***NB: Please tick the relevant box with X***

**PRIVACY STATEMENT**

**The personal information you provide on this form is collected to assess your research ethics application. The personal information will be entered into a database to assist with administration, correspondence, and statistical analyses. Your supervisor, office bearers and members of the Research Ethics Committee will have access to these records. The personal information will only be used for the purpose for which it is collected and will be retained for as long as necessary to achieve the purpose for which it was collected.**

**SECTION A: DETAILS OF THE RESEARCHERS**

**a1. TITLE OF PROPOSED STUDY**

|  |
| --- |
|  |

**a2. Personal particulars (PRINCIPAL INVESTIGATOR)**

|  |  |
| --- | --- |
| (a) Initials & Surname |  |
| (b) Staff/student number |  |
| (c) E-mail address |  |
| (d) Telephone number(s) |  |
| (e) Department |  |
| (f) Faculty |  |

**a3. PERSONAL PARTICULARS OF supervisor**

|  |  |
| --- | --- |
| (a) Initials & Surname  |  |
| (b) E-mail address  |  |
| (c) Department  |  |
| (d) Faculty |  |

**a4. PERSONAL PARTICULARS OF co-supervisor (iF aPPLICABLE)**

|  |  |
| --- | --- |
| (a) Initials & Surname  |  |
| (b) E-mail address  |  |
| (c) Department  |  |
| (d) Faculty |  |

**a5. PERSONAL PARTICULARS OF coLLABORATORS (iF aPPLICABLE)**

|  |  |
| --- | --- |
| (a) Initials & Surname  |  |
| (b) E-mail address  |  |
| (c) Department  |  |
| (d) Faculty |  |

**A6: ABSTRACT**

This abstract should be written in **lay terms** (non-technical, everyday language, MAX 250 WORDS) and include:

Study purpose

Setting

Study population and sample

Data collection and data analysis methods

Contribution

**SECTION B: DETAILS OF THE STUDY**

|  |
| --- |
| **B1** |
| **Nature of Project** | Honours/4th Year |  | Master’sMini-dissertation  |  | Master’sFull dissertation |  | Doctoral |  | Departmental Projects  |  |
| **B2** |
| **Does your research involve any of the following: (to make this a list)** | Human Health |  | Data collection from people |  |
| Children (Non-therapeutic research) |  | Children (Therapeutic research) |  | Other vulnerable persons |  | Special health and safety considerations |  | Desktop, fieldwork, or laboratory research only |  |
| Research on the environment  |  | Interference with nature |  | Hazards/ pollution |  | Conservation  |  | Intellectual Property (IP)/Community engaged research |  |
| **B3** |
| **Conflict of interests** |  (Researcher, funder, or participants) |  | **YES** |  | **NO** |  |
| **B4**Scope of study (select an item) |  |
| **B5**Source of Funding, i.e., NRF grant, Self-funded, etc. |  |
| **B6** Are there any restrictions or conditions attached to publication and/or presentation of the study results? If YES, elaborate (any restrictions or conditions contained in contracts must be made available to the Committee):

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

Comment: |
| **B7** Anticipated start and end date of data collection |
| **B8** Is this application related to any existing and active umbrella research project? If YES, provide the ethics reference number of the related umbrella project: |
| **B9**Is any insurance available for research-related injuries for participants and/or researchers? If NO, please specify what measures will be taken to address the deficiency in availability of insurance: |

**SECTION C: LIST OF REQUIRED DOCUMENTS**

|  |
| --- |
|  |
| **Documents submitted for ethics approval** | Project proposal |  | Letter requesting access to sites/ information/ participants |  |
| Survey Instrument/Questionnaire |  | Letter granting access approval |  |
| Translation (where appropriate) |  | Other documentation: |  |
| Observation sheet |  | Assent |  |
| Research instrument permission |  |  |  |
| Participant Informed Consent |  |  |  |
| Guardian Informed Consent |  |  |  |
| Copyright permission |  |  |  |

**SECTION D: 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 a high-risk level. If you selected ‘YES’ for any of the options below, provide a rationale in the comments section.

