Cairnmillar INSTITUTE

Treatment | Education | Research

Human Research Ethics Committee (HREC)

Guidelines and Procedures

1. Context

The Human Research Ethics Committee (HREC) is a standing committee of The Cairnmillar Institute Council (the Council) and is responsible for the oversight of all matters related to the ethics review of human research conducted through the Institute. The HREC ensures that any human research undertaken by the Institute staff, students or honorary associates is designed and conducted in accordance with the *Australian Code for the Responsible Conduct of Research;* and is ethically reviewed and monitored in accordance with the *National Statement on Ethical Conduct in Human Research* (NSECHR)

All research involving humans at the Institute must meet appropriate scholarly or scientific standards, and those conducting research are trained and qualified in appropriate research methodologies and applications, or in the case of being trained, are suitably supervised.

2. Guiding Principles

2.1. Values and principles of ethical conduct

Human research ethics ensures researchers and research students uphold the values and principles of ethical conduct when designing, conducting and reporting research findings. All research 'with or about people, or their data or tissue' (NSECHR) should reflect the following values:

2.1.1 Respect for human beings **-** requires respect for the privacy, confidentiality and cultural sensitivities of research participants. All people involved in research have the right to make informed decisions about matters that affect them. People must be protected and empowered if their capacity to make informed decisions is impaired.

2.1.2 Research merit and integrity - requires the use of methods, facilities and resources that are appropriate to achieve the aims of the research. Benefits of research must be justified, it should be supervised by researchers with appropriate expertise, and findings reported accurately and responsibly.

2.1.3 Justice - requires procedural fairness in the recruitment of participants and review of research. Research aims should be achieved using 'just' means that do not unfairly burden particular groups. The benefits of research should be distributed fairly between participants and the wider community, and research findings should be provided within a reasonable time.

2.1.4 Beneficence - requires sensitivity to the welfare and interests of participants, and the cultural and social implications of the research. The likely benefits to participants or the wider community must justify any risk of harm or discomfort to research participants.

2.2. Assessment of risk, harm, discomfort and inconvenience

2.2.1 Assessment of risks involves identifying risks, gauging their probability and severity, and then assessing ways in which the risks can be minimized and managed. Researchers need to be aware of how their research may lead to harms, discomforts and/or inconveniences for participants and/or others.

2.2.2 The National Statement on Ethical Conduct in Human Research identifies the following kinds of potential harms in research:

a) physical harms: including injury, illness, pain;
b) psychological harms: including feelings of worthlessness, distress, guilt, anger or fear related, for example to disclosure of sensitive or embarrassing information;
c) devaluation of personal work: including being humiliated, manipulated, or in other ways treated disrespectfully or unjustly;
d) social harms: including damage to social networks or relationships with others; discrimination in access to benefits, services, employment or insurance; social stigmatization; and findings of previously unknown paternity status;
e) economic harms: including the imposition of direct or indirect costs on participants;
f) legal harms: including discovery and prosecution of criminal conduct.

2.2.3 Less serious than harm is discomfort, which can involve body and/or mind. Examples include minor side-effects of medication, the discomforts related to measuring blood pressure, and anxiety induced by an interview.

2.2.4 Less serious than discomfort is inconvenience. Examples include filling in a form, participating in a street survey, or giving up time to participate in research.

2.3. HREC guide to ethical decision making

2.3.1 It is acknowledged that each research proposal will be unique and will entail potentially unique ethical issues for consideration.

2.3.2 Issues that the Committee should include in its deliberations, but are not limited to:

a) The research credentials of the investigators;
b) The merit and integrity of the research;
c) Respect for persons involved in the research, including the dignity, welfare, rights, beliefs, perceptions, customs, and cultural heritage of participants;
d) The likelihood and level of harm or discomfort to participants;
e) The burden of participation on individual participants or identified groups;
f) Any source of financial, or in-kind support, to researchers and/or participants, in particular where conflicts of interest may arise or be evident;
g) Confidentiality of participants and of all material relating to participants;
h) Security of data during and following completion of the project;
i) Documents and material used to inform participants and obtain informed consent;
j) Any necessity for advocates and or interpreters;
k) Appropriate supervision of student researchers in the conduct and reporting of the research.

