1. RISK MATRIX AND INDICATORS

The risk matrix is described in Table 1 below, along with indicators. It's essential to recognise that the indicators for each category are not exhaustive but serve as guidance to facilitate well-considered decisions regarding the anticipated risks of a study.

RISK LEVELS	INDICATORS AND DESCRIPTIONS	PROCESS
High risk Research in which there is an actual and foreseeable risk of unexpected negative consequences, harm and discomfort, which may lead to serious adverse consequences if not managed responsibly. Remedial actions are difficult to undertake when the harm occurs.	Research with human participants. • Research with children could be high risk, depending on the nature of the study. • Research with people suffering from mental health conditions that affect their cognitive, behavioural, or social functioning so that they cannot make informed decisions. • Any research done that is outside of the researcher's field of expertise can be seen as high risk. The researcher's competence within this field will be a determining factor for the risk assessment of the research. • Research involving human participants with research-related medical or psychopathology. • Research involving vulnerable human participants. • Research involving sensitive ethical dilemmas in society • Research that may affect public or environmental safety or sensitive ecosystems. • The research budget is higher than R10 million per annum. • Any research deemed a potentially high risk by any applicant or committee.	Please complete the UNIZULU Ethics application form and send all relevant documentation with the application to the relevant REC.
Medium risk Research in which there is a potential risk of unexpected negative consequences, harm or discomfort, e.g., physical, psychological, social and environmental harm, but where appropriate steps can be taken to mitigate or reduce overall risk. Remedial actions can be undertaken should harm occur.	• The research topic is 'sensitive'. • Information gathered is personal rather than opinion, attitudes, or a combination. • The information needs to be collected with personal identifiers. • Collaborative or umbrella research projects involving people, multi-centre studies involving people and long-term studies based on certain risk factors (see 5.7). • Research involving face-to-face or virtual psycho-social contact with participants, for example, through interviews or focus groups. The medium risk level could be attributed to the potential for participants to feel discomfort or emotional burden during the interview process or to suffer a moderate loss of status or damage to public image. • Human intervention studies individually or in communities. • Non-clinical research/research with vulnerable communities/people (older persons and their caregivers, patients and health-care professionals, students and teachers, persons with life-threatening diseases and their caregivers, people living with HIV, wards of the state and guardians or caregivers, employees and employers, prisoners and the relevant prison authorities, members of the SA Defence Force and their supervisors, children, mentally ill persons own direct students).	Please complete the UNIZULU Ethics application form and send all relevant documentation with the application to the relevant REC.

RISK LEVELS	INDICATORS AND DESCRIPTIONS	PROCESS
	• A research budget between R500,000.00 and R10 million per annum. • An unrealistic budget that is not aligned with the objectives.	
Low risk / Minimal The potential of harm or discomfort anticipated in the research is not greater (in and of themselves) than those ordinarily encountered daily. Or Research in which the only foreseeable risk is one of minimal discomfort or inconvenience. Or The research will collect information that is generally not considered sensitive, such as opinions, rather than personal information.	All research not described under high risk or medium risk, but where the following criteria apply: • Surveys using validated interview schedules. • Documented data or analyses with identifiable human participants. • Simple questionnaire or instrument development. • Questionnaire or instrument development. • Research involving retrospective data. • System research using structured survey forms. • Interventions based on professional, scientific base protocols. • Research budget under R500 000 but higher than R100 000.	Please complete the UNIZULU Ethics application form and send all relevant documentation with the application to the appropriate REC. (Minimal risk to human participants)
Negligible risk No direct contact with human participants, animals or the environment	All research not described under high risk, medium risk or low risk, including the following: • Systematic reviews/Literature reviews. • Postal / surveys with validated questionnaires. • Document /artefact analyses without identifiable human participants. • Unidentifiable electronic surveys. • Public observation without interaction or intervention. • Work in fine Arts. NB: Not all research involving material in the public domain is 'negligible risk' e.g. research involving data extraction from the social media may need a higher level of ethics scrutiny.	**Only ethical clearance required from REC:** If you need ethical approval for funding opportunities / journal publications, follow the low-risk process.

