University of South Africa Research Ethics Committees	
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1 COMPILATION AND AUTHORISATION

Action	Designated person	Date	Signature
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2 DISTRIBUTION

Department/unit	Name	Date	Signature
URERC	Dr R G Visagie	18 April 2019	

3 DOCUMENT HISTORY

Date	Version no	Reason for revision
4 June 2015	1	Procedure approved by SRIPCC
14 February	2	Revised procedure approved by SRIPCC

4 ABBREVIATIONS AND/OR DEFINITIONS

Abbreviation	Definition/Description
CREC/CERC	College Research Ethics Committee (this term is synonymous with College Ethics Review Committee [CERC] or College Research Ethics Review Committee [CRERC] used in Unisa Policy documents). A College/Unit REC/ERC is attached to or based in a specific college/institute/centre and reports to the University of South Africa Research Ethics Review Committee. There is a minimum of one CREC per college. It plays a governance function within the unit.
Sub-unit RECs/ERCs	The sub-unit RECs/ERCs are school and departmental committees affiliated to and reporting to the college/institute/centre REC/ERC
HREC	Health Research Ethics Committee registered with the National Health Research Ethics Council to review human research in accordance with the National Health Act no. 61 of 2003.
Risk of harm	The concept of 'risk' denotes the possibility that research may cause varying degrees of harm to any participants and/or related contexts, including human participants, animal participants, the respective research institution(s), communities, the environment and society. Any such risks must be considered before commencing research.
Risk-benefit analysis	An assessment to evaluate whether there is an ethically justifiable balance between the anticipated research results and any harm or inconvenience that may be caused to any of the participants, research institution(s),

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	communities and society.
URERC	University of South Africa Research Ethics Review Committee Refers to the university RERC that has Unisa-wide jurisdiction and is not attached to or based in a single unit in Unisa. It is a subcommittee of the Senate Research, Innovation, Postgraduate Studies and Commercialisation Committee (SRIPCC).
SOP	Standard Operating Procedures
SRIPCC	Senate Research, Innovation, Postgraduate Studies and Commercialisation Committee The SRIPCC acts on behalf of and reports to Senate.

5. PURPOSE

The purpose of the Standard Operating Procedure for research ethics risk assessment is to provide office bearers of Unisa ERCs and researchers (Unisa and Non-Unisa) with a framework to identify, estimate and evaluate the potential risks of harm of research to human participants, animals, researchers, the academic department, institution, community, environment and/or society in order to conduct a benefit-risk analysis.

6. SCOPE

This Standard Operating Procedure provides a framework for Unisa researchers (including staff, research associates and post-doctoral fellows), Unisa students (including UNISA staff registered for qualifications at UNISA), Non-Unisa researchers (including visiting researchers), Non-Unisa students (including UNISA staff registered for qualifications at other higher education institutions) and Unisa Ethics Research Committees (hereafter ERCs) to engage in research ethics risk assessment.

7. RESPONSIBILITIES

7.1 Researchers have the primary responsibility to ensure that the research conducted in their respective disciplines will have a positive benefit-risk ratio, therefore maximising the potential benefits to human participants, animals, institutions, communities, society and/or the environment and minimising anticipated risks to research participants, animals, institutions, communities, the environment, society and/or researcher(s) themselves.

7.2 Unisa ERCs chairpersons (including the Unisa Research Ethics Review Committee [hereafter URERC], unit and sub-unit/departmental ERCs) are responsible for integrating the research ethics risk assessment in research ethics review processes

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with a view to differentiate between negligible, low, medium or high risk research in adherence to international and national research ethics review guidelines.

7.3 Members of the ERC are responsible to conduct a risk-benefit analysis as part of the review process.

7.4 The College Heads of Graduate Studies and Research, in collaboration with the ERC chairperson and the Manager: Research Integrity, are responsible to plan and implement sufficient capacity building opportunities in research ethics risk assessment for ERC members, supervisors and researchers to facilitate excellence in the execution of this task.

8. TYPOLOGY OF RESEARCH ETHICS RISKS OF HARM

8.1 Types of risk cover a range of potential risks of harm that include physical risks, psychological or emotional, social, legal and political risks.

8.2 Physical risks are risks of harm through physical intervention or involvement of participants in experiments that may alter the physical condition or physical health of the participants. Such risks are seldom encountered in research conducted in the humanities, social sciences and behavioural sciences. However, physical risk applies in particular to animal related research projects conducted within Unisa where animals may endure certain levels of irritation, stress or discomfort due to the experimental procedures applied.

8.3 Psychological or emotional risks are risks of harm related to the mental wellbeing of the participants or researchers, which may be caused through embarrassment, anxiety, or emotional distress. The risk of psychological harm must be evaluated on a scale of potential risks, ranging from mild discomfort to the possibility of severe trauma.

