II1 PR1 Reviewer Expertise for Evaluating Scientific Validity and Scholarly Merit

Overview

The regulations for Institutional Review Boards (IRB) membership require that members have varying backgrounds and expertise, and that members are sufficiently qualified through experience and expertise to promote complete and adequate review of research activities commonly conducted by the institution.

Appointments of voting IRB Committee members are made by the Institutional Official (IO) or the Office of Human Research Protection (OHRP) Director. Recommendations for board members come from a variety of sources. The IRB Chair or designee may request recommendations for faculty volunteers from the following:

- department chairs, deans or other responsible officials,
- institutional leadership, or
- investigators involved in research studies currently or previously approved by the IRB.

I1A Insuring Availability of Expertise

As needed, but at least annually, the IRB Chair or designee reviews the membership rosters to identify requirements for committee composition; and member knowledge, expertise and experience and will seek recommendations for committee members. These are often targeted searches to fill a specific need on the IRB.

The IRB Chair or designee will review each new member's curriculum vitae (CV), resume and demographic information (when available) for educational background, work history and her or his current vocation to determine the member's status (i.e., scientific versus non-scientific, affiliated vs. non-affiliated) on the IRB rosters. The Chair or designee will also identify areas of expertise based on the member's research, teaching experience or both. This information may be obtained from the CV or the member.

Members' areas of knowledge and expertise are recorded in the rosters for use by the Program Manager when assigning protocols to reviewers. Members' CVs are posted to IRBManager should one wish to further define a member's expertise.

For research involving primarily biomedical intervention, the primary reviewer will be a physician or health care practitioner with adequate expertise in the area of the research; the secondary reviewer will be another physician or a scientific member of the committee. The secondary reviewer's primary responsibility will be to review the consent document to ensure readability.

For social behavioral and psychosocial research, the primary reviewer will be a scientific member with adequate expertise in the area of the research. Social behavioral reviews generally do not require a secondary reviewer.

The IRB will seek the expertise of consultants or ad hoc reviewers if the IRB chair or the OHRP Director or Program Manager determines that the current membership of the IRB does not include the expertise necessary to evaluate the proposed research for scientific soundness and scholarly validity, and to assess subject risks and research benefits.

I1B IRB Review

The checklist for new protocols requires reviewers to assess scientific validity and scholarly merit by considering multiple, relevant factors such as:

- soundness of research design,
- reasonableness of hypothesis or study purpose,
- degree to which endpoints are defined,
- appropriateness of data analysis plan, and
- strength and relevance of background information.