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Eastern Health Research Protocol Template v1 dated 07Mar2023

# PROJECT PROPOSAL / protocol

***Acknowledgement****: This protocol template is based on the template developed by the Eastern Health Pharmacy Practice Research Group (PPRG) who has generously provided permission for use.*

*\*To use this template, delete the italic text and comments from each heading and fill in the details.*

*\*\*****DO NOT delete sections in CAPITAL LETTERS****.*

*Potential researchers are encouraged to discuss their project with their colleagues and senior staff at an early stage and ensure that their research proposal is submitted early to allow sufficient time for the Eastern Health Human Research Ethics Committee (EH HREC) to review the project, provide feedback then approval.*

***Ethics Consideration before Submission***

*Is an ethics approval required and if so what level of ethics approval?*

*Refer to Eastern Health Research and Ethics website to identify* ***Level-of-Risk*** *or further guidance.*

[Quick Links to Forms and Templates (easternhealth.org.au)](https://www.easternhealth.org.au/research-ethics/guidance/quick-links-to-forms-and-templates)or[Guidance (easternhealth.org.au)](https://www.easternhealth.org.au/research-ethics/guidance)

*\*Tips:*

* *Quality Assurance (QA) audits do not require ethics review. Use the QA protocol template on the Eastern Health Research and Ethics website. Submit the Quality Assurance (QA) VIC application form via Ethical Review Manager (ERM).*
* *For other projects not qualifying as QA, an ethics application must be lodged via the Ethical Review Manager (ERM) – NHMRC Human Research Ethics Application Form (HREA).*

*Ensure you submit this protocol and any other supporting documents such as data collection templates, surveys etc. with your ethics application.*

*Projects requiring ethical approval cannot commence until such approval is granted.*

*Contact the Office of Research and Ethics team for further details:* [*ethics@easternhealth.org.au*](mailto:ethics@easternhealth.org.au)

## PROJECT TITLE

*What is the title of the project? Ensure this reflects the aims and methodology.*

## Project team

*List the full name, affiliations, positions, responsibilities and contact details of all researchers involved in the proposed project. Include description of:*

* ***Coordinating Principal Investigator (CPI)*** *– only if multi-site/multi-organization project. All sites under Eastern Health are considered as one site.*
* ***Principal Investigator (PI)*** *– the person who has the overall responsibility of the whole project. There should be* ***only one PI*** *per project.*
* ***Associate Investigator (AI)*** *– all others who will be involved in the project.*

## RESOURCES

*What resources or funding would be required to undertake the project? What impact could the project have on staffing? Is there external funding available? Would additional resources or funding be required from Eastern Health? Are there any grants available that could help fund the project?*

*If the project is not funded by a grant or drug companies list as ‘No external grant funding’.*

## SYNOPSIS

*A brief but clear summary of what your research is about. It outlines the key aspects of what you will investigate as well as the expected outcomes. It briefly covers the what, why and how of your research. A good way to evaluate if you have written a strong synopsis is to get somebody to read it without reading the rest of your research proposal. Would they know what your research is about?*

## BACKGROUND

*In one or two paragraphs provide background information required to set the CONTEXT of the project. (i.e. what you think the problem is, do you have any proof that there is a problem or it is a perceived problem from your point of view.)*

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

## LITERATURE REVIEW

*Include a brief review of the literature. Has similar work been done before else were? What has been other people’s experience? Depending on the project this may be included in the background.*

*Use appropriate mix of evidence in correct order i.e. meta-analysis, systematic literature review, randomised controlled trials then other studies. Do not use outdated literature.*

*Consider using EndNote for referencing. Use Vancouver style. List references at the end.*

## RESEARCH QUESTION / AIM

**Research Question (PICO Population/Problem, Intervention, Comparison, Outcome):**

*What is the key question you are asking?*

*Hypothesis (Null & alternative) required if you are considering using statistics to answer your research question.*

**AIM/OBJECTIVE:**

*In one or two sentences clearly state the AIM of the project. This should match your research question above. There should only be 1 primary Aim/Objective.*

*There can be multiple secondary Aims/Objectives.*

*Always refer to your aim to ensure your methodology is correct. Once the project is complete, your aim also informs your conclusion.*

