**Scientific-Scholarly Review**

*What is Scientific Assessment?*

To justify the inclusion of human subjects in research, and to assess the balance between any risks that may be imposed upon human subjects, an assessment is required to evaluate the scientific question and appropriateness of the methods planned to answer the scientific question. The role of the IRB is not to assess science unless the project is so poorly designed that it affects risks or benefits.

The review must be performed by independent reviewers. Only one method of scientific review (see below) is required prior to review by the IRB.

**Applicability**

Scientific assessment is required for all human research. The actual protocol being submitted to the IRB must have been reviewed in its current form.

**Acceptable Methods for Scientific Assessment**

1. Nationally-based, federal funding organizations (NIH, NSF) when research projects have been subjected to full peer review (e.g., review by a study section or grant committee).
   - Peer review of a grant that describes a clinical trial in general terms **does not** satisfy this criterion.
   - Industry-sponsored clinical trials designed by the sponsor with or without external consultants **do not** satisfy this criterion for independent peer-review.

2. Nationally based non-federal funding organizations (March of Dimes, American Academy of Pediatrics) employing peer review mechanisms for awarding of funding
   - Peer review of a grant that describes a clinical trial in general terms **does not** satisfy this criterion.
   - Industry-sponsored clinical trials designed by the sponsor with or without external consultants **do not** satisfy this criterion for independent peer-review.

3. Locally constituted mechanisms using peer review for awarding of funding, or for permission to use resources, including:
   - Departmental peer review (Advisors may sign on behalf of students they mentor regarding scientific review)
Review Requirements
The scientific review should include assessment of the following:

- Is the rationale for the study clearly stated and is the rationale scientifically sound?
- Are the aims and corresponding hypothesis clearly stated?
- Is the primary outcome (and secondary outcomes, as appropriate) clearly defined?
- Are there adequate preliminary data in the literature (or from the investigator) to justify the proposed research? Has an adequate literature review been done to support this study?
- Is the question or hypothesis being tested providing important knowledge to the field?
- Is the design of the study appropriate for the questions that are posed?
- Have the validity and reliability of measures been established or are there methods proposed for establishing validity and reliability?
- Is the proposed subject population appropriate?
- Are statistical considerations, including sample size and justification, estimated accrual and duration, and statistical analysis clearly described and adequate to meet the study objectives?
- Are all the proposed tests or measurements requested necessary to answer the scientific question?
- Are the investigators well qualified to conduct this study?

Procedures to Satisfy Review

1. Select one of the scientific review methods.

2. Document fulfillment of the scientific review requirement and include with the IRB application submission.

   Note: Applications will not be reviewed by the HSRP until documentation of scientific review is provided.