

**Policy Number: 14**

**Title: IRB Review of Human Subjects Research – Full Committee**

**Date of Last Revision: 08/10/05, 10/05/10, 01/24/11, 05/04/12, 06/05/13, 05/01/16, 08/16/17, 02/26/20**

**Policy:**

It is the policy of the UC Irvine (UCI) Institutional Review Board (IRB) that all human subjects research activities under its jurisdiction be reviewed according to the criteria described in the Federal regulations.

**I. Full Committee Eligibility**

- A. An Investigator may suggest a particular type of review, but the final determination is made by the IRB.
- B. The IRB at a convened meeting must review studies not qualifying for IRB review under the exempt or expedited review procedures.
- C. The IRB has the authority to approve, require modification to, or disapprove all research activities that fall within its jurisdiction.

**II. IRB Quorum Required for Full Committee Review**

- A. The IRB Committee may only review proposed research at a convened meeting where a quorum is present. A majority of the voting members of the IRB Committee are present, including at least one member whose primary interests are in nonscientific areas.
- B. IRB meetings are not convened if a nonscientist is not present.
- C. A non-affiliated member is present at convened meetings. The non-scientist and non-affiliated member may be the same individual.
- D. No official actions take place at a meeting where a majority of the voting members are not present.
- E. Should quorum be lost during a meeting, the IRB cannot take votes until the quorum is restored.
- F. Wherever possible, IRB Committee meetings take place with all participating IRB members physically present. However, circumstances sometimes warrant conducting IRB meetings with a member present by telephone conference call (e.g., member has expertise but is unexpectedly unable to attend meeting). OHRP recognizes that “convened” IRB meetings can be conducted via teleconference, provided that each participating IRB member:
  - 1. Has received all pertinent material prior to the meeting to allow adequate time for review and the request of additional information, if needed.
  - 2. Can actively and equally participate in the discussion of the protocol (i.e., each member can hear and be heard by all other participating members).
  - 3. The minutes of such meetings clearly document that these two conditions have been satisfied in addition to the usual regulatory requirements (e.g., attendance; initial and continued presence of a majority of members, including at least one nonscientist member; actions taken by the IRB; the vote on such actions; discussion and resolution of controverted issues).

- G. No IRB member may participate in the review of research (e.g., new submissions, continuing review, amendments/modifications, unanticipated problems, or potential noncompliance issues) in which the member has a conflict of interest. If a conflict exists, the Committee member can provide information requested by the IRB Committee but cannot be present for the discussion and the vote.
- H. The IRB will defer a protocol to another meeting, if at least one person (i.e., IRB member or consultant) with appropriate scientific or scholarly expertise is not available to conduct an in-depth review of the protocol.
- I. When the convened IRB reviews research involving prisoners, the prisoner representative is present.

### III. **Required Review**

- A. Substantive review of protocols takes place at convened meetings. Applications undergoing review are individually presented and discussed at a convened meeting of the IRB Committee.
- B. In conducting the full IRB Committee review, the majority of the Committee must agree that materials are in sufficient detail to determine the study meets criteria 45 CFR 46.111 and if applicable, 21 CFR 56.111 for approval:
  - 1. Risks to subjects are minimized by (a) using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (b) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes;
  - 2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB Committee should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB Committee should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility;
  - 3. Selection of subjects is equitable considering the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations and the potential need for additional protections, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons;
  - 4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by Federal and State regulations and Institutional policies and procedures including the IRB;
  - 5. Informed Consent will be appropriately documented, in accordance with, and to the extent required by the Federal and State regulations and Institutional policies and procedures including the IRB;
  - 6. When appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects;
  - 7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data;

