ABOUT THIS GUIDE!

This Guide outlines the process for applying for and conducting research involving human participants. It should be read in conjunction with the Research at ACAP Introductory Guide, which is available online at www.acap.edu.au/research.html.
Research involving Human Participants at ACAP

Research undertaken by ACAP students, staff and research partners that involves human participants requires ethical review and approval by the ACAP Human Research Ethics Committee (ACAP HREC) prior to commencement. ACAP HREC approved human research projects are also subject to annual ethical review by the Committee.

Research involving humans may include, but is not limited to:

- Administering questionnaires/surveys,
- Conducting interviews or focus groups,
- Investigating or observing human behaviour,
- Conducting experiments with human participants,
- Analysing records of data already collected from human participants, and/or
- Any other testing involving human participants.

The ACAP HREC is registered with the National Health and Medical Research Council (NHMRC). The NHMRC has allocated ACAP's HREC with following identification numbers: HREC: EC00447 | Organisation: ORG0576.

All ACAP students, staff¹ and research partners engaged in research that involves human participants must adhere to the standards of ethical conduct prescribed in and the National Statement on Ethical Conduct in Human Research, in addition to adhering to the research standards prescribed in the Australian Code for the Responsible Conduct of Research.

Steps in Applying for Approval for Research involving Human Participants

1. It is a requirement that:

   - Students and staff seeking to apply to undertake human research read and follow the National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research.
   - Students seeking to apply to undertake human research read and follow all relevant procedures and other requirements stipulated by their research supervisor², including all relevant policy and guidelines of the College and their School.
   - ACAP staff supervising students undertaking human research and engaged in human research read and follow all relevant policy and guidelines of the College and the applicable School.

2. Before commencing to prepare your human research application submission you must have fully developed a well-planned research proposal.

   For students this will require working with an assigned supervisor who is a member of staff of the College. Your course coordinator or educator will ensure that you have an assigned research supervisor for any research that you will be conducting.

3. Prepare your Human Research Application for submission to the ACAP Human Research Ethics Committee (ACAP HREC) for ethical review and approval, as follows:

   Your final Human Research Application submission will consist of the following three documents which must be submitted together.

   - A completed ACAP Human Research Application submission Cover Sheet.
     This cover sheet can be obtained from the College website at www.acap.edu.au/research.html (login to my.acap required).
   - A completed National Ethics Application Form (NEAF).
     To access this form type the following address into your web browser www.neaf.gov.au. Your research supervisor will provide you with comprehensive information on completing the online NEAF form. Once you have completed the online form you should save and print it as pdf report. This pdf version of your completed NEAF application is to be included in your Human Research Application as the item that immediately follows the Cover Sheet.
   - Your completed Research Proposal. Your proposal should include your written proposal, proposed Participant Information Sheet and Consent Form, which must contain among other information, the contact details of the ACAP HREC Secretary, who is the person nominated to receive complaints or concerns from research participants. Templates of these documents can be obtained from the College website at www.acap.edu.au/research.html (login to my.acap required).
     Your proposal must also include all other proposed materials to be used in the research. This may include, among other things, your participant recruitment materials (e.g., advertisements, letters of invitation, information sheets) and unpublished research instruments (e.g., surveys, questionnaires, interview questions). Your research proposal and publications must also follow the American Psychological Association (APA) referencing style. For further details refer to the Referencing Style guidelines in the College’s Academic Skills Guide.

¹ ACAP staff includes all permanent, casual and contracted employees of ACAP.
² For students, research supervisor means your primary research supervisor who must be an ACAP staff member.
4. Arrange for your Research Supervisor/s³ to review and approve your proposed Human Research Application for submission to the Head of School for approval consideration.

Compile all three documents together to form one submission, individually number each page beginning with the cover as page 1, and provide a hard copy to your research supervisor/s for her/his review, comment and/or approval (signature required).

Upon receipt of your research supervisor/s approval forward your full, approved submission to the Head of School for final approval consideration. The Head of School on approving your submission will arrange for its forwarding to the ACAP HREC Secretary.

It is recommended that you create a compiled PDF copy or electronic scan of your full approved application submission for your research records before submitting it to the Head of School.

Upon receipt of your research supervisor/s approval forward your full, approved submission to the Head of School for final approval consideration. The Head of School on approving your submission will arrange for its forwarding to the ACAP HREC Secretary.

Only you, as the researcher, may submit your Human Research Application to the Head of School.

Fees for Applying for Approval for Human Research
No fees are charged by ACAP for applying for ACAP HREC Ethical Review.

Submission Timeframe
Human Research Applications must be received by the ACAP HREC Secretary a minimum of 3 weeks (15 working days) before the Committee is scheduled to meet for the application to be considered for review at that meeting. This permits enough time for applications to be circulated to members for their consideration before the meeting.

When the Head of School submits your approved Human Research Application to the ACAP HREC, a lodgement receipt notice is emailed to you by the ACAP HREC Secretary.

