CSUB IRB Staff and Member Roles and Responsibilities

The staff and members of the CSUB IRB play a vital role in the research life of the university and in the safety of the community. The members, Chair, Vice-Chair, RERC, and Research Compliance Analyst work together to ensure the rights and safety of research participants.

Responsibilities of the Members

Primary members attend IRB meetings as voting members. Alternative members attend IRB meetings as voting members only when replacing a Primary member to establish a quorum. When quorum is established by Primary members, Alternative members attend as non-voting members. Alternative members are welcome to attend all meetings and to take part in discussions even when not a voting-member.

In carrying out their duties, IRB chairs and members:

- execute their responsibilities in accordance with University policies and applicable federal, state, and local and laws;
- complete and keep current the required human subjects protection training;
- ensure that the criteria for IRB approval at 45 CFR 46.111 are met for all review assignments including expedited and full committee reviews;
- when assigned as primary, secondary, or expedited reviewer, review and assess recruitment materials and procedures, and use of recruitment incentives when applicable to confirm the equitable selection of participants;
- maintain confidentiality for all matters before the IRB, all expedited reviews, and IRB consultations;
- comply with the University or Affiliate institution's conflict of interest policy;
- disclose conflict of interests for a project subject to IRB review at a convened meeting; refrain from the discussion except to provide information requested by the IRB, and leave the room during voting; and
- when the chair/member has a conflict of interest for a project they have been asked to review by expedited procedures, disclose the conflicts of interests and decline the review.

IRB members are expected to:

- attend all scheduled training and review meetings;
- notify IRB Chair and staff in advance if there is a need to be absent from a scheduled meeting;
- arrive promptly and stay at convened meetings until all committee business and training has been completed;
- prepare for meetings by reviewing the assigned Cayuse IRB protocols with attached materials (including recruitment and consent materials) for all projects on the agenda for Full Board IRB meetings in which they are attending;

- Enter in all review comments in the Cayuse IRB protocol and prepare a summary of the review when assigned as the primary or secondary reviewer;
- participate in IRB discussions of protocols; and
- Enter all review comments in Cayuse IRB for expedited reviews in a timely manner (within 7-10 business days of receipt). Act as resources for researchers in the design of participant protection aspects of protocol development; and participate in training opportunities offered outside of IRB meetings. The IRB Community Member has the responsibility to bring the perspective of the volunteer research participant to the review process.

IRB Member Training

CITI Training

All prospective IRB Committee members are required to complete the required CITI training and to maintain currency on this training.

It is recommended that new IRB Committee members observe at least one IRB committee meeting prior to functioning as a voting member.

Continuing Education

IRB members will receive, on an ongoing basis, continuing education related to human research protection issues and requirements. This will usually occur at one of the regular Full Board meetings or in a summer retreat.

Additional Responsibilities of the IRB Chair and Vice Chair

The Chair and Vice Chair are voting members of the IRB and assume the same responsibilities of IRB Members. In addition to their responsibilities as a voting IRB member, the IRB Chair oversees IRB meetings to ensure reviews and approvals align with regulatory requirements, the Belmont Report, state laws, and University policy.

The IRB Chair is authorized to sign all documents relevant to the review and approval of human research projects (e.g., waivers of HIPAA authorization) and documents submitted for post-approval monitoring (e.g., safety reports that are not unanticipated problems; acknowledgement of and notifications from external IRBs), except IRB Institutional Agreements, which are signed by the Institutional Official or designee).

The role of the Vice Chair is to act as proxy for the IRB Chair when the Chair cannot fulfill their duties due to illness or other emergency or in situations of conflict of interest. The IRB Chair may designate signature authority to the Vice Chair. In this case the Vice Chair signs their own name. If the IRB Chair is unable to fulfill their duties, the IRB Chair may authorize the Vice-Chair to lead meetings and conduct non-compliance investigations.

