

Know Your Ethics Review Process (KYERP)

INFORMATION SHEET

Overview

The ethics review process at Strathmore University systematically evaluates research proposals to ensure ethical conduct. This process applies to research involving both secondary and primary data sources.

Ethics Review Committee

The ethics review at Strathmore University is performed by the Strathmore University Institutional Scientific and Ethics Research Committee (SU-ISERC).

This committee is comprised of members and a pool of reviewers with expertise in scientific research, offering a multi-disciplinary and multi-sectoral approach.

Necessity of Ethics Review

The ethics review is vital for ensuring that research respects the dignity, rights, and wellbeing of both human and animal participants and maintains the integrity of the research outcomes be it with the use of primary or secondary data.

Responsibilities of SU-ISERC



Scientific and ethical review:

The SU-ISERC conducts both scientific and ethical reviews of research proposals before the study begins.



Monitoring:

It monitors approved research for ethical compliance, including modifications, extensions, adverse events, protocol deviations, and violations.



Advisory:

The committee identifies ethical issues and advises on modifications to resolve these issues without compromising the scientific validity of the research.

Review Concerns by the SU-ISERC Research Studies

Scientific Review:

Includes an assessment of the study's aims, objectives, rationale, scientific validity, and the expertise of the research team.

Ethical Review:

Focuses on risk-benefit analysis, informed consent, and privacy concerns.



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Studies that Need Approval

Scientific and ethical review:

All research studies require approval, including but not limited to:

- 📄 Clinical trials, interventional studies, diagnostic tests and devices, medical records review, quality improvement, surveillance, interviews and surveys and any research collecting primary data.
- 📄 Secondary data review that includes identifying information.
- 📄 Medical case reports (1-3 cases) and data needed for research in the open domain where consent may not be required.

Review Duration and Follow-up

The initial review process typically takes up to three weeks (**14 working days**), but an expedited review can be requested by the PI for special cases and decision made by the SU-ISERC. An expedited review takes 5- 6 working days. Following submission, the SU-ISERC may approve the research, request revisions, or require additional information. There is no limit to the number of revisions a researcher/PI may be required to make.

After Document Submission

Once you have submitted all required documents, the SU-ISERC Secretariat performs a preliminary check. If the submission is complete, it will proceed to be reviewed by the ethics committee (SU-ISERC). Depending on their assessment, they may either approve your research, request revisions or ask for additional information.

Handling Incomplete Submissions

If your submission is incomplete or missing documents, the online platform through the Secretariat will prompt you to provide the necessary documentation before any form of review begins. Review only commences once all necessary documentation is submitted.

Addressing Revisions

If revisions are required by the ethics committee, you should address their feedback, make the necessary changes, and resubmit the revised documents for further review.



Document Requirements

Compulsory for master's or PhD students

- Research proposal/protocol (proposal defence version having already worked on comments given during the defence)
- Declaration page (signed by both you and your supervisor)
- Curriculum Vitae
- Participant Informed consent forms (If you are using primary data. Note too that the SU-ISERC can provide you with a template as a guide)
- Any data collection tools (e.g., surveys, questionnaires)
- Gatekeeper permission letter (subject to your SU-ISERC approval)
- Budget
- Workplan
- Plagiarism report with a similarity index of 25% on TURNITIN or below. (Turnitin is the only software accepted)
- Detailed progress report (For study renewals/extensions)

Compulsory for project-based research

- Research proposal/protocol
- Curriculum Vitae (All PIs and co-PIs)
- Declaration page
- Participant Informed consent forms (If you are using primary data)
- Safeguarding commitment
- Any data collection tools (e.g., surveys, questionnaires)
- Ethical certificates (All PIs; Not more than 2 years old)
- Gatekeeper permission letter (a letter requesting to collect secondary data from an organisation)
- Budget
- Workplan
- Evidence of payment (Advisable to send it via email before submission or during submission)
- Delegation log listing the roles and responsibilities of all investigators involved in the study (For studies with more than one investigator)
- Plagiarism report with a similarity index of 15% on TURNITIN or below (Turnitin is the only software accepted).
- Detailed progress report (For study renewals/extensions)

Common Reasons for Approval Delays

Delays in the approval process are often caused by:

- Incomplete or incorrectly filled submission forms by the researcher/PI.
- Failure to respond to communications from the Secretariat.
- Insufficient detail in addressing the comments raised by the committee.

Submission Procedure

Research proposals are submitted via the **RHInno Platform**. Submissions must include all necessary documents, clearly labelled and attached as specified in the platform instructions.

Study Amendments

An amendment must be submitted when there are changes to the study proposal, study tools, or consent forms after the initial ethical approval has been granted. However, these changes should not alter the study's objectives.

Study Renewals or Extensions

If your study is ongoing and the ethical approval is about to expire, you should apply for renewal or extension at least **6 WEEKS** before the expiry date.

Penalties for Delayed Renewals

If there is a delay in renewing your ethical approval while the study is still ongoing, a penalty fee of **\$50** for project based research and **\$30** for SU research will be charged. For Strathmore University students, this fee is covered by the respective faculties. Failure to renew ethical approval is considered a protocol deviation.

Non-Approval of an Application

An application may not receive ethical approval if:

- The researcher has begun data collection or analysis before obtaining ethical clearance.
- The committee decides not to approve the application after review.
- The researcher does not respond to the committee for 6 months or more.

Tips for a Smooth Review Process


To ensure a smooth review process, researchers should:


- Ensure that all required documents are complete and correctly filled out.
- Respond promptly to any feedback from the ethics committee.
- Engage their supervisors throughout the review process (for students).


Validity of Ethical Approval

Ethical approval letters are valid for one year. For studies that last beyond this period, researchers must apply for annual reapproval or extension.

PLEASE NOTE

 There is no fixed limit to the number of iterations the review process can go through. The process continues until all ethical and scientific concerns are adequately addressed by the researcher/PI.

 Research activities **MUST NOT** begin until full ethics approval has been granted. This approval comes in the form of an official letter from the SU-ISERC Secretariat.

 It is **NOT ALLOWED** to submit a proposal for ethical review **AFTER DATA COLLECTION OR DATA ANALYSIS** has already commenced. Doing so constitutes a protocol violation and can severely impact the chances of publication and research integrity by the researcher.

Approved by:
SU-ISERC



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