in writing of the outcome of their application and any reasons for its decision. All conditions required by the IREC must be met before continual approval will be granted. If the principal investigator appeals the decision, the IREC must ensure there is a fair hearing of the query.

11.2 Safety monitoring

The IREC will monitor compliance with respect to the approved research protocol ensuring the protection of the research participants. Such continued monitoring allows for early intervention should proceedings deviate intentionally or unintentionally from the approved sequence of events. A Safety Monitoring Committee (SMC) will be formulated by the IREC and function as a sub-committee thereof.

The role of the SMC is to perform the following functions:

1) Investigate and report on the following:
   - Ascertain if an approved study is being conducted according to its approved protocol
   - Ascertain whether an approved study is being conducted according to the conditions of approval by the IREC
   - Ascertain whether amendments to the original protocol are necessary.
2) Monitor and report on the following:
   - Progress made in an approved study in respect of the anticipated timeframe as indicated in the proposal
   - Outcomes and findings of such approved studies upon completion thereof
3) Review and investigate if required:
   - All adverse events should they arise and advise the IREC accordingly
   - Report to the IREC the findings of the SMC with respect to each adverse event.

Composition of the SMC:

The SMC will comprise, at minimum, a member of the IREC and at least 2 additional people who meet the following criteria:

- Suitable expertise and experience in the field of study to be reviewed
- Neutrality with regard to the site, to the principal investigator, and to other relevant parties involved.

In the absence of suitable expertise necessary, the IREC may source such expertise from other academic institutions or from industry.

Monitoring procedure:

1. Safety monitoring reports

The principal investigator will submit a safety monitoring and recertification report form annually (appendix F), along with any other supporting documentation, to the IREC, a minimum of three months before ethical approval of the study lapses. In situations where the IREC deems fit, additional safety monitoring reports may be requested. Such situations may include:

- Studies involving vulnerable population groups
- Studies graded as Level 3 (possible risk/ risk to humans, environment or sensitive/ highly sensitive research)
- Studies in which additional factors warrant more stringent monitoring e.g. sample size, complexity of design, location and number of trial sites, degree of financial outlay, number of investigators, degree of

experience of the site and staff, degree of manpower involved OR other factors deemed to justify such additional monitoring by the IREC
- Studies with sites from which complaints have been received
- Studies suspected to be not complying with approved protocol.

2. Site inspection
In order to perform the first function, the SMC may conduct site inspections/audits on behalf of the IREC. Such site inspections may include inspections of the following:

- The presence and suitability of all trial documentation and essential documents (appendix F)
- Appropriateness and suitability of facilities and infrastructure at the trial site
- Suitability of expertise and staff recruited to participate in or facilitate the research process
- Investigational equipment for monitoring and interventions made
- Investigational products and interventions with respect to storage, labelling, dispensing, counselling of participants, administration, stock control, and disposal thereof
- Administration and storage of all trial documentation
- Evidence of recruitment strategy and practice applied (including informed consent)
- Evidence of provisions made for patient/ participant confidentiality
- General evidence to support the degree of compliance with the approved research protocol.

All studies categorised, as Level 3 as defined in the proposal document, will be subject to a minimum of one annual, compulsory site inspection by the SMC. All other studies will be subject to site inspections as deemed fit by the IREC based on random selection or based on the factors warranting greater than one annual safety monitoring report.

3. Progress monitoring
In order to perform the site inspection, the SMC may request progress reports from the principal investigator; such reports if necessary, may be required to be substantiated by the submission of additional evidence or by undertaking site inspections. Studies which do not meet the anticipated progress targets set in the approved protocol will be reported to the IREC for review and intervention.

4. Investigation of adverse events
In order to perform progress monitoring, all Adverse Event Reports submitted to the IREC will be delegated to the SMC for investigation, corroboration and reporting. The SMC may request additional supporting evidence and documentation from the principal investigator, conduct an appropriate site inspection, or interview involved parties and stakeholders should it be warranted. Upon concluding its investigation, a report of the findings will be submitted to the IREC for review.

5. Independent site/trial audit
The IREC may request an independent site audit should it be warranted; such an audit may be instituted in the following situations:

- Studies/sites in which significant evidence of non-compliance or transgression of research protocol exists
- Studies/sites from which serious or multiple complaints have been received
- Studies/sites from which serious adverse events or serious adverse drug reactions are reported
- Studies/sites suspected of committing fraudulent acts
- Studies/sites suspected serious of breach of confidentiality and or poor handling of participants
- Any additional situations in which the IREC deems an independent audit necessary.

In such situations, an independent suitably qualified auditor will be appointed by the IREC to act on its behalf and conduct the audit, the aim being to determine if the research is being conducted according to and in keeping

with the approved research protocol; that participants are protected and treated fairly and ethical standards are maintained.

12. SUSPENSION AND DISCONTINUATION OF RESEARCH PROPOSAL

12.1 Suspension or termination by IREC:

Where the IREC is satisfied that such circumstances have arisen that a research project is not being conducted in accordance with the approved protocol and that, as a result, the welfare and rights of participants are not or will not be protected, the IREC may withdraw approval. The IREC shall also inform the researcher and the institution or organisation of its action, and shall recommend that the research project be discontinued or suspended, or that other appropriate steps be taken.

Where ethical approval has been withdrawn, a researcher must discontinue the research and comply with any special conditions required by the IREC. A report to this effect has to be submitted to the IREC within 2 weeks of suspension/ discontinuation of the project.

When the safety of participants is at risk, the Chairperson of the IREC in consultation with an IREC subcommittee and/or other co-opted parties will call a meeting as soon as possible but not more than seven days after receipt of such information. The outcome of such a meeting will be reported to IREC at the next quorate meeting. IREC will give a detailed written reason for suspending or terminating the study to the relevant parties e.g. the principal investigator, the relevant DVC, the study sponsor or agency, the investigator's departmental head, the South African National Health Research Ethics Council and the SAHPRA (if applicable).

