



HUMAN RESEARCH ETHICS COMMITTEE HANDBOOK

WELCOME FROM THE CHAIR

Welcome to Alphacrucis College's Human Ethics Research Committee. As a member of the committee which seeks to help staff and students do research ethically, your role is of great significance. Each member brings a unique and important perspective to the collective wisdom of the Committee.

This brief handbook contains relevant information to assist you in familiarising yourself with the Committee, its responsibilities and its working procedures.

It is a privilege to serve the staff and students of Alphacrucis College with you.



Rev Professor Philip Hughes
Chair of Human Research Ethics Committee

Human Research Ethics Committee Handbook

Establishment and Responsibilities of the AC HREC

1. A Human Research Ethics Committee (HREC) is a standing committee of Alphacrucis College (AC) accountable to the Academic Board. The purposes of the HREC are:
 1. to help ensure that research projects conducted by members of the staff and students of AC are conducted in accordance with the Ethics Policy of the College, the *National Statement on Ethical Conduct in Human Research*, and the laws regarding privacy and confidentiality in whatever location the research is taking place;
 2. to help ensure that an ethically sound research culture is developed in AC and that appropriate facilities are in place for this purpose, including appropriate storage of confidential materials, such as survey results and transcripts of interviews;
 3. to help staff and students to conduct their research ethically by providing advice and feedback on proposed projects.

2. The HREC fulfils its mandate in following ways:
 1. developing protocols for research such as Ethics Application Forms and templates for Information Sheets and Consent Forms;
 2. examining research proposals submitted to it;
 3. communicating with the researchers and their supervisors to discuss their research proposals providing feedback and advice on ethical aspects of research and approval or disapproval for research to be conducted;
 4. receiving reports, at least annually, of all projects for which it has been given approval, and receiving reports that projects have been completed and whether they were completed in accordance with the agreed protocols;
 5. receiving complaints from participants in research and seeking appropriate resolution, and, if a complaint cannot be resolved, referring it to the Director of Research; and
 6. seeking information from staff of AC about the ethical conduct of research.

3. HREC members.
 - a. The HREC shall consist of:
 - i. A chairperson;
 - ii. At least one male and one female laypersons who do not have any other affiliation with AC and who are not engaged in any medical, scientific, legal or academic work;
 - iii. At least one person with knowledge and current experience in professional care, counselling and treatment of people;
 - iv. At least one minister of religion;
 - v. At least one lawyer, not engaged to advise the institution; and

- vi. At least two people with current research experience in fields similar to that of the projects being considered.
- b. The members of the HREC shall undertake some professional development in ethics at least once every three years.
- c. Appointments to the HREC will be made by the Academic Board and will be reviewed at least every three years.
- d. The HREC shall appoint a secretary who will be responsible for:
 - i. preparing agendas and minutes;
 - ii. calling meetings and sending the materials to members of the HREC;
 - iii. presenting applications for ethical review;
 - iv. informing the HREC of potential or actual conflicts of interest;
 - v. managing monitoring of research projects;
 - vi. recording the details of research projects and the decisions of HREC, and reporting the decisions of the HREC to researchers, supervisors, the Research Committee and the National Health and Medical Research Council (NHMRC);
 - vii. receiving complaints relating to ethical matters;
 - viii. communicating between the HREC and the researchers;
 - ix. communicating between the HREC and the Research Committee; and
 - x. reporting annually to the NHMRC.
- e. In the consideration of projects, the Chairperson is responsible for:
 - i. appropriate processes in meetings;
 - ii. ensuring that the Committee attends to the ethical aspects of projects and does not extend beyond its mandate to discussion of research methods or the details of the presentation of the project;
 - iii. assisting the Committee to reach conclusions as to its approval of projects and what, if any, amendments are advised.
- f. Complaints about the decisions or conduct of the HREC can be made at any time to the Director of Research by researchers.

Working Procedures of the HREC

1. **Frequency of meeting.** The committee shall meet every November or December at which time it will receive reports on current projects for which it has given Ethical Approval as well as consider new projects. It shall also meet on other occasions during the year as required and as projects are referred to it by staff, students or the Director of Research.
2. **Attendance at meetings.** All members of the committee are expected to attend each meeting either physically or electronically. If that is not possible, apologies should be sent to the secretary of the HREC prior to the meeting along with comments on the proposals to be considered. The chair must be satisfied that the views of those absent who belong to the minimum membership have received and considered. The secretary of HREC will also attend but shall not vote. Other staff members of AC may be invited to the meeting for specific considerations.

