STANDARD OPERATING PROCEDURES (SOP) and GUIDELINES[1]

of the

RESEARCH ETHICS COMMITTEE[2],

VAAL UNIVERSITY OF TECHNOLOGY

This Standard Operating Procedure (SOP) Manual operationalises the Policy on Research Ethics of the Vaal University of Technology (VUT), as well as the Terms of Reference of the Research Ethics Committee of the Vaal University of Technology.

1. INTRODUCTION:

1.1 As a publically funded University, with the mission to generate research, amongst other missions, VUT acknowledges the necessity to develop, maintain, administer and manage all research undertaken by VUT in such a way that the research complies with the national and international research ethical demands and practices, namely such research that engages with human subjects, animals and that research which might impact on the environment. Fundamentally this means that all research needs to be scrutinised for its potential impact on the ethical engagement with humans, animals and the environment, prior to the commencement of the research so that ethical clearance can be granted to or waived for the research project. *Following from this, VUT accepts that ALL research undertaken (and claimed as "research outputs" by the university) must have been scrutinised and approved by the research ethics organs of the university*. In this way any activity that gathers and analyses data and/or information for the purposes of implementing the findings and/or placing the findings in the public domain has research ethics implications.

1.2 To guide the application of ethics for research, VUT accepts the basic principles of identifying and managing research that may (a) engage with the *vulnerability* of participants, animals or the environment, and (b) might be deemed to be *invasive* of such participants, animals or the environment.

1.3 To concretise these principles VUT acknowledges the following ethical principles:

i. *The science principle*, which argues that bad science is ethically bad, and which implies, therefore, that research proposals and practices cannot divorce the technical and scientific arguments from their ethical arguments;
ii. *The beneficence principle*, which argues that research processes and outcomes need to demonstrate the potential for doing good;
iii. *The non-malfeasance (or non-maleficence) principle*, which argues that research processes and outcomes should not be to the detriment of any or all involved in the research project (include the research team, the researched and the University), and where this might occur suitable measures are taken;

[1] VUT acknowledges with gratitude the ethics standard operating procedures and guidelines of Tshwane University of Technology in the drawing up of its own SOP and guidelines.

[2] This SOP engages with what shall occur in the VUT Research Ethics Committee. It is expected that, in time, and once promulgated, the Faculty Research Ethics Committee will generate their own SOPs that align themselves with their own Faculty specific demands, align themselves with the SOP here contained, and have such newly developed SOPs approved by the REC and affirmed by Senate through the office of the Institutional Official (IO).

iv. *The risk/benefit principle*[3], which acknowledges that research processes and outcomes always have the potential to be harmful in some way and that therefore a clear engagement with the determination of risk, the processes of curtailing, controlling and responding to risk, and the potential benefits to humanity be considered, declared and evaluated;

v. *The justice principle*, which declares that research processes and outcomes should be fair, and should also not be deceptive in the long term;

vi. *The autonomy principle*, which acknowledges the right of the participant freely to decide to be part of, or to withdraw from, research projects, without harm;

vii. *The dignity principle*, which accepts the United Nations declaration of the rights of the individual, and forms the bedrock of the concepts contained in the Information Leaflet and the Informed Consent; and

viii. *The principle of an over-researched domain*, which stipulates that research undertaken in these domains is either a duplication of other concluded research or the population that is targeted has encountered too much research contribution to be fair to that population.

2. TERMS OF REFERENCE:

The REC is a committee of the Vaal University of Technology's Senate. This Senate appoints an Institutional Official (IO) to oversee and confirms the workings of the REC. The members of the REC are appointed by the Institutional Official and the REC reports to the Institutional Official. The IO confirms all matters pertaining to the REC and, on an annual basis submits a report on those workings to Senate for ratification. Furthermore, the establishment of the VUT REC also falls under the auspices of the National Health Research Ethics Committee (NHREC), who approve the Terms of Reference, the Policy and the working procedures of the REC. The primary function of the VUT REC is to scrutinise all research projects (and other, relevant, official data-gathering processes initiated by VUT) undertaken under the auspices of the university to ascertain compliance with research ethical principles, as outlined above. In carrying out this function the REC may:

2.1 Grant ethical clearance for the research project;

2.2 Grant provisional ethical clearance, subject to documented corrections and changes to the research project/proposal;

2.3 Refer the project back for clarification and revision, after which the proposal must be resubmitted for consideration and scrutiny;

2.4 Reject the proposal on the grounds of ethical unacceptability.

2.5 Grant an ethical waiver if it is deemed that the research contains no research ethical problems.

2.6 It is noted that, where research is conducted in domains where other research ethical clearances need to be obtained, the ethical considerations that are deemed to be the most stringent shall be taken as the appropriate research procedure[4].

3. RESEARCH ETHICS COMMITTEE MEMBERSHIP

[3] It is noted that in the literature and in practice the risk/benefit ratio is referred to as the 'harm/benefit ratio' in Animal Research Ethics practice.

[4] An example of this might be where the researcher is registered at VUT, but is conducting research in another country where ethical clearance from that country is required. In this case, the ethical clearance with the more stringent demands shall be the dominant one, and shall be used for adherence to research ethical processes for that project. In such a case, the dominant one might be that of VUT, but it might also be that of the research domain. The decision on which is the more stringent is taken by the VUT REC.

3.1 COMPOSITION:

3.1.1 The REC will consist of the following members, where each appointment is formally confirmed, in writing, by the IO:

i. Each FRIC shall nominate a primary and secondary member (*secundus*) from its Faculty to serve on the REC. The nomination will be confirmed by the Executive Dean of the Faculty and ratified, in writing, as duly appointed, by the IO. The s*ecundus* will represent the faculty when the primary member has indicated, in writing to the Chair, his or her unavailability to attend a specified meeting. Both members from a Faculty, besides being experts in their fields, should either have demonstrated their expertise in the field of research ethics, or have indicated a desire and willingness to be upskilled within an acceptable passage of time in these matters. In all cases, besides where formal qualifications or acceptable courses have been concluded, all members must complete a 2 day training session enabled by VUT. Any further and necessary upskilling must be financed by the university.

ii. One member of the committee, appointed by the IO, should be well versed in the laws of the country and in the regulations and procedures of VUT;

iii. One member, nominated by the Director of Research and appointed by the IO, should represent the Research Directorate;

iv. One member, nominated by the REC and appointed by the IO, should have expert knowledge in the domain of Qualitative research methods;

v. One member, nominated by the REC and appointed by the IO, should have expert knowledge of Quantitative research methods, but also and particularly, statistical operations that are pertinent to research and are used in such methods;

vi. Two community members, who are not attached to VUT but will represent the interests and aspirations of the non-academic/non-research domain. Ideally, such members should be part of a particular community in which a fair amount of research is undertaken by VUT scholars, so that these community members might better serve the protection of that community, and who, in the opinion of the REC, will add value to the ethical review deliberations. The two members are nominated by the REC and are appointed by the IO. These members are entitled to a set honorarium per meeting, financed by the Directorate of Research.

vii. Additional members may be nominated by the REC and appointed by the IO, where these members carry specialist knowledge (such as the protection of Intellectual Property, or Indigenous Knowledge Systems). Such members are appointed for a full term and have full voting rights, but the number of additional members appointed may not exceed the number of primary members that come from the Faculties.

viii. The IO, or his or her nominee (the nominee is officially appointed and subject to the same confidentiality agreements as all other members) is an *ex-officio* member of the REC.

ix. The Directorate of Research shall appoint at least one full-time, non-voting administration officer.

x. The REC may, from time to time and on an *ad hoc* basis, draw on expertise that might be necessary for a particular project. Such *ad hoc* members are in an advisory capacity only, have no voting rights, and are subject to the same declarations of confidentiality as are incumbent on all members of the REC.

xi. In the case of ii, iv and v, above, such expertise may be deemed to reside in one or more of the other members of the committee, as appointed in that other representative capacity in the committee. Centrally, the REC must have access to sufficient research knowledge to adjudicate aspects of law and VUT policy, the application of Quantitative methods and of Qualitative methods.

xii. The chair and deputy chair of the REC are nominated by the committee, and formally appointed to these positions by the IO.

3.2 STANDING:

Each member of the REC shall be of good standing, shall be an expert in his or her field and shall have or shall develop the relevant training in research ethics, so that such a member can adjudicate research to ascertain the research project's ethical implications, make recommendations on such implications and monitor the process of the research to ascertain compliance with the agreed upon research ethical processes and procedures.

3.3 RULES AND FUNCTIONING:

The rules and functioning of the REC are contained in the relevant VUT Research Ethics Policy (No. XXXX) document 3.9.2 to 3.9.22

4. ADMINISTRATIVE SUPPORT STRUCTURE

4.1 BACKGROUND

The Administrative Officer that is duly appointed by VUT to administer all research ethics matters for the full functioning of the Research Ethics Committee is located in the domain of the Directorate of Research and is a fulltime, dedicated position. The overarching function of the Administrative Officer is to ensure that the administration of the Research Ethics Committee's tasks function effectively.

