IRB Member Manual

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What is the purpose of this member manual?

This document, "HRP-109-IRB MEMBER MANUAL," is designed to guide you through membership expectations and related information for your service on the IRB at UC Irvine. This manual also includes guidance on the review of Human Research[1] and other related information.

1. What is the role of an IRB Member?

As an IRB Member, you are a key member of the UC Irvine Human Research Protection Program (HRPP). The role of an IRB Member is to protect research participants by determining whether Human Research submitted for review meets, or continues to meet, the regulatory criteria for approval. This means that you may play a role at initial review of research, review of modifications to previously approved research, continuing review of previously approved research, and review of reports of new information (e.g., events that represent potential problems for participants).

You have been formally appointed to serve in this role because you are in a position to make a valuable contribution to the HRPP's mission, whether due to your subject matter expertise or your experience with particular participant populations. When appointed, you were assigned to a particular committee or panel as either a regular member or an alternate.

2. What is the HRPP Toolkit?

The HRPP Toolkit is a comprehensive set of manuals, workflows, standard operating procedures (SOPs) Worksheets and Templates. The HRPP Toolkit provides the IRB Office and IRB Members with the review tools needed to protect Human Research participants in a compliant and efficient manner.

As an IRB Member, you will primarily use the Worksheets within the HRPP Toolkit.

For example, the regulatory criteria for approval of non-Exempt Human Research are included within "HRP-314-Criteria for Approval." You must always consider whether the criteria for approval have been satisfied when reviewing non-Exempt Human Research. When the convened IRB (Committee) or a Designated Reviewer (Non-Committee) approves a Human Research study, it means that the criteria for approval were considered and the applicable criteria for approval were met.

You will be typically notified in advance which Worksheets are applicable, as IRB staff consider this as part of their pre-review processes. But sometimes you may independently identify that an additional Worksheet is indicated, as it may assist you in your review process.

When vulnerable populations and waivers are requested, the Principal Investigator will complete one (or more) Worksheets, as applicable. You will use these completed Worksheet/s as part of the IRB review process. The IRB will decide the final review determinations by considering the information provided both by the PI and through accessing and reviewing other relevant Worksheets. IRB staff can help you if you have questions about whether and how to use these tools.

3. What are the expectations for an IRB Member?

As an IRB Member, you are expected to do the following:

[1] Any double-underlined word throughout this review handbook is defined in "HRP-001 - SOP: Definitions".

- Prepare for IRB meetings by reviewing all agenda items in advance of the meetings.
- Participate as a primary reviewer of submissions at IRB meetings when assigned and complete any assigned expedited reviews in accordance with the timelines outlined in HRP-302-Approval Intervals.
- Utilize this manual and other HRPP Toolkit documents in preparation for IRB meetings.
- Contribute to the collegial discussion of agenda items at IRB meetings.
- Confirm attendance for and attend **scheduled IRB meetings**. IRB Staff may ask for your assistance with identifying an alternate to substitute on your behalf when you are unable to attend.
- Communicate well in advance to the IRB Staff when you cannot attend an IRB meeting or when you need assistance with accessing or interpreting submission or review materials.
- Report any Conflicting Interest for IRB Members to IRB Staff and IRB Chair (see "HRP-001-SOP-Definitions" for a definition).
- Stay current with all training requirements.
- Treat all oral and written information obtained as part of the review process as confidential; IRB members must not disclose or use confidential information without prior authorization, which includes refraining from communicating review results to Investigators separately from any official IRB communication.
- Inform the IRB Chair and IRB staff immediately if any life events arise that prevent fulfilling obligations as an IRB member as outlined above.
- Understand the compensation process for IRB Members.

4. Where does the review process begin?

The review process for a submission of any type begins after staff in the IRB Office, typically IRB Staff, finish conducting pre-review. The purpose of pre-review is to make a submission "review ready," that is, to obtain all study materials from the Investigator and to clarify any issues with the submission that might pose a challenge for the review itself.[2] Any substantive issues found during pre-review may be noted and left for IRB Members to address in the review process.

