University of South Africa Research Ethics Committees	
Title	SOP – Standard Operating Procedure on Ensuring the Validity of Research Ethics Approval Research Certificates
SOP No	SOP 5 (SRIPCC)_Valid research ethics approval certificates V1 (2020)
Date of approval	16/04/2020 (URERC) 14/05/2020 (SRIPCC)
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Pages	6

1. COMPILATION AND AUTHORISATION

Action	**Designated person**	**Date**	**Signature**
Compiled by:	Ms MK Gill (Research Ethics Officer) & Ms T Coetzee	9 April 2020	
Checked by:	Dr RG Visagie (Deputy Chairperson: URERC)	9 April 2020	
Approved by:	URERC Prof Les Labuschagne (Chair: URERC)	16 April 2020	
Authorised by:	VP: Research, Innovation, Postgraduate Studies and Commercialization: Prof T Meyiwa Chair of the SRIPCC	14 May 2020	

2. DISTIBUTION

Department/unit/committee	**Name**	**Date**	**Signature**

3. DOCUMENT HISTORY

Date	Version no	Reason for revision
16 April 2020	1	Not applicable (Approved by URERC)

4. ABBREVIATIONS AND/OR DEFINITIONS

Abbreviation/definition	Description
Research ethics approval certificate	A certificate that grants a researcher approval to proceed with a research study or project based on the outcome of an objective appraisal of the effect of the proposed research on the wellbeing of potential participants, animals, the environment, researchers, institutions, collectives and communities by an established Ethics Review Committee.
SOP	Standard Operating Procedure/s
ERC/REC	The Ethics Review Committee (synonymous with Research Ethics Committee) that is representing a specific UNISA business unit or College, either on unit or departmental level.
URERC	Unisa Research Ethics Review Committee
Unisa researchers	(a) is a permanently appointed UNISA employee and an employee on a contract of less than three years who has been tasked with conducting research; as well as a valid, current Academic Associate (excluding an Emeritus Professor) and a postdoctoral fellow. (b) is a registered UNISA student conducting research for postgraduate degree purposes.
Principal researcher	A permanently appointed UNISA employee and an employee on a contract of less than three years who has been tasked with conducting research as well as a valid, current Academic Associate (excluding an Emeritus Professor) and a postdoctoral fellow

Health research	Includes any research that contributes to knowledge of: • biological, clinical, psychological, or social processes in humans; • improved methods for the provision of health services; • human pathology; • the causes of disease; • effects of the environment on the human body; • development of new applications of pharmaceuticals, medicines and related substances; and the development of new applications of health technologies to improve health and health care.

4. PURPOSE OF THE SOP

This SOP aims to:

(a) Provide Unisa ERC/REC office bearers with best practice standards to issue valid research ethics approval certificates;

(b) Provide Unisa researchers with guidance on how to ensure that they are in possession of valid research ethics approval certificates for the duration of a research study;

(c) Provide advice to officers responsible for assessing the validity of a research ethics approval certificate about what constitutes a valid research ethics approval certificate.

5. SCOPE

The scope of the SOP relates to:

- Research ethics approval certificates issued by URERC, a College Ethics Review Committee (CRERC), School or departmental ERCs and the Professional Research Committee Workgroup.
- Research ethics approval certificates required for Research and Development (R&D) leave or any other internal or external funding opportunity.
- Research ethics approval certificates required for publication purposes.
- Feedback letters issued by an ERC to communicate referred back/disapproved decisions.

6. RESPONSIBILITIES

6.1 Office bearers of Unisa ERCs must issue valid research ethics approval certificates based on the standards set out in section 7 of this SOP.

6.2 Unisa researchers are responsible to ensure that their research ethics approval certificates are valid, especially as research projects change over time and amendments must be brought to the attention of the ERC.

6.3 If the research project changes or the researcher wishes to collect or capture new data, then the researcher must apply for an amendment by completing the Progress and Amendment Form (Form 4)

6.4 Officers involved in the assessment of internal or external funding applications must be aware of the SOP to promote fairness and transparency.

7. PROCEDURES

7.1 The URERC mandates the use of standardised (a) research ethics approval certificates and feedback letters for research projects that are (b) referred back/conditionally approved or (c) disapproved.

7.2 All College, School, and departmental ERCs must use the standardised templates to communicate the outcome of a decision made by an ERC.

7.3 A valid research ethics research ethics approval certificate must include:

7.3.1 The name of the research ethics review committee that issued the research ethics approval certificate.

7.3.2 The date when the research ethics approval certificate was issued.

7.3.3 The ERCs National Health Research Ethics Council (NHREC) registration number, if applicable (all health research must be approved by an ERC registered with the NHREC according to the Unisa Policy on Research Ethics).

7.3.4 A unique ERC reference number that identifies the year the research ethics approval certificate was issued, the name of the ERC, and the number allocated to the application as a minimum standard (2020_URERC_001).

