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| FORM 1: 2017Research ethics application form for conducting research involving either primary, or a combination of primary and secondary human participant data. For research that involves the explicit use of secondary data, please complete form 4. |

**PLEASE STUDY THE FOLLOWING BEFORE COMPLETING THE APPLICATION**

**INFORMATION FOR APPLICANTS**

1. **This template [© 2017] is the official application form that must be used by employees and students of the Graduate School of Business Leadership (SBL) to apply for research ethics clearance for research involving humans directly.** Applications made on previous versions of the template cannot be accepted and will be returned.
2. Research involving humans refers to any research that involves the direct or indirect participation of human participants and institutions, therefore creating an obligation to protect the rights and interests of human participants and institutions (see Unisa Policy on Research Ethics). FORM 1 provides for the application of research involving humans directly through fieldwork activities that meets the criteria for low to high risk (Category 2, 3 and 4). (Please refer to Section 2 of FORM 1 for risk assessment criteria.
3. Study the Unisa Policy on Research Ethics before completing this application:
4. http://staffcmsys.unisa.ac.za/cmsys/staff/contents/departments/res\_policies/docs/Policy%20on%20Research%20Ethics%20-%20rev%20appr%20-%20Council%20-%2015.09.2016.pdf
5. Study the Unisa Policy for conducting research involving Unisa employees, students or data (2013) to obtain information about acquiring permission from the Research Permissions Subcommittee of the Senate Research, Innovation, Postgraduate Degrees and Commercialisation Committee (SRIPCC) to do research that involves Unisa employees, students and/or data if applicable. Please note that permission should be obtained from the RPSC of the SRIPCC after ethical clearance has been obtained. The clearance certificate should be appended to the RPSC application.
6. This application form (**FORM 1**) provides for the following types of application involving humans directly through fieldwork activities:

5.1 **SBL** **Students** (**Master’s, Doctoral, and any other student engaged with research).**

5.2 **Research conducted by College employees** (non-degree purposes) to produce research output in the form of academic articles, papers to be presented at conferences or research reports.

5.3 **Research that involves Unisa employees, students, or data**.

5.4 **Research/contract research conducted by external researchers within the SBL.**

5.5 **The use of secondary data in consolidation with the use of primary data (involving human participants).**

1. **To apply for permission from the RPSC of the SRIPCC to conduct research involving Unisa Employees, Students or Data use RPSC form available at** [**https://staff.unisa.ac.za/secure/index.jsp**](https://staff.unisa.ac.za/secure/index.jsp)(This application form should be submitted to Ms N Motloi, motlonc@unisa.ac.za 10 days prior to the SRIPCC meeting).
2. **To apply for research ethics clearance for the use of Secondary Data use FORM 4.**
3. **To apply for research ethics clearance for a Conceptual Research study use FORM 5.**
4. The Unisa policy on research ethics (2014) does not apply retrospectively. If data collection has already started or is in progress the research ethics review committee (RERC) will not consider the application.
5. The SBL research ethics review system comprises of the Research Ethics Review Committee (RERC).
6. **Applications for research for non-degree purposes** (articles or other academic research projects) are dealt with by the SBL RERC.
7. **Late submissions to the SBL RERC cannot be accepted.** Late submissions will stand over to the next SBL RERC review meeting.
8. The SBL RERC will evaluate the ethical soundness of the application. Ethical soundness relates to scientific quality.
9. On submission, a research ethics clearance number will be allocated to the research project. This number should be used in all communications about the project with the SBL RERC.
10. The application form and supporting documents will enter a pre-approval phase where the research ethics chairperson or secretary will review the application for technical quality and ensure that all sections are complete., where after it is submitted for review according to the Unisa Standard Operating Procedure on Research Ethics Risk Assessment.
11. The applicant will be notified of the outcome of the application within two weeks after the meeting.
12. Decisions reached by the SBL RERC could be (see Annexure A of the policy section 9.8):
* Approved
* Referred back – requires modification, further information or clarification
* Disapproved with reasons.
1. Expedited review is possible for proposals which meet the criteria for negligible or low risk research projects (Category 1 and 2). The chairperson may assist with the expedited review or nominate three or more members to review the application based on the anticipated risk of the study.
2. Decisions will be communicated within two weeks after the meeting.
3. If the application was referred back, respond to the committee’s feedback within a month of receiving the formal feedback. A memorandum should accompany the revised application. All amendments should be clearly highlighted in the revised application form and supporting documents. The application will be removed from the SBL RERC’s agenda if no feedback is received within 3 months.

The SBL RERC will issue an ethics clearance certificate for use in the final copy of the dissertation or thesis which is submitted for examination. Some journals request a certificate from a RERC as proof of obtaining ethical clearance. This certificate will be signed by the Chairperson and the CEO of the SBL.

If you have any questions about or require assistance with the completion of this form, please contact your supervisor (master’s or doctoral students).

