

## Guidance

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# Conducting Scientific/Methodological Reviews

## Rationale for this Guidance Document

The Creighton University Institutional Review Boards (IRBs) are responsible for assuring that investigator-initiated research conforms to the highest standards of research methodology while most effectively minimizing risks to volunteer participants. In order to achieve this, both the Biomedical and Social-Behavioral IRBs require that research involving human subjects be reviewed for scientific/methodological merit by a Creighton University scientific/methodological reviewer *prior* to IRB review. If the research protocol being submitted does not have the benefit of peer review through a sponsor, then peer review from within the institution is required.

Evaluation of the scientific/methodological aspects of a research study may require specific expertise. As such, the CU IRBs have adopted policies and procedures that support accepting scientific/methodological review as internal peer review from appropriate disciplinary and content experts. This provides the IRB with assurances that they are approving meritorious research, similar to the assurances of peer-reviewed sponsored research projects.

Once the review is completed, the project is deemed meritorious, and it is determined that adequate resources are committed to conduct the project, the research protocol is submitted for initial IRB review, accompanied by the completed Reporting Form for Scientific/Methodological Review and any documentation generated by the scientific/methodological review committee.

## What is Scientific/Methodological Review?

*Scientific/methodological review* is a peer review process of applying expert knowledge of acceptable criteria to determine whether a research protocol is sufficiently meritorious to proceed. The process of review is applied to the written research *protocol*, which describes in detail how human participants are involved. The process of scientific/methodological review involves assessing the overall merits and identification of risks to human participants. Scientific/methodological review is a constructive process. The intent of the review is to assist investigators to meet a minimally sufficient set of criteria to conduct meritorious research.

## To Whom Does This Apply?

The process of review is applied to any investigator-initiated projects involving human participants by faculty, staff, residents, fellows, and students of Creighton University.

## Who Should Conduct the Scientific/ Methodological Review (also known as the “internal review”)?

- Faculty Research: The policies of the university require a scientific/methodological review committee to be used to fulfill the IRB requirements. It is generally considered best practice

to establish a peer review committee of a minimum of two reviewers, though more are preferred. The designation of more than one person may be impractical for some departments or divisions. In this case, faculty from other departments or schools may fulfill this responsibility. It is also a best practice to have the review performed by independent reviewers. Members of the research team should not participate in this review.

- **Student Research:** Students conduct research in such venues as summer student research programs, independent study, and degree-required coursework. Evaluations of student research projects can be accomplished several ways. One approach is to have the review conducted by the student's advisor or course instructor, depending on the venue of the research project. It is recommended that a review committee with at least one other faculty member be used as the reviewer when practical. The review committee may also include students; the primary motive being educational development opportunities for the student in the peer review process. Student project review is subject to the same rigor as faculty-initiated research.
- **Resident and Fellow Research:** The health professions also have post-graduate residents and fellows who conduct research. Resident and Fellow project review is subject to the same rigor as faculty-initiated research
- **Graduate Student Research:** Graduate students conduct research under the mentorship and direction of an advisor. Graduate student project review is subject to the same rigor as faculty-initiated research.

### **Who Is Responsible for Obtaining Peer Review?**

It is the responsibility of the Principal Investigator to establish a peer review committee of two or more individuals who are independent from the research project under review. These individuals must hold full-time academic appointments at Creighton University. The Principal Investigator solicits peer reviewers to participate.

### **What are the Responsibilities of the Review Committee?**

The scientific/methodological review determines the scientific/methodological acceptability of the project. The intent is to determine whether all aspects of a sound research project are addressed in the research protocol. While there may be differences of opinion among investigators and reviewers about the best scientific/methodological approach, this review is intended to be conducted to identify an acceptable approach. An acceptable approach would be a protocol that is designed using methodologies and ethical standards consistent with the particular discipline(s) while ensuring the safety and well-being of the participants. Reviewers are obligated to distinguish between acceptable (allowing the protocol to proceed) and their personal preferences (improvements beyond what is minimally needed to be sound and meritorious).