4.2 RESPONSIBILITIES OF THE RESEARCH ETHICS COMMITTEE ADMINISTRATIVE OFFICER.

The primary responsibilities of the REC Administrative Officer[5] are the following:

i. Receive research proposals and proposal-related documents submitted (electronically) by the various faculties for ethics review;
ii. Receive feedback from researchers regarding the ethics evaluation of their projects;
iii. Draft the agenda for the upcoming REC meeting;
iv. Compile and distribute the meeting documents (agenda and proposal documents) to all the REC members one week prior to the meeting;
v. Receive apologies from members who cannot attend the REC meeting;
vi. Invite the researchers and/or their supervisors whose projects will be evaluated, to attend the REC meeting where this is deemed useful, by the Chair, to the deliberations that are to occur – in the case where this might not be physically possible (as with satellite campuses), such attendance may take place through the use of electronic media;
vii. Take minutes of the REC meeting activities;
viii. Compile and distribute the minutes of the meeting to the REC members within a reasonable time after the meeting;
ix. Compile (in conjunction with the chairperson) and distribute formal letters to the researchers who have had their submissions evaluated at the meeting;
x. Conduct follow-ups with the relevant REC members regarding all issues raised at the meeting (e.g. appointments with specific researchers, writing of letters to specific individuals and/or sections, submitting documents to the Executive Senate Research and Innovation Committee – ESRIC);
xi. Arrange the booking for the REC meeting venue;
xii. Communicate with Faculty Research Officers or the Chairs of the Faculty Research and Innovation Committees regarding yearly REC meeting dates, and proposal submissions for evaluation and approval, and any other timeline requirements;
xiii. Compile annual reports for submission to a) the IO and b) Directorate of Research;
xiv. Handle the administration regarding formal ethics training sessions for REC members. This may include completion of registration documents, travel, accommodation and subsistence matters;

[5] It should be noted that these functions, and the wording of these functions, have predominantly been taken from the SOP of TUT, as they capture a complete picture of the functions of the Administrative Officer.

xv. Provide information and/or advice to staff and students regarding the submission of documents to the REC;
xvi. Maintain and secure the confidential storage of all documents in electronic format and hard copy format;
xvii. Obtain and distribute all relevant new/updated ethics codes to the REC members;
xviii. Arrange and document research site visits and audit visits;
xix. Keep a register of all the reported Serious Adverse Events;
xx. Facilitate engagements with the NHREC where this is required; and
xxi. Arrange meetings between the Chair of the REC and the IO where this is deemed necessary.

5. PRE-REC MEETING PROCEDURES

5.1 The purpose of this section is to note the various documents that need to be submitted to the Administrative Officer to be considered by the REC at its meeting, and the procedure for such submission.

5.2 All documents that need to be considered must reach the Administrative Officer in electronic form by no later than 7 working days before the scheduled meeting. The following matters may serve:

i. All proposals that have been approved by any FRIC and have been submitted to the relevant FREC, who have escalated the proposal to the REC;
ii. All proposals that have been approved by any FRIC, but that, because the research deals with matters that require direct consideration by the REC (as stipulated in the Policy), have been submitted via the relevant FRIC. Such proposals must be accompanied by all the relevant research ethics documents;
iii. Any revised proposals/corrected resubmissions;
iv. A list of all proposal titles, related students and appointed supervisors/promoters and co-supervisors/co-promoters, degree registered for, and department in which the research is to take place, where the projects have been granted ethical clearance by the relevant FRECs with VUT;
v. The minutes of the meetings of the FREC where the projects mentioned above have been decided upon;
vi. Copies of the letters sent out from the REC to researchers following the meeting at which the submissions had been considered by the REC;
vii. Any applications for research for non-degree purposes, where such proposals have been dealt with in the same manner as those that are for degree purposes;
viii. Any reports of SAEs;
ix. Any documentation around site visits (either as reports or as requests to conduct site visits);
x. Any documentation from the NHREC for consideration;
xi. Any copies of annual reports, when applicable;
xii. Any announcements concerning research ethics training courses;
xiii. Any matters that have been sent to the REC from the IO's office or from the NHREC;
xiv. Any other matter deemed relevant by the Chair for the REC.

5.3 All submissions for research ethical decisions by the REC must include an electronic copy of the following documents:

i. The complete proposal;
ii. The completed Ethics Application form (see Annexures C and D);
iii. A declaration that the research proposal has been approved by the relevant FRIC, signed by the Chair of that FRIC;
iv. Any annexures (where applicable) such as Information leaflets and Informed Consent documents, questionnaires, Interview Schedules, permission letters from organisations or gatekeepers, legal contracts containing engagement with IP for example, and any other relevant supporting documentation;

v. A VUT ethics declaration form (See Annexure B);
vi. Any document that engages with ethical clearance from any other institution or organisation, where this arises from the specific research project;
vii. Any documentation from prior applications for the same project;
viii. A declaration that the documents have been written ethically and that the candidate is aware of and has obeyed the VUT Plagiarism Policy requirements (See Annexure B).

6. MEETING PROCEDURE

6.1 The REC shall meet 6 to 8 times a year. The Chair has the right to constitute further meetings should this be necessary.

6.2 The agenda for the meeting shall be drawn up by the Administrative Officer in consultation with the Chair.

6.3 The Chair may, at his or her discretion, invite added expertise to the meeting to bolster the deliberations around a particular submission.

6.4 The agenda and all relevant documentation shall be distributed electronically to the members of the REC at least 5 working days before the meeting.

6.5 For the scrutiny of the submissions before it, the REC will use the principles outlined in 1.2 and 1.3 (i-viii) above. It is not the duty of the REC to scrutinise the research project proposed, except in as far as there are contradictions between the method and design of the project, and the way the ethics of the research is addressed by the applicant. Therefore, the validity of the science, the applicability and relevance of the research, and the cost factors of the research are not the concerns of the REC except where these matters might impact on humans, animals and or the environment (including matters of Intellectual Property, IKS and related matters)[6].

6.6 An attendance register, which includes a declaration of confidentiality, shall be signed by all present.

6.7 The Agenda for the meeting must contain the following Agenda points:

i. Opening and Welcome
ii. Personalia
iii. Absent with apology
iv. Absent without apology
v. Declaration of potential Conflict of Interest (COI)
vi. Setting the agenda/new matters
vii. Acceptance of the minutes of the previous meeting
viii. Matters arising from the minutes
ix. Letters sent to research teams following first time submissions from the previous meeting (for notification)
x. Letters sent to research teams for revised submissions considered at the previous meeting (for notification)
xi. Other letters that may have arisen from expedited review
xii. Evaluation of revised/resubmitted submissions
xiii. Evaluation of New submissions
xiv. Ratification of minutes from the FRECs

[6] In essence, therefore, the FRIC stands in for (or represents) the *university's* interest in the research, while the REC stands in for (or represents) the *participants, the animals and the environment* for that research.

xv. Letters from the FRECs to the researchers (for notification) where the chair deems these necessary
xvi. Annual reports from the FRECs (where applicable)
xvii. Reporting on any SAEs
xviii. Progress reports of projects (See Annexure E for template)
xix. Discussion of Supplementary Agenda
xx. Announcement of next meeting
xxi. Closure.

6.8 Decision making:

6.8.1 An REC meeting can only be quorate if 50% of the appointed members plus 1 are present.

6.8.2 In cases where there is a declared COI and that member recuses himself or herself, the original number present will still demonstrate quorum.

6.8.3 Any decision that is taken, at the time that the decision is taken, requires a quorate committee.

6.8.4 Any abstentions at the time that a decision is made, will reduce the attendance number of the meeting by the number of abstentions and will thus impact on the quorate number, unless the abstainer provides a reason for the abstention that is acceptable to the Chair, in which case that abstention will be noted as a recusal.

6.8.5 The REC strives for a decision by consensus. Where this is not possible, 75% of the quorum present at the meeting supporting the application will constitute approval. Those that vote against the application must have their reasons for this noted in the minutes.

6.8.6 The minutes of the REC meetings are a matter of public record and therefore it is important to protect confidentiality in the minuting of the reasons for not supporting the proposal.

6.8.7 The REC can make one of five findings:

i. The submission is accepted as it is presented, in which case the minutes will read “Full ethical clearance is granted.”
ii. The REC may decide that there are no ethical research implications, in which case the submission has an ethics submission number allocated, and the minutes will read: “An ethics waiver is granted.”
iii. The proposal application may require minor changes in which case the minutes will record: “provisional ethical clearance is granted” and the minutes will then present what needs to be changed. In many cases such a decision will lead to an expedited review of the new proposal and documentation, as determined by an application to this effect from the research team, and a decision by the Chair. (The process of Expedited Review is presented below, in Section 11 of this document).
iv. The proposal application may require robust changes, in which case the minutes will record “Referred back for clarification and correction”. All changes that are required need to be documented in the minutes. This decision will imply a full resubmission to the REC within a timeframe stipulated by the REC and presented in writing to the research team.
v. The REC may decide to deny ethical clearance to the project. When this decision is taken the reasons for this decision need to be minuted. Reasons for such a decision may include the following: in the opinion of the REC the risk to the participants it too high and the project cannot be altered to reduce the risk; the collection of data has already commenced and no retrospective ethical clearance will be granted; and the population that has been targeted has been “over-researched” and will, in the opinion of the REC, not contribute anything new to the study, particularly when the information sought can be found in already published research.

6.8.8 The REC reserves the right not to scrutinise an application submission where the submission will need to serve after the fourth (4^{th}) time at the committee.

6.8.9 The REC reserves the right to withdraw or suspend ethical approval/clearance because of serious SAEs, delays in the commencement of the study, lack of progress reports or any other information that might undermine the decisions of the REC, and potentially place VUT'S reputation as a research institution in jeopardy.

6.8.10 The REC reserves the right to scrutinise the full submissions of those projects that have been approved, or granted clearance by the relevant FREC. Such a situation may arise where the title of the registered project, for example, suggests research that might have more than minimal risk research or that might, in terms of the Policy definitions, have had to be escalated to the REC. As such, the purpose of this right is to fulfil the oversight role over the FRECs that the REC needs to fulfil.

6.8.11 No research/data collection may continue unless all the requirements of the REC have been met and the letter declaring "Full Final Ethical Clearance is granted," or ethical waiver, has been assigned and has been sent to the team, or, in the case where the approval or clearance is staggered, in which case the decision would be "Ethical Clearance is granted for this part of the study", where the part is clearly stipulated, and the excluded part is clearly stipulated.

7. **POST-MEETING PROCEDURES**:

7.1 The REC will make every effort to communicate the decisions of the committee to the researcher/PI and the supervising or promoting team, in writing, within 10 working days.

7.2 Over and above the trajectory of the clearance processes outlined in the next section (Section 8), the Administrative Officer can receive and channel any concerns, requests for clarification on decisions, and the like through that office to the Chair, who will direct the procedure to be followed thereafter.

