University of South Africa

|  |
| --- |
| FORM 1: 2021Research 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 2. |

If you have any questions about or require assistance with the completion of this form, please contact your supervisor (master’s or doctoral students), or the Research Ethics Administrator of the UNISA-CAES Health Research Ethics Committee (011-471-2862 or vwykmj@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** **vwykmj@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
 |  |  |

|  |  |
| --- | --- |
| *\*This section is needed for record keeping.* |  |
| DATE SUBMITTED TO ERC (\*for applicant use) |  |
| PREVIOUS APPLICATION NUMBER (\*for applicant use if applicable)*(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 ERC (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:** |

**Contents of this application form**

|  |  |
| --- | --- |
| **ITEM** | **PAGE NO** |
| **RESEARCHER’S DECLARATION** | **3-4** |
| **SECTION 1 – RESEARCHER(S) DETAILS**  | **5-7** |
| **SECTION 2 – RISK ASSESSMENT**  | **7-12** |
| **SECTION 3 – DETAILS OF PROPOSED RESEARCH** | **12-13** |
| **SECTION 4 – PROPOSAL SUMMARY SHEET**  | **13-18** |
| **SECTION 5 – DATA MANAGEMENT, ANALYSIS AND DESIGN QUALITY** | **18-19** |
| **SECTION 6 – ETHICAL CONSIDERATIONS** | **20-23** |
| **APPENDIX 1 – CHECKLIST (SEPARATE DOCUMENT)** |  |

|  |
| --- |
| **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 ERC 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) declare as follows:**

\*Double click on text box selected

|  |  |  |
| --- | --- | --- |
| 1. I completed all the sections of this form that are relevant to the proposed research study according to Appendix A.
 | [ ]  | Agree |
| 1. I have not commenced with fieldwork relating to any data collection in relation to the proposed research.
 | [ ]  | 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 ERC in writing of any adverse events that occur arising from harm experienced by participants.
 | [ ]  | Agree |
| 1. I shall notify the ERC in writing if any changes to the research are proposed that may affect any of the study-related risks for the research participants (e.g. methodology, sampling, questionnaire, interview schedule).
 | [ ]  | 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 and ethically 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 |
| 1. I accept the privacy information statement set out on page 2.
 | [ ]  | Agree |

**Applicant: Principal Researcher**

**CONSENT IN TERMS OF THE PROTECTION OF PERSONAL INFORMATION ACT NO 4. OF 2013**

1. I declare that all the information furnished by me on this form is true and correct and undertake to inform Unisa of any changes in my personal information.

2. I undertake to comply with all the rules, regulations and decisions of the university and any amendments to it and I have taken note of advice which may be applicable to Unisa researchers, non-Unisa researchers and postgraduate supervisors.

3. I, as a researcher and/or postgraduate supervisor, hereby consent that Unisa may collect, use, distribute, process and communicate my personal information for all required research ethics processes about my participation in Unisa research ethics activities, which may include, but is not limited to:

3.1 assessment of research ethics application;

3.2 internal administrative processing;

3.3 assessment of complaints and investigations of alleged violations of norms and standards for the ethical conduct of research; and

3.4 institutional and scholarly research.

4. I also consent that Unisa may share my personal information with other Universities of South Africa, third parties rendering database management facility on behalf of the university, the Department of Higher Education and Training, the National Health Research Ethics Council, Internal and External Auditors, and for the purpose of legislative requirements.

5. I understand that in terms of the Protection of Personal Information Act (POPIA) and other laws of the country, there are instances where my express consent is not necessary to permit the processing of personal information, which may be related to investigations, litigation or when personal information is publicly available.

6. I will not hold the university responsible for any improper or unauthorised use of personal information that is beyond its reasonable control.

