Policy Number: 7
Title: Composition of IRB Committees
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Policy:
It is the policy of the UC Irvine (UCI) Institutional Review Board (IRB) that the composition of IRB Committees is in accordance with Federal regulations.

I. UCI's Federalwide Assurance (FWA) designates four IRB Committees as follows:
   A. IRB00000393- IRB "A" (Biomedical)
   B. IRB00000394- IRB "B" (Biomedical)
   C. IRB00000395- IRB "C" (Social Behavioral)
   D. IRB00008624- IRB "E" (Regulatory & Institutional Compliance)

   UCI has registered through the Department of Health and Human Services and has obtained the following IORG Registration Number: **IORG0000236**

   Biomedical research is reviewed by three IRB Committees and supported by three Human Research Protections (HRP) teams.

   Social and behavioral research is reviewed by one IRB Committee (IRB C) and is supported by one HRP team.

   The purpose of IRB E is to review matters of suspected non-compliance related to human subject research conducted by a UC Irvine student, faculty member or staff. IRB E also reviews unanticipated problem reports that involve matters of potential non-compliance. IRB E will determine if non-compliance has occurred, if the event is "reportable" to federal agencies and whether a corrective action plan is appropriate. IRB E will also review all pending IRB transactions related to a protocol when a significant non-compliance matter is pending resolution. Recommendations from the IRB are provided to the Institutional Official, who has final authority to report the matter to federal agencies. Approved IRB E minutes are included on the IRB A, B, and C agendas.

II. **Composition -** Each IRB Committee must include at least one member whose primary interests are in a scientific area, one member whose primary interests are in a non-scientific area and one member who is not affiliated with UCI (i.e., not a family member or spouse of an employee, not an active alumnus). At least one non-affiliated member and one non-scientist should be present at convened meetings. The non-scientist and non-affiliated member may be the same individual.

   Except when an expedited review procedure is used, the IRB will review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive

the approval of a majority of those members present at the meeting. In addition, the IRB must have members with sufficient knowledge of the specific scientific discipline(s) relevant to the research that it reviews.

Scientist/Nonscientist - Members are assigned a scientist or non-scientist status based on their training, background, and expertise. Members whose training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral scientific or biomedical research discipline should be considered a scientist, while members whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline – whose primary concerns are in the "non-scientific" area, should be considered a nonscientist.

Affiliation - An employee or agent of the organization registering the IRB (or a member of that person's immediate family) is considered affiliated. Affiliated members include, but are not limited to, individuals who are: part-time employees; current students; members of any governing panel or board of the institution; paid or unpaid consultants; healthcare providers holding credentials to practice at the institution; and volunteers working at the institution on business unrelated to the IRB. An individual that has no affiliation with the organization registering the IRB, other than as an IRB member, is considered unaffiliated with the entity operating the IRB. Unaffiliated members may include people whose only association with the institution is that of a patient, subject, or former student at that institution. Paying unaffiliated members for their services would not make the member "otherwise affiliated" as stated in the regulations or cause the member to have a conflicting interest.

III. **Roster(s) -** An IRB Membership Roster is generated for each IRB Committee. The Roster contains the list of IRB Members identified by name, earned degrees, representative capacity, scientific status (i.e., PS= Primary Scientist, OS= Other Scientist, NS= Non-Scientist), affiliation status, indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations and any employment or other relationship between each member and the institution.

IV. Likewise, an IRB Membership Roster is generated for the listing of IRB Committee Alternate Members. Alternates formally listed on the IRB roster may vote in place of an absent voting member. Alternates are assigned according to their scientific or non-scientific status, as indicated on the Committee member rosters, and in accordance with the area of expertise required for adequate review. Meeting minutes must document when an alternate member attends a meeting.

A. Alternate members serve the same function as other IRB members. Alternate members participate in the review, discussion and vote of protocol transactions when an IRB member cannot attend the convened meeting. Alternates will have access to meeting materials in advance of an IRB meeting.