After pre-review is complete, IRB Staff will route a submission for either Non-Committee Review or review by the Committee.

5. What are the different submission types?

There are different types of submissions that require IRB review:

- New Study
- Modification to previously approved research
- Continuing Review of previously approved research
- Report of New Information (RNI)

[2] IRB Staff use "HRP-021 - SOP: Pre-Review" and "HRP-308 - : Pre-Review" and other necessary HRPP Toolkit documents to complete pre-review.

6. What are the different routes of review?

As stated above, an IRB Staff will route a submission for either Non-Committee Review or review by the convened IRB, with some caveats noted below.

- Non-Committee Review: A Designated Reviewer conducts Non-Committee Review, that is, review by a single individual. Non-Committee Review entails all review determinations made outside of the convened IRB. [3]
- Committee Review: The convened IRB conducts Committee Review. You have been assigned to a committee as part of your appointment to the IRB. At each meeting, your committee will have a handful of submissions to review.

IRB Staff select the route of review based on consideration outlined in the HRPP Toolkit. For example, if an IRB Staff believes that a new study entails no greater than Minimal Risk and that the procedures included in the research fall under one or more of the expedited review categories included in "HRP-313-Expedited Review," the IRB Staff will route that study for Non-Committee Review.

7. What are the expectations for a Scientific Reviewer?

The HRPP facilitates a scientific review process as part of the IRB review process when appropriate (see HRP-309 Ancillary Review Matrix). If you volunteer or as asked to serve as a reviewer for this process, you will be assigned submissions to review in addition to any submissions on your next IRB meeting agenda. When conducting scientific review, you are responsible for utilizing HRPP Toolkit documents such as "HRP-320-Scientific or Scholarly Review."

8. How do I conduct Committee Review as a Primary Reviewer?

IRB Staff are responsible for deciding whether a new study should be routed for Non-Committee Review or review by the convened IRB. If routed for review by the convened IRB, then the new study will be assigned to one of the IRB committees for review. If the new study is assigned to your committee, the IRB Staff in charge of your committee will prepare the new study for review.

Preparing a submission for convened IRB review entails assigning a primary reviewer for each submission, deciding whether additional expertise is needed from an outside consultant, and generating and distributing an agenda.

Once the agenda has been distributed, you will receive an email notification. That notification will include a link directing you into an area of the IRB system called the "Meeting Workspace." All submissions on your agenda, including any new studies, will appear in the Meeting Workspace. Primary reviewers are identified in the Meeting Workspace by having their names appear to the right of the submission Agenda Items.

To begin preparing for review of a submission for which you are the primary reviewer at the IRB meeting, follow these steps:

1. Look at the list of Agenda Items and note for which ones you are listed as a primary reviewer. All IRB members are expected to review all submission materials; however,

[3] The majority of Non-Committee Review submissions of any type assigned to you will be for non-Exempt Human Research. However, you may occasionally be asked to make a Human Research, Exemption, or Engagement determination, or to review a request for emergency use of a test article.

primary reviewers also assist the IRB Chair with review by presenting a summary of the submission and guiding other IRB members through the criteria for approval.

2. Review any pre-review issues or other notes the IRB Coordinator has shared. Take note of the issues raised as these may be relevant when preparing for your IRB meeting.
3. The IRB Staff will likely identify what HRPP Toolkit documents (e.g. Worksheets) you will need to use to prepare for your IRB meeting. Open the relevant documents to familiarize yourself with the content and to understand what you should be looking for with your review. As you review the study, you may identify other relevant HRPP Toolkit documents.
4. Review the application and study documents.
5. You may want to develop a routine to help you organize your review. For example, many IRB members find it useful to read the online application for high level study details before then reviewing the consent form (if any).