2.3.3 Where prior peer review has judged that a project has research merit, the question of research merit is no longer subject to ethical judgment.

2.3.4 The HREC will pay consideration to the general principles laid out in the National Statement, when considering research proposals relating to, or including, individuals from the following groups:

a) children and young people;
b) persons with an intellectual or mental impairment;
c) persons highly dependent on medical care;
d) persons in dependent or unequal relationships;

e) collectives;
f) Aboriginal and Torres Strait Islander Peoples;
g) persons who may be involved in illegal activities;
h) persons in other countries.

2.3.5 The HREC will also pay consideration to the general principles outlined in the National Statement with proposals that involve:

a) multi centre research;
b) clinical trials;
c) innovative therapy or intervention;
d) epidemiological research;
e) human genetic research;
f) the use of human tissue samples;
g) ionising radiation;
h) assisted reproductive technology; or
i) research that involves deception of participants, concealment or covert observation; are all to be reviewed in light of the specific guidelines and requirements set out in the NSECHR.

2.3.6 If the proposed research requires unsupervised access to individuals from a group such that a police check of the researchers is required, evidence of that police check must be declared in the research proposal.

2.3.7 For any proposals involving individuals or research of the kind described above, the Secretary will include a reference in the Agenda papers to the relevant section of the NSECHR to assist members in their deliberations.

3. Determining the level of ethical review of human research

3.1. Guidelines for determining whether research is of low risk

3.1.1 'Low risk research' describes research where the only foreseeable risk to participants is not greater than one of discomfort.

3.1.2 Research involving any of the following should **not** be reviewed as 'low risk research' and requires review by the full Committee:

a) interventions and therapies;
b) human genetics'
c) human stem cells;
d) women who are pregnant and the human fœtus;
e) people highly dependent on medical care;
f) people with cognitive impairment, an intellectual disability, or mental illness;
g) Aboriginal and Torres Strait Islander peoples;
h) people involved in illegal activities
i) people in other countries

3.2. Low risk review subcommittee

3.2.1 Research that meets the NSECHR criteria for classification as 'low risk research' may be submitted to the Low-Risk Review Subcommittee, which consists of members of HREC with the required experience and awareness of what constitutes ethical research.

3.2.2 All submissions to the Low-Risk Review Subcommittee will be examined by at least two members of the subcommittee.

3.2.3 The Chair of HREC will endorse the 'low risk research' reviewed by the subcommittee.

3.3. Multi-Centre Research

The NSECHR states that duplication of ethics review be avoided. Accordingly, the Institute accepts human ethics approvals from other human research ethics committees registered with NHMRC and processes multi-centre research applications under expedited review procedures (see 3.4.2) where the Institute researchers are involved but the Chief Investigator is from another institution.

The Institute reserves the right to place conditions on or refuse involvement should approved proposals not conform to the requirements of the NSECHR, other relevant legislation or potentially expose the Institute to undue risk.

Where the Chief Investigator is an Institute staff member, primary approval must still be obtained from the Institute HREC. Other institutions are expected to follow the recommendations of the NSECHR and to likewise accept approvals by the Institute HREC.

3.3.1 Review under Memorandum of Understanding (MoU)

The responsibility of ethical review of any projects conducted with organisations with which The Cairnmillar Institute has an existing MOU will follow process as indicated in the agreement. Where MOUs are with hospitals, generally the hospital will have full responsibility of ethical review and monitoring of the research. Staff from The Cairnmillar Institute are required to notify HREC of any approved projects and forward a copy of the approval letter and final application for the institute's records. No additional ethical review of the project will be undertaken.

3.4. Exemptions or Expedited Reviews

Researchers should refer to the *HREC Checklist for Researchers: Determining level of Ethical Review,* to determine their eligibility for exemption from ethical review or expedited review.

