6.0 HOW DO I APPLY FOR ETHICS APPROVAL?

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In order to be eligible to submit an application for ethical review, you must be affiliated with a registered Australian Human Research Ethics Committee (HREC) Institution. If you are not affiliated with an Australian HREC Institution you can approach a researcher affiliated with an Australian HREC Institution and propose a partnership. A member of an Affiliated Institution can then submit the application on your behalf. See section 8.0 for a list of Western Australian and Australian Health Research Ethics Offices.

Institutions that establish HRECs are required to set out and publicise their terms of reference, including their relationship to non-affiliated researchers. For information on application requirements that may be specific to the organisation or the HREC, researchers should contact the individual HREC.

Components of a typical ethics application

A typical ethics application will include the following components:

Project proposal:
Contains key information about your project (find example project proposals on the **SiREN website**).

Application form:
Each HREC will have their own application form.

Data management plan:
Typically outlines what data will be created during the course of a project, how data will be created, plans for sharing and storing the data and any restrictions to accessing data.

Participant information form:
Gives potential participants the necessary understanding for the motivation and procedures of the study and sources of information to answer any further questions, enabling them to give informed consent (find template and example participant information forms on the **SiREN website**).

Participant consent form:
Essentially reprises the information outlined in the participant information form to ensure the key points are understood and then records this understanding, usually with a signature. Consent may also be recorded electronically, for example through web-forms by clicking a button. More than one consent form may be needed (for adults and children separately, for example). Participant consent forms are usually in addition to participant information forms (find template and example participant information forms on the **SiREN website**).

Most HRECs will have certain clauses that must be included in participant information and consent forms i.e. background information of the issue under investigation, description of the project, what participants are expected to do, benefits and risks of participation, how participant data will be used, who will have access to that data, and whether participants have agreed to be video/audio recorded, photographed etcetera.

Survey instrument:
If applicable.

Interview/focus group questions:
If applicable. You can find guides for conducting interviews and focus groups on the **SiREN website**.

Recruitment materials:
Such as text to be used on media, direct emails, and recruitment flyers (find example recruitment flyers on the **SiREN website**).

Whilst this may seem like a lot of work to do before you submit your project's application for ethical review, the level of detail and planning required to develop and write your application will ultimately make your application stronger and once you have received approval you will be ready to start your project. For tips on preparing a good ethics application click **here**.

The ethics approval application process

STEP 1

Assemble your application documents package
This includes your application form and supporting documents (as noted in the previous section).

STEP 2

Sign off by Head of School (if submitting via a University) or equivalent (if submitting by other means)
Chief Investigator/Research Supervisor (affiliated with a registered Australian HREC Institution) submits the application package to the Head of School (or equivalent) and then forwards to the Human Research Ethics Office.

STEP 3

Risk assessment
The Human Research Ethics Office will assess the risk level of the application and allocate to a possible review pathway (see next section for how ethics applications are reviewed).

STEP 4

Ethics review body reviews application
The HREC will review the ethics application, request changes if necessary, and then approve the application after they are satisfied with the changes.

STEP 5

Notification of approval so the project can begin
The Human Research Ethics Office will notify the Chief Investigator/Research Supervisor that the ethics approval has been granted and that the project can begin.[10]

How are ethics applications reviewed?

Based on the level of risk involved in the human research outlined in the application, the human research ethics review system usually includes an exempt status and a 3-tier ethics review hierarchy.

Initial processing of ethics applications is undertaken by a Human Research Ethics Office on a continuous basis to allocate proposals to a Level 1, Level 2 or Level 3 approval pathway. Human research ethics applications that are assessed as either low risk (Level 2) or negligible risk (Level 1) do not need to be reviewed by a National Health and Medical Research Council-registered HREC (see section 8.0 for a list of Western Australian HRECs), which typically meet on a monthly basis.[11]

Level	Description	Approval timeframe
Exempt	**No risk** Activities that do not require formal ethics review.	Not applicable.
Level 1	**Negligible risk** Ethics review by the Human Ethics Office. Where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is not more than inconvenience.	Approximately 1 week.
Level 2	**Low risk** Ethics review by the Human Ethics Office. For research involving only the risk of inconvenience, or discomfort.	Approximately 2-3 weeks.
Level 3	**High risk** Ethics review by HREC. For example, research involving children less than 18 years, pregnant women, those who may be involved in illegal activities, Aboriginal or Torres Strait Islander People, or participants who are cognitively or emotionally impaired or in a dependent relationship with the researcher e.g. doctors wishing to conduct research with patients, teachers wishing to involve students in a research project.	Approximately 4-6 weeks depending on monthly meeting date.

It should be noted that research involving certain groups, methodologies or procedures, regardless of the level of risk, must be reviewed by a full HREC (Clause 5.1.6 of the National Statement).