   For new studies, after reading the consent form and getting a general understanding of the proposed research from the participants' perspectives, IRB members will typically read the UCI Protocol Narrative and Master Protocol (if any). As you proceed with these materials, note any questions, concerns, or clarifications you may need to have addressed. You may be able to resolve these issues on your own as you read through the different materials. You may not be able to resolve these issues. In that case, you may want to leave a note for your fellow IRB members to see what you would like resolved (see below).
6. While reviewing the study materials, you should begin deciding whether the submission may be approved.

   To determine whether the new study should be approved, you will use "HRP-314-Criteria for Approval" and any relevant Worksheets. As you walk through all of the approval criteria, decide whether they have been satisfied or whether the questions, concerns, or clarifications you identified earlier require resolution before you believe the convened IRB can determine that the approval criteria have been satisfied.
7. You are encouraged to record review notes prior to the IRB meeting.
   a. Option 1 (Add Review Comments): Click "Add Review Comments" from the submission Workspace and record your comments in the text box provided. To help organize your thoughts, you may choose to use "HRP-220-FORM-Criteria for Approval." This comments option includes a text box and the ability to upload documents. Other IRB members are able to see whatever you write or upload. You can even input a comment, post it, and return later to revise it.
   b. Option 2 (Request Clarification by Committee Member): *This option is reserved for the primary reviewer, IRB Chair, Committee, or IRB Staff.* If you are the primary reviewer and would like for the Investigator to clarify any items prior to the IRB meeting, click "Request Clarification by Committee Member" and type in your clarification request. The Investigator may respond to your request for clarification; however, this mode of communication does not open the submission to the study team to make edits. The information provided back to you may help clarify an item, but resolution of that item, e.g., a change to the consent form, may still require modifications prior to securing approval.
8. Repeat Steps 1-7 for each submission on the agenda.

9. If you would like to view your IRB colleagues' review notes, click on the "Reviews" tab in the Study Workspace. This will allow you to know what questions, comments, or concerns other members have as you prepare your own. If you are the first member to submit a comment, you can come back to the "Reviews" tab on the day of the IRB meeting to see what others have added.
10. When it is time to review a new submission at the IRB meeting, the IRB Staff or IRB Chair will ask the primary reviewer to lead the discussion. HRP-041-SOP-IRB Meeting Conduct outlines the process for reviewing submissions during an IRB meeting. If you are the primary reviewer, you should lead the discussion as follows:
    a. Provide a brief overview of the study, including the main study procedures, population(s) included, and any notable features of the study, (e.g., a rare disease or condition). *Remember: All members should have prepared for the IRB meeting, so you do not need to discuss all study details.*
    b. After your brief overview, ask your fellow IRB members whether there are any aspects of the study they do not understand, (e.g., they may need your help understanding how a particular procedure is carried out). Use this time specifically for clarification. If you are unable to clarify a particular aspect of the study, note that you may need to revisit that issue below.
    c. Using "HRP-314-Criteria for Approval," walk the committee through the criteria for approval. If the committee is able to determine that a particular criterion has been satisfied, then move to the next one. If the committee is not able to determine that a particular criterion has been satisfied, identify the modification(s) required by the investigator to satisfy that criterion. At this point, you should refer to the review comments your fellow IRB members included. Be sure to clearly articulate for the IRB Staff what modifications are required and why so the IRB Staff may relay this information to the investigator.
    d. After walking through the main criteria for approval, walk the committee through any required Worksheet(s). For example, if children are included as participants in the study, the PI must complete "HRP-416-WORKSHEET- Children." The Committee will consider the information in that document as part of their determinations for that population.
    e. Before making an official motion, review all of the information discussed in steps a-d above to make sure that your feedback to the investigator, if any, is reasonable and coherent. Every required modification should tie back to an approval criterion. If the committee is unable to justify a particular required modification against the criteria for approval, then remove it from the list.
    f. Make a motion.
        a. Approval: Made when all criteria for approval are met in HRP-314-Criteria for Approval.
        b. Modifications Required to Secure Approval: Made when IRB members require specific modifications to the research before approval can be finalized.
        c. Tabled: Made when the IRB cannot approve the research at a meeting for reasons unrelated to the research, such as loss of quorum. When taking this action, the IRB automatically schedules the research for review at the next meeting.