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| **IF YOU ANSWER YES TO QUESTION a.1 OR a.2, PLEASE CONTINUE FILLING IN THIS FORM. IF ALL ANWERS ARE NO, SEND A LETTER NOTIFYING THE SBL RERC THAT YOUR STUDY DOES NOT REQUIRE FORMAL APPLICATION FOR EHTICS CLEARANCE WITH YOUR PROPOSAL FOR REVIEW.**  |
| 1. The proposed study involves human participants
 | **YES** | **NO** |
| a.1 Directly through the collection of primary data  |  |  |
| a.2 Both directly and indirectly through the secondary use of data (If secondary data is the main data source, please complete Form 4, Secondary Data Application) |  |  |
| 1. Collecting personal or confidential information
 |  |  |
| 1. UNISA employees, students or data
 |  |  |
| 1. Potential conflicts of interest (real or perceived) could arise during the course of the research
 |  |  |

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| *\*This section is needed for record keeping.* |  |
| DATE SUBMITTED TO URERC (\*for applicant use) |  |
| PREVIOUS APPLICATION NUMBER (\*for applicant use)*(Applicant to indicate a previously allocated application number in case of a resubmission if applicable)* | **Previous Application** **Number** | **Not applicable** |
|  |  |

***\*This section is for office use only.***

|  |  |
| --- | --- |
| APPLICATION NUMBER |  |
| DATE PROCESSED (submitted to reviewers) |  |
| RISK LEVEL *(low, medium or high)*  |  |
| TYPE OF REVIEW (expedited or full committee review) |  |
| AGENDA DATE*(For expedited transactions, the agenda date is the date the expedited approval gets reported or ratified at the convened ERC)* |  |
| DECISION OF SBL (approved, referred back, disapproved) |  |
| DATE OF ISSUING APPROVAL CERTIFICATE OR FEEDBACK LETTER |  |
| **PERIOD FOR WHICH APPROVAL IS VALID** **(\*Valid only as long as approved procedures are followed)** | **From: To:** |

**PRIVACY INFORMATION:**

The information you provide on this form is collected for the primary purpose of assessing your research ethics application. This information will also be entered into a database to assist with administration, correspondence, and statistical analyses. These records are accessed by the Unisa Research Ethics Review Ethics office bearers and members of committee. Records will be made available to authorised third parties should the need arise. All records are kept in a manner that will ensure confidentiality and secure indefinite storage after the expiry of the term of approval. Although this information is not usually disclosed to other individuals, there may be some circumstances that require the information to be disclosed.

**Contents of this application form**

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| **RESEARCHER’S DECLARATION TO ADHERE TO THE UNISA CODE OF CONDUCT REGARDING THE ETHICS OF THE PROPOSED RESEARCH** |

**The declaration should be signed in a separate document and provided to the URERC in a scanned format as part of the application package. PLEASE DO NOT PDF THE APPLICATION FORM BELOW TO ALLOW THE COMMITTEE TO OPEN ATTACHMENTS.**

**By signing below, I**        **(full name of the main researcher) I declare as follows:**

|  |  |  |
| --- | --- | --- |
| 1. I completed all the sections of this form that are relevant to the proposed research study.
 | [ ]  | Agree |
| 1. I have acquainted myself with UNISA’s code on research ethics expressed in the UNISA Policy on Research Ethics and the Standard Operating Procedure on Research Ethics Risk Assessment. I shall fully comply with it.
 | [ ]  | Agree |
| 1. I shall conduct the research in an ethically responsible way by demonstrating respect for participants’ autonomy, considering a fair risk-benefit analysis and employing fair research procedures.
 | [ ]  | Agree |
| 1. I shall conduct the research in strict accordance with the approved proposal. I acknowledge that the approval is valid as long as approved procedures are followed.
 | [ ]  | Agree |
| 1. I shall notify the URERC in writing of any adverse events that occur arising from harm experienced by participants.
 | [ ]  | Agree |
| 1. I shall notify the URERC in writing if any changes to the research are proposed that may affect any of the study-related risks for the research participants.
 | [ ]  | Agree |
| 1. I shall maintain participants’ privacy and the confidentiality of records pertaining to the research.
 | [ ]  | Agree |
| 1. I shall not use the research and information in a manner that is detrimental to human participants or institutions unless it can be scientifically justified.
 | [ ]  | Agree |
| 1. I shall store research data securely and in accordance with the data management measures indicated in my application/proposal.
 | [ ]  | Agree |
| 1. I shall uphold research integrity and refrain from conduct that may taint the integrity of science, including, but not limited to plagiarism, fabrication and falsification of data.
 | [ ]  | Agree |
| 1. I shall refrain from the use of human participant data that was collected without a valid research ethics approval for the purpose of this research.
 | [ ]  | Agree |
| 1. I shall take the necessary steps to warrant that co-researchers, if applicable, familiarise themselves with the Unisa Policy on Research Ethics.
 | [ ]  [ ]  | N/AAgree |

To my knowledge I have addressed all aspects in my application for research ethics approval set forth in the University of South Africa’s Policy for Research Ethics. I confirm that the form is complete.I will ensure that the student notify the committee in writing if any changes to the research are proposed that may affect the methodology and any of the study-related risks for the research participants.