B. Alternate members abide by the same UCI Conflicts of Interest in Human Subjects Research policy as other IRB members.

C. A primary member of any IRB registered under the same IORG number may serve as an alternate for any comparably qualified member on any other IRB of that institution or organization. Primary members serving as alternate members do not need to be listed as an alternate on any roster.

D. When an alternate member substitutes for a primary member at an IRB meeting, the minutes must reflect the alternate member's expertise and that their scientific status is equivalent to that of the primary member the alternate will replace.

1. If both a primary IRB member and their alternate(s) attend the same IRB meeting, the primary member acts as the official voting member of the IRB for review of research protocols, unless the minutes clearly indicate otherwise. A designated alternate IRB member for a primary IRB member may substitute for the primary IRB member for an entire meeting or at any time during a meeting. Substitution during a meeting may occur when the primary member is (a) absent from the room for part of the meeting, or (b) recused from review of certain research protocols because the primary IRB member has a conflicting interest with respect to a specific research protocol. Whenever this occurs, the minutes of the IRB meeting should indicate clearly that the alternate IRB member has replaced the designated primary IRB member.

V. **Membership Selection -** Selections for IRB Committee member voting positions and Chairpersons for the IRB Committees are made by the Institutional Official (IO) with the assistance of the IRB Chairs and the Senior Director of Human Research Protections, based upon the specific needs of the IRB Committee, (e.g., medical specialty, vulnerable population representative, diversity, non-scientist, non-affiliated, etc.).

A. The biomedical IRB Committees are primarily made up of School of Medicine and UCI Medical Center faculty and staff with sufficient scientific expertise and scholarship to review each protocol to determine the study meets the criteria for IRB approval (i.e., 45 CFR 46.111 and if applicable, 21 CFR 56.111); while the social/behavioral IRB Committee is made up of faculty and staff from the School of Social Sciences, School of Social Ecology, School of Humanities; the Donald Bren School of Information and Computer Sciences; School of Medicine, School of Education; and School of Business with sufficient scientific expertise and scholarship to determine that each study meets criteria 45 CFR 46.111 and if applicable, 21 CFR 56.111.

B. In general, IRB E is comprised of IRB Chairs, IRB Vice-Chairs, senior members from IRB A, B and C, and a non-scientist member.

C. Non-affiliated members are drawn from the local Orange County community (e.g., clergy, attorneys, teachers, and advocates for vulnerable subject populations, etc.).

D. At least one member who represents the general perspective of participants is present at convened meetings, such as a former or current research participant or a research participant advocate or an individual who otherwise represents the general perspective of research participants. This member may be a non-scientist or non-affiliated member.

E. To support American Nurses Credentialing Center Magnet designation,

each Biomedical IRB includes at least one UCI nurse as a voting member.

F. The IRB Committee requests faculty volunteers and also seeks the advice of IRB Committee Chairs, IRB Committee Members, Division Chiefs, Department Chairs, and Deans in making its recommendations.

G. Decisions for selecting Committee members are made to assure that the IRB Committees retain diversity while maintaining regulations for required individuals to serve on the Committee.

H. Community-based participatory research (CBPR) is a form of community engaged research, involving a collaborative approach for participation, shared decision-making, and mutual ownership in all aspects of the research process by communities affected by the issue being studied, researchers, and organizational representatives.

1. When reviewing research that involves (CBPR) the IRB will assure that the committee has IRB members and/or consultants with CBPR expertise to review community-based participatory research project at UCI.
2. Should CBPR research grow at UCI the IRB will:
   a. Expand the number of community members on the IRB; or
   b. Engage community consultants as collaborators in the review process; or
   c. Coordinate with a community-based IRB.

I. Committee Chairs and Vice Chairs are selected as highly respected individuals from within the institution, fully capable of managing the IRB and matters brought before it with fairness and impartiality.