8.4 Social, legal and political risks are risks of harm due to loss of status, privacy, social standing, or financial risk as a result of confidentiality breaches. Such risks may also appear when the participants belong to marginalised or minority groups with contentious social or political characteristics that may be liable to legal persecution or social exclusion, if research data is not treated confidentially.

8.5 Ethical research must consider the ability of the participants to act in their own interest and the protection of researchers against potential risk of harm related to the conduct of a specific research project.

8.6 Researchers should also consider the potential for reputational risk of harm of institutions involved in the research.

8.7 The potential risks of harm involved in research must be assessed against the degree of vulnerability of the human participants (children or young people under the age of 18,

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the elderly, physical or mentally ill, people with learning difficulties, prisoners, students or colleagues, over-researched participants, non-English speaking participants or those with a low functional literacy, participants engaged in illegal activities). This ability may be impaired by the participants' lack of social and political autonomy in making independent decisions, or by a lack of mental or physical capability to understand the possible consequences of their involvement in the proposed research.

8.8 Any research that involves human participants must be based on the mutual understanding of all parties involved regarding the types of risk of harm that the research may entail. Any such project must also give the participants the opportunity to critically engage with the research and the researchers, ranging from the right to refuse to answer questions to the possibility of withdrawing altogether from the research without any negative consequences for the participants.

8.9 In addition, risk assessment must consider the following aspects:

8.9.1 Nature of human participant involvement or animal involvement (no involvement, indirect or direct involvement)

8.9.2 Perceived sensitivity of the research area (not sensitive at all, probability of being sensitive related to the context of the study and research that is usually categorised as sensitive in nature because it is controversial, contentious, embarrassing or upsetting in nature)

8.9.3 The type of research, invasiveness of the recruitment and data collection procedures (deceptive practices, coercion or incentives to participate, approaching participants in a public space)

8.9.4 Confidentiality issues relevant to covert observation of participants, recording or filming/photography, potential breaches and limitations of confidentiality, lack of anonymity and issues related to security and storage of data

8.9.5 Participation is not voluntary, or there is undue coercion or bribery of participants

8.9.6 Inappropriate financial interests of the researcher and/or the institution

8.9.7 Health and safety issues including equipment hazards, chemical or biological hazards

9. PROCEDURE OF RESEARCH ETHICS RISK ASSESSMENT

9.1 Research applications for ethics approval provided to ERCs must include a risk assessment (identification, estimation and evaluation of potential benefits and risks), and this information should be contained in the participant information sheet.

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9.2 The ERC should not rely exclusively on the view of the researcher when assessing the probability or the magnitude of harm. Independent expert opinion could be sought, whenever it is deemed necessary.

9.3 The ERC and researchers have an obligation, to ensure that the risks inherent in the proposed research have been reduced to the minimum necessary to achieve the research objective. This duty includes consideration of whether alternative methods of obtaining the research information are available and consideration of whether lower risks might prevail in a different group of participants.

9.4 The ERC may thus require that certain steps or measures should be taken by a researcher to mitigate or avoid potential ethical risks, in relation to a particular ethics review.

9.5 Negligible and low risk research applications can be processed by an expedited review procedure by sub-unit or departmental ERCs (refer to Table 4.1 and 4.2 for an outline of the procedure).

9.6 Medium and high-risk research is approved through a full Research Ethics review procedure (refer to Table 4.3 and 4.4 for an outline of the procedure) by the College ERC.

9.7 The ERC should ensure that there is regular monitoring and evaluation of the ethical risks of approved studies, particularly in research that entails medium to high ethical risks.

9.8 High-risk research must be reported in writing to the Executive Dean of the specific College or Unit as well as to URERC. The report must reflect the ERCs role in ongoing monitoring of the high-risk research.

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Table 4.1 RISK CATEGORIES, EXPLANATIONS, EXAMPLES AND THE RESEARCH ETHICS APPLICATION PROCEDURE

Risk category	Definition	Explanation and examples	Application procedure
4.1 Category 1: Negligible risk	Research that **does not involve** human participants **at all** or involve human participants **indirectly**. The probability or magnitude of risk of harm or discomfort anticipated in the research is unlikely and not greater in itself than that ordinarily experienced in daily life.	Research that involves non-invasive procedures with no apparent risk to participants (institutions and researchers) above the everyday norm related to NO or INDIRECT involvement of participants, a research topic that is not sensitive and de-identified data collection procedures. This could typically include studies based on the analysis of existing statistics, documents, databases and information in the public domain, for instance in public archives, on websites, newspapers, annual published reports of companies or newsletters. 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.	1) The departmental ERC or College ERC in the absence of a departmental/school ERC will follow an expedited process. URERC to follow a similar process if applicable relating to external applications. 2) Applicants complete Form 2 (secondary data) or From 3 (Conceptual research) 3) The application form and relevant supporting documents (e.g. research proposal, permission to access information, previous ethics clearance certificates) are submitted electronically to the relevant ERC. 4) The administrator/chairperson conducts an initial screening of the application to determine whether the application meets the requirements for negligible risk. 5) If so, the chairperson may review the application or the chairperson may