Signing of declaration \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name in Print \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date signed\_\_\_ \_\_\_\_

Applicant (Principal Researcher)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Approved by supervisor (if applicable) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

To my knowledge the student has addressed all aspects in his/her application for research ethics approval set forth in the University of South Africa’s Policy for Research Ethics. I confirm that the form is complete.I will ensure that the student notify the committee in writing if any changes to the research are proposed that may affect the methodology and any of the study-related risks for the research participants. Subsequently, I approve the submission and recommend that approval is granted for the research.

Name in Print Signature Date signed

**Please complete the rest of the form below.**

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| **SECTION 1: RESEARCHER’S DETAILS**  |

*\*This section should be fully completed to aid with the issuing of the clearance certificate and for record keeping.*

|  |  |
| --- | --- |
| **1.1** | **Details of main researcher (referred to as the applicant)** |
| Title | Full name & Surname | Staff / student no | Department/Unit  | Contact numbers | Email address |
|  |  |  |  | Mobile:Work:

|  |
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 |  |
| Abridged CV of main researcher (Do not attach C.V) | Please insert an abridged CV that **explicitly** provides evidence of:* Experience relevant to the proposed research
* Qualifications relevant to the proposed research
* Publications and other research outputs
* Research Ethics Training done within the past three years
 |

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| **1.2** | **Supervisor if the application is made by a student** |
| Title | Full Name & Surname | Staff / student no | Department/Unit | Contact numbers | Email address |
|  |  |  |  | Mobile:Work: |  |
| Abridged CV of supervisor **(Do not attach C.V)** | Please insert an abridged CV that **explicitly** provides evidence of:* Experience relevant to the proposed research
* Qualifications relevant to the proposed research
* Publications and other research outputs
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| **1.3** | **Co-supervisor if the application is made by a student\*****\*** if applicable  |
| Title | Full Name & Surname | Staff / student no | Department/Unit | Contact numbers | Email |
|  |  |  |  | Mobile:Work: |  |
| Abridged CV of co-supervisor(Do not attach C.V) | Please insert an abridged CV that **explicitly** provides evidence of:* Experience relevant to the proposed research
* Qualifications relevant to the proposed research
* Publications and other research outputs
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| **1.4** | **Internal and/or External Co-Researcher(s) \*****\*** if applicable  |
| Title | Full Name & Surname | Affiliation/ Organisation | Contact numbers | Email |
|  |  |  | Mobile:Work: |  |
| Abridged CV of co-researcher(Do not attach C.V) | Please insert an abridged CV that **explicitly** provides evidence of:* Experience relevant to the proposed research
* Qualifications relevant to the proposed research
* Publications and other research outputs
 |

*\*Please provide information of additional researchers if applicable by inserting additional rows below*

|  |  |
| --- | --- |
| 1.5  | Title or provisional title of the research project *10 - 16 words* |
|  |
| 1.6 | Type of application (more than one option may apply)*Place an ‘x’ in the box [provide details in the space allocated for comments if applicable]*  |
| Research for non-degree purpose (journal articles; conference presentations, etc.) |  |
| Research for degree purpose |  | Identify the proposed qualification for the project (in the case of research for degree purpose) |
| Collaborative research |  | Community Engaged Research (CER) |  |
|  Other |  |  |  |
| Comments:Justify why you deem this a CE research project OR collaborative research project OR identify the primary reason for conducting the research if you ticked “Other”. |

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| **1.7** | **Identify the data collection procedures that apply to this research**  | **YES** | **NO** |
| *Place an ‘x ‘in the box provided*  |
| a) Survey/questionnaire  |  |  |
| b) Focus groups |  |  |
| c) Observations |  |  |
| d) Interviews |  |  |
| e) Documents |  |  |
| f) Other. Please provide details. |  |  |

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| SECTION 2 – RISK ASSESSMENT |

Complete the Research Ethics Risk Assessment by answering each question below. If you answer **“YES”** to any of the items, the outcome of the risk assessment is considered to vary from a low to high risk level. The UNISA research ethics review system is based on the UNISA Standard Operating Procedure (SOP) for Research Ethics Risk Assessment. If you are unsure about the meaning of any of these concepts, please consult your supervisor or project leader.

