



Human Research Ethics Operational Guidelines

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1. PURPOSE OF FLINDERS UNIVERSITY’S HUMAN RESEARCH ETHICS COMMITTEES

The purpose of Flinders University’s Human Research Ethics Committees A and B (HREC A and HREC B) is to ensure that research conducted by Flinders University and Southern Adelaide Local Health Network researchers is conducted in an ethical and responsible manner compliant with the National Statement on Ethical Conduct in Human Research and other appropriate guidelines. Members are appointed and business is conducted in accordance with the committees’ terms of reference and procedures outlined in this Manual.

2. MEETINGS

2.1. Number of Meetings

HREC A and B will meet monthly between the months of February and December. Meeting dates will be published on Flinders University’s internal website and within *ResearchNow Ethics & Biosafety*, the University’s online ethics application system. Meetings will be held either online or face-to-face.

2.2. Quorum and Comments in Absentia

The quorum for meetings is a majority of the members with at least one third of those participating in the meeting external to the University. External members may not have a paid affiliation with the University. Where there is less than full attendance of members from the minimum membership categories at a meeting, the chairpersons must be satisfied that the views of the members who are not present have been received and considered by all members of HREC A or HREC B participating in the meeting before a decision is made.

If a member is unable to attend a meeting, the member may submit comments and recommendations on any applications via *ResearchNow Ethics & Biosafety* before the commencement of a meeting. Any comments relating to the Committees' business (other than review of applications) must be provided to the Research Ethics, Integrity & Compliance Office via email to human.researchethics@flinders.edu.au before the commencement of a meeting.

2.3. Conflict of Interest

The Agenda for each HREC A or HREC B meeting should state that members are required to declare a conflict of interest and must refrain from voting on, and remove themselves from the discussion of, an item of business in which they have a financial, personal or other conflict of interest.

When a member is an applicant on a project, or has another declared conflict of interest, the conflict must be declared and the member may leave the room or online meeting during the discussion of the project. The member must leave the room or online meeting during the decision-making process unless the committee agrees otherwise. Whilst a member may be given the opportunity to clarify aspects of the project with which they are involved in, this must not be a greater opportunity than is afforded to other applicants.

The Minutes of the meeting should clearly record whether a member with a conflict of interest was:

- absent from the meeting during discussion of an application or business item; or
- absent from the room during the decision-making process, and only responded to questions directed to the member by the Committee.

2.4. Agenda, Minutes and Meeting Papers

The Research Ethics, Integrity & Compliance Office will be responsible for assembling the meeting agenda and uploading papers using *ResearchNow Ethics & Biosafety*. The meeting agenda and papers may also be sent to members via email. The Research Ethics, Integrity & Compliance Office will further be responsible for taking minutes and recording decisions made by the Committees.

Applications to be reviewed will be available online in *ResearchNow Ethics & Biosafety*. The chairpersons and other members, in consultation with the Research Ethics, Integrity & Compliance Office, may also recommend inclusion of additional information, invitation of specific researchers or advisors to the meeting, or other inclusions necessary to the process of fair and reasonable consideration of applications or correspondence. These meeting papers will be uploaded a minimum of one week in advance of the meeting date. Addendums to the agenda will only be issued if there are matters for urgent consideration.

2.5. Observers at Meetings

Observers, including applicants, may be invited to attend meetings for particular items of business, or for complete meetings. Observers have no speaking rights, unless asked by the chairperson of the meeting. Observers must sign a confidentiality agreement before attending a meeting.

3. APPLICATION PROCESS

3.1. When to Apply for Ethics Approval

Ethics approval is required for all research projects involving human interactions. In accordance with the National Statement, human research 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:

- taking part in surveys, interviews or focus groups;
- undergoing psychological, physiological or medical testing or treatment;
- being observed by researchers;
- researchers having access to their personal documents or other materials;
- the collection and use of their body organs, tissues or fluids (e.g., skin, blood, urine, saliva, hair, bones, tumour and other biopsy specimens) or their exhaled breath;
- access to their information (in individually identifiable, re-identifiable or non-identifiable form) as part of an existing published or unpublished source or database.

Applications for ethics approval should be submitted at least two months prior to recruitment of participants and collection of research data to ensure sufficient time is allocated to the review process.