			delegate the review to a senior member of the ERC. 6) The administrator/chairperson communicates the decision to the applicant within seven working days. 7) The administrator/chairperson completes the departmental research ethics register. 8) The review report and decision are ratified at the next regular meeting of the ERC. 9) The researcher may proceed with the research on receipt of the approval letter. 10) The departmental ERC reports quarterly on all expedited applications to the College ERC. 11) The College ERC reports quarterly on all expedited applications to the URERC.
Risk category	**Definition**	**Explanation and examples**	**Application procedure**
4.2 Category 2: Low risk	Research involving human participants **directly** in which the probability or magnitude of risk of harm or discomfort anticipated in the research is not greater in itself than ordinarily experienced in daily	One or more of the following apply: • Research in which the investigation of largely uncontroversial topics is undertaken through interviews, surveys and observation. • The participants are adults and not considered a vulnerable research population. • The research will collect information that would generally be regarded as non-	1) The departmental ERC or College ERC in the absence of a departmental/school ERC will follow an expedited process. URERC to follow a similar process if applicable relating to external applications. 2) The applicant conducts a risk assessment to determine the risk category 3) Health research must be referred to an ERC registered to the NHREC. 4) The applicant completes Form 1 (human

	life. The researcher can easily mitigate the risk. (The concept of 'daily life' used as a benchmark should be that of daily life as experienced by the average person in the country the participants are living in).	sensitive. • The information can generally be collected anonymously or participants may not insist on keeping the collected information strictly confidential. Examples: • Use of questionnaires/surveys (that do not involve sensitive questions) sent to non-vulnerable adult participants, and returned anonymously so that participants cannot be identified. • Recording information from groups of participants (rather than individual participants) in an educational setting where participants are not identified.	subject application form). 5) The application form and relevant supporting documents (e.g. research proposal, permission to access information, previous ethics clearance certificates) are submitted electronically to the relevant ERC. 6) The administrator/chairperson conducts an initial screening of the application to determine whether the application meets the requirements for low risk. 7) The chairperson nominates two or more members to review the application (sub-committee). 8) If a consensus cannot be reached or members classify the research as more than low risk, the proposal must be given a full review. 9) An en banc/full meeting of the ERC may be required. 10) The administrator/chairperson of the ERC issues a clearance letter, subject to any amendments or requirements following from the review. 11) Normally an expedited low risk review will not take longer than 3 weeks to complete. 12) The review reports and decisions of the sub-committee are ratified at the next regular meeting of the ERC.

			13) The researcher may continue with the research upon receipt of the clearance letter while awaiting the ratification of the expedited review. 14) If any changes to the decision of the sub-committee is made at the ratification of an expedited review, the researcher and supervisor will immediately be informed. 15) The departmental ERC reports quarterly on all expedited applications to the College ERC. 16) The College ERC reports quarterly on all expedited applications to the URERC
Risk category	**Definition**	**Explanation and examples**	**Application procedure**
4.3 Category 3: Medium risk	Research involving human participants **directly** in which there exists a potential risk of physical, emotional and/or psychological harm and/or social stigmatisation, prosecution or persecution, but where appropriate steps can be taken to mitigate or reduce the overall risk. It is not expected that	One or more of the following apply: • The research topic is 'sensitive'. • Information gathered is personal rather than opinion, attitudes, or a combination of both. • The information needs to be collected with personal identifiers. • The research participants may come from a vulnerable or marginalised group • Research studies involving social media, could be medium risk, depending on the research question under investigation. Examples: • Interviews for the purpose of gathering	1) The College ERC follows a full ethics review procedure (medium risk research is not approved on departmental/school level by non-registered ERCs). 2) Applicants are required to complete Form 1 (human subject application form), to do a risk assessment and submit the application electronically to the relevant ERC. 3) A copy of the final research proposal, participant information sheet and informed consent form, data collection instruments, letters requiring institutional permission, abridged Curriculum Vitae's of researchers, letters from