12.2 Suspension or termination by researcher

In the case where a research project is prematurely suspended/ terminated the principal investigator/researcher must notify the IREC in writing of the reasons for suspension/termination and give a summary of the results obtained in a study thus far (Appendix H).

13. RESEARCH REQUIRING ADDITIONAL ATTENTION

The IREC will pay special attention to research involving certain participants and certain types of research. It may be necessary in these instances for the IREC to impose additional measures to protect the well-being of the research participants. Conducting post-research investigations may also be necessary to ensure that the additional measures were implemented. Where compliance is defective, ethical approval may be withdrawn. The IREC will follow the National Health Act section 71(3) (a), where research on children for non- therapeutic interventions must fulfil the following criteria: permission from the Minister, permission from the minors parent/s or guardian and, where the minor is capable of understanding and consenting, from the minor.

Classes of participants that require special attention include:

- Minors – those under 18 years of age
- Pregnant women
- Prisoners
- People with intellectual or mental impairment.
- People for whom English is not a first language
- People from vulnerable communities
- Or any other group deemed to be applicable

Types of research requiring special attention:

- Indigenous medical systems
- Emergency medical care
- Innovative therapy/interventions
- Research requiring ambiguity of information for participants

The IREC will follow the guidelines from the Department of Health, Ethics in Health Research: Principles, structures and processes, available at http://www.nhrec.org.za/?page_id=14

14. COMPLETION OF STUDY

A study is considered active or on going until all data is collected, follow up at all research sites is complete and participant participation is no longer needed. The principal investigator/researcher must submit a letter to the IREC informing them that the study is completed (appendix G) along with the final study report or a copy of the study abstract (in the case of student research). This should be done after the comments from the examiner's report have been addressed successfully. If a study is not closed but is allowed to expire (a lapse in approval) an administrative suspension letter may be sent to the principal investigator.

15. HANDLING OF COMPLAINTS

The IREC may receive complaints about researchers, the conduct of research, or about the conduct of the IREC. Complaints may be made by participants, researchers, staff of the institution, or others. All complaints should be handled promptly and sensitively.

Possible complaints cover a broad spectrum from 'inadvertent technical deviations' from established protocols to allegations of scientific misconduct or fraud. The primary concern in response to any complaint is the extent to which research participants are endangered. There may also be concerns about the degree to which researchers are fulfilling their responsibilities, questions around culpability for misconduct and misleading reports being published by a researcher accused of misconduct or fraud. Often the IREC will be the most appropriate body to consider complaints in the first instance, although ultimately, the responsibility lies with DUT.

The Chairperson of the IREC will receive the complaints; he/she may delegate this responsibility to a member of the IREC. All complaints will be dealt with and may require the assistance of other persons (not necessarily members of the IREC). The letter of information and consent (appendix B) provided to study participants will provide the contact details of IREC Administrator should participants wish to lodge a complaint. The IREC Administrator will forward the complaint on to the Chairperson/complaints officer.

Procedure for complaint:

- complaint referred to the Chairperson of the IREC
- the Chairperson would consider the complaint - including, where necessary, reference to original protocol, contact with researchers, contact with complainant
- action would be taken including, if warranted, implementing an investigation with the complainant being advised accordingly
- a report will appear at the next IREC meeting.

Where the complainant is not satisfied with the actions taken, the complaint would be referred to the relevant DVC.

15.1 Procedures for responding to complaints

The Chairperson will respond urgently when there is any suggestion of harm to research participants, researchers or any other person. In extreme circumstances, an immediate demand to suspend a research study may be necessary while concerns are adequately investigated. In other cases, prompt action may be required to rectify or remove the cause of concern. Having determined the urgency of the need for action, the Chairperson should take any, and possibly all, of the following steps according to the circumstances:

- make a clear and full written record of the complaint;
- seek further information from all relevant parties;
- convene an urgent meeting of the IREC; and
- if necessary, confer with the highest level of management and authority within the relevant institution.

15.2 Procedures for investigating complaints

Where initial investigations reveal a situation that requires further investigation and review, the following procedures are recommended:

- Invite the researcher(s) to explain the situation to the IREC and to demonstrate why the project should not be discontinued and ethical approval withdrawn.
- Advise researcher(s) that they may be accompanied by one or more colleagues.
- Reconsider the original research proposal and seek additional information from the researcher(s) in relation to the conduct of the study, or any other relevant factors, before making a final decision whether to revise or reconfirm the original decision to approve the project.

Having considered the matter, the committee may:

- withdraw approval resulting in suspension of the project,
- require amendments to the original research proposal or to the conduct of the research; or
- allow the project to continue without amendment.

The IREC will inform the principal investigator/research in writing of the decision of the IREC explaining the reasons for the recommendations. It may be necessary to inform research participants that the research they have been participating in has been modified or discontinued. In this instance, the IREC will take advice from the researcher(s) about the wording of the notice to participants.

An appeal against a decision can be made and should be referred to a mediator independent of the IREC and related activities.

15.3 Allegations and complaints of serious research misconduct

Research misconduct includes any of the following:

- Fabrication, falsification, plagiarism, or deception in proposing, carrying out, or reporting results of research.
- Deliberate, dangerous, or negligent deviations from accepted practice in carrying out research. This includes failure to follow established protocols if this results in unreasonable risk or harm to human beings, or the environment and also the facilitating of misconduct by collusion in, or concealment of, such actions by others.
- Failure of informed consent.
- Breaches of confidentiality.
- Deception in research process.
- Misrepresentation or falsification of credentials.

Misconduct does not include honest error or honest differences in the design, execution, interpretation, judgment in evaluating research methods or results of misconduct (including gross misconduct) unrelated to the research process.

