Human Research Ethics Committee

**Guidelines for Applicants to the Human Research Ethics Committee (HREC)**

Ethical Conduct in Research Involving Humans

PART A: POLICY AND PROCESS

1. **NEED TO OBTAIN ETHICS APPROVAL FROM THE HREC**

1.1 Australian Catholic University’s Human Research Ethics Committee (HREC) is established in accordance with the provisions of the *National Statement on Ethical Conduct in Human Research (2007)*.

1.2 The primary role of the Human Research Ethics Committee (HREC) is to facilitate the conduct of research which protects the welfare and the rights of all human participants in research and to ensure that the principles of integrity, respect for persons, beneficence and justice are upheld.

1.3 All research projects involving contact with human participants and/or access to their records/files/specimens must be reviewed by the HREC. This includes both funded and unfunded research, as well as undergraduate and postgraduate student research projects, where applicable. Researchers must submit an application to the HREC, and have obtained approval from it, before contacting potential participants. Researchers’ responsibilities extend beyond the *National Statement* to include documents such as *Values and Ethics* and *ACRCR* etc.

1.4 Ethics approval is required for a number of reasons. These include:

- protection of human research participants from any physical or mental discomfort, or from danger, intrusion, or harm that may result from particular research procedures;
- protection of the researcher’s right to carry out a legitimate investigation;
- safeguarding the University’s reputation for the research that it conducts and sponsors;
- minimising the potential for breaches of legislation and for claims of negligence that might be brought against the researcher and the University;
- ensuring that the requirements of privacy legislation are met;
- satisfying the funding bodies’ requirements to obtain ethics approval before research funds are released; and
- satisfying the requirement to present a letter of approval from an HREC as a precondition for publication in certain journals.

1.5 In the case of student researchers, it is the responsibility of their supervisors to assist them in their application for ethics approval and to ensure it is completed satisfactorily in compliance with all relevant policies and procedures.
1.6 Research which is deemed to be **negligible risk**, where this is defined as research involving no more than inconvenience to the participant and in which there is no foreseeable risk of harm or discomfort (see page 10 of the *National Statement*), may be reviewed by a Chair of an Ethics Review Panel (*National Statement* 5.1.22 (a)).

1.7 Research which involves only the use of existing collections of data or records that contain only non-identifiable data about human beings does not need ethics approval. However, researchers must apply to the HREC for an endorsement of this exemption from ethics review and approval. Researchers should apply for this exemption using the “Non-identifiable data” form on Orion. (*National Statement* 5.1.22(b)).

1.8 Applications which are deemed as negligible risk or use non-identifiable data (see 1.7 above) will still need to show that the research meets the requirements of the *National Statement* and is ethically acceptable (*National Statement* 5.1.23).

1.9 If the research involves another organisation (e.g., a hospital or a university), researchers will need to check whether ethics approval has also to be obtained from the organisation concerned. See also Part B Section 3.

1.10 If the research requires ethics approval from another organisation with an NHMRC-recognised HREC (e.g., an Australian hospital or university), usually it will be only be subjected to one review, with the secondary HREC accepting the approval of the first. In most cases, the primary HREC will be the one where the Primary Investigator is based. In cases where hospital ethics approval is required, the hospital HREC will be the primary HREC. Approval should be sought through the primary HREC first. In cases where ACU HREC is the secondary HREC, researchers should complete the “Registration of External Ethics Approval” form in Orion and attach all documentation approved at the primary HREC, including application form, all attachments and approval letter.

1.11 If the research involves another organisation (i.e., school, hospital, or other) researchers will need to check whether other non-ethics approvals or permissions are required (i.e., from the Catholic Education Office, Department of Education, Schools, Principals, Organisation management etc). If so, researchers must provide to the HREC both the letter of request for this approval and the final approval before ethics approval can be granted.

1.12 Researchers are expected to be familiar with the Australian Code for the Responsible Conduct of Research, and the National Statement of Ethical Conduct in Human Research, and to conduct research activities in accordance with these codes. Copies of the *National Statement* are available from:

- Campus libraries;
- branches of the Research Services Office in each State;
- [Research Services website](#);
- [NHMRC website](#).