	the research will cause severe risk or negative physical, emotional, social, cultural or political consequences. (This research may require mitigation in the form of counselling, debriefing or other forms of support.)	biographical data, which may contain embarrassing or intimate personal details, whose publication may not result in serious legal or social consequences but could lead to a moderate loss of status or damage to public image. • Research where participants are in a dependent relationship to any of the researchers and this may affect their decision to participate e.g. research on inmates in a prison by a prison officer or on students by a lecturer.	translators/interpreters, etc. should be attached. 4) The chairperson selects a sub-committee consisting of three members of the ERC to conduct the review prior to the meeting to ensure adequate scrutiny of the application. 5) All members of the ERC should adequately prepare for the meeting to participate in the final decision. 6) The application is tabled for full committee review at the relevant ERC. 7) The administrator/chairperson of the ERC issues a clearance letter, subject to any amendments or requirements following from the review and the full committee deliberations. 8) Normally applicants will receive feedback in writing on the outcome of the review within fourteen days of the meeting date at which the decision was made. 9) Amendments are either expedited by the chairperson and/or the original reviewers, or submitted for full review by the ERC depending on the risk nature of the proposed amendments. 10) Normally an expedited review of amendments will not take longer than ten working days to complete.

Risk category	Definition	Explanation and examples	Application procedure
4.4 Category 4: High risk	Research involving human participants **directly** in which there is a real and foreseeable risk of emotional or psychological harm and/or social stigmatisation or prosecution, which may lead to a serious adverse event, if not managed in a responsible manner.	Research that may reveal information that requires action on the part of the researcher that could place the participant or others at risk. One or more of the following apply: • Research involving highly sensitive topics • Research involving vulnerable and marginalised individuals or communities • Research involving deception of research participants • Any research that may place the researcher, participant, animals, at real risk of harm. • Any plant, biological or molecular related research that may result in contamination, injury to the researcher or destruction of the environment in any form • Information revealed during the course of the research that may place the researcher at risk of breaking the law Examples: • Research investigating gang activities and possession of illegal firearms • Research involving child victims of physical or sexual abuse, victims of domestic violence or research dealing with HIV/AIDS.	1) An NHREC registered College/ departmental ERC follows a full ethics review procedure 2) Refer to section 4.3 above. 3) Applicants are required to complete Form 1 (human participant involvement) and submit it electronically to the relevant ERC. 4) A copy of the final research proposal, participant information sheet and informed consent form, data collection instruments, letters requiring institutional permission, abridged Curriculum Vitae's of researchers, letters from translators/interpreters, etc. should be attached. 5) The application will be tabled for full committee review at the relevant ERC. The chairperson selects a sub-committee consisting of three members of the ERC to conduct the review prior to the meeting to ensure adequate scrutiny of the application. All members of the ERC must adequately prepare for the meeting

			to engage in the final decision. 6) The chairperson of the ERC issues a clearance letter, subject to any amendments or requirements following from the review. 7) Normally, applicants will receive feedback in writing on the outcome of the review within fourteen days of the meeting date at which the decision was made. 8) Minor amendments could be reviewed by an expedited review process or by the chairperson depending on the nature of the amendments. 9) High-risk research must be reported in writing by the chairperson of the relevant ERC to the Executive Dean of the specific college and to URERC (refer to 3.12).

10. RISK ASSESSMENT TOOL

In order to assess the ethical risk of a proposed research project, the researcher engages in a systematic and comprehensive assessment of the project. For the researcher and the ERC, it provide a means to examine whether potential risks that will be presented to participants (and other entities) are justified. For prospective participants, the assessment will guide their decision whether to participate or not to participate, after reading the Informed Consent documentation.

The checklists below have been designed to guide researchers to assess the potential risk of the proposed research. If the researcher answers YES to any of the questions below, the research may use more invasive research methodology or represent more complex ethical or privacy issues, in which case the researcher needs to explain the ethical implications and procedures to minimise harm to the participants (animals, institutions, communities and/or society).

Category 1 (Research involving negligible risk): The probability of anticipated harm or inconvenience in the research is not greater than that experienced in daily life. For a research project to be considered to involve negligible risk to participants, all boxes on the checklist will typically be “NO”. All exceptions should be motivated.

Category 2 (Research involving low risk): Research in which the only foreseeable risk is one of potential inconvenience or discomfort to the participants. It is possible that some items on the ethical risk checklist are ticked “YES” but the project could still be considered to be low risk e.g. there may be cases where individuals may wish to be identifiable, e.g. collection of an oral history, or where individuals wish to have their opinions attributed to them. In cases where a researcher has ticked “YES” to items on the ethical risk checklist, but still believes that the research is of low risk to participants, an explanation should be provided. In most cases, the explanation can determine if the project may be considered low risk.

Category 3 (Research involving medium risk): Research in which there is a potential risk of harm or discomfort, but where appropriate steps can be taken to mitigate or reduce overall risk. If any items on the ethical risk checklist in SECTION 2 and 3 are ticked “YES”, the research may be likely to involve medium risk to the participant. The applicant needs to indicate how

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participants will benefit from the research and describe the steps that will be undertaken to mitigate the risk.