(Adapted from Department of Health. Second edition. Ethics in Health Research. Principles, Processes and Structures, 2015; NWU August 2019, Risk Assessment in human research; UNIZULU (2023) Guidelines for writing the research proposal)

2. RISK ASSESSMENT FORM

Each research proposal involving humans should assess the likelihood of the study's risk of harm to human participants, researchers, communities and environments guided by the following risk assessment tool adapted from the Unisa Risk Assessment Tool[1].

RISK ASSESSMENT TOOL

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.

1	**Does your research contributes to knowledge of**	**YES**	**NO**
Place an 'x' in box [if yes, provide details in the space allocated for comments]			
a)	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]		
b)	Improved methods for the provision of health services		
c)	Human pathology		
d)	Causes of disease		
e)	Effects of the environment on the human body		
f)	Development or new application of pharmaceuticals, medicines and related substances		
g)	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]		
Comments: If you selected yes to any option above, please describe it in detail here.			
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 the application form.			
b) Persons living with disabilities *(physical, mental and/or sensory)*[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.)*			

[1] Adapted from the Unisa Standard Operating Procedure (SOP) for Research Ethics Risk Assessment, 2023.
[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)
[3] Definition of health research, NHA 61 of 2003, p.8

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) UNIZULU employees, students or alumni		
f) Persons who cannot read, speak or understand the language used for the research i.e. English Attach the translated data collection instrument(s), interview guide(s), participant information sheet and consent form in the participants' first language. 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.		
h) Animals		
i) Other[5]. Please describe.		
Comments: If you selected yes to any option above, please describe it in detail here.		

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 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			
d) Personal, identifiable information to be collected outside or transferred outside of South Africa			
e) Personal, identifiable information to be shared with third parties for research purposes			
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		
n) Research involving any sensory analysis through the ingestion, smell, taste or feel of food or food related products of any kind.		
p) 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 the test administration is in South Africa or of an equivalent board if the administration is non-South African.*

4	**Does your research involve any activity that could potentially place the researcher(s) and/or field workers 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 increased exposure to risks in everyday life and social interactions, including working with hazardous materials or sensitive information or in a pandemic situation			
Comments:	If you selected yes to any option above, please describe it in detail here.		

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 interest, real or perceived, that could be seen as compromising the researcher(s) professional judgement in carrying out or reporting on the research			
f) Research will be funded by UNIZULU 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.			

6	**Guided by the information above, classify your research project based on the anticipated degree of risk.** ***[The researcher completes this section. The REC critically evaluates this benefit-risk analysis to protect participants' rights]*** *Place an 'x' in the box provided*				
	Low risk The potential of harm or discomfort anticipated in the research is not greater (in and of themselves) than those ordinarily encountered daily. Or Research in which the only foreseeable risk is one of minimal discomfort or inconvenience. Or		**Medium risk** Research in which there is a potential risk of unexpected negative consequences, harm or discomfort, e.g., physical, psychological, social and environmental harm, but where appropriate steps can be taken to mitigate or reduce overall risk.		**High risk** Research in which there is an actual and foreseeable risk of unexpected negative consequences, harm and discomfort, which may lead to serious adverse consequences if not managed responsibly. Remedial actions are difficult to undertake when the harm occurs.

	The research will collect information that is generally not considered sensitive, such as opinions, rather than personal information.		Remedial actions can be undertaken should harm occur.		

6.1 Briefly justify your choice/classification.
6.2 Indicate the potential benefits of the study for the research participants and/or communities or other entities.
6.3 Describe the risks of the research procedures, which participants, communities, or third parties may or will suffer.
6.4 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.).
6.5 Describe the steps to be taken in the case of adverse events or if the participants experience injury or harm attributable to participation in the study.
6.6 Describe your arrangements regarding indemnity/compensation for research-related adverse events (if applicable).

3. REVIEW

On the recommendation of the HREC and all relevant structures, the Senate may review and amend sections of the SOP, in which event the amendments take effect on the date of Senate approval.

4. REFERENCES

- Department of Health (DoH). (2015). Ethics in Health Research: Principles, Processes and Structures (2nd Edition).
- National Department of Health (NdoH). (2023). South African Ethics in Health Research Guidelines: Principles, Processes and Structures (Revised 3rd Edition, Draft).
- North-West University. (2019). Risk Level Descriptors for Human Participants for Use at the North-West University.
- University of South Africa. (2023). Standard Operating Procedure on Research Ethics Risk Assessment.