J. Individuals with potential competing business interests cannot serve on the IRB or be involved in the day-to-day operations of the review process. For example, the Senior Director of Sponsored Projects, the Vice Chancellor for Research or others who are responsible for raising funds or garnering support for research cannot not serve on the IRB or be involved in the daily operations of the review process.

VI. **Number of Members** - The IRB Committees are required to have a minimum of five members each (on average 12-20 members), with varying backgrounds and expertise to provide complete and thorough review of research activities commonly conducted by the Institution.

VII. **Qualifications of IRB Members**

A. The IRB Committee membership must be:

1. Sufficiently qualified through the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel; and
2. Able to ascertain the acceptability of proposed research in terms of institutional commitments, regulations, applicable law, and standards of professional conduct and practice;

B. Additional Qualities of IRB Committee Members and Chairpersons.

1. Need to be committed to the workload;
2. Understand time commitment;
3. Come to meetings prepared for discussion;
4. Commitment to institutional goals for human research protections;

5. Good communication skills;
6. Willing to contact Lead Researchers to discuss issues and initiate solutions prior to the meeting; and
7. When applicable, have
    a. Strong clinical expertise; and/or
    b. Research experience.
8. The Chair must possess strong leadership skills to effectively organize, influence and expedite IRB meetings, have a strong command of the regulations pertaining to human subjects research, be a tenure track faculty member and have a M.D. for the biomedical committees; or a Ph.D. in a related field for the social-behavioral committee.

C. The Institutional Official, the Senior Director of Human Research Protections or designee and the IRB Chairs continually assess the composition of the IRB Committees' membership to ensure that each committee is adequately charged in light of the anticipated scope and complexity of UCI's research activities, and the subject populations likely to be involved in the research.

D. Term of Service.
1. Committee Members
    a. Committee members are requested to serve a renewable three-year term.
    b. Committee members are requested to serve as alternate members at the completion of their term.
2. IRB Chairs
    a. It is recommended that Chairs serve one year as a Committee member prior to assuming the role of Chair.
    b. The Chair shall serve a two-year term and shall be considered for re-appointment at the end of each term.
    c. Chairs may be requested to serve six months or longer as a Committee member at the completion of their term to mentor the newly selected Chair to promote consistency and continuity. In addition, this will provide a resource for the newly selected Chair and Committee members on historical perspectives, rationale for decisions made regarding policy, and meeting facilitation skills.
    d. Chairs are requested to serve as alternate members at the completion of their term.

E. <u>Child Representative</u> - An IRB Committee considering a protocol involving children as participants should:
1. Assess its needs for pediatric expertise among the IRB voting membership to assure that it possesses the professional competence necessary to review the specific research activities.
2. When the IRB reviews research involving children (or other participants vulnerable to coercion or undue influence), the IRB will ensure that one or more individuals who are knowledgeable about and experienced in working with children (or other vulnerable groups as appropriate) are present. To fulfill this requirement, the IRB Committee may invite nonvoting consultants to assist in the review of issues which require expertise beyond, or in addition to, that available among voting IRB members. Should the IRB be unable to obtain expertise in this area, the IRB will defer review until such expertise

can be obtained through membership or consultation.

3. When reviewing proposed research on handicapped children or mentally disabled persons sponsored by the Department of Education, the UCI IRB must also include a member with expertise with this population.

F. Prisoner Representative - Federal regulations require that when the IRB Committee will review research involving prisoners, at least one member of the IRB Committee shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity.

G. Pregnant Women, Human Fetuses and Neonates - The IRB Committee considers all applicable Federal regulations regarding research with this population and may request review by an expert, as needed.

H. Individuals with Impaired Decision-Making Capacity -The IRB Committee may include, if necessary, at least one member with expertise in the area of individuals with impaired decision making capacity population when reviewing studies with this population or studies in which the participants may become cognitively impaired through the course of the research.

I. Economically or Educationally Disadvantaged*:* The IRB Committee will consider this population as potentially vulnerable to coercion and undue influence and may request review by an expert, as needed.