7.3.5 It is useful for sound administration to indicate the type of application (this will improve the accuracy of reporting on the types of applications processed):

- Full Review (2020-URERC_001_FR)
- Expedited Review (2020_URERC_001_Exp)
- Exempted (2020_URERC_001_Ex)
- Resubmission (add RS – 2020_URERC_001_FR/RS)

7.3.6 The start and expiry date of an approved research project/study:

- No new data may be collected after the expiry date on a research ethics approval certificate;
- Ethics approval for health, animal and high-risk research studies is issued for one year (DOH, 2015 guidelines);
- The researcher must submit a progress report and apply for an extension of a study on form 4 in a timely fashion or the study will be suspended;
- Ethics approval for non-health, low risk honours research projects involving human participants is granted for 2 years;
- Ethics approval for non-health, low risk masters research studies involving human participants is granted for 3 years;
- Ethics approval for non-health, low risk doctoral research studies is granted for 5 years;
- Ethics approval for non-health, medium risk studies is granted for 1 – 3 years depending on the risks inherent to the study;

- Depending on the anticipated risks of harm anticipated in a study, ERCs may, in all instances, request progress reports at more regular intervals such as three-monthly, six-monthly, etc.;
- Ethics approval for non-degree negligible risk studies are granted for 3 years;
- It is common practice to disseminate research findings by means of conference papers, journal articles or book chapters even if the validity period of a study has expired (a) if no new data collection activity took place and (b) no changes were made to the original application, thus, only publishing or disseminating findings from data that had already been collected. However, if the publisher requires an updated research ethics approval certificate, the researcher should apply for an amended certificate indicating the new approval period.

7.3.7 The names of all researchers involved in the research project/study
- If new researchers join a research project, the amendment process must be followed to update the research ethics approval certificate with the names of the additional researchers who joined the project.

7.3.8 The contact details of the principal researcher. This information is important to deal efficiently with enquiries.

7.3.9 The name(s) of the postgraduate supervisor(s) if applicable.

7.3.10 The contact details of the principal postgraduate supervisor. This information is important to deal efficiently with enquiries.

7.3.11 The student number of student researchers and the staff number of Unisa/external employee researchers.

7.3.12 The working title of a research project. If the title changes, the onus is on the researcher to inform the ERC to issue an amended research ethics approval certificate with the new title.

7.3.13 If it acceptable to use the original research ethics approval certificate for multiple research outputs if the researcher can prove that (a) no new data collection activity took place and (b) no changes were made to the original application.

7.3.14 The qualification or the type of research, for example, for non-degree purposes.

7.3.15 A statement that no further data collection activities may continue after the approval expiry date on the research ethics approval certificate.

7.3.16 The risk category of the study and the type of Review.

7.3.17 The standard provisions that are set out in the URERC endorsed research ethics approval certificate.

7.3.18 Add any additional provisions, for example, the requirement that a study may not commence without approval from a legitimate gatekeeper such as the Unisa Research Permissions Committee.

7.3.19 Signed by the chair of the ERC and the Executive Dean of the College. If the Executive Dean delegates this task to another senior member of management, this arrangement must be tabled for noting at the URERC and included as such in the Terms of Reference of the ERC.

7.4 The Policy on Research and Development (R&D) Leave requires all researchers to be in possession and provide a valid research ethics approval certificate when they apply for their R&D Leave.

7.5 If applicants for R&D Leave have an expired research ethics approval certificate and can prove to the relevant committee that they have completed the data collection stage and will not collect any new data during the R&D Leave, they may be granted

provisional R&D Leave, on condition that they will renew their research ethics approval certificate and will provide the relevant R&D Committee with the amended ethics approval research ethics approval certificate.

7.6 The onus is on the researcher to apply for the amendment of a research study or project if the study design changes from the date on which the initial research ethics approval certificate was issued.

7.7 If a principal researcher, or any member of the research team transfers from one college/university/unit to another, and requires an amended research ethics approval certificate, the ERC that issued the original certificate must approve the amendment and remain the committee of record for the duration of the study.

7.8 An ERC that disapproves of a research study or project must communicate the decision on the URERC endorsed template designed for this purpose. It is important that the feedback clearly states the main reasons for disapproval linked to ethical considerations.

7.9 An ERC that refers and application back must communicate the decision on the URERC endorsed referred back feedback letter template.

7.10 The referred back feedback letter must indicate a deadline for resubmission. This is usually within 3 months. If no response is received after regular follow-up in the 3-month window, the application is withdrawn from the agenda and the applicant informed of this action.

7.11 All resubmissions must include a cover letter explaining how the applicant addressed the ERCs requests for clarification or amendment. Additionally, the application form should be amended, and all recommended changes highlighted to streamline the review process.

7.12 Researchers must use the ethics clearance number in all correspondence with the ERC.

8. REFERENCES

8.1 Policy on Research and Development (R&D)

8.2 2019 Form 4 Progress Report-Amendment request (26.06.19)

8.3 Policy on Research Ethics (Approved by Council 15.09.2016)

8.4 National Department of Health (DOH). (2015) Ethics in Health Research Principles, Processes and Structures