The ethics approval process is independent of grant allocations, contract negotiations or other deadlines and may require additional time. Researchers must allocate ample time for the ethics approval process in their research proposals. Research involving human participants cannot proceed without clearance from one of Flinders University's Ethics Committees.

3.2. Internal and External Applicants

Applications are accepted from Flinders University staff, students and affiliates as well as staff and affiliates of the Southern Adelaide Local Health Network (SALHN). No fees will be charged for applications from Flinders University and/or SALHN researchers.

Applications from external applicants will not be considered.

3.3. Higher Risk Applications

HREC A and HREC B will review higher risk applications. Higher risk applications must be submitted by the stipulated meeting deadlines advertised on the University's internal website to ensure sufficient time is available for review.

3.4. Lower Risk Applications

Lower risk applications will be referred to the Low Risk Panel for review out of session. These applications can be submitted at any time. Applications approved by the Low Risk Panel will be ratified at a meeting of HREC A or HREC B. HREC A or HREC B members may request additional information during the ratification process.

3.5. Submission of Applications and Required Information

Applications must be submitted online through *ResearchNow Ethics & Biosafety*. Hard copy applications will not be accepted.

The following themes must be discussed in the application:

- Risk (harm, discomfort, inconvenience)
- Benefit (personal, social, economic, educational)

- Participants (characteristics, recruitment, relationships, respect)
- Consent (informed, withdrawal rights)
- Data (confidentiality, storage, disposal)
- Research merit (rationale, methodology, interventions)

All relevant information must be included within the application form. Information provided must satisfy the committees that the proposed research is justified and complies with the ethical principles of the National Statement on Ethical Conduct in Human Research. Applications should be written in plain English at a level that can be understood by someone who is not an expert in the field of the respective research. Technical terminology should be avoided. Applications will be reviewed by the Research Ethics, Integrity and Compliance Office before they are assigned to a meeting. This may require revisions by the applicant and if so, the application will be returned to the applicant with feedback.

All research data must be stored in accordance with the University's Data Management Procedures. It is strongly recommended that applicants submit a Data Management Plan via Service One before applying for Ethics approval.

Applications must include copies of information provided to potential participants, including recruitment documents, letters of invitation, questionnaires, surveys and participant information and consent forms.

All sections of the application form must be completed. Application forms will not be accepted until all sections are complete.

The following application forms are accepted:

- HREC Application Form (*for new Higher Risk and Lower Risk projects*)
- HREC Cross-Institutional Approval Form (*for projects approved by another HREC*)
- HREC Project Transfer Form (*for the transfer of approved projects to Flinders University*)
- HREC Teaching & Learning Application Form (*for the evaluation of multiple teaching projects for research purposes*)

3.6. Review of Applications

At least two lead reviewers will be nominated as spokespersons per application. These reviewers will be called upon by the chairperson at the meeting to summarise the application for the committee, identify any administrative issues for the application, and present any ethical issues for discussion. Other members of the committee may provide further comments and recommendations. The chairperson will convene and direct this discussion to conclusion and committee decision. The committee will agree whether the corrections are able to be approved by the Research Ethics, Integrity & Compliance Office, the Chair and/or the reviewers or must come back to the committee.

3.7. Outcomes Following Committee Consideration

The consideration of an application will normally result in one of the following outcomes:

- **Approved**

The application is approved outright at a meeting and applicants may commence the research project following receipt of the approval letter.

- **Approval Pending – Changes Required**

The approval is pending changes and/or clarifications. Modifications to the application are requested by the committee before the research project may commence. A Pending Approval Notice will be issued and the submission of the requested modifications may be approved out of session by the Research Ethics, Integrity & Compliance Office, the Chair and/or the reviewers, as agreed upon by the committee.

- **Not Approved – Resubmit**

Where an application provides insufficient information for a proper assessment to take place, or where an application does not address the ethical requirements outlined in the National Statement and/or AIATSIS Code of Ethics, the applicant will receive a Not Approved – Resubmit Notice. The committee may request that it be resubmitted for approval, and specific concerns should be communicated to the applicant, indicating what areas need to be revised before a new application can be submitted.