Category 4 (Research involving high risk): Research in which there is a real and foreseeable risk of harm and discomfort, which may lead to a serious adverse event if not managed in a responsible manner. If a number of items on the ethical risk checklist in SECTION 1, 2 and 3 are ticked "YES", the research may be likely to involve significant risk to the participants, researcher(s), institutions or Unisa. The applicant needs to indicate how participants will benefit from the research and describe the steps that will be undertaken to mitigate the risk.

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 urerc@unisa.ac.za; internal applicants can click on this link to obtain the document. If you are unsure about the meaning of any of these concepts, please consult your supervisor or project leader.

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][1]		
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[2]		
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**	**YES**	**NO**

[1] *Health* is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity (Collins English Dictionary)

[2] Definition of health research, NHA 61 of 2003, p.8

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	groups of participants *(Refer to Section 4 in the SOP)*		
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)*[3] *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 alumni Indicate that you will apply for permission at the UNISA Research Permission Subcommittee (RPSC) in 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. English 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 in the application form. 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[4]. 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 (consult the summary of the POPIA on this link).			
c) Personal, identifiable information to be collected about individuals from available records			

[3] Describe whether and how proxy or gatekeeper consent will be obtained in section 6.1 relevant to items 2.1. a – e

[4] Form 1 does not apply to plant, molecular or cell research, animal and environmentally related research.

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(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 test administration is in South Africa or of an equivalent board if 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 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.		

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]			

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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.		

2.5	**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	a	**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.	b	**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.	c	**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.	d

(a) Briefly justify your choice/classification

(b) Indicate the potential benefits of the study for the research participants and/or communities or other entities.

(c) 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 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.

(d) 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.).

(e) 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.

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(f) Describe your arrangements regarding indemnity/compensation for research-related adverse events (if applicable).

11. ACKNOWLEDGEMENT AND DOCUMENTS CONSULTED

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12. GLOSSARY

Most of the concepts in this Glossary were adopted from the University of Stellenbosch, Standard Operating Procedure (2012), Human Research Ethics Review Committee, with permission from Dr Therina Theron, Senior Director: Research and Innovation (ttheron@sun.ac.za). The Glossary is based on the definitions of the NHREC Glossary available on http://www.mrc.ac.za/ethics/DOHEthics.pdf. Definitions marked by an asterisk (*) do not appear in the Glossary of the NHREC. Definitions marked by a double asterisk (**) refers to Unisa-specific definitions as indicated in the Policy on Research Ethics and the Policy for conducting research involving Unisa staff, students and data. The definitions in this Glossary aim to assist readers to interpret the SOP. These definitions can be updated by URERC, unit and sub-unit ERCs on an ongoing basis.

Adverse event

Any undesirable or unintended response or occurrence in a research participant, i.e. a clinical sign, symptom, condition, or psychological reaction, to a research intervention, which does not necessarily have a causal relationship with the intervention being researched.

*Elaborated in terms more appropriate to social research**

Any undesirable or unintended response or occurrence that emerges in research, which does not necessarily have a causal relationship with the research process, for example, a research participant disclosing unsolicited information that reveals an emergency situation.

Applicant

A qualified researcher undertaking the scientific and ethical responsibility for a research project, either on his/her own behalf or on behalf of an organisation/firm, seeking a decision from an ethics committee through formal application.

*Within Unisa four main categories of applicants or researchers are defined:***

Non-UNISA researchers (including visiting researchers)

Non-UNISA students (including UNISA staff registered for qualifications at other higher education institutions)

UNISA researchers (including staff, academic associates, postdoctoral fellows)

UNISA students (including UNISA staff registered for qualifications at UNISA)

Approval (in relation to the Ethics Review Committee)

The Ethics Review Committee's affirmation that the research protocol has been reviewed and that the research may be conducted by the applicant according to the constraints set out by the ethics committee, the institution and legal requirements.

Approval conditions

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Conditions to be met by the applicant prior to the start of the research. Approval conditions are issued by the Research Ethics Committee with the final letter confirming a favourable ethical opinion. (Note: Approval conditions are distinct from the further information or clarification requested from the applicant when issuing a provisional opinion).

Anonymous Samples or Data

See De-identified samples or data

Assent *

Permission to participate in research provided by a minor, or someone under legal guardianship.

Benefit

That which positively affects the interests or welfare of an individual or group, or the public generally.

Chairperson

The member of an Ethics Review Committee appointed to be the chairperson by the appointing authority. Where the Chairperson is unavailable for any reason, his/her duties may be performed by the deputy-Chair/secundus.

Child

Subject to law in the relevant jurisdiction, a child is a minor who lacks the maturity and legal ability to make a decision whether or not to participate in research.

Collectivities

Distinct human groups with common identity, their own social structures, common customs and designated leaders or other persons who represent collective interests in dealing with researchers. Collectivities may include cultural or ethnic groups, and indigenous communities.