7.3 An applicant may lodge an appeal against the *decision* made by the REC with the Chair of the REC. The Chair will attempt to resolve the appeal. Should this not occur, the Chair must approach an external Research Ethics Committee of good standing to review the application as a new submission. The decision of the appointed external REC will be final. Should the review of the appeal be successful VUT will carry the cost of such a review, should this be required. Should the review be unsuccessful and the decision of the VUT REC be upheld, the applicant will be required to pay the cost of the external review.

7.4 An applicant may lodge an appeal against the *procedure*s followed (as read against the VUT accepted Standard Operating Procedures) by the REC in reaching its decision, with the Chair of the REC. The Chair will attempt to resolve the appeal. Should this fail, the IO will be approached to adjudicate whether there were procedural aberrations or not. The decision of the IO will be final in these matters.

7.5 In both the above cases, the final decision will be minuted in the relevant REC minutes.

7.6 At times stipulated by the IO, all matters pertaining to the REC shall be made available to the IO for confirmation. From this, the IO will generate a report to be submitted to Senate for ratification. Such a procedure must occur at least once a year.

8. **TRAJECTORY OF THE RESEARCH ETHICS APPLICATION**[7]

8.1 This section outlines the trajectory of the research ethics clearance process, from the initiation of the submission to final clearance.

[7] This section should be read as pertaining to processes for both the REC and the FRECs

8.2 The submission with its relevant ethical documentation shall be declared as acceptable by the supervising/promoting team and submitted to the RF/DRIC for consideration.

8.3 Once the documentation is acceptable to the DRIC it is submitted to the FRIC for consideration.

8.4 The FRIC scrutinises the documentation, approves the research aspect of the project, taking note of the ethical considerations.

8.5 The approved project is then forward to the FREC for consideration (see FREC procedure, below), with the necessary accompanying documentation (see the relevant Annexures).

8.6 The Chair of the FREC considers each proposal and decides whether the project should serve at the FREC or immediately be escalated to the REC. In the latter case, the Chair informs the Chair of the FRIC of this decision, in writing.

8.7 The FREC meets to scrutinise the submission for its ethical considerations and the alignment of the ethical matters to the research matters.

8.8 The FREC may decide to waive the ethical consideration, or that the project needs to be escalated to the REC, based on its judgement on the minimal risk nature of the project, or on the decision that it meets the escalation criteria contained in the Policy. This latter particular decision should be taken with caution, as it is in the best interests of research to empower the FRECs to make such decisions, but at the same time provide an acceptable safety net where there is doubt in the minds of the FREC. If such a decision is taken, the Chair of the REC reserves the right to return the application to the FREC for final decision making.

8.9 If the FREC addresses the application and comes to a conclusion on the ethics of the project, based on the 5 possible decisions outlined above, the research team is notified in writing of the decision, and a copy of the decision letter is sent to the Chair of the FRIC, for notification at the next FRIC meeting, and a copy of the letter is sent to the PI/Research team.

8.10 If the proposal is escalated to the REC, the REC deliberates on the matter, reaches a decision, informs the research team, and submits a copy of the decision to the Chair of the relevant FREC for notification at the next meeting.

8.11 Upon receipt of the letter from the REC, the Chair of the FREC sends a copy of the letter from the REC to the relevant FRIC for notification at the next meeting.

8.12 In both the cases of the REC letter and the FREC letter, the following information shall be provided to the research team (an example is appended as ANNEXURE A):

i. The letterhead of the University and the address of the FRIC
ii. The date of deliberations of the REC/FREC meeting
iii. The name of the PI (Principle Investigator/researcher/masters or doctoral student)
iv. The name(s) of the supervising panel (where appropriate)
v. *The reference number for initial submission*. *The reference number is used for collating all correspondence that arises between the submitting panel and the relevant ethics committee will be the student or staff number. It is not the final research ethical clearance number (see vi, below*). All correspondence between the FRIC and the applicant will need to contain the reference number. The reference number will also be used for filing purposes.
vi. The ***Final Ethics Clearance number*** is the number given to the research submission once all of the matters raised by the various ethics committees have been attended to, to the satisfaction of the REC. Such a reference number will be constructed as follows: the first three letters will be in capitals and will provide the initials of the Faculty (FHS, for example, for the Faculty of Human Sciences). The next series of numbers will indicate the date of the REC/FREC meeting at which the final decision was made (13/05/2015, for example). The last numbers will be drawn from the point on the agenda in which the application captured (14/1, for example). Thus, in this example, the clearance number would read FHS/13/05/2015/14/1.The decision of the committee will present one of the five options that

the committee can entertain and these are captured above in 6.8.7 (i-v). All correspondence from this time forward needs to use the Final Ethics Clearance number.

vii. In the three cases that constitute situations of not final clearance, reasons must be provided for the decision. The committee is not bound to provide suggestions for improvement but may do so if deemed necessary.

viii. To address the Ethics concerns raised by the review process, the methodology of the research project my need to be reconfigured. It is critical that what the *researcher* intends to do, and what the *participants* potentially will be required to do are in agreement.

ix. The letter needs to declare, specifically, that there are no perceived Conflicts of Interest, or, where these are at play, they are adequately addressed, or, if not, why this is seen as the case, in the opinion of the REC (See Section 13 and 14, below, on Conflict of Interest).

x. Upon resubmission the reasons provided by the REC or FREC for the decision should form the basis of the report on changes that the researcher should submit with the changed documents.

xi. The letter needs to be signed by the relevant Chair (REC or FREC) (or delegated substitute).

xii. The letter needs to have a dedicated block that informs the researcher that, with this approval/clearance/waiver the researcher undertakes:

a. To follow only those procedures for which the approval has been given;
b. To inform the committee should there be significant deviations from that which has been approved;
c. To report to the committee any Adverse Events (AEs) that might occur, within 14 days of the event (following the Guidelines procedure presented in Section 15, below);
d. To submit to the committee annual progress reports on the particular date (presented to the research team/PI in the letter) allocated to the research project (see 17.1.2, below) by the committee; and
e. To inform the committee on the completion of the project, when the findings have entered the public domain.

xiii. In the case of a project being referred back, the last due date for submission of corrections needs to be stipulated.

8.13 All decisions taken at the FREC are tabulated with the information as outlined above, and submitted to the REC for ratification.

9. INFORMED CONSENT GUIDELINES

9.1 VUT acknowledges the necessity, following national and international guidelines, to obtain consent from all researched participants (i.e., the selected population members targeted for data collection) to participate in the research. The standard approach is to acknowledge the freedom to grant such consent (without coercion) and the right to have enough information so that such an informed consent can be made. Furthermore, such consent must be witnessed as being granted, either through signature or through witnessed verbal consent or, in the case of questionnaires, such consent has been taken as given once the participant submits answers to the questionnaire, whether in written or spoken form – in such cases the right to receive enough information to contribute such information is not waived.

9.2 It is accepted that, to all intents and purposes, the Information Leaflet and concurrent signed Informed Consent constitute a binding legal contract between the University through its surrogates (the research team), and the participants. As such, the process must be handled with great care.

9.3 Such an Information leaflet (IL) that leads to Informed Consent (IC) (a) shall contain sufficient and clear information for an informed consent to be made, (b) shall be written in a language

and style of language that is judged to be accessible and acceptable to the proposed target participants and (c) shall not be coercive or deceptive.

9.4 It is acknowledged that the completion of questionnaires might not require as much Information Leaflet detail be provided to participants as the detail required to be presented for more potentially invasive procedures. The adequacy of information for the questionnaire consent must not be jeopardised.

9.5 The REC, in assessing the IL and IC, will correlate the methods and design contained in the proposal with the information contained in the IL and IC and only then will engage with the ethical concerns around the involvement of the participants.

9.6 GUIDELINES: The following guidelines for the drawing up of the Information Leaflet are strongly recommended:

i. The IL should appear on an official letterhead.
ii. The title of the project, the PI and the supervisors/promoters (with their highest qualifications) and the degree for which the PI is registered, should head the IL.
iii. The IL should be structured like a letter to the potential participant.
iv. The potential participant should be addressed directly (the use of "you" and "I" is encouraged, where appropriate, for example).
v. The purpose of the study should be delineated.
vi. The reason for the approach to the participant should be presented (this refers to exclusion and inclusion criteria).
vii. The entire procedure that the participant will go through needs to be described clearly.
viii. The potential negative effects (if any) need to be stipulated, and how the research team will remedy these effects should the need arise.
ix. The potential positive effects, both for the participant and for the development of new knowledge and its application, need to be stipulated. This will also include the benefits to be incurred by participation[8].
x. The voluntary basis of participation must be accentuated, including the right to withdraw, or not to participate, or selectively participate, where so decided by the participant.
xi. However, there are cases where gatekeepers are involved, to whom the participant may need to report. In this case, the IL needs clearly to state what protection measures have been put in place to shield/protect the participant from such gatekeepers[9].
xii. The IL should also indicate the right of the research team to terminate participation.
xiii. The process of maintaining anonymity and confidentiality must be clearly explained, including what will become of the data on completion of the project, and how the results will enter the public domain and, in this case, how anonymity will be protected. However, it is critical that the participants also be informed, directly and unambiguously, that the law might insist on the revealing of certain types of information, and, as such the participant can only be protected "as far as the law allows." Furthermore, who will have direct access to the data needs to be documented – normally this is only the research team, but in the case of transcribers and translators, such access will be controlled by a confidentiality agreement.
xiv. The treatment of the raw data after the completion of the project needs to be stipulated.
xv. A declaration of evidence as to the competency of the researchers must to be made.
xvi. The IL should indicate that the project has received ethical clearance from VUT, and the clearance number should be displayed. Such a display may occur at this point in the trajectory of the IL, or it may be more prominently displayed at the beginning of the Information Leaflet.

[8] It must be noted that VUT, as with most national and international research bodies, does not condone (but does not exclude) financial incentives to be part of the research project. However, VUT encourages the research project to address any out-of-pocket expenses that the participants might incur through participation, where applicable, such as travelling expenses and meals.