7. I confirm that I have read the notice and understand the contents thereof.

**Note:** The nature of personal information collected can be viewed in the Personal Information Inventory Lists published on the Unisa webpage at [www.unisa.ac.za](http://www.unisa.ac.za)

Full name in Print:

Signature­­­­­­­­­­­­­: Date signed:

**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 according to Appendix A (checklist). I will ensure that the student notifies the committee in writing if any changes to the research are proposed that may affect any of the study-related risks for the research participants such as methodology, sampling, questionnaire, interview schedule, etc. Subsequently, I approve the submission and recommend that approval is granted for the research.

Full name in Print:

Signature: Date signed:

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

|  |
| --- |
| **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 where you are currently registered or employed |
|  |  |  |  |
| Contact numbers | Mobile:Work: |
| Email address |  |
| Abridged CV of main researcher explicitly providing evidence of: | * + 1. Experience relevant to the proposed research
		2. Qualifications relevant to the proposed research
		3. Publications and other research outputs
		4. Research Ethics Training done within the past three years
 |
| **1.2** | **Supervisor if the application is made by a student** |
| Title | Full name & Surname | Staff / student no | Department/Unit where you are currently registered or employed |
|  |  |  |  |
| Contact numbers | Mobile:Work: |
| Email address |  |
| Abridged CV of supervisor explicitly providing evidence of: | * + 1. Experience relevant to the proposed research
		2. Qualifications relevant to the proposed research
		3. Publications and other research outputs relevant to the study
		4. Research Ethics Training done within the past three years
 |
| **1.3** | **Co-supervisor if the application is made by a student\*****\*** if applicable |
| Title | Full name & Surname | Staff / student no | Department/Unit where you are currently registered or employed |
|  |  |  |  |
| Contact numbers | Mobile:Work: |
| Email address |  |
| Abridged CV of co-supervisor explicitly providing evidence of: | * + 1. Experience relevant to the proposed research
		2. Qualifications relevant to the proposed research
		3. Publications and other research outputs relevant to the study
		4. Research Ethics Training done within the past three years
 |
| **1.4** | **Internal and/or External Co-Researcher(s) \*****\*** if applicable |
| Title | Full name & Surname | Staff / student no | Department/Unit where you are currently registered or employed |
|  |  |  |  |
| Contact numbers | Mobile:Work: |
| Email address |  |
| Abridged CV of co- researcher(s) explicitly providing evidence of: | * + 1. Experience relevant to the proposed research
		2. Qualifications relevant to the proposed research
		3. Publications and other research outputs relevant to the study
		4. Research Ethics Training done within the past three years
 |
| 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]*  |
| 1.6.1 Research for non-degree purpose (journal articles; conference presentations, etc.) |  |
| 1.6.2 Research for degree purpose |  |
| 1.6.3 Identify the qualification for the project (in the case of research for degree purpose) |
|  |
| 1.6.4 Collaborative research |  | 1.6.5 Community Engaged Research (CER) |  |
| 1.6.6 Health or Health related research[[1]](#footnote-1)(If you ticked “yes”, your application should be cleared by one of Unisa’s committees registered to the National Health Research Ethics Council – consult your supervisor or the secretariat of the ERC) |  | 1.6.7 Other  |  |
| 1.6.8 Identify the relevant research niche area(s) *(Unisa researchers and postgraduate students only)*1. Knowledge generation and human capital development in response to the needs of South Africa and the African continent
 |  |
| 1. The promotion of democracy, human rights and responsible citizenship
 |  |
| 1. Innovation and capacity building in science and technology
 |  |
| 1. Economic and environmental sustainability
 |  |
| 1. ODL/ODeL
 |  |
| 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”. |
| **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. |  |  |

|  |
| --- |
| 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 an external applicant, a copy of this document can be requested from vwykmj@unisa.ac.za

If you are unsure about the meaning of any of these concepts, please consult your supervisor or project leader.

