**Outline of writing an investigator initiated Research Proposal/ Protocol**

**Components of a typical research proposal/ protocol**

A. Abstract or Brief Summary of the study

1. Aim - research study question(s )and/or hypotheses
2. Framework/ Theoretical
3. Review of Literature with critique and indicate level of evidence as applicable
4. Research Design / Methodology- how will the question(s) be answered
5. Data Collection
6. Data Analysis
7. References - current and most relevant evidence to support the research

**Abstract**

Generally an abstract is around 200 words & consists of: 1) introduction –why this study is important and background 2) Methods – describes the study design, who is studied, what was measured, and how data analyzed. 3) Results – plan for data analysis or the. After study the main finding of the study in narrative and then numbers. 4) Conclusion- what is the clinical meaning and implications for practice, policy or need for specific further research.

**AIM**

**The Aim of the study** addresses the problem to be addressed where there is a gap in knowledge, or the research question.

See heading/tab : Defining the Clinical Question

* **Hypotheses** identify the variables to be manipulated and is predicative of the outcomes.

**Theoretical Framework**

For some studies, particularly social and behavioral studies a theoretical framework will support the research design and identifies a concept, relationship, and/or theory that provide the basis for the study.

**Review of Literature**

**The Review of Literature** is a systematic review of information and relevant research that is published about your topic and supports why your study is needed.

Refer to tab/heading: Searching Literature

**Design/ Methodology**

**Research Design** tells the method used to answer the research question or achieve the aim.

Include sampling strategy, size, setting and type.

* **Descriptiv**e-describes new situations, events or concepts
* **Experimental-**controlled investigation among groups leading to drawing conclusions about causal relationships
* **Quasi-experimental**-examines causal relationships or effects of one variable on another , but subjects cannot be assigned or randomized to groups
* **Case control** – compares characteristics of a case to matched controls
* **Cohort** –study of specific group over time
* **Correlational**-examines the relationships concepts
* **Longitudinal-**study something over a long period of time-Framingham Heart Study
* **Qualitative**-used in behavioral and social sciences and based upon observation and interaction and generally the findings are descriptive. The goal is to understand meaning and not producing generalizable knowledge. Investigates attitudes, feelings, beliefs and themes emerge. Types include interviews, focus groups, case studies, ethnography and phenomenology.

**Protection of Human Subjects**

Plans for recruitment and consent of the participants. How identifiers and data will be protected and secured. Risks/ benefits to participants.

Refer to: (<http://university.ghs.org/research-protection/>)

**Data Collection**

Plan for what data to be collected and how. Include data collection sheet or case report form.

If using research instruments, need to have been tested for validity and reliability.

**Validity** - does it measure what it is supposed to measure without bias.

* **Construct** validity – most Important level –Items are designed to measure a specifically defined domain through a scientific process.; **Criterion** validity – ***concurrent*** - how well does the measure relate to other manifestations of the construct and does it ***predict*** performance? **Convergent** validity – are results of this tool similar to other tests? **Discriminant** validity – does it measure what it is not supposed to measure, in other words, does it *discriminate?* **Face** validity---lowest level - as the name suggests, is a measure of how representative a research project is 'at face value,' and whether it appears to be a good project.

**Reliability** –what extent a test is *repeatable* with consistent scores and known as internal consistency. State the measurement of reliability and score. If using a tool, include permission from copyright holder to use the tool.

**Data Analysis**

Statistical analysis will depend on what type of study used for your research. Recommend discussion with statistician early in your design development phase.

**References ( List citations in APA or AMA format)**

**Funding**

Include information about any funding or sponsor of the study or intended submissions for grant funding and how data/findings will be shared.