[9] It is generally accepted that gatekeepers may be of two potential kinds. In the first instance they are the people who grant access to the domain in which the research participant operates (schools, classrooms, businesses, offices, and the like). In the second instance they are domains where customary law is in place.

xvii. The IL should indicate who the participant may contact (a) to gather more information, or (b) report potential adverse events. In the case of (a) the contact details for the researcher and at least one supervisor/promoter, as well as the Chair of the REC (or his or her nominee for this project) should be made available. In the case of (b) details for the Chair of the REC and the dedicated VUT whistle-blower hotline shall be made available.

xviii. The IL should indicate a note of appreciation for both considering the possibility of taking part, and a note of gratitude to actually participate. In the latter case, the participant is invited to complete the Informed Consent (IC) document.

9.7 Informed Consent (IC)

9.7.1 The IC should contain the name of the project, the name of the PI and a place for the PI to sign.

9.7.2 The IC should contain a declaration that the participant attests to – through signature and date – that they have been adequately informed about the project; that they have had an opportunity to raise questions and have had these questions adequately addressed; that they are fully aware of what will happen to the data and how their anonymity will be protected; and that they accept any other terms and conditions.

9.7.3 *Verbal Consent*: In the case where it is expected that only Verbal Consent can be granted, the Verbal Consent needs to be witnessed by at least two witnesses, one of which declares that they have read and explained the IL to the participant, and they have read the declaration to the participant, and that, in both cases, the participant has verbally indicated agreement to participate in the project.

9.7.4 The witnessing must be dated.

9.7.5 All participants are entitled to a copy of the IL.

9.7.6 In *the case of minors*: In cases where research is to be conducted using those participants who are defined as minors, Information Leaflets and Informed Consent documents are prepared for the parents/guardians of such minors. Such ILs are phrased in such a way as to garner Consent from the parents/guardians for participation by the relevant minors. However, the researcher is also required to generate a "Letter of Assent" that is addressed to the minor that, to all intents and purposes, in a language the minor will understand, mirrors the parental/guardian IL and IC. Such a Letter of Assent is not a binding contract (as the parental/guardian one is) but is offered as a common courtesy to the minor, and which will facilitate potential acquiescence from the minor. In the Letter of Assent, the parent/guardian should also be seen as a potential gatekeeper, as outlined above (see 9.6.xi, above and Footnote 9), and the implications thereof addressed.

10. THE TRANSLATION OF ILs, ICs AND DATA GATHERING TOOLS

BACKGROUND

VUT acknowledges the multilingual nature of South Africa, and also acknowledges that more accurate and nuanced data will occur when the data gathering is carried out in the first language of participant. As such, the following procedures will be followed:

10.1. The REC and the FREC will only consider and grant ethical clearance to documents (ILs, ICs, Questionnaires, Interview Schedules, Focus Group discussion themes, and the like) that are presented to it in English.

10.2 Where these documents are to be operationalised in a language other than English, it is the duty of the research team to provide an adequate translation.

10.3 Before final ethical clearance can be granted, the translated document, with a declaration from an accredited translator that the translation is a fair[10] translation, needs to be lodged with the REC or FREC (as the case may be) as well as copies of the translated documents.

11. EXPEDITED REVIEW

BACKGROUND

The research environment in universities is fast-paced, deadlines are often tight, and projects are planned to run on specific deadlines. VUT acknowledges this reality, but also acknowledges the necessity to maintain quality and standards and, in the case of research ethics, an environment that meets national and international standards and expectations, but also its citizen responsibility towards humans, animals and the environment. Therefore, in an attempt to engage with both demands, the potential for an expedited ethical review process is posited.

11.1 PROCESS AND PROCEDURES FOR EXPEDITED REVIEW:

11.1.1 A Research team may consider their project, which has been approved by the relevant FRIC, to be of such a nature that it constitutes special circumstances. When this occurs the PI and the primary supervisor/promoter may draft and sign an expedited review appeal to the Chair of the FREC or the Chair of the REC for consideration.

11.1.2 The appeal to the Chair of the FREC (for minimal risk research) or the Chair of the REC (under special circumstances) can be justified drawing on one or more of the criteria below:

i. The access to participants or related research domains falls within a very restrained and focused time period that would be prohibitive should the proposal follow the normal channels[11];
ii. The research is of an extremely limited minimal risk range, as 'minimal risk' is defined in the Policy;
iii. The research project has initially received a "provisional ethical clearance" indication, and the relevant and required changes have been made for resubmission;
iv. Any other condition that the research team considers may assist the Chair of the FREC/REC to make an informed decision.
v. It should be noted that there are research conditions that can *only* be considered by the full REC, and these are stipulated in the VUT Policy on Research Ethics.

11.1.3 Upon receipt of the appeal for expedited review and the related documents, the relevant Chair may convene a sub-committee consisting of that Chair and at least one member of the REC or relevant FREC who is deemed to carry the necessary subject expertise to assist in the deliberations.

11.1.4 Upon completion of the deliberations the Chair can make one of two decisions: The Chair and sub-committee may decide to grant ethical clearance to the project, in which case the normal ethical clearance letter, as documented above (section 8.12), proceeds. Alternatively, the Chair may decide not to grant the expedited nature of the request, whereupon the Chair enters the

[10] The notion of a "fair" translation is an important one. Doing a "direct" translation has the potential to provide terminology that the target participants may not grasp. As such "fairness" does not mean "adequate or fairly good" but means finding acceptable equivalents where the translator deems this necessary, and embroidery on the contents for clarity's sake, where this, too, is considered necessary. Oral traditions, for example, are ripe with provocative metaphors and where the translator thinks the use of such metaphors – to engage with scientific language, for example -- will enhance understanding, they are to be encouraged.

[11] An example of this might be a national disaster that requires immediate responses from research teams. Yet even in these cases normal research ethics considerations are in play. It should, however, also be noted that applications for expedited review will not be entertained where it is clear that there has been a tardiness on the part of the research team to follow the correct procedures and make timely submissions.

documentation (excluding the appeals letter) into the Agenda of the next meeting, and informs the appellant of the decision.

11.1.5 Such an expedited review may take place, at the discretion of the Chair, by 'round-robin.' In this case the relevant research ethics application documentation (including the appeal letter) will be sent electronically to the selected committee members with the request for review, recommended decision, declared justification of that decision and (where applicable) recommendations for clarification. These will be submitted electronically to the Chair. All electronic correspondence in such a case should declare the confidentiality requirements for such a review. The Chair collates the responses and issues the relevant letter.

11.1.6 The submission, the ethics review panel, and the decision must be ratified at the following FREC or REC meeting.

11.1.7 A decision for expedited review, and the decision that emanated from such a review process, taken at the FREC level, may be overturned or rescinded, and the related ethical clearance withdrawn by the REC. Such a decision can be made following an expedited review of that decision, by the REC, where the panel consists of the Chair and at least two other members with no declared potential Conflicts of Interest (COIs).

12. UNDERGRADUATE ETHICAL REVIEW

BACKGROUND

VUT acknowledges that more and more undergraduate work (up to and including BTech, and, in the new curriculum development arena, Advanced and Post-Graduate Diplomas) will engage with formal research and research processes. Because VUT accepts that all research should be subject to research ethical review, the following procedures are to be followed.

12.1 PROCEDURES

12.1.1 The appointed supervisor/lecturer appointed to offer a particular course that might set out to do research is the primary adjudicator of the ethics involved in such a project, and carries the responsibility for the ethical clearance of that project[12].

12.1.2 In the case where the research is of minimal risk yet the supervisor/lecturer does not feel competent to adjudicate the research ethics, the supervisor/lecturer may approach the departmental representative to the FREC for guidance.

12.1.3 Such a representative may then recommend that the project be escalated to the FREC level.

12.1.4 However, where research exceeds the bounds of minimal risk research, or falls within those domains that are determined to be the domain of the REC, such research needs to be escalated to the REC.

12.1.5 In the case of the project being escalated to the FREC or the REC, sufficient documentation must be provided to allow the committees to engage adequately with the ethics of the research.

12.1.6 Where the project is escalated to the FREC or REC, the supervisor needs to provide evidence that the science of the project has been scrutinised and approved by at least one qualified and non-conflicted member of the DRIC/RF.

13. CONFLICTS OF INTEREST IN THE RESEARCH TEAM

[12] The implication of this is the necessity to have regular and rigorous training in research ethics in the university.

BACKGROUND

VUT acknowledges that in all research endeavours the potential exists for some form of conflict of interest (COI) to occur. Such a COI must not cloud the judgement of the researchers involved. Indeed, the declaration of a potential COI speaks directly to the integrity and insight of the declarer. If the potential for COI is carefully managed then fair, transparent and ethically acceptable research can take place. One such process, for example, is the notion of "peer-review" (blind or otherwise). Therefore, such mechanisms need to be operationalised.

13.1 Conflicts of Interest may occur under a number of circumstances, ranging from the benign and inevitable to the more insidious and destructive. The following list is not exhaustive but offers guidelines for consideration:

i. COIs may arise when the supervisor/promoter is part of the committee that is to approve the research to be undertaken;
ii. COIs may arise when the research project is sponsored by a commercial or industrial organisation[13];
iii. COIs may arise where the research participants report to, or are beholden to the researcher and/or the supervisors/promoters in his or her (their) professional capacity(ies) (such as student participants to lecturer researchers);
iv. COIs may arise when there is any form of external pressure to produce results that will lead to commercialisation.
v. COIs may arise when any member of the research team holds direct or indirect positions in outside companies or state organs that might benefit from the research;
vi. COIs may occur when the supervisors/promoters are external to VUT, are appointed by VUT but the research is to be conducted in the facilities or domains in the control of such external supervisors / promoters;
vii. COIs may occur where donations of money, time and equipment are provided where such donators might be seen to appear to have a vested interest in the project. This is particularly important if such donations might become part of the university inventory after the completion of the project;
viii. COIs may occur where the equipment to be used in the research belongs to the supervisor(s)/promoter(s) privately.

