

GUIDANCE: SETTING UP A DEPARTMENTAL REVIEW PROCESS

Background: The Institute of Medicine Report Research: A Systems Approach to Protecting Research Participants (2002) recommended that all protocols involving human participants should undergo an independent and rigorous scientific review to assess scientific quality, the importance of the research to increase knowledge, and the appropriateness of the study methodology to answer a precisely articulated scientific and, in some cases, clinical question. For example, the design of clinical trials should be based on sound statistical principles and methodologies, including sample size, use of controls, randomization, population stratification, stopping rules, and the feasibility of relating endpoints to objectives.

The Association for Accreditation of Human Research Protection Programs (AAHRPP) recommends that institutions have a process for evaluating scientific or scholarly validity. CPHS relies on one or more of the following mechanisms to determine that proposed research is scientifically valid before it can be approved:

- Draw on its own knowledge and disciplinary expertise,
- Rely on the knowledge and disciplinary expertise of others, such as review by a funding agency, an organizational scientific review committee
- Rely on expertise of department review committee or department chairs.

Objectives: The objective of initial departmental review is to assess scientific validity and feasibility of successful completion of the study. Ongoing departmental oversight will help to ensure that the research is progressing well and troubleshoot when there are unanticipated problems. The department review mechanism will achieve its objectives by:

- Facilitating conduct of research protocols which meet the department research goals.
- Advising on the scientific validity of proposed protocols.
- Assessing the feasibility of proposed protocol:
 - Whether the protocol would answer the research question,
 - Whether investigators are qualified by experience, education and training to conduct the research,
 - Whether the investigator has access to adequate resources including facilities and research staff,
 - Whether there are recruitment plan will be able to meet target accrual.
- Establishing prioritization for recruitment when there are multiple open protocols with similar eligibility criteria.
- Assist researchers to conduct research according to the good clinical practice guidelines.
- Oversee the progress of various projects in the department's research program.

Process: Department review may be achieved by several mechanisms depending on the size and breadth of research program.

- Review by Department / Division Chair
- Review by designated Faculty or Staff
- Review by Research Review Committee

Submission: Investigators should submit a research protocol and any other relevant documents including investigator brochures, consent documents etc. for review. Protocols may be

submitted by email or via iRIS. If the department wishes to use iRIS, prior arrangements would have to be made to enable routing to the Departmental Review Process. Protocol should contain all the basic elements (see attachment).

Departmental Review: Depending on the research profile of the department, reviews may be scheduled weekly, biweekly or monthly. The review should include the following:

- Review of new protocols
- Review status of all departmental / division trials

When a department chooses to set up a Review Committee, the Committee may assign Primary for each agenda item. The department may use a review checklist to ensure that all the issues have been covered. A template of the review checklist is attached, departments may customize this checklist to suit their needs.

Support: The department review program should have administrative support. The administrator should help coordinate submissions from investigators, arrange committee meetings (or meetings between reviewer and investigator), issue outcome letters and facilitate communication and timely reviews.

Outcome: The possible outcomes of departmental review may be:

- May proceed for IRB review
 - Approved without comments.
 - Approved with suggestions for improvement.
- Deferred
 - Substantive issues need to be resolved before approval.
- Disapproved
 - Study may not proceed in its current state.

Attachments:

- [Protocol template](#)
- [Departmental Review Form](#)