

Improving Learning

ACER Human Research Ethics Committee

TERMS OF REFERENCE

December 2023

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1 OVERVIEW

This document details the Terms of Reference developed for the Australian Council for Educational Research (ACER) Human Research Ethics Committee (HREC). The ACER HREC is registered with the National Health and Medical Research Council (NHMRC) and follows the *National Statement on Ethical Conduct in Human Research*.

The ACER HREC has been established to review and, where appropriate, approve and monitor human research projects undertaken by ACER researchers. It has three core objectives:

- I. To protect the mental and physical welfare, rights, well-being and safety of research participants;
- II. To facilitate research that is ethical through efficient and effective review processes; and
- III. To ensure that all research projects are reviewed in accordance with the *National Statement*.

All research involving human participants (including projects exploring secondary data) will complete the ACER Human Ethics Form to determine the level of review required by the ACER HREC. This relates to projects involving the collection and/or analysis of data from people within Australia as well as projects involving participants in other countries.

In accord with the *National Statement*, ACER Research projects will be categorised into the following categories for the purpose of ethical review:

- Exempt
- Minimal Risk
- Low Risk
- High Risk

The level of risk associated with a project will be identified through completion of the ACER Research Ethics Form at the beginning of each project and verified by the ACER HREC Officer and/or Chair.

Each category of risk will require a different approach by the ACER HREC. ACER's approach to review and monitoring of each level of risk is outlined in the flow chart below.

Membership of the ACER HREC reflects the requirements of the NHMRC, with members of the committee covering a range of categories. The committee will consist of at least eight (8) members, with at least one third of members coming from outside of ACER.

The ACER HREC will meet at least four times per year to review and assess submitted research applications. In addition to this, Low Risk and some Higher Risk applications will be reviewed out of session by the Chair and committee members.

An HREC Officer will facilitate the ACER HREC submission, review and approval processes, and work alongside the ACER HREC Chair and committee members. Communication of the outcomes of applications will be efficient and with a focus on ensuring the highest quality ethical processes are applied to all ACER research.

2 PURPOSE & OBJECTIVES

The Australian Council for Education Research (ACER) Human Research Ethics Committee (HREC) Terms of Reference are set out in accordance with Section 5 of the *National Statement on Ethical Conduct in Human Research* (2020); citing other sections of the *National Statement* as appropriate. The ACER HREC is established to review and, where appropriate, approve and monitor human research projects undertaken by ACER researchers.

The HREC is registered with the National Health and Medical Research Council (NHMRC) (Human Research Ethics Committee: EC00474; Organisation: ORG00593)

The HREC has three core objectives:

- I. To protect the mental and physical welfare, rights, well-being and safety of research participants;
- II. To facilitate research that is ethical through efficient and effective review processes; and
- III. To ensure that all research projects are reviewed in accordance with the *National Statement*.

All research projects at ACER are subject to review to establish a category of risk and the extent to which assessment by the ACER HREC is required. The categories developed for the ACER HREC are listed below (and detailed further in the 'HREC Review' section of this document):

- Exempt
- Minimal Risk
- Low Risk
- High Risk

The level of risk associated with a project will be identified through completion of the ACER Research Ethics Form at the beginning of each project and verified by the ACER HREC Officer and/or Chair.

3 HREC ACCOUNTABILITY

The HREC is accountable to the ACER Chief Executive Officer (CEO) regarding conduct of its business. As detailed in the 'Reporting' section of this document, copies of HREC minutes and reports are provided to the CEO on a regular basis.

4 SCOPE OF HREC RESPONSIBILITY

The HREC is responsible for ethical review of research which:

- is carried out by any person (either alone or jointly with others) who is a full-time, part-time or casual ACER staff member; and/or
- is carried out using equipment, data, facilities or premises owned or controlled by ACER.

Types of research assessed by the HREC for ethical acceptability may include, but are not limited to, those that involve human participants:

- taking part in surveys, interviews or focus groups;
- being observed by ACER researchers; or

- projects where ACER researchers have access to personal documents or other materials that includes information in individually identifiable, re-identifiable or non-identifiable form as part of an existing published or unpublished source or database.

Furthermore, the HREC reviews ethical acceptability of projects:

- where access is sought to records or information held by ACER;
- where research participants are to be recruited, either directly or indirectly, through a service provided by ACER; and
- where a research project is being undertaken under supervision through an ACER-run education course.