1.13 Research involving Aboriginal or Torres Strait Islander peoples must first be supported by ACU’s Centre for Indigenous Education and Research (CIER) before submission to the Human Research Ethics Committee.
2. APPLICATIONS FOR ETHICS APPROVAL

2.1 Completed applications must be submitted online through ORION Ethics.

2.2 The HREC will not consider applications that are incomplete or have inaccurate information. The Ethics Officer will review the application and request amendments on standard points (e.g. applications missing essential features such as appropriate letterhead, research proposal, two consent forms etc.) before sending the application for review.

2.3 Once the application has been checked by the Ethics Officer and is deemed complete, the application will be submitted for processing and review.

2.4 Applications must be submitted at least six weeks before the proposed date of commencement of the research project. If a project is approved before this time, the start date will be brought forward so that researchers can begin research as soon as ethics approval is granted.

2.5 Before submission to HREC, all applications must be peer reviewed in accordance with the procedures set out by the researcher’s School, Institute or Centre.

3. HREC PROCEDURES WHEN CONSIDERING APPLICATIONS

3.1 Applications which are designated “negligible risk” are considered, normally within ten working days following receipt, by an Ethics Review Panel Chair who will determine whether the application meets the designation of “negligible risk”.
   (a) If the Ethics Review Panel Chair accepts the designation as “negligible risk”, the application is then reviewed by the Panel Chair.
   (b) If the designation of “negligible risk” is not accepted, the Ethics Review Panel Chair will ask the Research Ethics Officer to refer the application to either (i) an Ethics Review Panel if he or she deems it to be “low risk” or (ii) the full HREC if he or she deems it to be “more than low risk” or falling within those categories named by the National Statement as requiring assessment and approval by the full meeting of the HREC (see 3.4 below and section B.2 of the online application form).

3.2 Applications which have been designated by the researcher/s as "more than low risk" are forwarded immediately to the next meeting of the HREC. HREC meets 11 times each year. HREC meeting dates and deadlines for submission of applications are on the ACU website.

3.3 Applications which are negligible or low risk and do not fall within the categories requiring assessment by the full HREC (see 3.4 below), can be submitted at any time and do not need to be submitted on or before the HREC deadline dates.

3.4 Applications which fall in one of the categories named by the National Statement as requiring consideration by the full HREC cannot be assessed by the panel review process, but must be immediately referred to the HREC to be considered at its next full [monthly] meeting. This applies to research projects in the following categories:
   (i) Interventions and therapies, including clinical and non-clinical trials, and innovations (National Statement Chapter 3.3);
   (ii) Human Genetics (Chapter 3.5);
   (iii) Human Stem Cells (Chapter 3.6);
   (iv) Women who are pregnant and the human foetus (Chapter 4.1);
(v) People highly dependent on Medical Care who may be unable to give consent (Chapter 4.4);
(vi) People with a cognitive impairment, an intellectual disability, or a mental illness (Chapter 4.5);
(vii) People who may be involved in illegal activities (Chapter 4.6);
(viii) Aboriginal and Torres Strait Islander Peoples (Chapter 4.7).

3.5 Applications which have been designated by the researcher/s as "low risk" are considered, normally within ten working days following receipt, by an Ethics Review Panel (ERP) comprising either two or three members of the HREC. In reaching a determination the ERP may consult with other expert advisors.

3.6 If the ERP determines that the designation "low risk" is insufficient and/or that there are other serious ethical matters to which the researcher has not attended, the application is immediately referred to the HREC to be considered at its next meeting.

3.7 If the ERP accepts that the designation "low risk" is accurate, and judges that there are no other serious ethical considerations to which the researcher has failed to attend, the application is reviewed as “low risk”.

3.8 If the ERP accepts the designation “low risk” is accurate but determines that there are special conditions to be met then ethics approval is granted once the Panel Chair or HREC Chair is satisfied that the researchers have met the conditions laid down by the ERP.

3.9 Applicants will be formally notified of the outcome of their applications and informed of the standard terms and conditions, and of any specific conditions governing their approved projects. In some circumstance, this may lead to further conditions of ethics approval being imposed.

3.10 As part of the quality assurance process, a selected number of projects approved by the panel review process will be reviewed at full meetings of the HREC. This could result in researchers being advised of further conditions.

