***PROTOCOL #*** IRB- **Primary Reviewer:**

 **Secondary Reviewer:**

1. **Introductory comments-** Please outline the research question being asked and the study design.

1. **Considerations For Review:** Please indicate if the following areas are acceptable as wrtten. if not, pleae discuss concerns and required changes

**Acceptable?**

Y [ ]  N [ ]  Scientific Rationale

Y [ ]  N [ ]  Study Design

Y [ ]  N [ ]  End points N/A

Y [ ]  N [ ]  Project and Accrual Feasibility

## Y [ ]  N [ ]  Safety

Y [ ]  N [ ]  Correlative Laboratory Studies

Y [ ]  N [ ]  study staff issues

Y [ ]  N [ ]  Priority N/A

 **Comments:**

1. **Does this trial overlap with any existing trials? Y** **[ ]  N** [ ]   **If yes, please discuss.**

1. **Are there any potential problems in Performance, Quality Assurance or Regulatory Issues?**

**Y [ ]  N** [ ]   **If yes, please discuss.**

1. **Other Required Changes/Clarifications:**

**6. RISK ASSESSMENT**:

[ ]  Research not involving greater than minimal risk

[ ]  Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

[ ]  Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

1. **RECOMMENDATION**

[ ]   ***Approval*** (no changes required; protocol ready for IRB review as is)

***[ ]  Conditional Approval*** (minor changes/clarifications required; administrative or reviewer approval of revised document/response necessary prior to IRB review)

***[ ]  Deferral*** (requires significant clarification/modification; response requires re-review by full committee)

***[ ]  Disapproval*** (protocol terminated; if desired, PI must revise & resubmit as a new protocol)