

Policy Number: 8

Title: Committee Member Compensation and Responsibilities

Date of Last Revision: 01/29/09, 10/23/10, 01/24/11, 09/15/11, 07/06/12, 05/01/13, 01/28/15, 05/01/16, 11/02/16, 06/27/18, 12/10/19, 03/04/22, 09/12/22, 12/04/23, 08/15/24

Policy:

I. Compensation

UC Irvine IRB members and chairpersons serve as volunteers. In recognition of the vital service provided by these individuals to the campus research community and the Human Research Protection Program, the University provides nominal compensation to each individual as outlined below. Compensation is intended to recognize the time invested by the individual in committee activities, offset a possible loss of income to the home department, facilitate recruitment to the committee and encourage attendance. IRB Chairpersons have received compensation for travel expenses and research-related costs from the Office of Research since the 1990's. Compensation to vice chairpersons and members was effective starting January 1, 2008.

A. Coverage

1. *Faculty and Staff Included in a Health Sciences Compensation Plan*

For IRB members, vice chairs and chairs from organizational units where unit members are covered by a compensation plan, funds will be transferred to the member's home department to compensate the unit for the member's time and proportionately relieve the member's earnings obligation. The use of these funds is governed by UCI expense policies, Academic Personnel additional compensation policies, and/or faculty compensation plan policies.

2. *Faculty Not Included in a Health Sciences Compensation Plan*

For IRB members, vice chairs and chairs from organizational units where unit members are not covered by a compensation plan, funds will be transferred to the member's home department. The use of these funds is governed by UCI expense policies, Academic Personnel additional compensation policies, and/or faculty compensation plan policies.

3. *Staff Employees*

For IRB members who hold staff positions, current policy does not allow compensation for committee participation.

4. *Community Members*

For IRB members who are not University employees, compensation will be provided by check.

B. Compensation Process and Rates

1. Funds related to the IRB service of faculty and staff members, including IRB chairpersons will be transferred the member's home department quarterly, in arrears. Checks related to the IRB service of

community members will be issued quarterly, in arrears, directly to the individual member.

2. **IRB Committee A & B and IRB Team D (Biomedical) Members**

a. *Committee Vice Chairperson's Rate*

Effective January 2011, IRB vice chairpersons (1 per committee) will receive a monthly research allowance of \$500 per month of appointment.

b. *Academic Appointee Rate*

IRB members who hold faculty positions will earn \$200 for each full committee meeting attended with engagement in the meeting for 75% of the duration.

c. *Staff Appointee Rate*

IRB members who hold non-Office of Research staff positions will earn \$200 for each full committee meeting attended with engagement in the meeting for 75% of the duration.

d. *Community Member Appointee Rate*

IRB members who are unaffiliated with the university will earn \$200 for each full committee meeting attended with engagement in the meeting for 75% of the duration.

e. *Acting Chair Rate*

When the IRB Chair delegates responsibilities of the IRB Chair to another experienced member of the IRB, in the absence of the IRB Chair and IRB Vice Chair, additional compensation may be provided to the IRB member for that meeting, not to exceed \$350.00 total, per meeting.

3. **IRB Committee C (Social, Behavioral & Educational) Members**

a. *Committee Vice Chairperson's Rate*

Effective January 2011, the IRB vice chairperson will receive a monthly research allowance of \$500 per month of appointment.

b. *Academic Appointee Rate*

IRB members who hold faculty positions will earn \$100 for each full committee meeting attended with engagement in the meeting for 75% of the duration. In addition, members will receive \$50 for each week of subcommittee service (approximately 9 weeks annually) with participation for 75% of the meeting duration.

c. *Staff Appointee Rate*

IRB members who hold non-Office of Research staff positions will earn \$100 for each full committee meeting attended with engagement in the meeting for 75% of the duration. In addition, members will receive \$50 for each week of subcommittee service (approximately 9 weeks annually) with participation for 75% of the meeting duration.

d. *Community Member Appointee Rate*

IRB community members will earn \$100 for each full committee meeting attended with engagement in the meeting for 75% of the duration.

4. **IRB Committee E (Noncompliance) Members**

a. *Academic Appointee Rate*

Effective January 1, 2020 the IRB Chair will earn \$600 per month and IRB members will earn \$200 for each full

committee meeting attended with engagement in the meeting for 75% of the duration.

b. **Staff Appointee Rate**

IRB members who hold staff positions will earn \$200 for each full committee meeting attended with engagement in the meeting for 75% of the duration.

c. **Community Member Appointee Rate**

IRB members who are unaffiliated with the university will earn \$200 for each full committee meeting attended with engagement in the meeting for 75% of the duration.