The ACAP HREC meets several times each year to undertake ethical review of human research applications and approved researchers annual progress reports. A schedule of ACAP HREC meeting dates is available from your School.

The ACAP HREC may invite research applicants and/or supervisors of research applicants to be present at the meeting to speak to their submission. Applicants, including any member of the Committee who has an application being considered, must not be present during the final consideration of an application and any decision by the Committee regarding its approval.

Overview of the ACAP HREC’s Ethical Review of Human Research Applications
The ACAP HREC undertakes ethical review of Human Research Applications and the annual progress reports of ACAP HREC approved research projects. The membership of the Committee includes both internal and external members and complies with the National Statement on Ethical Conduct in Human Research.

Ethical Review is a process of ensuring the proposed research is ethically acceptable and in accordance with relevant standards and guidelines. In considering Human Research Applications the ACAP HREC may, in accord with the National Statement on Ethical Conduct in Human Research, determine to exempt the proposed research from further ethical review if the Committee determines it is:

- negligible risk research where there is no foreseeable risk of harm or discomfort, and any foreseeable risk is no more than inconvenience; and
- involves the use of existing collections of data or records that contain only non-identifiable data about human beings.

In such cases, the ACAP HREC Secretary will advise the applicant accordingly and the applicant will not be required to lodge any further reports concerning their proposed research to the ACAP HREC.

The ACAP HREC, when undertaking ethical review of Human Research Applications, abides by and ensures that the protocol and procedures for the proposed research comply with:

- the Values and Principles of Ethical Conduct outlined in the National Statement on Ethical Conduct in Human Research, issued by the National Health and Medical Research Council (NHMRC) in accordance with the NHMRC Act, 1992 (Cth.). These are summarised below. (see also http://www.nhmrc.gov.au/guidelines/publications/e72);
- the Australian Code for the Responsible Conduct of Research jointly issued by the National Health and Medical Research Council, the Australian Research Council and Universities Australia (2007); (see http://www.nhmrc.gov.au/guidelines/publications/r39); and

³ ACAP staff who are not required to have a research supervisor should forward their submission to the Head of School for approval consideration.
The Values and Principles of Ethical Conduct outlined in the National Statement on Ethical Conduct in Human Research [March 2007] encompass:

- **Merit and integrity**: the research has merit, and the researchers who are to carry out the research must have integrity, for the involvement of human participants in the research to be ethically justifiable.
- **Justice**: the research has regard for the human sameness that each person shares with every other; the issues of inclusion and exclusion, access and exploitation; and the distribution of the benefits of the research fairly.
- **Beneficence**: the research has consideration of the risks of harm and the potential benefits to participants and to the wider community, including a sensitive regard to the welfare and interests of the people involved and the social and cultural implications of the research. The risks of harm to research participants, and to others, will be ethically acceptable only if its potential benefits justify those risks.
- **Respect**: the research has a recognition of an individual’s intrinsic worth and right of autonomy and, for persons with diminished autonomy, their entitlement to inclusion and protection. Persons taking part in research must do so on the basis of informed consent.

These values guide the design and conduct of human research and help shape a relationship of trust between researchers and research participants.

**Notification of outcome of ACAP HREC Ethical Review of Human Research Applications**

Human research applicants will be notified of the outcome of the ACAP HREC review by the Committee Secretary via email within 5 working days of the ACAP HREC meeting at which their application submission was considered.

This notice will make clear either:

- that the ACAP HREC exempted the research from review and the researcher is not required to liaise further with the ACAP HREC concerning their planned research; or
- that the application is still under consideration by the Committee; or
- that the ACAP HREC has completed its ethical review and arrived at a decision. There are generally four possible review decision outcomes, these being that the proposed human research has either been:
  1. Approved to proceed;
  2. Approved to proceed subject to the conditions stated by the Committee;
  3. Is required to be resubmitted by the applicant reflecting the adjustments requested by the Committee; or
  4. Rejected on ethical grounds.

If the applicant’s human research proposal has been approved, or approved with Conditions, this notice will also contain an ACAP HREC Approval Number and state the duration that the approval authorisation remains valid. Researchers should reference the ACAP HREC Approval Number in all research materials and correspondence they issue when undertaking their research.

This notice will also provide the name and contact details of the person that the researcher may contact for further information concerning this ethical review process.

Human research applicants are responsible for contacting the ACAP HREC Secretary within 10 working days of the ACAP HREC Committee Meeting date that followed their submission if they have not received an email advising of them of the status of their submission.

Human research applicants who have a grievance concerning the outcome of the ethical review process can address their concern through the College’s academic grievances and appeals processes. For further details, refer to the College’s Academic Appeals and Grievances Policy and Procedures.
Commencing and Undertaking ACAP HREC Approved Human Research

Research can commence immediately following the researcher’s receipt of the written notice containing the ACAP HREC Approval Number from the ACAP HREC Committee Secretary.