|  |  |  |  |
| --- | --- | --- | --- |
| **D1** | **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 Attach the parental or guardian consent letter and an assent letter to the application. |  |  |
| b) Persons with disabilities (physical, mental and/or sensory) that could potentially be at risk of harm when participating in this research. |  |  |
| c) Persons or communities 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, etc.)* |  |  |
| d) UNIZULU employees, students or alumni |  |  |
| e) Persons who cannot read, speak or understand the language used for the research, i.e., EnglishThe committee will require the translated data collection instrument(s), interview guide(s), participant information sheet and consent form in the participants’ first language, and a letter from the language practitioner certifying the credibility of the translated material if applicable.  |  |  |
| f) 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. |  |  |
| g) Other. Please describe. |  |  |
| Comments: If you selected yes to any option above, please provide a rationale for your choice: |
| **D2** | **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 (except for 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 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 (such as transcribers, co-coders, etc.). *Attach confidentiality agreements with third parties if applicable.*  |  |  |
| 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) Any form of deception of participants, concealment or covert observation. |  |  |
| h) Examining potentially sensitive or contentious issues that could cause harm to the participants or conducting research which may be prejudicial to participants. |  |  |
| i) Research which may intrude on the rights of third parties or people not directly involved. |  |  |
| j) Audio-visual recordings of participants which may be of a sensitive or compromising nature (with or without consent). |  |  |
| k) Disclosure of the research findings could place participants at risk of criminal or civil liability or damage their financial standing, employability, and professional or personal relationships. |  |  |
| l) Any form of physically invasive diagnostic, therapeutic or medical procedure such as blood collection, an exercise regime, body measurements or physical examination. |  |  |
| m) Data collection procedures that could spread diseases during face-to-face interviews, etc.  |  |  |
| n) Will you be using equipment of any sort with the consent of the participants (e.g., one-way mirrors, recordings, videos, etc.)?  |  |  |
| o) Will you be using equipment of any sort without the consent of the participants (e.g., one-way mirrors, recordings, videos, etc.)? |  |  |
| Comments: If you selected yes to any option above, please provide a rationale for your choice: |

|  |  |  |  |
| --- | --- | --- | --- |
| **D3** | **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 and/or the nature of what is disclosed. |  |  |
| b) There is a possible risk of being in a compromising situation, where there might be accusations of improper behaviour. |  |  |
| c) There is increased exposure to risks in everyday life and social interactions, such as working with hazardous materials, sensitive information or in settings that could be unsafe to the health of the researcher or field workers. |  |  |
| Comments: If you selected yes to any option above, please provide a rationale for your choice: |
| **D4** | **Does any of the following apply to your study?** | **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 because they participated in the research. |  |  |
| c) Any other potential conflict of interest, real or perceived, that could be compromising the researcher(s) professional judgement in carrying out or reporting on the research (such as working with the targeted participants) |  |  |
| Comments: If you selected yes to any option above, please describe it in detail here. |
| **D5**  | **Guided by the information above, how will you classify your research study? *[The applicant completes this section in consultation with the supervisor in case of postgraduate student research. The REC critically evaluates the benefit-risk analysis to protect participants’ rights]****Place an ‘x’ in the space provided.*  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Risk Classification** The study presents: (please tick one) | Low Risk  |  | Medium Risk |  | High Risk  |  |

|  |
| --- |
| **D6** Briefly justify your choice/classification below:  |
|  |
| **D7** Indicate the potential benefits of the study for the research participants and/or communities or other entities. |
|  |
| **D8** Describe the potential risks of the research procedures, which participants, communities or third parties may 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 relating to the answers provided in sections the risk assessment tool.* |
|  |
| **D9** 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, distress protocol, etc.). |
|  |
| **D10** Does the person administering the project have previous experience with the risk factors? If YES, please specify:  If NO, please specify what measures will be taken to address the deficiency in experience:  |
|  |
| **D11** List any ethics training acquired by the researcher in the past three years |
|  |

