



ASSESSING THE SCIENTIFIC OR SCHOLARLY VALIDITY OF A RESEARCH PROTOCOL

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During initial and continuing review of a research protocol, the DUHS IRB works together with other institutional and non-institutional review committees, departmental or Site Based Research (SBR) Group reviewers, and, when needed, independent consultants to assess the scientific or scholarly validity of a proposed research study.

The IRB uses a combination of methods to ensure a complete review of each proposed protocol's scientific or scholarly validity. Evaluation of the research proposal includes consideration of research design, subject selection process, randomization process, end point analysis, and the importance of the knowledge to be gained from the research. Prior to granting approval of a research protocol, IRB members consider the following questions in their review for scientific or scholarly validity:

- Will the investigator use procedures that are consistent with sound research design?
- Will the investigator use procedures that do not unnecessarily expose subjects to risk?
- Will the research design permit the investigator to answer the research question?
- What is the importance of the knowledge expected to result from the research?

The Role of Other Review Committees

The IRB values scientific or scholarly review by other institutional and non-institutional committees, such as the Duke Cancer Protocol Committee (CPC), the Duke Clinical Research Unit (DCRU) Scientific Advisory Committee, the National Cancer Institute (NCI) central Institutional Review Boards (cIRBs), and reviews carried out by representatives of the U.S. Food and Drug Administration, and in the case of NIH-funded studies, the NIH Integrated Review Groups (IRGs). In general, such reviews are conducted prior to submission of the research protocol to the IRB and must be completed prior to the protocol being considered by the convened board. The review group's findings are given to the IRB member who serves as the protocol's primary reviewer and are included in the protocol file.

The Role of Clinical Departmental or Site Based Research Reviewers

Review by representatives of the principal investigator's clinical department or Site Based Research (SBR) Group (where applicable) occurs prior to IRB submission. Reviewers are oriented to use the "DUHS IRB Protocol Submission Checklist - Departmental or SBR Reviewer" to consider whether the investigator will use procedures that are consistent with sound research design. It is the responsibility of the Reviewer(s) to contact the investigator to address and resolve any significant issues or concerns relative to the scientific or scholarly validity or research design prior to department or SBR approval and subsequent submission to the IRB. Requests for modifications, if not resolved prior to IRB review and if the request is confirmed by the IRB, will be incorporated with any additional requests from the convened IRB and conveyed in writing to the principal investigator.

Departmental or SBR review and approval is documented by the electronic signatures (on the submission form for new and continuing review applications) of the department IRB member or SBR reviewer (for clinical departments only) and the department chairperson or designee. The signature of a department chairperson (or designee) on an IRB protocol submission certifies that the proposed research protocol and consent form have been reviewed for scientific validity and quality and are recommended to the IRB for approval. In addition, the signature of the chairperson (or designee)



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certifies that the department or SBR Group and the investigator have the resources necessary to ensure the protection, care and safety of research participants during the conduct of the research, and to complete the research. Such resources may include staffing and personnel in terms of availability, number, expertise, and experience; psychological, social, or medical services, including counseling or social support services that may be required because of research participation; ancillary care and equipment needed to protect participants; and resources for participant communication, such as language translation services.

The Role of the Primary Reviewer

The primary reviewer, an IRB member who presents the protocol to the convened board, reviews the comments of the Departmental or SBR Reviewer and any other pre-IRB-submission reviewers to ensure that prior recommendations either were addressed by the investigator or are noted as requiring further consideration by the board. While the board's review does not require the level of disciplinary expertise necessary for merit or peer review by a funding agency, IRB members are oriented to perform a thorough and detailed review of the study and, if possible, to discuss and resolve any unanswered questions with the investigator before presentation to the convened board. All members are oriented in the use of the "Primary Review Checklist for New Protocols" and the "Primary Review Checklist for Continuing Review (Renewal) Protocols" which prompt reviewers to consider whether each of the criteria for IRB approval of research has been met (45 CFR 46.111 and 21 CFR 56.111).

The Role of Consultants

A consultant who is independent of the investigator and protocol may serve as an ad hoc reviewer when the IRB needs added scientific or scholarly expertise in a specific area. The expert must receive all relevant information available to the IRB in order to perform an in-depth review of the research, and must understand the background, aims and methods of the research. The consultant is asked to attend the IRB meeting to present his/her findings relative to the scientific merit of the study and risks and benefits to subjects, and to answer questions; however, if the consultant is unavailable to attend the meeting, s/he may provide written comments for distribution to the IRB members in attendance (See DUHS IRB Policy on Use of Consultants). The IRB does not delegate its responsibility to judge whether the regulatory criteria for IRB approval are met.

REFERENCES

45 CFR §46.111(a)(1)(i), 45 CFR §46.111(a)(2)
21 CFR §56.111(a)(1)(i), 21 CFR §56.111(a)(2)