WESTERN SYDNEY UNIVERSITY

REDI HUMAN RESEARCH ETHICS

RESEARCH | ENGAGEMENT | DEVELOPMENT | INNOVATION

Guidance on completing the Project Description

The Project Description is a mandatory component of a submission using the HREA. The Western Sydney HREC has determined that Western Sydney University researchers should complete this bespoke version of the Project Description to ensure the committees are given the information they require to make an efficient assessment of a new application.

The HREA website provides a different template. Although similar to this one there are key differences.

Therefore, please do not use the HREA template.

The Project Description:

- Will be the first document read by the reviewers and should provide a succinct overview of the project.
- Its purpose is to provide the scientific and academic background and context of the project.
- It should be written in language that is comprehensible for a non-technical reviewer.
- Please remain within the character counts where they are specified.
- You can delete the sections that are not applicable to your project.
- For most applications the Project Description should be no more than 7 pages in length.

This guidance sheet aims to help you to complete the document.

If you have any further enquiries please contact the ethics team at humanethics@westernsydney.edu.au

Document format

The template is a Word document. If you are unable to use the tick boxes on the template, please delete the option/s which do not apply.

The template has some specific guidance in the grey title sections.

Where appropriate the template refers to the section of the HREA that cross references with a particular section of 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.

Guidance

Section 2: Western Sydney University School or Institute approval

2.1. Which Institute/School/Centre/Group will be administering this project?
Ethics applications are logged in the REDI database, and reported against, in relation to a School or Institute. Please list the School or Institute this project should be aligned to.

2.2. Does your School or Institute have a requirement that human research projects are agreed to before an ethics application comes to the ethics committee?

The ethics committees provide ethical review for the project. Projects may need other approvals including approval from a Dean or School based research committee. It is the researchers' responsibility to ensure the research complies with any School or Institute requirements.

As at August 2017 it is known that the Dean of Education must sign off on all applications and research which involves students from the School of Nursing and Midwifery also needs School sign off. Research which will involve students from the School of Medicine must also undergo a prior review process.

Section 4: Background

The character count for this whole section (4.1. – 4.4.) is 4,000 characters including spaces.

Section 5: Sites and Methodology

The character count for this whole section (5.1. – 5.2.) is 2,000 characters including spaces.

5.2. Q1.17 of the HREA asks you to nominate your methodologies or answer 'none of the above'. The HREA provides guidance on what each option is considered to cover. In the Project Description you are asked to restate the methodology chosen (by deleting those that aren't applicable) and also explain why the options left best fit your project. If you have said 'none of the above' please explain what the methodology could be classified as.

Section 7: Active Participant Details

This section can be removed if not applicable to your project. If applicable, copy the full list of questions in section 7 and complete for each participant group.

7.5. *Sample size and statistical power issues (if appropriate to the research methodology)*
This question will not be relevant to all research projects. Sample size calculation tools can be found online at
http://powerandsamplesize.com/Calculators/ (quantitative)
http://stat.ubc.ca/~rollin/stats/ssize/index.html (quantitative)
http://eprints.ncrm.ac.uk/2273/4/how_many_interviews.pdf (qualitative)

7.9. What is the approach to consent for this group?
Written: The usual approach is by using the Participant Information Sheet and the associated Consent form. The consent form is signed by the participant. If the participant signs something saying they understand and agree to take part this option should be chosen.

Verbal: If the participant has the project explained to them and verbally agrees to take part this option should be chosen.

Implied consent is not expressly given but can be implied by someone's actions eg a participant may fill in a survey without having signed a consent form. The participant still needs to have been told what the survey is about and what will be done with the data collected.

Assent: is sought when consent for participation was given by another party, not the participant, but you will still ask them if they also agree to take part eg a child participant whose parents provide consent.

Waiver of consent: means you won't be seeking consent from the 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. For more information see *the National Statement on Ethical Conduct in Human Research*, Chapter 2.3 https://www.nhmrc.gov.au/guidelines-publications/e72

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 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 under *Ethics applications* and the *National Statement on Ethical Conduct in Human Research*, Chapter 2.3
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Section 8: Use of Pre-existing data

This section can be removed if not applicable to your project.
This section should provide an overview of ownership of the pre-existing data and the researchers' right to access it for this research project. That will include evidence of whether or not the people who provided the data for the original dataset consented to the future use of the data. If permissions for access are required the researcher needs to provide the committee with at least in-principle agreement from the data custodian before ethics review is undertaken.

Researchers should note that some data custodians will require evidence of ethics approval before granting access to the records.

For more information on using Western Sydney University students' pre-existing data see Accessing Student Records
https://www.westernsydney.edu.au/research/research_ethics_and_integrity/human_ethics/recruitment_considerations

Section 9: Data

9.1. For prospective data collection a general overview of the data should be provided and this should directly link to the copies of the research / data collection tools that are also attached to the application. Eg the interview questions, survey etc.

9.2. For existing datasets please list all the data items you will be requesting eg year of birth, postcode, gender, height etc. Note that if a waiver of consent is being requested the committee is required to determine if they approve access to all of the proposed data items.

9.4. Are any Data Linkages planned or anticipated?
"Data linkage is a technique for connecting pieces of information that are thought to relate to the same person, family, place or event."
Data Linkage Western Australia http://www.datalinkage-wa.org.au/what-is-data-linkage

This process requires a linking process of the data items to build a coherent whole. If your project or an anticipated project that will use this data will not be undertaking this process you should note this question as N/A.

Section 10: Results, Outcomes and Future Plans

10.1. Under the National Statement principle of Respect it is considered appropriate in many cases that participants' have access to the results of the research. This questions asks whether you will facilitate this and if so, how; if not, why not?

10.2. and 10.3. ResearchDirect, the University's research repository, is a digital archive of Western Sydney University's research output. The Repository contains two separate collections: Western Sydney University Research and Theses. Users can search either or both collections. Each is searchable by author, title, subject and/or publication date. For further information about ResearchDirect contact your School Librarian or the Research Services Coordinator http://library.westernsydney.edu.au/main/help/contact-us/research-services-coordinator

10.5, 10.6 and 10.7. If there are plans to share the dataset the researcher should use either the extended consent or unspecified consent information sheets and consent forms.
See https://www.westernsydney.edu.au/research/forms

Section 11: Clinical Trial

If your project is not a clinical trial you can delete this section of the form.

The ethics committees recognise that clinical trials may need to provide extensive additional documents for ethics review. Therefore, clinical trial proposals may complete this form including Section 11 Clinical Trials, or may provide an alternate protocol template and associated documents.

More information about Australian Clinical trials practice can be found at
https://www.australianclinicaltrials.gov.au/

What other attachments are required?

The Project Description must be sent with the HREA form. Your application package may also need:

- Participant information sheet(s) - Western Sydney template at https://www.westernsydney.edu.au/research/forms
- Participant consent form(s) - Western Sydney template at 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 email 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