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

Please Note:
- the form must be completed in typed script;
- that handwritten applications will not be considered;
- this form deals only with the use of human participants; and
- any other research needs to use the relevant form.

SECTION A COMPULSORY TO COMPLETE

APPLICANT'S PERSONAL DETAILS

Full name of Principle Investigator	
Surname	
Gender[1]	
Race[2]	
Student Number (where applicable)	
Staff Number (where applicable - of Principal 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[3]	
Mobile number of PI	
e-mail of PI	

[1] Optional
[2] Optional
[3] The PI is the Principal Investigator. In the case of degree research, this is the student

SECTION B COMPULSORY TO COMPLETE

SUPERVISORS / PROMOTERS AND OTHER RESEARCHERS' DETAILS

	Name	Contact Number	e-mail	Department / Institution	Qualifications
1.					
2.					
3.					

SECTION C COMPULSORY TO COMPLETE

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/DRIC*	Please attach a copy of the approval letter or extract from the minutes
Date of FRIC/DRIC* Approval	

*NDP studies need DRIC approval only; please indicate the relevant approving body if not DRIC/FRIC

QUESTION 1

Does your study cover research involving:	***YES***	***NO***
Children		

Does your study cover research involving:	***YES***	***NO***
Persons who are intellectually or mentally impaired		
Persons who have experienced traumatic or stressful life circumstances		
Persons who identify as 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		
Access to confidential personal data 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		
Will any of the following instruments be used for purposes of data collection:	***YES***	***NO***
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 Annexure 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)		
That participants are free to withdraw from the research at any time, before data is de-identified, 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 Annexure 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 gatekeepers (including caretakers or legal guardians in the case of minor children)?

Describe the measures, here, and append the relevant documents with their titles and Annexure numbers to this document.

QUESTION 6

STORAGE, MANAGEMENT AND DISPOSAL OF RESEARCH DATA:

Please note that it is of the utmost importance that all research data must be stored in a secure location, inaccessible to unauthorised persons, for a period of 5 years. This data must then be disposed of in a manner which is irreversible. In the box below you are requested to describe, in detail, where and how such data will be safely stored and what procedure you will follow to destroy and dispose of this data at the end of the fifth year, on a stated date. If the data will be stored electronic, please indicate what platforms will be used and whether they are password protected. You must furthermore ensure and state that your storage and disposal procedure has been authorised and confirmed by your supervisor

Please also indicate how compromised data would be dealt with in the case that data was breached, and personal information was disclosed. Steps to mitigate the effects of the breach, undertaking to inform the data subject of the breach of personal information should be noted. Please also provide an undertaking that the data will not be shared with unauthorised third parties and that it will only be used for the purpose that it was collected for.

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 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 is 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

D	D	M	M	Y	Y	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.

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

D	D	M	M	Y	Y	Y	Y

SIGNATURE OF SUPERVISOR OR PROJECT LEADER DATE

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 and named Annexure A	
2. FRIC Chair declaration of approval of project (both degree and NDP), named Annexure B	
3. Fully completed and signed application form with all Annexures indicated (This document: Annexure C).	
4. 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). Annexure D_1, D_2 etc.	
5. Research instrument such as questionnaires, interview guides and similar documents, named Annexure E-1, E-2 etc	
6. Letter(s) of permission from relevant bodies (if applicable), named Annexure F_1, F_2 etc	
7. Did you language edit the application and proposal, i.e. did you check for grammar and spelling errors?	
8. 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 – Annexure G	
9. 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 – Annexure H	
10. Description and/or amounts of compensation including reimbursements, gifts or services to be provided to participants (if applicable) – Annexure I	
11. Description for arrangement for indemnity (if applicable) – Annexure J	
12. Description of any financial cost to participant (if applicable) Research budget to be included and source of funding declared. Annexure K	
13. Description of provision of insurance coverage to participants (if applicable)- Annexure L	
14. 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 (Included in Annexure C)	
15. Statement agreeing to comply with ethical principles set out in the VUT Ethics Review Guidelines has been signed on page 8 (Formalisation of the application).	