- 3. Conduct and structure of meetings and deliberations.** The chair will lead each meeting. The agenda will include the following components:
 1. review of the minutes of the previous meeting;
 2. review of existing projects at least annually;
 3. receiving reports of completed projects;
 4. consideration of new projects;
 5. receipt of any complaints;
 6. any other business – such as reviews of Ethics Application Forms.

The chair may request that researchers and supervisors attend, electronically or in person, the meeting of the HREC where their project is being considered so that matters can be discussed with them and decisions can be made expeditiously in relation to the project.
- 4. Timely distribution of papers before meetings.** All research applications will be distributed (usually by email) to all members of the committee at least one week prior to the meeting.
- 5. Presentations of applications for ethical review.** All applications from both students and staff will be submitted using the agreed Ethics Application Form. All documents to be used in recruiting potential research participants, including advertisements, letters of invitation, information sheets and consent forms, must be appended to the application, along with interview schedules and surveys that will be used in the research.
- 6. Timely consideration and review of applications.** Most meetings of the committee will occur after students have completed their studies in Research Methods and have received confirmation of their Research Proposals. To meet special circumstances and allow for the timely conduct of research, the chair of the Ethics Committee may determine that projects may be circulated by email to the members of the Ethics Committee and the members be given one week to respond to the project. Special Committee meetings may be convened at the chair's discretion.
- 7. Managing researchers' conflicts of interest.** In evaluating research projects, the HREC will investigate any perceived or actual conflicts of interest in research, such as when a researcher has professional responsibilities such as being a pastor or teacher to those who are researched, or where research is being done for an external institution which has vested interest in particular results being obtained. It will make its decisions on how best to manage those conflicts of interest, either through
 - a. disclosing those conflicts of interest to research participants;
 - b. requiring a person other than the researcher to make the initial approach to participants, or conducting the research;
 - c. disclosing conflicts of interest in reports of the research; or
 - d. refusing permission for the research to be conducted.
- 8. Managing conflicts of interest in the Ethics Committee.** Members of the HREC and any experts from whom advice is sought are required to inform the HREC of any actual or potential conflict of interest through personal involvement in the research, financial or other interest in institutions involved, or involvement in competing research. In such cases, the HREC will exclude those members from any deliberation involving the research or the researchers with whom the conflict of interest exists.

- 9. Communicating with researchers.** In general, the Ethics Committee will meet with researchers and their supervisors face-to-face, either physically or through electronic means, when considering their projects. This will assist in clear communications with the researcher. It will give the Committee the opportunity to raise concerns the Committee may have, and to hear the response of the researcher. It provides the opportunity for issues to be resolved quickly through agreement by the HREC, the researcher and the supervisor. It encourages the review to be educational in tone. Researchers are informed that complaints about the HREC procedures and decisions can be made to the Research Committee and will be examined by that body. Decisions of the HREC will be communicated in a written form to the students and their supervisors or to other researchers who bring projects for consideration to the HREC.
- 10. Reporting on its activities to the institution.** The HREC will provide a report of its activities and decisions to the Research Committee each December.
- 11. Methods of decision making.** All members of the HREC will receive the applications for consideration for Ethical Approval at least one week in advance of its meetings. Comments by members of the HREC who are unable to personally attend or attend through video link will be accepted by email. Decisions will be made, where possible, by consensus of all members. If consensus cannot be reached, a vote of at least 75 per cent of members will be necessary for a project to be given approval.
- 12. Prompt notification of decisions.** All decisions of the HREC will be communicated in writing to the researchers and their supervisors (if the researcher is a student) within one week of the decision, linking the reasons for the decision to the *National Statement*. The secretary of the HREC will have this responsibility.
- 13. Record keeping.** The secretary of the HREC shall keep the minutes of the meetings of the HREC and will also record decisions made by email connections. These minutes and decisions will be reviewed at the following meeting of the HREC. For each research project, the following details will be recorded:
- a. name of the institution to which the research approval is provided;
 - b. project identification numbers;
 - c. name(s) of the researchers and their supervisors (where the research is undertaken by students);
 - d. title of the project;
 - e. correspondence between the review body and the researcher about the review;
 - f. acceptance or rejection of any changes to the proposal;
 - g. proposed date of completion of the proposal;
 - h. formal advice of final ethical approval or non-approval, with date;
 - i. terms and conditions of any approval of any proposal;
 - j. duration of the approval;
 - k. name of any other review body whose opinion was considered;
 - l. relevance, if any, of the Commonwealth, State or Territory legislation or guidelines relating to privacy of personal or health information.