Where there has been an allegation of serious misconduct, the institution should ensure the following:

- Protection of participants;
- Appropriate confidentiality (in case the allegation proves to be groundless);
- Protection of 'whistle-blowers'; and
- Natural justice for those who are the subject of any allegations or complaints.

Confidentiality, protection for complainants and natural justice for the person complained about will be dealt with by the review process outlined as follows:

1. Determine whether the allegation falls within scientific misconduct.

2. Determine whether there is prima facie evidence of scientific misconduct.
3. Institute a formal investigation to evaluate all relevant facts to determine whether scientific misconduct has been committed and, if so, by whom, as well as the seriousness of the misconduct. The integrity of the research data must be evaluated and all appropriate groups advised if inaccurate, misleading or invalid data have been published or submitted to other agencies.

15.4 Complaints concerning IREC review processes

Most complaints received by IRECs concern the review process itself or the manner in which researchers and their projects have been considered and dealt with. For example, researchers may complain when the IREC has rejected a proposed project, when a committee is perceived to be taking undue time considering a proposal, or when conflict has arisen between a committee and researchers. In many situations, the problem may simply be one of inadequate communication between the committee, its officers, and the complainant(s). The Chairperson/complaints officer will attempt to deal with the concern or complaint without formal investigation where possible. If the matter remains unresolved, the principle investigators may lodge a formal complaint with the relevant DVC. If the complainant is dissatisfied with the decision of the relevant DVC, an appeal maybe lodged with the Vice-Chancellor. The decision of the Vice-Chancellor is final and binding.

16. CONFLICT OF INTEREST BY RESEARCHERS

Conflict of interest arises when the individual's private or personal interests and professional obligations are divergent to such an extent that an independent observer may have doubt as to whether or not the individual's professional actions are influenced by personal considerations, financial or otherwise. Any conflict of interests should be avoided, and all researchers must make known any potential conflict of interests. Interference by clients or funders that could compromise the integrity of the research is unacceptable.

Possible conflict of interests:

- Financial relationships of any kind by the researcher e.g. equity, stock
- Proprietary interests e.g. patents, intellectual property
- Sponsorship/donations e.g. conferences, equipment
- Funding e.g. for additional staff or facilities, payments to departments
- Co-authorship of articles
- Positions on various boards e.g. Pharmaceutical Advisory board
- Grants and retainers.

Conflict of interests that are not disclosed may have a negative impact on the well-being of the research participants; therefore, the IREC must be duly informed in order to protect the participants. All principal investigators are required to sign a conflict of interest form (Appendix C).

17. AUDITING OF IREC

The IREC may be audited by the National Health Research Ethics Committee or the DUT Institutional Research Committee.

18. FEES TO BE CHARGED FOR EXTERNAL PROPOSALS

The IREC, with the approval of the relevant DVC and Senate, will levy a schedule of fees for review of external proposals. The schedule of fees must be approved by the relevant DVC from time to time as required. The fees received may be used for expenses related to the operation of the IREC, for continuous professional development or specific ethics training. All staff and students registered at DUT will be exempt from paying fees. Students from other academic institutions will pay a nominal fee.

19. Appendices

Appendix A

Independent Research Proposal

Faculty	
Department	

Name of Principal Investigator[1]			**Title**	
Postal Address				
Tel (W)	**Tel (H)**	**Cell**	**Fax**	**e-Mail**
Name of Co-investigator[1]	___			_____
Title of Study				

Ethics Category	**1**	**2**	**3**

Research will result in a patent	**Yes**		**No**		**Unsure**	

Summary of the study (150-200 words)
[Please include a brief account of the nature and scope of the study, its purpose, and the research approach and methodology to be used.]

1. Context of the Research
This section provides the general information regarding the research that will be undertaken and should make it clear why the problem is worth addressing. It sketches the background and, where appropriate, should provide a brief theoretical framework within which the problem is to be addressed. (Maximum length: 250 words)
2. Research Problem and Aims
This section should either set out the specific question(s) to which the researcher hopes to find an answer, or the research problems which are to be solved or state any hypotheses to be tested. In the case of open-ended topics in the Humanities, outline the subject/area/field to be critically investigated.

It should indicate clearly what the research intends to achieve and the intended products of the research.

3. Literature Review
This section includes a brief review of the main, seminal literature sources (mainly scholarly journals, but text books, media articles, Internet and other sources can be used). Use the Harvard Method of referencing**.** Show clearly how the literature is linked to your topic, the problem statement and the research objectives.

4. Research Methodology
In this section the researcher is advised to state the research paradigm; qualitative/quantitative or both. The research approach/strategy will also need to be stated. e.g. Qualitative: Action research, developmental research, case study research, ethnographic research, grounded theory research, etc. Quantitative: Mathematical, modelling and simulation, experimenting, testing, etc.

5. Key References
List key references which you have cited in the above sections using the Harvard referencing style

Section C: Ethics							
Tick as appropriate:							
Humans		**Organisations**		**Animals**		**Environment**	
Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
Indicate Category (X)							
1.	**Exempt from Ethics and Biosafety Research Committee Review (straightforward research without ethical problems)**						
2.	**Expedited review (minimal risk to humans or environment)**						
3.	**Full Ethics and Biosafety Research Committee review recommended (possible risk to humans, environment, or a sensitive research area)**						

Attach Addendums (if any)

Declarations

Researcher Declaration

I, the undersigned, certify that:

- ☐ Where I have used the work of others this has been correctly referenced in the proposal and again referenced in the bibliography. Any research of a similar nature that has been used in the development of my research project is also referenced.
- ☐ This project has not been submitted to any other educational institution for the purpose of a qualification.
- ☐ All subsidy-earning outputs (artefacts and publications) will be in accordance with the Intellectual Property Policy of the Durban University of Technology.
- ☐ Where patents are developed under the supervision of the Durban University of Technology involving institutional expenditure, such patents will be regarded as joint property entitling the Durban University of Technology to its share, subject to the Durban University of Technology's policy on the Management and Commercialisation of Intellectual Property.
- ☐ I understand that plagiarism is wrong, and incurs severe penalties.

