

PROTOCOL DEVELOPMENT FORM

INVESTIGATOR'S INFORMATION

Investigator's
name: _____

Date: _____

Department: _____

RESEARCH

Research Question:

Significance:

HYPOTHESIS

Study Hypothesis:

Study "null" Hypothesis:

VARIABLES

Independent (Intervention):

Dependent (Outcome):

Extraneous (Confounding) list at least three:

- 1.
- 2.
- 3.

STUDY DESIGN

Proposed Study Design (e.g., RCT, cohort, cross sectional):

Sampling Method:

Randomization? (If yes, how):

Study Size Calculation

1. What is the expected rate of the dependent variable in the study population? _____
What is the percent of absolute (not relative) differences in the primary outcome measure that would be clinically significant to detect in your study? _____
What are desired alpha _____ and desired beta _____ and anticipated variance? _____
Is variance expected to be normally distributed and similar between groups? _____
2. Perform sample size calculation for your study (e.g., using computer program or statistician).
How many study subjects will you need in each group?

INCLUSION AND EXCLUSION CRITERIA FOR YOUR STUDY

Inclusion Criteria

Exclusion Criteria

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.

MEASUREMENTS

Proposed Study Measurements (e.g., Hct, Pain): How measured (ABG machine, VAS, etc.)

Initial

- 1.
- 2.
- 3.

Post Intervention

When (timing)

- 1.
- 2.
- 3.

Method of validation of Primary Study Measurements or Scales:

List an appropriate statistical test or analysis for the major outcome measurement(s) above:

- 1.
- 2.