RESEARCH SERVICES | ETHICS AND INTEGRITY | Human Research Ethics | WESTERN SYDNEY UNIVERSITY

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 the 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 template found on the HREA site.

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.
- Use Plain English and clear descriptions in each section, remembering that the application is being reviewed by a multi-disciplinary committee, with members from different backgrounds i.e. Academics, lawyers, community members, researchers etc.
- Please remain within the character counts (or word limits) 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.
- Clinical trials should adhere to Good Clinical Practice guidelines in relation to the documentation they submit with their ethics application. A full trial protocol may be more appropriate.

This guidance sheet aims to help you to complete the Project Description. It does not have advice on every question in the form. This version of the Project Description guidance has been updated to reflect changes in the 2018 updated *National Statement on Ethical Conduct in Human Research*. It should be referred to for all new ethics applications. https://www.nhmrc.gov.au/guidelines-publications/e72

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

Clarification about length of the final document

As much as possible, the Project Description without Attachments A or B should be around 7 pages only. It is accepted that a project with multiple participant groups may exceed the page limit because each group must have its own set of questions and answers at section 6.
Below are some ways to approach editing of the documents:

- Don't provide extraneous information when answering the questions. Focus on the question being asked and only provide relevant information
- The HREA form seeks more information on the ethical aspects of the project so this does not need to be addressed in the Project Description unless the question specifically asks it.
- Keep the text in Section 4 within the word count limits. The text should be edited to provide a succinct overview of the literature review, rationale, research question and outcomes.
- If either Section 6 or 7 aren't applicable to the project it is acceptable to delete the questions from the form.

Section 2: Western Sydney University School/Institute approval

2.1. Which Institute/School/Centre will be administering this project?
Ethics applications are logged in the university's database, and reported against, in relation to a School/Institute/Centre as provided by the applicant. Please list the School/Institute/Centre this project should be aligned to for reporting purposes.

2.2. Does your School/Institute/Centre 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/Institute/Centre requirements.

As of August 2019, it is known that the School of Education and School of Nursing and Midwifery have sign off procedures. Research which will involves 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 500 words. This section corresponds to Q1.2 in the HREA. Information in the summary of the project can be reworded to sit under the corresponding headings in this section.

Section 5: Sites and Methodology

The word count for this whole section (5.1. – 5.2.) is approx. 250 words.

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 covers. 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 6: Active Participant Details

This section can be removed if not applicable to your project. If applicable, please fill in the table for each participant group.

6.2 State the number of groups in this project. Create a separate table of questions 6.2 – 6.14 for each group.

6.8. Sample size and statistical power issues
Although different research methodologies will approach this question differently, the researcher must justify why the number of participants noted at 6.7 is sufficient to answer the research question. If necessary, refer to the literature.
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)

6.9 Participant Engagement

This requires a straight forward answer about what each participant group will do as part of the research project. What is written here should be compatible with what is described in the participant information sheet.

6.10. 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 e.g. 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 the participant if they agree to take part e.g., a child participant whose parents provide consent. If seeking assent, you should also provide a Dialogue Sheet – the text you will use to seek assent.

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
The Project Description must list the data items the researcher wants to access at 7.3 or 8.2 as appropriate. If seeking a waiver of consent for any of the data in the project Section 11 of the Project Description must also be completed.

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 .

Your application needs to explain the process that will allow people to let you know they don't want to participate. You can provide this as an attachment to the application.

6.11 Recruitment
These answers should be in line with the answers in the HREA form Q2.11.
The National Statement lists the key questions that researchers should address when discussing recruitment issues. These are at Chapter 3 Element 2: Recruitment.
https://www.nhmrc.gov.au/guidelines-publications/e72

6.14 Please list the risks for that group. A more detailed explanation of risk for the whole project, and your mitigation strategies, will be provided in the HREA form.

Section 7: Use of Pre-existing data
This section can be removed if not applicable to your project.

7.1 This section should provide an overview of ownership of the pre-existing data and the researchers' right to access it for this research project.

7.2 Is there evidence that the people who provided the data for the original dataset consented to the future use of the data in research? The researcher may need to seek clarification and evidence from the data custodian to answer this question accurately.

7.3 List all the data items you will be requesting/collecting 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 ie you must have ethics approval before you collect data.