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| **2.1** | **Does your research include the direct involvement of any of the following groups of participants**  | **YES** | **NO** |
| *Place an ‘x’ in box [if yes, provide details in the space allocated for comments]*  |
| a) Children or young people under the age of 18 Include the parental consent letter and explain how assent will be obtained in section 6.1 of the application form. |  |  |
| b) Persons living with disabilities *(physical, mental and/or sensory)* |  |  |
| c) Persons that might be considered vulnerable, thus finding it difficult to make independent and/or informed decisions for socio, economic, cultural, political and/or medical reasons *(such as the elderly, the dying, unconscious patients, prisoners, those in dependant relationships, women considered to be vulnerable due to pregnancy, victimisation, etc.)* |  |  |
| d) Communities that might be considered vulnerable, thus finding it difficult to make independent and informed decisions for socio, economic, cultural, political and/or medical reasons |  |  |
| e) UNISA employees, students or alumniIndicate that you will apply for permission at the UNISA Research Permission Subcommittee (RPCS) in section 3.1 of the application form to involve any of these participant groups in the proposed research. |  |  |
| f) Persons whose native language differs from the language used for the researchAttach the translated data collection instrument(s), interview guide(s), participant information sheet and consent form in the participants’ first language, as well as a letter from the language practitioner certifying the credibility of the translated material. The services of an interpreter may need to be secured for field work activities.  |  |  |
| g) There is a likelihood that a person or definable group will be identified during the research process and it is likely to be of concern. |  |  |
| h) Other. Please describe. |  |  |
| Comments: If you selected any option above, please describe it in detail here.  |

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| **2.2** | **Does your research involve any of the following types of activity that could potentially place the participants at risk of harm?** | **YES** | **NO** |
| *Place an ‘x’ in the box provided [if yes, provide details in the space allocated for comments]* |
| a) Collection, use or disclosure of personal, identifiable information without the consent of the individual or institution that is in possession of the required information (with the exception of aggregated data or data from official databases in the public domain) |  |  |
| b) Collection, use or disclosure of personal, identifiable information directly from participants with consent |  |  |
| c) Personal, identifiable information to be collected about individuals from available records (e.g. employee records, student records, medical records, etc.) and/or archives |  |  |
| b) Participants being exposed to questions which may be experienced as stressful or upsetting, or to procedures which may have unpleasant or harmful side effects |  |  |
| e) Participants being required to commit an act which might diminish self-respect or cause them to experience shame, embarrassment, or regret |  |  |
| f) Any form of deception of participants, concealment or covert observation |  |  |
| d) Examining potentially sensitive or contentious issues that could cause harm to the participants |  |  |
| g) Research which may be prejudicial to participants |  |  |
| f) Research which may intrude on the rights of third parties or people not directly involved |  |  |
| f) Audio-visual recordings of participants which may be of a sensitive or compromising nature (with or without consent) |  |  |
| g) Disclosure of the findings of the research could place participants at risk of criminal or civil liability or be damaging to their financial standing, employability, professional or personal relationships |  |  |
| h) Any form of physically invasive diagnostic, therapeutic or medical procedure such as blood collection, an exercise regime, body measurements or physical examination |  |  |
| k)\*Psychological inventories / scales / tests |  |  |
| q) Other. Please describe |  |  |
| Comments: If you selected any option above, please describe it in detail here. |

*\*Please add details on copyright issues related to standardised psychometric tests and registration at the HPSCA of test administrator if test administration is in South Africa or of an equivalent board if administration is non South African.*

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| **2.3** | **Does your research involve any activity that could potentially place the researcher(s) at risk of harm?** | **YES** | **NO** |
| a) There is a possible risk of physical threat, abuse or psychological trauma as a result of actual or threatened violence or the nature of what is disclosed during the interaction |  |  |
| b) There is a possible risk of being in a compromising situation, in which there might be accusations of improper behaviour |  |  |
| c) There is an increased exposure to risks in everyday life and social interactions, such as working with hazardous materials or sensitive information |  |  |
| Comments:  | If you selected any option above, please describe it in detail here. |

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| **2.4** | **Does any of the following apply to your research project?** | YES | NO |
| *Place an ‘ x’ in the box provided [if yes, provide details in the space allocated for comments]* |
| a) Participants will be offered inducements or incentives to encourage their involvement in the research |  |  |
| b) Participants will incur financial obligations as a result of their participation in the research |  |  |
| c) The researcher(s) can anticipate financial gains from involvement in the research (i.e. contract research) |  |  |
| d) Any other potential conflict of interests, real or perceived, that could be seen as compromising the researcher(s) professional judgement in carrying out or reporting on the research |  |  |
| e) Research will make use of Unisa laboratories |  |  |
| f) Research will be funded by UNISA or by an external funding body that could compromise the integrity of the research project |  |  |
| Comments: If you selected any option above, please describe it in detail here. |

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| **2.5**  | **Guided by the information above, classify your research project based on the anticipated degree of risk. *[The researcher completes this section. The ERC critically evaluates this benefit-risk analysis to protect participants’ rights]****Place an ‘x’ in the box provided* |
| **Category 1****Negligible**No to indirect human participant involvement. If you choose this option, stop completing this form and contact URERC@unisa.ac.za |  | **Category 2****Low risk**Direct human participant involvement. The only foreseeable risk of harm is the potential for minor discomfort or inconvenience, thus research that would not pose a risk above the everyday norm. |  | **Category 3****Medium risk** Direct human participant involvement. Research that poses a risk above the everyday norm, including physical, psychological and social risks. Steps can be taken to minimise the likelihood of the event occurring. |  | **Category 4****High risk**Direct human participant involvement.A real or foreseeable risk of harm including physical, psychological and social risk which may lead to a serious adverse event if not managed responsibly. |  |
| 1. Briefly justify your choice/classification