|  |  |  |  |
| --- | --- | --- | --- |
| **2.1** | **Does your research contribute to knowledge of** | **YES** | **NO** |
| *Place an ‘x’ in box* ***[if yes, provide details in the space allocated for comments]*** |
| 1. The biological, clinical, psychological or social processes in human beings [social processes refer to those activities, actions, and operations that involve the interaction between people][[2]](#footnote-2)
 |  |  |
| 1. Improved methods for the provision of health services
 |  |  |
| 1. Human pathology
 |  |  |
| 1. Causes of disease
 |  |  |
| 1. Effects of the environment on the human body
 |  |  |
| 1. Development or new application of pharmaceuticals, medicines and related substances
 |  |  |
| 1. Development of new applications of health technology referring to machinery or equipment that is used in the provision of health with the exception of medicine[[3]](#footnote-3)
 |  |  |
| Comments: If you selected yes for any of the above options, please provide a detailed explanation for your selection. If your research includes people in a focus group, an interview or survey, and can possibly entail a social process, you need to tick (a). If you ticked (a), clearly motivate if the research does or does not relate to the generation of knowledge relating to any aspect of health. If it does contribute to the generation of knowledge relating to any aspect of health, please send the application to a registered Unisa committee. |
| **2.2** | **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 6.6 of the application form. |  |  |
| b) Persons with disabilities (physical, mental and/or sensory)[[4]](#footnote-4) that could potentially be at risk of harm when participating in this research. |  |  |
| 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 dependent 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 (RPSC) in section 3.1 of the application form to involve any of these participant groups in the proposed research. |  |  |
| f) Persons who cannot read, speak or understand the language used for the research i.e. EnglishAttach 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 in Section 4.13. The services of an interpreter may need to be secured for fieldwork 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. |  |  |
| 1. Animals
 |  |  |
| 1. Other[[5]](#footnote-5). Please describe.
 |  |  |
| Comments: If you selected yes to any option above, please describe it in detail here. |
| **2.3** | **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 processing 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 and processing of personal, identifiable information directly from participants with prior informed 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 |  |  |
| d) Personal, identifiable information to be collected outside or transferred outside of South Africa *(if collected from outside SA you must have consent; if transferred across the border the participant must consent & the country must have adequate privacy laws to protect the personal information)* |  |  |
| e) Personal, identifiable information to be shared with third parties for research purposes *Attach the confidentiality agreements in Section 6.23 & ensure that prior consent has been obtained from the research participants* |  |  |
| f) Participants being exposed to questions which may be experienced as stressful or upsetting, or to procedures which may have unpleasant or harmful side effects |  |  |
| g) Participants being required to commit an act which might diminish self-respect or cause them to experience shame, embarrassment, or regret |  |  |
| h) Any form of deception of participants, concealment or covert observation |  |  |
| i) Examining potentially sensitive or contentious issues that could cause harm to the participants |  |  |
| j) Research which may be prejudicial to participants |  |  |
| k) Research which may intrude on the rights of third parties or people not directly involved |  |  |
| l) Audio-visual recordings of participants which may be of a sensitive or compromising nature (with or without consent) |  |  |
| m) 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 |  |  |
| n) Any form of physically invasive diagnostic, therapeutic or medical procedure such as blood collection, an exercise regime, body measurements or physical examination |  |  |
| o) \*Psychological inventories / scales / tests |  |  |
| p) Research involving any sensory analysis through the ingestion, smell, taste or feel of food or food related products of any kind.  |  |  |
| q) Other. Please describe |  |  |
| Comments: If you selected yes to 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.*

|  |  |  |  |
| --- | --- | --- | --- |
| **2.4** | **Does your research involve any activity that could potentially place the researcher(s) and/or field workers at risk of harm?** **[if yes, provide details in the space allocated for comments]** | **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 yes to any option above, please describe it in detail here. |
| **2.5** | **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 yes to any option above, please describe it in detail here. |
| **2.6**  | **Guided by the information above, classify your research project based on the anticipated degree of risk. *[The researcher completes this section. The REC/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. Indicate the potential benefits of the study for the research participants and/or communities or other entities.
 |
| 1. Describe the risks relating to the research procedures, which participants, communities or third parties may or will suffer.