3.8. Agreement on Decisions

The committees will endeavour to reach a decision by general agreement or consensus. If a decision is not made unanimously, dissent should be recorded in the minutes of the meeting, including the reason for the dissent if requested by the dissenting member.

3.9. Provision of and Responding to Feedback

Feedback will be provided to applicants in written form within seven working days of the meeting date. If an application has been assessed as 'Approval Pending – Changes Required' or 'Not Approved – Resubmit', the feedback will set out the aspects and sections of the application which need to be clarified.

Applicants may accept the feedback provided and make the relevant changes. However, applicants may also not agree with the feedback and suggested changes. In this case, a justification should be provided as to why an applicant does not agree and the committee may reconsider the requested changes if the justification meets the principles of ethical research as outlined in the National Statement.

Applicants are required to respond to the feedback provided by the committees within three months. Failure to do so may result in the closure of a project due to inactivity. Applicants may contact the Research Ethics, Integrity & Compliance Office to request an extension of time to respond.

3.10. Approval Period

Applications may be approved for up to five years. However, approval is dependent on submission of annual reports. Failure to submit annual reports will result in the closure of projects.

4. EXTERNALLY APPROVED PROJECTS

4.1. Cross-Institutional Approval

Consistent with the National Statement, Flinders University will recognise approvals issued by other NHMRC-registered HRECs. Approval may also be accepted from an overseas HREC if approval was obtained under an ethical framework consistent with the National Statement.

Flinders University researchers are required to inform the human research ethics committees of projects approved by an external HREC. To do so, Flinders University researchers must submit the 'HREC Cross-Institutional Approval Form'. The committees reserve the right to request additional information as required. All future modification requests and reports must be submitted to the original Ethics Committee, and it remains responsible for the ethical oversight of the project.

Applications submitted via the 'HREC Cross-Institutional Approval Form' will be ratified at a meeting of HREC A or HREC B.

4.2. Transfer of Approved Projects to Flinders University

Researchers may also transfer a project approved by an external HREC to Flinders University. In this case researchers must submit the 'HREC Project Transfer Form'. Following approval of the transfer request, Flinders University will be responsible for the project. Therefore, all future modification requests and reports must be submitted to one of Flinders University's ethics committees. Transferred projects will be ratified at a meeting of HREC A or HREC B.

Researchers should advise the original HREC of the transfer to Flinders University and request that the project be closed to avoid duplicate review.

4.3. Approval Received from Non-Registered HRECs

A full review may be required where the external HREC or review body is not registered with the NHMRC or where the project was approved under an ethical framework not consistent with the National Statement.

5. MODIFICATIONS

5.1. Minor Modifications to an Approved Project

Over the duration of a project, circumstances may change and it may become necessary to modify approved projects. Minor modifications could include, but are not limited to, adding new researchers, updating surveys, extending the expiry date and additional recruitment of participants. Modifications must be submitted via *ResearchNow Ethics & Biosafety* and approved before they are implemented. Modifications may be approved out of session or referred to a meeting.

5.2. Major Modifications to an Approved Project

Major modifications to an approved project such as significant changes to the methodology and aims of the research, addition of vulnerable participant groups or higher risk research topics, including mental health related research, may not be approved and a new application may be required. The Research Ethics, Integrity & Compliance Office will inform researchers in writing if a new application is required.

6. ADVERSE EVENTS

6.1. Definition and Required Information

An adverse event is an event that was not foreshadowed in the application approved by the committees. Any adverse events must be reported within 24 hours of the event. The 'HREC Adverse Event Form' must be submitted via *ResearchNow Ethics & Biosafety*. The report must include the following information:

- Summary of circumstances leading up to the adverse event;
- Actions taken from the time the problem was noticed; and
- Proposed actions to prevent or correct the specific or probable cause of the problem.

Following the review of the adverse event report, the committees may request modifications to the approved protocol to prevent further adverse events. The Deputy Vice Chancellor Research will be notified immediately of any serious adverse events. Additionally, Minor or Major Breach Notices may be issued to researchers.

6.2. Minor Breach Notice

A Minor Breach Notice is issued when an unintentional or minor breach has been identified that is deemed by the committee to be a minor infringement to the conditions of approval. When a Minor Breach Notice is issued, the project may continue without interruption provided that all identified

breaches have been rectified and that the conditions as set out in the approved protocol are strictly adhered to.

