

Project Description

To be submitted with a human research ethics application (HREA)

**IMPORTANT**

**You must attach the project description to your online HREA before emailing the completed application to** **humanethics@westernsydney.edu.au****.**

The Project Description is the first form that the Human Research Ethics Committee will read. It is there to provide the committee with the context, scientific and academic background to your Human Research Ethics Application (HREA). It should be written in Plain English, using non-technical terminology so that committee members from non-academic backgrounds are able to understand your project. It sho–uld be written alongside your HREA and together the forms should give the committee insight into how you are dealing with ethical issues that might arise in your proposed project. The HREC may also review the research merit of your application through an expert drawn from outside the committee.

A brief definition should follow any technical term(s) that need to be included in your application. A glossary of terms should precede the background section if your application needs to include multiple technical terms. Your Project Description (without attachments A or B) should be no longer than 10 pages in length.

A [guidance document](https://www.westernsydney.edu.au/research/research_ethics_and_integrity/human_ethics/useful_resources) has been developed to assist in completing this form.

Please contact the Human Research Ethics Officers if you are unsure about your requirements [humanethics@westernsydney.edu.au](file:///C%3A%5CUsers%5C30042650%5CAppData%5CLocal%5CMicrosoft%5CWindows%5CTemporary%20Internet%20Files%5CContent.Outlook%5CVEQKXA0R%5Chumanethics%40westernsydney.edu.au)

**If you are unable to use the tick boxes on this template, please delete the option/s which do not apply.**

# Section 1: Overview

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| --- | --- | --- |
| **1.1.** | Project Title: |  |
| **1.2.** | Project Acronym or short title (if applicable): |  |
| **1.3.** | Version Number: |  |
| **1.4** | Does this project already have funding logged with the Grants Services team? |  [ ]  Yes [ ]  No |
|  | If yes, what is the Project ID allocated by Research Services? (eg **P00012345):**(This information enables us to link your funding to your ethics approval) |  **P** |

# Section 2: Western Sydney University School or Institute approval

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| --- | --- | --- |
| **2.1.** | Which Institute/School/Centre will be administering this project? |  |
| **2.2.** | If your Institute/School/Centre has a requirement that human research projects are reviewed or agreed to before an ethics application comes to the ethics committee, has this occurred? See [Guidance sheet](https://www.westernsydney.edu.au/research/research_ethics_and_integrity/human_ethics/useful_resources) for more information. | [ ]  Yes[ ]  No[ ]  NA |

# Section 3: Project Team Named in the HREA

# (Provide names only. Additional details should be included in HREA Q1.9)

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| --- | --- | --- |
| **3.1.** | Chief Investigator / Principal Supervisor: |  |
| **3.2.** | Chief Student (if applicable): |  |
| **3.3.** | Other Investigators/Supervisors: |  |
| **3.4.** | Other Students: |  |
| **3.5.** | Role/s yet to be assigned (e.g. future Research Assistant): |  |
| **3.6.** | Will students be added to this project in the future? [ ]  Yes [ ]  No |
| If yes, what degree program will they be enrolled in, and what will their role/s be on the project? Will they be working on activities that are documented in this application, or  |
|  |

# Section 4: Background (Limit to 500 words for all of section 4. Overly long entries will be returned to the researcher for editing.)

This section corresponds to Q1.2 in the HREA. The two sections can be written together whereby elements of the summary included the HREA form can be copied into the section here.

**4.1.** Literature Review (include citation details):

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**4.2.** Rationale/Justification (i.e. how the research will fill any gaps, contribute to the field of research or contribute to existing or improved practice):

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**4.3.** Research questions/aims/objectives/hypothesis:

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**4.4.** Expected Outcomes:

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# Section 5: Sites and Methodology (Limit to 250 words for all of section 5)

**5.1.** List the *specific* sites based on your answers to HREA Q1.4. (e.g. *which* Universities, workplaces, schools or public places?):

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**5.2.** What methodologies will be used in this project?

 **(Delete the options which are not applicable)**

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| Action ResearchBiospecimen AnalysisData LinkageEpidemiological ResearcherEthnographic Research (including autoethnography)InterventionClinical TrialObservationalSurveyInterviewFocus GroupTextual Analysis |
| Other:  |  |

**5.2.1** Explain why these methodologies are appropriate for this study:

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# Section 6: Active Participant Details (YOU MUST copy questions 6.2. to 6.14 as a table for every participant group. Delete this Section if you are only collecting/using pre-existing data.