4. MONITORING OF APPROVED PROJECTS

4.1 The Commonwealth Government requires the University to monitor compliance with the conditions under which projects are approved. Researchers must submit a "Progress Report" at the end of the approved period of data collection and a "Final Report" at the conclusion of the project. For this reason HREC asks researchers to complete progress reports at the end of the project. The Ethics Officer will initiate this process by sending the relevant form to researchers four (4) weeks prior to the completion date of the approved period of data collection/project.

4.2 Ethics approval is strictly limited to the project as approved. Researchers must notify the HREC of any variation to the research protocol that would have the effect of altering the status of the project. In such cases, researchers should complete the form "Application for Approval to Modify a Research Project", which is available on the Research Services website.

4.3 The NHMRC and AHEC require that regular audits be carried out to ensure that research projects conform to legislative requirements. A selected number of “negligible to low risk” projects may be audited each year to ensure that processes and conditions have been fulfilled as approved. All projects deemed to be “More than Low Risk” may be audited.

5. APPEALS AGAINST HREC DECISIONS
5.1 If an application has been rejected by the HREC, the researcher may:

- re-submit the application after satisfying the concerns of the HREC, or
- request the Chair of HREC to review the application, or
- request the University Research Committee to review the HREC's decision.

A researcher seeking a review must make a case that the policy and process as set out in these Guidelines have not been observed.

5.2 If, following the outcome of the review by the University Research Committee, the researcher still considers that inadequate consideration has been given to the case, appeal may be made to the Vice-Chancellor or his nominee.

5.3 The same procedures are to be followed in the case of a researcher who considers that the conditions placed by the HREC upon the project may have an adverse effect on the quality of the research.
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PART B: SPECIFIC ELEMENTS OF ETHICAL IMPORTANCE

1. Risk of Social, Mental or Physical Harm (National Statement 1.6, 1.7, 1.8, 1.9 and Chapter 2.1)

1.1 Risks of social, mental or physical harm may arise if the project involves:

- survey and/or interview processes which could cause distress or lead to invasion of privacy;
- contact with people who are particularly vulnerable, e.g., by reason of their social or legal status, or because of their age or physical or mental condition;
- collection of body tissues or fluid samples;
- causing pain;
- administration of any substance or agent;
- treatments or therapeutic techniques;
- deception.

1.2 In cases of research projects in which there is a risk of harm to participants, the HREC will be guided by the following considerations: (National Statement 2.1.3)

(i) Researchers should make every effort to minimise the risk of harm.

(ii) In particular, researchers need to consider whether a change in procedure might have the effect of reducing or eliminating the perceived risk of harm, while leaving the good to be produced essentially unaltered. The alternative, less risky, procedure may, of course, be one that creates greater inconvenience for the researchers themselves.

(iii) There will still be projects that carry some risk of harm to participants, even after all reasonable measures to avoid these have been taken. In these instances, it is essential that prospective participants be fully informed of the risks involved and that professional assistance (e.g., in the form of medical or counselling staff) be readily available in case some adverse effect should result.

1.3 In particular, researchers should be alert to risks of psycho-social harm which may arise, for example, in relation to issues of privacy and reputation. The information dossier generated in the course of a research project may contain sensitive details of the private lives of research participants which, if divulged to unauthorised others, could have serious adverse consequences for the individuals concerned. For this reason it is essential that researchers ensure that adequate arrangements exist for the storage, restriction of access to, and eventual disposal of all data. If the results of the study are to be disseminated in any form, the participants’ right to confidentiality must be protected. Researchers must be familiar with the National Privacy Principles (NPPs) and Information Privacy Principles (IPPs) as well as relevant State legislation.

1.4 It is expected that all researchers acknowledge that “negligible risk” is not equivalent to no risk. It is also inappropriate to respond that the consideration of risk is not applicable in a “negligible risk” application. When completing this section researchers are encouraged to consider how to mitigate adverse consequences to participants even if the risk of such consequences arising is negligible. Also noteworthy is that harmful consequences to
participants may not be apparent distress or alarm; it may be that non-obvious issues of concern arise as a direct result of participation for which the participant may need support of a more general kind.

