Application for Ethical Review of Research Involving Human Participants

GUIDELINES FOR APPLICATIONS

The following guidelines have been developed to assist with the completion of the VU Application for Ethical Review of Research Involving Human Participants (Ethics Application form). All documents and information pertaining to the application form are electronically available at http://research.vu.edu.au/hrec.php, or may be obtained on request from the Ethics and Biosafety Administration Group, the details of which are listed at the end of this document.

An Ethics Application Kit is available on the Victoria University Human Research Ethics Website. The Application Kit includes this document, an Applications Process flow chart, the new Application Form and Supplementary forms, the old Application form, a sample Consent Form for Participants, a sample Information for Participants Form and an Application Review Checklist. You are advised to download the Application Form from the website so as to ensure that a current version of the form is being used.

Submission of ethics applications

<table>
<thead>
<tr>
<th>Level of Risk</th>
<th>Submission Requirements</th>
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<tbody>
<tr>
<td>Negligible risk</td>
<td>8 hard copies (signed) + 1 electronic copy of the full application (including all attachments) to be sent to the Ethics &amp; Biosafety Administration Group nominating the relevant Faculty or discipline-based HREC.</td>
</tr>
<tr>
<td>Low risk</td>
<td>8 hard copies (including one signed original) + 1 electronic copy of the full application (including all attachments) to be sent to the Ethics &amp; Biosafety Administration Group nominating the relevant Faculty or discipline-based HREC.</td>
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<tr>
<td>High risk</td>
<td>18 hard copies (including one signed original) + 1 electronic copy of the full application (including all attachments) to be sent to the Ethics &amp; Biosafety Administration Group nominating the VUHREC.</td>
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Submit electronic copies of the application to:

- VUHREC: researchethics@vu.edu.au
- Arts, Education and Human Development HREC: AEHDEthics@vu.edu.au
- Business and Law HREC: BLEthics@vu.edu.au
- Health, Engineering and Science HREC: HESEthics@vu.edu.au

Submit hard copies of the full application to:

(Insert name of approving HREC)
C/O Ethics & Biosafety Administration Group
Office for Research
Victoria University
PO Box 14428
Melbourne, VIC 8001

Or deliver in person to:
Ethics & Biosafety Administration Group
Office for Research
Building C, Room C302-314
Footscray Park campus.
9919 4781 or 99194461

It is important to note that submission deadlines differ for the VUHREC and Faculty HRECs, which may influence the timelines of your project. Details of submission deadlines for the relevant Committees and HREC meeting dates are available at http://research.vu.edu.au/hrec.php.

Determining level of risk

To assist researchers assess the level of risk associated with their research projects, a Human Research Risk Assessment form has been developed and is available on the Victoria University Human Research Ethics Website. All researchers should use this assessment tool in determining the level of risk of their project and the appropriate HREC to review their ethics application.
The New Ethics Application form

The new Ethics Application form comprises two parts: (1) a generic Ethics Application form that all researchers complete, and (2) Supplementary forms that relate only to certain types of research or certain participant populations. The Supplementary forms request very specific information relating to the research, as required by the NHMRC (refer to relevant sections of National Statement).

Supplementary forms will need to be submitted if the research project:

<table>
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<tr>
<th>Condition</th>
<th>Supplementary Form</th>
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<tbody>
<tr>
<td>a) involves a therapeutic intervention or clinical trial;</td>
<td>Form A</td>
</tr>
<tr>
<td>b) involves participants who are Aboriginal and/or Torres Strait Islanders (as the target population);</td>
<td>Form B</td>
</tr>
<tr>
<td>c) involves participants under the age of 18 years;</td>
<td>Form C</td>
</tr>
<tr>
<td>d) involves participants who are highly dependent on medical care;</td>
<td>Form D</td>
</tr>
<tr>
<td>e) involves participants who have a cognitive impairment, intellectual disability or mental illness;</td>
<td>Form E</td>
</tr>
<tr>
<td>f) involves participants in other countries;</td>
<td>Form F</td>
</tr>
<tr>
<td>g) involves pregnant women (with a research focus on the pregnancy) and/or the foetus (in utero or ex utero) or foetal tissue; or</td>
<td>Form G</td>
</tr>
<tr>
<td>h) seeks disclosure of information relating to illegal activities or is likely to lead to disclosure of information relating to illegal activities.</td>
<td>Form H</td>
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</tbody>
</table>

Supplementary forms, where required, should be submitted together with the generic Ethics Application form.

