HREA PROCESS FAQ

Creating and Submitting the Application

Who owns and manages the HREA website?
The site was developed, and is owned and managed, by the Australian Government, not by Western Sydney University. This means that any functionality issues you have with the site need to be directed to the HREA Support desk, not the Western Sydney ethics officers.
help@hrea.gov.au or (02) 6217 9902

How do I rework the application following feedback?
Prior to submitting the form on the HREA site you can share the application and download a draft to share with colleagues and get feedback.

Revisions should not be made to the Word document (outside of the website) because the form is 'dynamic' - changing some questions on the website will result in other questions also changing.

The HREA website only holds submitted applications for 90 days post submission. To go back into the form after you have submitted it on the website, for example to make changes after you receive the ethics committee's review, you will need to reload the 'omni' file into the website.

Information on how to do this is available in the HREA *How to Guide*, and *How to Download and Save your completed HREA* at

https://www.nhmrc.gov.au/research-policy/ethics/human-research-ethics-applications-hrea/human-research-ethics-applications-hrea-resources

What is the Format for the Project Description?
The HREA must be sent with the Project Description. Western Sydney University has created a bespoke template for the Project Description. Please access the template from
https://www.westernsydney.edu.au/research/forms

A Guidance document on how to complete the Project Description is available at
https://www.westernsydney.edu.au/research/research_ethics_and_integrity/human_ethics/useful_resources

What other Attachments Are Required?
- Data management plan. This is mandatory and should be attached to your application. You can develop a plan here: https://researchdirect.westernsydney.edu.au/

Your application package may also need:
- Participant information sheet(s). Templates available https://www.westernsydney.edu.au/research/forms
- Participant consent form(s) Templates available https://www.westernsydney.edu.au/research/forms
- Recruitment text/script/flyers
- An age appropriate dialogue text for children's assent
- Copies of the documents you will use to collect the data eg survey, interview questions
- An e-mail from the Graduate Research School confirming you have completed the Confirmation of Candidature (PHD) or Presentation of Proposal (MRes) process
- Permission to access participants or a site or an existing dataset

How is the Application Submitted?

The project description and attachments should firstly be uploaded to the HREA site. The application can then be "generated". The resulting zip folder must then be emailed to humanethics@westernsydney.edu.au

At the time that you download the zip folder you should also download the omni file (The file you will need if you need to make changes to the application later on.) You should save this to your computer.

NOTE: The HREA site does not automatically send or transfer your application to the ethics office. You MUST email the application to the university.

What is the Project's ID?

The HREA site will assign an ID to the application. However, this is not the ID Western Sydney will use. Once you receive the Western Sydney ID number please use it in all communications with Western Sydney. It will start with the letter H followed by some numbers. Eg H19679

HREA SPECIFIC QUESTIONS

Questions that refer to 'any relevant sections of your Project Description'

There are questions in the HREA that cross reference with the information in the Project Description. The key difference about the information provided in the HREA is that it is seeking an explanation of the ethical aspects and approach for the project, the Project Description needs to provide a clear overview of the project.

For a question like: "*Q3.5 Describe any ethical considerations relating to the collection and/or use of the information/data in this project",* the researcher should answer the question in the text box provided.

However, other questions are worded like: "*Q2.1.1 Indicate how you will identify and recruit participants for your research, referencing any relevant sections of your Project Description/Protocol as appropriate".*

In these questions you should summarise in the HREA and give more detail in the Project Description, with a cross reference notation.

How is Risk Assessed?

The National Statement on the Ethical Conduct in Human Research
says: *"2.1.6 Research is 'low risk' where the only foreseeable risk is one of discomfort. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk."*

The National Statement also mandates that research with certain types of participants be reviewed by the HREC and not the Low and Negligible Risk committee.

The form allows you to advise the ethics committee of the risk level you consider appropriate for the application. When the application is received by the ethics team they will also do a risk assessment and the application will be assigned to the committee they consider appropriate for the project.

The importance of the 'options' questions

Q1.17 Research methods options
Q1.18 Participation options
Q1.19 Types of participants options

Choosing the correct options impacts on what questions will be generated later in the form. The website holds information on how to define each option and you are advised to ensure you follow those guidelines. You can choose more than one option when appropriate.

In completing the form you shouldn't think "that's an option but it's not a risk so I won't tick it"; or "I have an acceptable management plan so I won't tick it". It is only by choosing the option that you will get the questions that allow you to show the committee you will manage the issues appropriately.

If you tick an option and then get later questions relating to that choice that seem irrelevant to the project you should reconsider whether that was an appropriate option for the project.

The Type of Participant option should be chosen when that 'type' is an intended type for your project. Usually that means that you will collect and analyse data that will distinguish people from other 'types' of participants.

Who can sign the application on behalf of the team? (Q1.9.11)

At Western Sydney University no one has delegation to sign on behalf of the team. Therefore the answer for each researcher must be 'no'.

