ACU Research

ETHICS APPROVAL PROCESS

Before preparing your application

How do I apply for ethics approval?

You need to fill in an ethics application form available through Orion. Based on the type of protocol you intend to implement you will be asked to attach documents to support your application. Before starting a new application on Orion, you may want to refer to the:

- Self-Directed Learning - Orion (Ethics) (PDF 68KB)
- FAQs Orion forms

What do I need to do before I submit my ethics application?

Your research project must be **peer reviewed** in accordance with the procedures set out by your affiliated School, Institute or Centre. In some cases ACU HREC may require that you attach evidence of peer review approval to your ethics application. For more information refer to the HREC peer review policy (PDF, 205.64 KB).

When do I need to submit my ethics application?

Submit your application at least six weeks before you intend starting your data collection.

What other guidelines might impact upon my research?

You should conform to any relevant **additional guidelines that apply** to the research you are conducting and the protocol you intend to utilise. Some of the most common guidelines are in the area of:

- Child Protection and Working With Children Checks
- Access to government and non-government schools
- Research involving Aboriginal and Torres Strait Islander people
- Privacy
- Clinical Trials
- Insurance and Indemnity
- Biosafety

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The proposed **protocol must comply with:**
- National Statement on Ethical Conduct in Human Research
- Australian Code for the Responsible Conduct of Research
- ACU Code of Conduct for Research
- National Privacy Principles (NPPs)
- Information Privacy Principles (IPPs)
- Any additional State/Territory legislation

You are required to provide **documentation to support your application** and to help ACU HREC understand the protocol you are proposing. For your convenience the Orion form is set up so that you can upload all necessary supporting evidence – see section M in the Orion form (Attachments).

For more information refer to the [Guidelines for Applicants to the HREC (PDF 235KB)](#).

When can I start collecting data?

If ACU HREC is the only Ethics Committee involved in the approval of your protocol you can commence contacting potential participants from the date indicated in the email you receive confirming the approval of the proposed protocol.

Be aware that the decision and authority to commence collecting data may be dependent on factors beyond the control of the ACU ethics review process.

If your research requires ethics clearance or permissions from other organisations data collection should not commence until you have also satisfied these requirements.

How many forms are available?

There are three different forms. You will find them on [Orion](#) when you select: *Ethics/Applications/Create New Application*. The forms are:

Form 1 - Registration of external approval form

When ACU is not the Primary HREC use this form and answer question A.1.4 by selecting the **External Approval Registration option.**

By selecting this option, you indicate that the primary HREC is external; the Secondary HREC is ACU.

In most cases ACU HREC will accept the approval of the Primary (External) HREC up until the agreed end date.

When ACU is the Primary HREC use this form and answer question A.1.4 by selecting the **Approval Transfer** option.

By selecting this option, the Primary HREC is ACU; the Secondary HREC is external.

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In most cases, ACU HREC will accept the approval of the Secondary (External) HREC up until the agreed end date.

Attach all documentation that was approved by the External HREC, including a copy of the approved application, together with relevant information such as your approval letter, participant information and any subsequent modifications or progress reports.

You may be asked to make changes, such as participant information material, to meet ACU requirements. You will also need to report on your research to ACU HREC at least annually and at the conclusion of your research.

If you do not have a continuing collaboration with your previous institution, you should advise the Secondary HREC (External) that the ethics approval for the project has been transferred to ACU HREC and that ACU HREC is now the Primary HREC. You should also ensure that the institution affiliation and contact details on your letters and consent forms are changed to ACU.

Attach all documentation that was approved by the external HREC, including full application form, the approval letter and any subsequent modifications or progress reports.

Remember that you are agreeing to:

- keep ACU HREC notified of any changes to the project or any complaints relating to the project;
- send ACU HREC copies of all annual progress report forms approved by the Primary HREC.

ACU HREC reserves the right not to accept an External HREC's approval, in which case we will ask you to submit a New ACU Project form for full review.