d. Deferred: Made when the IRB determines that the board is unable to approve research, and the IRB suggests modifications that might make the research approvable. When making this motion, the IRB describes its reasons for this decision, describes modifications that might make the research approvable, and gives the investigator an opportunity to respond to the IRB in person or in writing.

e. Disapproval: Made when the IRB determines that it is unable to approve research, and the IRB cannot describe modifications that might make the research approvable. When making this motion, the IRB describes its reasons for this decision and gives the investigator an opportunity to respond to the IRB in person or in writing.

f. The IRB Chair or Committee Chair will ask for another member to second your motion and, once seconded, will call for a vote.

g. Repeat steps a-g for each submission (new study, modification, continuing review) on the agenda.

9. How do I conduct Committee Review if I am not an assigned reviewer?

IRB members who are not assigned as a primary reviewer but are attending the meeting are expected to review all submissions on the agenda in order to contribute to the discussion and deliberation of each item and participate in the vote. Each IRB member will utilize the Toolkit materials to review the submission in accordance with regulatory requirements and local policies. IRB members who do not review submissions in advance of the IRB meeting should abstain from the vote.

IRB members who are not presenting submissions as the primary reviewer contribute to the collegial discussion of agenda items at IRB meetings. Follow the steps outlined above to access the meeting materials and each submission in advance of the meeting. Enter comments into the IRB system as needed to provide feedback about the submission or to ask questions of the primary reviewer. Reviewing submissions in advance of the meeting will assist the primary reviewer to prepare for the discussion and potentially resolve issues in advance of the meeting.

10. When do I recuse or abstain from a vote during Committee Review?

IRB members attending convened meetings are asked to participate in the discussion and vote for each submission under review. However, there are instances where IRB members must recuse themselves and may not vote because they have a conflict of interest related to the research or choose to abstain from voting without a need to state a reason.

Recusal for Conflicting Interest: The HRPP Toolkit, HRP-001-SOP- Definitions defines conflicting interest and provides examples of interests in the sponsor, product, or service being tested or is a competitor of the sponsor. IRB members should be prepared to disclose interests if they believe their interest will impede their ability to provide an unbiased review. When a conflicting interest is identified, the conflicted IRB member should not participate in the review of the study except to provide information requested by the IRB. The IRB member must leave the room or virtual meeting space during the IRB's deliberation and vote. This is considered a *recusal* and is recorded in the IRB meeting minutes.

Abstain: If an IRB member does not have a conflict but feels that he/she/they should not vote on a study, the member may *abstain* from voting. IRB members typically abstain from voting

when they have not reviewed the materials for a particular submission on an agenda and are not able to determine if the criteria for approval are met, they were not present at the meeting during the deliberation of a submission, they do not agree that a controverted issue has been resolved and/or do not have enough information to vote on a motion for a particular submission. Abstentions are recorded in IRB meeting minutes.

IRB staff are responsible for monitoring quorum during IRB meetings. If quorum is lost due to a recusal or abstention, the submission will be removed from the current agenda and placed on the agenda for a future meeting.

As a reminder, if both an alternate IRB member and the regular IRB member for whom the alternate IRB member can substitute for are present at a meeting, only one member is voting and only one member counts towards quorum.

11. What are the expectations for a Designated Reviewer?

A Designated Reviewer is an IRB Member who conducts Non-Committee Reviews. If you volunteer or are asked to serve as a Designated Reviewer, you will be assigned submissions to review on your own in addition to any submissions on your next IRB meeting agenda. When conducting Non-Committee Reviews, you are responsible for utilizing HRPP Toolkit documents such as “HRP-312-Exemption Determination” and “HRP-313-Expedited Review.”

