

Protocol Template Guidance: Biomedical Research – General Institutional Review Board (IRB) & Scientific Review Committee(SRC)

General advice

- Do not assume that the person reviewing your proposal is an expert in your field
- Spell out acronyms and define technical terms
- Provide relevant references to support your arguments
- Provide details of methodology and logistics to demonstrate project feasibility

Introduction

A brief paragraph that gives a 30,000 ft view of your proposed project

- State the problem that you propose to study
- State your question
- Explain (in 1-2 sentences) what you are going to do to answer it
- Describe your anticipated outcome

Background

This section builds the rationale for why your project is important. Describe studies by yourself and by others, which provide the clinical and scientific background to your project, explain its importance, and support the likelihood that it will be successful. In the last paragraph, provide a more detailed overview of your study and anticipated outcome(s).

Hypothesis

“an idea or explanation that you then test through study and experimentation”

Provide a brief (1-2 sentence) description of the hypothesis that is driving your study questions (Specific Aims).

Specific Aims

The Specific Aims are operational statements that define what you are going to do to address your hypothesis. Each Specific Aim may be followed by a brief summary describing how it will be achieved.

Significance

- Why is your question important?
- How will your project, if successful, move knowledge forwards?

Methods

Human Subjects

This section describes your proposed study population and, if the study is prospective, how you will identify and enroll participants and obtain their informed consent. The bulleted list gives examples of elements you may need to describe (the first three items should always be included).

- Population/ recruitment site(s)
- Inclusion/exclusion criteria
- Number of subjects
- Recruitment plan (prospective studies and clinical trials)
- Enrollment/ informed consent (logistics, any ethical issues)
- Compensation/incentives provided to participants
- Follow-up plan (if relevant)
- Randomization plan (if relevant)

Data Collection and management

This section describes the methods you will use to collect the data needed to complete your study, and how those data will be handled. Distinguish between data collected as part of usual care and data collected for research purposes. Depending on the structure of your study, this information could be organized by Specific Aim. The bulleted list gives examples of elements you may need to describe.

- Data extracted from medical record (electronic/ manual)
- Permission to access data
- Persons extracting the data (self, CPI, honest broker, other)
- Use of existing database
- Data collection instruments (attach any surveys, questionnaires etc)
- Sample collection and handling (phlebotomy, biobank)
- Laboratory studies
- Clinical procedures
- Plan for data safety: storage and movement of data (where and to whom), platform and method used to prevent unauthorized access (electronic or physical barriers) and how patient confidentiality (PHI) will be protected.

Data analysis

Provide details of the statistical methods that you will use to analyze your data, and how these analyses relate to your Specific Aims and anticipated outcomes. Include information about your sample size calculation.

Potential problems

Consider problems that realistically might occur during your study, and describe ways in which you could address them. E.g., if low enrollment is a possibility, suggest alternative or additional strategies that could be used to reach potential participants.

Timeline

It is always helpful to include a Gantt chart, schedule of events (or similar Figure) that gives a visual overview of study logistics and displays the timing or time allotted to accomplish each of the required elements (e.g. planning, recruitment, data collection, data analysis etc).

For additional guidance please contact the *Research Navigation Team* at navigation@mmc.org