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Research Ethics Policy and Procedure HEPP61

PURPOSE

This document describes the policy and procedures for:

- Staff or external applicants seeking ethics approval to conduct research
- SCEI-HE students seeking research ethics approval to conduct student research as part of their assessments

SCOPE

The scope of this document applies to:

- All SCEI-HE staff and students wishing to conduct research either inside SCEI-HE or external to SCEI-HE within the community or
- All research involving the gathering of information about SCEI-HE staff or students
- All individuals or entities proposing to conduct research on, with, or within SCEI-HE premises, systems, staff, or students

The scope of this document does not apply to:

- Stakeholder consultation for the purpose on ongoing course design and improvement
- Stakeholder consultation through Course Advisory Committees
- Surveys linked to government or regulatory contexts
- Surveys linked to cohort course progression

DEFINITIONS	
SCEI-HE	Southern Cross Education Institute (Higher Education)
Student Research	A course assessment project that may or may not involve human participants in the gathering of data. At an undergraduate level, research is generally limited to the collating and examination of collected data to reveal a deeper understanding of the question at the heart of the project.
Low Risk	Research where the only foreseeable risk is discomfort (National Statement 2.1.6)
Negligible Risk	Research with no foreseeable risk of harm or discomfort; only inconvenience (National Statement 2.1.7)
Research Ethics	The analysis of ethical issues that are raised when people are involved as participants in research projects, even at undergraduate levels of investigation.
	DOLLCY

- Research ethics approval must be requested and granted prior to commencing any research about SCEI-HE staff or students.
- Only research proposals approved by SCEI-HE's Research Ethics Committee may be undertaken. Research includes the involvement of human participants through:
 - 2.1. Responses to surveys, interviews or sharing experiences through focus groups
 - 2.2. Responses to emotionally charged questioning
 - 2.3. Observation by researchers
 - 2.4. Researchers having access to participants' personal documents or other materials
 - Access to their information as part of an existing published or unpublished source or database 2.5.
- Research Ethics approval ensures:
 - 3.1. high ethical standards in regard to human participation in data gathering
 - 3.2. confidentiality of participants' names and any identifying data or communication records
 - 3.3. informed consent by participants
 - 3.4. sensitivity to the culture, traditions and circumstances of the persons and groups involved
 - 3.5. potential conflicts of interest are acknowledged and recorded
 - that data management complies with relevant privacy controls and State and Federal legislation
- This policy is based on the National Statement on Ethical Conduct in Human Research (2023) and the Australian Code for the Responsible Conduct of Research (2018).

The National Statement defines Human Research which is conducted with or about people, or their data or tissue. Human participation in research is therefore to be understood broadly, to include the involvement of human beings through:

- 4.1. taking part in surveys, interviews or focus groups;
- 4.2. undergoing psychological, physiological or medical testing or treatment;
- 4.3. being observed by researchers;

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- 4.4. researchers having access to their personal documents or other materials;
- 4.5. the collection and use of their body organs, tissues or fluids (e.g. skin, blood, urine, saliva, hair, bones, tumours and other biopsy specimens) or their exhaled breath;
- access to their information (in individually identifiable, re-identifiable or non-identifiable form) as part of 4.6. an existing published or unpublished source or database".
- 5. Research as defined in the following chapters in the National Statement will not be approved by the Research Ethics Committee unless explicitly assessed as low or negligible risk under Section 2.1 and justified by the applicant:
 - Chapter 3.3: Interventions and therapies, including clinical and non-clinical trials and innovations
 - Chapter 3.5: Human genetics
 - Chapter 3.6: Human stem cells
 - Chapter 4.1: Women who are pregnant and the human foetus
 - Chapter 4.4: People highly dependent on medical care who may be unable to give consent
 - Chapter 4.5: People with a cognitive impairment, an intellectual disability, or a mental illness
 - Chapter 4.6: People who may be involved in illegal activities
 - Chapter 4.7: Aboriginal and Torres Strait Islander Peoples
- 6. The Research Ethics Committee will only approve research deemed to be of low or negligible risk as defined in paragraphs 2.1.6 and 2.1.7 of the National Statement:
 - 6.1. 2.1.6 Research is 'low risk' where the only foreseeable risk is one of discomfort. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk".
 - 6.2. 2.1.7 Research is 'negligible risk' where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk".
- 7. Research outcomes must be recorded, stored, and disseminated responsibly in accordance with the Australian Code for the Responsible Conduct of Research (2018), including secure data storage and ethical publication
- 8. All researchers (staff, students, and external applicants) must complete mandatory research integrity training prior to submitting a research ethics application, as specified by the Research Ethics Committee.
- The Research Ethics Committee will monitor approved research through periodic progress reports and audits to 9. ensure ongoing compliance with ethical standards.
- 10. References

