RESEARCH PROPOSAL TEMPLATE

Please note that for biostatistical support we recognize that this may be a draft, and may change. This should be 1-2 pages.

1. TITLE*: A title which clearly and succinctly explains what the research is about

e.g. "Incident hip fracture and socio-economic status in a regional population of Australian women aged 65 years and over."

2. PURPOSE OF STUDY*

Describe the purpose, specific aims, or objectives. State the hypothesis to be tested or the research questions that will guide the study. You may have more than one aim, or one main aim and several lesser aims. State them all in logical order. This website has more detailed instructions on writing specific aims, if needed.

e.g. "The objective of this study is to determine the effect of an onsite mental health professional on GP's management of mental health clients in a regional centre in Queensland. *The aims of the study will be:* *Aim1: To determine the prevalence of mental health presentations in participating general practices.* *Aim 2: To examine the management strategies of GPs in practices with and without an onsite mental health practitioner.*

3. BACKGROUND AND RATIONALE*

Briefly describe the following:

- The relevant current context of the study and gaps in current knowledge.
- Provide the scientific or scholarly background for, rationale for, and significance of the proposed research based on the existing literature.
- Describe the significance of the research including potential benefit for individual subjects or society at large (i.e., how the research might contribute to generalizable knowledge). Describe how public health and social welfare might be enhanced, if applicable.
- Include applicable references at the end of the protocol.

4. BRIEF RESEARCH PLAN*

Study design: How are you going to conduct your research: will it be a data linkage; a retrospective cohort study; a prospective cross sectional study; a double blind randomised experiment?

e.g. "*Prospective cohort study*" or *"Retrospective chart audit"*

***Sample Population*:** Who are the group/s you are interested in? Describe the study population including total number of subjects to be enrolled and/or data records/samples to be accessed.

e.g. all patients/all males/males over 50; with a particular diagnosis/undergoing a certain procedure; in all Qld hospitals/all public hospitals/only your hospital/your clinic/all GP practices; in the past 10 years/12 months/the next 6 months

Inclusion and Exclusion Criteria:

e.g. All adult patients with a diagnosis of X who attended the participating medical centres between April 2014 and March 2015 will be included. *Patients will be excluded if they have any of the following:* *-being treated for condition of interest with X,Y, or Z therapies* *-have a co-diagnosis of A, B or C conditions* *-are pregnant or undergoing fertility treatment*

RECRUITMENT METHODS AND CONSENT* (Not required for this application) *: How will you inform potential participants about the research and invite them to participate? Describe the different methods for recruiting subjects into the study. Describe how potential subjects will be identified, as well as when/where/how potential subjects will be recruited Will the study require IRB approval?

STUDY PROCEDURES

Provide a brief description of study procedures, assessments, and subject activities.

- Source of record or measures that will be used for any data collection (e.g., medical records, pathology, surveys).
- Indicate if any research data will be included in the subject's medical record (e.g., lab test results, drug assignment, or indication of study participation)
- Describe randomization procedures, if applicable.
- Duration of individual's participation in the study and overall anticipated duration of the study.
- Provide a schedule of all study assessments and subject activities, including a tabular representation or timeline, as applicable

Measurements and Outcomes:

What will you measure, how, how frequently, on what equipment, by whom and how will the results be stored? If you are using a survey, is this already drafted and validated? If this is a chart review, what variables will be collected, and will this be done electronically or manually? If applicable, list out independent/exposure variables, primary and secondary outcome variables, and possible confounding variables etc.

e.g. A structured physical health assessment and Health Intelligence assessment will be conducted by the clinician and practice nurse, at the medical practice. The following data will be collected from each participant at the baseline interview. Where available it will be taken from the patient file. Where clinical and laboratory parameters are missing from the patient file, procedures will be undertaken to provide the data.

- *Demographics: age, sex, income level, health fund membership, postcode, marital status*
- *Diagnosed physical conditions/past medical history*
- *Clinical parameters: weight, height, waist/hip ratio, blood pressure, heart rate, capillary oxygen saturation, spirometry*
- *Health behaviors (i.e. structured lifestyle questionnaire)*
- *Health Intelligence (i.e. structured health awareness questionnaire)*

Changes in health behaviors and health intelligence will be assessed at 6 and 12 month follow up visits with administration of the health and lifestyle questionnaires.
Data will be saved into a password protected database, by the nurse/researcher/medical health professional.

DATA ANALYSIS PLAN

- Describe the sample size and basis for the determination
- Describe the statistical/analytical methods to be used for the research data, as appropriate,

Note: This doesn't have to be completed upon your application. Our biostatistician can help you with this section after meeting and discussion

5. RISKS TO SUBJECTS (Not required for this application)

If applicable

6. POTENTIAL BENEFITS TO SUBJECTS (Not required for this application)

If applicable

7. SUBJECT WITHDRAWALS (Not required for this application)

If applicable

8. PRIVACY AND CONFIDENTIALITY OF SUBJECTS AND RESEARCH DATA (Not required for this application)

If applicable

9. REFERENCES

List references cited within the protocol, as applicable.

***These sessions are essential components to a research project, therefore are required upon application. However, it is ok if they are not finalized at the moment.**