3.4.1 Exemption from ethical review

Projects may be eligible for exemption from ethical review if: (a) all data to be used is already in the public domain; (b) the project involves only the use of existing collections of non-identifiable data; or (c) the project uses only Cairnmillar Institute SFI or SFT survey data only. In these cases, researchers should complete the *Application for Exemption from Ethical Review* and submit this to the HREC Secretary.

Applications for exemptions from ethical review will be assessed by one or more members of the HREC Executive, depending on level of complexity or risk. The HREC Secretary will notify researchers of the outcome of their application.

Teaching activities and quality assurance activities are not required to make a formal exemption request, but researchers can do so if they want to create a record of their decision.

3.4.2 Expedited review

Projects may be eligible for expedited review if they have received approval from an external HREC (refer to Section 3.3 of these guidelines and procedures). Researchers are required to complete the *Application for Expedited Review* and submit to HREC Secretary,

with a copy of the approval letter from the external HREC and their final approved application form.

Applications under this category will be assessed by one or more members of the HREC Executive, depending on level of complexity or risk, who must ensure that the research proposal has been reviewed appropriately according to the National Statement. Unless the level of review is deemed inappropriate, HREC will issue an approval based on the external HREC's review.

4. Compliance and reporting procedures

4.1. Compliance with regulations

4.1.1 Researchers are required to comply with conditions advised by the HREC. In turn, the HREC, or the Institute, will provide information from its records as required by the NSECHR to the NHMRC or other mandated authority, provided at all times that the rights and welfare of researchers and participants is respected.

4.1.2 The HREC will maintain a Register of applications and the outcome of each application.

4.2. Reporting

4.2.1 The HREC must report regularly to the Academic Board (the Board), including minutes of HREC meetings (to be forwarded within two weeks after a meeting) and annual reporting to be completed by 31 March covering the previous calendar year. The annual report must include:

a) numbers and types of projects assessed and approved or rejected;
b) numbers of complaints received and how they were dealt with;
c) activities that have supported the educational needs of HREC members;
d) procedural changes;
e) administrative or other difficulties being experienced; and
f) any matters that may affect the Institute's ability to maintain compliance with the *National Statement* and if necessary, the provision of suitable recommendations.

4.2.2 The HREC will report annually to the NHMRC, or other mandated party, information relevant to its procedures that is requested by the NHMRC or that party, in accordance with the NSECHR or its equivalent at the time.

5. Procedures for review of research protocols

5.1. Applying for HREC approval

5.1.1 Researchers will submit the completed appropriate application form (Low risk or Standard) and attach copies of any supplementary documentation. The form must be complete with AHoS Research or nominee signature before submitting to HREC Secretary. The HREC Secretary will issue the researchers with notification of receipt followed by notification of outcome from the HREC once the application has been reviewed.

5.1.2 Researchers must complete and lodge an Annual/Final report to the HREC Secretary for each approved project.

5.1.3 In line with the NSECHR, human research projects may be subject to audit by the HREC. As part of the audit process, an HREC may invite researcher(s) to be present for discussions of

the research and may request amendments to the research protocol. The emphasis of the audit process will be on research that presents higher than normal risk for participants.

5.2. Standard applications

5.2.1 Projects determined to be greater than low risk research proposals or other research requiring full review by the HREC, excluding proposals considered under the Multi-Centre processes (see 3.3) should be submitted to the HREC Secretary using the current *HREC Application Form*. Applications must be complete with necessary signatures and supporting documents attached (e.g. recruitment advertisements, questionnaires, interview schedules, Plain Language Information Statement, Consent Form, Evidence of approval from external agencies related to the research, evidence of approval from other HRECs).

5.2.2 Completed proposals will be receipted and entered into the database by the HREC Secretary, and then assigned to the next available HREC meeting.

5.2.3 Meeting dates for HREC and due dates for agenda items are published online. Attendance at HREC meetings by researchers or other observers is strictly by invitation.