13.2 When any of the above (or others that can be convincingly argued to be related in sentiment to these) is in play it is imperative that the particular research member, or the research project declare such a potential COI.

13.3 Once this has been declared, the research team must strategize, and commit to writing, how this potential COI is going to be controlled or mitigated. Such a strategy must be embedded in the research proposal but must also be declared in the relevant section of the Ethics Application Form (see Annexures C and D).

13.4 The REC, or FREC, when relevant, must decide on whether the COI has been adequately addressed and the correspondence to the research team must state this overtly and under a separate point in the letter to the research team.

14. CONFLICTS OF INTEREST IN THE RESEARCH ETHICS COMMITTEE

14.1 It may occur that the members of the REC are potentially conflicted in terms of their independence in the ethical research deliberations. To make sure that the ethical clearance is acceptable, and is seen to be acceptable, such potential COIs must be declared at the

[13] Research that is financially sponsored by VUT is, to all intents and purposes, excluded from this, as is much of the financial sponsorship from organisations such as the NRF. However, state or commercial organisations that sponsor research that may or may not lead to the development of IP need to be treated with equal circumspection.

beginning of the meeting, and then the committee must be reminded of this declaration at the time that the particular submission that sparked the COI is debated.

14.2 When such a declaration of potential COI is presented, the Chair of the REC may make one of three decisions and these decisions are minuted:

i. The Chair may decide that the COI is so negligible as not to warrant any action beyond the declaration. It is the right of the committee, by majority vote, to over-rule this decision;
ii. The Chair may decide that the conflicted person should stay in the deliberations until such time as the REC needs to finalise a decision, at which time the Chair will ask the conflicted person to recuse himself or herself until such time as the decision is taken. The REC might, through majority vote, overrule this decision. The minutes of the meeting must reflect the moment in the deliberation that the recusal commenced and the conflicted person left the meeting. It is important that, when the recused person returns to the meeting, the decision made in his or her absence is NOT presented, but the normal outcome of the results procedure followed.
iii. The Chair may decide that the conflicted person may not be part of the deliberation and therefor, at the start of the particular deliberation the conflicted person is requested to recuse himself or herself, and will only return to the meeting once the decision is made. As above, the decision made by the committee following the deliberations on the submission will only be communicated to the recused person by the normal channels.

14.3 The following is a list of potential areas of conflict of interest:

i. Where the applicant has a family connection to the particular member of the REC;
ii. Where the REC member has a vested interest in the sponsors of the research;
iii. Where the REC member has been part of a similar research project that has failed to be granted research ethical clearance;
iv. Where any of the COIs that are documented under the researcher's potential COIs is at play.

15. SERIOUS ADVERSE EVENTS (SAEs)

15.1 DEFINITION: Serious Adverse Events may be defined as any event, arising from the research process, which has led to *unforeseen consequences* that threaten or endanger, or have led to serious injury or worse, of participants in the research, or to animals in the research, or to the environment. In the cases where SAEs are applicable to the research that is targeted at the environment, these occur when events have led to unforeseen damage to the environment, such as spills, floods, pollutions or the detrimental changing of the landscape or environment through collapses, explosions or destructive erosion. As can be deduced, the notion that there are *unforeseen consequences* speaks to the critical consideration.

15.2 It is accepted that if an SAE occurs, and that the SAE has occurred during the carrying out of the research project as it implements the approved method and design, and the ethics have been approved, all by the various relevant committees, the fallout from such an SAE will be covered by VUT's insurance policy in this regard.

15.3 When such events occur there is, almost inevitably, a case for liability. Therefore, as soon as such events occur, detailed reporting needs to be undertaken.

15.4 Such reporting needs to generate as much evidence and documentation as can be garnered. Such evidence may include photographs, testimonies, documented observations, a trail or sequence of events that led to the SAE, and so forth.

15.5 The occurrence of an SAE must be reported as quickly as possible to the Chair of the REC.

15.6 The full report on the SAE must be sent to the Chair of the REC as quickly as possible, but no later than 10 working days after the event and the initial report.

15.7 The report needs to contain the following:

i. The title of the project;
ii. The ethics clearance number;
iii. The names of all the research team members;
iv. A clear description of the domain in which the event occurred, with any evidence that is deemed useful;
v. A clear description of the sequence of events that led up to the SAE;
vi. A clear description, in as much detail and with as much evidence as possible, of the actual SAE;
vii. A thorough description of any actions taken after the occurrence of the SAE, which includes who was involved, what was done, what the consequences thereof were, and any other information that is deemed relevant by the research team; and
viii. Any indications that the processes that led to the SAE might have deviated from what was originally approved by both the FRIC for the research component, and by the REC for the ethics component of the research.

15.8 The Chair of the REC, with the relevant university authorities, sets up a panel to further investigate the event, and prepares a report for Institutional Official on the matter, for his or her deliberation and action.

16. SITE VISITS

16.1 It is the prerogative of the REC to carry out site visits where research is undertaken. Such sites may be particular to a specific research project, or such sites may be standing research entities that are regularly used, such as laboratories, workshops, farms, galleries, and the like. The purpose of such visits is to ascertain whether the sites are being run according to accepted national and international standards, whether standard site SOPs are in place and are being adhered to (such as the disposal of chemicals, the use of safety gear, the removal of waste, and the storage of hazardous materials, for example) and whether, where applicable, the particular research project is being run following agreed upon lines.

16.2 The Chair of the REC puts together a site visit panel, from the REC members, and, where deemed necessary, from relevant university or outside specialists to conduct the site visit, where the committee consists of no less than 5 members. The non-REC members of the site visit committee are required to sign a declaration of confidentiality.

16.3 The REC may be invited to perform a site visit, or may undertake the task on its own volition.

16.4 The Chair of the REC may, out of courtesy, plan the site visit and contact the relevant authorities beforehand to set up the site visit, but it is also his or her prerogative to arrive with the panel, unannounced.

16.5 At the conclusion of the site visit the Chair will write a report on the findings of the site visit, which the members of the committee will acknowledge as a fair reflection of the operation of the site.

16.6 The report will serve at the next REC meeting, at which the course of remedial or disciplinary action (where this might be warranted, following the recommendations of the report) will be considered and the Chair mandated by the committee to institute the course of action.

16.7 Once the report has been tabled at the REC meeting, the report will be forwarded to the relevant site manager or researcher with a covering letter indicating what remedial work is required, or, alternatively, what the next step in the process will be.

16.8 In a case where the site visit calls for drastic and immediate action (such as closing the facility, or halting the research) the Chair with the site visit committee, if they agree on that course of action unanimously, may proceed with such action as intervention. A full report of the intervention must be drawn up by the Chair, which is accepted by the committee, and which

will immediately be sent to the IO for notification. Following that, the same report will be sent to the relevant site authority or researcher, and will be tabled at the next REC meeting.

17. RESEARCH REPORTS (See Annexures E and F)

17.1 Where research ethical clearance has been granted for research to continue, the research team must provide progress reports on an ongoing research. There are two type of reports: Completion reports and progress reports.

17.1.1 Completion reports:

At the completion of the study the research team will inform the REC, in writing and on the relevant template, that the research is completed. This is undertaken for two reasons: firstly, the file on the project may now be closed and archived, and secondly, the declared maintenance of the data for the allotted and agreed upon time will commence from the moment of submission. The report needs to present the same information as the progress report (see below).

17.1.2 Progress reports:

Each research project shall submit an annual progress report (unless otherwise stipulated) on their research to a special committee meeting of the REC. The committee will entertain these reports twice a year (for the June and November meetings). The research team will be informed, in the final approval/clearance letter, which meeting they must report to (See 8.12. xii (d) above).

17.2 Unless otherwise decided upon, the report is seen as a way of monitoring progress, and of documenting particular research problems that may speak to the ethical clearance granted.

17.3 The research report should present:

i. The names and titles of the research team;
ii. The title of the research project;
iii. The Ethical Clearance number;
iv. The date on the final ethical clearance letter (See 8.12. iv);
v. A discussion as to progress as plotted against the accepted time line contained in the proposal, and approved by the FRIC, with potential reasons for possible deviations;
vi. Any minor deviations from the original method and design and ethical clearance agreement, for example sampling size, language concerns, and minor changes in questionnaire or interview schedules, with a short description of what led to the changes;
vii. Any potential SAEs that might be developing, and planned interventions to be undertaken to prevent this;
viii. Any publication that has already come from the research;
ix. Any other comments that the research team feel the REC should know about so that the REC can offer advice, guidance or assistance.

17.4 The Reports will serve at the REC meeting for noting, unless, in the opinion of the REC Chair, the matter should be discussed by the committee.

17.5 The REC may decide, in the case of minimal risk research, to empower the FRECs to handle the research reports, and supply the REC with the received and accepted research reports.

18. RECORD-KEEPING

18.1 It is the task of the REC to maintain adequate records of all proceedings of the committee, all decisions made, all documentation that has been submitted to the REC for deliberation, and all documentation that arises from these deliberations and the workings of the REC. Furthermore,

it is the task of the REC to maintain the declaration of good standing of each member of the REC, including copies of appointment letters and any further training that the member has undergone that enhances the member's insights and abilities to better conduct research ethics reviews.

18.2 All records shall be kept in an archival system that allows for easy access and for the easy transfer of proceedings of record keeping to newly appointed Administrative Officers and Chairs.

18.3 All such records are to be kept in three places:

18.3.1 The hard copies of all matters shall be housed in a secured location that can maintain the strictest control over anonymity and confidentiality, as far as the law allows;

18.3.2 All documents shall be committed to electronic format, be stored with the Administrative Officer in a password protect manner;

18.3.3 The set of hard copy or electronic documents shall also be housed in a safe location off campus, and be housed in such a way that access is restricted to only those who are cleared to access them.