2. **RECRUITMENT OF PARTICIPANTS**

2.1 **Recruiting student/patient/client participants** (National Statement 2.2.9 and Chapter 5.4)

Researchers who intend to use their own students, patients, clients, family members etc. as participants need to be especially aware of the potential risks that such participation may entail, e.g., coercion, misuse of power. The application must demonstrate the steps taken to avoid coercion.

Student researchers who wish to recruit fellow students may do so, provided that the student participants are, generally speaking, neither friends nor acquaintances of the researchers.

2.2 **Approval for access to recruit from schools and other external agencies** (National Statement 2.2.13)

Letters from the appropriate authorities granting approval for ACU researchers to recruit school children, agency clients, company employees etc. are not required at the time of application to the ACU HREC. Once such approvals have been received, however, they must be provided to the HREC. Applications need to demonstrate that they are meeting privacy legislation requirements in accessing and recruiting participants. Research may not commence until all required permissions/approvals have been received by the ACU HREC.

3. **APPROVALS FOR MULTI-CENTRE RESEARCH** (National Statement Chapter 5.3)

3.1 **When the Principal Investigator or Principal Supervisor is from ACU**

In the case of a multi-centre research project in which the Principal Investigator or Student Supervisor is from ACU, the researchers are required to apply for ethics approval from the ACU HREC, using the “New ACU Project” form on Orion. The project must not proceed until such approval has been granted.

3.2 **When the Principal Investigator is external to ACU**

In the case of a research project in which ACU staff or students collaborate as co-investigators but the Principal Investigator is employed by another institution and ethics approval has been sought from the Principal Investigator’s Institution, the co-investigators are not required to seek additional ethics approval from the ACU HREC. They must, however, submit the “Registration of External Ethics Approval” form in Orion, and attach the completed application form and attachments that have been approved at the Primary HREC, the approval letter from that HREC, and an explanation of their involvement in the research.

3.3 **When ACU students conduct research in hospitals or in other institutions which require ethics approval by their own HRECs**

In order to expedite the process of approval, supervisors may advise ACU students conducting research in hospitals or in other institutions which require ethics approval from their own HRECs, to submit the same application form to the University’s HREC as they have submitted to the other institution’s HREC. This does not obviate the need to gain ethics approval from the ACU HREC. Students and supervisors must ensure that all ACU HREC
requirements have been met. Researchers should complete the “Registration of External Ethics Approval” form in Orion.

3.4 **When the researcher is an ACU staff member enrolled as a student in another institution**

Staff of the University who are enrolled as students in another institution do not need to obtain ethics approval from the ACU HREC, provided that they do not use ACU resources or seek to access ACU colleagues or students as research participants.

3.5 Notwithstanding the above, researchers may use the National Ethics Application Form if their research involves multiple institutions.

4. **CONSENT** (National Statement Chapter 2.2)

4.1 Where non-identifiability cannot be maintained, researchers must ensure that participants provide written consent to participate in the research. Consent may be in writing or established in some other way. (National Statement 2.2.5)

4.2 Information on the "Consent Form" should indicate what the participants are taking part in, and time commitment required (e.g. completing a 10-minute questionnaire, participating in a 30-minute interview/focus group, being audio/videotaped etc.). The proposed participants should be offered ample opportunity to familiarise themselves with the contents of the "Information Letter to Participants" before being requested to return the completed "Consent Form". (National Statement 2.2.4)

4.3 Samples of a "Standard Consent Form" and a "Parent/Guardian Consent Form" are available from the ACU website at http://www.acu.edu.au/about_acu/research/for_researchers/research_ethics/

4.4 Written consent might not be required in some cases, e.g., mass-distribution questionnaires where the anonymity of the participants is completely protected, or observational research in public places. In the case of such questionnaires, a statement should be attached to the front of the document or should be displayed in a prominent place, informing prospective participants that return of the questionnaire will be taken as voluntary consent to participate in the research.