7.5 What is the approach to consent for this data?
See the information at 6.10 above.

7.6 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 8: Data

8.1 The scope of consent relates to whether the data to be collected is just for this project (specific consent) or you want the participant's agreement for the (usually de-identified) data to be re-used in future projects. You can seek extended or unspecified consent even if you don't know what that immediate use may be. The data management plan should outline, among other things, under what conditions that re-use would be appropriate.
When the project's scope of consent is either extended or unspecified the researcher must also attach an explanation of these terms to the Participant Information Sheet that is used for the project. The template, which must be tailored for the project, is at https://www.westernsydney.edu.au/research/forms

8.1.1 If you are seeking specific consent from your participants you must state your justification for this choice. The 2018 revised version of the National Statement says that the scope of consent should allow for possible re-use unless there is an ethically justifiable reason why re-use wouldn't be appropriate. See section 3.1.50 of the National Statement
https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018

8.2. Prospective data is the data you will collect during the project (not previously existing). At this question provide a general overview of the data. This overview should directly relate to the copies of the research/data collection tools that are attached to the application.

8.3 This answer requires the researcher to provide an overview of the data analysis plan. Just naming the analysis software is not sufficient information.

8.4. 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 9: Results, Outcomes and Future Plans

9.1. Under the National Statement principle of Respect, it is considered appropriate in many cases that participants' have access to the results of the research. However, there may be situations in which it isn't

appropriate, or possible, to share the results or findings with the participants. This questions asks whether you will facilitate this and if so, how; if not, why not?

9.3 and 9.4 If there are plans to share the dataset the researcher should use either the extended consent or unspecified consent information sheets and consent forms and outline the process of sharing or reuse in the data management plan.
See https://www.westernsydney.edu.au/research/forms

9.6 Briefly outline your intentions in relation to the IP and copyright issues associated with this project. In addition, if the researchers will have an IP or copyright agreement that differs from the standard WSU policy this should be explained and a justification for this provided.

For more information see page 41 of the National Statement and the WSU policies on copyright [https://policies.westernsydney.edu.au/document/view.current.php?id=148&version=5] and intellectual property [https://policies.westernsydney.edu.au/document/view.current.php?id=85&version=4]. Where appropriate researchers should refer to the project contract for funded research.

If IP and copyright issues impact on participant's rights this should be explained in the Participant Information Sheet and consent form. In some cases, a copyright release form may need to be provided to participants.

What other attachments are required?

The Project Description must be sent with the HREA form and the data management plan. Your application package may also need a range of additional items. The most common ones are:

- 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 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

Before sending the application for review please edit all documents and ensure consistency of information. Lack of consistency in answers and attachments is a key reason why the review process is delayed.
The attachments to your application should be named to describe the information it is representing. I.e. Participant consent form V1, Participant Information sheet V1.

Attachment A. Section 10: Clinical Trial

You can delete this section if not applicable.
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 10 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/

Researchers who will need to log a trial on the TGA website under the Western Sydney account should contact the human ethics team for more information.

Attachment B. Section 11: Request for a Waiver of Consent

You can delete this section if not applicable. If completing this section, one of the consent types in the Project Description must be 'waiver'.

Researchers should refer to Section 2.3 of the N*ational Statement on Ethical Conduct in Human Research-Qualifying or Waiving Conditions for Consen*t and any relevant State or Federal legislation before completing this form.

When you should complete this form

A waiver of consent means that you will be using a participant's data without asking the individual for consent to use the data. This agreement for use from the individual participant is different from, and in addition to, any agreement you might have from the current owner/custodian of the data to access it.

The most common reason a waiver request occurs is because the participant's data forms part of an existing dataset. If consent to use the data in multiple research projects was sought at the time of the original collection of the data, then you will be able to state that consent was obtained. But if you have no evidence that consent was obtained, you will need to ask the Western Sydney ethics committee for a waiver of consent.

To do this you must complete the Project Description and this attachment appropriately, plus acknowledge the waiver in the HREA Form and answer the resulting questions.

The requirements of a request for a waiver of consent

As outlined in the National Statement, a request for a waiver of consent places an obligation on the researcher and the ethics committee to ensure certain actions or considerations are undertaken.

In answering the questions in Section 11 you will be helping the committee make a decision as to whether those requirements will be met. Your answers and arguments should show knowledge of the National Statement and the relevant Privacy Legislation.

The ethics committee is also obliged to report to the NHMRC and others when a waiver of consent for the use of personal (identifiable) information in research has been agreed to under the 'use in research' exemption in the Privacy Legislation.

The committee must also agree to the exact data variables, or information, that the project will have access to. You should outline what these are at question 7.3 and/or 8.2 (as appropriate to this project) of the Project Description. You should not access the data until you have ethics approval.

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

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