***A guidance to what you should include in a Research Protocol for the IRB to consider***

*The purpose of this guidance template is to assist investigators, researchers and students in planning and preparing their research project. It is important to note that:*

* *A well-written and complete protocol is essential for achieving a high quality research study.*
* *Must include the following:*
  + ***Why*** *the study is being done*
  + ***What*** *will be done in the study*
  + ***Where*** *the study will be done*
  + ***Who*** *is involved in the research study*
  + ***When*** *study interventions will take place*
* *Time spent on writing a detailed protocol will avoid delays during the review process and also avoid any problems while the study is being conducted hence will make publishing the results easier.*
* *A complete protocol is also essential for the study to be approved by the ethics committee.*

***Minimum Criteria the IRB looks at are:***

* **Purpose and Rational of the study**
* **Targeted participant population and justification**
* **Sample size justification**
* **Method of recruitment and approaching participants**
* **Informed consent procedure and process**
* **Study procedures**
* **Anticipated risks and potential benefits to participants**
* **Methods to ensure confidentiality and anonymity of the data collected**
* **Steps taken to protect participants including management of adverse events, as applicable.**

*The following is a tool to facilitate the development of a Research Protocol. It is by no means a definitive layout for a protocol but more to provide guidance to the kind of things expected. Not all of these sections will be relevant for every protocol and the exact form of your protocol will depend on the specific study research design. It is recommended that the section headings in the Research Protocol should not be deleted. An \* indicates sections that should appear in all protocols.*

***General comments***

* *Make sure to include page numbering in the form of “X of Y” (1 of 10, 2 of 10 etc.) in the footer of the document – as shown in this document*
* *Indicate the date of the draft, or once it has been formally submitted for approval, the date of the version in the header or footer*
* *Always use the same Research Protocol title throughout your document and all related documents such as Informed Consent, submission applications etc.*
* *Italic content is for reference only and must be deleted from the final Research Protocol Document*
* *Once done, update “Table of Content” by clicking on the table of content and clicking on Update Table, then click on Update Entire Table*

***“Title of Research Protocol / Project”***

*Investigators & personnel*

1. *Indicate the principal investigator*
2. *Other investigators and /or Study Personnel and their affiliations*

*Institution(s) responsible for the running of the study*

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# Synopsis

*This is similar to an abstract and should be about the same length (250-300 words). It acts as a stand alone summary of the study and should be present in large protocols. It generally consists of a background (1-2 sentences) then the concise objective or aim followed by a brief outline of description of participants, intervention, methods, outcome measures and proposed analysis.*

# Background Information and Introduction \*

*This should include the following:*

* *Introduce the topic of interest and a description of the issue the study is addressing*
* *Mention what is known already - a literature review of relevant findings (Brief and focused)*
* *Highlight area (s) where there is missing information in the literature*
* *Describe the study population*
* ***Indicate impact*** *- this is where you indicate how the study will substantially add to science, change practice, save money and best of all save lives or improve quality of life in substantial numbers of people. Include an economic impact if possible. (note impact is sometimes placed at the end of the protocol)*

*The background should not be an exhaustive literature review. At the end, the reader should have a clear idea of what the research question is, an understanding that it is original and relevant, and how this research will help fill the gap in the literature.*

*\*Note: the content of each point could be written more concisely to avoid wordiness*

# Objectives \*

* *Write a clear statement of the primary and secondary objectives and purpose of the study*
* *If relevant, include a clearly defined hypothesis here*

# Project timelines and flow chart

*It is important to highlight project timelines if the study will be conducted over a period of time and multiple factors are expected*

# Study Methodology \*

The scientific integrity of the study and the credibility of the data obtained is dependent on the study design. This section should include:

* *Primary and secondary endpoints and how they will be measured*
* *Type of study*
* *Where is it going to be carried out (also known as setting)*
* *Sample size calculation or justification of numbers (Should be based on previous data )*
* *Study comparison & intervention \**
* *What interventions are you comparing? If you are doing a cohort study or survey then what are the exposures or predictors of interest?*
* *Details of the interventions – this has to be very detailed if you are planning a drug / device study.*

# Study population\*

* *Subjects* 
  + *Source of participants - where and when are you going to recruit them?*
  + *How are you going to recruit them*
  + *How many participants?*
  + *Sample justification to the number of participants*
  + *Inclusion/Exclusion criteria*

# Study procedure \*

* *Include the participant informed consent process, if applicable. Who will approach the participant, how informed consent is sought*
* *Specify the time that each phase of the project is likely to take, along with a detailed month by month timeline for each activity to be undertaken.*
* *Provide details on how interventions are going to be delivered if applicable* 
  + - * 1. *Who is going to deliver them?*
    1. *Blinding*

*For randomized studies; how participants are going to be randomized (a simple diagram showing treatment arms is often useful here)*

* *Include other details of particular ways the subject will be treated during the study independent to the specific intervention(s) (for example: will other drugs not be allowed or will participant’s diet or environment be controlled)*
* *Highlight the outcome \* (Note there should be only one primary outcome)*
  + *What are the primary and secondary outcomes?*
  + *Details of the outcome measures used*
* *Clarify data collection \** 
  + *What data are you going to collect, how is it collected, who collects it and when?* 
    - *Details of intervention data*
    - *Details of outcome data*
    - *Details of all demographic data and other potentially confounding data*
    - *Details of safety data and adverse events*
* *Provide further subject follow-up, if applicable*
* *When and for what? Especially for adverse events*
* *How often?*
* *What data is collected at each time point?*
* *Mention study timelines: Expected duration of the study & start times, stages of the study such as screening, treatment phase (Visit numbers), etc, as applicable*
* *Consider participants’ withdrawal* 
  + *Are there any conditions that will cause a participant to be withdrawn from the study?*
  + *What happens if a participant wishes to withdraw consent?*
* *Note Risk / benefit*

*\*Note: the content of each point could be written more concisely to avoid wordiness*

# Data Management \*

* *Where and how is data going to be stored?*
* *Case record forms*
* *Database*
* *Will there be any attempts to de-identify data?*
* *Measures to ensure Privacy and Confidentiality*

# Assessment of Safety and Efficacy

# Statistical Analysis

* *Analysis plan* 
  + *Details on how the primary and secondary outcomes will be analyzed.*
  + *Statistical methods to be used*
  + *Who is going to carry out the analysis?*

# Quality assurance, monitoring & safety

*Any external committees overseeing the study such as Study Steering Committees or Data and Safety Monitoring Committees?*

* *Will there be an interim analysis?*
* *How will adverse events be identified and acted upon?*
* *Are there any specific safety measures or is there important safety data being collected?*

# Ethical Issues\*

*This section should describe ethical considerations relating to the study and measures taken to protect human participants*

*Provide information on how or from whom the ethics approval will be taken*

*Describe how the investigator(s) plan to obtain informed consent from the research participants (the informed consent process).*

# Finance and resource use\*

*Details of funding bodies*

*Budget including direct and indirect costs*

# Dissemination of Results and Publication policy

*The protocol should specify not only dissemination of results in the scientific media, but also to the community and/ or the participants, and consider dissemination to the policy makers where relevant. Publication policy should be clearly discussed- for example who will take the lead in publication and who will be acknowledged in publications, etc.*

# Archiving

* *Specify what documents to be archived*
* *Specify archiving location*
* *Recommendation to retain all study documents and results for at least 15 years*

# References \*

# Appendices