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| 1. In medium and high risk research, indicate the potential benefits of the study for the research participants and/or other entities.
 |
| 1. In medium and high risk research, indicate how the potential risks of harm will be mitigated by explaining the steps that will be taken to minimise the likelihood of the event occurring (e.g. referral for counselling, debriefing, etc.).
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| **SECTION 3 – DETAILS OF PROPOSED RESEARCH** |
| **3.1**  | **Does your project involve institutions that need to grant permission for research activities?** **(If the number of institutions to be consulted is less than 5, then permission must be provided with this application.****If the number of institutions is more than 5 then a pro-forma letter for the request of permission and list of institutions to be consulted must accompany this application** |
| *Place an ‘x’ in the box provided* |
| 3.1.1 | **NO** |
| 3.1.2 | **YES** (Generally, permission to conduct research involving institutions should be obtained prior to field work activities. Provide URERC with a copy of the pro-forma letter if the permission is pending. Alternatively, the signed permission letters should be attached if permission has already been obtained. In case of research involving UNISA employees, students and data, the application form and standard operating procedure can be obtained from RPSC@unisa.ac.za Application for permission to involve UNISA employees, students and data should be obtained subsequent to ethics clearance. |
| 1. Name of organisation (i.e. UNISA)
 | 1. Name of person or committee granting permission & contact details (i.e. Research Permission Subcommittee, RPSC@unisa.ac.za)
 | 1. Their role in the organisation (i.e. mandated to provide institutional research permissions)
 | 1. Has permission been granted and is the signed/pro-forma letter attached?

*Place an ‘x’ in the box provided* |
| **YES** | **NO**  | **Pending** |
|  |  |  |  |  |  |

*Please copy, paste and complete table for additional institutions.*

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| 3.2 | Are any of the researcher’s members of, or do they have any association with the organisations in which you wish to conduct your research?  |
| 3.2.1 | **NO** |
| 3.2.2 | **YES** (Please explain the association clearly in the comment section below)(please ensure that there is a permission letter from the respective organisations granting permission) |
| Comments: |

 *Place an ‘x’ in the box provided*

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| 3.3 | **Does your research involve collectives and / or communities?** (Group of people sharing social ties, similar interests and a geographic location) |
|  | **NO** |
|  | **YES** (Please explain what measures you have taken to consult and engage with those communities and / or representative groups regarding your research project.) |
| Explanation if applicable: |
| **3.4** | **Is your project funded or sponsored by any organisation?** |
|  | **NO** |
|  | **YES** (Please complete table below) |
|  | Name of organisation | Name of contact person and contact details | Their role in the organisation | Funding amount  |
|  |  |  |  |  |
| **3.5** | **Describe your arrangements regarding indemnity/compensation for research-related adverse events (if applicable).** |
|  |
| **3.6** | **Has this proposal been submitted to another ethics review committee?** If yes, indicate the name of the institution and the outcome. If previously rejected, provide the reasons. |
| \*Insert proof of ethics clearance here |
| **3.7** | Is this research a sub-study linked to an existing or main study? *Place an ‘x’ in the box provided* |
|  | **NO** |
|  | **YES** (Please provide details relevant to the existing or main study in the comments section below) |
| **Comments** |  |

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| **SECTION 4 – PROPOSAL SUMMARY SHEET** |

*\*Proposal to be submitted in case of postgraduate student applications, as well as evidence of proposal acceptance by a relevant scientific committee.*

*(\*Insert copy of the proposal and the letter of proposal acceptance here)*

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| **4.1** | **Introduction, motivation and literature review** *One page (provide a well referenced scientific justification to the study)*  |
|  |
| **4.2** | **Research Questions / Hypotheses** |
|  |
| **4.3** | **Aims and Objectives** |
|  |

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| **4.4** | **Research Paradigm** *Place x in applicable box* |
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|  |  |
| --- | --- |
| 1. **Quantitative**
 |  |
| 1. **Qualitative**
 |  |
| 1. **Mixed methods**

  |  |
| 1. **Other**
 |

Substantiate your choice of paradigm: |

|  |  |
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| 4.5 | Research Design / Approach / Procedures*Name & describe the research design you intend to use, e.g. descriptive correlation, case study, grounded theory, etc. If your research will proceed in different phases, describe each phase sequentially.* |
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| 4.6 | Details of the participants of the proposed research project *\*Add additional rows if more than one sampling group is used* |

