**Title:**

**Principal Investigator:**

**Co-Investigator(s):**

**Affiliation(s)**

**Abstract:**

**Background:**

**Aim:**

**Hypothesis:**

**Setting:**

**Design:**

**Conclusion:**

**A. Hypothesis and Specific Aims:**

**B. Background and Significance**

**D. Research Plan**

1. **Study Population:**

Inclusion Criteria:

Exclusion Criteria:

1. **Subject Recruitment and Enrollment:**
2. **Plan for Obtaining Consent/Assent**
3. **Privacy protection and Data Confidentiality:**

1. **Study Design:**

**Study Procedure:**

**E. Statistical Methods**

1. **Gender/Minority/Pediatric Inclusion for Research**
2. **Assessment of Resources:**
3. **Risks and discomforts and how minimized**
4. **Compensation for injuries**
5. **Benefits to subjects**

**K. Costs to subjects**

**L. Alternative to participation**

**M. Payment to subjects**

**N. Provisions for subjects from vulnerable populations**

**O. Data and safety monitoring plan**

**P. Plans for subjects at the end of the protocol**

**Q. Literature Cited**