The HREC shall also retain a copy of each research proposal and application for ethical approval along with relevant documentation including information sheets, consent forms, interview schedules and surveys, and relevant correspondence.

The HREC will also record decisions related to the approval with reasons for those decisions, linking those reasons to the National Statement. The HREC will also record details of any other review body involved, the decisions and the details of any amendments required by other review bodies.

14. **Monitoring of approved research.** The HREC monitors approved research in the following ways.
 - a. It requires reports of all approved research projects at least annually and will require researchers to inform the HREC of the completion of projects and whether those projects were completed within the approved protocols, and whether records and data have been kept securely.
 - b. It requires researchers and/or supervisors of research projects to report immediately any adverse event or unexpected outcome which occurs in the course of the research which could lead to unexpected harm to participants or the researcher.
 - c. It requires annual reports of from all heads of faculties to whom has been delegated the responsibility of ethical approval of minimal risk projects.
 - d. It examines the arrangements at the various AC Campuses of the confidential storage of data relating to completed projects.

15. **Reporting and handling of adverse events.** All research and/or supervisors are required to report immediately to the HREC secretary any adverse event or unexpected outcome which occurs in the course of the research which could lead to unexpected harm to participants or the researcher. The HREC will then consider whether:
 - a. research protocols need to be modified to ensure protection for research participants and researchers; or
 - b. ethical approval for the project should be withdrawn and the project suspended.

16. **Receiving and handling complaints.** All information sheets and surveys shall include contact details for the secretary of the HREC to receive complaints from participants in research projects. Processes for receiving complaints relating to the ethical conduct of research shall also be made available on the AC website. When a complaint is made that cannot be resolved by discussion between the secretary of the HREC and the person making the complaint, the complaint will be reported to the HREC. Depending on the nature of the complaint, the HREC may:
 - a. conduct an investigation or inquiry into the situation;
 - b. require the researcher to change the protocol for the research;
 - c. report the researcher to the relevant Program Director at AC according to the procedures of the Academic Integrity and Misconduct Policy of AC ; and/or
 - d. seek additional advice from experts as to how to resolve the issue.

17. **Advising the institution of decisions to withdraw ethical approval of a research project.** If the HREC decides to withdraw ethical approval for a research project, then it will inform

both the researcher, supervisor(s), and the Institution immediately of that decision, along with the reasons for it.

18. Attendance as observers of people other than members or researchers at meetings.

Supervisors are expected to attend meetings of the HREC along with students when student proposals are considered. Researchers may request permission for other people to be present at discussions of their proposals. HREC may also invite experts who may provide assistance in relation to specific projects to be present at meetings. All observers at meetings will be bound by the same confidentiality requirements as HREC members. Any conflicts of interest between observers and projects should be disclosed and managed. It is not generally appropriate for a funding sponsor to be present at an HREC meeting.

19. Fees to be charged. For all projects of AC staff and students, no fees will be charged for ethical review. If there is agreement by HREC and AC to provide ethical review for other institutions, then appropriate fees may be charged to cover the costs of the review and the appropriate monitoring.

20. Appropriate confidentiality of the content of applications and the deliberations of review bodies. The members of HREC and all who attend the meetings of HREC are required to keep confidential the content of applications and the deliberations of the review. Any communication about the decisions of HREC will be referred to the chair of the HREC who, where appropriate, may communicate the decisions of the HREC and the reasons for the decision. As appropriate, information about the decisions of HREC shall be provided to the Research Committee and to the NHMRC as required.

21. Privacy Act compliance. Where personal information that might identify individuals is not required for a project, then it should not be collected. Where it is needed, such as in projects where researchers need to match data over time, methods should be used to keep the identity of participants separate from the data, and only use codes in the data set. In other projects where the privacy of an individual cannot be guaranteed, such as in a project which included the examination of a few people in identifiable leadership positions, the consent of the individual to the potential of making their opinions or information about them public should be obtained before they participate in the project.

It is noted that there are some cases where identifiable information, such as information related to health, is needed for projects. In all reports, that information should be 'de-identified' or reported only within the context of general patterns. Where health information is required for research relevant to public health or public safety, the Guidelines under Section 95A of the Privacy Act 1988 must be followed. The HREC must weigh the public interest considerations against the concerns for the privacy and dignity of the individuals whose information might be used.

Reference:

National Health and Medical Research Council, (2007) *National Statement on Ethical Conduct in Human Research 2007*. (Updated 2018), Canberra: Australian Government. (Available from: <https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018>).