The IRB Chair, or in their stead the Vice Chair, oversees IRB meetings to ensure reviews and approvals comply with regulatory requirements, the Belmont Report, state laws, and University policy. During IRB meetings, the Chair:

- reminds members who have a conflict of interest to leave the room during deliberation and voting;
- ensures ample time is allowed for discussion for each study;
- ensures the criteria for IRB approval and other relevant requirements (e.g., consent waivers/alterations, waivers of signed consent, determinations for vulnerable populations) are met before projects/protocols are approved; and
- ensures a determination is made and voting takes place for each action item on the agenda.

For reportable events, the IRB Chair:

- may review investigator problem reports when referred by the RERC, to assess for possible noncompliance or unanticipated problem involving risks to participants or others and Full Committee Review;
- review reports of initial allegations of serious and/or continuing noncompliance

With respect to their relationships with other members, the IRB Chair:

- provide guidance to the RERC and IRB members during and outside of meetings as appropriate; and
- consult with the RERC regarding IRB member needs.

The IRB Chair works with the RERC to:

- review IRB policy, documents (e.g., forms and worksheet), and correspondence,
- provide consultation and guidance to faculty and members,
- receive training and support respective to the duties and functions of the position, and
- conduct IRB meetings.

In the event that the IRB Chair is not available to assume these responsibilities due to emergency or conflict of interest, they may assign them to the Vice-Chair.

Responsibilities of the Research Ethics Review Coordinator (RERC)

The RERC works to coordinate the smooth operation of the IRB, to assign protocols to the appropriate level of review, and to act as the reviewer for protocols that fall into the Exempt category.

The Duties of the RERC include:

- Coordinate the Review of Human Subjects Institutional Review Board (HSIRB) Protocols to include:
    - Review incoming protocols in the CAYUSE IRB system and determine the appropriate level of review.
    - Perform all reviews that are determined “Exemption from Full Board Review.”
    - Process all Expedited Reviews assigning board members to complete the review.

    - For Expedited Reviews, provide PI with board member reviewer comments and confirm reviewer comments are addressed, then approve.
    - Attend convened board meetings.
    - For Full Board Reviews, assign primary and secondary board member reviewers.
    - At convened board meetings, take notes for minutes and generate conditions for approval letters, and work on behalf of the board to assure conditions are met by PI for approval.
    - Review and process External Investigator Requests, 118 Designations and Cooperative Agreement Requests.
    - Review and approve requests for modifications of protocols.
    - Review and approve requests to renew protocols.
- Other Administrative Duties include:
    - Work with HSIRB Logistics staff to develop agendas for full board meetings.
    - Recruit potential HSIRB members.
    - Provide member recommendations to Provost.
    - Conduct orientation/training sessions for new HSIRB members.
    - When available, serve as guest speaker for courses and groups.
    - Offer campus wide training sessions for faculty during each semester.
    - Coordinate investigations of possible non-compliance.
    - Review, modify and develop, as needed, HSIRB policies and procedures.
    - Review RCU and SRS projects for compliance.
    - Complete Annual Provost Report.
    - Reports to the AVP of Grants, Research and Sponsored.

Responsibilities of the Research Compliance Analyst (RCA)

The RCA works in multiple roles both for the IRB and within the GRASP office. The Duties of the RCA include:

- Acting as the go-to expert on Federal regulations for the protection of Human Subjects involved in Research as per 45 CFR 46.
- Maintaining the FWA (Federal Wide Assurance) and IRB registration records and their currency.
- Working with the RERC to revise and update the HSIRB policies and procedures as needed.
- Working with the RERC to revise and update the Cayuse IRB protocol forms as needed.
- Providing technical assistance for Cayuse IRB protocol submissions & working with the Cayuse ITS Support team as needed.
- Conducting the Pre-review phase of all protocol submissions.
- Overseeing the CITI Research Ethics training program and providing technical assistance to HSIRB RERC, members, faculty, staff, and students.
- Providing logistical support for HSIRB meetings and assisting with preparation and maintenance of meeting materials.
- Assisting with updating the HSIRB website.
- Working with the RERC to provide campus-wide training as requested by faculty and staff.
- Assisting with Cooperative Agreement process.
- Assisting PIs with International Research.