**SCIENTIFIC MERIT AND ADMINISTRATIVE CERTIFICATION**

**FOR RESEARCH INVOLVING HUMAN SUBJECTS**

**DIRECTIONS: Use this supplemental form when the department chair or division/center director is providing both the Scientific Merit review and the Administrative Certification. This document must be signed by an individual who is not a member 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

Based on this review, the scientific merit of this proposal is: [ ]  Confirmed [ ]  Not confirmed

Department/Division/Center:

This review was conducted by:

[ ]  Department Chair/Division or Center Director

[ ]  Chair/Director Designee

Comments:

Name of Reviewer:

**Administrative Certification**

As Department Chair, Division/Center Director or designee, I approve the submission of this proposal. The principal investigator is qualified, and adequate resources (in terms of time, assistance, equipment, support services and finances) are available to safely conduct the research and protect the participants. The investigator has access to a population that will allow recruitment of the necessary number of participants. The investigator has access to medical or psychosocial resources that participants might need as a consequence of the research.

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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.