6.3. Major Breach Notice

A Major Breach Notice is issued when an intentional, negligent or a major breach has been identified that is deemed by the committee to be a significant incident or a major infringement to the conditions of approval. Each project is only allowed to receive a maximum of one Major Breach Notice. Any future incidence of non-compliance (warranting a second Major Breach Notice) can result in immediate suspension of the project.

6.4. Research Integrity

Any adverse events caused by intentional, negligent or reckless actions will be referred to the University's Research Integrity Office for investigation and dealt with in accordance with the University's Research Integrity Policy and Breach of Research Integrity Procedures.

7. MONITORING OF RESEARCH

7.1. Annual or Final Reports

Researchers are required to report to the committees at least annually. Annual or Final Reports must be submitted via *ResearchNow Ethics & Biosafety*. Failure to submit a report may lead to suspension of approved projects until a completed report is submitted.

7.2. Other Monitoring Options

Monitoring of research may also involve, but is not limited to, site inspections, safety reports, desktop audits and interviews with researchers.

8. APPEALS AND COMPLAINTS

8.1. Appeals against Committee Decisions

Where the committees have made a decision on an application, an applicant may:

- Respond to the committees' feedback,
- Submit a new application; or
- Lodge an appeal with the Research Ethics, Integrity & Compliance Office who will discuss this matter with the chairperson and respond directly on the outcome of the appeal. An appeal must be lodged within three months of the decision communicated to the applicant.

The Research Ethics, Integrity & Compliance Office and the chairperson will consult with the applicants, and the Deputy Vice Chancellor Research, if necessary, in order to resolve the issue. A letter will be sent to the researchers and, in the case of a student project, the supervisor, advising of the committee's response and/or decision.

8.2. Complaints about the Review Process

Complaints against the review process must be submitted in writing to the Research Ethics, Integrity & Compliance Office via email to human.researchethics@flinders.edu.au. The submission must include details for the grounds of the complaint and the name and contact details of the complainant. The Research Ethics, Integrity & Compliance Office, the chairpersons and/or the Deputy Vice Chancellor Research will make a recommendation based on the evidence provided. If a resolution cannot be reached through internal processes, the complaint may be referred to an external agency or person upon mutual agreement by the parties concerned.

8.3. External Complaints

Complaints from persons external to the University must be submitted in writing to the Research Ethics, Integrity & Compliance Office via email to human.researchethics@flinders.edu.au. The submission must include details for the grounds of the complaint and the name and contact details of the complainant. The Research Ethics, Integrity & Compliance Office and/or the chairpersons will consider complaints about the conduct of an approved research project. If complaints include

allegations of research misconduct, the complaint will be referred to the University's Research Integrity Office for investigation and dealt with in accordance with the University's Research Integrity Policy and Breach of Research Integrity Procedures.

8.4. Record of Complaints

The Research Ethics, Integrity and Compliance Office will keep a record of all complaints received, noting the outcome of the complaint or its referral.

9. RECORD KEEPING AND REPORTING

9.1. Storage and Security of Records

Full documentation of the committees' business will be maintained and managed by the Research Ethics, Integrity & Compliance Office. All records pertaining to research projects or protocols must be retained in accordance with the Government of South Australia General Disposal Schedule 24, with a minimum storage period of seven years after the last action is completed.

9.2. Flinders University Reporting

The committees will provide reports to the Deputy Vice Chancellor Research and other relevant University bodies at least annually. The reports will include information on membership, meetings, the number of research proposals reviewed, complaints received and their outcomes, along with any other relevant matters.

9.3. NHMRC Reporting

The committees will provide a true and transparent Annual Report to the National Health and Medical Research Council.

10. COMMUNICATION WITH RESEARCHERS, THE PUBLIC AND MEDIA

10.1. Communication with Researchers

All official communication from the committees will be sent through the Research Ethics, Integrity & Compliance Office. All researcher communication to the committees will be sent via Research Ethics, Integrity & Compliance Office.

10.2. Communication with the Public and Media

The Research Ethics, Integrity & Compliance Office will respond to all public inquiries. Media inquiries will be referred to Flinders University News.