## METHODOLOGY

*Describe project design, including rational for choice of method and any control arm.*

*Describe who is doing what in the project. Consider the roles of CPI/PI/AI etc*

*Intervention (if any)*

*If your study includes assessment of an intervention, such as a new service, provide details of the intervention, including evidence supporting choice and design of the intervention.*

*Define Intervention Arm (if any)*

*Who will receive the intervention? How are they selected?*

*Controls (Control Arm if any)*

*Describe any controls. This could include randomised controls, controlled cohorts, or historical controls.*

**Participants:**

* *Description of participants*
* *Inclusion & exclusion criteria*
* *Participant recruitment strategies and timeframes*
* *Approach to provision of information to participants and/or consent*
* *Participant follow-up*

**Sample size and statistical or power issues**

* *Describe how the sample size will be determined. This may not be necessary for some types of research, such as retrospective data collection.*
* *For quality assurance projects (QA) this is usually a sample of convenience.*
* *If you do want to prove that the change (difference) observed is statistically significant, then a ‘power’ calculation should be done to determine the sample size to enable you to detect this difference. (see below)*

**Data Collection/database:**

* *What information are you going to collect/gather?*
* *Ensure any data collection tools such as Excel/REDCap/GoogleSheets are attached to the application.*
* *How will you store, provide access to, disclose, use/re-use, transfer, destroy or archive the information that you collect/gather. Research data stored on personal computers, USBs and other portable electronic devices must not be identifiable.* ***No*** *patients’ names or UR numbers must be stored on these devices. Electronic storage devices must be password protected or encrypted. If data is to be published, then it must be kept for at least 5 years post publication on the* ***Eastern Health network****.*
* *Describe how confidentially will be maintained.*

## Risks and benefits

*What are the potential benefits? May be benefits to participants directly / indirectly or at a broader level.*

*What are the risks? E.g.: any physical / emotional harm or distress, potentially infringe the rights, privacy or professional reputation of participants, etc.*

## OUTCOME MEASURES /STATISTICAL ANALYSIS

*How exactly are you going to answer/prove your research question?*

*Define your outcome measures (study endpoints). This may require collaboration with others in order to ensure that endpoints in fact satisfy your strategy.*

**Primary outcome(s):** *usually 1*

**Secondary Outcome(s):** *usually max 5*

**Data Analysis:**

*How are you going to analyse your results? Will you use simple/descriptive stats (means, ranges, medians, percentages) or apply statistical significance tests?*

*Consider:*

* + *Matching and sampling strategies*
  + *Accounting for potential bias, confounding factors and missing information*
  + *Statistical power calculation*

*\*Tips for consideration of statistical analysis and power calculations:*

* *You must first identify what measurement (****variance****) you are going to test/prove (go back to your research question)*
* *Create a null hypothesis (‘there is no difference’), if your statistics reject this then alternative hypothesis is correct.*
* *Your hypothesis should describe the* ***magnitude of change*** *required to observe a difference. (example, if you are testing for medication adherence, you need to define what adherence means for your study. If you decide that adherence is 99% compliance with instructions then you are testing a difference of 1% (very small magnitude of change), if you decide adherence is 90% compliance then the magnitude of change that you will be testing is much larger – Note: it is easier to prove a larger change).*
* *To statistically prove a small difference (small magnitude of change), you need a very large study power (hence very large sample size) and vice versa.*
* *It is the responsibility of the project team to discuss and define the variance and magnitude of change with respect to evidence in literature.*
* *This information is required by the statistician to calculate study power, sample size and method of statistical analysis.*

## TIMELINE

*Include a realistic timeline for your project and any deadlines or dates that may need to be met.*

## DISSEMINATION of results

*How do you plan to disseminate your results? Is the project likely to be published? Are the results likely to be presented at a conference or meeting? Will the result be shared with participants? How will the privacy of participants be protected?*

## CONFLICT OF INTEREST

*Do you have any conflicts of interest to declare relating to this research project?*

## REFERENCES

*If applicable list the references here. Unless otherwise specified use Vancouver style:*

[*http://jppr.shpa.org.au/lib/pdf/reference\_citation\_guide.pdf*](http://jppr.shpa.org.au/lib/pdf/reference_citation_guide.pdf)