|  |  |
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| **4.6.1** | **Describe the participants (in groups) involved in your research project, including the site population, site population size and age category.** |
|  | Identify the participant groups’ targeted for the research | Site population size*(How many individuals known to have similar characteristics?)* | Age category of group |
| Group 1\* |   |  |  |
| Group 2\* |  |  |  |
| **4.6.2** | **Explain step by step how you will select participants in each group** *(sampling method, predicted sample size and justification for the sample size).* |
|  | Sampling method | Sample size | Justify sample size |
| Group 1\* |  |  |  |
| Group 2\* |  |  |  |

|  |  |
| --- | --- |
| 4.6.3 | Please specify the inclusion criteria for each participant group. |
| Group 1\* |  |
| Group 2\* |  |

|  |  |
| --- | --- |
| 4.6.4 | Please specify the exclusion criteria for each participant group. |
| Group 1\* |  |
| Group 2\* |  |

|  |  |
| --- | --- |
| **4.6.5** | **Describe how much time you require of participants in each group and when the data will** **be collected/ interviews will take place.** |
|  | Time required | When will data be collected? |
| Group 1\* |  |  |
| Group 2\* |  |  |

|  |  |
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| 4.6.6 | Explain how you will obtain the contact details of participants AND provide step-by-step details of how you will recruit them to participate.If from a public domain source – please identify the source. If from a previously approved database – please confirm how consent will be obtained. Attach consent as an appendix to the application if you are in possession of it. |
| Group 1\* |   |
| Group 2\* |  |

|  |  |
| --- | --- |
| 4.6.7 | Will any dependent or unequal relationship exist between anyone involved in the recruitment and the participants? *Place an ‘x’ in box provided* |
|  | NO |
|  | **YES**  |
| Explain if applicable and how will it be managed.  |

|  |  |
| --- | --- |
| **4.7** | **Collection of data material and procedures** |
| **Indicate which data collection methods will be used.** *Place an ‘x’ in the box provided* |
| 4.7.1 **(a) Questionnaire/survey**

|  |  |
| --- | --- |
| **YES** |  |
| **NO**  |  |

|  |  |
| --- | --- |
| 1. Self-designed
 |  |
| 1. “Borrowed”
 |  |
| 1. Adapted
 |  |

|  |  |
| --- | --- |
| 1. Fully identifiable (name on it) or using a consent form
 |  |
| 1. Potentially identifiable (coded)
 |  |
| 1. Anonymous (can never be identified)
 |  |

 |

|  |
| --- |
| 1. Questionnaire(s)/ survey(s)
 |
| Insert questionnaire or survey here |

|  |  |  |
| --- | --- | --- |
| 1. If the questionnaire is borrowed, was approval granted by the developers?
 | Yes  | No  |
| Insert proof of approval here |
| 1. If not, justify why:
 |

 |
| 1. **Explain how the data collection instrument will be administered?**
 |
| 1. **Please specify how the survey will be returned to you.**
 |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 4.7.2 **(a)** **Interviews**

|  |  |
| --- | --- |
| **YES** |  |
| **NO**  |  |

|  |  |
| --- | --- |
| 1. In-depth
 |  |
| 1. Semi-structured
 |  |
| 1. Unstructured
 |  |

|  |  |
| --- | --- |
| 1. Audio taped
 |  |
| 1. Video taped
 |  |

 |

|  |  |
| --- | --- |
| 1. Interview questions/ list of topics attached as addendum to application

\* Insert here |  |

|  |
| --- |
| 1. If a central research question will be asked, state the exact question below
 |
|  |

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| --- | --- | --- | --- | --- | --- |
| 4.7.3 **(a) Focus groups**

|  |  |
| --- | --- |
| **YES** |  |
| **NO**  |  |

 | (i) Focus group questions/ list of topics attached as addendum to application \* Insert here(ii) Confidentiality cannot be guaranteed in a group setting.  |
| 4.7.4 **Other**

|  |  |
| --- | --- |
| **YES** |  |
| **NO**  |  |

 | (ii) Identify, briefly describe each data collection method and insert data collection tools\* Insert here |

|  |  |
| --- | --- |
| **4.8** | What is the nature of the data that will be collected? (e.g. personal information including all identifying information stipulated by the Protection of Private Information Act, no. 4 of 2013) |
|  |

|  |  |
| --- | --- |
| **4.9** | Where will the data be collected? If not known, please provide suggested locations. |
|  |

|  |  |
| --- | --- |
| **4.10** | **By whom will the data be collected? (Researcher and/or field workers)?** Explain any measures that you will take to prepare yourself or field workers to optimise data collection activities. Field workers should sign a confidentiality agreement form if applicable. |
| \* Insert confidentially agreement here |

|  |  |
| --- | --- |
| **4.11** | **Will participants be subjected to any form of intervention (manipulation of the participant or the participants’ environment)?** *Place an ‘x’ in the box provided* |
|  | **NO** |  | **YES**  |
| Please explain the intervention in full. |

|  |  |
| --- | --- |
| **4.12** | **Does the research involve participants who have specific cultural needs, i.e. specific consent arrangements or sensitivities?** *Place an ‘x’ in the box provided* |
|  | **NO** |  | **YES** *Place x in box* |
| Please explain the intervention in full. |