The research described above relates to projects involving collection and/or analysis of data from people within Australia as well as projects involving participants in other countries.

Additional to ethical reviewing responsibilities, the HREC is also required to maintain accurate records of its deliberations concerning all research projects it has reviewed during a calendar year for reporting purposes (via a Compliance Annual Report to the NHMRC) and in accordance with the *National Statement*.

The ACER HREC is not responsible for ethical review of projects conducted by ACER researchers where the project has already been approved by another NHMRC registered Human Research Ethics Committee (for example this may be the case where ACER researchers are partnering with another institution which has completed ethics clearance through its own NHRMC registered committee). Furthermore, non-research projects at ACER, for example the sale of products and services, are not included in the scope of the ACER HREC.

5 HREC REVIEW CATEGORIES & PROCESS OVERVIEW

As stated above, the ACER HREC is responsible for reviewing research projects conducted by ACER staff. ACER staff are involved in a vast range of different projects that could be considered as ‘research’, but not all projects involve human participants, or analysis of data relating to human participants.

To recognise and respond to the range of different projects and approaches in ACER research projects, four categories are used by the ACER HREC for ethical review. The categories are described in the table below, referencing the *National Statement* and with indicative examples of types of projects that might fit in each category based on the ACER context.

Table 1: ACER HREC review categories

Risk Category	NHMRC definition (from <i>National Statement</i>)	Examples of ACER-relevant projects/participant groups
Exempt from Review	Research that ‘involves the use of existing collections of data or records that contain only non-identifiable data about human beings.’	Literature reviews, consultancy and advisory projects, policy reviews/analyses, evaluation projects not involving the analysis or collection of data from human participants. Use of secondary, non-identifiable data. (Note that if any of these types of projects contain activities or features listed in the risk categories below, they will not be deemed exempt.)
Minimal Risk	Research activity where there is ‘no risk of harm or discomfort;	Anonymous self-administered short surveys with non-sensitive content. Observational studies (with no form of intervention) of

	<i>potential for minor burden or inconvenience.'</i>	people undertaking non-sensitive, benign activities in a public space that will not be recorded or photographed and will not identify individuals.
Low Risk	Research activity where there is <i>'no risk of harm; risk of discomfort'</i>	Surveys, interviews or focus groups where the research topic and guiding questions will not (or do not have the potential to) induce distress or cause harm. Research involving participants undergoing a non-clinical intervention/assessment task that induce discomfort but will not (or will not have the potential to) induce distress, cause harm, and/or involve an element of active concealment or planned deception.
High Risk	Research activity where there is <i>'risk of harm'</i> to participants. Specifically, <i>'where a person's reactions exceed discomfort and become distress, they should be viewed as harms.'</i> [note, for ACER HREC, this category of risk covers both the <i>National Statement's</i> 'Greater than Low Risk' and 'High Risk Categories' (see 2.1 of the NS)]	Any research activity where the topic or approach may induce distress or cause harm. This includes physical harm, psychological harm, devaluation of personal worth, cultural harm, social harm, economic harm and/or legal harm (see <i>National Statement</i> section 2.1). In addition, all research activity involving Aboriginal and Torres Strait Islander people, or people with a cognitive impairment, intellectual disability, or mental illness are considered High Risk projects.

The risk category relevant to each ACER research project is initially identified through answers to the ACER Research Ethics Form completed by the Project Director. The ACER Research Ethics Form begins with a number of questions designed to provide initial assessment of the category of risk, or exemption status, associated with a project. This initial level of risk will be reviewed by the HREC Officer who will confirm the relevant categorisation and will liaise with the HREC Chair in cases where initial determination of risk level may not be accurate.

The categorisation of risk of a project will determine the need for and any subsequent review and approval process to be undertaken by the ACER HREC. The process applied to each categorisation of risk is outlined in the figure below.