Departments may choose to have the scientific reviewer(s) remain anonymous to the investigational team. Any department that chooses this method must set up a process for anonymous scientific review to allow a scientific reviewer to remain anonymous. For any anonymous reviews that are conducted, the Departmental or Divisional Chairperson or a designee will sign the Reporting Form for Scientific Methodological Review certifying that the scientific review was conducted.

For reviews that are not conducted anonymously, documentation of the review process occurs when each reviewer signs off on the Reporting Form for Scientific/Methodological Review associated with IRB Policy108, "Guidelines for Scientific/Methodological Review of Investigator-Initiated Research." If the protocol is deemed sound and meritorious, no additional documentation of

deficiencies is needed, and the reviewers sign off on approval. If deficiencies are noted, these are documented in brief statements by each reviewer with the specific deficiencies that need correction noted; these statements are provided to the Principal Investigator, who then makes changes in the research protocol prior to approval. After incorporation of these suggested changes into the research protocol, the Principal Investigator files all of these documents with the Initial IRB review application.

### **What Happens if the Protocol Does Not Meet the Review Criteria?**

The review committee provides written documentation about the areas for improvement required in the research proposal. The Principal Investigator takes these recommendations and incorporates those that are appropriate into the research protocol. For recommendations that the Principal Investigator does not deem appropriate, the investigator should prepare a written justification in response. Both of these documents should be forwarded to the IRB when the proposal is submitted for IRB review.

### **What are the Recommended Review Criteria?**

Review criteria include the following:

- The names and affiliations of the investigators are included.
- The title is reflective of the project planned.
- The project's purpose is clearly described.
- A research question is clearly stated.
- Project aims are clearly stated and consistent with the proposed methodology.
- Project design is appropriate for the question.
- Research methods are appropriate for the design and research question.
- Sound rationale for the project is clearly described.
- The question posed or hypothesis being tested provides important knowledge to the field.
- Adequate literature review is described, consistent with the design and methodology.
- Adequate evidence is identified in the literature, or preliminary data from the investigator is provided, that is sufficient to justify the proposed research.
- There is a clear description of how project results are intended to contribute to the advancement of knowledge.
- Hypotheses or posits are clearly stated and consistent with the proposed research methodology.
- The research endpoints are clearly described.
- The validity and reliability of measures is established, or methods are proposed for establishing validity and reliability of the findings.
- The project setting and location are described.
- There is evidence that the investigators have access to the project setting and location.
- The proposed subject population is appropriate for the question and design.
- The number of participants anticipated to be included in the project is described.
- There is evidence that the investigators have access to the proposed subjects.
- The proposed sampling methodology is appropriate for the question and design.
- *If applicable*: The statistical considerations, including sample size and justification, estimated accrual and duration, and statistical analysis are clearly described and adequate to meet the project objectives.
- All of the proposed tests, measurements, or data collection processes requested are necessary to answer the question.

- Data collection and storage procedures that ensure the security of individually identifiable data are described.
- A plan for the destruction of records or removal of individual identifiers from the records upon research completion is described.
- *If applicable*: Whenever possible, the protocol uses data being collected from procedures already being used with the participants for non-research reasons.
- Any possible risk or discomfort that may be experienced as a result of participation is described.
- The protocol describes a process for monitoring data to ensure the safety and well-being of participants.
- The limitations of the proposed research protocol are identified by the investigator and are appropriate for the methodology.
- The Principal Investigator is qualified to conduct the study.
- The research team is qualified to conduct the study.

### **Are Adequate Resources Secured for Conducting the Protocol?**

No research should begin on any project if there are not adequate resources secured to begin it. The proposal should describe that the Principal Investigator has secured adequate resources to carry out the study. The department chair signature assures that there are adequate resources secured for the research protocol to be implemented.

### **What Happens if the IRB has Additional Scientific/Methodological Concerns?**

The IRB reviews the scientific/methodological design with an emphasis on human subject protection and may have additional requirements prior to approval.