I HEREBY DECLARE THAT THE ABOVE FACTS ARE CORRECT.

Signed: _____ **Date:** _____

ETHICAL ISSUES CHECKLIST FOR RESEARCH APPROVAL

To be completed by all researchers wishing to conduct research projects under the auspices of Durban University of Technology.

1. Use the Durban University of Technology's Research Ethics Policy and Guidelines to ensure that ethical issues have been identified and addressed in the most appropriate manner, before finalising and submitting your research proposal.

2. Answer all questions by indicating your response in the relevant cell by means of an 'X'.

3. Type the motivations/further explanations where required in the cell headed COMMENTS.

4. Attach Addendums/Annexures (if any) and label them clearly and in a logical order.

NO.	QUESTION	YES	NO	N/A
	DECEPTION			
1.	Is deception of any kind to be used? If so provide a motivation for acceptability.			
	COMMENTS			
	CONFIDENTIALITY			
2.	Does the data collection process involve access to confidential personal data (including access to data for purposes other than this particular research project) without prior consent of participants? If yes, motivate the necessity.			
	COMMENTS			
3.	Will the data be collected and disseminated in a manner that will ensure confidentiality of the data and the identity of the participants? Explain your answer.			
	COMMENTS			
4.	Will the materials obtained be stored and ultimately disposed of in a manner that will ensure confidentiality of the participants? If no, explain. If yes specify how long the confidential data will be retained after the study and how it will be disposed of.			
	COMMENTS			
5.	Will the research involve access to data banks that are subject to privacy legislation? If yes, specify and explain the necessity.			
	COMMENTS			
	RECRUITMENT			
6.	Does recruitment involve direct personal approach from the researchers to the potential participants? Explain the recruitment process.			

NO.	QUESTION	YES	NO	N/A
	COMMENTS			
7.	Are participants linked to the researcher in a particular relationship, for example employees, students, family? If yes, specify how.			
	COMMENTS			
8.	If yes to 7, is there any pressure from researchers or others that might influence the potential participants to enrol? Elaborate.			
	COMMENTS			
9.	Does recruitment involve the circulation/publication of an advertisement, circular, letter etc.? Specify.			
	COMMENTS			
10.	Will participants receive any financial or other benefits as a result of participation? If yes, explain the nature of the reward, and safeguards.			
	COMMENTS			
11.	Is the research targeting any particular ethnic or community group? If yes, motivate why it is necessary/acceptable. If you have not consulted a representative of this group, give a reason. In addition, explain any consultative processes, identifying participants. Should consultation not take place, provide a motivation.			
	COMMENTS			
	INFORMED CONSENT			
12.	Does the research fulfil the criteria for informed consent? [See guidelines]. If yes, no further answer is needed. If no, specify how and why.			
	COMMENTS			
13.	Does consent need to be obtained from special and vulnerable groups (see guidelines). If yes, describe the nature of the group and the procedures used to obtain permission.			
	COMMENTS			
14.	Will a Letter of Information be provided to the participants and written consent be obtained? If no, explain. If yes, attach copies to proposal. In the case of participants for whom English is not the preferred language, explain what arrangements will be made to ensure comprehension of the Letter of Information, Informed Consent Form and other questionnaires/documents.			
	COMMENTS			
15.	Will results of the study be made available to those interested? If no, explain why. If yes, explain how.			

NO.	QUESTION	YES	NO	N/A
	COMMENTS			
	RISKS TO PARTICIPANTS			
16.	Will participants be asked to perform any acts or make statements which might be expected to cause discomfort, compromise them, diminish self-esteem or cause them to experience embarrassment or regret? If yes, explain.			
	COMMENTS			
17.	Might any aspect of your study reasonably be expected to place the participant at risk of criminal or civil liability? If yes, explain.			
	COMMENTS			
18.	Might any aspect of your study reasonably be expected to place the participant at risk of damage to their financial standing or social standing or employability? If yes, explain.			
	COMMENTS			
19.	Does the research involve any questions, stimuli, tasks, investigations or procedures which may be experienced by participants as stressful, anxiety producing, noxious, aversive or unpleasant during or after the research procedures? If yes, explain.			
	COMMENTS			
	BENEFITS			
20.	Is this research expected to benefit the participants directly or indirectly? Explain any such benefits.			
	COMMENTS			
21.	Does the researcher expect to obtain any direct or indirect financial or other benefits (not including a qualification) from conducting the research? If yes, explain.			
	COMMENTS			
	SPONSORS: INTERESTS AND INDEMNITY			
22.	Will this research be undertaken on the behalf of or at the request of a pharmaceutical company, or other commercial entity or any other sponsor? If yes, identify the entity.			
	COMMENTS			
23.	If yes to 22, will that entity undertake in writing to abide by Durban University of Technology's Research Committee's Research Ethics Policy and Guidelines? If yes, no further explanation is required. If no, explain.			
	COMMENTS			
24.	If yes to 23, will that entity undertake in writing to indemnify the institution and the researchers? If yes, no further explanation is required. If no, explain.			

NO.	QUESTION	YES	NO	N/A
	COMMENTS			
25.	Does permission need to be obtained in terms of the location of the study? If yes, indicate how permission is to be obtained.			
	COMMENTS			
26.	Does the researcher have indemnity cover relating to research activities? If yes, specify. If no, explain why not.			
	COMMENTS			
27.	Does the researcher have any affiliation with, or financial involvement in, any organisation or entity with direct or indirect interests in the subject matter or materials of this research? If yes, specify.			
	COMMENTS			

Please note: Questions 28-34 deal with research in clinical settings. If your proposed project does not involve clinical research, please answer these items with 'No'.

