

CALIFORNIA STATE POLYTECHNIC UNIVERSITY, POMONA
ACADEMIC SENATE

FACULTY AFFAIRS COMMITTEE

REPORT TO

THE ACADEMIC SENATE

FA-003-167

Institutional Review Board Membership

Faculty Affairs Committee

Date:

Executive Committee
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Academic Senate

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First Reading
11/29/2017
Second Reading

Referral

Institutional Review Board Membership

Background

Although there are federal mandates regarding Institutional Review Boards (IRB), membership policies outside of these mandates are drafted by the institution. According to the constitution of the academic senate, the IRB membership policies should be ratified by the Academic Senate for two reasons: One, the Cal Poly Pomona IRB is comprised largely of CPP faculty (Unit 3 members). Two, there is a very close relationship between teaching and research at CPP and, therefore, membership policies of the IRB affect instruction and as such are the purview of the academic senate.

Resources

Please provide a list of persons and documents that could be consulted for additional information on this topic.

- David Adams (previous IRB Chair), Professor in Philosophy
- Dr. Jeff Mio (immediate previous IRB Chair), Professor in Psychology and Sociology, Graduate Coordinator
- Dr. Bonny Burns-Whitmore (present IRB Chair), Professor in Nutrition and Food Science, Graduate Coordinator
- Dr. Heather Wizikowski (Vice IRB Chair), Assistant Professor in Education
- Bruce Kennedy (Compliance Associate), Office of Research
- FA-003-167, Institutional Review Board Membership Page 4 of 5 Federal regulation 45 CFR 46.107 found at: http://www.ecfr.gov/cgi-bin/text-idx?SID=9e24b1e7de385ee0452198e45b24b708&mc=true&node=pt45.1.46&rgn=div5#se45.1.46_110730T

Recommendation

The Academic Senate recommends the approval of the IRB membership policies (Section 14 of the CPP IRB Policies and Procedures) that were recently adopted by the IRB (See Below).

Section 14.## Service as a Member of the IRB -- FINAL DRAFT

(version 7/1/16, revised 7/11/16, 8/5/16, 8/8/16, 8/18/16, 8/23/16, 3/31/17, 4/4/17, 4/24/17, 4/25/17, 5/4/17, 6/1/17, 6/7/17, 8/3/17, 10/08/17)

The mission of the CPP IRB is to support human subject research (HSR) through representation by faculty members of the various disciplines of research conducted on the campus. Serving on the IRB -- conducting protocol reviews, creating guidelines to ensure the ethics of the research program, etc. - is an important task for other HSR investigators (including faculty, students, and administrators) in the CPP research community. As a volunteer on the IRB, it can be time-consuming, but the rewards include learning the IRB process, knowing the kinds of research occurring at CPP, obtaining service credit, assuring regulatory compliance when ethical research with human subjects is conducted, and deriving satisfaction from other IRB-associated aspects.

Reference is made to section 5 of this Policies and Procedures manual, especially 5.2 "Appointment of Members to the IRB" and 5.9 "Review of IRB Performance."

Recruitment and Appointment

The composition of an IRB is defined by federal regulation at 45 CFR 46.107: "Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution." Because CPP is a polytechnic university, many disciplines are necessarily represented on the IRB and consequently the size exceeds the minimum.

The President has delegated, according to regulatory requirements, the authority to officially appoint the members of the IRB to the Institutional Official (IO). Recruitment of members may be from any source. The IO will consult with the Chair (who has consulted with existing Board members) and may consult with college deans and/or department chairs for recommendations on appointments. Persons may nominate themselves or be nominated. Recruitment from unit 3 employees (faculty and lecturers) via a call for service opportunity from the Academic Senate, and will be initiated by the IO. Staff may serve as members.

The Board must be constituted as per federal regulations, which include having at least one non-scientific person and having others who possess specific characteristics in terms of cultural and professional experience. The members include the chair, the vice-chair, regular members and their discipline-aligned alternate, and an unaffiliated (outside) member who represents the community and public interests. Recruitment of the unaffiliated position shall be independent of the senate process, since federal regulations require the unaffiliated person to be independent of the institution. Recommendations for the unaffiliated position may be solicited from IRB members and after a Board quorum vote, the chair will make a recommendation to the IO for appointment.

