**STANDARD OPERATING PROCEDURE FOR RESEARCH ETHICS RISK ASSESSMENT**

1. **INTRODUCTION**
   1. This Standard Operating Procedure provides a framework for Unisa researchers (staff, academic associates, post-doctoral fellows and students), Non-Unisa researchers (visiting researchers and students) and Unisa Ethics Research Committees (ERCs) to engage in research ethics risk assessment.
   2. 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 at large. Any such risks must be considered before commencing research.
   3. The assessment of any proposed research must 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), communities and society at large. This process is referred to as risk/benefit analysis.
   4. Researchers have the primary responsibility to ensure that the research conducted in their respective disciplines will have a *positive risk: benefit 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).
   5. Research that is conducted by researchers that are connected to Unisa (Unisa researchers and Non-Unisa researchers) must be assessed by the researchers and the respective ERCs to identify, estimate and evaluate the potential risks to human participants, animals, institutions, communities, the society, the environment and/or the researchers.
   6. A basic prerequisite for conducting the risk assessment is a critical reflection on and deliberation about the potential ethical risk(s) of the research and not on the completion of the risk assessment as a mere administrative requirement.

1. **PURPOSE**
   1. The purpose of the Standard Operating Procedure for research ethics risk assessment is to assist researchers (Unisa and Non-Unisa) and ERCs to identify, estimate and evaluate the potential risk of research to human participants, animals, the researcher or a research team, the academic department, institution, community, environment and/or the society in order to conduct a risk-benefit analysis.
2. **PROCESS OF RISK ASSESSMENT**
   1. Unisa ERCs are responsible for integrating the ethics risk assessment in their research ethics review process with a view to differentiate between negligible, low, medium or high risk research in adherence to international and national research ethics review guidelines.
   2. This Standard Operating Procedure provides the office bearers of ERCs with standardised documentation and information on risk assessment in research, and where appropriate, training will be offered by the Research Department to the office bearers to ensure conformity and high standards in the execution of this task.
   3. The ERC must ensure that researchers and supervisors are informed of the risk assessment process and where necessary training and guidance should be offered to Unisa researchers by Colleges, departments and/or relevant units.
   4. Research applications for ethics approval provided to ERCs must include a risk assessment (identification, estimation and evaluation of potential risks), and this information should be contained in the participant information sheet.
   5. The ERC should not rely exclusively on the view of the researcher when assessing the probability or the magnitude of harm. Independent expert opinion should be obtained whenever deemed necessary.
   6. 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.
   7. 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.
   8. Negligible and low risk research applications can be processed by an expedited review procedure (refer to Table 4.1 and 4.2 for an outline of the procedure).
   9. Medium and high risk research is approved through a comprehensive Research Ethics review procedure (refer to Table 4.3 and 4.4 for an outline of the procedure).
   10. High risk research must be reported in writing to the Executive Dean of the specific College or Unit as well as to the Unisa Research Ethics Review Committee (URERC). The report must reflect the ERCs role in ongoing monitoring of the high risk research.
   11. 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.
3. **TYPOLOGY OF RESEARCH RISKS**
   1. Types of risk cover a range of potential risks that include physical risks, psychological or emotional, social, legal and political risks.
   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.
   3. Psychological or emotional risks are risks 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.
   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 ostracisation if research data are not treated confidentially.
   5. Ethical research must consider the ability of the participants to act in their own interest and the protection of researchers against potential risks related to the conduct of a specific research project.
   6. Researchers should also consider the potential for reputational risk of institutions involved in the research.
   7. The potential risks involved in research must be assessed against the degree of vulnerability of the human participants (children or young people under 18, 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 literary, 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. Any research that involves human participants must be based on the mutual understanding of all parties involved regarding the kinds of risks 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.
   9. In addition, risk assessment must consider the following aspects:
      1. Nature of human participant involvement or animal involvement (no involvement, indirect or direct involvement)
      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 - controversial, contentious, embarrassing or upsetting in nature)
      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)
      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 of personal data
      5. Participation is not voluntary, or there is undue pressure or bribery of participants
      6. Inappropriate financial interests of the researcher and/or the institution
      7. Health and safety issues including equipment hazards, chemical or biological hazards