Form 2 - Non-Identifiable data

You are required to attach a short research proposal and a letter of permission from the owners of the data stating that they have authority to give permission to use the data, that you have permission to use the data for this research project and confirming that the data is non-identifiable.

Form 3 - New ACU Project

Use this form if you are starting a new project at ACU that does not involve ethics approval from other institutions or organisations.

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Which form do I use?

Use the scenarios below to understand which form to use:

- **I am a Lecturer in Charge of a unit of study in which students are required to undertake a small research project or activity.**
  Taught Units are no longer reviewed by the HREC. Please contact your Associate Dean (Teaching and Learning) to determine requirements. Refer to Taught Unit Guidelines.

- **I am working on a collaborative project with another institution. How do I let ACU know that the ethics protocol has already been approved by the other institution's HREC (Human Research Ethics Committee)?**
  Use the Registration of external approval form and answer question A.1.4 by selecting the Human External Approval Registration option.

- **The ethics protocol for the project I am working on was approved by another institution. There have been changes to the project and now ACU is the Primary HREC. How do I make sure that ACU HREC approves this change?**
  Use the Registration of external approval form and answer question A.1.4 by selecting the Human External Approval Transfer option.

- **I am a new member of staff and would like to continue working on a project that received ethics approval from the HREC of my former affiliation.**
  If you are the Principal Investigator (PI) and the project will be transferred to ACU, use the Registration of external approval form and answer question A.1.4 by selecting the Human External Approval Transfer option.
  or
  If you are the Co-Investigator and the project is not being transferred to ACU, use the Registration of external approval form and answer question A.1.4 by selecting the Human External Approval Registration option.

- **I am a Graduate Research student from another Institution and would like to transfer my candidature to ACU.**
  Use the *Registration of external approval* form and answer question A.1.4 by selecting the Human External Approval Transfer option.

- **My project only involves the use of previously collected, non-identifiable data (eg from a databank).**
  Use the Non-Identifiable data form.

- **I am a member of staff of ACU and would like to get ethics approval on a new protocol.**
  Use the New ACU Project form.

- **I am an ACU Graduate Research student. I am just starting my Higher Degree research project and would like to get my ethics protocol approved before I start collecting data for my research.**

Use the New ACU Project form after you have successfully completed your confirmation of candidature.

- **My situation is different from all the above. I know that my research protocol must be approved, but I still do not know which form to use.**
  Contact the Ethics Officer for advice.

How long will it take to process my application?

We aim to process your applications in less than six weeks.

However the time it takes may vary as the reviewers need to understand the details of the protocol you are proposing.

In general: **Negligible** or **Low risk** protocols are usually processed within ten working days from receipt.

More than low risk protocols are referred to the HREC at its next monthly meeting. Refer to HREC Meeting Dates and Submission Deadlines (PDF 510KB) for submission.

If your research involves Aboriginal and Torres Strait Islander peoples please refer to the IREAP Guidelines.

Note that 'More than low risk' includes applications falling within those categories named by the National Statement on Ethical Conduct in Human Research as requiring assessment and approval by the full meeting of the HREC. They are:

- Interventions and therapies, including clinical and non-clinical trials and innovations (National Statement Chapter 3.3);
- Human Genetics (National Statement Chapter 3.5)
- Human Stem Cells (National Statement Chapter 3.6)
- Women who are pregnant and the human foetus (National Statement Chapter 4.1)
- People highly dependent on Medical Care who may be unable to give consent (National Statement Chapter 4.4)
- People with a cognitive impairment, an intellectual disability, or a mental illness (National Statement Chapter 4.5)
- People who may be involved in illegal activities (National Statement Chapter 4.6)
- Aboriginal and Torres Strait Islander Peoples (National Statement Chapter 4.7)

Section B.2 of the Orion online application form will ask you a series of questions to understand whether your protocol is concerned with these categories.

What documentation do I need to support my application?

You are required to produce:
- A brief summary of your research project - feel free to include illustrations.

