UNIVERSITY OF SOUTH AFRICA

|  |
| --- |
| FORM 4: 2019  RESEARCH ETHICS PROGRESS/AMMENDMENT REPORT FOR RESEARCH INVOLVING HUMAN PARTICIPANTS [[1]](#footnote-1) |

If you have any questions about or require assistance with the completion of this form, please contact your supervisor (master’s or doctoral students), or the Research Ethics Administrator of the (012 429 4502 or engelm1@unisa.ac.za), or the Chair of the ERC (engelm1@unisa.ac.za)

|  |
| --- |
| **IMPORTANT:**  **GUIDELINES FOR COMPLETING THE PROGRESS REPORT** |
| 1. **Ethics approval is valid for the time period stipulated on the research ethics approval certificate** in accordance with the risk category of the study (**non-health negligible risk studies** = between 3 and 5 years; **low risk PhD studies** = maximum of 5 years**; low risk Master and non-degree studies** = maximum of 3 years; **Medium and High risk studies** = validity period is risk dependent and annual renewal could be required; **health research** = annual renewal) |
| 1. A **progress report** is an application for (a) **renewal of ethics approval**, a (b) **request for amendment** to a current application or (c) **notification of a completed/terminated research project**. It must be submitted well before the ethics approval expiry date, so that the progress report can be reviewed and the project re-approved prior to the expiry date. |
| 1. **No research may continue without a valid research ethics certificate and re-approval.** |
| 1. The **progress report** should contain **sufficient information** to allow the ethics review committee (ERC) to conduct a substantive and meaningful review of the progress of the project, including any challenges or problems encountered. |
| 1. **Requests for amendments** must be accompanied by supporting documents essential for review purposes, i.e. updated Informed Consent Leaflets, Data Collection Instruments, Risk Assessment, Measures to Ensure Data Security, etc. |

|  |  |
| --- | --- |
| For applicant use  *\*This section is needed for record keeping and reporting.* |  |
| DATE OF REPORT (when submitted to the ERC) |  |
| ETHICS CERTIFICATE REFERENCE NUMBER |  |
| CURRENT ETHICS APPROVAL WAS GRANTED UNTIL |  |
| EXPECTED DATA OF RESEARCH COMPLETION (MONTH & YEAR) |  |
| TYPE OF REPORT   1. Report of ongoing project to renew ethics approval |  |
| 1. Request for amendments |  |
| 1. Report of completed/terminated project |  |

***\*This section is for office use only.***

|  |  |
| --- | --- |
| APPLICATION NUMBER |  |
| DATE PROCESSED (submitted to reviewers) |  |
| RISK LEVEL *(low, medium or high)* |  |
| TYPE OF REVIEW (expedited or full committee review) |  |
| AGENDA DATE  *(For expedited transactions, the agenda date is the date the expedited approval gets reported or ratified at the convened ERC)* |  |
| DECISION OF ERC (approved, referred back, disapproved) |  |
| DATE OF ISSUING APPROVAL CERTIFICATE OR FEEDBACK LETTER |  |
| **Period for which approval is valid**  **(Approved until/next renewal date)** |  |
| **Signature Chairperson of the ERC**  **Date signed:** |  |
| **Comments to principal researcher from the ERC** | |

**PRIVACY INFORMATION:**

The personal information you provide on this form is collected for the primary purpose of assessing your research ethics application. This personal information will be entered into a database to assist with administration, correspondence, and statistical analyses. Office bearers of the Ethics Review Committee (ERC) have access to these records. Records will be made available to authorised third parties should the need arise such as the National Health Research Ethics Council (NHREC) and Unisa structures such as the Unisa Research Ethics Review Committee (URERC). All records will be retained for as long as necessary to achieve the purpose for which it was collected.

|  |
| --- |
| **RESEARCHER’S DECLARATION TO ADHERE TO THE UNISA CODE OF CONDUCT REGARDING THE ETHICS OF THE PROPOSED RESEARCH** |

Sign the declaration in a separate document and scan it electronically to the Ethics Review Committee as part of the application package.