8. There are adequate provisions to protect the rights and welfare of vulnerable populations from coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. The IRB Committee must determine if additional safeguards need to be included in the study to protect the rights and welfare of these subjects; and
  9. When appropriate, the Informed Consent Document should include the additional elements of informed consent.
- C. The full IRB Committee determines a review interval for the research as appropriate to the degree of risk, but not greater than one year from the last date of IRB approval. The following factors are taken into consideration when determining the appropriate review interval, but are not limited to:
1. Research with procedures that pose risk and have never been tested in humans before;
  2. Phase I research studies;
  3. Involvement of recombinant DNA or other types of gene transfer protocols;
  4. Research that involves procedures where there is a high likelihood of serious harm or death;
  5. Studies conducted by researchers who have been determined to be in serious non-compliance in the past two years; and
  6. Other situations where the IRB believes that more frequent continuing review is required.
- D. The regulations make no provision for any grace period extending the conduct of research beyond the expiration date of IRB approval. Therefore, continuing review and re-approval of the research must occur on or before the date when IRB approval expires. The study expires at midnight of the date specified on the approval letter and the informed consent document.
- E. Approval Period for Full Committee Research:
1. For research reviewed and approved by at the full Committee at a convened IRB meeting, the approval period starts on the date of the convened meeting. The expiration date (the last day the research is approved) is the last day of the approval period. For example, if the IRB approves the research for one year at a convened meeting held on April 12, 2005, the approval period is April 12, 2005-April 11, 2006.
  2. For research that was determined by the full Committee to require minor modifications, the approval period begins on the date a Reviewer, usually the IRB Chair, verifies that the investigator has made the revisions requested by the full Committee. (For example, if the IRB determines that minor modifications are required at a convened meeting held on April 12, 2005 and approval is for a one year period, when an IRB Chair verifies the changes and approves the research on April 27, 2005, the approval period is April 27, 2005-April 11, 2006.)
  3. In all cases the expiration date (the last day the research is approved) is the last day of the approval period. Research may be conducted on the expiration date, but may not be conducted after the expiration date without continuing approval. (For example, if the approval period is April 27, 2005-April 11, 2006, the expiration date is April 11, 2006. Research must end at midnight on April 11, 2006 unless the Investigator receives continuing approval of the research.)
- F. Standard requirements for informed consent or its waiver or alteration apply to all studies meeting the criteria for approval by the full IRB Committee.

- G. All research approved by the full IRB Committee is conducted in accordance with all applicable UCI policies and procedures.
- H. The decisions and requirements for modifications by the IRB Committee are promptly conveyed to the Investigator electronically by HRP Staff. Written notification from the IRB of a decision to disapprove a protocol, the correspondence is accompanied by the IRB Committee's reasons for the decision and may include an invitation for reply by the Investigator, either in person or in writing.

**References:**

45 CFR 46

21 CFR 50 and 56

ICH-GCP: 3.2.2, 3.2.3., 3.3.3, 3.3.4.

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**Procedure Number: 14.A**

**Title: Procedure for IRB Review of Human Subjects Research – Full Committee**

**Procedure:** This procedure provides guidance for the review of human subjects research activities that qualify for full IRB Committee review under the Federal regulations.

- I. **Lead Researcher (LR) Responsibilities**
  - A. The IRB Application is completed in its entirety and electronically submitted to the HRP staff for processing. One original IRB Application with signatures (Lead Researcher, Department Chair, and Faculty Sponsor, if applicable) is submitted and any additional documentation not previously uploaded.
  - B. The Consent form(s) is written using the template consent document.
  - C. Studies that include vulnerable populations are submitted with applicable appendices demonstrating added protections and a rationale as to why these populations are to be included in the proposed research.
    1. Vulnerable Population - Pregnant Women, Fetuses, and Neonate (Appendix B)
    2. Vulnerable Population - Prisoners (Appendix C)
    3. Vulnerable Population - Children (Appendix D)
    4. Vulnerable Population - Cognitively Impaired (Appendix E)
  - D. The Investigator replies to all “requests for revisions and/or clarifications” requested by the pre-reviewers or reviewers, when applicable, and provides an explanation if the requested revisions are not made.
  - E. If an Investigator disagrees with any IRB comments and/or requests for revisions, the investigator should provide written justification for his/her position for review by the original IRB committee.
  - F. Any proposed changes to IRB approved documents are submitted to the IRB using the electronic “Modification Request” process. The Investigator must receive written IRB approval before implementing any changes to the research study.
  - G. All unanticipated problems to participants or others are submitted to the IRB using the electronic “Unanticipated Problems (UP) Report.”
  
