

<b>P&amp;P: OR 201</b> <b>Version No: 1.3</b> <b>Effective Date: 5/21/2021</b>	<b>COMPOSITION OF THE IRB</b>	<b>Supersedes: CPHS</b> <b>Policies and Procedures</b> <b>9/8/2014</b>
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## 1. POLICY

Each IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. Each IRB should also be able to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

Therefore, each IRB must consist of at least five members. Qualified persons from multiple professions shall be considered for membership. The institution will make every effort to have a diverse membership appointed to the IRB, within the scope of available expertise needed to conduct its functions.

### Specific Policies

#### 1.1 Membership Selection Criteria

The members of each IRB shall be sufficiently qualified through experience and/or expertise to review research proposals in terms of regulations, applicable law standards of professional conduct and practice, and institutional commitments and fields of research. Therefore, the IRB shall include persons knowledgeable in these areas.

Selection for membership shall include consideration of ethnic group, gender, cultural backgrounds, clinical experience, healthcare experience, and sensitivity to such issues as community attitudes to assess the research submitted for review. There shall be at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. There shall be one member who has no affiliation with this institution, either through self or family member.

#### 1.2 Composition of the Board

Members: The backgrounds of the members shall be varied in order to promote appropriate reviews of the types of research activities commonly reviewed by each IRB. Members must include:

- A. Non-affiliated member(s): The non-affiliated member(s) can be either scientific or non-scientific reviewers willing and able to discuss research issues. Consideration will be given to recruiting individuals from groups which the University of California (UC) Berkeley routinely draws its research subjects and their knowledge and expertise should be fully utilized by the IRB.
- B. Scientific members: An individual who has formal education and training as a physician or other medical professional, a Master's or Doctoral level physical, biological, or social-behavioral scientist, or significant post-baccalaureate work experiences in the physical, biological or social-behavioral disciplines. Such members satisfy the requirement for at least one scientist. When an IRB encounters studies involving science beyond the expertise of the members, the IRB will use a

consultant to assist in the review, as provided by 45 CFR 46.107(f) and 21 CFR 56.107(f).

- C. Non-scientific member: The intent of the requirement for diversity of disciplines is to include members whose main concerns are not in scientific areas. Therefore, non-scientific members are individuals whose education, work, or interests are not primarily in medical or scientific areas.
- D. Representatives of special groups of subjects: When certain types of research are reviewed, members or consultants who are knowledgeable about the concerns of certain groups may be required. For example, if an IRB reviews research involving prisoners, an individual who can represent this group (e.g., an ex-prisoner or an individual with specialized knowledge about this group) must be included in the IRB discussion.
- E. Chairs: The individual IRB Chair(s) must be employed by the UC Berkeley as members of the faculty and be fully capable of providing leadership to the IRB and the matters brought before it with fairness and impartiality.
- F. IRB Alternate Members: All Alternates for IRB members must complete the same training as new IRB members prior to serving as an Alternate and through their expertise, training and/or affiliation are designated to serve as an Alternate for one or more IRB members.
- G. The Director of the Office for the Protection of Human Subjects shall be a member of the UC Berkeley IRB and the Assistant Director shall serve as his/her alternate.

### **1.3 Composition of the IRB Executive Committee**

- A. The Chair(s), Vice Chair(s), IO (or his/her designee), the Assistant Vice Chancellor for Research Administration, the OPHS Director and Assistant Director will serve as the Executive Committee.
- B. This committee reviews and recommends policies, procedures, guidelines and other matters to the IRBs for review and approval.
- C. This committee is charged with general oversight of the Human Research Protection Program at UCB and may be involved in the investigation and resolution of serious and/or continuing noncompliance incidents and other activities as deemed necessary.

## **2. DEFINITIONS**

*An affiliated member* is an employee or agent of the UC Berkeley (or a member of that person's immediate family). Affiliated members include, but are not limited to, individuals who are: Full- or part-time employees; current students; members of any governing panel or board of the institution; paid or unpaid consultants; health care providers holding credentials to practice at the institution; and volunteers working at the institution on business unrelated to the IRB.

A *non-affiliated member* is an individual who has no affiliation with the UC Berkeley other than as a member of research ethics review committees. Non-affiliated members may include people whose only association with the institution is that of a patient, subject, or former student at that institution.

An *alternate member* is an individual who has the experience, expertise, background, professional competence, and knowledge comparable to that of the primary IRB member(s) whom the alternate would replace.

A *scientific member* is an individual who has formal education and training as a physician or other medical professional, a Master's or Doctoral level physical, biological, or social-behavioral scientist, or significant post-baccalaureate work experience in a physical, biological, or social-behavioral sciences .

A *non-scientific member* is an individual who may have formal education and training in a discipline generally considered to be non-scientific (e.g. humanities, law, business) and/or is engaged in an occupation or role that is generally considered to be non-scientific (e.g. law enforcement, management, minister) even if the individual did have some formal training in a scientific field unrelated to his/her current occupation and career. A *consultant* is an individual with competence in a special area whom the IRB has invited to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB as per 45 CFR 46.107(f).

### **3. SCOPE**

These policies and procedures apply to the membership of all IRBs.

### **4. RESPONSIBILITY**

The Institutional Official (IO) is responsible for ensuring the IRB has adequate resources to identify and recruit qualified potential members.

The IO (or his/her designee) is responsible for collaborating with the IRB Chair(s), OPHS Director, Assistant Director and IRB Administrator(s) to identify and recruit potential IRB members.

The UC Berkeley Faculty Senate may annually provide the IO (or his/her designee) with a list of suggested names to consider as potential IRB members.

The IO is responsible for appointing all IRB members (members and alternates).

The Assistant Vice Chancellor for Research Administration and Compliance or the OPHS Director is responsible for ensuring compensation as needed for consultants and nonaffiliated members.

The IRB Chair, OPHS Director and Assistant Director or Administrator are responsible for training new IRB members.

The OPHS Director is responsible for designating Alternates to serve for IRB members.

## **5. PROCESS OVERVIEW**

The IO (or his/her designee) acting through the OPHS Director and Assistant Director or Administrator ensure the overall diversity of the IRB membership (e.g., sex, race, ethnicity, community affiliation and professional experience) through establishing non-discriminatory selection methods.

The IO (or his/her designee) in collaboration with the Director and the IRB Chair select new members and replace members who resign or otherwise leave IRB service.

The IO appoints members to the IRB annually on or about July 1, except for vacancies that must be filled as needed.

The OPHS Director is responsible for ensuring that the IRB Registration documentation for IRB membership is kept current with the Office for Human Research Protections.

The OPHS Director maintains a roster of all regular and alternate members and a file on all members (to include their curriculum vita and other evidence of professional ability). The Director may also maintain a roster of available consultants who are qualified to review protocols and attend meetings as invited consultants.

## **6. APPLICABLE REGULATIONS AND GUIDELINES**

45 CFR 46.107

21 CFR 56.107