*This refers to, but is not limited to 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.* |
| 1. 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.).
 |
| 1. Describe the 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, communities or third parties.
 |
| 1. Describe your arrangements regarding indemnity/compensation for research-related adverse events (if applicable).
 |
|  |
| **SECTION 3 – DETAILS OF PROPOSED RESEARCH** |

|  |  |
| --- | --- |
| **3.1**  | **Does your project involve institutions that need to grant permission for research activities?**Generally, permission to conduct research involving institutions should be obtained prior to field work activities. 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*.* |
| **YES / NO** *(Underline the applicable answer)* |
| 1. Name of organisation(s), state authorities or community advisory boards if appropriate (i.e. UNISA)
 | 1. Name of person or committee granting permission (i.e. Research Permission Subcommittee, RPSC@unisa.ac.za)
 | (c) Contact details of authorised person or committee granting permission (E-mail address or telephone number) | 1. Has institutional permission been granted?

*Place an ‘x’ in the box provided* |
| **YES** | **NO** | **Pending** |
|  |  |  |
|  |  | E-mail address:Telephone number: |  |
| 1. Insert the permission letter here or append to the application.
 |
| 1. If permission is pending, provide an explanation and indicate your planned efforts in obtaining the permission. *Insert a Pro-forma permission letter here or append to the application.*

*Note that the approval for the study may be conditional.* |

*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 the organisations in which you wish to conduct your research? |
| **YES / NO** *(Underline the applicable answer)* |
| If YES, please explain the association clearly in the comment section below. |
| Comments: |

 *Place an ‘x’ in the box provided*

|  |  |
| --- | --- |
| 3.3 | **Does your research involve collectives and / or communities?** (Group of people sharing social ties, similar interests and a geographic location) |
| YES / NO *(Underline the applicable answer)* |
| Please explain what measures you have taken to consult and engage with those communities and / or representative groups regarding your research project below. |
|  |
| **3.4** | **Is your project funded or sponsored by any organisation?** |
| **YES / NO *(Underline the applicable answer)*** |
| 1. Name of funder/sponsor
 | 1. Contact details or funder/sponsor
 | (e) Amount funded/sponsored if applicable | (f) Will the identity of any funders be made known to the participants? |
|  | E-mail address:Telephone number: |  |  |
| **3.5** | **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 |
| **3.6** | Is this research a sub-study linked to an existing or main study? |
| **YES / NO *(Underline the applicable answer)*** |
| 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 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 or append to the application)***