- II. **IRB Committee Responsibilities**
  - A. Research that involves greater than minimal risk must be reviewed by the full IRB Committee at a scheduled convened meeting. Each UCI IRB Committee meets once a month. IRB Applications for full Committee review are accepted per posted submission deadlines.
  - B. The assigned IRB Committee receives a copy of the IRB application prior to the scheduled meeting (usually seven days in advance) to allow adequate time for review and the request of additional information, if needed (e.g. supporting documentation from the Investigator, literature search, etc.)
  - C. IRB members and consultants with a conflict of interest are asked to disclose at the beginning of the meeting and must absent themselves from the meeting room during the discussion and vote on the research in which they have a conflicting interest. IRB Committee Members and consultants are considered to have a conflicting interest if they or his or her immediate family member have any:

1. Disclosable financial interest; (See IRB Policy 9 for definition)
  2. Role in the conduct of or participation in the research; or
  3. Other individual conflict of interest that could impede or discourage objective decision-making on behalf of human subjects.
- D. Each new study submitted as posing greater than minimal risk is assigned a Primary and Secondary Reviewer. The reviewers assigned will have expertise in the area of the research adequate to the scope and complexity of the research. The Reviewers conduct an in-depth review of all pertinent documentation.
1. The Primary Reviewer is to present the study in summary form to the full IRB Committee highlighting any controverted issues and recommending modifications, if applicable.
  2. The Secondary Reviewer is prepared to provide any additional information not presented by the Primary Reviewer highlighting any controverted issues and recommending modifications, if applicable.
  3. If the Committee does not have a member available with expertise adequate to the scope and complexity of the research, a consultant with expertise in the area of research will be asked to review the study and provide written recommendations or may be asked to attend the Committee meeting. The consultant may not count toward the quorum or vote. If the Committee is unable to secure adequate expertise the protocol is held over for another convened meeting.
  4. The Reviewers will assess the protocol for both scientific and scholarly merit in relationship to the level of risk.
  5. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, economically or educationally disadvantaged persons, the IRB Committee determines if additional safeguards need to be included in the study to protect the rights and welfare of these subjects (See IRB Policies 36-40). The Primary and Secondary Reviewers complete the "IRB Reviewer's Checklist" indicating the additional protections provided for the vulnerable population(s).
  6. All Committee members are given the opportunity to review, ask questions of the reviewers, and request modifications in the proposal.
  7. The Committee reviews the proposed research, consents, and applicable documents to determine whether the study meets criteria 45 CFR 46.111 and 21 CFR 56.111 if applicable, for approval. In order to provide written documentation of these criteria, the Primary and Secondary Reviewer completes the "IRB Reviewer's Checklist" detailing how each of these criteria is met.
  8. The Committee determines the review interval appropriate to the degree of risk, but not less than once per year.
  9. Typically, although not required, the Primary Reviewer makes the motion regarding the status of the study in accordance with applicable UCI IRB policies and procedures.
- E. Non-scientists: The primary duties of IRB members with non-scientific status consist of reviewing the informed consent document and the recruitment materials of new IRB Applications 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). Non-scientists may also represent the general

perspective of research participants. IRB members with non-scientific status are not assigned primary and secondary reviewer responsibilities.

### III. IRB Administrator Responsibilities

- A. The Administrator conducts a pre-review for studies submitted requesting full Committee review. **If the Administrator determines that the study meets criteria for exempt or expedited review, the IRB Chair is consulted for confirmation.**
- B. The Administrator requests any additional documents needed for the review, as well as any pre-review changes.
- C. E-mails requesting pre-review changes may be sent by the Administrator to the Investigator.
- D. The Administrator places the new study on the next available Committee agenda, assigns reviewers, and prepares the Reviewer and Committee packets.
  1. In general, the IRB agenda is limited to 25 items to allow for adequate discussion of each item.
- E. The Administrator assigns reviewers with expertise in the area of the research adequate to the scope and complexity of the research. If the Committee does not have at least one member available with expertise adequate to the scope and complexity of the research, the Administrator assists in arranging review by a consultant with the required expertise.
- F. The Administrator may be asked to arrange for the consultant to attend the Committee meeting. The consultant may not count toward the quorum or vote.
- G. The Administrator gathers the following documents for all Committee Members to review:
  1. A completed IRB application
    - a. Investigator's Assurance document
    - b. Disclosure of Investigators' Financial Interest form
  2. Protocol Narrative
  3. Sponsor's Master protocol, if applicable
  4. Proposed informed consent document(s) and/or Study Information sheet and/or script as appropriate;
  5. Copies of surveys, questionnaires, or videotapes;
  6. Copies of letters of assurance or cooperation with research sites;
  7. Investigator's brochure, if applicable
  8. Advertising intended to be seen or heard by potential subjects, including e-mail solicitations.
  9. DHHS-approved sample informed consent form, if applicable
  10. DHHS-approved protocol, if applicable
  11. DHHS grant application – human subjects section, if applicable and considered to be in a fundable range
- H. The Administrator and the HRP team monitor quorum status throughout the meeting.
- I. In addition, HRP staff takes notes of discussions of controverted issues, all IRB recommendations, determinations, motions, and votes for each study reviewed during the Committee meeting in accordance with applicable UCI IRB policies and procedures. The minutes of the IRB Committee meeting clearly reflect the determinations regarding risk and approval period (review interval). If a member has a conflicting interest, it is noted in the minutes that a conflict exists and the Committee member was absent during the discussion and vote for that specific research study.