**If there is more than one participant group, you must copy the table and complete questions 6.2 - 6.14 for each participant group.**

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| **6.1.** | How many participant groups will be in this project?Examples of participant groups include teachers, students and parents.(You will need 1 table for each group.) |  |

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| --- | --- | --- |
| **6.2.** | **Participation Group Number (eg 1, 2 etc)** |  |
| **6.3.** | **Group name** |  |
| **6.4.** | **Characteristics of the group that are relevant to the aims of the project** |  |
| **6.5.** | **Inclusion criteria** |  |
| **6.6.** | **Exclusion criteria** |  |
| **6.7.** | **Expected number and age of participants** |  |
| **6.8.** | **Sample size and statistical power issues**Justify the number of participants needed for this study. |  |
| **6.9.** | **Describe what these participants will be asked to do** |  |
| **6.10.** | **Follow up plans** |  |
| **6.11.** | **Recruitment**How will you identify and recruit participants? Include whether screening takes place before or after consent; who will initially approach the participants; how participants will receive the recruitment documentation; how much time a participant will have to consider participation.**Will participants be offered any form of reimbursement?**This can be written in conjunction with question 2.1.1 of the HREA. |  |
| **6.12.** | **Consent type**If you are seeking a waiver of consent for the use of pre-existing data, you must complete Section 11 of this form. | [ ]  Written [ ]  Verbal[ ]  Implied [ ]  Waiver[ ]  Opt-out [ ]  Assent |
| **6.13.** | **Summary of consent process**The summary can be adapted from Question 2.2.1 of the HREA. |  |
| **6.14.** | **Summary of project risks**(do not respond with N/A or ‘none’)The summary can be a condensed version of information included in question 2.3.1 of the HREA. This section should relate to risks to this group of participants. |  |

# Section 7: Use of Pre-existing Data

# Delete this section if not applicable

**7.1.** Where or who are you obtaining this data from? Eg Electoral Roll, ABS data, Chief Investigator of another research project?

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**7.2.** Who is the current data custodian/owner?

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**7.3.** Have you obtained permission to access the data from the data owner/custodian (e.g. previous researcher, WSU Chief Student Experience Officer)? In most cases at least in-principle agreement from the data owner is required prior to sending the application for ethics review.

[ ]  Yes Attach evidence

[ ]  No What will be the process to obtain approval from the data custodian?

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**7.4.** Describe the data. Include the expected number of records to be accessed, and the information you want to collect and use for this project. Eg name, age, postcode, years in employment.

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**7.5.** Will the data you collect include information that could make individuals identifiable (to the researchers or others)? [ ]  Yes [ ]  No

**7.6.** Did the original participant/s consent to the data being used for research?

[ ]  Yes: What was the process for obtaining consent (eg signed consent form, verbal consent):

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[ ]  No: Please apply for a waiver of the requirement to seek consent in Section 11 below.

# Section 8: Data

**8.1.** What is the scope of consent you will seek for this project? – relates to HREA 2.2.2.1

[ ]  **Specific consent** should be selected when consent is restricted to the specific project under consideration.

 If seeking specific consent, what is the ethically justifiable reason for this approach? (see section 3.1.50 of the National Statement on Ethical Conduct in Human Research):

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[ ]  **Extended consent** should be selected when there is intention to use data or tissue in future research projects (This refers to extended, closely related, ongoing projects or projects in the same general area of research). This also includes permission to enter original data or tissue into a data/tissue bank.

[ ]  **Unspecified consent** should be selected when there will be a need to use data or tissue in any future research. This also includes permission to enter original data or tissue into a data/tissue bank and needs to be clearly outlined to participants.

**8.2.** For prospective data collection, what information are you going to collect/gather?

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**8.3.** How will you measure, manipulate and/or analyse the information that you collect/gather? When relevant include matching and sampling strategies, accounting for potential bias, confounding factors and missing information. Providing just the name of the software program is not enough information.

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**8.4**. Are any Data Linkages planned or anticipated? If yes, please describe. See [Guidance sheet](https://www.westernsydney.edu.au/research/research_ethics_and_integrity/human_ethics/useful_resources) for more information.

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Section 9: Results, Outcomes and Future Plans

**9.1.** Will the results or findings of the research, e.g. a summary of the findings, be returned to participants?

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| --- | --- | --- |
| [ ]  Yes | How? This section relates to question 3.16.1.1 of the HREA. |  |

|  |  |  |
| --- | --- | --- |
| [ ]  No | Why not? |  |

**What are your plans for the following activities?**

**9.2.** Dissemination and publication of project outcomes (e.g. thesis, journals, Research Direct)

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**9.3.** Other potential uses of the data at the end of the project (e.g. Sharing or future use of the data, follow up research).

