| P&P: OR 203<br>Version No: 1.1<br>Effective Date: 10/1/2009 | DUTIES OF IRB MEMBERS | Supercedes: CPHS Policies and Procedures 11/1/2007 |
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## 1. POLICY

The primary responsibility of IRB members is the protection of the rights, safety, and welfare of the individual human beings who are serving as the subjects of research. In order to fulfill their duties, IRB members are expected to be versed in regulations governing human subjects protection, research ethics, and the policies of University of California Berkeley germane to human subjects protection.

**Specific Policies**

### 1.1 Duty to the University of California at Berkeley

The IRB is appointed as an Institutional Committee. As such, the IRB members serve the institution as a whole, rather than a particular school or department. Therefore, members must not allow their own interests or those of their department to supercede their duty to protect the rights, safety, and welfare of research subjects.

### 1.2 Term of Duty

1.2.1 IRB members and IRB alternate members are expected to commit to a one-year term and, during that time, to fulfill certain duties. Each IRB member is expected to understand fully the duties of the IRB.

1.2.2 The IRB Chair(s) are expected to commit to at least a one-year term and, during this time, to fulfill certain duties. These duties will be described by the Institutional Official (IO, or his or her designee) or Director of the Office for the Protection of Human Subjects prior to appointment. The prospective IRB Chair is expected to understand fully the duties prior to accepting his or her appointment as IRB Chair.

### 1.3 Specific Duties

1.3.1 Members. In general, IRB members (or their designated alternates) are expected to read all full board applications and research protocols; and, to attend and participate in the review discussion and vote on each proposed research protocol at the convened full board meetings to which they are assigned. In addition, IRB members are expected to participate on special subcommittees as assigned by the IRB Chair and contribute to discussions of regulations and interpretations that lead to policies and investigator guidance.

1.3.2 There are four types of members (see definitions section of P & P: OR 201) who may vote:

A. Affiliated members. Individuals associated with the University of California Berkeley (UCB) in a variety of capacities.

B Nonaffiliated members. Nonaffiliated members are not currently affiliated with the institution and are not part of the immediate family of a person who is currently affiliated with the institution. They are expected to provide input regarding the local community (research context) and be willing to discuss issues and research from that perspective as well as to comment on the comprehensibility of the consent document.

C. Scientific members. Scientific members are expected to assess whether risks to subjects are reasonable in relation to anticipated benefits. These members should also be able to advise the IRB if additional expertise in a nonscientific or other scientific area is required to assess if the protocol adequately protects the rights, safety, and welfare of subjects.

D. Nonscientific members. Nonscientific members are expected to provide input on areas germane to their knowledge, expertise, and experience, professional and otherwise. Nonscientific members should advise the IRB if additional expertise in a nonscientific area is required to assess if the protocol adequately protects the rights, safety, and welfare of subjects, and/or to comment on the comprehensibility of the consent document.

E. Individual members of the IRB may meet more than one type as described above (i.e. a nonscientific member may be either affiliated or unaffiliated with UCB).

1.3.3 Primary and Secondary Reviewers

In addition to the duties described in section 1.3.1, each member will be expected to act as a Primary Reviewer for assigned protocols at convened meetings. Secondary Reviewers may also be assigned as needed based on expertise, experience or other germane criteria. The Primary and Secondary Reviewers present their findings resulting from review of relevant materials, provide an assessment of the soundness and safety of the protocol, and recommend specific actions to the IRB. The reviewers may be required to review additional material requested by the IRB for the purpose of study approval.

1.3.4 Delegation of Responsibilities

The Chair(s) are responsible for managing committee discussion and deliberation and ensuring that all members who may wish to comment, do so. They also have primary responsibility for expedited (subcommittee) reviews.

The Vice Chairs are expected to participate on a regular basis in assisting the Chair with his or her IRB duties. An Acting Chair as appointed by the IO may also be called upon to participate on an as needed basis to assist the Chair with his or her IRB duties.

The Chair may appoint an IRB member to assist or act on his or her behalf in particular IRB matters on a case-by-case basis (e.g. If the Chair must recuse him/herself from the vote on a particular protocol and a Vice Chair or Acting Chair is not present to lead the meeting. This action would be noted in the minutes of a convened meeting). The Chair may also delegate any of his or her responsibilities as appropriate to other qualified (i.e. experienced) IRB member(s). Such delegation documentation should be in writing and maintained by the Director.

## 2. SCOPE

These policies and procedures apply to all IRB members.

## 3. RESPONSIBILITY

The IO is responsible for appointing the Chair(s) and Vice Chair(s) of the committee(s).

The IO and AVCR-RAC are responsible for providing resources to support continuing education of OPHS Administrative staff members, IRB Chairs, and IRB members.

The IO (or his or her designee) and OPHS Director are responsible for clearly articulating all IRB members' duties to potential and current IRB members, periodically reviewing members' duties to ensure that members are carrying out their expected functions, and evaluating whether there is adequate staff support to ensure members are able to function as documented.

IRB Manager or Administrator is responsible for answering questions from IRB members as needed, and making recommendations to the Director regarding changes to staffing, training, meeting scheduling, and other factors that affect members' ability to perform their responsibilities.

## 4. APPLICABLE REGULATIONS AND GUIDELINES

OHRP IRB Guidebook