***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)