Competence

The ability of a person or a group to understand and make choices in accord with their own fundamental values. The term 'legal competence' indicates that a person's age and mental state satisfy certain basic legal requirements.

Confidentiality

The obligation of people not to use private information – whether private because of its content or the context of its communication – for any purpose other than that for which it was given to them.

Conflict of interest (research)

In the research context: where a person's individual interests or responsibilities have the potential to influence the carrying out of his or her institutional role or professional obligations in

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research; or where an institution's interests or responsibilities have the potential to influence the carrying out of his or her research obligation.

Conflict of interest (Ethics Review Committee)

A conflict of interest arises when a member (or members) of the Research Ethics Committee holds interests with respect to specific applications for review that may jeopardize his/her (their) ability to provide a free and independent evaluation of the research focused on the protection of the research participants. Conflicts of interests may arise when an Ethics Review Committee member has financial, material, institutional, or social ties to the research.

Consent

A person's or group's voluntary agreement based on adequate knowledge and understanding of relevant material, to participate in research. Informed consent is one possible result of informed choice; the other possibility is refusal.

Data

Data are facts, observations or experiences on which an argument, theory or test is based and include any information, records, files or other evidence, irrespective of their content or form (e.g. in print, digital, physical or other forms), that comprise research observations, findings or outcomes, including primary materials and secondary data. Data may be numerical, descriptive or visual. Data may be raw or analysed, experimental or observational[5].

Deception

Deception includes the withholding of essential information from research participants, deliberately misleading them about procedures and purposes, including studies in which participants are deliberately given misleading information about the purpose of a research study.

De-identified (not re-identifiable, anonymous) Samples or Data

The process of de-identification may be irreversible where the identifiers have been removed permanently or the data has been de-identified. These data are referred to as 'de-identified'. It should be recognised that the term 'de-identified' is used frequently, in documents other than this statement of the Ethics and Health Research: Principles, Structures and Processes, to refer to sets of data from which only names have been removed. Such data may remain 'potentially identifiable'.

See also **Identified Samples or Data** and **Potentially Identifiable Samples or Data**.

[5] Definition adapted from: University of Melbourne Management of Research Data and Records http://research.unimelb.edu.au/integrity/conduct/data/review cited in the Australian National Data Service Guide. (2011). web@ants.org.au. (Accessed on 31 March 2015).
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Discomfort

A negative accompaniment or effects of research, less serious than harm.

Ethical/Unethical

Right or morally acceptable on one hand, wrong or morally unacceptable on the other. Conforming to the rationally acknowledged norms and standards of behaviour, or failure to conform to such norms and standards.

Ethical review**

An objective appraisal of the effect of the proposed research on the wellbeing of potential participants, animals, the environment, institutions, collectivities and communities by an established Ethics Review Committee.

Ethical risk [in human research, non-medical] *

An action, procedure or method used in the research and in its reporting that can compromise the dignity, rights, safety, and well-being of participants in research, or those affected by that research.

Ethics

A branch of moral philosophy concerned with the rational evaluation of the concepts of right and wrong, justice and injustice, virtue and vice, good and bad, and activities to which these concepts apply.

Ethics Review Committee (Research Ethics Committee [ERC])

An independent body whose responsibility is to ensure the protection of the rights, safety and wellbeing of human participants involved in research. An ethics committee provides public assurance of that protection, by, reviewing and approving the protocol, the suitability of the investigator's facilities, and the methods and material to be used in obtaining and documenting the informed consent of the participants. Ethics committees should be independent of political, institutional, professional and market influences. The legal status of *health research* ethics committees in South Africa is established under the National Health Act, 2003 (Act No. 61 of 2003). ERCs within the Unisa context are constituted by the Senate Research and Innovation and Higher Degrees Committee of the University, and has been authorised to carry out ethical review of research.

Harm

Harm relates to the negative outcomes of research which adversely affects the interests or welfare of an individual or a group. Harm includes physical harm, anxiety, pain, psychological disturbance, devaluation of personal worth and social disadvantage.

High risk (research)

Research in which there is foreseeable risk of harm and discomfort, which may lead to a serious adverse event, if not managed in a responsible manner.

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*Elaborated in terms more appropriate to social research**

Research in which potential exists for a level of emotional or psychological distress and/or social stigmatisation, prosecution or persecution where there is a likelihood that harm could be done to the well-being of the participant even if due care is taken and mitigation is provided for. (Refer to 4.4 in the SOP).

Human subject research

'Health research[6]' may be understood to include but is not limited to research that contributes to knowledge of

- biological, clinical, psychological, or social welfare matters as regards humans
- the causes of disease
- effects of the environment on humans
- methods to improve health care service delivery
- new pharmaceuticals, medicines, interventions and devices
- new technologies to improve health and health care

Inconvenience

A minor negative accompaniment or effect of research, less serious than discomfort.

