GV Health	**RESEARCH PROTOCOL TEMPLATE (LOW RISK RESEARCH PROJECT AND CLINICAL AUDITS)**

When drafting your protocol:

- Discuss project design and scope with supervisors/peers.
- Discuss appropriate statistical analysis methods with a statistician.
- Proposals for all studies which involve patient contact should be presented to the relevant clinical unit for approval prior to submission.
- Delete sections that are not applicable and blue text.
- Add version number and document date in the footer.

STUDY TITLE

STUDY SHORT TITLE

STUDY INVESTIGATOR(S)

Principal Investigator

Title and Name	
Position	
Department	
Qualifications	
Phone	
Email	

Associate Investigator

Title and Name	
Position	
Department	
Qualifications	
Phone	
Email	

Note: Copy table and repeat for each additional associate investigator or delete table if there are no associate investigators.

1. SUMMARY

The summary should be concise but sufficient to orientate the reader to the main purpose of the study, how it will be conducted and its expected benefits.

2. BACKGROUND

Consider the following where appropriate to the project:

- Overview / Context
- Current practice / current theory
- Literature review
- Rationale of current study (why are you doing this study)
- Significance - contribution to the broader field of study/practice

3. AIM(S) AND OBJECTIVES OF STUDY

The aims of a study describe what you hope to achieve. The objectives detail how you are going to achieve your aims.

4. RESEARCH PLAN/METHODOLOGY

4.1. Participants

Selection criteria (Source of patients/data, identification, inclusion and exclusion criteria, start and end dates of entry)

Participant/data (de-)identification procedures

Suggested wording: Identifiable patient data will be replaced with a code/unique number. The master list of names and matching codes will be stored electronically and password protected by the PI / or kept in locked facilities of GV Health (in the Department of ……).

4.2. Measures

Describe primary and secondary endpoints (if applicable). Identify all data that will be collected for use in evaluating project outcomes.

4.3. Procedures

Consent process(es) (if applicable)

Include a detailed description of proposed recruitment method, including how approach will be made and by who. Include all documents to be used in the recruitment process as separate documents e.g. letters, brochures, PICFs

Privacy issues (if applicable)

Consider issues such as collecting data from another centre, data being analysed by an external statistician or involve an external researcher.

Details of data collection, processing and analysis

Record keeping procedures, including storage of data access and destruction

Please state: what data is being stored e.g. consent forms, demographic data; where it is being stored; how it is secured e.g. password protected; who is responsible for security; how long is the information being kept; who is responsible for destruction of the information.

Examples of wording:

- The patient data will be kept strictly confidential according to the NHMRC National Statement on Ethical Conduct in Human Research (2007) - Updated 2018 and the Australian Code for the Responsible Conduct of Research, 2018.
- Patient research data will be accessed only by the named investigators.
- Electronic records of research data will be retained on password protected computer(s) in databases requiring password access. This data will be stored separately from the master list of patient names.
- Any hard copies of data will be kept in locked facilities of GV Health (in the Department of ……).
- Any laptop computer will be password-protected and electronic records stored on it will be coded and in databases requiring password access. Only study investigators will have access to the data.
- Patient data will be only be transferred and analysed in a coded form.
- Individual patients will not be identifiable from the presented or published material.

5. STATISTICAL CONSIDERATIONS

Include detailed description of statistical analyses to be used.

6. ETHICAL CONSIDERATIONS

You must state that the study will be conducted in full conformance with the NHMRC National Statement on Ethical Conduct in Human Research (2007 and updates), World Medical Association Declaration of Helsinki (2013 and updates), Good Clinical Practice (GCP), and within the laws and regulations of the state and country in which the research is conducted.

Describe proposed publication or presentation of results.

7. REFERENCES

8. APPENDICES

Include a list of appendices (e.g. questionnaires, surveys, interview scripts, phone scripts, data collection forms, assessment forms, rating scales). Provide the appendices as separate documents and any documents to be provided to participants should be presented in the form that they will be provided to the participant.