**By signing below, I**        **(full name of the main researcher) declare as follows:**

|  |  |  |
| --- | --- | --- |
| 1. I have completed all the sections of this form that are relevant to the proposed research study. |  | Agree |
| 1. I have acquainted myself with UNISA’s code on research ethics expressed in the UNISA Policy on Research Ethics and the Standard Operating Procedure on Research Ethics Risk Assessment. I shall fully comply with it. |  | Agree |
| 1. I conducted (or will conduct in case of amendments) the research in strict accordance with the approved proposal. |  | Agree |
| 1. I shall notify the ERC in writing if any changes to the research are proposed that may affect any of the study-related risks for the research. |  | Agree |
| 1. I maintain privacy and the confidentiality of records pertaining to the research. |  | Agree |
| 1. I shall not use the research and information in a manner that is detrimental to individuals or institutions unless it can be scientifically justified. |  | Agree |
| 1. I shall store research data securely and in accordance with the data management measures indicated in my application/proposal. |  | Agree |
| 1. I shall uphold research integrity and refrain from conduct that may taint the integrity of science, including, but not limited to plagiarism, fabrication and falsification of data. |  | Agree |
| 1. I shall refrain from the use of human participant data that was collected without a valid research ethics approval for the purpose of this research (retrospective use of participant data). |  | Agree |
| 1. I shall take the necessary steps to warrant that co-researchers, if applicable, familiarise themselves with the Unisa Policy on Research Ethics. |  | N/A  Agree |
| 1. I accept the privacy information statement set out on page 2. |  | Agree |

**Signing of declaration**

Applicant/Principal Researcher:

Name in Print:

Date signed

Signature

Approved by supervisor (if applicable)

To my knowledge the student has addressed all aspects in his/her application for research ethics approval set forth in the University of South Africa’s Policy for Research Ethics. I confirm that the form is complete according to Appendix A. I will ensure that the student notifies the committee in writing if any changes to the research are proposed that may affect any of the study-related risks for the research participants such as methodology, sampling, questionnaire, interview schedule, etc. Subsequently, I approve the submission and recommend that approval is granted for the research.

Supervisor:

Name in Print

Date signed

Signature

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

|  |
| --- |
| **SECTION 1: RESEARCHER’S DETAILS** |

|  |  |  |
| --- | --- | --- |
| **1.1** | **Details of main researcher (referred to as the applicant)** | |
| Title | |  |
| Full Name & Surname | |  |
| Staff / student no | |  |
| Department/Unit where you are currently registered or employed | |  |
| Contact number | |  |
| Email | |  |
| **1.2** | **Internal and/or external co-Researcher(s) \* (Only complete if changes occurred)**  **\*** if applicable | |
| Title | |  |
| Full Name & Surname | |  |
| Staff / student no | |  |
| Affiliation/Organisation/  Department | |  |
| Contact number | |  |
| Email | |  |
| **1.3** | **Academic supervisor/co-supervisor (Only complete if changes occurred)** | |
| Title | |  |
| Full Name & Surname | |  |
| Staff no | |  |
| Department/Unit where you are employed | |  |
| Contact number | |  |
| Email | |  |

***\*Please provide information of additional researchers if applicable***

|  |
| --- |
| **SECTION 2 – DETAILS OF RESEARCH** |

**2.1 Title of the Research Project (this is the title indicated on the most recent valid ethics clearance certificate)**

|  |
| --- |
|  |

**2.2 Request for an amendment to title of the research**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes | No | N/A |
| 1. Do you want to notify the ERC of a change to the title of the study? If so, indicate the revised title below. |  |  |  |
|  | | | |
| 1. Provide a reason for the title change. | | | |
|  | | | |

**2.3 Risk category of protocol or amendments requested[[2]](#footnote-2)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Classify the risk category of the research based on the previously approved application or the anticipated degree of risk of amendments requested.***Tick the relevant category* | | | |
| **Category 1**  **Negligible**  No to indirect human participant involvement. | **Category 2**  **Low risk**  Direct human participant involvement. The only foreseeable risk of harm is the potential for minor discomfort or inconvenience, thus research that would not pose a risk above the everyday norm. | **Category 3**  **Medium risk**  Direct human participant involvement. Research that poses a risk above the everyday norm, including physical, psychological and social risks. Steps can be taken to minimise the likelihood of the event occurring. | **Category 4**  **High risk**  Direct human participant involvement. A real or foreseeable risk of harm including physical, psychological and social risk, which may lead to a serious adverse event if not managed responsibly. |
|  |  |  |  |
| |  | | --- | | **Based on your experience of the research, indicate whether the level of risk of the research has: (please double click on the appropriate box)**  a.1 Increased  a.2 Decreased  a.3 Shown no change  **If there has been change or change is anticipated, please explain:** | |  | |  | | | | |

**2.4 Provide a description of the Research Project (Aim and objectives, research design and methods and significant contribution) [or attach a valid research proposal or methodology chapter]**

|  |
| --- |
|  |

**2.5 Progress to date or outcome in the case of completed research**

|  |
| --- |
| **Provide a summary of the progress of the research to date including the overall progress since the last report. Include relevant comments/issues you would like to report to the ERC.** |
|  |

