# CGE RESEARCH INSTITUTE

# PROTOCOL OUTLINE

Title of Research

Principal Investigator

Other investigators

Institutions

**I. BACKGROUND AND SIGNIFICANCE**

A. Background information on condition or problem to be studied
B. Previous studies looking at the same problem/literature review
C. Why this research is important and why it is significant, relevant and needed.

**II. STUDY OBJECTIVES/RESEARCH QUESTION (SPECIFIC AIMS AND/OR HYPOTHESES)**

A. **What is the research question? What is the question that the researcher is trying to answer?** A research question is a question that the researcher sets out to answer. Good research questions seek to improve knowledge on an important topic. The research question needs to be concisely and accurately stated. It is the most important step in the research process.
B. What hypotheses are to be tested? (null hypothesis/alternative hypothesis)

**III. METHODS**

A. Study Design
    1. Definitions
    2. Prospective/retrospective/controlled/randomized/observational
    3. Study drugs, device, or intervention
    4. Randomization/sampling (if appropriate to the design)
    5. Instruments/equipment for measurement of variables
    6. Measurement Variables
        a. Independent variables (drug dose/that which the researcher manipulates, etc.)
        b. Dependent variables (outcome variable/endpoint)
B. Study Population
    1. Human/animal/
    2. Inclusion/exclusion criteria
    3. Experimental vs control group
C. Assessment of Resources

    Indicate how the investigator will ensure that the study:

    1. Has sufficient access to the study population (humans/animals).
    2. Has sufficient time to conduct and complete the study.
    3. Is qualified to carry out the details of the study.
    4. Facility is adequate (with adequate equipment) to carry out the research.
    5. Researcher and staff are adequately trained and have the skills to carry out the experiment.
D. Study Procedures
    1. Plans for recruitment/securing patients/animals.

2. Procedures for handling patients/animals (storage, etc.).
3. If a drug study, include instructions for administering drugs, etc.
4. For preparation of animals explain the source and how the animals will be prepared.
5. For biological samples, explain how they will be collected, stored, as well as testing and disposal methods.
6. If instruments are to be used to measure samples, state exactly how this will be done with what equipment, etc. List the qualifications of the person who will be using the equipment.

**IV. DATA COLLECTION**

A. How and what data will be collected (by whom).
B. Create and have approved a "data collection form".

**V. DATA ANALYSIS**

A. Sample size calculations
   1. Power analysis and sample size calculations (if appropriate).
B. Sampling methodology
   1. Random sampling
   2. Convenience sampling
C. Statistical methodology
   1. Create "dummy data" and choose the appropriate statistical test.
   2. Choose the level of significance considered appropriate to conclude a significant difference between groups.
   3. Using the "dummy data" do the statistics.

**VI. ANTICIPATED RESULTS**

A. What results does the researcher expect?

**VII. STUDY LIMITATIONS**

A. Potential limitations of the study design, etc.

**VIII. ETHICAL CONSIDERATIONS**

A. If animal study, does the design comply with animal study requirements.
B. If human study, is the study in compliance with the Helsinki protection of human rights guidelines?
   1. Is informed consent required?
   2. Risks and side effects?
   3. Adverse events?

**IX. PLANS FOR DISSEMINATION OF INFORMATION**

A. How does the researcher plan to disseminate the results of the research?
B. Create graphs and charts using the "dummy data" to illustrate how the data will be presented and explained.
C. What are the plans for publication of the results of the research?

**X. REFERENCES**

A. List all references.

**XI. APPENDICES**

A. Instruments, rating scales, consent forms, data collection forms, examples of statistical analysis of "dummy data", graphs and charts of the results.