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**9.4.** Summarise the arrangements regarding intellectual property (individual, community, organisational, commercial) and copyright related to the data ownership and outputs of the research.

See [Guidance](https://www.westernsydney.edu.au/research/research_ethics_and_integrity/human_ethics/useful_resources) sheet for more information.

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Conflicts of Interest

Have you disclosed any financial or non-financial interests at Q1.10 in the HREA which relate to a conflict *other than* a HREA Committee Member i.e. research-related commercial activity, Western Sydney staff members?

|  |  |
| --- | --- |
| [ ]  Yes | please ensure that any conflicts of interest are recorded on the University’s[Conflict of Interest Register](https://erm.protecht.com.au/wsu/worms/client/app/anonymousWidget.html?widget=AnonymousRegisterEntry&appId=1121&tablename=table_137120) |
| [ ]  No | continue to next question |

Research in Public Schools

Will you be conducting research in an Australian public-school setting?

|  |  |  |
| --- | --- | --- |
| [ ]  Yes |  |  |
|  | [ ]  In NSW | You may need to complete a [SERAP application](https://app.education.nsw.gov.au/serap/UserGuide/Display?page=National%20research%20application%20process) |
|  | [ ]  In other state/s | Please contact the Department of Education (or equivalent) in the relevant state/s for advice about whether any specialist review is required. |
| [ ]  No | continue to next question |

Conducting research with children

Does your research require you to work with children?

|  |  |
| --- | --- |
| [ ]  Yes | Anyone who works face-to-face with children in a paid, self-employed or voluntary capacity, must have a Working with Children Check (WWCC) clearance, unless they qualify for an exemption. Please ensure that your status is valid and up to date. |
| [ ]  No | continue to next question |

Research in Public Health Organisations

Will you be conducting research in an Australian public health organisation, such as a hospital?

|  |  |  |
| --- | --- | --- |
| [ ]  Yes |  |  |
|  | [ ]  In NSW | You may need to apply for ethics approval via a [Local Health District ethics committee](https://www.medicalresearch.nsw.gov.au/ethical-scientific-review/#:~:text=All%20human%20research%20that%20takes%20place%20in%20NSW,of%20Human%20Research%20in%20NSW%20Public%20Health%20Organisations.).  |
|  | [ ]  In other state/s | please contact the relevant state Health Department for advice about whether any specialist review is required. |
| [ ]  No | continue to Attachment Checklist |

Attachment Checklist

The file names should reflect the contents of the document. Document formats should usually be Word or PDF.

**Mandatory Attachments**

[ ]  Project Description on WSU template <https://www.westernsydney.edu.au/research/forms>

[ ]  HREA form <https://hrea.gov.au/>

☐ WSU Data Management Plan (mandatory as per the University’s Research Data Management Plan and Element 4 of the National Statement) <https://researchdirect.westernsydney.edu.au/>

**Other possible attachments**

The attachments required will depend on the project. Below are the most usual attachments.

* 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/flyer
* 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 confirming you have completed the Confirmation of Candidature (MPhil, PhD) or Evidence of successful completion of Viva (MRes)
* Permission to access participants or a site or an existing dataset

Clinical Trials – Continue to Section 10 below

Requesting a Waiver of Consent – Continue to Section 11 below

**This project description forms one part of your ethics application. It can either be uploaded to the online HREA system, or attached when you email your application to the ethics team.**

Attachment A. Section 10 – Clinical Trial

**Delete this section if not applicable or you will be supplying a clinical trial protocol instead. If completing this section you also need to have completed Sections 1-10.**

**10.1.** Is this research a Clinical Trial? [ ]  Yes [ ]  No

The WHO defines a clinical trial as “any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.”

<http://www.who.int/topics/clinical_trials/en>

 The National Statement says:

*3.1.7 For any research project that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes, researchers must register the project as a clinical trial on a publicly accessible register complying with international standards (see information on the International Clinical Trials Registry Platform (ICTRP) on the World Health Organisation website) before the recruitment of the first participant.*

**10.2.** Will you register this trial on a publicly available register? [ ]  Yes [ ]  No

If no, why not?