Individually identifiable data

Data from which the identity of a specific individual can reasonably be ascertained. Also refer to personal information below.

Identified Samples or Data

Data that enables the identification of a specific individual is referred to as 'identified data'. Examples of identifiers may include the individual's name, date of birth or address. In particularly small sets of data even information such as a post code may be an identifier. *See also:* De-identified Samples or Data and Potentially Identifiable Samples or Data.

Integrity

Honesty and probity as qualities of character and behaviour.

Investigator or researcher

A qualified scientist *(or researcher)* who undertakes scientific and ethical responsibility, either on his/her own behalf or on behalf of an organization/firm, for the ethical and scientific integrity of a research project at a specific site or group of sites. In some instances, a coordinating or principal investigator may be appointed as the responsible leader of a team of sub investigators.

[6] National Department of Health (DoH). (Revised draft 2014). Ethics in Health Research: Principles, Processes and Structures.

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*Elaborated in terms more appropriate to social research**

The terms “investigator” and “researcher” can be used interchangeably; and it should be noted that research in the humanities may not be site-specific.

Justice

This concept concerning fairness or equity is often divided into three parts. Procedural justice is concerned with the fair methods of making decisions and settling disputes; distributive justice seeks to ensure fair distribution of benefits and burdens, while corrective justice is concerned with correcting the wrongs and harms through compensation or retribution.

Low risk (research)

Research in which the only foreseeable risk is one of discomfort.

*Elaborated in terms more appropriate to social research**

Research in which the potential exists for minor emotional discomfort, e.g. the subject matter may have a low degree of personal, social or political sensitivity that could cause embarrassment to participants. This risk can be easily mitigated by a sensitive approach by the investigator. (Refer to 4.2 in the SOP).

Monitoring (of research)

Monitoring of research refers to the process of verifying that the conduct of research conforms to the approved proposal. Monitoring may take several forms, including review of annual reports, formal review of the informed consent process, establishment of a safety monitoring committee, a periodic review by a third party of the documents generated by the study, a review of reports of adverse events, and a random audit of the particular processes.

Medium risk

Research in which there is a probable risk of harm or discomfort, but which can be fairly easily managed to pose the minimum risk to the participant.

*Elaborated in terms more appropriate to social research**

Research in which the potential exists for a level of emotional or psychological distress and/or social stigmatisation, prosecution or persecution that could be harmful to the participant if due care is not taken by the investigator, and could require mitigation, e.g. counselling or other forms of support. (Refer to 4.3.)

Minimal risk

The probability or magnitude of harm or discomfort anticipated in the research is not greater in itself than that ordinarily encountered in daily life.

*Elaborated in terms more appropriate to social research**

Research involving the analysis of existing statistics, as well as literature, documents, databases and information in the public domain, for example in public libraries, public archives, on websites, newspapers, or newsletters. Any anticipated harm or discomfort to third parties

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related to this research is no greater than ordinarily encountered in daily life. (Refer to 4.3 in the SOP.)

No risk research*

See Minimal risk.

Personal information (according to the Protection of Personal Information Act no 4 of 2013)*

"Personal information" means information relating to an identifiable, living, natural person, and where it is applicable, an identifiable, existing juristic person, including, but not limited to—

a) information relating to the race, gender, sex, pregnancy, marital status, national, ethnic or social origin, colour, sexual orientation, age, physical or mental health, well-being, disability, religion, conscience, belief, culture, language and birth of the person;

b) information relating to the education or the medical, financial, criminal or employment history of the person;

c) any identifying number, symbol, e-mail address, physical address, telephone number, location information, online identifier or other particular assignment to the person;

d) the biometric information of the person;

e) the personal opinions, views or preferences of the person;

f) correspondence sent by the person that is implicitly or explicitly of a private or confidential nature or further correspondence that would reveal the contents of the original correspondence;

g) the views or opinions of another individual about the person; and

h) the name of the person if it appears with other personal information relating to the person or if the disclosure of the name itself would reveal information about the person.

Privacy

Privacy implies a zone of exclusivity where individuals and collectives are free from the scrutiny of others. It may also include control over the extent, timing and circumstances of sharing oneself with others, whether physically, intellectually or in terms of behaviour.

Protocol or proposal

A document that provides the background, rationale and objectives of the research and describes its design, methodology, organisation and the conditions under which it is to be performed and managed.

Public domain*

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Generally, a zone of common, unrestricted access shared by individuals and collectives. Elaborated in terms more appropriate to intellectual property right on research instruments* "Works are in the public domain if the intellectual property rights have expired, if the intellectual property rights are forfeited, or if they are not covered by intellectual property rights at all. In a general context, public domain may refer to ideas, information, and works that are "publicly available", but in the context of intellectual property law (which includes copyright, patents, and trademarks), public domain refers to works, ideas, and information which are intangible to private ownership and/or which are available for use by members of the public." Wikipedia

Record*

PAIA defines a record as:

“record” of, or in relation to, a public ....body, means any recorded information-

a) regardless of form or medium;

b) in the possession or under the control of that public …body, …; and

c) whether or not it was created by the public …body…

A request for access to information must be done in terms of the Promotion of Access to Information Act.