This should generate a section for each team member to sign at the end of the form and you will be given options for how

How does WSU accept 'signatures'?
The form can be signed online – electronically or via a screen signature, or you can print out those pages, sign, scan and upload.

If signing on the form is too difficult eg a research team member is overseas, then an email from that researcher acknowledging that they have read the application and agree to it going forward can be submitted as an attachment.

Q1.12 Has the scientific merit or academic merit of the research project been evaluated?
If the project has had scientific merit review done prior to ethics review please state how. However, at Western Sydney scientific merit review will be done of all applications that don't have Category 1 funding or haven't been reviewed through the Confirmation of Candidature (for PHD) or Presentation of Proposal process (for MRES).

Q2.2.2.1 Scope of consent
This question asks about the <u>scope</u> of consent you will be seeking from participants. There are 3 options:

- Specific – the data collected will be used for this project only
- Extended - the data collected will be used for this project and may be used for similar future projects
- Unspecified - the data collected will be used for this project and may be used for other projects in the future, not necessarily directly related to this project and not necessarily by these researchers (open access).

How this question is answered impacts on the data management questions and on the information sheets and consent forms that should be used.

To assist researchers to create information sheets and consent forms which reflect the practical application of these consent scopes for different types of participants, templates are available at

https://www.westernsydney.edu.au/research/forms

Q2.2.4 Will there be an opportunity to confirm or re-negotiate consent during the research project?
In most cases participants have the right to withdraw their data, themselves or both from a research project at least up to the point of data analysis. This right to withdraw is different from a planned process of re-negotiating consent.

Whatever the approach it must be clearly explained in the participant information sheet.

Q2.2.7 Are you proposing to use an opt-out approach with respect to some or all of the participants?
'Opt out' has a specific meaning in an ethics application. It means that you will inform the participants about the research and you will collect and use their data unless they inform you they don't want to be involved. It is a suitable approach in only a limited number of research scenarios.

If you intend to seek approval for opt out consent you should read the National Statement Section 2.3.5 and the Western Sydney *Guidance on the use of 'Opt Out' or passive consent in human research.*

https://www.westernsydney.edu.au/research/research_ethics_and_integrity/human_ethics/useful_resources

Q2.2.8 Are you requesting a waiver of the requirement for consent with respect to some or all participants?
In order to assess a waiver request the ethics committees require the researcher to address the HREA questions in way that shows the project will satisfy the requirements of privacy legislation.

If you intend to seek approval for a waiver of consent you should answer the questions in line with section 2.3.9 of the National Statement.

Risk Questions
You must refer to the guidance and advice in the National Statement Section 2.1, regarding definitions of risk and how to gauge risk to be able to answer this question adequately.

Section 3 Data and privacy question: What is personal information?
Definitions of personal, health and sensitive information can be found via the HREA website guidance.

Basically, the term **Personal information** covers information that can make an individual identifiable whether on its own or in combination with other information or circumstances. Whether or not the information is identifiable at the collection, use or dissemination stages impacts on many considerations in the ethics consideration. Researchers are therefore advised to make themselves familiar with the terminology before answering these questions.

Section 4
Q4.3 Select the Organisation that hosts the HREC or other review body.
If you are sending your ethics application to Western Sydney choose Western Sydney University; Western Sydney University Human Research Ethics Committee from the drop down list.

Q4.5 Under which review pathway are you intending to submit this application?
You can nominate the review pathway you think is appropriate – HREC or LNR. However, ethics staff will assign the risk after their screening of the application, irrespective of what you choose here.

Q4.6 Will this application be reviewed under the National Mutual Acceptance scheme?
For Western Sydney review this answer is 'no'.

More information is on the Western Sydney website

https://www.westernsydney.edu.au/research/research_ethics_and_integrity/human_ethics/privacy_principles_and_research

Human Research Ethics Guidance Documents available from Research Services

- Guidance for Researchers New to Human Ethics Review
- Guidance Human Research Ethics Protocols for Coursework Masters
- Guidance on Choosing the most appropriate PIS and Consent
- Guidance on Completing the Project Description
- Guidance on Creating Research Project Flyers
- Guidance on Data Storage and Retention Questions
- Guidance on Ethics Review Exemption
- Guidance on Issues with Informed Consent in Research
- Guidance on Levels of Risk and the Ethical Review Process
- Guidance on Making an Amendment to an Approved Project
- Guidance on Organisations in Research
- Guidance on Questions Related to Cultural Sensitivities
- Guidance on Questions Related to Restrictions on Publication of Results
- Guidance on Receiving and Responding to Ethics Committee Assessor Comments
- Guidance on Research Projects Seeking to use Western Sydney Staff as Participants

- Guidance on Reimbursements
- Guidance on The use of 'Opt Out' or Passive Consent in Human Research
- Guidance on Writing Participant Information Sheets and Consent Forms
- Guidance on Research Involving Young People
- Guidance on Research Projects and DFAT Advice
- Guidance on Using Focus Groups in Research

Human Research Ethics Team Contact: humanethics@westernsydney.edu.au