

**Information about this form:**

* Inclusion of a Project Description is a **mandatory** component of a submission using the HREA.
* The purpose of a Project Description is to provide the scientific and academic background and context of a research project, so the ethics review body can assess the merit of the research project.
* Clinical trial proposals **should not** use this protocol template.
* The section headings in this project Description template represent a structure for presentation of information about a research project that meets the needs of an ethics review body.
* Not all headings or sub-headings in this template are relevant for each research project.
* Researchers may choose to submit an existing document (such as the MQ research protocol or project description that has already been developed) instead of developing a new document.
* If researchers choose to submit an existing document instead of using the templates provided, they may need to provide indications to the ethics review body of where in the submitted document the content corresponding to the relevant fields in the template are located.
* There is no need to duplicate information in the HREA in the Project Description or vice versa.
* Language that is understandable to non-technical reviewers should be used.
	+ Researchers must collect and save their research data in Macquarie University-endorsed platforms. Refer to the *Refer to Macquarie University Research data management framework for guidance (*[*staff*](https://staff.mq.edu.au/research/strategy-priorities-and-initiatives/research-data-management-framework)*/*[*students*](https://staff.mq.edu.au/research/strategy-priorities-and-initiatives/research-data-management-framework)*) on data collection/management.*

Researchers are strongly encouraged to address the following headings in their Project Description. Each dot point provides an example of the information that researchers might want to include, if relevant to their project.

**HREA Project Description Form**

**Title**

* Acronym (if appropriate)
* Version number

|  |
| --- |
|  |

**Project Team Roles & Responsibilities** *(add extra rows in table below where required)*

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Position on project** | **Affiliation** | **Responsibilities** |
|  | Chief Investigator |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**Resources**

* *Resources necessary for the project to be conducted*
* *Funding/support being sought or secured*

|  |
| --- |
|   |

**Background**

* *Literature review*
* *Rationale/Justification (i.e., how the research will fill any gaps, contribute to the field of research, or contribute to existing or improved practice)*
* *Research questions/aims/objectives/hypothesis*
* *Expected outcomes, what is hoped to be achieved*

|  |
| --- |
|  |

**Project Design**

|  |
| --- |
| **Research project setting:** * + *physical sites, online forums, and alternatives.*

**Methodological approach:*** + *Rationale for choices of method/s (tied to project aims/objectives).*
	+ *Rationale for choice of any control arm.*
	+ *Are there any risks associated with the study, and the strategies for minimising those risks.*

**Participants:*** + *Description of how potential participants will be identified and from where.*
	+ *How many participants will be recruited.*
	+ *Inclusion and exclusion criteria.*
	+ *Sample size and statistical or power issues.*
* *Participant recruitment strategies and timeframes (as required in addition to that outlined in the HREA).*

**Consent:** Approach/es to provision of information to participants and/or consent (as required in addition to that outlined in the HREA).* + *Explain how a potential participant will be enrolled into the study.*
	+ *Will consent be obtained for future use of the data collected from this study?*
	+ *If necessary, the type, timing, and context of consent provided to different participant groups, when and where, and any arrangements to confirm that consent.*
	+ *If necessary, details of who will be confirming or re-negotiating consent with participants and the process/es that will be undertaken.*

**Research Activities:** What are you going to do?* + *Participant commitment.*
	+ *Project duration.*
	+ *Participant follow-up.*

**Data Collection/Gathering:** What information are you going to collect/gather? (As required in addition to that outlined in the HREA)* + *Data collection/gathering techniques: How will you collect/gather the information?*
	+ *Impact of and response to participant withdrawal.*
	+ Refer to the *Refer to Macquarie University Research data management framework for guidance (*[*staff*](https://staff.mq.edu.au/research/strategy-priorities-and-initiatives/research-data-management-framework)*/*[*students*](https://staff.mq.edu.au/research/strategy-priorities-and-initiatives/research-data-management-framework)*) on data collection/management.*

**Data Analysis:** How will you measure, manipulate and/or analyse the information that you collect/gather?* + *Matching and sampling strategies.*
	+ *Accounting for potential bias, confounding factors, and missing information.*
	+ *Statistical power calculation.*

**Data Management:** How will you store, retain, provide access to, disclose, use/re-use, transfer, destroy or archive the information/data that you collect/gather? Are there any risks associated with the data management plan and the strategies for minimising those risks. (As required in addition to that outlined in the HREA). * *Include a data management plan in accordance with the* [*National Statement on Ethical Conduct in Human Research*](https://www.nhmrc.gov.au/research-policy/ethics/national-statement-ethical-conduct-human-research) *2023 Section 3.1.44 and 3.1.55 and* [*The Australian Code for the Responsible Conduct of Research 2018*](https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018)*.*
* *Research data must be saved in Macquarie University-endorsed storage platforms to ensure that their data is securely and safely stored and backed up. Refer to the Refer to Macquarie University Research data management framework for guidance (*[*staff*](https://staff.mq.edu.au/research/strategy-priorities-and-initiatives/research-data-management-framework)*/*[*students*](https://staff.mq.edu.au/research/strategy-priorities-and-initiatives/research-data-management-framework)*) on data collection/management.*

**Data Linkage:** What linkages are planned or anticipated?**Outcome measures:*** For research involving an investigational drug or device as part of a clinical trial: What is/are the drug(s) and/or device(s):
	+ *Approved name*
	+ *Trade name (if any)*
	+ *Manufacturer*
	+ *Supplier of drug/device (e.g., manufacturer/pharmacy)*
	+ *Approved therapeutic indication, dosage/duration in Australia*
	+ *Believed mode of action*
	+ *Dosage regimen*
	+ *Mode of excretion*
	+ *Known adverse events*
	+ *Known contra-indications or warnings*
	+ *If arrangements have been made for the Pharmacy Department to receive or dispense the drugs involved in this project, explain how the drugs will be received and dispensed for the purposes of the research project.*
 |

**Results, Outcomes and Future Plans**

* *Plans for return of results of research to participants*
	+ *Include an ethically defensible plan in accordance with the* [*National Statement on Ethical Conduct in Human Research*](https://www.nhmrc.gov.au/research-policy/ethics/national-statement-ethical-conduct-human-research) *2023 Section 3.1.64 or 3.2.15 or 3.3.36-3.3.61, as appropriate.*
* *Plans for dissemination and publication of project outcomes*
* *Other potential uses of the data at the end of the project*
* *Project closure processes*
* *Plans for sharing and/or future use of data and/or follow-up research*
	+ *Anticipated secondary use of data*

|  |
| --- |
|  |