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

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| **Risk category** | **Definition** | **Explanation and examples** | **Application procedure** |
| **4.1 Category 1: Negligible risk** | The probability or magnitude of harm or discomfort anticipated in the research is not greater in itself than that ordinarily experienced in daily life.  (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). | Research that involves non-invasive procedures and 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.  Examples:   * Research involving the analysis of existing statistics, as well as literature, documents and information in the public domain, for example in public libraries, public archives, on websites, newspapers, or newsletters, as well as data relating to natural persons who have been dead for more than 20 years (The above research is generally not considered ‘human subject research’.) * A literature study of the life and work of an 18th century philosopher. * Market research surveys could fit in this category.   NB: Not all research involving material in the public domain is ‘minimal risk’ e.g. research involving data extraction from the social media. | An expedited process will be followed.  Applicants fill in an expedited application form designed to obtain information needed to ensure a high quality review.  The review form and supporting documents (if applicable) are submitted electronically to the relevant ERC.  The chairperson conducts an initial screening of the application to determine whether the application meets the requirements for negligible risk.  If so, the application may be reviewed by the chairperson or the chairperson may delegate the review to a senior member of the ERC.  The chairperson communicates the decision to the applicant within seven working days.  The review report and decision are ratified at the next regular meeting of the ERC.  The researcher(s) may continue with the research upon receipt of the clearance letter while awaiting the ratification of the expedited review. |
| **4.2 Category 2: Low risk** | Research involving human participants directly in which the only foreseeable risk is one of inconvenience. | * Research in which the investigation of largely uncontroversial topics is undertaken through interviews, surveys and observation. * The participants are adults and not considered to be a vulnerable research population. * The research will collect information that would generally be regarded as non-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 | An expedited review process may be followed.  The applicant completes a low risk application form and provides a copy of the informed consent form and any other relevant documents.  The chairperson may nominate two or more members to review the application.  The chairperson circulates the reviewers’ decisions and comments to the rest of the members for their decision.  If a consensus cannot be reached or a member expresses some concerns, the proposal must be given a full review.  An en banc meeting of the ERC may be required.  The chairperson of the ERC issues a clearance letter, subject to any amendments or requirements following from the review.  The review reports and decisions are ratified at the next regular meeting of the ERC.  The researcher may continue with the research upon receipt of the clearance letter while awaiting the ratification of the expedited review.  If any changes to the decision of the Chairperson are made at the ratification of an expedited review, the researcher and supervisor will immediately be informed.  Normally an expedited review will not take longer than seven working days to complete. |
| **4.3 Category 3:**  **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. It is not expected that the research will cause severe risk or negative physical, emotional, social, cultural or political consequences. | One or more of the following apply:   * Participants are directly involved as part of field work activities. * The research topic is ‘sensitive’. * Information gathered is personal rather than opinion or 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, e.g. ‘tweets’ or ‘Facebook’ profiles, could be medium risk, depending on the research question under investigation.   Examples:   * Interviews for the purpose of gathering biographical data, which may procure 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. | A full ethics review procedure is followed.  Applicants are required to complete a detailed application form and submit it electronically to the relevant ERC.  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.  The application is tabled for full committee review.  The chairperson of the ERC issues a clearance letter, subject to any amendments or requirements following from the review.  Normally applicants will receive feedback in writing on the outcome of the review within fourteen days of the meeting at which the decision was made.  Minor amendments could be reviewed by an expedited review process. |
| **4.4 Category 4:**  **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. | 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 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. | A comprehensive or full application process is followed.  Refer to 5.2 for the procedure.  In addition, high risk research must be reported in writing to the Executive Dean of the specific College or Unit as well as to the Unisa Research Ethics Review Committee (URERC). The report must reflect the ERCs role in ongoing monitoring of the high risk research. |

1. **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**, it provides a means to examine whether the proposed research is properly designed. For an **ERC**, it is a method for determining whether the risks that will be presented to participants (and other entities) are justified. For **prospective participants**, the assessment will guide their decision whether or not to participate.

The checklists below have been designed to guide researchers to assess the potential risk of 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 onthe checklist should be ticked **“NO”.**

**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 their opinions to be 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 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.