**SECTION E: STUDY POPULATION, SAMPLING AND SAMPLE SIZE**

|  |
| --- |
| TARGET PARTICIPANT GROUP |
| E1 Inclusion criteria: describe particular characteristics that are required to be present in participants in the target group (e.g., particular age, cultural derivation, background, physical characteristics, disease status, etc.):  |
| E2 Exclusion criteria: describe particular characteristics (not listed above) that will automatically exclude volunteers from participation (e.g., particular age, cultural derivation, background, physical characteristics, disease status, etc.) please specify:  |
| E3 Are participants drawn from a school, institutional population (e.g., hospital, prison, mental institution) or any particular/unique cultural community (e.g., a particular nation, social group, etc.) population? If YES, please specify the name(s):  |
| E4 If any records will be consulted for information to complement the data collected, please specify the source of records:  |
| E5 Are all participants 18 years of age and above? If NO, state justification for inclusion of minors in the study:  |
|  |
| **SECTION F: CONSENT, ASSENT (in the case of minors) OF PARTICIPANTS AND GATEKEEPER PERMISSION** |
| 1. Will consent be given in writing? If NO, state reasons why written consent is not appropriate in this study:
 |
| 1. Assent (if any participant is younger than 18): Will assent be given in writing?

If NO, state reasons why written assent is not appropriate in this study:  |
| 1. Are any participant(s) subject to legal restrictions preventing them from giving effective informed consent?

If YES, please justify:  |
| 1. Do any participant(s) operate in an institutional environment, which may cast doubt on the voluntary aspect of consent?

If YES, state what special precautions will be taken to obtain legally effective informed consent:  |
| 1. Do any participant(s) exist in a power relationship with the researcher(s), which may cast doubt on the voluntary aspect of consent?

If YES, state what special precautions will be taken to obtain an effective informed consent:  |
| 1. Will participants receive reimbursement/remuneration/incentives for their participation?

 If YES, justify and state on what basis the reimbursement/remuneration/incentives is/are calculated, and how the accuracy of the information can be guaranteed: How will the exclusion of the reimbursement/remuneration/incentive(s) from the study possibly affect the study’s outcome?  |
| 1. Which gatekeeper(s) will be approached for initial permission to gain access to the target group? (e.g. principal, nursing manager, chairperson of school governing body, etc.)
 |
|  |
| INFORMATION TO PARTICIPANTS AND FEEDBACK |
| 1. What information will be offered to the participant at the point of recruitment (i.e. before he/she consents to participate)? (Attach written information given as and any oral information given as (Appendix 11b)

  |
| 1. Who will provide this information to the participant? (Give name and role)

  |
| 1. What information will be offered to the participant at enrolment (i.e. when he/she consents to participate)?

  |
| 1. Will feedback be given to participants?
2. If YES, specify whether feedback will be written, oral or by other means and describe how this is to be given (e.g. to each individual immediately after participation, to each participant after the entire project is completed, to all participants in a group setting, etc.):
3. If NO, motivate reasons why it is not possible to provide participants with feedback:
 |
| 1. If you are working in a primary/secondary school or other institutional setting, will you be providing teachers, school/institutional authorities or equivalent a report summarising your results\*?

If YES, specify:if NO, motivate:  |
|  |
| PRIVACY, ANONYMITY AND CONFIDENTIALITY OF DATA |
| 1. Will the participant be identified by name in your research?

 If YES, justify:If NO, specify the provisions made to protect the participant’s rights to anonymity:   |
| 1. Are provisions made to protect participant’s rights to privacy and to preserve confidentiality with respect to data?

 If NO, justify. If YES, specify:  |
| 1. How will data collected be stored?
 |
| 1. Will stored data be made available for re-use in any subsequent research?

 If YES, how will participant’s consent be obtained for such re-usage and how exactly will the data be re-used?   |
| 1. Are there any contractual secrecy or confidentiality constraints on the data collected?

If YES, specify:  |
|  |
| DECLARATION |
| I am aware that data collection will only commence once final approval for the study has been granted and I am in receipt of an approval letter to this effect, and I declare that I shall not collect data until this time. Principal Researcher Signature Date |

|  |
| --- |
| **For Office Use** |
| **Faculty REC comments:*** Reasons for recommendation to the UZREC
* Why/how the benefits outweigh the risks associated with the research
* Special conditions to be attached to the approval
 |  |
| **Faculty REC Chairperson’s Signature** |  | **Date** |
| **Print Name** |  |