CLINICAL RESEARCH SYNOPSIS TEMPLATE

Please complete the synopsis and submit electronically to clinical.research@mqhealth.org.au

Title
Make sure the title specifically describes what the clinical research is about. It could end up being the title of your publication, for example.

Background and Rationale

Background - Provide short overview of the current state of the literature in relation to the research question

Rationale/ justification for the project

Do this in dot points. Use single sentences. Make it brief. State what the problem is. Say what is already known. Say what is not known.

Research questions/aim/hypothesis

Briefly say what your aim is and how you are going to test it. This is really important. You have to know what your aim is. Usually starts as:
To determine whether ....
You can have more than one aim

Hypothesis
This is the idea or proposition you are going to test.

Objectives/ Endpoints

Primary objective or endpoint: This is critical. If you don’t have a primary objective or endpoint you can’t do a study!

What is the main thing you are going to measure to determine the success or failure of the study?

If you have a well-defined aim, you can then focus on how to design the study, how many patients you need etc. The design of the study determines what statistical test(s) will be applied and how large cohort will be required for each arm of the study (i.e. each treatment or control).

Secondary objectives/endpoints: - You may or may not have other objectives/endpoints.

Overview of research methods/ study design

Describe the type of research methods you will be using. E.g. observation, qualitative study, mixed method study. Is it randomised controlled trial, etc? How many arms (or treatments) are required?

What about controls? If clinical trial - Is it a phase-1, -2, -3 or -4?

Intervention

Is there an intervention? If so, what is it? e.g. drug, surgical procedure, new medical device or technology, health related education, etc.

Participants and recruitment

List key inclusion (eligibility) criteria (not the entire list you would put in the protocol), as well as any key exclusion criteria.
Outline where and how you are anticipating on recruiting the cohort(s) from (e.g. MQ Health, other institution, community setting).

How many will be recruited at MQ Health and how? Who is conducting the recruitment? Do you need to have certain access permissions to get access to participants?

**Participant numbers**

Estimated participant/patient numbers for clinical research (eventually should be based on appropriate power calculations for the statistical testing to be applied in the study).

**Study Procedures**

Provide a brief description of how the clinical research will work. This will allow the reviewers to get an idea of the logistics and the resources that may be required for the research.

**Resources**

What resources from MQ Health will be required? E.g. staff, equipment, infrastructure, MMI, laboratory.

**Data management**

Describe the information that will be collected directly from participants at MQ Health or via access to samples or patient medical records database. Be specific where appropriate. How will you ensure secure access and storage?

**Significance**

Short note on how the results of the trial might change clinical practice or inform further research. How do you anticipate the project will contribute to the MQ Health work?

**Budget**

<table>
<thead>
<tr>
<th>Item</th>
<th>Per unit cost</th>
<th>Number</th>
<th>total</th>
</tr>
</thead>
<tbody>
<tr>
<td>List items, procedure or services, e.g. lab tests, MRI, staff time per patient, laboratory procedures, transcribing services for qualitative interviews etc.</td>
<td>0</td>
<td>0</td>
<td>$0</td>
</tr>
<tr>
<td>List any IT resources required for data collection, analysis and storage. E.g. software licence purchase</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Costs can be estimate at this stage</td>
<td>0</td>
<td>0</td>
<td>$0</td>
</tr>
<tr>
<td>Include travel reimbursement and any cost for refreshments to study participants</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Even if the cost is $0, it is best to list it e.g. data collection; ethics submission</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td></td>
<td></td>
<td>$XXXX</td>
</tr>
</tbody>
</table>