Study Protocol Template

Title

Study Protocol Version: (every change in the protocol requires a protocol amendment and change of version)

Date: (every change in the protocol requires a protocol amendment and change of date)

Principal Investigator (include Name/Title)

Co-Investigators (include Name/Title)

Table of contents (if necessary)

INTRODUCTION AND BACKGROUND

The introduction should explain the background of the study, including a complete literature review to establish the existing knowledge in the area of inquiry or development. The following should be included:

PURPOSE AND JUSTIFICATION

State the purpose of your study or area of inquiry. Explain the need for your study and justify why it should be completed.

Research Objective(s):

Research Hypothesis:

METHODS

Study Design:

Include research design (e.g. outpatient clinic, hospital), method (non-probability sampling (convenience), probability sampling (random), study population, number of sites involved if applicable)

Inclusion Criteria:

1.
2.
3.

Exclusion Criteria:

1.
2.
3.

Method of Recruitment:

Describe how subjects will be recruited; including how prospective subjects will be identified and how initial contact will be made. Include description of any recruitment tools (i.e. advertisements) that might be used.

Study Procedures:

Randomization: (describe randomization procedures)

Intervention: (Identify what is standard and non-standard of care where possible)

Study visits: (Identify all procedures, including outcome, length of visit, how many visits, and over what period of time. Also identify data to be collected at each visit)

Follow-up visits: (Timeline and type of data collected specific for each visit. Include rationale for follow up time intervals (e.g. baseline, 3 months, and 6 months)

Data collection: (include all data collection tools including site selection and time frame for data collection. Also describe how validity and reliability of data collection will be verified)

Analytical plan:

Sample size

Indicate how many subjects you will recruit for the study: total number and subgroups (if applicable). Provide the method used and rationale in determining the sample size.

Statistical plan:

Explain how missing data and outliers will be handled in the analyses. Also include the variables and confounding variables to be analyzed, the time point(s) (e.g. at baseline), and how these are to be reported (e.g. means, standard deviations, proportions).

Ethical considerations

Potential benefits: (you must indicate that there may be no benefit to participants)

Potential risks: (you must list a data breach as a potential risk)

Subject Safety Provisions:

REFERENCES