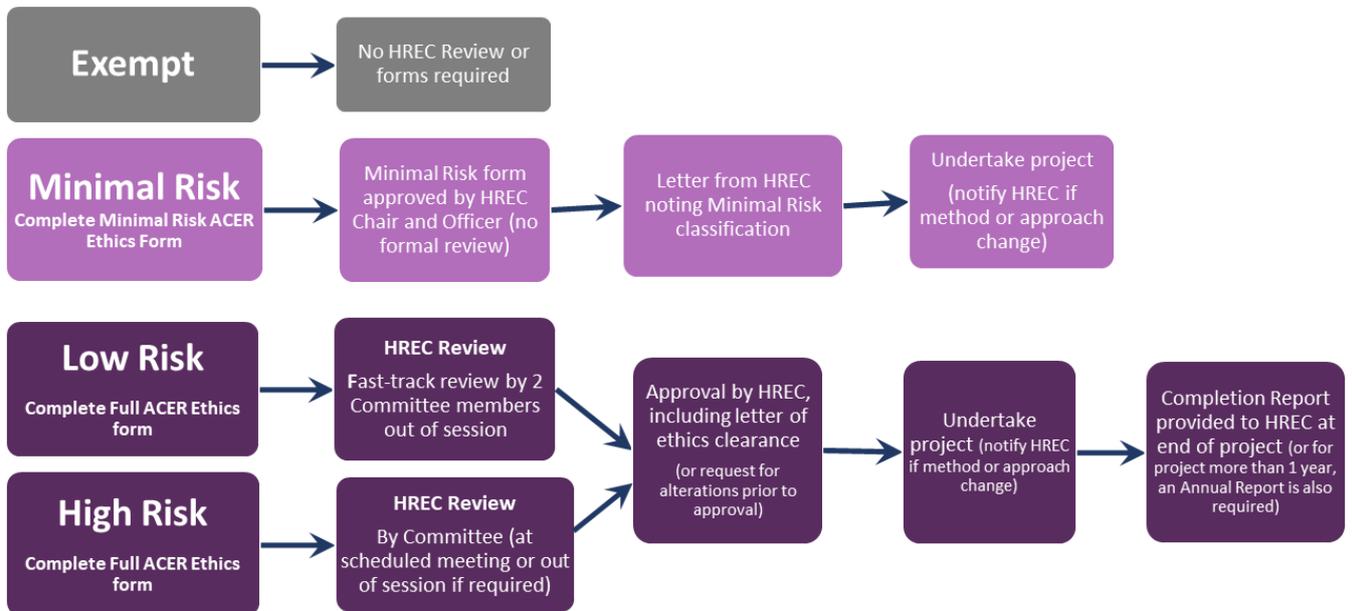


Figure 1: Overview of ACER HREC process by category of project risk

6 MEMBERSHIP

6.1 HREC Composition

The membership of the ACER HREC will comprise:

- A Chair (Category A);
- Two people who bring a broader community or consumer perspective and who have no paid affiliation with the institution (Category B);
- At least one person with knowledge of and current experience in professional care, counselling or treatment of people (for example a nurse or allied health professional) (Category C)
- At least one person who performs a pastoral care role in the community (for example minister of religion or Aboriginal elder) (Category D);
- At least one lawyer (Category E); and
- At least two people with current research experience that is relevant to the research proposals to be considered at the meetings they attend (Category F).

In addition to the above:

- No member will be appointed in more than one of the categories listed above;
- There will be a minimum of eight members;
- There will be a balance of men and women (noting the committee will recognise and be open to membership of people identifying as gender intermediate/intersex/unspecified);
- There will be at least one member of First Nations/Aboriginal and Torres Strait Islander descent; and
- At least one third of members will be from outside of ACER.

6.2 Appointment of Members to the HREC

HREC members are recruited by direct approach, nomination or by advertisement.

HREC members are appointed by the ACER CEO. The HREC Chair in consultation with the Directors of ACER Research Divisions will make recommendations to the CEO on membership. All members are appointed on an individual basis for their knowledge, qualities and experience, and not as representatives of any organisation, group or opinion.

Each new HREC member will receive a letter of appointment signed by the ACER CEO. This letter will outline: the date of appointment; the length of tenure; an assurance that indemnity will be provided in respect of liabilities that may arise during bona fide conduct of their duties as a HREC member; HREC meeting attendance responsibilities; and general responsibilities as an HREC member.

Each member of the HREC will be appointed for an initial term of three (3) years (NS 5.1.34). At conclusion of this period, a member may be re-appointed for a further three years' tenure, if agreed by all parties.

6.3 Responsibilities of HREC Members

In accordance with the *National Statement*, HREC members must:

- be responsible for deciding whether, in their own judgement, a proposal submitted to the HREC meets the requirements of the *National Statement* and is ethically acceptable. To fulfil that responsibility, each member of the HREC should:

- become familiar with the *National Statement* and consult other guidelines relevant to the review of specific research proposals,
- prepare for and attend scheduled meetings of the HREC or, if unavailable, provide opinions on the ethical acceptability of research proposals before meetings, subject to institutional policies on absences, and
- attend continuing education or training programs in research ethics.
- disclose any actual, potential, or perceived conflict of interest, including any financial or other interest or affiliation that bears on any research coming before the review body.