5.2.4 Researchers will be notified via email of the review outcome for their project within 10 days of the HREC meeting at which the proposal is considered. Issues that are to be addressed by researchers will be outlined in the outcome letter from HREC. If there are no issues to be addressed, researchers will receive an approval letter. Proposals which have issues to be addressed will only be approved subject to researchers addressing these issues to the satisfaction of the HREC Chair, nominee or committee. Refer to the Flowchart in Appendix A for an outline of possible decision outcomes.

5.2.5 Researchers cannot commence collection of any human data for their proposed project until HREC approval has been obtained. All approvals are granted subject to conditions specified on the approval letter from HREC.

5.3. Low risk applications

5.3.1 Projects considered 'low-risk' (refer to Section 3) can be submitted at any time to the HREC Secretary, using the *HREC Application Form.* Applications must be complete with necessary signatures and supporting documents attached (e.g. recruitment advertisements, questionnaires, interview schedules, Plain Language Information Statement, Consent Form, Evidence of approval from external agencies related to the research, evidence of approval from other HRECs).

5.3.2 Completed applications will be receipted by the HREC Secretary and entered into the database. The HREC Secretary will then assign the application to two members of the Low-Risk Review Subcommittee, excluding any members who are listed as researchers on the application.

5.3.3 Reviewers may decide that the research requires full review by HREC. In such cases, researchers will be required to submit a standard application as outlined in Section 5.2.

5.3.4 Researchers will be notified via email of the review outcome within 3-4 weeks of submission of the completed application. Issues that are to be addressed by researchers will be outlined a letter from HREC.

5.3.5 Proposals that have issues to be addressed will be approved subject to researchers addressing these issues to the satisfaction of the HREC Chair or nominee. Refer to the Flowchart in Appendix A for an outline of possible decision outcomes.

5.3.6 Researchers cannot commence collection of any human data for their proposed project until HREC approval has been obtained. All approvals are granted subject to conditions specified on the approval letter from HREC.

5.4 Possible outcomes

The 'Notification of Outcome' sent to you by the HREC Secretary will record one of five possible outcomes from your application: 'Approved', 'Approved with Comment', 'Approved with Provisions', 'Approval Withheld', or 'Not Approved'.

5.4.1 Approved

a) Your application has been approved and no further action is required.
b) You are free to commence your project on the commencement date outlined in the notification.

5.4.2 Approved with Comment

a) Your application has been approved and no further action is required; however, the comments made should be noted as they may be helpful.
b) You are free to commence your project on the commencement date outlined in the notification.

5.4.3 Approved with Provisions

a) Your application has been approved but there may be small oversights in the application, or small changes required to some part of the methodology where the latter has ethical implications.
b) You need to attend to the issues specified and resubmit your application for review by the HREC Chair or nominee. The application will not need to be submitted for re-review by the full HREC or by the Low-Risk Review Subcommittee.
c) Researchers need to submit a cover letter which clearly states how each of the issues raised by the HREC have or will be addressed.
d) Following a review, researches will be issued with a new notification outcome.

5.4.4 Approval Withheld

a) Your application has not been approved; the committee has some concerns.
b) You need to address the concerns raised and resubmit your application for consideration by HREC.
c) Your resubmitted application should address the issues outlined in the notification. Submit this response in a cover letter to HREC.
d) The resubmitted application will be re-reviewed by HREC.
e) Following this review, you will be issued with a new Notification of Outcome.

5.4.5 Not Approved

a) Your application has not been approved, and the committee has serious concerns regarding the research.
b) You need to address the major concerns and submit a new application for consideration.
c) Submit the new application together with any necessary documentation to the HREC Secretary for consideration at an HREC meeting.
d) Following this consideration, you will be issued with a new Notification of Outcome.

5.5 Appealing against outcomes

5.5.1 If researchers wish to appeal against any decision made by HREC committees about their research project or express concerns about the ethics administration process, they should initially approach the Head of School, who in turn will inform the HREC Chair of the nature of the complaint. Consultation will take place between the Chair and the Head of School, and if the researcher is not satisfied with the result the matter will be referred to the Chair of the Academic Board.