18.4 The records shall be kept up to date as far as this is possible.

18.5 The records may only be made available (besides the normal running of the REC) under two conditions:

18.5.1 When an order of the court has been made, or

18.5.2 When a properly accredited person (such as the official NHREC representative doing an audit of the functioning of the REC) has signed a declaration of confidentiality.

ANNEXURE A: DUMMY ETHICS LETTER

VUT LETTER HEAD

The Chair

Faculty Research Ethics Committee

Faculty of Human Sciences

Vaal University of Technology

14th April, 2016

RESEARCHER: (Researcher's Name)

PROJECT TITLE: *Assessing the efficacy of Community Engagement Projects over a long term: A case study from a University of Technology*

SUPERVISOR/PROMOTER: Dr R.L Mendes (CCd)

CO-SUPERVISOR/CO-PROMOTER: Ms F. Naidoo (CCd)

Decision: Provisional Approval

Ethics Reference Number:

Staff or student number

Dear (Researcher's name)

Thank you for submitting the above project for ethical consideration and approval. The following comments emanated from the deliberations and require your attention, and a letter, signed by yourself and your supervising/promotion team that the matters have been addressed, and how they have been addressed. The letter, the revised proposal and any other revised documentation needs to be lodged with the Committee, after which, if all is satisfactory, final approval can be granted through expedited review.

In all correspondence that follows the listed ethics number should be prominently displayed.

Discussion:

1. The committee noted that the potential Conflict of Interest between Co-supervisor Ms F Naidoo, as owner of the facility where the research is to be undertaken, and the research team has been adequately addressed.
2. The committee noted in the questionnaire that demographic data will be collected concerning race. Yet nowhere in the research proposal is there an indication as to how knowledge of race might impact on the results of the survey. Kindly either justify the use of race demographics, or delete this from the questionnaire.
3. The committee notes the engagement with anonymity and confidentiality with appreciation, but requests that you insert the words "as far as the law allows" into your undertaking in this regard, in the Information Leaflet.
4. The committee notes that there is an expectation that some of the respondents will not be English speakers (and indeed in some cases there will be no command of English). Kindly indicate how you intend addressing this matter. Should you select a particular alternative language, kindly indicate which one, why this one was selected, and the procedures you will undertake to have the Information leaflet, Informed Consent and Questionnaire translated. (Once the changes have been made to the IL, as requested in (2) above, the process of translation can proceed). Kindly lodge with the committee a declaration from the translator that the translation is a fair one.

5. Please insert into the proposal that the statistician who will assist you with processing the data will sign a confidentiality agreement.

Please also note the following:

In all correspondence concerning this research project please use the Ethics Reference Number provided above.

Any revisions to the research documents, as shared in this letter, must reach the REC by the following date XXXXXXXXXXX:

As the primary researcher you undertake:

- *To follow only those procedures for which the approval has been given;*
- *To inform the committee should there be significant deviations from that which has been approved;*
- *To report any Adverse Events that might occur, within 14 days of the event (following the Guidelines procedure);*
- *To submit to the committee annual progress reports, where your reporting date is XXXXXX; and*
- *To inform the committee on the completion of the project, when the findings have entered the public domain.*

We wish you well with your studies.

Sincerely

Prof XXXXXXXXXXX

(Telephone number yyyyy)

CHAIR: Faculty Research and Innovation committee

Faculty of Human Sciences

Vaal University of Technology

ANNEXURE B: RESEARCH ETHICS DECLARATION

I, _____ do hereby declare the following:

1. That I am conversant with the guidelines laid down by this university and in national and international guidelines on the needs for, processes followed, and procedures implemented in generating research results though ethical means;
2. That no data beyond Literature Review or Survey of Scholarship has taken place before the date signed to, below;
3. That I shall undertake the research project that has been approved by all the relevant VUT authorities and has been granted ethical clearance by the VUT REC or its delegated FREC;
4. That, should any changes in the research processes and procedures occur I shall report these to the relevant Ethics Committee that granted the approval;
5. That, should any Serious Adverse Events occur, I shall report on these following the correct procedures and guidelines as quickly as possible by not later than 10 working days from the event;
6. That I shall submit timeously a research report on the date stipulated by the REC/FREC and a final report once the research project has been completed;
7. That, where a contract concerning the sharing of Intellectual Property has been drawn up and signed, I shall obey all aspects of such a contract; and
8. That, in developing the dissertation, thesis or article I shall refrain from non-academic practices including plagiarism and related concerns and shall fully accredit all sources of information.

Signature: _____ Date: _____

Witnessed by at least one supervisor:

SUPERVISOR'S NAME: _____

SUPERVISOR'S SIGNATURE: _____

ANNEXURE C: HUMAN PARTICIPANTS ETHICS APPLICATION FORM

VAAL UNIVERSITY OF TECHNOLOGY

RESEARCH ETHICAL APPLICATION FOR THE USE OF HUMAN PARTICIPANTS:
REVIEW FORM

Please note that the form must be completed in typed script. Handwritten applications will not be considered.
Please note that this form deals only with the use of human participants. Any other research needs to use the relevant form

APPLICANT'S PERSONAL DETAILS

Full name of Principle Investigator	
Surname	
Gender[14]	
Race[15]	
Student Number (where applicable)	
Staff Number (where applicable - of Principle Investigator for Non-Degree Purposes)	
Department	
Faculty	
Existing Qualifications	
Proposed Qualification for Project (In the case of research of degree purposes – otherwise declare this a "Non-Degree Purpose")	
Contact number of PI[16]	
Mobile number of PI	
e-mail of PI	

SUPERVISORS/ PROMOTERS AND OTHER RESEARCHERS' DETAILS

	Name	***Contact Number***	***e-mail***	***Department / Institution***	***Qualifications***
1.					
2.					

[14] Optional
[15] Optional
[16] The PI is the Principle Investigator. In the case of degree research, this is the student.

3.					

ETHICAL ISSUES

The VUT Research Ethics Policy applies to all members of staff and postgraduate students who are involved in research on or off the campuses of VUT. In addition, any person not affiliated with Vaal University of Technology who wishes to conduct research with VUT students and / or staff is bound by the same ethics framework. Each member of the University community is responsible for implementing this Policy in relation to scholarly work with which she or he is associated and to avoid any activity which might be considered to be in violation of this Policy. ***By signing this application, the signatories bind themselves to the following conditions:***

1. That the project presented here and in the submitted proposal will be carried through as it is documented here;
2. That any deviations from the application and proposal that are significant enough to change the methodologies and methods envisioned must be reported and an amendment to the project be approved by the CREC (via the relevant FREC, where applicable);
3. The reporting of any Serious Adverse Events (SAEs) will be undertaken within the guidelines laid out by the VUT Standard Operating Procedures;
4. Progress reports will be submitted according to the dates presented in the Approval letter, and a completion report will be submitted;
5. That, by submitting this application, the PI and the research team declare that no data collection beyond that which is required for the preparation for the proposal and this application has taken place;
6. The ethics clearance number will be presented in any correspondence with the REC.

Title of Project	
Name of Approving FRIC	Please attach a copy of the approval letter or extract from the minutes
Date of FRIC Approval	

QUESTION 1

Does your study cover research involving:	***YES***	***NO***
Children		
Persons who are intellectually or mentally impaired		
Persons who have experienced traumatic or stressful life circumstances		
Persons who are HIV positive		
Persons highly dependent on medical care		
Persons in dependent or unequal relationships		
Persons in captivity		
Persons living in particularly vulnerable life circumstances		

*If any of above are marked **"Yes"**, indicate what measures you will take to protect the autonomy of respondents and (where indicated) to prevent social stigmatization and/or secondary victimisation of respondents. If you are unsure about any of these concepts, please consult your supervisor/promoter.*

IF YES, *Describe the situation that brings about the measures, and then define the measures that are to be taken.*

QUESTION 2

Will data collection involve any of the following:	***YES***	***NO***
Access to confidential information without prior consent of participants		
Participants being required to commit an act which might diminish self-respect or cause them to experience shame, embarrassment, or regret		
Participants being exposed to questions which may be experienced as stressful or upsetting, or to procedures which may have unpleasant or harmful side effects		
The use of stimuli, tasks or procedures which may be experienced as stressful, noxious, or unpleasant		
Any form of deception		

*If any of above are marked **"Yes"**, explain and justify. Explain, too, what steps you will take to minimise the potential stress/harm.*

IF YES, *Describe the situation that brings about the measures, and then define the measures that are to be taken.*

QUESTION 3

Will any of the following instruments be used for purposes of data collection:	***YES***	***NO***
Questionnaire		
Survey schedule		
Interview/Focus group schedule		
Psychometric test		
Other/ equivalent assessment instrument		

*If any of above is marked **"Yes"**, attach copy of research instrument. If data collection involves the use of a psychometric test or equivalent assessment instrument, you are required to provide evidence here that the measure is likely to provide a valid, reliable, and unbiased estimate of the construct being measured. If data collection involves interviews and/or focus groups, please provide a list of the topics to be covered/ kinds of questions to be asked.*

ADD THE INFORMATION HERE and indicate that the instrument has been appended to this document under a specific name and Appendix number. *In the case of the Psychometric test indicate which one and attach evidence that you have permission to use it. Where the test is to be administered by a professional, provide the information of the professional.*

QUESTION 4

Will the autonomy of participants be protected through the use of an informed consent form, which specifies (in language that respondents will understand):	***YES***	***NO***
The nature and purpose/s of the research		
The identity and institutional association of the researcher and supervisor/project leader and their contact details		
The fact that participation is voluntary that responses will be treated in a confidential manner		
Any limits on confidentiality which may apply		
That anonymity will be ensured where appropriate (e.g. coded/ disguised names of participants/ respondents/ institutions)		
The fact that participants are free to withdraw from the research at any time without any negative or undesirable consequences to themselves		

The nature and limits of any benefits participants may receive as a result of their participation in the research		
Is a copy of the informed consent form attached?		

