Professional Research Committee (PRC) Research Ethics Work Group (REW)

|  |
| --- |
| **FORM 1: 2017**  **RESEARCH ETHICS APPLICATION FORM FOR UNISA PROFESSIONAL AND ADMINISTRATIVE RESEARCHERS FOR CONDUCTING RESEARCH** |

If you have any questions about or require assistance with the completion of this form, please contact the Research Ethics Administrator of the PRC\_REW (PARC@unisa.ac.za), or the Chair, Dr M Molapo (molapmp@unisa.ac.za)

|  |  |  |
| --- | --- | --- |
| **IF YOU ANSWER YES TO QUESTION a.1 OR a.2, PLEASE CONTINUE FILLING IN THIS FORM. IF ALL ANWERS ARE NO, CONTACT** [**PARC@unisa.ac.za**](mailto:PARC@unisa.ac.za) | | |
| 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 2, 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 |  |  |

**NOTE:** For research that involves direct human participant involvement or a combination of direct human participant involvement and the collection of secondary information, continue completing **Form 1.**

For research involving secondary data/information only (with exception of aggregated data of employees, students or institution), complete **Form 2.**

For research that involves NO human participant involvement, complete **Form 3.**

|  |  |  |
| --- | --- | --- |
| **For applicant use**  ***\*This section is needed for record keeping.*** |  | |
| **DATE SUBMITTED TO PRC\_REW** |  | |
| **PREVIOUS APPLICATION NUMBER**  *(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 PRC REW (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)** |  |

**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’s Professional Research Committee\_ Research Ethics Workgroup’s office bearers and members of the workgroup. 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.

|  |  |
| --- | --- |
| **TABLE OF CONTENTS** | **Page** |
| **RESEARCHER’S DECLARATION** | **2** |
| **SECTION 1: RESEARCHER(S) DETAILS** | **4** |
| **SECTION 2: RISK ASSESSMENT** | **5** |
| **SECTION 3: DETAILS OF PROPOSED RESEARCH** | **9** |
| **SECTION 4: PROPOSAL SUMMARY SHEET** | **11** |
| **SECTION 5: DATA MANAGEMENT, ANALYSIS AND DESIGN QUALITY** | **15** |
| **SECTION 6: ETHICAL CONSIDERATIONS** | **16** |

|  |
| --- |
| **PRINCIPAL 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 PARC 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 principal researcher) 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 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 PRC\_REW in writing if any changes to the research are proposed that may affect any of the study-related risks for the research. |  | Agree |
| 1. I shall maintain 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 individuals 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 (retrospective use of participant data). |  | 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/A  Agree |

Signature of principal researcher \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date signed \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

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

***\*FULL INFORMATION REQUIRED FOR cERTIFICATE issuing***

|  |  |
| --- | --- |
| **1.1** | **Details of main researcher (referred to as the applicant).** |
| Title |  |
| Full Name |  |
| Staff No |  |
| Department/Unit |  |
| Contact number | Work no Mobile no |
| Email address |  |
| Abridged CV of main researcher  (Attach an abridged CV relevant to the proposed research here) | Please insert an abridged CV with the following information:   * Experience relevant to the proposed research * Qualifications relevant to the proposed research * Publications and other research outputs |

|  |  |
| --- | --- |
| **1.2** | **Internal and/or External Co-Researcher(s) \***  **\*** if applicable |
| Title |  |
| Full Name |  |
| Staff no |  |
| Department/Unit |  |
| Contact numbers | Work no Mobile no |
| Email address |  |
| Abridged CV of co-supervisor  (Attach an abridged CV relevant to the proposed research here) | Please insert an abridged CV with the following information:   * 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***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1.3 | Title or provisional title of the research project  *10 - 16 words* | | | |
|  | | | | |
| 1.4 | Type of application (more than one option may apply)  *Place x in box [if other, provide details in the space allowed for comments]* | | | |
| Staff application for non-degree purpose (journal articles; conference presentations etc.) | |  | Collaborative research |  |
| Research and Development (R&D) Leave | |  | Community Engaged Research |  |
| Other | | | |  |
| **Justify why you deem this a Community Engaged research project OR collaborative research project:**  N/A | | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **1.5** | **Stipulate clearly which aspects of the proposed research need ethics clearance.** | **YES** | **NO** |
| *Place ‘x’ in box* | | | |
| a) Survey/questionnaire | |  |  |
| b) Focus groups | |  |  |
| c) Observations | |  |  |
| d) Interviews | |  |  |
| e) Documents | |  |  |
| f) Other. Please provide details. | |  |  |

|  |
| --- |
| 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. Applicants can click on this [link](http://staffcmsys.unisa.ac.za/cmsys/staff/contents/departments/research/docs/SOP_Risk%20assessment_approved%20by%20SRIHDC%20on%204%20June%202015.doc) to obtain the document. If you are unsure about the meaning of any of these concepts, please consult the chairperson of the PRC\_ REW.