5.6 Withdrawal of HREC approval

5.6.1 HREC approval is limited strictly to the research proposal as submitted in an application.

5.6.2 Failure to submit an annual progress report will mean approval for the project will lapse.

5.6.3 If the HREC Chair believes that the research project is not compliant or cannot comply with the protocol as it was approved, the HREC may withdraw approval. In such cases, the HREC will inform researchers of the withdrawal of the approval and recommend to the Institute that the research project be discontinued, suspended or other steps be taken.

5.6.4 A researcher must not continue with a project if ethical approval has lapsed or been withdrawn and must comply with any special conditions required by the HREC.

5.7 Reporting to HREC after approval

Research projects are approved to the proposed completion date stated on the application. Projects may be renewed yearly for up to a total of three years. If a project is to continue beyond three years a new application will normally need to be submitted.

The HREC is responsible for monitoring approved research to establish that the ethical standards of research are being maintained. As part of this monitoring process, the HREC requires as a condition of approval that the Principal Researcher keeps the HREC informed of the project's progress, its status (completed, discontinued, any variations to the research protocol, and any serious or unexpected adverse effects.

Researchers should note that these reporting requirements are a condition of HREC approval and any failure to report may result in approval being suspended or withdrawn.

5.7.1 Reporting progress

a) If the project has a duration of longer than 12 months, the researchers must submit annual reports. The first annual report is due 12 months from the date of initial approval.

b) Upon approval of the project, researchers will be informed of the dates on which they are required to submit reports. These can be found on the approval notification form.

5.7.2 Reporting completion or discontinuation

a) To report completion of a project, researchers should complete an HREC Final Report form and submit this to the HREC Secretary.

b) If a decision is made to discontinue a project after it has been given HREC approval, researchers must inform the HREC by completing a Final Report Form, and provide reasons for the decision. Once advised, the HREC will assess whether any participant has been or will be disadvantaged as a result of the project's discontinuation.

5.7.3 Reporting proposed amendments

a) A formal request must be submitted to the HREC for consideration and approval of any amendments or modifications researcher/s wish to make to an HREC-approved project. If the HREC determines that the proposed changes are significant, researchers may be required to submit a new application.

b) To request project amendments, researchers should complete a Request for Amendments to Existing Project form and submit this to the HREC Secretary as soon as possible.

5.7.4 Reporting a requirement for extension

a) HREC approval is granted until the proposed completion date stated on the application. If an extension to this completion date is sought, the researcher is required to submit a Request for Extension to Existing Project form to the HREC Secretary as soon as the need for an extension is clear.

5.7.5 Reporting adverse or unforeseen effects and events.

a) Researchers must report immediately to the a member of the HREC Executive anything that might warrant review of the ethical approval of the protocol, including serious or unexpected adverse effects on participants and unforeseen events that might affect

continued ethical acceptability of the project. Failure to do so may result in discontinuation of approval and/or disciplinary action.

b) The Principal Researcher is responsible for reporting any issue or occurrence that may warrant review of the ethical approval of the project, including any occurrence of serious or unexpected adverse effects of the research on participants, and any problems relating to the conduct of the project.

c) The report should detail the events, outline their significance, describe how they relate to the research, and whether any amendments to the research protocol will be required. The report should also detail any steps that have been taken or are proposed to be taken to address the adverse effects/events being reported. These details should also be included in any Annual / Final Report.

6. Privacy

When collecting personal information, researchers should give serious consideration to privacy and confidentiality issues. These include such factors as who will (and who will not) have access to information collected during the project; the adequacy of proposed storage and security measures; the measures proposed to protect confidentiality; and the manner and form in which results will be published, and whether these adequately protect the confidentiality of information and privacy of participants.

6.1 Responsibilities of researchers

The National Statement distinguishes between the responsibilities of researchers in respect to three different categories of personal information:

6.1.1 Identified: Data that allow the identification of a specific individual are referred to as ‘identified data’. Examples of identifiers may include the individual’s name, date of birth or address. In particularly small sets of data, even information such as a postcode may be an identifier.