|  |  |
| --- | --- |
| **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 approval was or will be obtained. Attach the approval letter on an official letterhead from the authorised person/committee as an appendix to the application form if you are in possession of it. If not, explain why approval could not be obtained. |
| Group 1\* |   |
| Group 2\* |  |
| 4.6.7 | Will any dependent or unequal relationship exist between anyone involved in the recruitment and the participants? [i.e. person in a position of power is recruiting participants which could compromise voluntary participation]  |
| **YES / NO** ***(Underline the applicable answer)*** |
| Explain if applicable: |
| **4.7** | **Collection of data material and procedures** |
| **Indicate which data collection methods will be used.**  |
| **4.7.1** | **Questionnaire / Survey** |
| **YES / NO *(Y or N in each block to indicate your response)*** |
| i) Self-designed |  |
| ii) Borrowed |  |
| iii) Adapted |  |
| iv) Fully identifiable (name on it) or linked to a consent form |  |
| v) Potentially identifiable (coded) |  |
| vi) Anonymous (can never be identified) |  |
| vii) Questionnaire(s) / Survey(s) Insert questionnaire or survey here or append to the application |
| viii) If the questionnaire / survey is borrowed, was approval granted by the original developer?  |  |
| ix) Proof of approval from the original developerInsert proof of approval here or append to the application |
| ix) If not, justify why: |
| 1. Explain how the questionnaire/survey will be administered?
 |
| 1. Specify how the questionnaire/survey will be returned to you to ensure confidentiality.
 |
| **4.7.2** | **Interviews** |
| **YES / NO *(Y or N in each block to indicate your response)*** |
| i) In-depth |  |
| ii) Semi-structured |  |
| iii) Unstructured |  |
| iv) Audio-taped |  |
| v) Video-taped |  |
| vi) Insert the interview questions / list of topics below or attached as an addendum to the application \* Insert here |
| vii) If a central research question will be asked, state the exact question here |
| **4.7.3** | **Focus groups**Note: Confidentiality cannot be guaranteed in a group setting – this must be included in the Informed Consent leaflet and explained as part of the consent process |
| **YES / NO *(Y or N in the block to indicate your response)***  |  |
| i) Insert the focus group questions/ list of topics below or attached as an addendum to the application \* Insert here |
| **4.7.4** | **Other** |
| **YES / NO *(Y or N in the block to indicate your response)*** |  |
| i) Identify each additional data collection method, describe it briefly and insert data collection tools or attach it as an addendum to the application\* Insert here |
| **4.8** | Where will the data be collected? If not known, please provide suggested locations. |
|  |
| **4.9** | **By whom will the data be collected? (Researcher/field workers/community members)?** Explain any measures that you will take to prepare yourself/field workers/community members to optimise data collection activities. Field workers/community members are required to sign a confidentiality agreement form. |
| \* Insert confidentially agreement(s) for fieldworkers/community members here if applicable |
| **4.10** | **Will participants be subjected to any form of intervention (manipulation of the participant or the participants’ environment)?**  |
| **YES / NO *(Underline the applicable answer)*** |
| Please explain the intervention in full. |
| **4.11** | **Does the research involve participants who have specific cultural needs, protocol requirements or/and specific consent arrangements?**  |
| **YES / NO *(Underline the applicable answer)*** |
| Please clarify your response. |
| **4.12** | **Will you require the use of a translator or will you use documentation translated into a language other than English?** |
| **YES / NO *(Underline the applicable answer)*** |
| Describe how the translator will be used.*Insert or append the translated data collection instrument(s), interview guide(s), participant information sheet(s) and consent form(s) in the participants’ first language, as well as a letter from the language practitioner certifying the credibility of the translated material.* |
| **4.13** | **Is there a dependent or unequal relationship between any person collecting the data (e.g. researcher) and the participant?**  |
| **YES / NO *(Underline the applicable answer)*** |
| If **YES**, Please give details and explain the measures taken to manage this situation. |
| **4.14** | **Does your research project involve the collection and analysis of documents or secondary data?** |
| **YES / NO *(Underline the applicable answer)*** |
| 1. Please explain the sampling method of the relevant categories of documents and the predicted sample size, followed by a justification for sample size (add more rows if necessary)
 |
|  | **Sampling method** | **Sample size** | **Justify sample size** |
| Data set/ document 1\* |  |  |  |
| Data set/ document 2\* |  |  |  |
| 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.
 |
| 1. 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** | **List the references used in the application form** |
|  |
| **5.6** | **Indicate the timeline** *(\*Insert additional rows if necessary)* |
| **Planned research activities (i.e. ethics clearance, data collection, analysis, report writing, editing, printing, etc.)** | **Anticipated completion time** |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
| **5.7** | **Indicate the budget** *to justify the financial feasibility of the research (\*Insert additional rows if necessary)* |
| **Planned research activities (i.e. ethics clearance, data collection, analysis, report writing, editing, printing, etc.)** | **Estimated cost** |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
| **5.8**  | **If you do run out of funding to cover your budget, do you have a contingency fund to complete the study?**  |
|  |

