**Primary Reviewer Draft Outline for Amended Study Oral Presentations**

**Study Number:**

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

**Study Population: \_\_\_adults only \_\_\_minors \_\_\_\_vulnerable populations, who:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

 **\_\_\_\_\_\_\_\_number to be enrolled \_\_\_\_\_\_\_\_\_number approved by IRB \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Study Length**

**Summarize requested changes to the study protocol *(Don’t need to cut & paste unless you want to from the submission):***

 **Reason for requested changes:**

**PR Questions/Concerns:**

**Stipulations:**

**Recommendation: \_\_\_\_\_\_\_\_Approval\_\_\_\_Approve with Stips \_\_\_Defer \_\_\_\_Suspend/Stop**

**Recommended Approval Period:**