6.4 Education

Each new member of the HREC will be provided with induction material; to include a copy of the *National Statement* and copies of relevant Standard Operating Procedures (SOPs). Each member shall also receive mentoring from the Chair and other seasoned HREC members on Committee process.

During appointment, all members will be required to attend continuing education and training in research ethics and this should occur, as a minimum, every three years. In addition, members will have the opportunity to attend workshops, conferences and other training events, supported by ACER, that are relevant to the roles and responsibilities of the HREC.

6.5 Remuneration

Committee members who are not ACER staff are generally appointed on a voluntary basis. In some circumstances, a sitting fee is offered to non-ACER committee members. This decision is made by the Chair in consultation with the ACER CEO or their delegate.

6.6 Liability

ACER accepts legal responsibility for decisions made and advice given and indemnifies all members of the HREC.

6.7 Management of Conflict/s of Interest

The ACER HREC will maintain a register of interests and update it as new Conflicts of Interest arise. The register will be included in the agenda papers and will be endorsed for accuracy at each meeting.

On appointment, HREC members will be required to both sign a Confidentiality Undertaking and a Declaration of Interests form which together state that:

- all matters of which they become aware during their work on the HREC will be kept confidential;
- any conflicts of interest, which exist or may arise during their tenure on the HREC will be declared; and
- they have not been subject to any adverse finding in a professional context or professional disciplinary matter, which may prejudice their standing as an HREC member.

On receipt of the agenda for a forthcoming HREC meeting, or prior to the meeting, any HREC member who perceives they have a potential conflict of interest, should notify the Chair accordingly. For the duration of discussion of an application for which the member has identified a potential conflict of interest, that member shall remove themselves from the meeting.

7 SECRETARIAT SUPPORT

The HREC Officer will provide secretariat support to the ACER HREC. Support will include preparation of agendas, submissions and minutes of HREC meetings (as per SOPs), dissemination of HREC deliberations to ACER researchers and generation of reports. The ACER HREC will use MS Teams as a platform for document sharing and online meetings.

8 CONDUCT OF BUSINESS

The HREC will conduct its business in accordance with implemented SOPs. SOPs will be reviewed at least every two years and amended and updated as necessary. All HREC members shall have access to copies of the procedures and shall be consulted regarding changes.

8.1 Meetings- Frequency & Forum

As a minimum, four (4) formal HREC meetings will be conducted annually using Microsoft Teams as a meeting platform. Meeting dates will be widely published across all ACER channels towards the end of the preceding calendar year. Where necessary or useful for the HREC, Project Directors of projects under review will be invited to attend the meetings.

Should numbers of research applications warrant additional out of session HREC meetings, the Chair, with administrative support from the HREC Officer, will canvass members as to their availability.

The Chair may cancel a scheduled meeting if it has been determined that there are insufficient agenda items to warrant a meeting, or a quorum cannot be achieved.

8.2 Preparation & Distribution of HREC Documentation

As per SOP 006 and 010, High Risk applications submitted to the HREC Office will be included on the HREC agenda for the next formal meeting. If the timelines for a High Risk project require review outside of the formal meeting schedule, an out of session meeting of HREC will be arranged.

Prior to inclusion on the agenda, the HREC Officer will determine that the application is complete. If incomplete, the application will be returned to the researcher for remedial attention prior to a resubmission.

All new applications will be uploaded by the ACER Project Director involved in the project on to ACER's Salesforce platform. Once uploaded the HREC Officer will process applications and where necessary liaise with the Chair to determine the risk category for the project.

For High Risk projects, the applications will be compiled and distributed to HREC Members by the HREC Officer. Where possible, the meeting to review an application will be one of the four formal ACER HREC meetings planned each year. In circumstances where the meeting schedule is not amenable to a project timeline, an out of session ACER HREC meeting will be convened.

All other submissions, including Low Risk projects and amendments to existing projects approved by the Chair out of session, and annual reports for approved projects, will be included on the HREC agenda for noting and/or ratification where appropriate.

The HREC Officer will upload final agendas on the Microsoft Teams HREC members' space, for access by members attending the forthcoming HREC meeting at least seven working days prior to the meeting. This timeframe will allow HREC members to review all submissions and contribute their views in the decision-making process.

