**Primary Reviewer Draft Outline for Initial Study Oral Presentation**

**Study Number:**

**PI:** **Department:**

**Funding Sponsor: NIH Concordance Declaration: Y/N**

**Phase: \_\_\_Pilot \_\_\_1 \_\_\_2 \_\_\_3 \_\_\_4**

**Primary Objective(s) of the study:**

**Secondary Objective(s) of the study:**

**Study Design:**

**Study Population: \_\_\_adults only \_\_\_minors \_\_\_\_vulnerable populations \_\_\_number to be enrolled**

**Investigational Drug or Device? #\_\_\_\_\_\_\_\_ Holder of IND/IDE:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ NSR: Y/N\_\_\_\_**

**Questions/Concerns:**

**Consent Form Recommendations:**

**Stipulations:**

**Recommendation & approval period:**