5. **IRB Alternate Members**

- a. Alternates called upon to attend meetings will be compensated on a per meeting basis in accordance with their appointment and the provisions of this policy.

6. **Biostatistics, Epidemiology and Research Design (BERD) unit in the Institute for Clinical and Translational Science (ICTS) – IRB Members**

- a. BERD statistician reviewers may serve as IRB members, to maximize the efficiency of their review process, which generally precedes the RB review of an Investigator Initiated Study.
- b. BERD reviewers who hold staff or faculty positions will earn \$300 monthly compensation for their efforts. Compensation is to be issued quarterly.

II. **IRB Member Responsibilities**

- A. UCI IRB has the responsibility to uphold the ethical principles of the *Belmont Report* to all proposed research involving human participants regardless of sponsorship. The ethical principles set forth in the *Belmont Report* are:
1. Respect for Persons: Recognition of the personal dignity and autonomy of individuals and special protection of those persons with diminished autonomy;
 2. Beneficence: Obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risk of harm; and
 3. Justice: Fairness in the distribution of research benefits and burdens.
- B. It is the responsibility of the UCI IRB to:
1. Understand federal regulations, state laws, and University of California (UC)/UCI policies regarding the protection of human subjects in research.
 2. Verify that all protocols reviewed by the IRB Committees conform to Federal regulations, state laws, Department of Defense (DoD) requirements, Department of Justice (DoJ) requirements, Department of Energy (DOE) and UC/UCI policies relevant to the health, welfare, safety, rights, and privileges of human subjects, and to assist investigators in complying with these regulations and policies.
 3. Evaluate each research protocol based on the criteria for IRB approval, including consideration of scientific merit relative to the risk/benefit profile and to the complexity of the study. Research should be scientifically sound and clearly described.
 4. The IRB, in conjunction with the Biostatistics, Epidemiology and Research Design (BERD) unit in the Institute for Clinical and

Translational Science (ICTS) consider scientific review to ensure that risks to subjects are:

- a) Minimized by using procedures that are consistent with sound research design, and which do not unnecessarily expose subjects to risk;
 - b) Reasonable in relation to any anticipated benefits and the importance of the knowledge that may reasonably be expected to result.
 - (1) As applicable, outside groups (e.g., NIH review, Cooperative Group review) and other campus committees/entities (e.g., the Chao Family Comprehensive Cancer Center Protocol Review and Monitoring Committee (PRMC)), Department Chairs, and School Deans) may also review the study's scientific merit relative to the research design and the likelihood of the research achieving its aims.
5. For research conducted within the Bureau of Prisons, the research must have an adequate research design and also contribute to the advancement of knowledge about corrections.
 6. For studies that involve DoD-supported research with human subjects, independent review of the research for scientific merit or scholarship is required prior to IRB review.
 7. Review and approve, require changes to, or withhold approval of proposed human subject research activities.
 8. Conduct continuing review of on-going research activities at least every 365 days. (See Policy #13 for extended three-year IRB approval exception.)
 9. Determine which studies require review more often than annually.
 10. Determine if the proposed use of placebo is acceptable. (See Policy # 43.)
 11. Determine the specific risk category for children, pregnant women, fetuses, fetal tissue, neonates and prisoners as satisfied by the conditions of the applicable subparts. (See Policies # 36, 37 and 38.)
 12. Evaluate available clinical and nonclinical information on an investigational product to determine if the information is adequate to support the proposed clinical trial.
 13. Determine whether an investigational device poses significant or non-significant risk and if, accordingly, an Investigational Device Exemption (IDE) applies. (See Policy # 42.)
 14. Determine if an Investigational New Drug (IND) application is needed for a single agent or a combination of agents. (See Policy # 41.)
 15. Determine if the use of Short Forms, surrogate consent or other alterations to the informed consent process are appropriate. (See Policies # 30, 31 and 39.)
 16. Monitor on-going research, including review of unanticipated problems involving risks to human subjects or others and oversight of investigator compliance with research requirements.
 17. Determine whether additional expertise, not available among IRB members, is required for a protocol review. If the IRB does not have the required expertise, the IRB will follow the policies and procedures to obtain *Expert Consultants* (Note: IRB members are encouraged to directly consult with colleagues for information, provided that

confidentiality of submitted protocols and IRB proceedings is maintained.)

18. Assure that conflicts of interest in protocol review and conduct of research are avoided. Committee Members must declare any conflict of interest before review of any research under IRB jurisdiction. Members with conflicting interests must absent themselves from the meeting during the discussion and vote on the affected research protocol. IRB members with a conflicting interest do not count towards quorum. Members agree to abide by the UCI Conflicts of Interest in Human Subjects Research policy when they sign the UCI IRB Members Standards document upon appointment to the IRB.
19. Report serious or continuing noncompliance, unanticipated problems involving risks to human subjects or others and any suspension or termination of IRB approval to University officials and governmental oversight entities.

