**PROTOCOL**

**Study** **Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Co-Investigator(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Staff: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Sponsor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**IRB #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Version #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Initial Document Approval Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**A.0 ABSTRACT**

**B.0 SPECIFIC AIMS**

**B.1 Specific Aim 1**

To …

**B.2 Specific Aim 2**

To…

**C.0 BACKGROUND AND SIGNIFICANCE**

**C.1. Title of Topic**

The …

**C.2 Title of Next Topic**

The …

**D.0 PERSONNEL AND PRELIMINARY DATA**

**D.1 Principal Investigator(s)….**

**D.2 Preliminary Data**

**E.0 RESEARCH DESIGN AND METHODS STUDY FLOW**

 (The sections below may be different depending on the research you are conducting and your study design. Diagrams are recommended.)

**E.1. Overview**

**E.2 Recruitment**

**E.3 Description of Participant Population**

**E.3.1 Inclusion Criteria**

**E.3.2 Exclusion Criteria**

**E.4 Screening for Eligibility**

**E.5 Screening Visit**

**E.5.1 Procedures at the screening visit**

**E.6 Experimental Groups (or Cohorts)**

**E.6.1 Control Group**

**E.6.2 Experimental Group**

**E.6.3 Experimental Group**

 **E.7 Informed Consent**

 **E.8 Data Collection and Sources**

**5.8.1 Confidentiality and Data Storage**

 **5.8.2 Data Integrity**

 **E.9 Risks and Benefits**

 **E.10 Statistical Analysis**

**F.0 Conclusion, Summary and/or Benefits of the Knowledge Gained**