



University of South Africa Research Ethics Committees	
Title	Standard Operating Procedure on applying for ethics approval from URERC
SOP No	SOP 8_URERC
Date of approval	20/11/2020
Revision date	2023
Pages	

### 1 COMPILATION AND AUTHORISATION

Action	Designated person	Date	Signature
Compiled by:	Ms MK Gill (Research Ethics Officer) and Dr RG Visagie	20 November 2020	
Checked by:	Dr RG Visagie (Deputy Chairperson: URERC)		
Approved by:	URERC Prof Les Labuschagne (Chair: URERC)		
Authorised by:	VP: Research, Innovation, Postgraduate Studies and Commercialization Prof T Meyiwa Chair of the SRIPCC and		

### 2 DOCUMENT HISTORY

Date	Version no	Reason for revision
20 November 2020	1	Not applicable (Approved by URERC)

### 3. DISTRIBUTION

College/department/committee	Name	Date	Signature

--	--	--	--

#### 4. ABBREVIATIONS AND/OR DEFINITIONS

Abbreviation/concept	Description/definition
Non-Unisa (External) researchers:	<ul style="list-style-type: none"> <li>a) Researcher associated with another institution or organization, who has obtained research ethics approval certificate and permission certificate from Unisa to conduct research at Unisa</li> <li>b) Unisa employee who has registered for a qualification at another university and has obtained ethics approval certificate and permission certificate to conduct research at Unisa</li> </ul>
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.
Internal applicant:	Unisa employee, Unisa employee registered for a qualification with Unisa and a postgraduate Unisa student
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
Research	A systematic investigation aimed at the development, or contribution to knowledge through acceptable means of scientific dissemination.
SOP	Standard Operating Procedure/s
URERC	Unisa Research Ethics Review Committee

Unisa participants	<p>a) Unisa employees; they could be permanent or on contract, and could be academics, professional, administrative or support staff.</p> <p>b) Unisa students, whether registered for a Short Learning Programme, undergraduate or postgraduate studies.</p>
Unisa Researcher:	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;
SRIPCC	Senate Research, Innovation, Postgraduate Studies and Commercialisation Committee

## 5. Objectives of the Standard Operating Procedure

- 5.1.1 Provide a detailed explanation of the procedure the researchers are to follow when applying for ethics approval from URERC
- 5.1.2 Provide clear guidance as to who qualifies to apply for ethics approval from URERC
- 5.1.3 Provide a clear explanation of the requirements for ethics review by URERC

## 5.2 Overview of the Unisa research ethics system

- 5.2.1 Research ethics review operations at Unisa are decentralized, due to the large number of postgraduate students applying for research ethics.
- 5.2.2 The Unisa Research Ethics Review Committee (URERC) oversees and provides support to the College, School and Departmental Ethics Review Committees (ERCs), but it is not prescriptive on the formation of the structures at the College and departmental levels. The Colleges have greater degree of autonomy, as long as the structures are in compliance with the requirements of the South African National Health Research Ethics Council (NHREC).
- 5.2.3 Under URERC there are College wide Ethics Review Committees. Each College has its own Ethics Review Committee (ERC).
- 5.2.4 Under the Colleges, there are specific School or Departmental Ethics Review Committees. This is particularly relevant to larger colleges that have a high number of students, such as the College of Economic and Management Sciences (CEMS), the College of Human Sciences (CHS). The College of Science, Engineering and Technology (CSET) has several School ERCs.

- 5.2.5 Smaller Colleges have one ERC, such as the College of Accounting Sciences (CAS) and the School of Business Leadership (SBL).
- 5.2.6 All academic employees and postgraduate students must apply for ethics approval from the departments where they are affiliated. Medium and high-risk applications should be escalated by the Chair of the Departmental ERC to the College ERC.
- 5.2.7 The URERC reviews appeals against decisions taken by the College ERCs.
- 5.2.8 ERCs that receive a high number of health research applications must register with the NHREC.
- 5.2.9 All health and health-related studies must be reviewed by a registered ERC. Therefore, non-registered ERCs must escalate/refer a health and health-related study to a registered ERC within Unisa.

### **5.3 Scope**

- 5.3.1 The scope of this Standard Operating Procedure applies to applications for ethics approval by the URERC, but the process is typically similar to the review process followed by College, School and Departmental ERCs.
- 5.3.2 The URERC only processes applications from Non-Unisa (external) applicants.
- 5.3.3 The URERC may process an internal application when escalated to it by the College ERC based on the discretion of the Chairperson.

## **6. Responsibilities of the researcher to Unisa**

- 6.1 The researcher needs to conduct his/her research in an ethical manner, at all times.
- 6.2 The researcher needs to be familiar with the Unisa Policy on Research Ethics and closely follow it during the entire research tenure.

## **7. Responsibilities of URERC to researchers**

- 7.1 The URERC will review the application objectively, without bias and with integrity.
- 7.2 The URERC will as far as it is possible, speedily review the applications for ethics approval.

## **8. Application requirements for ethics approval at the URERC**

### **8.1 Non-Unisa researchers and non-Unisa students**

- 8.1.1 Non-Unisa researchers and non-Unisa students (external applicants) complete a URERC application form based on the type of research they wish to conduct. For studies where the researcher will

collect data directly from human participants, they will complete (Form 1) and it is obtainable from the link, [\[Application Forms\]](#).