6.1.2 Potentially identifiable (coded, re-identifiable): Data may have identifiers removed and replaced by a code. In such cases it is possible to use the code to re-identify the person to whom the data relate so that the process of de-identification is reversible. In these cases the data are referred to as ‘potentially identifiable’.

6.1.3 De-identified, (not re-identifiable, anonymous): The process of de-identification can be irreversible if the identifiers have been removed permanently, or if the data have never been identified. These data are referred to as ‘de-identified’. It should be recognised that the term ‘de-identified’ is used frequently, in documents other than the National Statement to refer to sets of data from which only names have been removed. Such data may remain ‘potentially identifiable’.

Greater care is required where the research involves identifiable or potentially identifiable information.

Although HREC consider the privacy implications of each proposal as part of the review process, researchers must be aware of the information privacy principles and how they may apply to the collection, use and disclosure of any personal, health or sensitive information about research participants involved in any part of their research project.

7. Complaints

7.1 Complaints about human research

7.1.1 All complaints about human research conducted at staff, students or associates as part of research conducted at The Cairnmillar Institute or the outcome of an ethical review approved by the institute's HREC should be initially sent to the HREC Secretary who will notify the Associate Head of School (Research). The Associate Head of School (Research) may seek to resolve the matter or forward to the HREC Chair or other members of the HREC Executive for consultation.

7.1.2 For matters forwarded to HREC, the HREC Chair and/or HREC Executive will act on behalf of the committee to fully investigate the complaint. The investigation will be conducted in reference to the relevant policy documents and privacy legislation.

7.1.3 The outcome of the investigation will be communicated to the complainant, the researchers. The HREC Secretary will document the complaint and resolution.

8. Management of Human Research Data

8.1 Institutional responsibilities

8.1.1 The Institute must ensure that research data and records created by students, staff and honorary staff are:

- Stored, secured, and disposed of in accordance with the requirements of the Records and Privacy Act 2002, the Australian Code for the Responsible Code of Research 2007, and the National Statement on Ethical Conduct in Human Research
- Accurate, complete, authentic and reliable
- Identifiable, retrievable, and available when needed
- compliant with legal obligations and the rules of funding bodies

8.1.2 In addition, the Institute must:

- Retain research data and records for a minimum of five years after publication or public release of the work of research
- Establish and implement departmental processes for the storage and retention of research data and records
- Secure and/or provide suitable physical and electronic (or virtual) storage space for research data and records

8.2 Researcher responsibilities

Researchers must ensure the following processes are followed:

- appropriate processes are developed for the collection, storage, use, re-use, access and retention of research data and records associated with their research program, including confidential research data and records and that the information is incorporated in to the research data management plan.
- Integrity and security of the research data and records is maintained, and that this material is stored in a retrievable way
- Researchers are aware of confidentiality restrictions, any relevant agreements that impact access to or disclosure of information and report any breach of confidentiality to the Associate Head of School Research and Head of School.

- Planning for the ongoing custodial responsibilities for the research data and records at the conclusion of the research project or on departure from the Institute, including information about access and potential re-use of the data
- Researchers must establish and document clear procedures for the collection, ownership and storage of research data and records when involved in a joint research project
- When a research project is undertaken under contractual agreement, the principal investigator has overall responsibility for the management of data and records
- In the case of multi-institutional projects, the institution of the principal investigator is ultimately responsible
- Research students must be jointly responsible with their supervisor, for the collection, storage, security and use of research data and records, including confidential research data and records. In addition, research students must deposit research data and records associated with their thesis to the Institute immediately following thesis submission. Students must also provide their supervisor with full details of the location of research data and records

9. Resources and References

- Australian Code for the Responsible Conduct of Research
- National Statement on Ethical Conduct in Human Research
- HREC Checklist for Researchers: Determining level of Ethical Review
- HREC Application Form (Standard and Low Risk)
- Application for Exemption from Ethical Review
- Application for Expedited Review
- Annual / Final Report Form
- Request for Extension to Existing Project Form
- Request for Amendments to Existing Project Form

HREC Application Flowchart