III. ***Specific Member Duties***

- A. All IRB members are expected to make every effort to attend Committee meetings. Members are asked to attend at least 75% of full committee meetings and be available for subcommittee service. In the event that an IRB member is unable to attend, sufficient advance notice must be provided to the HRP staff so that alternate arrangements can be made as necessary to achieve quorum.
- B. Duties of IRB Chairperson
 1. Convene IRB meetings
 - a. Assure the members review applications and related documentations consistent with federal criteria for approval of human subjects research and HRP policies and procedures.
 - b. Open debate and request amendments to the motion, if necessary.
 - c. Guide debate and ask for a formal motion.
 - d. Call for a vote (i.e., second, all those in favor, against, abstain).
 - e. State whether motion carries.
 - f. If motion does not carry, reopen discussion and propose new motion.
 2. Review and approve minor modifications in approved research, in accordance with federal regulations.
 3. Review and register exempt research proposals, as requested in accordance with 45 CFR 46.101(b) (1-6), taking into consideration 45 CFR 406.301(a), 45 CFR 46.401(b) and 21 CFR 6.104(d).
 4. *Biomedical Chairpersons* – Advise on emergency use of an investigational test article, in accordance with 21 CFR 50.23(a-c), 21 CFR 56.102(d) and 21 CFR 56.104(c).
 5. Review reportable events and problems including unanticipated problems involving risks to human subjects or others, protocol violations, and subject complaints and determine whether the event constitutes an unanticipated problem involving risks to human subjects or others.
 6. Make decisions in emergency situations to protect subjects and remain in compliance with regulations.
 7. Suspend the conduct of research when subjects are placed at unacceptable risk or, if warranted, when investigators do not comply

with IRB guidelines, Federal regulations, State laws or UC/UCI policies.

8. Relate concerns of IRB members to HRP administration and Institutional Official (IO) regarding issues involving human subject safety and IRB review procedures.
9. Facilitate communication and dissemination of information from the IO and HRP staff to the IRB members and to the research community in general.
10. Act as an advisor to UCI's research community.
11. Sign official approval documentation on behalf of the UCI IRB.
12. Call special meetings, as necessary.
13. Be available for consultation with HRP staff.
14. Attend IRB Working Group meetings with HRP staff.
15. Delegate any of his/her responsibilities as appropriate to other qualified and duly appointed members of the IRB.
16. Lead the full IRB in addressing serious and continuing non-compliance
17. Participate in quality assurance reviews of on-going research, when appropriate.
18. Participate in IRB member education and training sessions.

B. *Duties of IRB Vice Chair*

1. Perform duties of the IRB Chairperson in his/her absence.
2. Assist the IRB Chairperson as needed.

C. *Duties of IRB Members*

1. Attend convened meetings so that protocols may be reviewed in accordance with 45 CFR 46.108(b) and 21 CFR 56.108(c).
2. Serve as primary or secondary reviewer or discussant on assigned full committee or expedited protocols.
3. Maintain confidentiality of IRB meeting proceedings and any information contained in protocol reviews.
4. Review IRB applications and other reportable items to ensure they are in compliance with applicable Federal regulations, State laws and/or UC/UCI policies.
5. Disclose any potential conflict of interest to the IRB Chair and HRP staff as soon as it is recognized.
6. Participate in protocol audits for possible noncompliance, as requested.
7. Understand UC/UCI policy and procedures regarding the protection of human participants in research.
8. Participate in IRB member education and training opportunities.

D. *Duties of Non-Scientist*

1. The duties of IRB members with non-scientific status primarily consist of reviewing the informed consent document and the recruitment materials to ensure that the information provided to the participant or the participant's legally authorized representative is in an understandable language and format. Non-scientists also provide additional expertise relevant to the subject populations they represent (e.g., cognitively impaired participants). IRB members with non-scientific status are not assigned primary and secondary reviewer responsibilities.

- IV. **Reporting of Undue Pressure or Influence upon IRB Members and Human Research Protections Staff**
- A. IRB members and HRP staff are expected to report any exertion of undue pressure or influence/coercion to the Director of Human Research Protections or designee, the Associate Vice Chancellor for Research or the Vice Chancellor for Research to assure that the IRB members and staff can function without outside pressures.
 - B. Reports of undue pressure or influence/coercion can also be made to the designated officials named in the UCI Whistleblower Policy and Procedures.
 - C. Reports of undue pressure or influence/coercion can be made in writing, by phone and in person.
 - D. Appropriate action and follow-up with the individual exercising undue pressure or influence/coercion and the individual's supervisor (e.g., Dean, Department Chair, etc.) will be performed to prevent any further problems from the individual on IRB members and staff.
- V. In an effort to create a transparent process, the IRB roster is available on the Human Research Protections website. Proceedings of IRB meetings are confidential; therefore, investigators should not attempt to contact individual committee members to discuss individual committee deliberations.