NO.	QUESTION	YES	NO	N/A
28.	Will the research involve the use of no-treatment or placebo control conditions? If yes, explain how the participant's interests will be protected.			
	COMMENTS			
29.	Does the protocol require any physically invasive, or potentially harmful procedures [e.g. drug administration, needle insertion, rectal probe, pharyngeal foreign body, electrical or electromagnetic stimulation, etc.?] If yes, outline below the procedures and what safety precautions will be used.			
	COMMENTS			
30.	Will any treatment be used with potentially unpleasant or harmful side effects? If yes, explain the nature of the side-effects and how they will be minimised.			
	COMMENTS			
31.	Will any samples of body fluid or body tissues be required specifically for the research which would not be required in the case of ordinary treatment? If yes, explain and list such procedures and techniques.			
	COMMENTS			
32.	Are any drugs/devices to be administered? If yes, list any drugs/devices to be used and their approved status.			
	COMMENTS			
	GENETIC CONSIDERATIONS			

NO.	QUESTION	YES	NO	N/A
33.	Will participants be fingerprinted or DNA "fingerprinted"? If yes, motivate why necessary and state how such is to be managed and controlled.			
	COMMENTS			
34.	Does the project involve genetic research e.g. somatic cell gene therapy, DNA techniques, etc.? If yes, list the procedures involved			
	COMMENTS			
35.	Are there any project-specific ethical issues not covered by the above questions? If yes, please explain.			
	COMMENTS			

N.B. For ethical clearance for categories 2 and 3, kindly refer to the IREC web page: http://www.dut.ac.za/research/institutional_research_ethics.

The undersigned declare that the above questions have been answered truthfully and accurately

PRINCIPAL INVESTIGATOR----------

SIGNATURE---------- **DATE----------**

CO-INVESTIGATOR----------

SIGNATURE---------- **DATE----------**

Appendix B

LETTER OF INFORMATION

Title of the Research Study :(In full)

Principal Investigator/s/researcher: (Name/s, qualifications)

Co-Investigator/s/supervisor/s: (Name/s, qualifications)

Brief Introduction and Purpose of the Study: (The following should be covered in the sequence provided. Do not use the subheadings in the Letter of Information).

Greeting (Start with a greeting, Hello, Good morning, Good Day, How are you etc.).

Introduce yourself to the participant (I am a 4th year student at DUT doing research for my Bachelors degree in ……..)

Invitation to the potential participant (I would like to invite you to participate in the research)

What is Research (Research is a systematic search or enquiry for generalized new knowledge)

(Address the Research Participant directly in the second person pronoun "you." Do not address the research participant as "participant," "patient", "sir" or "madam". The language must be free of jargon and unexplained acronyms and must be easily understood by the potential research participant. Technical terminology, must be clear and explained. Consider the age, target population, home language, educational level, frame of mind, etc. of the participant. An explanation to the potential participant that he/she can ask as many questions as he/she wish because it is important that he/she fully understand the study. Participants are entitled to discuss the study with their family and friends and are under no obligation to commit at this stage. For this purpose, a copy of the Letter of Information document is given to the potential participant to take home.)

Outline of the Procedures: (Provide a brief summary of the Research. Its aims and objectives**.** A description of the procedures to be followed. Responsibilities of the participant, consultation/interview/survey details, venue details, inclusion/exclusion criteria, explanation of tools and measurement outcomes, any follow-ups, any placebo or no treatment, how much time required of participant, what is expected of participants, randomization/ group allocation. The expected duration of the participant's commitment. The approximate number of participants to be involved in the study.)

Risks or Discomforts to the Participant: (Describe any foreseeable risks or discomforts to participants if applicable e.g. Transient muscle pain, VBAI, post-needle soreness, other adverse reactions, etc. A statement on what measures will be in place to minimize the risk of harm.)

Explain to the participant the reasons he/she may be withdraw from the Study: (That the research may be terminated early in particular circumstances viz. Non-compliance, illness, adverse reactions, etc. State that the participant is entitled to withdraw from the study at any time should they wish to do so and will still continue to receive the appropriate standard of care; Explain to the potential participant that the research may be terminated early in particular circumstances. That the researcher may, under certain circumstances, decide to withdraw the participant from the study; Explain what procedures are in place for an orderly termination of participation by the participant.)

Benefits: (A description of any benefits to the participant or others which may reasonably be expected from the research–both during and after the research. Detail the nature of the benefits, if any.)

Remuneration: (Will the participant receive any monetary or other types of remuneration? What, if any, compensation will be paid to the participant; whether reimbursements are *pro rata* if the participant does not complete the study.)

Costs of the Study: (Will the participant be expected to cover any costs towards the study, including treatment.)

Confidentiality: (A statement describing how privacy and confidentiality of the participant's information will be maintained. How will confidentiality be maintained so that participants are not identifiable to persons not involved in the research. Any limits to confidentiality needs to be explained – who might have access to the data and under what circumstances.)

Results: (Explain how the researcher plans to disseminate the results of the research. Explain if any significant new findings developed during the course of the research how it will be conveyed to the participant.)

Research-related Injury: (What will happen should there be a research-related injury or adverse reaction? Will there be any compensation? A disclosure of any appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant)

Storage of all electronic and hard copies including tape recordings (How, where, who has access, security measures in place, duration of storage, fate of the data at the end of the study, etc.)

Persons to contact in the Event of Any Problems or Queries:(Supervisor and details) Please contact the researcher (tel no.), my supervisor (tel no.) or the Institutional Research Ethics Administrator on 031 373 2375. Complaints can be reported to the Acting Director: Research and Postgraduate Support Prof K Motaung on TtiDirector@dut.ac.za

General:

(This section must be deleted before attaching document to your PG 2a)

A copy of the information letter should be issued to participants. The information letter and consent form must be translated and provided in the primary spoken language of the research population e.g. isiZulu.

