

Project Description/Protocol

Note that:

1. the purpose of a Project Description is to provide the scientific and academic background and context of a research project;
2. a Project Description is a **mandatory** component of a submission using the HREA;
3. 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;
4. not all headings or sub-headings in this template are relevant for each research project;
5. submissions of clinical trial proposals may use alternative protocol templates, such as the [SPIRIT statement](#);
6. researchers may choose to submit an existing document (such as a protocol or project description that has already been developed) instead of developing a new document;
7. if researchers choose to submit an existing document instead of using one of 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;
8. there is no need to duplicate information in the HREA into the Project Description or vice versa; and
9. language that is understandable to non-technical reviewers should be used.

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.

Title

- Acronym (if appropriate)
- Version number

Project Team Roles & Responsibilities

- Names, affiliations, positions and responsibilities of investigators and other key project team members (as required in addition to that outlined in the HREA)

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

Project Design

- Research project setting (physical sites, online forums and alternatives)
- Methodological approach
 - Rationale for choices of method/s (tied to project aims/objectives)
- Participants
 - Description and number
 - 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)
- Approach/es to provision of information to participants and/or consent (as required in addition to that outlined in the HREA)
 - If necessary, the type 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 you are 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
- Data Management: How will you store, provide access to, disclose, use/re-use, transfer, destroy or archive the information that you collect/gather? (as required in addition to that outlined in the HREA)
- 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 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
- 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