Research**

Research means a systematic investigation aimed at the development of, or contribution to, knowledge.

Researcher**

Researcher refers to all permanently appointed UNISA employees and current Academic Associates (excluding Emeritus Professors) and collectively refers to Developing Researchers, Emerging Researchers and Proven Researchers. Student researchers refer to any registered student that is conducting research under the supervision of a qualified supervisor.

Research Participant

Living individual (or group of living individuals) about whom a researcher conducting research obtains data through intervention or interaction with the person or identifiable private information.

Respect for Persons

This has two fundamental aspects:

- Respect for the autonomy of those individuals who are capable of making informed choices, and respect for their capacity for self-determination;
- Protection of persons with impaired or diminished autonomy, that is, those individuals who are incompetent or whose voluntariness is compromised.

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Research Ethics (health)

Reviews invasive types of research, e.g. intervention studies collecting blood or tissue, drug trials, using surgical procedures or chart reviews involving biomedical subject areas.

Research misconduct

Includes fabrication, falsification, plagiarism or deception in proposing, carrying out or reporting the results of research, and failure to declare or manage a serious conflict of interest. Also includes failure to follow research proposals approved by a research ethics committee, particularly where this failure may result in unreasonable risk or harm to humans, animals or the environment. Also includes the wilful concealment or facilitation of research misconduct by others.

Requirements

In the context of decisions, requirements are binding elements that express ethical considerations whose implementation the ethics committee requires or views as obligatory in pursuing the research.

Revision of application

Any changes made to the terms of an application at the request of the Ethics Review Committee following the meeting or, following issue of an opinion, before the research has started. Revision is not permitted prior to the Research Ethics Committee meeting once the application has been validated.

Risk

The function of the magnitude of harm and the probability that it will occur. (See Addendum 3 for a classification of risk types.)

Standard Operating Procedures (SOPs)*

Standard operating procedures are issued by the Research Ethics Committee to describe the activities necessary to conduct tasks in accordance with relevant statutes and regulatory frameworks.

Sponsor

An individual, company, institution or organization that takes responsibility for the initiation, management, and/or financing of research.

Voluntary participation

Participation that is free of coercion and pressure.

Vulnerable person / groups

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Those whose willingness to volunteer in a research study may be unduly influenced by the expectation of benefits associated with participation.

*Elaborated in terms more appropriate to social research**

Individuals or categories of participants can be vulnerable prior to research, or rendered vulnerable because of research, due to factors including, but not limited to:

1. Reduced ability to make a voluntary decision, because of factors including, but not limited to age, mental disarray, subordinate position, and impoverished position.

2. Reduced ability to make an informed decision, because of factors including, but not limited to lack of familiarity with the scientific method, linguistic barriers, inability to read or write, reticence to ask questions about the research.

3. Breaching of confidentiality by the researcher in any stage of the research.

4. Exposing participants unfairly to the risks of the research, or bestowing on participants unfairly the benefits of the research.

5. Exposing participants or third parties not directly involved in the research, to any complications that may be caused by the research.

*It may thus include***:*

Children (i.e. those individuals under the age of 18 years), the elderly, pregnant women, people with a cognitive or mental impairment, prisoners or people on parole, students, people living with HIV/AIDS, people in dependent relationships, people with disabilities, socio-economically disadvantaged people, indigenous people and indigents.

UNISA Ethics Review Committee (URERC)*

URERC refers to the Unisa Research Ethics Review Committee and is a body constituted by the Senate Research, Innovation, Postgraduate Degrees and Commercialisation Committee to carry out ethical review of Non-Unisa researchers and students. The membership consists of the chairpersons of the College/Unit ERCs. URERC also deals with appeals on College levels and may review high-risk research applications on request of Unit/College ERCs.

Unit Ethics Review Committee (Unit ERC)*

Unit Ethics Review Committees refer to a College/Unit Body. The unit ERCs are attached to or based in a specific college/institute/centre. There is a minimum of one unit ERC per college which has been constituted by the College Research Committee to carry out ethical review of research. The Unit ERC carries out high-risk research ethics applications and reports to the URERC.

Sub-unit Ethics Review Committee (Sub-unit ERC)*

A sub-unit ERC refers to a Departmental Body, which has been constituted by the College/Unit ERC to carry out ethical review of research. The sub-unit ERC carries out all negligible, low and medium risk research ethics application. The sub-unit ERC reports to the unit or College ERC.

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