|  |  |
| --- | --- |
| **4.13** | **Will you require the use of a translator or will you use documentation translated into a language other than English?** *Place an ‘x’ in the box provided* |
|  | **NO** |  | **YES** *Place x in box* |
| Please describe how the translator will be used. If using translated documents, please provide a copy of the documentation in English and a certified copy of the translation. Indicate what measures will be used to prevent meaning “being lost in translation”. |

|  |  |
| --- | --- |
| **4.14** | **Is there a dependent or unequal relationship between any person collecting the data (e.g. researcher) and the participant?** *Place an ‘x’ in the box provided* |
|  | **NO** |  | **YES**  |
| Please give details and explain the measures taken to manage this situation. |
| **4.15** | **Does your research project involve the collection and analysis of documents or secondary data?***Place an ‘x’ in the box provided*

|  |  |
| --- | --- |
| **YES**  | **NO** |

**Please explain the sampling method of the relevant categories of documents and the predicted sample size, followed by a justification for sample size.**  |
|  | Sampling method | Sample size | Justify sample size |
| Group 1\* |  |
| Describe the conditions under which the data was collected initially and the reasons why it was collected. If applicable, describe the number of participants and demographics applicable to the secondary data analysis. |
| Was ethical clearance granted for the original data gathering phase by this or by another research ethics committee if appropriate? |

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| **SECTION 5: DATA MANAGEMENT, ANALYSIS AND DESIGN QUALITY** |

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| --- | --- |
| **5.1** | **Describe the data analysis method that you will use (qualitative data analysis method or quantitative statistical procedures).** |
|  |
| **5.2** | **Provide the contact details of the statistician or/and external coder that you will use** (if applicable) 1. Statistician
2. Transcriber
3. External coder
 |
|   |

|  |  |
| --- | --- |
| 5.3 | For a quantitative study or phase of your research, provide a brief description of the measures YOU WILL TAKE with regard to your study to ensure validity and reliability, taking into account: (Please ensure you describe the activities)  |
| 1. Internal and External validity of the research design
2. Validity and Reliability of data gathering instrument
 |

|  |  |
| --- | --- |
| 5.4 | For a qualitative study or phase of your research, provide a brief description of the measures YOU WILL TAKE with regard to your study to ensure trustworthiness and/or authenticity, for instance taking into account: (Please ensure you describe the activities)  |
| 1. Credibility
2. Dependability
3. Conformability
4. Transferability
5. Authenticity
 |

|  |  |
| --- | --- |
| **5.5** | **References** |
|  |
| **5.6** | **Indicate the timeline** *(\*Insert additional rows if necessary)* |
|

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| --- | --- |
| **Research activities**  | **Expected target data** |
|  |  |
|  |  |
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| **5.8** | **Indicate the budget** *(\*Insert additional rows if necessary)* |
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| **Research activities** | **Expected cost** |
|  |  |

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| SECTION 6: ETHICAL CONSIDERATIONS |

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| **6.1** | **Description of the process of obtaining Informed Consent** |
|  Insert the information sheet and informed consent document(s) hereInsert evidence of gatekeeper permission obtained here. |

*[\*If other, provide details in the space allowed for comments]*

|  |  |
| --- | --- |
| **6.2** | **Measures taken to protect confidentiality:**  |
| 6.2.1 | Paper-based records must be kept in a secure location and should only be accessible to personnel involved in the study. **Please indicate who will have access to the data and where will it be retained.** |
|  |
| 6.2.2 | Computer-based records must only be available to personnel involved in the study through the use of access privileges and passwords. **Please indicate who will have access to the computer-based records.** |
|  |
| 6.2.3 | Personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable information. **Please indicate who will be required to sign confidentiality agreements and append the agreements to the application.** |
|  |
| 6.2.4 | *Place an ‘x’ in the box provided* |
|  | Personal identifiers will be removed from research-related information |  |
|  | Encryption |  |
|  | Use of pseudonyms |  |
|  | Participants in focus groups will be advised that confidentiality cannot be assured |  |
| Comments: |

|  |  |
| --- | --- |
| 6.3 | Data Storage and Procedures for Disposal of the data |
| 6.3.1 | For what period of time will the data be retained? The Unisa Policy on Research Ethics stipulate that data should be retained for a minimum period of 5 years. Please note that this time period presents a minimum standard. |
|  |
| 6.3.2 | What reasonable steps will be taken to dispose of or permanently de-identify personal information if it is no longer needed for the purpose of research? |
|  |

|  |  |
| --- | --- |
| **6.4** | **What are the anticipated benefits of the study (participants, community and/or broader society)?** |
|  |

|  |  |
| --- | --- |
| **6.5** | **Description of the risks of the procedures which participants may or will suffer as well as the level of risk.** *(Please indicate any participant discomfort, pain/physical or psychological problems/side-effects, persecution, stigmatisation or negative labelling that could arise during the course or as an outcome of the research undertaken).* |
|  |

|  |  |
| --- | --- |
| **6.6** | **Description of steps to be taken in the case of adverse events or if injury or harm attributable to participation in the study is experienced by the participants.** |
|  |