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CONSENT

Statement of Agreement to Participate in the Research Study:

- ☐ I hereby confirm that I have been informed by the researcher,_____(name of researcher), about the nature, conduct, benefits and risks of this study - Research Ethics Clearance Number:_____
- ☐ I have also received, read and understood the above written information (Participant Letter of Information) regarding the study.
- ☐ I am aware that the results of the study, including personal details regarding my sex, age, date of birth, initials and diagnosis will be anonymously processed into a study report.
- ☐ In view of the requirements of research, I agree that the data collected during this study can be processed in a computerised system by the researcher.
- ☐ I may, at any stage, without prejudice, withdraw my consent and participation in the study.
- ☐ I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the study.
- ☐ I understand that significant new findings developed during the course of this research, which may relate to my participation will be made available to me.

_____	_____	_____	_____
Full Name of Participant	**Date**	**Time**	**Signature / Right Thumbprint**

I, _____ (name of researcher) herewith confirm that the above participant has been fully informed about the nature, conduct and risks of the above study.

_____	_____	_____
Full Name of Researcher	**Date**	**Signature**
_____	_____	_____
Full Name of Witness (If applicable)	**Date**	**Signature**
_____	_____	_____
Full Name of Legal Guardian (If applicable)	**Date**	**Signature**

Please note the following:

(This section must be deleted before attaching document to your PG2a)

Research details must be provided in a clear, simple and culturally appropriate manner and prospective participants should be helped to arrive at an informed decision by use of appropriate language (grade 10 level - use Flesch Reading Ease Scores on Microsoft Word), selecting of a non-threatening environment for interaction and the availability of peer counselling (Department of Health, 2004)

If the potential participant is unable to read/illiterate, then a right thumb print is required and an impartial witness, who is literate and knows the participant e.g. parent, sibling, friend, pastor, etc. should verify in writing, duly signed that informed verbal consent was obtained (Department of Health, 2004).

If anyone makes a mistake completing this document e.g. a wrong date or spelling mistake, a new document has to be completed. The incomplete original document has to be kept in the participant's file and not thrown away, and copies thereof must be issued to the participant.

References:

Department of Health: 2004. *Ethics in Health Research: Principles, Structures and Processes* http://www.doh.gov.za/docs/factsheets/guidelines/ethnics/

Department of Health. 2006. *South African Good Clinical Practice Guidelines*. 2nd Ed. Available at: http://www.nhrec.org.za/?page_id=1

Appendix C

CONFLICT OF INTEREST

I,_____(staff/student number: _____) would like to disclose the following conflict of interests:

Conflict of interest is when an individual's private or personal interests and professional obligations are divergent to such an extent that an independent observer may have doubt as to whether or not the individual's professional actions are influenced by personal considerations, financial or otherwise.

Indicate YES or NO and state the nature of the conflict and explain how it will affect the integrity of the research.

There is a conflict of interest due to either myself or a close family member benefiting in terms of:	**YES**	**NO**
Funds or research sponsorship Explain:		
Use of DUT facilities Explain:		
Purchasing of major equipment by the University for this project Explain:		
Delay of dissemination of the results resulting in benefit Explain:		
Discounts or concessions Explain:		
Employment Explain:		
Other Explain:		

_____ _____

Principal Investigator/Researcher Date

_____ _____

HOD Date

Appendix D

APPLICATION FOR APPROVAL OF AMENDMENT

To be completed electronically by the principal investigator/researcher in accordance with the Standard Operating Procedures of the IREC.

Title of the study:			
Institution:		Date:	
Name and qualification of principal investigator/researcher:		Name and qualification of supervisor(s):	
Name of qualification:		Student Number:	
Ethical approval number:		Research site:	
Nature of amendment:			
Effect on risk benefit profile of participants:			
Please submit the following documentation: • Amended proposal (changes to be underlined) • Changes to letter of information and consent • Any other relevant documentation			
	Signature:	**Date:**	
Researcher:			
Supervisor:			
Head of Department:			
Chairperson of FRC			

TO BE COMPLETED BY THE CHAIRPERSON OF THE IREC.			
Date received:		Review required:	
		Expedited	
TO BE COMPLETED BY THE CHAIRPERSON OF THE IREC			
The amendment is:	Yes	No	N/A
Approved – there are no evident grounds for concern or further investigation.			
Approved subject to minor changes			
Needs to be re-submitted after recommendations are met			
Approved however a site inspection is recommended.			
Denied (please see attached)			

	Signature:	**Date:**
Chairperson of IREC		

Appendix E

ADVERSE EVENT REPORTING FORM

To be completed electronically by the principal investigator in accordance with the Standard Operating Procedures for reporting adverse events of the IREC for all adverse events (AE), serious adverse events (SAE), adverse drug reactions (ADR) and serious adverse drug reactions (SADR) and forwarded to the IREC.

Title of the study:				
Institution:				
Name and qualification of principal investigator (researcher):				Name and qualification of supervisor(s):
Name of qualification:				Student Number:
Ethical approval number:				Research site:
AE	SAE	ADR	SADR	Date of event:
Brief description of the event (include patient/participant reference number):				
Relationship of event to research process:				
Description of the outcome:				
Description of intervention thus far:				
TO BE COMPLETED BY THE CHAIRPERSON OF THE IREC.				
Date received:				Review required:
				Emergency: / Standard
Comments:				
Recommendations/interventions imposed by the IREC:				

	Signature:	**Date:**
Researcher		
Supervisor		
Head of Department		
Executive Dean of Faculty/ Chairperson of FRC		
Chairperson of IREC		