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| **5.1** | **Does your research include the direct involvement of any of the following groups of participants/research objects?** | **YES** | **NO** |
| *Place x in box [if yes, provide details in the space allowed for comments]* | | | |
| a) Children or young people under the age of 18 | |  |  |
| b) Persons with a cognitive disability or mental impairment of any kind | |  |  |
| c) Prisoners or people on parole | |  |  |
| d) Children who are in custody of the State | |  |  |
| e) Persons highly dependent on medical care | |  |  |
| f) Military personnel | |  |  |
| g) Communities that may be considered as vulnerable | |  |  |
| h) Persons unable to give consent themselves (e.g. consent through a gatekeeper) | |  |  |
| i) People aged 65 and older | |  |  |
| j) Unisa employees or students | |  |  |
| k) Persons not usually considered to be vulnerable but would be considered vulnerable in the context of this research project | |  |  |
| l) Non-English speaking participants | |  |  |
| m) Women considered to be vulnerable (pregnancy, victimisation, etc.) | |  |  |
| n) People living in poverty | |  |  |
| o) People with little or no education | |  |  |
| p) Plants | |  |  |
| q) Molecular or cell research | |  |  |
| r) Animals | |  |  |
| s) Environmental related research | |  |  |
| p) Other. Please describe. | |  |  |
| Comments: | | | |

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| **5.2** | **Does your research involve any of the following types of activity?** | **YES** | **NO** |
| *Place x in box [if yes, provide details in the space allowed for comments]* | | | |
| a) Collection, use or disclosure of information WITHOUT the consent of the individual or institution that is in possession of the required information whose information, with the exception of aggregated data or data from official databases such as StatsSA, SARS, etc. | |  |  |
| b) Causing discomfiture to participants beyond normal levels of inconvenience | |  |  |
| c) Deception of participants, concealment or covert observation | |  |  |
| d) Examining potentially sensitive or contentious issues that could cause harm to the participants | |  |  |
| e) Seeking disclosure of information which may be prejudicial to participants and third parties | |  |  |
| f) Using intrusive techniques, e.g. audio-visual recordings of participants which may be or a sensitive nature | |  |  |
| g) Study of or participation in illegal activities that could place individuals and/or groups at risk of criminal or civil liability or be damaging to their financial standing, employability, professional or personal relationships. | |  |  |
| h) Innovative therapy or intervention | |  |  |
| i) Personal and social information collected directly from participants | |  |  |
| j) Identifiable information to be collected about people from available records (e.g. medical records, staff records, student records, etc.) | |  |  |
| k)\*Psychology inventories / scales / tests | |  |  |
| l) Activities which may place the researcher(s) at risk | |  |  |
| m)Collecting physical data from the participants such as body measurements, blood samples, etc. | |  |  |
| n) Collecting physical samples from animals such as blood, etc. | |  |  |
| o) Harvesting indigenous vegetation | |  |  |
| p) Harvesting vegetation or soil from privately owned land | |  |  |
| m) Other. Please describe. | |  |  |
| Comments: | | | |

*\*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 outside South Africa*

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| **5.3** | **DOES ANY OF THE FOLLOWING APPLY TO YOUR RESEARCH PROJECT?** | YES | NO |
| *Place x in box [if yes, provide details in the space allowed for comments]* | | | |
| a) Reimbursement or incentives to any participants. | |  |  |
| b) Financial obligations for the participants as a result of their participation in the research. | |  |  |
| c) Financial gains to be anticipated by any of the involved researchers. | |  |  |
| d) Any other potential conflict of interest for any of the researchers (real or perceived personal considerations that may compromise a researcher’s professional judgement in carrying out or reporting research, such as conducting research with colleagues, peers or students). | |  |  |
| e) Research is done on the premises of Unisa or any of its units. | |  |  |
| f) Research will make use of some of Unisa’s facilities such as computers, office space, library, etc. | |  |  |
| g) Research will make use of Unisa laboratories. | |  |  |
| g) Research will be funded by Unisa or funding for it was acquired through Unisa. | |  |  |
| Comments: | | | |

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| **5.4** | **Guided by the information above, classify your research project based on the anticipated degree of risk. *[The researcher completes this section. The ERC critically evaluates this risk/benefit analysis to protect participants and other entities.]***  *Place x in box* | | | | | | | |
| **Category 1**  **Negligible** | |  | **Category 2**  **Low risk** |  | **Category 3**  **Medium risk** |  | **Category 4**  **High risk** |  |
| 1. **Briefly justify your choice/classification** | | | | | | | | |
| 1. **In medium and high risk research, indicate the potential benefits of the study for the research participants and/or other entities.** | | | | | | | | |

1. **ACKNOWLEDGEMENT AND DOCUMENTS CONSULTED**
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