|  |  |  |  |
| --- | --- | --- | --- |
| **2.1** | **Does your research include the direct involvement of any of the following groups of participants *(Refer to Section 4 in the SOP)*** | **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)*[[1]](#footnote-1) | |  |  |
| 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 alumni  Indicate 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 research  Attach 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[[2]](#footnote-2). Please describe. | |  |  |
| Comments: If you selected any option above, please describe it in detail here. | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **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.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **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. | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **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. | | | |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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  |  | | --- | |  | | | | | | | | | |
| 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.). | | | | | | | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **SECTION 3 – DETAILS OF PROPOSED RESEARCH** | | | | | | |
| **3.1** | **Does your project involve organisations or institutions that need to grant permission for research activities?** | | | | | | |
| *Place ‘x’ in box* | | | | | | | |
|  | **NO** | | | | | | |
|  | **YES** (You are required to seek approval from each organisation and provide PRC\_REW with a copy of the letter seeking permission at specified organisation). | | | | | | |
| Name of organisation | | Name of person granting permission & contact details | Their role in the organisation | Has permission been granted and is letter attached?  *Place x in appropriate box* | | | |
| **YES** | **NO** | **Pending** | |
|  | |  |  |  |  |  | |

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

|  |  |
| --- | --- |
| 3.2 | Are any of the Researchers members of or do they have any association with, any of the organisations in which you wish to conduct your research? |
|  | NO |
|  | YES |
| *Please explain the association clearly in the space provided below.* | |

*Place ‘x’ in box provided*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 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?** *Place ‘x’ in box* | | | | | |
|  | | **NO** | | | | | |
|  | | **YES**  Please complete table below and attach signed contractual agreement documents. | | | | | |
|  | | 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).** | | | | | |
| Comment: | | | | | | | |
| **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** | | | | | |

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

*\*Proposal to be submitted, optionally*

|  |  |  |
| --- | --- | --- |
| **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** |
|  | | |

|  |  |
| --- | --- |
| **4.4** | **Research Paradigm** *Place ‘x’ in applicable box* |
| |  |  | | --- | --- | | 1. **Quantitative** |  | | 1. **Qualitative** |  | | 1. **Mixed methods** |  | | 1. **Other** | |   **4.4.1 Substantiate your choice of paradigm:** | |

|  |  |
| --- | --- |
| **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.* |
|  | |

|  |  |
| --- | --- |
| **4.6** | **Details of the participants of the proposed research project**  *\*Add additional rows if more than one sampling group is used* |

|  |  |  |  |
| --- | --- | --- | --- |
| **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\* |  |  |

|  |  |
| --- | --- |
| **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. | |

|  |  |  |
| --- | --- | --- |
| **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 | |  | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 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. | | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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? | | | | | |

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

|  |  |
| --- | --- |
| **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 external coder that you will use** (if applicable) |
|  | |

|  |  |
| --- | --- |
| 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: |
| 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: |
| 1. Credibility 2. Dependability 3. Conformability 4. Transferability 5. Authenticity | |

|  |  |  |
| --- | --- | --- |
| **5.5** | | **References** |
|  | | |
| **5.6** | **Indicate the timeline** *(\*Insert additional rows if necessary)* | |
| |  |  | | --- | --- | | **Research activities** | **Expected target data** | |  |  | |  |  | |  |  | |  |  | | | |
| **5.8** | **Indicate the budget** *(\*Insert additional rows if necessary)* | |
| |  |  | | --- | --- | | **Research activities** | **Expected cost** | |  |  | | | |

|  |
| --- |
| SECTION 6: ETHICAL CONSIDERATIONS |

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

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

|  |  |  |
| --- | --- | --- |
| **6.2** | **Measures taken to protect confidentiality:**  *(adapted from University of Cape Town, research ethics application)* | |
| 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.** |
|  | |

|  |  |
| --- | --- |
| **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) |
|  | |

**PLEASE REMEMBER TO COMPLETE AND APPEND THE CHECKLIST TO YOUR APPLICATION**

**🙦 🙦 🙦 🙦**

1. Describe whether and how proxy or gatekeeper consent will be obtained in section 6.1 relevant to items 2.1. a – e [↑](#footnote-ref-1)
2. Form 1 does not apply to plant, molecular or cell research, animal and environmentally related research. [↑](#footnote-ref-2)