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| --- | --- |
| **6.7** | **Description of anticipated community participation in the study** |
|  |

|  |  |
| --- | --- |
| **6.8** | **Description of possible adverse effects on the community, including steps to be taken in the case of adverse effects, as well as the level of anticipated risk.** |
|  |

|  |  |  |  |
| --- | --- | --- | --- |
| **6.9** | **Checklist to ensure that the participant information sheet and consent form meet ethical requirements** *The participant information sheet ought to explain all criteria stipulated below, with the exception of (l) and (r) that may only apply to specific studies****. Standard participant information sheets and consent forms are available on the research website or can be requested from URERC@unisa.ac.za*** | **YES** | **NO** |
| *Place an ‘x’ in the box provided* |
| a) The identity and position of the researcher(s) and the organisation collecting the information? |  |  |
| b) The purposes for which the information is being collected? |  |  |
| c) Reason why the participant has been selected and procedures for selecting participants? |  |  |
| d) Participant’s actual role in the study? |  |  |
| e) Expected duration of participation? |  |  |
| f) Statement that participation is voluntary and that there is no penalty or loss of benefit for non-participation? |  |  |
| g) Benefits to the participant and others? |  |  |
| h) Potential risks as well as measures that will be taken if injury or harm attributable to the study occurs? |  |  |
| i) Statement that participant can withdraw at any time without obligation to explain or any adverse effects? |  |  |
| j) Compensation/gifts/services for participants? |  |  |
| k) Reimbursement and any costs incurred by participants? |  |  |
| l) Indemnity if applicable? |  |  |
| m) The period for which the records relating to the participant will be kept? |  |  |
| n) The steps taken to ensure confidentiality and secure storage of data? |  |  |
| o) The types of individual or organisation to which your organisation usually discloses information of this kind? |  |  |
| p) How privacy will be protected in any publication of the information? |  |  |
| q) How feedback will be provided? |  |  |
| r) Any exclusion to confidentiality? (e.g. when focus groups are used) |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **6.10** | **Checklist to ensure that the process of obtaining assent meets ethical requirements (IF APPLICABLE).** | **YES** | **NO** |
|

|  |  |
| --- | --- |
| *Not applicable* |  |

*Place an ‘x’ in the box provided* |
| a) A statement of the purpose of the research or study? |  |  |
| b) A description of the procedure to be applied in dealings with the minor? |  |  |
| c) A statement that the minor’s identity will not be revealed? |  |  |
| d) A description of the potential risks or discomfort associated with the research? |  |  |
| e) A description of any direct benefits to the minor? |  |  |
| f) A statement that the minor is not compelled to participate? |  |  |
| g) A statement that the minor is free to withdraw at any time? |  |  |
| h) A statement that the minor should discuss participation with the parents prior to signing the form? |  |  |
| i) A statement that the parent(s)/guardian(s) of the minor will be asked for permission on behalf of the minor? |  |  |
| j) A statement that the parent(s)/guardian(s) of the minor will receive a copy of the signed form? |  |  |
| k) Invitation to ask questions? |  |  |
| l) Contact details of researcher? |  |  |
| Note that only the minor and the researcher obtaining assent should sign the child assent form. A copy of the child assent form should be given to the parent or legal guardian. |

|  |  |
| --- | --- |
| **6.11** | **How will participants be informed of the findings or results and consulted on potential or actual benefits of such findings or results to them or others?** (Copy of journal article, book, chapter, summary report to organisation, on-line web based, oral presentation, other)  |
|  |

|  |  |
| --- | --- |
| **6.12** | **Description of participants’ access to products developed from the study and how the benefits from products developed may be shared in case of collaborative projects.** |
|  |

|  |  |
| --- | --- |
| **6.13** | **Indicate how you envisage publishing this research.**(thesis, journal article, book, chapter, on-line web based, oral presentation, other) |
|  |

|  |  |
| --- | --- |
| **6.14** | **Describe the nature and amount of compensation including reimbursements, gifts, services or incentives to be provided to each group of participants.** (if applicable) |
|  |
| **6.15** | **Describe any financial costs that might be incurred by participants.**(if applicable) |
|  |
|  |

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Checklist of Documents** | **YES** | **NO** |
|

|  |  |
| --- | --- |
| *Not applicable* |  |

*Place an ‘x’ in the box provided* |
| a) Proof of current registration  |  |  |
| b) Proposal |  |  |
| c) Questionnaire/Interview questions |  |  |
| d)Information Sheet |  |  |
| e) Informed Consent |  |  |
| f) Permission letter from the organisation where the research will be conducted, the letter must be on a letterhead of that particular company and the position of the person granting permission must be clearly stated. The letter must be signed |  |  |
| g)Colloquium letter( for DBL students) |  |  |

**🙦 🙦 🙦 🙦**