**2.6 Status of data collection phase of the research**

|  |  |
| --- | --- |
| Please select the most appropriate option and indicate the relevant date | |
|  | Date (Month & Year) |
| 1. Data collection was completed on … |  |
| 1. Data collection will be ongoing until … |  |
| 1. Data collection commenced, but was prematurely terminated on … |  |
| 1. Data collection never started and the project was terminated on ... |  |
| 1. Other | |

|  |
| --- |
| Provide the **reason/s for project termination** if (**c) or (d)** applies to this report: |

**2.7 Research procedures as per the approved research proposal [provide evidence of compliance with the approved protocol/application & any conditions of approval]**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes | No | N/A |
| 1. Have the research procedures been implemented in accordance with the approved proposal? |  |  |  |
| 1. If **NO**, have any changes and/or amendments that have an impact on the risk profile of the research participants been submitted for ethics approval? |  |  |  |
| 1. If **NO**, provide the details of the variations/amendments and the reason/s why this has not been submitted for research ethics approval: | | | |

**2.8 List amendments required (if applicable), complemented by an indication of any study-related risks to the participants and mitigating actions. Attach the amended supporting documents, i.e. amended data collection instruments.**

|  |  |  |
| --- | --- | --- |
| 1. **Amendment requested** | 1. **Study related risks** | 1. **Proposed mitigating actions** |
|  |  |  |
|  |  |  |
|  |  |  |

**2.9 Recruitment of research participants: Provide information about the current enrolment status (numbers, active or closed)**

|  |  |
| --- | --- |
| 1. **How many** research participants have been **recruited/enrolled** in the period since the last progress report/commencement of research? |  |
| 1. **How many** research participants should still be **recruited/enrolled** in order to meet the objectives of the research? |  |
| 1. Indicate any **ethical difficulties**[[3]](#footnote-3) that have been encountered to **obtain consent** from potential research participants (if applicable) | |

**2.10 Amendments to the Informed Consent documentation or procedure**

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| 1. Should the informed consent documentation/procedure be revised to accommodate requested amendments to the research? |  |  |
| 1. If **YES**, provide the details of the variations/amendments and attach the revised informed consent documentation. Changes on the original documentation should be highlighted. | | |

**2.11 Withdrawal of consent**

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| 1. Have any of the research participants (including a parent or legal guardian in the case of minors) withdrawn their consent during the conduct of this proposal? |  |  |
| 1. If **YES**, provide the details of the number of participants, their reason for withdrawal (if known) and any action taken by the researcher/s: | | |

**2.12 Unexpected ethical issue management**

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| 1. Did any of the research participants experience **serious adverse events[[4]](#footnote-4)** (SAE) or other **harms** during the report period? *Note that the occurrence of any* ***serious adverse events*** *should always be immediately reported to the Research Ethics Committee; formal reporting of SAEs should not be delayed until submission of the annual progress report.* |  |  |
| 1. If **YES,** provide the details (date, event and outcome) and the action taken by the researcher/s: | | |
| 1. If **YES**, indicate how and when the Research Ethics Committee was notified of the serious adverse events: | | |

**2.13 Research participant complaints**

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| 1. Did any of the research participants lodge **complaints** with the researcher about any ethics-related aspect of the project? |  |  |
| 1. If **YES,** provide the details (date, complaint and outcome) and the action taken by the researcher/s: | | |

**12.14 Other ethical issues**

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| Have any **research participants been withdrawn** from the project by the researcher / supervisor/s? |  |  |
| Are there any other ethical issues (e.g. breaches of anonymity or confidentiality; loss of data through theft or computer failures) that you would like to bring to the attention of the Research Ethics Committee? |  |  |
| If **YES** to any of the above issues, please provide details: | | |

**2.15 Describe changes relating to the security of the records if appropriate**

|  |
| --- |
|  |

**🙦 🙦 🙦 🙦**

1. This document is based on the content of the following reports: 1) Research Ethics Progress Report Human Research Ethics, Tshwane University of Technology & 2) Progress Report, Health Research Ethics Committee, Faculty of Health Sciences, Stellenbosch University and Form FHS 16, University of Cape Town. [↑](#footnote-ref-1)
2. Refer to the Unisa Standard Operating Procedures on Research Ethics Risk Assessment. [↑](#footnote-ref-2)
3. “Ethical difficulties” refer in this case to the issues that made it hard or impossible for the researcher / fieldworkers to obtain verbal or written consent from potential research participants, e.g. unwillingness to sign consent form, being suspicious of research, demands for incentives (money or other material items), and insistence on providing collective rather than individual consent. [↑](#footnote-ref-3)
4. . [↑](#footnote-ref-4)