Duration of Ethical Approval

Applications are approved for 2 years. This period is from the date of the approval memo. In the event that the research project is not completed within the approved time period, the researchers are required to apply to the approving HREC for an extension of ethical approval for the project.

The Chief Investigator

The Chief Investigator of a research project is the person responsible for the research project and for ensuring that all aspects of the research undertaking comply with the ‘National Statement on Ethical Conduct in Human Research’. Student projects should list the Principal Supervisor or Unit Coordinator as Chief Investigator. All communications from the Victoria University Human Research Ethics Committee (VUHREC) and Faculty HRECs will be directed to the Chief Investigator of a research project.

Research projects with prior ethical approval from an external HREC.

Research projects will normally not be required to undergo full ethical review through the VU human research ethics approval process if:

1. the research has already received approval from an approved HREC that is external to the University; and
2. the research is being undertaken by a VU member of staff.

In this case, a copy of both the approved ethics application and the letter of approval from the administering HREC are required to be submitted to the VU HREC.

If the externally-approved research project is being undertaken by non-VU staff, the name and contact details of the VU staff member who is ‘sponsoring’ the research must also be forwarded to the VU HREC [refer to ‘Research by External Researchers (non-VU staff)’].

Research projects that have prior ethical approval from an external HREC will normally be reviewed and, where appropriate, approved by the Chair of the VU HREC.

Research by external researchers (non-VU staff)

Victoria University will consider applications for research involving human participants from researchers who are not staff members of VU and who require access to the cohort of VU staff or students to undertake their research. Such research proposals would normally be ‘sponsored’ by a member of VU staff, who would be required to take responsibility for all interactions with the University and the HREC in relation to ethical issues and their management.

Victoria University HREC may also consider research proposals on behalf of organisations not having their own properly-constituted HRECs, on conditions to be set by the VUHREC. Such applications would not require a VU ‘sponsor’, as the HREC would only be acting in an advisory role.
All research proposals for ethical review from non-VU staff must be submitted on the Victoria University Application for Ethical Review of Research Involving Human Participants, or, if part of a multi-centre research program, on the standard DHS or NEAF form.

If the research project by non-VU staff has already received ethical approval from an approved, external HREC, the requirements will be the same as for “Research projects with ethical approval from an external HREC”.

An administration fee may be charged for the ethical review of research proposals by external (non-VU) researchers.

**Higher Degree by Research (HDR) projects**

PhD, Professional Doctorate and Masters by Research projects should be approved by a Postgraduate Research Committee before being submitted for ethical review. Unapproved HDR research projects may, in special cases, be reviewed by an HREC; however, researchers are required to provide good reason as to why ethical approval for the project is being sought prior to gaining approval from the Postgraduate Research Committee. Please note that if the Postgraduate Research Committee requests changes to research that has already been approved by an HREC, the Chief Investigator on the project is required to submit a request for amendment to the approving HREC.

**Preparing the Ethics Application form for submission**

All questions in the Application form must be completed. In general, the most important issues to consider within the application relate to:

- the supporting rationale for the research;
- a detailed and clear description of all procedures / methodologies;
- evidence that the researchers have the appropriate qualifications and/or experience and skills to undertake the research;
- evidence that demonstrates that the researchers have considered the effects of participation in the research upon the participant(s);
- appropriate procedures to ensure that participants (or legal guardians) provide voluntary and informed consent and can withdraw from the study at any time;
- the likelihood and severity of risks and inconveniences posed to participants in this research - risks may involve physical, psychological, social and/or legal aspects;
- risks to the researchers or Victoria University and/or to other individuals or organisations involved in the research;
- appropriate minimisation and management of risks (potential or expected);
- a risk-benefit analysis of the research – where research poses any risks to participants, the researchers, Victoria University or other individuals / organisations involved in the research, the researchers need to demonstrate that the benefits of the research outweigh the associated risks;
- protection of participants’ privacy and confidentiality - related to participant identity and the collection, storage and disposal of data;
- signatures: application includes signed Declaration by all investigators AND authorisation by Head of School/Department/Centre (or equivalent).