J. Expert Consultants - On a case-by-case basis, the IRB Committee may request review by an individual with competence in a scientific or scholarly area not represented by the Committee membership.

1. Before the convened meeting the HRP administrative staff review the agenda to confirm that the Committee has the expertise to review the scheduled research in consultation with the IRB Chair as needed. If it is determined that a consultant is needed to address specific issues that require expertise or qualifications beyond or in addition to the IRB Committee membership, HRP staff will obtain a consultant.
2. Consultants will either participate in the discussion of the protocol in-person, telephone, teleconference, or provide written comments which will be given to the reviewers and IRB Chair to present at the convened meeting. IRB members may obtain copies of the consultants' comments.
3. If the consultant participates in the meeting, the minutes will document the key information provided by the consultant. Written comments will be retained in the protocol file.
4. The consultant will sign a UCI IRB Consultant Standards document to ensure the confidentiality of the review and to assure that no conflicting interest exists with the protocol under review. If a consultant declares a conflicting interest as defined in the UCI Conflicts of Interest in Human Subjects Research policy, the HRP staff and/or IRB Chair will arrange for another consultant. A consultant's conflict of interest is determined on a protocol-by-protocol basis.
5. Consultants are not IRB members, and their presence is not counted towards quorum.

VIII. **Assignment to IRB Committees**

In general, the Lead Researcher's primary school, department, or program determines whether a protocol is reviewed by a biomedical committee or by the social/behavioral/educational committee. For example, School of Medicine protocols will be reviewed by one of the biomedical committees, while School of Social Sciences protocols will be reviewed by the social/behavioral/educational committee.

A. The social/behavioral/educational committee may review research that involves prospective collection of biological specimens (e.g., blood, saliva, deciduous teeth) and/or collection of data via non-invasive measures (e.g., magnetic resonance imaging, tests of sensory acuity, electrocardiography) that customarily may be considered clinical in nature, as long as the procedures involve no more than minimal risk (e.g., procedures that qualify for Expedited review under Categories 2, 3 or 4 of the Federal regulations [(Federal Register: November 9, 1998 (Volume 63, Number 216)].

B. Research involving access, creation, use, and/or disclosure of individually identifiable private health information will be reviewed by a biomedical Committee.

IX. **IRB Committee Member and Chair Performance Evaluations**

A. Committee members and Chairs complete an annual self-evaluation which includes the following:
   1. Knowledge and application of the Federal regulations;
   2. Knowledge and application of IRB policies and procedures;
   3. Participation in Committee meeting discussions;
   4. Interaction with Investigators; and
   5. Affiliation status.

B. The self evaluations and other verbal and written feedback from members and Chairs are used to identify areas where additional member education may be required.

C. IRB Committee Members and Chairs may be replaced on the Committee at the discretion of the Vice Chancellor for Research based upon the Committee needs for specific areas of expertise, or performance issues such as a breach of confidentiality, excessive absences, etc.

References:

45 CFR 26.103(b)(3)
45 CFR 46.107
OHRP Step by Step Instructions on Registering an IRB
21 CFR 56.108(c)
21 CFR 56.115(a)(5)
34 CFR 350 and 356
ICH-GCP: 3.2.1, 3.2.6
AHRQ Publication No. 04–E022-2: *Community-Based Participatory Research: Assessing the Evidence*, July 2004
Clinical and Translational Science Awards Consortium Community Engagement Key Function Committee Task Force on the Principles of Community Engagement Principles of Community Engagement – Second Edition
Federal Register: November 9, 1998 (Volume 63, Number 216)
NIH: Office of Behavioral and Social Sciences Research Community-Based Participatory

Research
OHRP IRB Guidebook
OHRP Compliance Activities: Common Findings and Guidance, July 10, 2002
University Policy on the Protection of Human Subjects in Research: 18-261
UCI IRB Members Standards – Core Voting Members
UCI IRB Members Standards – Alternate Voting Members
UCI IRB Non-Voting Consultants Standards