12. How do I conduct Non-Committee Review for a new study?

When an IRB Staff assigns you a submission to review as a Designated Reviewer, you will receive an email notification from the IRB staff member according to their procedures and that submission will appear in the IRB system in the Reviews tab of a place called “My Inbox.”

Review the materials provided by the staff members using the following steps: Navigate to the Submission Workspace in the IRB system to begin your review and follow these steps:

1. Click into the Reviews tab to view any pre-review issues or other notes the IRB staff left for you. Take note of issues raised as these may be relevant when conducting your review.
2. The IRB staff will identify what HRPP Toolkit documents you will need to use to complete your review. Navigate to the HRPP Toolkit library in the IRB system to open the relevant documents. Scroll through each document to familiarize yourself with the content and to understand what you should be looking for with your review. As you review the study, you may identify other relevant HRPP Toolkit documents.
3. Next, click “View Study” to review the online application and attached study documents. Although you must review all study information prior to making a determination, you may want to develop a routine to help you organize your review. For example, many IRB Members find it useful to peruse the online application for high level study details before reading over the consent form (if any).

   After reading the consent form and getting a general understanding of the proposed research from the participants’ perspectives, IRB Members will typically read the Protocol Narrative and Master Protocol (if any). As you proceed with the review, note any questions, concerns, or clarifications you may need to have addressed. You may be able to resolve these issues on your own as you read through the different materials. You may not be able to resolve these issues. In that case, you may require additional information from the Investigator.

4. While reviewing the study materials, you should begin deciding whether the study may be approved and, if so, under what category. Because IRB Staff will generally route to you only those new studies which they cannot review themselves, the majority of new studies you will review qualify for expedited review.

   To determine whether the new study should be approved, and under what approval category or categories, you will use "HRP-313-Expedited Review," "HRP-314-Criteria for Approval," and any relevant Worksheets. As you walk through all of the approval criteria, decide whether they have been satisfied or whether the questions, concerns, or clarifications you identified earlier require resolution before you can determine that the approval criteria have been satisfied.

5. When you are ready to submit your review, click Submit Designated Review in the IRB system, select the appropriate determination, complete the remaining required fields. After you select OK, the new study will be routed back to the IRB Staff for post review activities.

13. How do I conduct Non-Committee Review for a follow-on submission?

Follow-on submissions include Modifications and Continuing Reviews. The same approval criteria that apply at initial review of the study also apply with these submissions. For these submissions, the main question is whether the criteria for approval *continue to be satisfied*. As such, you will use the same HRPP Toolkit documents you (or another IRB Member) used for initial review.

1. As you begin your review, you will want to note what has changed since the last review. To do this, click View Differences in the Submission Workspace. You will then see where answers to the application have changed or where new or revised documents were uploaded. From there, review the changes in relation to what was previously approved to determine whether the changes are acceptable.
2. For CRs, review the study in its entirety to confirm that the criteria listed in "HRP-314-Criteria for Approval" are still met. A CR-only submission does not allow for the Investigator to make any changes to the online application or study documents previously reviewed. This means that you do not need to click View Differences. Instead, simply review the online application and study documents as you would at initial review to determine whether the study may continue for another approval period.

There are specific criteria for being able to review follow-on submissions by Non-Committee Review. For non-Exempt Human Research, these criteria are included in "HRP-313-Expedited Review." Since you receive Non-Committee Review assignments from IRB Staff and since they have been trained on when Non-Committee Review is appropriate, you will likely be asked to review only those follow-on submissions that are actually eligible for this review route. However, you are always welcome to disagree with an IRB Staff's routing decision. In the IRB system, click "Assign to Committee Review" to route the submission for review by the convened IRB. Include a note in the text box required so the IRB Staff can see your rationale for changing the route of review.

