**Protocol ###, Title**

**Sub-study Form**

**Last Updated: [Date]**

**IRB Protocol Number:**

**Sub-study Number (Internal Lab Number):**

**Date:**

**Sub-study Lead Investigator’s name:**

**Sub-study Additional Investigators:**

**Title of Sub-study:**

**Abbreviated Title:**

**Type of sub-study:**

(E.g., exploratory, hypothesis-driven, training | randomized controlled trial with intervention, cross-sectional, observational, etc.)

**Description of Study:**

Background and Rationale:

Study Aims:

Study Hypotheses:

Big Picture Takeaway (in 3 sentences or less): If successful, this study will demonstrate…

**Methods & Procedures:**

This sub-study will require use of the following procedures:

Overall protocol:

Detailed protocols for each procedure:

**Subject Accrual Planned:**.

**Subject Accrual Rationale (Power Analysis):**

**Who will be consenting the subjects?**

**What is the timeline for completing the study?**

**Payment for subjects:**

**Are all methods and procedures in compliance with the protocol?** Yes

**Progress Updates:**

*Use this section to record updates on subject accrual, changes in the methods/procedures, or other changes of relevance to this sub-study.*