Appendix F

SAFETY MONITORING AND RECERTIFICATION REPORT			
To be completed electronically by the principal investigator/researcher in accordance with the Standard Operating Procedures for Safety Monitoring and Recertification of the IREC and submitted to the IREC.			
Title of the study:			
Name and qualification of principal investigator (researcher):	Name and qualification of supervisor(s):		
Name of qualification:	Student Number:		
Ethical approval number:	Research site:		
Select nature of application:			
Safety Monitoring Report	Recertification		
Section A – *To be completed by the principal investigator/researcher*			
Has sufficient progress been made with respect to anticipated timeframes in the research protocol? (If not, please specify and explain why in an attached report)	Yes	No	N/A
Have there been any deviations (intentional/unintentional) from the approved research protocol (If yes, please detail in an attached report)			
Have any adverse events occurred since commencing the research?			
If yes to the above, has an adverse event reporting form been submitted to the IREC?			
Have there been any unforeseen events or circumstances which have/may jeopardise participant safety or result in contravention of the approved research protocol. (If yes, please detail in an attached report)			
Are you aware of any complaints (formal/informal) from participants or staff or stake holders regarding the conduction of the research? If yes please detail in an attached report)			
Are you aware of any incidents whereby participants have been managed/treated in a manner other than that stated in the approved research protocol? (If yes, please detail in an attached report)			
Has appropriate informed consent been obtained from all participants in keeping with the method stated in the research protocol and is documentary evidence thereof available for inspection? (If no, please detail in an attached report)			
Has it been necessary to exclude any participants who were previously recruited for the study? (If yes, please detail in an attached report)			

Have any participants requested to be withdrawn from the study prematurely? If yes, please details the reasons for such withdrawal in an attached report)			
Have any participants absconded from the study? (If yes please detail in an attached report)			
Are the infrastructure, equipment and manpower at the research site/sites suitable and/or appropriate for the successful conduction of the research in keeping with the approved protocol? (If no, please detail in an attached report)			
Are the experimental interventions being applied or administered in keeping with those described in the research protocol? (If no, please detail in an attached report)			
Is experimental medication being stored, labelled, dispensed, coded and administered according to the approved protocol? (If no, please detail in an attached report) if applicable			
Is all critical documentation (see attached list) available for inspection at the research site(s)? (If no, please detail in an attached report)			
Is all critical documentation (see attached list) including confidential data, results and reports safely stored at the research site(s)? (If no, please detail in an attached report)			
Are you aware of any reason which warrants temporary/permanent suspension of the research activity? (If yes, please detail in an attached report)			
Are you aware of any reason that may warrant re-evaluation/ suspension of the ethical clearance by the IREC? (If yes, please detail in an attached report)			

	Signature:	**Date:**
Researcher/principal investigator:		
Supervisor:		
Head of Department:		
Executive Dean of Faculty/ Chairperson of FRC		

Section B – *To be completed by the designated Chairperson of the IREC or Safety Monitoring Committee of the IREC.*

The findings of the IREC/SMC with respect to the above mentioned research are detailed as follows:

	Yes	No	N/A
1. The respective study is approved to continue – there are no evident grounds for concern or further investigation.			
2. The respective study is approved to continue –however some evidence exists of potential minor transgressions and/or irregularity warranting re-assessment and reporting within 1 month but not requiring a site inspection.			
3. The respective study is approved to continue –however a site inspection by the SMC is warranted is recommended.			
4. The respective study warrants temporary withdrawal of ethical approval - pending a site inspection by the SMC - evidence of potential significant transgressions and/or irregularity exists.			
5. The respective study warrants immediate withdrawal of ethical approval and suspension and an independent trial audit – significant evidence of transgression and/or irregularity exists.			

If yes for points 2-5 is selected – a detailed report by the Chairperson is to be completed below:

Any additional comments to be detailed below:

	Signature:	**Date:**
Chairperson of SMC (if necessary)		
Chairperson of IREC		

List of documents that must be available at the site:

The following documents should be available for inspection at the relevant research site (if applicable):

- ☐ Copy of final approved research protocol (and revisions thereof if applicable)
- ☐ Copy of ethics clearance certificate by IREC
- ☐ Copy of regulatory authority approval letters (Department of Health, Site management etc.)
- ☐ Copy of all participant information letters and informed consent forms
- ☐ Copy of all other recruitment documentation i.e. advertisements posters etc.
- ☐ Signed agreements with other involved parties (sponsors, suppliers, diagnostic services etc.)
- ☐ CVs of researchers (investigators)
- ☐ Subject screening log
- ☐ Subject enrolment log
- ☐ Blinding and or randomisation schedules (if applicable)
- ☐ Investigational equipment service and calibration documents
- ☐ Experimental medication stock control documents, dispensing log, labelling protocol (if applicable)
- ☐ Dispensing protocol/schedule (if applicable)
- ☐ Copy of dispensing licence or pharmacist registration documents (if applicable)

Appendix G

COMPLETION OF STUDY

To be completed electronically by the principal investigator/researcher.

Research title:			
Principal investigator/researcher:			
Co-investigator/supervisor:			
Contact details:	Tel. no.	Cell no.	Email:
Ethics approval number:		Institution:	
Ethics approval date:			
Date of starting data collection:			
Date of completion (final report/dissertation/thesis)			

Information regarding the Study:

Include abstract for notification of completion of study
Was deception used? If yes, were the participants who were received informed of the deception? If requested by the participants who were deceived, was their information removed from the study?[1]
Was there any deviation from the IREC-approved protocol? If so, please explain.
Any other relevant information:

Principal Investigator/Researcher Date

Co-investigator/supervisor Date

References:

1) DOH Guidelines, p 35

Appendix H

INTERRUPTION OF STUDY

To be completed electronically by the principal investigator/researcher.

Research title:			
Principal investigator/researcher:			
Co-investigator/supervisor:			
Contact details:	Tel. no.	Cell no.	Email:
Ethics approval number:		Institution:	
Ethics approval date:			
Date of starting data collection:			
Date of interruption			
If applicable, when might the study be expected to resume?			