8.3 Meeting Conduct

As per the *National Statement*, as far as possible, each HREC meeting should be arranged to enable at least one member in each category to attend. Where there is less than full attendance at a meeting, the Chair should be satisfied, before a decision is reached, that the views of those absent who belong to the minimum membership have been received and considered.

If the quorum is lost during the meeting, decisions will be finalised out of session.

Every HREC member will have an opportunity to contribute their views in the decision-making process for each application.

Following consideration of each new High Risk application, the HREC, guided by the Chair, will reach agreement on specific points to be communicated to the applicant and select one from the following range of decisions:

- a) Approved with no changes. The project may proceed as submitted.
- b) Approved subject to minor or major changes. Changes are required and are to be reviewed by the Chair and/or HREC members before the project can go ahead.
- c) Not approved. The project will be unable to proceed until issues relating to ethical conduct and scientific merit are addressed. A new HREC submission will be required once the project is re-developed.

The HREC may reject an application which fails to meet HREC requirements.

HREC members will endeavour to reach a decision on an application by general agreement. However, this need not involve unanimity (NS 5.2.8).

In exceptional circumstances, the HREC may seek advice from experts to assist with consideration of a research proposal, provided that such experts have no conflicts of interest in relation to the proposal under consideration.

9 REPORTING

Copies of confidential HREC minutes, signed by the HREC Chair, will be provided to the ACER CEO on a post-meeting basis. Additionally, the HREC Officer will submit a summary report on the HREC's activity quarterly for dissemination to staff as part of the ACER Quarterly Staff Forum.

In addition to this, an HREC Annual Compliance Report will be prepared for the NHMRC in line with the requirements of the *National Statement*. This report will include current membership details and any membership changes, educational activities undertaken by HREC members, detail of application numbers, details of research proposals, and provision of information regarding complaints and complaints processes.

10 DISSEMINATION OF HREC DECISIONS

As per SOP 008, meeting proceedings will be captured as minutes by the HREC Officer. Minutes will record major issues discussed, concerns expressed, decisions taken and reasons for rejection or requirement for change to the protocol and where necessary link those reasons to the *National Statement*.

The HREC Officer will promptly notify the applicant in writing, advising whether the application, which the HREC has considered, has received ethical approval and any conditions of that approval. If not approved the researcher will be advised of what changes to the application are required and a rationale for these.

Where possible, intended timelines for notification of HREC decisions (from the date a completed ACER HREC Form is submitted) will be: 10 working days for applications determined as Low Risk, and 15 working days for applications determined as High Risk.

Notification of the HREC's deliberations will be made directly to the Project Director of research projects undergoing HREC approval.

11 MONITORING OF APPROVED RESEARCH

The HREC will monitor the progress of all projects to which it has granted ethical approval. In doing so, the HREC may request and discuss information on any relevant aspects of the project with the researchers at any time. Furthermore, Project Directors are obliged to notify the HREC of any changes to an approved project. SOPs 013, 014, 015 and 016 detail the approaches to monitoring, amendments and reporting of approved projects.

Monitoring responsibilities will include, at a minimum, obtaining a final report at the project's completion and for projects that span more than one year, an annual report on the progress of the project. The report should include:

- a) any proposed changes to the project or its conduct;
- b) any and all adverse events that take place;
- c) any unforeseen events that might affect continued ethical acceptability of the project; and/or
- d) a reason for a project being abandoned/discontinued (if relevant).

A final report should be provided to the HREC Office on completion of the project and if required, an annual report should be provided to the HREC Office on the anniversary date of approval. HREC approval will cease at date of receipt of the final report by the HREC Office.

12 COMPLAINTS PROCESS

Research participants and researchers involved in each project will be informed of avenues for lodging complaints or concerns about projects approved by the HREC. Any complaint about the conduct of a project will be brought to the attention of the HREC Officer in the first instance, detailing the grounds of the complaint (see SOP 016).

13 REFERENCES

ACER HREC, (2021), *Standard Operating Procedures (SOPs)*, Australian Council for Educational Research Human Research Ethics Committee.

National Health and Medical Research Council, Australian Research Council and Universities Australia (2023). *National Statement on Ethical Conduct in Human Research*. Canberra: National Health and Medical Research Council (NHMRC). www.nhmrc.gov.au/about-us/publications/national-statement-ethicalconduct-human-research-2023