

UCLA INSTITUTIONAL REVIEW BOARD (IRB) Member Standards and Responsibilities Document (Last updated August 22, 2011)

Members of the IRB provide an invaluable service to the UCLA research community. Faculty, staff and community members participating on IRBs have an obligation to maintain the highest standards of judgment relative to their duties as members. This document provides an overview of each member's responsibilities related to performing IRB reviews at UCLA.

Regular Attendance:

- Voting members of the IRB establish the committee quorum; therefore, members are expected to attend at least three-quarters of convened meetings annually (18 of 24 meetings).
- Voting members are expected to arrive promptly and stay at convened meetings until all committee business has been completed, whenever possible.
- When attendance is not possible, IRB members must notify the HRPP staff allowing sufficient time in advance of the meeting to locate an alternate member to reach a quorum. Because member packets are prepared and sent to members a week before the meeting date, members should whenever possible notify staff at least one week if not two weeks before the meeting date that they will not be able to attend a meeting.

Knowledge of Federal Regulations and University Policies and Procedures:

In order to gain and increase knowledge of the ethical, regulatory and procedural requirements for reviewing and approving research involving human subjects IRB members are

- Expected to participate in initial orientation and ongoing training as provided at the regular IRB meetings.
- Expected to understand the three basic ethical principles of the [Belmont Report](#) (i.e., Respect for Persons, Beneficence, and Justice).
- Either use or have a working knowledge of the [UCLA IRB Reviewer Checklists](#) (i.e., UCLA General Campus Review Checklist and/or UCLA Medical IRB Reviewer Checklist).
- Expected to be familiar with the [OHRPP website](#).
- Expected to be familiar with the criteria for IRB approval of research (i.e., [45 CFR 46.111](#), and [21 CFR 56.111](#) when the research is regulated by the Food and Drug Administration).
- Encouraged to participate in training opportunities offered outside of the IRB meetings.

Meeting Preparation and Review of Protocols:

- Members are expected to conduct a systematic evaluation of the assigned protocols according to
 - The 3 principles in the [Belmont Report](#),
 - The federal criteria for IRB approval of research ([45 CFR 46.111](#), and [21 CFR 56.111](#) when the research is regulated by the Food and Drug Administration),
 - And the policies and procedures described on the [OHRPP website](#).
 - The full list of requirements is in the [UCLA IRB Reviewer Checklists](#).These requirements are provided to each member, posted on the website, and available at the meetings.

- **Primary reviewers** are assigned a study based on their particular expertise in relation to the study. The primary review is expected to present a brief oral summary of the application at the beginning of the committee discussion and then to provide detailed comments about the protocol, and consent forms if appropriate (typically requests for additional information or revisions). A **secondary reviewer** is also assigned as backup and to provide additional comments and sometimes to provide comments in a particular area. These sets of comments should be written and handed in to the Committee Administrator, either before or after the meeting as directed by the Committee Chair. The primary and secondary reviewers will recommend a committee action.
- **All members** are expected to be familiar with all protocols on the agenda.
- At the end of the committee discussion, members will vote on the outcome of the review: approved, accepted pending modification, deferred, tabled, or disapproved.

Maintaining Confidentiality

- Service on the IRB includes the review of documents that contain personal, confidential and proprietary information. Members of the IRB are responsible for maintaining all committee proceedings and documents in strict confidence. Such information may not be used for any purpose other than the IRB review and may not be disclosed to anyone outside of the IRB unless permission is granted in writing by the Vice Chancellor for Research.
- The one exception to this is that it is permissible but by no means required for IRB reviewers to contact a PI before the meeting to obtain additional information that may be helpful in reviewing a particular protocol. This contact should be disclosed at the meeting.

Conflict of Interest Disclosure:

It is the expectation of the University that IRB members will voluntarily recuse themselves from review and discussion of research protocols if they have a conflict of interest. Members of the IRB must disclose to the IRB Chair or Administrator any undisclosed conflict of interest that may arise in the review of research or compliance matters for the IRB. See [IRB Member Conflict of Interest Policy](#) for detailed information. A summary of these requirements are below:

- Members who are an investigator or faculty sponsor on the project under review, or whose spouse or child is an investigator or faculty sponsor, must recuse themselves from committee action.
- Members who believe existing circumstances may directly affect their objectivity may request that they be recused from committee action.
- Members who have any disclosable financial interests (a) that would reasonably appear to be affected by the research; or (b) in entities whose financial interests would reasonably appear to be affected by the research, must recuse themselves from committee action.

Subcommittee Service:

IRB members may be asked to serve on an IRB subcommittee and are expected to do so whenever possible. The following are examples of subcommittee activities:

- Federal regulations and IRB procedures allow some reviews to be accomplished by an IRB subcommittee outside of the monthly meeting. Voting members may be assigned as expedited reviewers and are responsible for providing written comments, when necessary, to the OHRPP staff in a timely fashion.
- The Chair may appoint an *ad hoc* committee to meet with an investigator to discuss a project.
- The Vice Chancellor for Research may appoint an *ad hoc* committee to investigate an allegation of noncompliance.
- IRB members may be asked to provide feedback or advice with special projects or initiatives including but not limited to the development of webIRB, the revision of consent forms, and the development of guidance.