

Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 108	
CHAPTER: Institutional Review Board	ISSUED: 4/2010	REVISED/REVIEWED: 12/2010; 11/2013
POLICY: Scientific/Methodological Review of Investigator-Initiated Research	PAGE 1 OF 3	

1. PURPOSE

This policy ensures that the conduct of research conforms to the highest standards of research methodology while most effectively minimizing risks to volunteer subjects, who are asked to participate in projects posing more than minimal risk and all clinical trials.

2. INTRODUCTION

This policy covers investigator-initiated research that has not been subjected to formal peer review. These types of studies shall be submitted for departmental, divisional, or other internal scientific/methodological review before submission to the IRB. The scientific/methodological reviewer(s) shall have the appropriate expertise to evaluate the scientific/methodological merit of the research protocol. Consistent with the Institute of Medicine's 2002 Report, *Responsible Research: A Systems Approach to Protecting Research Participants*, this policy is designed to allow the IRB to focus its efforts primarily on ethical issues regarding human subjects protection. These guidelines will enable those with the most relevant scientific/methodological expertise to have principal responsibility for assessing scientific/methodological merit. The IRB will continue to review issues of scientific/methodological design and subject safety.

3. STUDIES SUBJECT TO SCIENTIFIC/METHODOLOGICAL REVIEW REQUIREMENT

Prior to submission to the IRB, protocols (posing more than minimal risk and clinical trials) to conduct research that are Creighton University investigator-initiated shall undergo review for scientific/methodological merit, to include the following elements: background literature review, appropriate experimental design, statistical data analysis, and research subject risk assessment.

Examples of investigator-initiated research requiring departmental or divisional scientific/methodological review include those without external funding, or with:

- Funding granted to the investigator by national or local funding agencies, such as American Heart Association, American Cancer Society, etc., when this research does not receive external review.
- Industry-supported research that an investigator designs and initiates.

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- Any human subjects research (other than projects that qualify for exemption) that does not undergo external review.

Multi-center clinical trials in which the Creighton University investigator is not the Principal Investigator ordinarily will not need scientific/methodological review before submission to the IRB. Research protocols that qualify for exemption from federal regulations per 45 CFR 46.101(b) (exempt review categories 1 – 6) or expedited review do not require scientific/methodological review separate from the IRB review.

4. NATURE OF REQUIRED SCIENTIFIC/METHODOLOGICAL REVIEW

All projects that require review at a convened IRB meeting shall be subject to peer review. Before submission to the IRB, investigator-initiated research protocols shall be submitted to a departmental or divisional scientific/methodological review committee or representative. Reviewer(s) shall have appropriate expertise to evaluate the scientific/methodological merit of the protocol. The peer reviewer(s) shall review the protocol for adequacy of background literature review, appropriate scientific/methodological design, data analysis, and safety oversight. Additionally, as part of this review, the scientific/methodological reviewer shall determine whether the research uses procedures consistent with sound research design and whether the research design is sound enough to yield the expected knowledge. For more information on conducting scientific/methodological review, see IRB Document 108.2, “Guidance on Conducting Scientific/Methodological Reviews.”

Scientific/methodological reviewers shall be in a position to conduct an objective review of scientific/methodological design; therefore, the IRB shall not allow scientific/methodological reviews to be completed by a research team member on a given protocol.

After the peer reviewer(s) have completed the scientific/methodological review, the scientific/methodological reviewer(s) shall sign the “Reporting Form for Documentation of Scientific/Methodological Review” and submit it to the Department or Divisional Chairperson. The Department or Divisional Chairperson shall then sign the form to provide assurance that sufficient resources (either from the investigator’s grant or from departmental funds) shall be made available to conduct and monitor the study.

Peer review may also be conducted anonymously. If the reviewer(s) choose to remain anonymous, he/she shall submit the unsigned review form to the Department or Divisional Chairperson (or his/her designee as per school/department/division SOPs) for certification that the review was conducted. The Department or Divisional Chairperson

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shall then sign the form to provide assurance that sufficient resources (either from the investigator's grant or from departmental funds) shall be made available to conduct and monitor the study.

The IRB shall then conduct a standard review of the research protocols and related documents. All protocols that are deferred for a perceived lack of scientific/methodological merit or lack of safety monitoring shall be returned to the investigator. These deferred protocols shall be resubmitted for scientific/methodological review prior to resubmission to the IRB, and the resubmission shall have a review sheet attached that confirms review of the revised protocol.