Note: It is the Chief Investigator’s responsibility to ensure that the above issues have been addressed fully in the Ethics Application.
Other considerations when preparing the application

- **TRANSLATION OF DOCUMENTS:** If you are seeking to involve participants whose principal language is non-English and whose understanding of written (or spoken) English is limited, appropriate and accurate translations of all documents given to potential participants (e.g., Information to Participants form, Consent form) must be undertaken. Approved translators include (although may not be limited to) NAATI-accredited translators or a native speaker of the language who is independent of the research team. It is highly recommended that researchers have a back-translation of translated documents undertaken as a check for the accuracy of translations. Copies of any documents that are translated into other languages (English and translated versions) must be submitted to the approving HREC with the Ethics Application.

- **GOVERNMENT SCHOOL STUDENTS:** If you are seeking to involve participants who are students at a government school, you are required to provide the VU HREC with formal letters of authorisation from both the Department of Education and Early Childhood Development (DEECD) and the specific schools from which students will be recruited.

- **CHILDREN AND YOUNG PEOPLE:** Except under special circumstances, parental consent must be sought for any participant under the age of 18 years.

- **VU STUDENTS:** Applications seeking to involve Victoria University students must develop procedures to ensure voluntary and, where possible, anonymous involvement, in such a manner that students can be assured that their participation or non-participation will not afford them any academic or other disadvantage.

- **RESEARCH COLLABORATIONS:** Applications that involve collaboration with other institutions must describe the arrangements with the other institution(s) for managing the research undertaking including, where appropriate, confidentiality, intellectual property, ethics and safety clearances, reporting to appropriate agencies, and the dissemination of research findings.

- **WEB-BASED MATERIAL AND HYPERLINKS:** In conducting research, it is essential that researchers only copy or display content or material from external (non-VU) websites where permission has been obtained from the operators of those websites. Where the research involves using a hyperlink to a non-VU website, researchers must ensure that the content of that website is appropriate and does not breach copyright (or any other law).

**Important**

To avoid unnecessary delays, please ensure the following:
- All questions in your application are answered appropriately;
- A full application (signed original copy, appropriate number of duplicate hard copies, attachments and supplementary forms) is received by staff at the Ethics & Biosafety Administration Group by the submission deadline for the relevant HREC;
- An electronic application is submitted to staff at the Ethics & Biosafety Administration Group;
- Applications have appropriate authorisation (by Head of School/Department/Centre or equivalent).

**RESEARCHERS ARE REMINDED THAT:**

Projects must not commence without formal written approval from the appropriate Human Research Ethics Committee (HREC).

and

Approval of research projects by an HREC is conditional upon the provision of an Annual Report within 12 months of approval or Final Report on completion of the project, whichever is earlier.
If you require additional information or assistance in completing any aspect of the application, please refer to the Victoria University Human Research Ethics website: [http://research.vu.edu.au/hrec.php](http://research.vu.edu.au/hrec.php)

Or direct your queries to the Ethics and Biosafety Administration Group located at:
Office for Research
Building C, Room C302-314
PO Box 14428
Melbourne, VIC 8001
Ph: 9919 4781 / 9919 4461
Human Research Ethics Applications Process Flow Chart

Start

Submit Application

Risk Assessment

Non Minimal Risk

Approved?

NO

Applicants must submit:

a) authorised hard copy application to Ethics & Biosafety Administration Group (including required number of duplicate copies) and;

b) an electronic application to relevant Ethics Officer (EO).

\*Note: The discipline and level of risk will determine the appropriate HREC to review the application. Refer to Guidelines for Applications and Human Research Risk Assessment form.

EO in consultation with relevant HREC Chair assesses level of risk. HREC database updated & application reference number generated.

Applications prepared by CI

Forwarded to VUHREC

VUHREC Reviews Application

Approved?

NO

Application granted ethics clearance (research project may commence)

Review by VUHREC Chair

Minor Amendments

Review by HREC Chair

Minor Amendments

Revise Application

No ethics clearance (research project may NOT commence)

Review by HREC Chair

Minor Amendments

Revise Application

Faculty HREC Reviews Application

Approved?

NO

Non Minimal Risk applications to VUHREC

Forward to Faculty HREC

Faculty HREC

Approved?

NO

Minimal & Negligible Risk applications to Faculty HREC

Revise Application

PI advised by a) e-mail and b) signed hard copy notification.

HREC: Human Research Ethics Committee
EO: Ethics Officer
CI: Chief Investigator

For further details, refer to the Victoria University Human Research Ethics web site: http://research.vu.edu.au/hrec.php