*If **NOT**, this needs to be explained and justified, also the measures to be adopted to ensure that the respondents fully understand the nature of the research and the consent that they are giving.*

Refer to the relevant Information Leaflet and Informed Consent appended to this document by title or Appendix number. *In the case where any of the responses are indicated negatively (i.e as "NO") provide a justification why this decision has been made and the information has been omitted, here.*

QUESTION 5

Specify what efforts been made or will be made to obtain informed permission for the research from appropriate authorities and gate-keepers (including caretakers or legal guardians in the case of minor children)?
Describe the measures, here, and append the relevant documents with their titles and Appendix numbers to this document.

QUESTION 6

STORAGE AND DISPOSAL OF RESEARCH DATA: Please note that the research data should be kept for a period of at least five years in a secure location by arrangement with your supervisor. Declare in the box below where this is to occur.

QUESTION 7

In the subsequent dissemination of your research findings – in the form of the finished thesis, oral presentations, publication etc. – how will anonymity/ confidentiality be protected? Provide a detailed description

QUESTION 8

Is this research supported by funding that is likely to inform or impact in any way on the design, outcome and dissemination of the research?	**YES**	**NO**
If YES, this needs to be explained and justified here. Append any documentation that will assist the Ethics Committees in reaching a conclusion.		

QUESTION 9

Are extra arrangements necessary to indemnify the research team members and/or the participants?	**YES**	**NO**
If YES, please indicate here why this is deemed necessary and then indicate how the arrangements have been made. Append supporting documentation and refer.		

QUESTION 3.10

Is it deemed necessary to have insurance cover, over and above the VUT insurance, for this research project?	**YES**	**NO**
If YES, please indicate why this deemed necessary and present evidence of how this is to be done. Append supporting documentation.		

QUESTION 11

Are the participants to be compensated in any form?	**YES**	**NO**
If YES, please indicate what that compensation entails here.		

QUESTION 12

APPROVAL BY OTHER ETHICS COMMITTEES. Are other, non-VUT, Ethics Committee approvals required?	**YES**	**NO**
*If YES, please indicate who these Ethics Committees are. Append copies of their approval letters. (It is acknowledged that the other committee will first require VUT approval before granting their approval. In such a case, the original committee must commit to a '**provisional approval pending VUT approval.'** This should be appended.)*		

QUESTION 13

Has any organization/company participating in the research or funding the project, imposed any conditions to the research?	**YES**	**NO**
If YES, please indicate what the conditions are. Append supporting documentation.		

FORMALISATION OF THE APPLICATION

APPLICANT

I have familiarised myself with the University's Research Ethics Review Guidelines and undertake to comply with them. I understand that it is also my duty to inform the University timeously in cases where Serious Adverse Events occur and to take every precaution to avoid these happening.

The information supplied above is correct to the best of my knowledge.

NB: PLEASE ENSURE THAT THE ATTACHED CHECK SHEET IS COMPLETED

SIGNATURE OF APPLICANT

D D M M 2 0 Y Y
DATE

NB: Please ensure that the applicant has completed the attached Check Sheet and that the Form is forwarded to your Faculty Research Ethics Committee.

NOTE: In the case of research for Non-Degree purposes, this signature is not necessary.

SIGNATURE OF SUPERVISOR / PROJECT LEADER

D D M M 2 0 Y Y
DATE

VAAL UNIVERSITY OF TECHNOLOGY

RESEARCH ETHICAL APPLICATION FOR REVIEW FORM FOR HUMAN PARTICIPANTS

PROPOSAL AND ETHICS APPLICATION RELATED DOCUMENTS

		PLEASE TICK OR INDICATE AS "Not Applicable" (N/A)
1.	Full Research Proposal is attached	
2.	FRIC Chair declaration of approval of project (both degree and NDP)	
3.	Information Leaflet and Informed Consent forms, in English (an accredited translation in the language of the potential participants may be required at a later stage).	
4.	Description and/or amounts of compensation including reimbursements, gifts or services to be provided to participants (if applicable)	
5.	Description for arrangement for indemnity (if applicable)	
6.	Description of any financial cost to participant (if applicable) Research budget to be included and source of funding declared.	
7.	Description of provision of insurance coverage to participants (if applicable)	
8.	Description of steps to be undertaken in case of and adverse event or when injury of harm is experienced by the participants attributable to their participation in the study	
9.	Statement agreeing to comply with ethical principles set out in the VUT Ethics Review Guidelines has been signed	
10.	Disclosure of any previous ethics review action by other ethics review bodies (if applicable). In the case of external applications proof that the research has been approved by the researcher's institutional research ethics body.	
11.	Research instrument such as questionnaires, interview guides and similar documents	
12.	CV's of principal investigators in the case of research for Non-Degree Purposes. In the case of external Research Ethics Application the CVs of the PI (in the case of research for Non-Degree Purposes) or consulting supervisor or promoter must be appended	
13.	Letter(s) of permission from relevant bodies (if applicable)	

ANNEXURE D: NON-HUMAN PARTICIPANTS ETHICS APPLICATION FORM

VAAL UNIVERSITY OF TECHNOLOGY

RESEARCH ETHICAL APPLICATION FOR THE USE OF NON-HUMAN RESEARCH PROJECTS:
REVIEW FORM

Please note that the form must be completed in typed script. Handwritten applications will not be considered.
Please note that this form deals primarily with research that is undertaken in non-human projects. The research team, however, is considered a part of the project. Where human participation is planned for, the relevant form should also be used.

APPLICANT'S PERSONAL DETAILS

Full name of Principle Investigator	
Surname	
Gender[17]	
Race[18]	
Student Number (where applicable)	
Staff Number (where applicable - of Principle Investigator for Non-Degree Purposes)	
Department	
Faculty	
Existing Qualifications	
Proposed Qualification for Project (In the case of research of degree purposes – otherwise declare this a "Non-Degree Purpose")	
Contact number of PI[19]	
Mobile number of PI	
e-mail of PI	

SUPERVISORS/ PROMOTERS AND OTHER RESEARCHERS' DETAILS

	Name	***Contact Number***	***e-mail***	***Department / Institution***	***Qualifications***
1.					

[17] Optional
[18] Optional
[19] The PI is the Principle Investigator. In the case of degree research, this is the student

2.					
3.					

ETHICAL ISSUES

The VUT Research Ethics Policy applies to all members of staff and postgraduate students who are involved in research on or off the campuses of VUT. In addition, any person not affiliated with Vaal University of Technology who wishes to conduct research with VUT students and / or staff is bound by the same ethics framework. Each member of the University community is responsible for implementing this Policy in relation to scholarly work with which she or he is associated and to avoid any activity which might be considered to be in violation of this Policy. ***By signing this application, the signatories bind themselves to the following conditions:***

7. That the project presented here and in the submitted proposal will be carried through as it is documented here;
8. That any deviations from the application and proposal that are significant enough to change the methodologies and methods envisioned must be reported and an amendment to the project be approved by the CREC (via the relevant FREC, where applicable);
9. The reporting of any Serious Adverse Events (SAEs) will be undertaken within the guidelines laid out by the VUT Standard Operating Procedures;
10. Progress reports will be submitted according to the dates presented in the Approval letter, and a completion report will be submitted;
11. That, by submitting this application, the PI and the research team declare that no data collection beyond that which is required for the preparation for the proposal and this application has taken place;
12. The ethics clearance number will be presented in any correspondence with the REC.

Title of Project	
Name of Approving FRIC	Please attach a copy of the approval letter or extract from the minutes
Date of FRIC Approval	

LABORATORY WORK

This section is to be completed for all use of a laboratory for research purposes, as outlined in the proposal and in the descriptions that follow, whether the research is only partially going to be conducted in a laboratory or not. Please also note that an IT laboratory, even with only one workstation, is also considered a laboratory.

Is the laboratory that is to be used a VUT laboratory? If so, in the space below, indicate which laboratory, by Department and Room number. If an outside laboratory is being used, fully name the laboratory, and attach a copy of the Letter of Agreement with the owners of that laboratory to this application as an Annexure. *Such a Letter of Agreement needs to declare and list all the relevant Standard Operating Procedures that are pertinent to the research project.*
Describe briefly the procedure you are following, paying particular attention to the areas that might present hazardous situations. (Please do not ask to cross-refer to the proposal).

In the space below document the hazardous material that you might be using in your research. If there is no use of hazardous material, declare this in the space. (Please do not indicate this as N/A or Not Applicable).
In the space below describe the apparatuses that you will be using in your research that might be considered dangerous to yourself and your co-workers. If there is no danger, declare this in the space. (Please do not indicate this as N/A or Not Applicable).
Provide a list of VUT Standard Operating Procedures (SOPs) that you will be following in your specific laboratory work. (Please note that all laboratories need to have SOPs in place. If the SOPs are not in place, ethical clearance will automatically not be granted).
Provide a description of how you plan to protect yourself and your fellow researchers during the carrying out of the laboratory research, should this be necessary. If this is not the case, declare in the space below that this is not necessary. (Please do not indicate this as N/A or Not Applicable).
In the space below describe how you plan to dispose of the waste and residue that will follow your research. Please refer to the VUT SOP that is relevant to this procedure. If there is no waste or residue, declare this in the space. (Please do not indicate this as N/A or Not Applicable).

If there are any products, processes, patents and the like connected to Intellectual Property that might emanate from your research, please declare it in the space below, and provide, as an Annexure, evidence that you have begun the process of registering such products, processes, patents and the like with VUT systems. If there are no products, patents, processes that are registerable, beyond what is contained in written outputs from the research, please declare this in this space. (Please do not indicate this as N/A or Not Applicable).
If the research is reliant on cooperation or contribution from sources outside VUT, where such cooperation or contribution might bring about outputs sharing, please describe the situation, and provide, as an Annexure, copies of all agreements pertaining to this situation. If this does not apply, please declare so, in the space. (Please do not indicate this as N/A or Not Applicable).

RESEARCH THAT IS UNDERTAKEN *IN SITU* OR ON SITE

This section refers to all research where the research is undertaken in any physical domain that is not a *bona fide* laboratory as defined, under Question 4. PLEASE NOTE: in this situation the environment or domain might normally be utilised by people and/or animals (as defined in the VUT Research Ethics Policy) who are NOT directly considered as *participants* in the research but whose wellbeing must be considered because the presence and aftermath of the research project might be invasive of their habitat and render them vulnerable.

