# Clinical Research Study Protocol

Your name:

Project Title/ Topic:

**Background**

Rationale (2-3 sentences): *Describe the relevant prior experience and gaps in current knowledge*. *Provide the scientific or scholarly background and significance of the research based on the existing literature and how will it add to existing knowledge.*

Research Question/ Aim: *Describe the purpose of the study.*

Hypothesis: *Describe what you expect the outcome will be.*

**Methods**

Study design: *What study design best answers your question?*

Data source: *Are you using existing data? Collecting original data? Reviewing the literature?*

Patients/ sample: *Describe the criteria that define who will be included or excluded in your study sample*. *Describe how individuals will be screened for eligibility*.

Intervention: *What is the treatment of interest?*

Comparison: *Placebo? Another treatment? Is there no comparison?*

Outcomes (primary, and secondary as applicable): *What primary and secondary outcome measures will be used to answer the research question*? *Provide citations demonstrating the validity and reliability of tools where appropriate*.

Timing (when and how often outcomes are collected): *What is the duration of an individual participant’s participation in the study? When will you collect outcomes (e.g. baseline? Week/ month X?)*

Setting/ site: *Describe when and where the study will be conducted*.

Main analysis (for the primary outcome): *In general terms, describe the statistical analyses plan including any statistical procedures.*

Sample size: *Indicate the total number of participants to be recruited for the study. This may be based on a convenience sample, saturation (qualitative research), or estimated using a sample size calculator.*

Additional notes