- J. Letters requesting revisions from reviewers, and approval letters are drafted using the appropriate template.
- K. Modifications, unanticipated problems involving risks to human subjects or others, and continuing reviews are completed per corresponding policies and procedures.
- L. Appropriate HPS database entries are completed.
- M. Approved documents are processed.
- N. The Protocol File (FileNet) is updated.



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**Procedure Number 14.B****Title: Procedure for Initial Application Materials to be Reviewed by the Full IRB Committee****Procedure:**

This procedure outlines the initial application materials to be reviewed by the full IRB Committee in order to make preliminary or final determinations on the approval of the proposed research activities.

**I. Lead Researcher (LR) Responsibilities**

- A. The following materials are to be provided by the LR in order for the IRB Committee to obtain information in sufficient detail to make the preliminary or final determinations required by the Federal regulations for research approval:
  - 1. A completed IRB application including
    - a) Signatures of LR, Department Chair, and Faculty Sponsor, if applicable;
    - b) Appendices applicable to research activities, vulnerable populations, etc.
    - c) Investigator's Assurance document; and
    - d) Disclosure of Investigators' Financial Interest form
  - 2. Protocol Narrative
  - 3. Sponsor's protocol and Investigator's brochure, if applicable;
  - 4. Proposed Informed consent documents and/or information sheets and/or scripts, as appropriate;
  - 5. Copies of research instruments (e.g., surveys, questionnaires, videotapes);
  - 6. Copies of letters of cooperation or IRB approval letters for each research site, if applicable;
  - 7. All advertising materials intended to be seen or heard by potential participants, (e.g., email solicitations, TV/radio spots, flyers/brochures).
  - 8. DHHS-approved sample informed consent form, if applicable
  - 9. DHHS-approved protocol, if applicable
  - 10. DHHS grant application – human subjects section, if applicable and considered to be in a fundable range
- B. Investigators will provide the IRB reviewers/staff with additional information as requested.

**II. IRB Committee Responsibilities**

- A. The materials listed in the Lead Researcher's section of this policy will be distributed to all Committee members via electronic agenda and reviewed by the Primary and Secondary Reviewers for presentation at the full IRB Committee meeting. The materials will be received by members sufficiently in advance (usually seven days) of the meeting date to allow review of the material and the request of additional information, if needed.
- B. In addition to the above materials all Committee members will receive the IRB Reviewer's Checklist initiated by the HRP staff during the administrative review process. The reviewers must provide their completed and signed checklists to the HRP team.

- C. If NIH-supported, the IRB Committee must receive and review a copy of the NIH-approved sample informed consent document (ICD) and the full NIH-approved Investigator's protocol as a condition for review and approval of the local ICD. In addition, if any deletions or substantive modification of information concerning risks or alternative procedures contained in the sample ICD, they must be approved by the IRB Committee.
- D. If a DHHS grant application exists, an IRB member should review the human subjects section of the application, to ensure that the research described in the IRB application is consistent with the grant application. The grant application does not need to be reviewed by every IRB member.

III. **The Human Research Protections (HRP) Team Responsibilities**

- A. The HRP team (Administrator, Sr. Analyst, and Analyst) under the direction of the Administrator will verify that all of the required documents as described in the Lead Researcher's section of this policy have been submitted.
- B. The HRP team will verify that appropriate signatures have been obtained.
- C. Additional requests will be sent via e-mail to the LR.
- D. The HRP team prepares the "IRB Reviewer Checklist" for the Reviewer(s) during the administrative review process.
- E. The HRP team prepares the agenda per applicable procedures.
- F. If study is NIH-supported, any deletion or substantive modification of information concerning risks or alternative procedures contained in the sample ICD must be approved by the IRB Committee and reflected in the IRB Committee minutes.