N.B. Whilst there might not be a need to obtain written consent from participants in such instances, researchers are reminded that they are nonetheless required to submit an application to the HREC for ethics approval. (National Statement 2.2.5)

4.5 The voluntary nature of participants' consent should be safeguarded at all times. Researchers should ensure that consent is not affected by ignorance, inducement, or fear of experts. (National Statement 2.2.1)

4.6 In the educational context, the possibility exists that students might be subtly coerced to participate in research projects. The HREC will, therefore, exercise every care to ensure that those who are asked to participate in a piece of research are properly informed as to what they are being asked to do and as to what the likely consequences for them are, should they choose to participate. (National Statement 2.2.9)

4.7 Researchers also need to make clear in the Information Letter to prospective participants that they will suffer no disadvantages/penalties or adverse consequences (apart from the cessation of any benefits that simply ensue from research participation itself), if they choose not to participate in the research or to withdraw from it. (National Statement 2.2.6(g))
4.8 If the participant is under eighteen, informed consent must, apart from exceptional circumstances as determined by the HREC, be obtained from a primary care giver. (National Statement 4.2.7) Whenever minors have sufficient competence to make a decision to participate, assent must also be obtained from them. (National Statement 4.2)

5. INFORMATION LETTER TO PARTICIPANTS AND CONSENT FORM

5.1 It is essential that participants be provided with a written summary of the research procedure, its expected benefits, and possible harms and risks. (National Statement 2.2.1 and 2.2.2)

5.2 It is important that the "Information Letter to Participants" and the "Consent Form" be completely consistent. Participants are to be requested to sign and date both copies of the "Consent Form", one copy of the form to be returned to the researcher and the other copy to be retained by the participants. (National Statement 2.2.6 and 2.1.6)

5.3 The "Information Letter to Participants" should be concisely phrased and written in a style that is accessible to the proposed participants. The Information Letter should be addressed directly to the participants; for example, begin with

   Dear Participant,

   You are invited to [body of letter].  (National Statement 2.2.6, 5.2.16)

The letter should also state the basis on which participants are invited to participate, and be signed at the end by all researchers. Sample letters are available from the ACU website.

5.4 At the time of application, the researcher/s must supply the HREC with all relevant materials, including questionnaires, interview schedules, the "Information Letter to Participants" and the "Consent Form". Only after the HREC has granted approval to proceed may these materials be provided to research participants. (National Statement 5.2.23)

5.5 The "Information Letter to Participants" and the "Consent Form" must clearly identify:

   • Australian Catholic University as the host institution for the research, or participating institution;
   • the name of the University Committee which has approved the application, i.e., Human Research Ethics Committee;
   • the names of the researchers who are ultimately responsible for the project;
   • those who will actually make direct contact with the participants;
   • whether the research project is being undertaken by a student, and, if so, details of the award for which he or she is enrolled;
   • a means (e.g., address and standard telephone number) by which the participants are able to be in touch with the researchers (and, in the case of student research, the supervisor) to ask further questions etc. Private addresses and telephone numbers, including mobiles, must not be provided;
   • the voluntary nature of participation and the participants’ right to withdraw at any time without being required to indicate why they are withdrawing;
   • if the study is anonymous, please demonstrate how anonymity will be maintained throughout the study;
   • if the study is confidential, please demonstrate how confidentiality will be maintained throughout the study and specify the level of confidentiality;
• the address to which complaints or concerns may be referred if the researchers are unable to reply to participants’ questions;
• if required, add the standard University privacy statement;
• an offer from the researchers to provide appropriate feedback to participants on the results of the project; and
• whether it is the researchers’ intention to make the data available to others – in aggregated form or otherwise – through publications, seminars, teaching, etc. (National Statement 2.2.6)

5.6 Some hospitals or other organisations may require that the "Information Letter to Participants" and the "Consent Forms" be on their own letterhead. The University’s preferred position is that research under the supervision of the University should ordinarily be communicated under ACU letterhead. In some instances, however, the ACU HREC may permit the use of joint letterhead. In such cases, the section on complaints must include ACU contact details.

5.7 In all cases it must be clearly stated that the research being undertaken is research under the auspices and supervision of ACU. The "Information Letter to Participants" may include the hospital HREC contact details in addition to the ACU contact details in the section on complaints. (National Statement Chapter 5.3)

6. LIMITS TO INFORMED CONSENT

6.1 In general, the HREC will need to be satisfied that the researcher has in hand appropriate procedures to obtain the informed consent of prospective participants and other relevant persons or authorities.