8.1.2 The accompanying checklist for Form 1 application form is obtainable here, [\[Application Forms\]](#).

8.1.3 If a Non-Unisa applicant wishes to conduct research involving Unisa secondary data only, he/she will complete Form 2, obtainable here [\[Application Forms\]](#)

8.1.4 If the external researcher wishes to conduct research not involving any human participants nor secondary data, but just desktop research using information that is already in the public domain, he/she will complete Form 3, the relevant form is obtainable here, [\[Application Forms\]](#).

8.1.5 Before applying to Unisa for ethics approval, the Non-Unisa applicants must first obtain ethics approval from their university/institutions.

8.1.6 Application for Unisa ethics approval may be waived by the relevant Unisa Unit/College Research Ethics Review Committee if the Non-Unisa applicant's institution's RERC is registered with the National Research Ethics Review Council (NHREC).

8.1.7 To apply and qualify for a research exemption at Unisa, the Non-Unisa applicant will be required to submit to URERC or College ERC, the application form and supporting documents that were submitted to his/her institution's registered ERC.

8.1.8 When submitting the completed URERC application form for ethics approval, [Non-Unisa applicants](#) must submit the following:

- Ethics approval certificate from their university/institution
- Clearly completed and signed URERC application form and the accompanying checklist
- A research proposal
- The participants' information letter and informed consent letter that addresses all the important aspects of obtaining informed consent. The letters must be on appropriate letterheads, i.e. the letterheads of the university/institution where the researcher/student is registered for a qualification or institution with which the [Non-Unisa applicant](#) is affiliated
- The survey/questionnaire/interview guide, where appropriate.
- Any other supporting documentation, such as recruitment material, etc.
- Abridged curriculum vitae (VC) of the student researcher and his/her supervisor or all research team members in the case of a team-based research project. The CV needs to cover the following main areas regarding research

- Experience relevant to the proposed research
- Qualifications relevant to the proposed research
- Publications and other research outputs
- Research Ethics Training done within the past three years

## **8.2 URERC procedure after receiving the application**

- 8.2.1 After receiving the application, a URERC Administrator should acknowledge receipt of the application, usually within 48 hours of reception.
- 8.2.2 The Administrator will check that all the required documents mentioned in point 6.1.8 above have all been submitted.
- 8.2.3 Then the Administrator will ascertain that the information letter and informed consent letter forms meet the minimum required international standards as set out in the Unisa template.
- 8.2.4 The Administrator will also go through the application form to ensure that all the fields are properly completed and the research declaration is signed by all the relevant signatories.
- 8.2.5 If the application form is not properly completed; if there are any missing supporting documents or if the information letter does not meet the international and Unisa minimum required information, the Administrator will refer the application back to the Non-Unisa applicant, with clear comments on the areas of concern or incomplete or inadequately answered questions.
- 8.2.6 The Administrator may repeat this process until the application is in a satisfactory state. The Administrator does this in order to save both the applicants and reviewers time. The committee does not review incomplete applications.
- 8.2.7 When the application is ready for review, the Administrator will select a sub-committee of three reviewers from the URERC committee and send them the application, requesting them to review it.
- 8.2.8 Typically, the Administrator will request the reviewers to send in their review report after a week.
- 8.2.9 After a week, the Administrator may send a reminder and will do this until she has received all the three reviewers' reports.
- 8.2.10 If all the three independent reviews are in agreement, the Administrator will write an approval ethics certificate, attach the signature of the Chairperson or Deputy Chairperson of URERC and issue the certificate.
- 8.2.11 If there are divergent reviews or all the reviewers express certain concerns with the research study, the Administrator will issue a refer back feedback letter, specifying clearly the concerns; scientific and ethical, that the reviewer(s) have cited and issue a signed feedback letter. She will request the external applicant to attend to the reviewers' concerns adequately and clearly highlight the new changes in the revised

application form as well as write a short memorandum that explains exactly how he/she has dealt with the reviewers' concerns. This step is intended to streamline the second review process and save the applicant time.

8.2.12 The Administrator will send the new highlighted resubmitted application form to the reviewer(s) who had picked up some concerns.

8.2.13 Usually after this step, the reviewers are satisfied with the improved application and if the reviewers are all satisfied, the Administrator will issue a signed approval ethics clearance certificate from URERC.

8.2.14 The URERC does not issue retrospective ethics clearance certificate, i.e. it does not review any applications for ethics approval after the data collection activity has commenced.

8.2.15 In a case where the researcher inadvertently commenced with the data collection activity and only became aware of the need and procedure to apply for ethics approval afterwards, the researcher will be required to abandon and destroy the data already collected without the proper ethics approval certificate.

### **8.3 Requesting amendment to the research study or extension of the approval period**

8.3.1 Should it happen that the researcher needs to make some amendments to the study methodology or change the unit of analysis or the data collection methods or even request to extend the ethics approval certificate validity period, the researcher must notify URERC of the intended changes and request an amended ethics clearance certificate.

8.3.2 To request an amendment, the Non-Unisa research should complete a progress report and amendment request form, Form 4, obtainable here [\[link to 'Application Forms'\]](#).

8.3.3 When applying for an amendment, the researcher needs to submit a properly completed progress report and amendment request application form, previous ethics approval certificate and an amended research proposal, where the researcher requests for amendments to the research methodology.

8.3.4 All declarations in all the application forms must be signed by the main applicant and the supervisor, in the case of a student applicant.