National Statement on Ethical Conduct in Human Research 2023 https://www.nhmrc.gov.au/aboutus/publications/national-statement-ethical-conduct-human-research-2023

Australian Code for the Responsible Conduct of Research 2018 https://www.nhmrc.gov.au/aboutus/publications/australian-code-responsible-conduct-research-2018

Tertiary Education and Quality Standards Agency, Higher Education Threshold Standards 2021 https://www.tegsa.gov.au/higher-education-standards-framework-2021

RPROCEDURE

Responsibility for Staff or External Applicants for Research Ethics Approval

- Direct any pre-application queries related to the approval process or ethics requirements to the Executive 1.1. Officer, Research Ethics Committee or Academic Director directly.
- 1.2. Complete mandatory research integrity training as specified by the Research Ethics Committee prior to application submission.
- 1.3. Complete the Research Ethics Application form and submit to the Executive Officer, Research Ethics Committee for review.
- 1.4. The Executive Officer will convene the Committee members for review of the application.
- 1.5. Dependent on Committee member availability the review process may up to 15 business day, after which the Executive Officer will collate the member's findings and make a recommendation of
 - a) Approve;
 - b) Approve subject to minor changes; c) Re-submit with significant changes, or;
 - d) Denied
- 1.6. Re-submit the revised application, if applicable and await signed approval from the Executive Officer before commencing research data collection.
- 1.7. Submit periodic progress reports as required by the Research Ethics Committee to ensure ongoing

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compliance.

2. Responsibility for Student Applicants for Research Ethics Approval

- 2.1. Complete mandatory research integrity training as specified by the Research Ethics Committee prior to application submission.
- 2.2. Submit a completed Research Ethics Application form to the class teacher at least 3 weeks prior to research data collection schedules.
- 2.3. The teacher will collect multiple student applications and submit them to the Executive Officer, Research Ethics Committee, for dissemination to the Committee members.
- 2.4. The Executive Officer will convene the Committee members for review of the application.
- 2.5. Dependent on Committee member availability the review process may take 2 3 weeks, after which the Executive Officer will collate the member's findings and make a recommendation of
 - a) Approve;
 - b) Approve subject to minor changes;
 - c) Re-submit with significant changes, or;
 - d) Denied
- 2.6. The annotated applications will be passed back to the class teacher, who will distribute them to the owners, for revision or action.
- 2.7. Students will re-submit revised applications, where applicable, to the class teacher and await signed approval from the Executive Officer before commencing research projects.
- 2.8. Submit periodic progress reports as required by the Research Ethics Committee to ensure ongoing compliance.

3. Management of Adverse Events and Complaints

Any adverse events or complaints related to approved research must be reported immediately to the Executive Officer, Research Ethics Committee, who will initiate an investigation in accordance with the Research Ethics Committee Terms of Reference.

RELATED DOCUMENTS

Research Ethics Committee Terms of Reference Research Ethics Application form

LEGISLATIVE CONTEXT

National Statement on Ethical Conduct in Human Research (2023) Australian Code for the Responsible Conduct of Research (2018) Higher Education Standards Framework (Threshold Standards) 2021

RESPONSIBILITIES

Class teacher: Collects and submits student ethics applications; communicates decisions back to students. **Student applicant:** Completes training, prepares the application, and allows sufficient review time.

Executive Officer/Academic Director: Oversees all ethics approval and monitors compliance.

DOCUMENT AND RECORD CONTROL	
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