References:

21 CFR 50
21 CFR 56
45 CFR 46
OHRP IRB Guidebook
OHRP Compliance Activities: Common Findings and Guidance, July 10, 2002
UC Irvine Administrative Policy & Procedures Sec. 700-06 (Whistleblower Policy)
UCOP Research Integrity – Policy and Procedures for Reporting Improper Governmental Activities and Protection against Retaliation for Reporting Improper Activities, October 2002
DoD: SECNAVINST 3900.39D, para 8c(6)
DoJ: 28 CFR 512.11(a)(2)
ICH-GCP: 2.4, 2.5, 3.2.3, 3.2.4

Procedure Number: 8.A**Title: Procedure for Maintaining Quorum Required for IRB Committee Review****Procedure:**

This procedure provides guidance on the maintenance of quorum that must occur when the UC Irvine (UCI) Institutional Review Board (IRB) Committees review and approve research under its jurisdiction.

I. IRB Committee Responsibilities**A. Quorum**

1. An IRB Committee meeting may convene at an announced meeting and render a vote only under the following conditions:
 - a. Quorum requires a majority of the Committee voting members to be present, defined as more than half of the membership (e.g., 10 voting members requires 6 voting members for quorum; 9 voting members requires 5 voting members for quorum); and
 - b. A minimum of one non-scientist present.
 - c. The Committee member may not send a proxy to vote in their absence either by phone or in person.
2. The IRB Committee meetings will take place with all participating IRB members present in person, via telephone, or via a teleconference call.
3. Each Committee member will receive access to all pertinent materials prior to the meeting.
4. Committee members attending via telephone or teleconference call will actively and equally participate in the discussion of all protocols (e.g., each member can hear and be heard by all other participating members).
5. Only members who participate in the IRB review and discussion should vote/provide their opinion and/or advice.
6. When the IRB Chair calls for a vote, members either raise their hands, or vote via teleconference poll in favor or against the determination or abstain from the vote. A majority vote in favor of the determination constitutes IRB approval.
7. When reviewing research that involves children or prisoners, a committee member, an alternate member or an expert consultant who has special knowledge of these vulnerable populations is required to be present during the review process. If the reviewer providing the expertise with regard to the vulnerable population is not included on the IRB roster as a voting member or alternate, he or she may not vote and may not count towards quorum. Additionally, when reviewing research sponsored by the Department of Education, the Committee must include one person with expertise in dealing with children with physical disabilities or mentally disabled persons when reviewing research on those populations.
8. *Failure of Quorum during a Convened Meeting.* Should quorum fail during the meeting (e.g., those with conflicts of interest being excused, early departures, loss of the non-scientific member), the meeting should be suspended until quorum can be restored or terminated.

- B. Conflict of Interest
 - 1. IRB Committee members must absent themselves from the deliberative discussion and vote during the initial or continuing review of a project in which the member has a conflicting interest, except to provide information requested by the IRB Committee.
 - 2. IRB Committee members should inform the IRB Administrator of any potential conflicts on the agenda prior to the meeting or at the beginning of the meeting and absent themselves from the meeting when the IRB Committee discusses and votes on the research in which they have a conflict of interest, which should be noted in the Committee minutes.

II. The Human Research Protections (HRP) Team Responsibilities

- A. The HRP team (Administrator, Senior Analyst, and Analyst), under the direction of the Administrator, will maintain attendance logs in order to assure that quorum is maintained, despite absences and conflicts of interests, for scheduled IRB Committee meetings.
- B. The team members in attendance at the Committee meeting are responsible for recording accurate quorum notes and assuring that quorum is maintained throughout the meeting.
- C. The HRP team will note any absences due to conflicting interest for each protocol in the IRB Minutes. IRB members with a conflicting interest may not participate in any portion of the review of research activities except to provide information requested by the IRB and must absent themselves from the meeting during the IRB's deliberative discussion and vote on the affected research.
- D. When the IRB Committee reviews research that involves a vulnerable population, the Administrators or Analysts will assure that the IRB Committee Members present, includes someone who is knowledgeable and meets the requirements to review the proposed research, or assist in scheduling a consultant or alternate reviewer to conduct the review.
- E. The HRP team records the votes for each item under IRB Committee review in the "IRB Agenda- Notes Version" worksheet, as well as electronically via Zoom.