

APPLYING FOR ETHICS REVIEW

ALBURY WODONGA HUMAN RESEARCH ETHICS COMMITTEE (AWHREC)

The Albury Wodonga Human Research Ethics Committee is a duly constituted Ethics Committee under the guidelines of the NHMRC, responsible for approving, overseeing and monitoring the conduct and performance of research throughout the North East region.

By obtaining appropriate ethical approval for human research work, researchers:

- Receive assistance and advice to help conduct human research in accordance with the relevant regulations and legislation
- Improve human research by ensuring that ethical considerations are an integral component of the project design
- Ensure that those involved in research should be indemnified.

The Ethics Committee must approve all research projects to be conducted by staff members and visiting clinicians and all projects involving patients/clients or staff members of Albury Wodonga Health and partner organisations.

Research involving humans must not be undertaken until formal signed approval has been confirmed by AWHREC.

- NHMRC <http://www.nhmrc.gov.au/>
- The Privacy Act <http://oaic.gov.au/privacy/privacy-act/the-privacy-act>

APPLICATION PROCESS

Thank you for enquiring about your proposed research project at Albury Wodonga Health.

To get your ethics application under way you will either submit a full ethical review application or a Low and Negligible Risk ethical review application electronically via the Online Forms website www.ethicsform.org/au

The online forms website will ask you to log-in or create an account if you are a first time user. You will then be able to create a NEAF (National ethics application form) and a SSA (site-specific assessment). When completing the NEAF the researcher is strongly advised to refer to the relevant section of the National Statement (2007) to understand the ethical implications of their answer.

The Victorian Specific Module form is required for research conducted in Victoria and can be obtained via the Department of Health website <http://www.health.vic.gov.au/clinicaltrials/application-instructions.htm>

The Participant Information and Consent form (PICF) is to be constructed on one of the Victorian Department of Health master templates available at <http://www.health.vic.gov.au/search.htm?q=PICF>

New versions (June 2014) of PICF templates (except for Participant Partner Pregnancy) have been modified to address guidance on the new Australian Privacy Principles and amendment to the compensation clauses for clinical trials.

FULL ETHICAL REVIEW APPLICATION

There are 8 essential completed documents to submit.

1. Cover Letter – <http://docs2.health.vic.gov.au/docs/doc/HREC-Applications-Cover-Letter>
2. NEAF (National Ethics Application Form) - from Online Forms website www.ethicsform.org/au
3. Study Protocol
4. CV for researchers (if not previously submitted)
5. VSM (Victorian Specific Module) – www.health.vic.gov.au/clinicaltrials
6. Supporting documents e.g., questionnaire/s, data collection tools, advertisements, letters of support, investigator brochures, etc.
7. PICF (Participant Information and Consent Form)
8. You also need approval from the site involved.
9. Ethics checklist – <http://docs.health.vic.gov.au/docs/doc/Ethics-checklist>

LOW / NEGLIGIBLE RISK ETHICAL REVIEW APPLICATION

There are 7 essential completed documents to submit.

1. Cover Letter – <http://docs2.health.vic.gov.au/docs/doc/HREC-Applications-Cover-Letter>
2. Low / Negligible Risk Ethics Application – from Online Forms website www.ethicsform.org/au
3. Study Protocol
4. CV for researchers (if not previously submitted)
5. Supporting documents e.g., questionnaire/s, data collection tools, advertisements, letter of support, investigator brochures etc.
6. PICF (Participant Information and Consent Form)
7. You also need approval from the site involved.
8. Ethics checklist – <http://docs.health.vic.gov.au/docs/doc/Ethics-checklist>

SUBMISSION REQUIREMENTS

All submissions are received electronically via the Online Forms website.

TIMELINES

The Albury Wodonga Human Research Ethics Committee meets at least six times annually.

Committee meeting dates for 2016 are:

Meeting Date	Submission Deadline
Wednesday, 24 th February	10 th February
Wednesday, 27 th April	13 th April
Wednesday, 22 nd June	8 th June
Wednesday, 24 th August	10 th August
Wednesday, 26 th October	12 th October
Wednesday, 14 th December	30 th November

PAYMENT METHODS

Fees are payable in FULL following HREC review. Invoices will be sent out to the Principal Investigator as nominated on the application.

The Albury Wodonga Human Research Ethics Committee Fees Policy can be found at:

<http://www.awh.org.au/education-research/research/201432135094.asp>