Reporting and Handling of Adverse Events during Research

Researchers must promptly notify the ACAP HREC Secretary via email of any serious or unanticipated adverse effects of their research on participants, and unforeseen events that might affect continued ethical acceptability of the project. The Secretary will then promptly forward this notification to the Committee Chair.

Receiving and Handling Complaints from Research Participants

Researchers who receive a complaint from a research participant must promptly notify their research supervisor and the ACAP HREC Secretary via email of the complaint. The Secretary will then promptly forward this notification to the Committee Chair.

Receiving and Handling of Notifiable Events during Research

Any serious or unanticipated adverse event affecting the safety or welfare of participants or of the researcher must be reported to the ACAP HREC Secretary immediately via email. The Secretary will then promptly forward this notification to the Committee Chair. Should the ACAP HREC believe that the discontinuation will compromise participants' welfare and that further actions are required by the researcher, the researcher will be advised accordingly.

Changes to Research following ACAP HREC Approval

Any changes that are to be made to ACAP HREC approved research, including an increase in the proposed number of participants or a change in method of recruiting participants, must be approved by the ACAP HREC prior to the changes being implemented. Researchers seeking ‘ACAP HREC Research Change’ approval must set out clearly in a letter, addressed to the HREC Chair and sent to the ACAP HREC Secretary, the nature of the change being made and the reason for the change. If the ACAP HREC determines that the requested change is a major change it may request that another research application be submitted. In such cases, where the new research application is approved, the existing approval will be withdrawn and a new approval number issued.

Annual Progress Reports for ACAP HREC Approved Research

ACAP HREC approved researchers are required to complete and submit the ACAP HREC Annual Progress Report Form 12 months after receipt of their ACAP HREC Approval Number.

The Progress Report provides the ACAP HREC with information on the progress or outcome of the research, maintenance and security of records, compliance with the approved proposal and compliance with any conditions of approval.

The ACAP HREC Annual Progress Report Form can be downloaded from the College website at http://www.acap.edu.au/research.html. Instructions on completing and submitting the annual progress report are provided on the report form. Researchers must arrange for their research supervisor to review and approve their Progress Report prior to it being submitted to the ACAP HREC Secretary.

Researchers are responsible for ensuring that they submit their Annual Progress Report for approval consideration by their research supervisor within 12-13 months of receipt of their ACAP HREC Approval Number.

ACAP staff who are not required to have a research supervisor should forward notifications to their Head of School.
Overview of ACAP HREC Ethical Review of Researcher’s Annual Progress Reports

The deliberations of the ACAP HREC when undertaking ethical review of Annual Progress Reports of researchers are similar to those undertaken by the Committee when reviewing the initial research application. Additionally, the Committee will review the degree of compliance of the researcher with any conditions applied to the research approval.

The researcher and researcher’s supervisor will be notified by the Committee Secretary via email of the outcome of the ACAP HREC review of their Progress Report within 5 working days of the ACAP HREC meeting at which their Annual Progress Report was considered.

This notice will make clear that the Progress Report has been either:

- Deemed satisfactory, as it has satisfied the requirements of human research ethical review and complies with National Statement on Ethical Conduct in Human Research – March 2007, Section 1, and the conditions attached the initial ACAP HREC research approval;
- Is required to be amended by the applicant as stated by the Committee and resubmitted to the Committee for further consideration;
- Is still under consideration by the Committee and that further advice will be provided to the researcher in a stated timeframe; or
- Deemed unsatisfactory on ethical grounds. If the ACAP HREC believes that the continuance of a research project will compromise participants’ welfare the Committee will commence a process for establishing whether ethical approval for the project should be suspended. This process will ensure that researchers and others involved in the project are treated fairly and with respect.

Suspension of ACAP HREC Human Research Approval

If the ACAP HREC considers that a particular research project should be suspended on grounds of research misconduct and/or on grounds of a reasonable belief that that continuance of a research project will compromise participants’ welfare, the Committee Chair will issue a suspension order to the researcher and researcher’s supervisor/s. The suspension order will be in writing and state the date from which the order takes effect and any requirements that must now be met by the researcher to meet the needs of participants.

The researcher must satisfy the ACAP HREC and the College that s/he has suspended the research and has made any required arrangements to meet the needs of participants as stated in the suspension order.

When ethical approval for a research project has been suspended by the ACAP HREC the research may not be resumed without Resumption Approval by the ACAP HREC. Such approval will only be granted if the researcher has subsequently established, in writing, to the satisfaction of the ACAP HREC:

- that continuance of the research will not compromise participant’s welfare; and
- that, if required, the research has been modified to provide sufficient protection for participants.

Withdrawal of ACAP HREC Human Research Approval

If a researcher fails to comply with a suspension order and/or does not attain Resumption Approval by the ACAP HREC within 12 months of the suspension order, the ACAP HREC will withdraw the Committee’s approval of the research and the researcher will not be permitted to seek Resumption Approval from the ACAP HREC. Should the researcher seek ACAP HREC approval for further research undertakings a new ACAP HREC Approval Application form must be lodged in the manner prescribed by ACAP.