OFFICE OF THE INSTITUTIONAL REVIEW BOARD

| Standard Operating Procedures | | |
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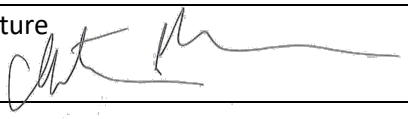
| **SOP #203.3 Revision 3** | **TITLE: Review of Scientific Validity and Merit** | Effective Date: 3/1/2019 |
| Approved By: OIRB Director | Signature  | Date 3/1/2019 |
| Approved By: IRB Chair | Signature  | Date 3/1/2019 |

**PURPOSE**
To describe policy and procedure for conducting the review of scientific validity and merit of human research projects.

**REVISIONS FROM PREVIOUS VERSION**
Add FDA reference and administrative changes

**POLICY**
The requirement for a determination of adequate scientific validity or scholarly merit of proposed research projects can be met in one of the following ways:

1. Review by the department chair/center director/designee in which the Principal Investigator (PI) is administratively located for purposes of leading or supervising the research;
2. For graduate student thesis or dissertation research, review by the student's dissertation or master's thesis committee chair (if allowed by the department);
3. For externally funded research, documented (scored) peer review.

The scientific review process evaluates the soundness of the research design, the ability of the research to answer the proposed questions and provides the IRB the information it needs to determine whether regulatory criteria for approval are met (i.e. risks to participants are minimized by using procedures consistent with sound research design, and risks to participants are reasonable in relation to anticipated benefits, if any, and the important knowledge that may reasonably be expected to result). The signature of the reviewer indicates that the research design and procedures meet the department's disciplinary standards for scholarly or scientific merit and validity.

Because the IRB is ultimately responsible for assessing both the potential benefits of proposed research and the adequacy of minimization of its associated risks, final decisions regarding the validity and merit of the research as it pertains to the minimization of risk to research participants are the responsibility of the IRB.

**RESPONSIBILITIES**
Execution of SOP: OIRB Staff, IRB, Researcher, Department Chair/Center Director/designee or Graduate Student Committee Chair

**PROCEDURE**
1. Proposed new human research projects are to undergo scientific validity review by a thesis/dissertation committee, Chair/Center Director or designee, or external funding peer review

within the primary scientific discipline relevant to the research. Such review is to encompass scientific merit, adequacy of research design, and available resources.

2. Researchers will submit a copy of the signed Scientific Validity Review form or documentation of external peer review (by NIH, NSF, etc.) via IRBNet with other submission documents.
3. It is the responsibility of the PI to ensure the scientific validity review has been completed according to department policy.
4. No protocol will be reviewed by the IRB unless and until the scientific validity review has been completed. Exceptions may be made at the discretion of the IRB Chair/HRPP Director.

**REFERENCES**

45 CFR 46.111
21 CFR 56.111
28 CFR 512.11(a)(2)
Scientific Validity Review Form