Describe the environment in which the research will take place. Pay attention, at least, to the following: ✓ A description of the place where the research is to be undertaken, including size, vegetation, human and animal habitation and utilisation. ✓ A description of how the environment is currently being utilised. ✓ Describe any measures that are in place that protect the environment before the arrival of the research project
Justify why the project needs to be undertaken in this environment.

Describe the permission and procedures to access the environment, including daily access and departure procedures, and any specific procedures that are connected to this. Document any particular prohibitions placed on the project because of the access to the environment. Attach a copy of the permission letter to access to environment, as an Annexure.
Briefly describe the procedures to be carried out in the environment. Please do not ask to cross-refer to the relevant sections in the proposal but present the description here.
Document any use of hazardous material that might be part of the research on site. Include in this the process of transportation of the material. If there is no use of hazardous material please declare this in the space below. (Please do not indicate this as N/A or Not Applicable).
Document any machinery that is to be used in the research project on site, specify the SOPs of each machine, and indicate how the machinery is to be transported to and from the site, or made safe when the research team is not there. (This includes reference to all provisions of power for the machinery, such as electricity, fuel and the like). If there is no use of machinery please declare this in the space below. (Please do not indicate this as N/A or Not Applicable).
Stipulate how you are going to dispose of any hazardous or pollutant waste, upon completion of the research project. Where applicable, refer to the relevant SOPs.

Document the procedures you will undertake, upon completion of the research project, to return the environment to its original state, or, where applicable, indicate how the environment will be enhanced.
If there are any products, processes, patents and the like connected to Intellectual Property that might emanate from your research, please declare it in the space below, and provide, as an Annexure, evidence that you have begun the process of registering such products, processes, patents and the like with VUT systems. If there are no products, patents, processes that are registerable, beyond what is contained in written outputs from the research, please declare this in this space. (Please do not indicate this as N/A or Not Applicable).
If the research is reliant on cooperation or contribution from sources outside VUT, where such cooperation or contribution might bring about outputs sharing, please describe the situation, and provide, as an Annexure, copies of all agreements pertaining to this situation. If this does not apply, please declare so, in the space. If this does not apply, declare this in the space. (Please do not indicate this as N/A or Not Applicable).

FORMALISATION OF THE APPLICATION

APPLICANT

I have familiarised myself with the University's Research Ethics Review Guidelines and undertake to comply with them. I understand that it is also my duty to inform the University timeously in cases where Serious Adverse Events occur and to take every precaution to avoid these happening.

The information supplied above is correct to the best of my knowledge.

NB: PLEASE ENSURE THAT THE ATTACHED CHECK SHEET IS COMPLETED

D	D	M	M	2	0	Y	Y

SIGNATURE OF APPLICANT DATE

NB: Please ensure that the applicant has completed the attached Check Sheet and that the Form is forwarded to your Faculty Research Ethics Committee.

D	D	M	M	2	0	Y	Y

SIGNATURE OF SUPERVISOR / PROJECT LEADER

DATE

ETHICS CHECKLIST FOR NON-HUMAN RESEARCH

	Yes	No	N/A
Was DRIC approval received?			
Was FRIC approval received?			
Is the laboratory that is to be used a VUT laboratory?			
If an outside laboratory is being used, was the laboratory fully named?			
Was a Letter of Agreement from the owners of that laboratory received?			
Did you describe briefly the procedure you are following regarding hazardous situations?			
Do you follow Standard Operating Procedures (SOPs) for transporting and discard of hazardous materials?			
Did you document the hazardous material that you might be using in your research?			
Did you document the apparatuses that you will be using in your research that might be considered dangerous to yourself and your co-workers?			
Did you provide a list of VUT SOPs that you will be following in your specific laboratory work?			
If you are using Non-VUT laboratories, have you included the contract between VUT and that laboratory, including the SOP documents?			
Did you provide a description of how you plan to protect yourself and your fellow researchers during the carrying out of the laboratory research?			
Did you provide a description of how you plan to dispose of the waste and residue that will follow your research? (Please refer to the VUT SOP that is relevant to this procedure)			
Did you declare any products, processes, patents and the like connected to Intellectual Property that might emanate from your research? **OR**			
Did you declare what written outputs will derive from the research?			
Is the research reliant on cooperation or contribution from sources outside VUT?			
Did you provide an agreement towards the partnership?			
Is your research funded by an outside entity?			
Are there any specific demands you have to adhere to because of the external funding? (Please add the list of demands in your documentation)			

Did you supply a description of the place where the research is to be undertaken, including size, vegetation, human and animal habitation and utilisation?			
Did you supply a description of how the environment is currently being utilised?			
Did you describe any measures that are in place that protect the environment before the arrival of the research project?			
Did you justify why the project needs to be undertaken in this environment?			
Did you describe the permission and procedures to access the environment, including daily access and departure procedures, and any specific procedures that are connected to this?			
Did you supply documentation on any particular prohibitions placed on the project because of the access to the environment?			
Did you receive a permission letter/access key to receive access to the environment?			
Did you describe the procedures to be carried out in the environment?			
Did you document any use of hazardous material that might be part of the research on site? (Include in this the process of transportation of the material)			
Did you declare that there is no hazardous material on site?			
Did you document the machinery and equipment that is to be used in the research project on site?			
Did you specify the SOPs of each machine and equipment, and indicate how the machinery and equipment are to be transported to and from the site, or made safe when the research team is not there? (This includes reference to all provisions of power for the machinery, such as electricity, fuel and the like)			
Did you stipulate how you are going to dispose of any hazardous or pollutant waste, upon completion of the research project? (Where applicable, refer to the relevant SOPs)			
Did you document the procedures you will undertake, upon completion of the research project, to return the environment to its original state, or, where applicable, indicate how the environment will be enhanced?			
Are there are any products, processes, patents and the like connected to Intellectual Property that might emanate from your research?			
Do you have evidence that you have begun the process of registering such products, processes, patents and the like with VUT systems?			

APPENDIX E: PROGRESS REPORT

PROGRESS REPORT / RENEWAL APPLICATION

Please note: The Progress report / Renewal application must be received by the date indicated on the Final Research Ethics clearance letter, otherwise the clearance will expire.

PLEASE NOTE: THIS IS AN OFFICIAL DECLARATION AND THEREFORE ANY MATTERS PRESENTED HERE ARE CONSIDERED BINDING.

(Please type)

Title of Project

Reference Number	
Final Ethics Clearance number	
Date of REC approval:	
Date Commenced Participant data collection commenced:	
Expected Date of Completion of data collection:	
Expected Date of Completion of the entire project:	
Renewal period requested:	
Name of Researcher/PI:	
E-mail address	
Name of Supervisor/Promoter (if applicable):	

E-mail address	

STATUS

Provide a brief description of the progress made in the study:

Progress report	**Yes**	**No**
Progress satisfactory		
Progress ***unsatisfactory (Please provide reasons)***		
Adverse Events (please provide a list of adverse events experienced in the study so far, if any). ***It is imperative that this section be filled in as a matter of formal declaration.***		
Extension of ethical approval required (please tick the appropriate box)	**Yes**	**No**

Publications		**Yes**	**No**
In Preparation			
If **completed**, were results published *(ATTACH ABSTRACT WITH ARTICLE DETAILS)* OR			
Submitted for publication			
• Title of paper			
• Name of Journal			
• Volume & page reference (If available)			
Abandoned (State reasons.)			

DEVIATIONS FROM ORIGINAL, APPROVED, PROJECT

*Please indicate any deviations that have occurred in the project, from the agreed upon procedures. (**The REC reserves the right to insist on a review of the project, given such deviations**).*

DECLARATION I confirm that the research has been conducted in compliance with the Research Ethical Clearance agreement, and that the report is true and correct		
Signature of Applicant	Print name	Date
Signature of Supervisor	Print name	Date

APPENDIX F: COMPLETION DECLARATION

DECLARATION OF COMPLETION OF RESEARCH PROJECT

PLEASE NOTE: THIS IS AN OFFICIAL DECLARATION AND THEREFORE ANY MATTERS PRESENTED HERE ARE CONSIDERED BINDING.

(Please type)

Title of Project

Reference Number	
Final Ethics Clearance Number	
Date of REC approval:	
Date Commenced Participant data collection commenced:	
Date on which ESRIC signed off on the research/OR	
(For Non-degree Purposes) **Date on which the data entered the public domain**	

FOR MASTERS AND DOCTORATE COMPLETION

	E-Mail Address and contact number
Name of Student:	

Name of Supervisor/Promoter:	
Name of Co-supervisor/Co-Promoter:	
Name of Co-Supervisor/Co-promoter:	

FOR RESEARCH FOR NON-DEGREE PURPOSES

(Supply all co-researcher names)

	Email address and contact number
Name of Principle Investigator:	
Name of Co-researcher:	
Name of Co-researcher:	
Name of Co-researcher:	

We, the undersigned, declare that:

1. The study, approved by the VUT Ethics structures under the Final Ethics Clearance number noted above, has been concluded according the dictates of that approval;
2. That any Serious Adverse Events that may have occurred during the course of the research have been reported and concluded;
3. That all data accumulated during the course of the study have been safely stored, according to the undertakings in the Ethics Application form; and
4. That the presentation of the findings of the study have met all the Ethics requirements stipulated by the University.

FOR MASTERS AND DOCTORATE COMPLETION

	SIGNATURE
Name of Student:	

Name of Supervisor/Promoter	
Name of Co-supervisor/Co-Promoter	
Name of Co-Supervisor/Co-Promoter:	

FOR RESEARCH FOR NON-DEGREE PURPOSES

(Supply all co-researcher names)

	SIGNATURE
Name of Principle Investigator:	
Name of Co-researcher:	
Name of Co-researcher:	
Name of Co-researcher:	