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

|  |  |
| --- | --- |
| **6.1** | **Describe the process of obtaining Informed Consent below** |
| a)  |
| b) Insert the information sheet and informed consent document(s) here or append as annexures to the application. Note: *The participant information sheet ought to explain all criteria stipulated below in 6.2, with the exception of those marked with \* (criteria marked with an \* may apply only to certain studies)* |
| **6.2** | **Checklist to ensure that the participant information sheet and consent form meet ethical requirements** ***Standard participant information sheets and consent forms are available on the research website or can be requested from the relevant ERC*** | **YES** | **NO** | **N/A** |
|  *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)\* |  |  |  |
| s) Consent for third party sharing of data e.g. statistician, coders if applicable\* |  |  |  |
| t) Consent for cross border data transfer if applicable\* |  |  |  |
| u) Consent for data sharing in a credible public repository if applicable\* |  |  |  |
| v) The steps taken to ensure that cultural protocol has been observed if applicable\* |  |  |  |
| **6.3** | **Checklist to ensure that the process of obtaining assent meets ethical requirements (IF APPLICABLE).** *Place an ‘x’ in the box provided below if not applicable*

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

 | **YES** | **NO** | **N/A** |
| 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. |

|  |  |
| --- | --- |
| **6.4** | **Measures taken to protect confidentiality:**  |
| a) | 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.** |
|  |
| b) | 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.** |
|  |
| c) | 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 insert below or append the agreements to the application.**  |
|  |
| d) |  *[Place an ‘x’ in the box provided]* |
| i) Personal identifiers will be removed from research-related information |  |
| ii) Encryption |  |
| iii) Use of pseudonyms |  |
| iv) Participants in focus groups will be advised that confidentiality cannot be assured |  |
| Comments: |
| **6.5** | **Data sharing (if applicable)***In the South African context, agencies including the National Research Foundation (NRF)**require that data supporting publications be deposited in an accredited open access (OA)**Data repository from March 2015 onwards with a registered Digital Object Identifier (DOI) for citation and referencing.* |
| a) | How will you obtain consent from the research participants and/or other stakeholders i.e. funders, participating institutions, etc. for further use of research information? Note that personal identifiable data cannot be shared without explicit prior consent.  |
|  |
| b) | Where, with whom and how will you share the data? |
|  |
| c) | How will you de-identify data to protect participants’ privacy during further processing? |
|  |
| 6.6 | Data Storage and Procedures for Disposal of the data |
| a) | 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.* |
|  |
| b) | 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? |
|  |
| **6.7** | **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)  |
|  |
| **6.8** | **In the case of the use of indigenous knowledge, how will you ensure that participants are not exploited/harmed for instance by protecting their Intellectual Property rights?** (if applicable) |
|  |
| **6.9** | **How will participants benefit, gain access or share in products developed from the study in case of collaborative projects or the use of indigenous knowledge?** (if applicable) |
|  |
| **6.10** | **Indicate how you envisage publishing this research.**(thesis, journal article, book, chapter, on-line web based, oral presentation, other) |
|  |
| **6.11** | **Describe the nature and amount of compensation including reimbursements, gifts, services or incentives to be provided to each group of participants.** (if applicable) |
|  |
| **6.12** | **Describe any financial costs that might be incurred by participants. If participants incur costs, how will you ensure that it is fair?**(if applicable) |
|  |

**PLEASE REMEMBER TO COMPLETE AND APPEND THE CHECKLIST TO YOUR APPLICATION – APPENDIX 1**

**🙦 🙦 🙦 🙦**

1. Consult the Policy on Research Ethics for a definition of health research. [↑](#footnote-ref-1)
2. Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity (Collins English Dictionary, 2018) [↑](#footnote-ref-2)
3. Definition of health research, NHA 61 of 2003, p.8 [↑](#footnote-ref-3)
4. Describe whether and how proxy or gatekeeper consent will be obtained in section 6.1 relevant to items 2.1. a – e [↑](#footnote-ref-4)
5. Form 1 does not apply to plant, molecular or cell research, animal and environmentally related research. [↑](#footnote-ref-5)