REVIEW ASSIGNMENTS OR, WHAT TO DO WHEN YOU ARE NOT ASSIGNED TO REVIEW A SPECIFIC PROTOCOL

Prior to each convened meeting, members are asked if they will attend the meeting. This is necessary to determine whether the requirement for quorum is met and that members with the appropriate scientific expertise will be in attendance. The IRB Chairpersons or designee reviews the agenda and list of members expected to attend and assigns reviewers to each protocol.

When making reviewer assignments, the IRB Chairpersons and alternates take into consideration the scientific area or discipline, the study population, and study procedures and the experience and expertise of the members attending the meeting.

Assignments are made based on the member's knowledge and expertise. When the agenda includes protocols that involve vulnerable populations, the IRB Chairpersons or designated alternate(s) are responsible for ensuring that at least one member attending the meeting has knowledge and experience in working with the study population. Partners IRBs reserve the right to reschedule protocols for review based on the experience and expertise of the members attending the IRB meeting.

When assigning primary and secondary reviewers, consideration is given to the reviewer's area of experience and expertise (e.g., pediatrics, obstetrics, neonatology, neurology, psychiatry) and representative capacity (i.e., physician scientist, nonscientist, other scientist).

Typically the primary reviewer is a physician scientist or other scientist with experience and expertise in the type of research under consideration, though this is not an absolute requirement, depending upon the type of study.

The secondary reviewer is typically an individual who can provide another perspective, for example, lay person, genetic counselor, nurse or parent. The secondary reviewer, therefore, complements the scientific expertise of the primary reviewer.

Both the primary and secondary reviewers are expected to fully and carefully review all aspects of the protocol, consent form and associated materials, including when applicable, the NIH grant application, with particular focus on "Section E" related to human subjects involvement.

The primary reviewer presents a brief synopsis of the research protocol, with the expectation that the other members have reviewed the protocol materials. The primary reviewer is expected to cover study design, how the research differs from and compares to standard care, rationale for subject selection, appropriateness of the inclusion/exclusion criteria, risks, benefits and alternatives, and other points relevant to implementation of the study. The primary reviewer is expected to refer to the reviewer worksheet and the document “Points to Consider” for the regulatory requirements for IRB approval, required elements for consent forms, and issues to consider. These documents are provided with the agenda and review materials.

Primary reviewers are encouraged, though not required, to contact the principal investigator if they have questions about the protocol, particularly if there are significant concerns related to the study, or the reviewer believes additional information is needed for the Committee to assess the risks and benefits.

Secondary reviewers are asked to present any additional clarifications or commentary on the study plan, and any questions or concerns, or modifications required for approval.

After the primary and secondary reviewer has presented the study and review comments, the protocol is opened up for discussion by the IRB members. The Chairperson may direct specific questions to the assigned reviewers or other members of the IRB with specific expertise or viewpoints (e.g., a layperson, nurse or other member who may bring a different perspective to the discussion).

Both the primary and secondary reviewers are asked to evaluate the consent form carefully. Both general comments on the reading level and style of the consent form are expected from both reviewers, as well as detailed suggestions for improvement. Consent form comments may be handwritten on the form, or provided in written commentary as part of the review.

Members who are not assigned to specific protocols on the agenda are expected to review the protocol summary, consent forms and any study specific items such as questionnaires or survey materials, as well as advertisements for subject recruitment.