

## Guidance: IRB Membership (last updated April 6, 2012)

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### IRB Membership Composition

In accordance with DHHS regulations at [45 CFR 46.107](#) and FDA regulations at [21 CFR 56.107](#), **each UCLA IRB:**

- Consist of **at least five members**. Overlapping membership between Boards is permitted;
- Include at **least one scientist member**;
- Include **at least one non-scientist member** (i.e., Non-Scientific Member);
- Include **at least one member who is not otherwise affiliated with UCLA** and who is not part of the immediate family of a person who is affiliated with UCLA (i.e., Non-UCLA Affiliated Member);
- Be **sufficiently qualified through the experience and expertise** of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote complete and adequate review of research activities commonly conducted by individuals at UCLA;
- 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;
- **When reviewing research involving a vulnerable population**, such as children, prisoners, pregnant women or handicapped or mentally disabled persons, the IRB includes one or more members who are knowledgeable about and experienced in working with these subjects (i.e., Subject Representative).

Each UCLA IRB will maintain **appropriate community member representation** according to the following standards:

- Comply with all Federal and UCLA requirements for non-affiliated member representation.
- Maintain diversity of representation to reflect potential research subject candidate population.

- Ensure adequate attendance.
- Ensure adequate representation of the cognitively impaired.
- Encourage non-affiliated members' active participation.

Unaffiliated members and/or non-scientist members represent the perspective of research participants. Each UCLA IRB has at least one member who represents the perspective of research participants.

The Vice Chancellor for Research and the OHRPP Director shall periodically, but no less than annually, review and adjust the membership of the IRBs to ensure that the composition meets all regulatory and organizational requirements.

## Member Nomination, Selection, and Service

The Vice Chancellor of Research appoints IRB members, Chairs and Vice Chairs. Appointments are typically from one to two years and renewable by mutual agreement, depending on the needs of the IRBs and the results of the yearly member evaluations.

Members are nominated by various sources including but not limited to the Chairs, Vice Chairs, other IRB members, Department Chairs, Division Chiefs, or the OHRPP Director or Assistant Directors in consultation with each other and the Vice Chancellor. Members are nominated based on expertise and experience and chosen to represent the types of research being reviewed by each IRB panel. The Vice Chancellor gives final approval to an appointment.

## Member Compensation

Stipends or other compensation provided to IRB members are made according to decisions made by the UCLA Human Research Policy Board.

## Alternate Members

**Alternates are designated for specific members.** If both the alternate and primary member attend a meeting, only one of these two may vote. When an alternate member substitutes for a primary member, the alternate member will receive and review the same material that the primary member received or would have received.

**Alternate members should have equivalent expertise,** including the same scientific or nonscientific status, as the primary member for whom they are substituting.

**Representatives of the same department may share** a membership in order to represent a specialty when it would not otherwise be possible due to conflicting commitments or schedules.

**Senior staff of OHRPP,** as designated on the IRB registration maintained with OHRP, may be designated as alternates.

## Consultants

Either before or during review of a protocol, the IRB or OHRPP may, at its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that routinely available on the IRB. Consultants may be asked to provide their expertise regarding a specific issue, or provide general comments

regarding a project. Consultants are asked to provide comments in writing, and may be asked to attend a convened IRB meeting but will be excused prior to the vote. A consultant may not vote or count towards quorum. Written consultant comments are retained in the protocol files.

## Conflicts of Interest

Member, alternate member, and consultant conflicts of interest are defined and handled according to [OHRPP Policy: IRB Member Conflict of Interest](#).

**Individuals responsible for business development do not serve on the IRB** nor are they involved in the day-to-day operations of the IRB. This restriction is made in order to assure that the IRB review process is free of conflict of interest so that the member's obligation to protect participants or ensure the integrity of the review process is not compromised by competing business interest or business development which could potentially influence the review process.

## Evaluation of IRB Members

**IRB members are evaluated on an ongoing basis** by the IRB Chairs and OHRPP Directors. However, formal evaluations occur annually. Members complete a self-evaluation form, which is reviewed by the IRB Chair and Director or Assistant Director. Performance is assessed according to the criteria outlined in [UCLA IRB Member Standards and Responsibilities](#). Member evaluation also includes determining whether a member should be designated to conduct IRB reviews using the expedited procedure. Written feedback is provided to all members about their performance within one month of evaluation.

**Chairs and Vice Chairs are also evaluated on an ongoing basis** by the OHRPP Directors. However, formal evaluations occur no less than annually. Chairs and Vice Chairs also complete a self-evaluation form, which is reviewed by the Director, Assistant Director, and IRB Administrator. Performance is assessed according to the same standards as members. In addition, Chairs and Vice Chairs shall also be assessed according to leadership ability, meeting management, engagement in the expedited review process, and effectiveness as representatives of the IRBs. Verbal feedback is provided to the Chairs in person, followed by written feedback within one month of evaluation.

## Confidentiality Agreement

Under the terms of the [UCLA IRB Members Standards and Responsibilities](#) IRB members must agree not to discuss, disclose, or reproduce any confidential IRB information, except as necessary to carry out IRB membership responsibilities or as required by law.

## Liability Coverage for IRB Members

Members of the IRBs, including lay members, are covered under the California Tort Claims Act of 1963. This act requires the Regents of the University of California to provide defense and indemnification with respect to claims resulting from the acts or omissions of University employees (or former employees) when acting in the course and scope of University employment, except where the employee acted or failed to act because of fraud, corruption or actual malice. Coverage is under the University of California Professional Medical and Hospital Liability Self-Insurance Program.

## Absence of the IRB Chair

Whenever the Chair is not available to perform his or her duties, the Chair may designate the IRB Vice Chair or another IRB member to assume his or her responsibilities during his or her absence.

## Documentation of Membership

OHRPP is responsible for filing and maintaining IRB Registration with OHRP. The IRB Registration shall serve as the official record of the primary members for whom alternate members may substitute.

The OHRPP Director or an Assistant Director notifies OHRP quarterly of changes to IRB membership. Copies of the modified IRB Registration will be retained by OHRPP.

The Administrator of each IRB Committee is responsible for maintaining a record for each current member, including but not limited to the member's curriculum vitae, any letters of appointment, renewal or recognition, and the member's signed confidentiality agreement.

Records relating to past members are stored according to Federal regulations and University policies regarding storage of IRB records.

OHRPP posts the current rosters of all five IRBs on its website.

## Regulations & References

### ***DHHS Regulations***

- IRB Membership: [45 CFR 46.107](#)
- IRB Review of Research: [45 CFR 46.109](#)

### ***FDA Regulations***

- IRB Membership: [21 CFR 56.107](#)
- IRB Review of Research: [21 CFR 56.109](#)

### ***UCLA OHRPP Guidance***

- [UCLA IRB Member Standards and Responsibilities](#)
- [Criteria Required by Federal Regulations for IRB Approval of a Human Research Study](#)
- [Criteria Required by Federal Regulation to Approve Informed Consent](#)
- [Criteria for IRB Approval of Research \(Biomedical\)](#)
- [Criteria for IRB Approval of Research \(Behavioral\)](#)