**SCIENTIFIC REVIEW OF RESEARCH INVOLVING HUMAN SUBJECTS**

**DIRECTIONS:**

**Scientific merit review is required for non-exempt, investigator-initiated research that has not undergone peer-review by groups such as NIH, PCORI, AHA, PRMC, Frontiers or dissertation/thesis committees.**

**Use this page only when the scientific merit is provided by an individual or committee within the KUMC Department, Division or Center. The scientific merit evaluation must be provided by an individual who is not part of the study team.**

Principal Investigator:

Protocol Title:

1. Is the rationale for the study clearly stated and is the rationale scientifically sound? Yes  No
2. Are the specific aims and objectives of this study clearly stated and measurable? Yes  No
3. Is the study design scientifically sound? Yes  No
4. Does the research use procedures that are scientifically sound, that are appropriate to Yes  No

the study, and that do not unnecessarily expose subjects to risk?

1. Is the study design adequate to achieve the specific objectives of this study? Yes  No
2. Are the principal and any other investigators well qualified to conduct this study? Yes  No
3. Are the data to be collected necessary to meet the objectives of the study? Yes  No
4. Are study facilities and resources adequate for safe conduct of the study? Yes  No
5. Are statistical considerations, including sample size, estimated accrual and Yes  No

duration, and statistical analysis clearly described, adequate, and appropriate

for the study objectives?

1. Does the knowledge expected to be gained from this study have scientific importance? Yes  No

Comments:

Name of Reviewer:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Reviewer (for paper signatures)**\*** Date

**\***In lieu of a paper signature, this document may be saved electronically and uploaded into the

eIRB system by the reviewer.