The term of membership for members is set at four (4) years, which is consistent with other CSU campuses. Some terms may be set shorter in order to maintain a staggered/overlapping balance of approximately one-fourth of the members being appointed each year. A member may be reappointed, or ask to be considered for reappointment. Consideration for reappointment will be by joint agreement of both the IO and Chair (who has consulted with existing Board members). While not required, it is anticipated that the alternate would assume the regular member's position. A regular member may assume an alternate position, too.

The selection of chair and vice-chair is made by the Board members with confirmation by the IO. The term for chair and vice-chair is set at two (2) years. A chair may be reappointed. While not required, it is anticipated that the vice-chair would assume the chair's position when vacated.

A member who leaves the Board in good standing may serve as a consultant. Consultants contribute information and experience but cannot vote per federal regulations. Consultants are not considered part of the Senate's definition of university committee; thus, they serve unofficially and do not require a call for service opportunity.

Compensation

Whitney (*Balanced Ethic Review – A Guide for Institutional Review Board Members*, Springer, 2016) wrote that “IRBs have long meetings with substantial additional time spent in preparation. Joining the IRB is a significant commitment.”, “Many IRBs require far more work than any other institutional committee.”, and “Some institutions do not (pay IRB members) on the ground that everyone has an obligation to participate in the institution’s governance.”

While there is no financial compensation, the chair and IO will recognize service in several ways, such as thank-you notes, letters regarding participation, and contributions to RTP (retention, tenure, and promotion) packages. Additionally, food is provided during most Board meetings.

Unaffiliated members may be compensated for their mileage and similar expenses.

Expectations

Members are obliged to:

- Attend a majority (>50%) of the meetings of the IRB, typically held monthly during the academic year, and other times as necessary. Extended absences and sabbaticals should be discussed with the chair and IRB office.
- Alternates are obliged to attend meetings if the member cannot. Alternates are welcome and encouraged to attend all meetings.
- Respond to Board communications (emails, protocol notifications, etc.)
- Contribute to the workload which includes review of protocols and help in the development of guidelines for Board business. Every year, the chair in collaboration with the IO, will set expectations for satisfactory member participation, which initially are set at completing five or more protocols and contributing substantially to two or more guidelines.
- Complete tasks within a reasonable time frame, and to inform the IRB office if delays are expected.
- Review and vote on minutes of Board meetings. Two-thirds of those present at the meeting, including alternates by previous Board decision, may vote electronically to approve minutes; otherwise, the vote is a simple majority of regular members at the following Board meeting.
- Learn the processes and procedures of the HSR program, including the use of the electronic protocol system.
- Be ambassadors of the IRB and HSR regulations within their academic units. That is, serve as an information resource to the CPP community engaged in HSR.
- Declare conflicts of interest when reviewing protocols and maintain confidentiality for matters brought to the board.
- Evaluate the potential risk and harm of proposed human activity primarily – human subject protections - while secondarily applying one’s research background. In other words, ethics comes before methodologies, but it is recognized that they are tied together. Provide review comments that address the ethical principles of human subjects protection (respect, beneficence, and justice).
- Complete the CITI group of modules designated for CPP IRB members for IRB training soon after appointment in order to be compliant with federal regulations. Further, members need to maintain their IRB knowledge familiarity with HSR regulations through continuing education.

Dismissal and Inability to Serve

Members of the IRB must be in good standing at the university. If a member has been deemed unacceptable for employment within the university, or can no longer serve as below, the member can be immediately dismissed from the Board. Confirmation may be received from Faculty Affairs or a comparable authorizing campus organization. Members may submit a letter of resignation to the IO, copying the chair.

All members (including unaffiliated) may be removed from the IRB for not fulfilling expectations, by mutual agreement of the chair(s) (unless one of the chairs is not available, or if one of the chairs might be dismissed) and IO, for reasons that include, but are not limited, as follows.

- Unable to attend IRB meetings.
- Unable to assist in implementing CPP policy.
- Unable to participate in protocol review.
- Failing to declare a conflict of interest.
- Breaching confidentiality.
- Being non-collegial or disruptive to governance of the Board.
- Being out-of-date with training or refusing to obtain continuing education pertinent to IRB matters.
- Participation in the Faculty Early Retirement Program (FERP). Faculty who “FERP” may serve only as consultants to the Board – not as a member. This is because of the logistical complications of serving during non-contracted academic periods.

IRB Office

The IRB office (aka research compliance office) will assist the IO:

- with preparing an appointment letter
- with preparing a dismissal letter
- with informing regulatory authorities (e.g., OHRP) about appointments and any related changes regarding the IRB.