14. What training does an IRB Member need to review Human Research?

You must complete the following trainings before you can participate as an IRB Member:

- *Orientation*: The purpose of orientation is to educate members about the current state of the IRB, the organizational structure of the HRPP/IRBs, to discuss roles and responsibilities of IRB membership, and share the next steps for training.
- *Shadow IRB Committee meetings*: An opportunity to learn about the committee review process and develop relationships with your IRB colleagues
- *Continuing Education*: IRB members are expected to participate in ongoing training offered or coordinated by the IRB Office. Trainings may be offered as workshops, during IRB meetings, webinars, and conferences.

As IRB policies and procedures change, there may be additional training requirements.

15. How is an IRB Member evaluated?

You will be evaluated informally on a regular basis. IRB Chairs or Vice Chairs, IRB Staff, and other IRB staff members will provide feedback on your contributions at IRB meetings and on Non-Committee Reviews. This feedback may include both strengths and opportunities for development.

In addition, you will be evaluated formally on an annual basis using "HRP-327-Performance Evaluation for IRB Members." The assessment form includes scores for knowledge, skills, performance, attendance, and trainings.

16. How long does an IRB Member serve?

An IRB Member generally serves on the IRB for a three-year term. However, your particular term of service is included in your IRB appointment letter. If you have any questions about your term of service, contact the IRB Directors.

17. How are IRB Members compensated?

In recognition of your commitment, you will be compensated for each full committee meeting attended, with a requisite attendance of at least 75% of the meeting. Please work with your primary department's financial team to ensure you have a KFS account linked to fund 66198 for allocations. Compensation is paid quarterly, in arrears, and as applicable, may be designated as a supplement to your salary and/or as an unrestricted research allowance.

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.

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.

Staff Employees

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

Community Members

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

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

Committee Vice Chairperson's Rate (1 per committee)
IRB vice chairpersons will receive a monthly research allowance of $500 per month of appointment.

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.

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.

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.

IRB Committee C (Social & Behavioral) Members

Committee Vice Chairperson's Rate
The IRB vice chairperson will receive a monthly research allowance of $500 per month of appointment.

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.

Staff Appointee Rate

IRB members who hold 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.

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.

IRB Committee E (Noncompliance) Members

Academic Appointee Rate
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.

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. *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.

IRB Alternate Members

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.

18. What is the role of an IRB Chair?

An IRB Chair is an IRB Member with certain additional responsibilities. The role of an IRB Chair is to guide IRB Members through the review, to serve as a mediator within the IRB to help resolve controverted issues, and (in the case of an IRB Chair only), to designate individuals to serve as Designated Reviewers.

If you are a Vice Chair, you have the responsibility to serve in the IRB Chair role for your committee in the absence of the IRB Chair (due to inability to attend a convened meeting or recusal due to a conflict of interest).

19. What are the expectations for an IRB Chair?

As an IRB Chair, you are expected to do the following:

- Stay in regular contact with IRB Staff to facilitate an efficient review process at IRB meetings; this includes holding regular check-ins to review agenda items for any potential issues to be flagged or addressed prior to IRB meetings.
- Confirm that IRB Staff has assigned agenda items to appropriate primary or other reviewers (including expert consultants).
- Request and communicate the need for expert consultants to your IRB Staff if they have not already identified this need.
- Preside over meetings of the fully convened IRB and ensure that the IRB carries out its duly authorized responsibilities as required by federal regulations, ethical principles, state laws and Legal Name of the Organization policy as represented in the HRPP Toolkit or other supporting materials.
- Ensure, at each meeting chaired, that the members present are sufficiently qualified through experience and expertise to review all research activities on the agenda, and that expert consultants have contributed, if applicable.
- Review and approve the minutes of each meeting chaired when asked by IRB Staff.
- Work with your IRB Staff to confirm that membership of the IRB is recruited, appointed, and oriented such that the IRB is duly qualified to fulfill its obligations to review, require modifications to, approve, or disapprove research protocols that represent the breadth of research submitted to the IRB by Legal Name of the Organization or affiliate researchers.
- Act on requests for emergency use of investigational drug, biologic, or device (physician scientist only).
- Serve as a liaison between the HRPP and the Legal Name of the Organization research community to promote communication and understanding of the concerns of the IRB, the research community, and other HRPP partners.
- Participate in local and federal investigations relating to protocols and actions, as required.

