***Maximum of 2 pages when completed***

**PLEASE CHANGE YOUR FONT SIZE TO “12” BEFORE COMPLETING.**

**DATE:** Click or tap to enter a date.

**STUDY TITLE:**

**PRINCIPAL INVESTIGATOR:**

**CO-INVESTIGATOR:**

**Co-Investigator Signature:**

***(I attest that I have read and agree to the proposed study protocol.)***

***Has the study been discussed at a working group session? Yes  No***

**PLEASE INCLUDE THE DATA COLLECTION FORMS ASSOCIATED WITH THE STUDY.**

Are Collection form attached?

**ESTIMATE THE TIME COMMITMENT ASSOCIATED WITH THE STUDY:**

**1. Principal Investigator estimated time per subject visit/per collection of required data:**

**2. Study Coordinator estimated time per subject visit/per collection of required data:**

1. **SYNOPSIS**:

2. **BACKGROUND AND SIGNIFICANCE**:

3. **HYPOTHESIS AND OBJECTIVES:**

4. **STUDY POPULATION:**

5. **METHODS:**

6. **RECRUITMENT:**

7. **JUSTIFICATION FOR USE OF PLACEBO:**

8. **JUSTIFICATION FOR THE USE OF HEALTHY RESEARCH SUBJECTS:**

9. **RISKS:**

10. **RISK MINIMIZATION:**

11. **PREGNANCY:**

12. **BENEFITS:**

13. **CONSENT AND ASSENT:**

14. **DATE/SITE:**

Include the estimated study endpoint date.

15. **MONETARY COMPENSATION:**

16. **BUDGET:**

17. **CONFLICT OF INTEREST:**

18. **REFERENCES:**