6.2 In some special cases, however, it will not be possible to obtain informed consent from the participants themselves, e.g., if they are very young children, or persons with a severe intellectual or mental impairment. What is required in every case is for the researcher to place her/himself in the position of the vulnerable participant and ask what she/he would wish to have done to ensure respect for her/his integrity and autonomy (albeit limited in this instance). It is essential that consent to participation in research by such persons be obtained from parents/guardians or other authorities having that responsibility at law. (National Statement 4.2, 4.3, 4.4 and 4.5)

6.3 Before approving a research proposal which involves any degree of deception of participants, concealment from them of the purposes of the study, or covert observation, the Committee must be satisfied that the criteria listed under 2.3.1 to 2.3.4 of the National Statement (2007) have been met.

7. PARTICIPANT CARE DURING RESEARCH

If, in the course of the research project, unintended adverse effects occur, then the researchers must:

• act quickly to ameliorate the situation;
• halt the project immediately so as to obviate further adverse effects;
• provide as soon as possible to the HREC details regarding the management of the adverse effects; and
• seek approval from the HREC to modify/continue the research protocol.

8. SECURITY AND DISPOSAL OF DATA
8.1 According to the Joint NHMRC / AVCC Statement and Guidelines on Research Practice (May 1997) (See Chapter 2 of the Australian Code for the Responsible Conduct of Research – ACRCR), 2.4, “wherever possible, original data must be retained in the department or research unit in which they were generated. Individual researchers should be able to hold copies of the data for their own use. Retention solely by the individual researcher provides little protection to the researcher or the institution in the event of an allegation of falsification of data.” In implementing this guideline, the University distinguishes between research projects that are deemed by the HREC as “more than low risk” and those deemed “low risk”:

- Original data associated with research projects deemed by the HREC to be “more than low risk” are to be stored on University premises in accordance with procedures approved by the University Research Committee. Responsibility for providing the facilities for the storage of such data shall rest with Research Services, which shall report regularly to the HREC.

- Responsibility for storage of data associated with projects deemed by the HREC to be “negligible or low risk” shall rest with the Principal Investigator or Supervisor in consultation with the Head of School.

8.2 It is required that primary data be retained by the University for seven (7) years following publication, or for seven (7) years following the completion of the project if the data are not used for publication. After this period, data are to be disposed of in accordance with the University's Retention and Disposal Schedule.

9. **ANONYMITY, CONFIDENTIALITY, PRIVACY**

9.1 **Anonymity.** Anonymity in this context, means that the identity of the respondent is not known in any way to anyone involved in the research, including the researchers themselves. Anonymity is therefore to be distinguished from confidentiality, as described below. Research interviewees, for example, are not anonymous, because their identity is known to the researcher/interviewer. The National Statement (2007) uses the term non-identifiable data in preference to anonymous data. Such data have never been labelled with individual identifiers or are data from which identifiers have been permanently removed, and by means of which no specific individual can be identified. (Chapter 3.2, page 29).

9.2 **Confidentiality.** Confidentiality refers to the obligation of people not to use private information - whether private because of its content or the context of its communication – for any purpose other than that for which it was given to them. (National Statement, 2007). The information given is to be used only for the research purposes stated in the protocol. Without the explicit permission of the person providing it, such information must not be divulged to others in any way that might allow it to be linked to that person.

Ensuring confidentiality will, in many situations, mean keeping names separate from data and reporting aggregated data only. Additional precautionary measures will need to be taken when reporting descriptive data from small samples or when reporting non-aggregated data. If there is any risk that participants might be able to be identified from reports, researchers are required to indicate how they propose to minimise that risk.

9.3 **Privacy.** Researchers should be familiar with the existence of relevant Commonwealth, State and Territory legislation regarding privacy. Of special note are the Information Privacy Principles and the National Privacy Principles.
CONTACT DETAILS

For further information regarding applications for ethics approval, researchers should contact their local Research Services Officer.

The contact details for your nearest Research Services Officer are:

VICTORIA
Research Services
Australian Catholic University
Melbourne Campus
Locked Bag 4115
FITZROY VIC 3065
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