- Provide support and expertise as needed with respect to investigation of complaints or allegations of non-compliance received by or referred to the HRPP.
- Work with IRB members, Institutional Officials, and Investigators to ensure that the rights and welfare of research participants are adequately protected.
- In conjunction with HRPP leadership, develop and revise HRPP and IRB policies, procedures, and guidelines to stay current with societal thinking, regulatory changes, and national best practice standards.

As an IRB Chair, you are also expected to do the following:

- Designate individuals to serve in the Designated Reviewer to conduct Non-Committee Review. Conduct Non-Committee Review when feasible.
- Participate in routine review and assessment of the HRPP per "HRP-060 - SOP- Annual Evaluations of the HRPP" (IRB Chairs only).
- Contributes to the routine evaluation of IRB member performance and assists with member performance management as needed.

20. What are the expectations for a Consultant to the IRB?

Sometimes, the IRB may need to invite subject matter experts with competence in special areas to assist the IRB in its review of issues which require expertise beyond or in addition to that available on the IRB. These subject matter experts are referred to as "consultants" to the IRB. Typically, these consultants will be members of the local research community, though in some cases external consultants could be needed.

When the need for a consultant to the IRB is identified (typically by the IRB Chair or IRB committee), IRB Staff will coordinate the process of arranging for consultant input and will work with consultants to provide them with instructions on how to access review materials and arrange to make the consultant's review available to the IRB either via in-person meeting participation by the consultant or in writing.

If you are asked to serve as a consultant to the IRB, you will likely be asked to review and consider the information included within HRP-320-Scientific or Scholarly Review to provide the IRB with guidance on considerations such as (but not limited to) whether the risks, benefits, and knowledge to be gained are accurate as described in the protocol.

21. How is an IRB Chair evaluated?

You will be evaluated informally on a regular basis. HRPP leadership and IRB Staff will provide you with feedback on your leadership at IRB meetings and performance on Non-Committee Reviews. This feedback may include both strengths and opportunities for development.

In addition, you will be evaluated formally on an annual basis using "HRP-326-Performance Evaluation for IRB Chairs." The assessment form includes scores for meeting preparation, meeting management, and communication. As an IRB Member, you may also be evaluated as described above.

22. Whom do I contact for help?

Your primary resource for any questions, concerns, or other issues is IRB Staff.

If your question, concern, or issue is about your IRB Staff, please reach out to one of the IRB Managers.

Questions and Additional Information for the IRB

The IRB Office wants your questions, information, and feedback. Contact and location information for the IRB Office is:

Beverley Alberola, CIP
Senior Director, Human Research Protections
Human Research Protections
Office of Research, University of California - Irvine
Irvine, CA 92697
Email: beverley.alberola@uci.edu
949-824-5746
(she/her)

Jessica Sheldon, CIP
Director, Human Research Protections
Human Research Protections
Office of Research, University of California - Irvine
Irvine, CA 92697
Email: jessica.sheldon@uci.edu
949-824-3831
(she/her)

Reporting and Management of Concerns
Questions, concerns, complaints, allegations of undue influence, allegations or findings of non-compliance, or input regarding the Human Research Protection Program may be reported orally or in writing. Employees are permitted to report concerns on an anonymous basis. Concerns may be reported to the IRB Chair, IRB Office, IO/OO, Legal Counsel, Deans, or Department Chairs. The IRB has the responsibility to investigate allegations and findings of non-compliance and take corrective actions as needed. The IO/OO has the responsibility to investigate all other reports and take corrective actions as needed.

Employees who report in good faith possible compliance issues should not be subjected to retaliation or harassment as a result of the reporting. Concerns about possible retaliation should be immediately reported to the IO/OO or designee. To make such reports, contact the IO/OO:

Aileen Anderson, Ph.D.
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Office of Research
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