Information regarding the Study:

Concise summary of activities since last review report:			
Explanation/reason for interruption (if applicable):			
Ethics category of Study (Please Tick)			
2		3	
If participants have already been recruited, what was the number recruited? What was the number of withdrawals?			
At what stage was the study interrupted? [1]			
If applicable, what steps have been taken to accommodate those who have participated in the study after interruption?			
Any other relevant information:			

Principal Investigator/Researcher Date

Co-investigator/supervisor Date

References:

South African good clinical practice guidelines. 2nd edition. Available at http://www.kznhealth.gov.za/research/guideline2.pdf

Appendix I

CONFIDENTIALITY AGREEMENT

I, the undersigned _____(hereinafter referred to as "the IREC member") with physical address at

_____

_____

HEREBY AGREE TO THE FOLLOWING:

☐ The IREC is a body constituted by appropriately qualified professionals tasked with the reviewing of novel proposals for research which is to be conducted on human and the environment.

☐ The work of the IREC 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.

☐ The Members of the IREC, supporting administrative staff and any ad hoc attendees hereby agree to be bound by the provisions of this Agreement for the duration of their service to and on the IREC.

1. INTERPRETATION

Unless the context indicates the contrary:

1.1 The term "Confidential Information" is defined, for the purposes of this document, to mean certain proprietary, personal, clinical or protocol-specific information. This includes all protocols relating to research with human or the environment and the associated documentation. Confidential Information may be presented in the form of written text, graphic, oral or physical form 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.

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 IREC member undertakes, 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 IREC as a whole, or communicated to him/her hereunder or otherwise in connection with the IREC member's role on the IREC. The IREC 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 IREC member; or

(b) Information which the IREC 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 IREC 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 Chairperson of IREC and any other relevant parties.

2.3 The confidentiality obligations contained in this Agreement shall endure beyond the confines of the IREC member's obligations to the IREC and without limit in time.

Signed: (IREC member) _____ Date: _____

WITNESS (1): Name: _____ Signed: _____

Date: _____

WITNESS (2): Name: _____ Signed: _____

Date: _____

Appendix J

ASSENT FORM: FOR MINORS

This template to assist you with designing a written informed assent form for minors (persons under the age of 18 years old). **Please write in SIMPLE, NON-TECHNICAL, CHILD-FRIENDLY language**. Note that this assent form template is appropriate for use for child participants aged between 8-13 years old. For adolescents (aged between 14-17 years old), please use the adult consent form template.

ASSENT FORM FOR MINORS

TITLE OF THE RESEARCH PROJECT: *Insert the title of your research project in simple, non-technical language.*

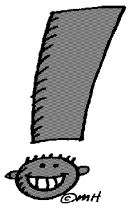
RESEARCHERS' NAME(S):

RESEARCHERS' CONTACT NUMBER:

What is a research study?

Research studies help us learn new things. We can test new ideas. First, we ask a question. Then we try to find the answer.
This paper talks about our research and the choice that you have to take part in it. We want you to ask us any questions that you have. You can ask questions any time.

Important things to know…



You get to decide if you want to take part.
You can say 'No' or you can say 'Yes'.
No one will be upset if you say 'No'.
If you say 'Yes', you can always say 'No' later.
You can say 'No' at any time.
We would still take good care of you no matter what you decide.

Why are we doing this research?

We are doing this research to find out more about _____

Explain your project in simple child friendly language. Adapt the information to the age of the children that you plan to include.

Why have I been invited to take part in this research project?

Answer this question in simple language

Who is doing the research?

Identify yourself and explain whom you work for and/or why you are doing the project

What will happen to me in this study?

Describe what the participant will be expected to do. Describe all procedures using simple language. Some examples are given below

If you decide to be in the research, we would ask you to do the following:

- *Blood draws: You may need a needle poke so we could test some of your blood. If possible, we will try to get blood without a new poke.*
- *Questions: We would ask you to read questions on a piece of paper. Then you would mark your answers on the paper.*
- *Talking: A person on the research team would ask you questions. Then you would say your answers aloud.*
- *Medical records: We will look at your past doctor visits and use information about your care.*

Can anything bad happen to me?

Explain any possible risks to the child, using simple terms. If something might be scary or anxiety provoking, state this in the assent form.

Can anything good happen to me?

Only describe known benefits to the participant and don't overstate the benefits. You may include any possible future benefits to others. If there are no known benefits, state so.

What else should I know about this research?

If you do not want to be in the study, you do not have to be.

It is also OK to say yes and change your mind later. You can stop at any time. If you want to stop, please tell the researcher.

You can say 'no' to what we ask you to do for the research at any time and we will stop.

Will anyone know I am in the study?

Explain in simple terms that the child's participation in the study will be kept confidential, but information about him/her will be given to the study supervisor. (NOTE: This information may not be applicable in assent forms for very young children).

Who can I talk to about the study?

List those individuals the child can contact (including their contact details) if he/she has any questions or has any problems related to the study.

What if I do not want to do this?

Explain to the child that he/she can refuse to take part even if their parents have agreed to their participation. Explain that they can stop being in the study at any time without getting in trouble.

Do you have any other questions?

If you want to be in the research after we talk, please write your name below. We will write our name too. This shows we talked about the research and that you want to take part.

Do you understand this research study and are you willing to take part in it?

YES	NO

Has the researcher answered all your questions?

YES	NO

Do you understand that you can STOP being in the study at any time?

YES	NO

Name of Participant _____
(To be written by child/adolescent)

Printed Name of Researcher

_____

Signature of Researcher _____

_____ _____
Date **Time**

References:

1. www.sun.ac.za

2. http://fhs.mcmaster.ca/healthresearch/documents/assent.pdf

20. REFERENCES:

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University of KwaZulu-Natal. 2009. Research Ethics. Available at: http://research.ukzn.ac.za/ResearchEthics.aspx

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