- Participant information letters - you are required to use the Information Letter Template available from the [ACU Research Ethics web page.](#)

You may be asked to provide:
- Consent forms - you are required to use the Consent Form Template available from the [ACU Research Ethics web page.](#)
- Advertisement Text/script.
- Peer Review evidence.
- Non-HREC Review Approval letter(s).
- Other approvals/permissions from overseas research sites.
- Ethics approval from overseas research sites.
- Investigators' Signatures.
- Questionnaires/Interview Questions - even if you intend to run semi-structured interviews.

During the review process

What happens after I submit my application?

- **Administrative review**

You will receive an email acknowledging that your application was successfully lodged.

The Ethics Officers will check your application for accuracy and to ensure all the correct attachments are uploaded. Within a week you may receive an email from Res.Ethics@acu.edu.au asking you to amend your application on Orion.

- **HREC Review**

Based on the type of risks associated with the proposed protocol, your application will be reviewed by the Ethics Review Chair (ERC) or the Ethics Reviewing Panel (ERP), or it will be referred to the HREC to be considered at its next full meeting. Refer to this document for [HREC Meeting Dates and Submission Deadlines (PDF 510KB)](#)

During the reviewing period you may receive an email asking you to amend your application (eg provide further details/evidence or reconsider aspects of the proposed protocol). The reviewers will continue asking for amendments until they are satisfied that there is enough information/evidence to complete the review of your application.

You will be notified of the outcome of the review via email.

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I received an email asking that I amend my application. Where do I start?

The details of the amendments are stored within the application form and are marked as Action or General comments. Refer to the Researcher Amendments Guidelines on the Research Ethics web page.

NOTE:
Please remember you must Action the application back to the Ethics Officer so that your approval can be finalised

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What should I do in case I have a concern or complaint about a decision of the HREC?

If you have concerns or complaints about any decisions of the HREC please contact the Chair or the Research Ethics Manager. If your concern or complaint is still not resolved, you should the Deputy Vice-Chancellor (Research). However, every attempt should be made to resolve such complaints and to address concerns before making such a referral.

After the application is approved

What happens once the application is approved?

You will receive an email from Res.Ethics@acu.edu.au letting you know that your protocol has been approved including the ethics clearance dates that apply to the protocol.

If you require a formal approval certificate, please respond to the approval email.

You will be asked to submit regular reports. Failure to do so may result in your ethics clearance being revoked and/or ethics clearances of other projects suspended.

How often do I need to submit progress reports?

The short answer is 'once a year', however, it is very likely that the due date for your progress report will coincide with the date of the final report, in which case you are only required to submit your final report.

As a courtesy the Ethics Officer will send you a reminder.

Note that if you are granted an extension to the protocol, you are still required to submit yearly progress reports.

My project has ended. What do I need to do?

You are required to submit a final report.

It is very likely that the due date for your progress report will coincide with the date of the final report, in which case you only have to submit your final report.

As a courtesy the Ethics Officer will send you a reminder.

What do I do in case of a complaint or an adverse event?

You are required to act immediately to ameliorate the situation and suspend any activity that is likely to cause further adverse effects.

In addition you are required to provide ACU HREC with a detailed report on the event that includes the steps undertaken to manage the issue and minimise the risk of it reoccurring. You will do so by contacting the Research Ethics Manager by phone or email (+61(02)9739 2519 Res.Ethics@acu.edu.au) as soon as possible.

Failure to do any of the above may impact on your ability to continue doing your research.

ACU HREC will assess the gravity of the event and give you approval on modifying or continuing with the agreed protocol.

You also need to consider your reporting obligations towards other non-ACU Primary or Secondary HRECs that approved the protocol.

What if I need to change the approved protocol?

Before implementing any changes you are required to obtain HREC approval on the amended protocol. In doing so, use one of the forms available from the Forms page (Changes to Protocol).

This type of change will normally be processed within 20 working days

Remember that changes to the protocol include staff changes.