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**10.3.** Will the research require registration with the Therapeutic Goods Administration? [ ]  Yes [ ]  No

For information on how to register a clinical trial under the Western Sydney TGA account contact the human ethics team [humanethics@westernsydney.edu.au](file:///%5C%5Cad.uws.edu.au%5Cdfshare%5CREDI%5CEthics%5CHuman%20Ethics%202019%5CPlanning%5CProject%20description%5Chumanethics%40westernsydney.edu.au)

**10.4.** Will the trial seek registration under the CTN/CTX scheme? [ ]  Yes [ ]  No

**10.5. For research involving an investigational drug or device as part of a clinical trial, what is/are the drug(s) and/or devices:** (Copy text as needed)

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| --- | --- | --- |
| **10.5.1** | Approved Name: |  |

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| --- | --- | --- |
| **10.5.2** | Trade name (if any): |  |

|  |  |  |
| --- | --- | --- |
| **10.5.3** | Manufacturer: |  |

|  |  |  |
| --- | --- | --- |
| **10.5.4** | Supplier of drug/device (e.g. manufacturer/pharmacy): |  |

|  |  |  |
| --- | --- | --- |
| **10.5.5** | Approved therapeutic indication, dosage/duration in Australia: |  |

|  |  |  |
| --- | --- | --- |
| **10.5.6** | Believed mode of action: |  |

|  |  |  |
| --- | --- | --- |
| **10.5.7** | Dosage regimen: |  |

|  |  |  |
| --- | --- | --- |
| **10.5.8** | Mode of excretion: |  |

|  |  |  |
| --- | --- | --- |
| **10.5.9** | Known adverse events: |  |

|  |  |  |
| --- | --- | --- |
| **10.5.10** | Known contra-indicators or warnings: |  |

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| --- | --- |
| **10.5.11** | If arrangements have been made for the Pharmacy Department to receive or dispense the drugs involved in the project, explain how the drugs will be received and dispensed for the purpose of the research project. |
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# Attachment B. Section 11 – Request for a Waiver of Consent

**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 National Statement on Ethical Conduct in Human Research <https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018>

*Qualifying or Waiving Conditions for Consent* and any relevant State or Federal legislation before completing this form.

**11.1.** Are you requesting a waiver of consent for (tick as many as apply):

[ ]  A de-identified dataset that it is not possible to re-identify (Under the Privacy Act, personal information is de-identified if the information is no longer about an identifiable individual or an individual who is reasonably identifiable.)

[ ]  Identifiable data

[ ]  A dataset which includes health information[[1]](#footnote-1). (Note that only an HREC can grant a waiver of consent for research using personal information in medical research or personal health information.)

[ ]  Research which is aiming to expose illegal activity

**11.2.** Does involvement in the research carry no more than low risk to participants?

[ ]  Yes

[ ]  No - the committee cannot waive the requirement to seek consent if the involvement of participants is not low risk. Please reassess the consent options for this project.

**11.3**. Why isn’t it possible to seek consent for the use of the data?

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**11.4**. Is there any reason for thinking that participants would not have consented if they had been asked?

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| --- | --- |
| [ ]  No |  |
| [ ]  Yes | Why wouldn’t participants have consented? |
|  |  |

**11.5.** How will the participant’s privacy and confidentiality be protected?

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**11.6.** If using **identifiable data** without consent:

 Why isn’t it possible to only use de-identified data?

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 Why does the public interest in the research substantially outweigh the public interest in privacy?

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**11.7.** For research aiming to expose illegal activity:

 How does the value of exposing the illegal activity justify the adverse effects on the people exposed?

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1. From the NHMRC *Guidelines approved under Section 95A of the Privacy Act 1988*, 2014

Health information is a particular subset of personal information. Health information is personal information

or an opinion:

• about an individual’s health or disability at any time (that is past, present or future)

• about an individual’s expressed wishes regarding future health services

• about health services provided or to be provided to the individual

• collected to provide or in providing a health service

• collected in connection with the donation or intended donation of body parts and substances; or

• genetic information about an individual in a form that is, or could be, predictive of the health of the individual or a genetic relative of the individual.

As indicated above, health information includes any information collected by a health service provider during the course of providing treatment and care to an individual, including:

• medical information

• personal details, such as name, address, admission and discharge dates, billing information and Medicare number

• information generated by a health service provider, such as notes or opinions about an individual and their health

• information about physical or biological samples, where it can be linked to an individual; for example, where they have a name or identifier attached. [↑](#footnote-ref-1)