

Policy Number: 5

Title: IRB Records and Documentation

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Policy:

It is the policy of the UC Irvine (UCI) Institutional Review Board (IRB) to maintain IRB office records for research activities under its jurisdiction.

- I. The IRB records must be maintained in a manner that contains a complete history of all IRB actions related to review and approval of a protocol, including continuing reviews, amendments (modifications), any serious or continuing non-compliance and any unanticipated problem(s) (UP).

- II. **Document Retention**
 - A. IRB records are stored for 10 years beyond the end of the calendar year in which the study is closed in both onsite and off-site locations. Records are stored electronically and on paper.
 1. IRB files for active studies are stored in the Office of Research Administration. IRB files for closed studies are archived off-site at an Iron Mountain Storage Facility.
 2. IRB minutes and rosters are stored in the Office of Research Administration; with the more recent documents (post-2008) being stored electronically.
 3. Completion of a study occurs when the Lead Researcher submits a closing report or 30 days after IRB approval of the study expires, whichever comes first.
 4. If a study is canceled without participant enrollment, records also are still maintained for 10 years beyond the end of the calendar year in which the study is closed.

- III. **Access to Documents**

The OR must make all IRB records accessible for inspection and copying at reasonable times and in a reasonable manner by:

 - A. Internal entities authorized to review IRB files including OR and the Office of Internal Audit.
 - B. Authorized representatives of any regulatory oversight agency such as the FDA, OHRP, National Institutes of Health (NIH) and other government sponsors of human research.
 - C. Administrative records (e.g., minutes, member lists, and budgets) are maintained indefinitely.
 - D. Access to UCI's electronic database, the Human Protocol System (HPS), is limited to appropriate Office of Research, OR staff and UCI partners as needed

- for business purposes (e.g., School of Medicine). Electronic systems are frequently backed up and have a data recovery and disaster management plan.
- E. For Department of Defense sponsored research there may be a requirement to submit records to the Department of Defense for archiving.

IV. **The HRP must prepare and/or maintain all of the following documents:**

- A. IRB Applications - Copies of all research applications/protocols reviewed (including studies that never enrolled subjects), including scientific and scholarly evaluations, if any, approved sample informed consent documents, data safety monitoring board/committee reports, progress reports submitted by the Lead Researchers, and reports of any unanticipated problems to participants including reports of injuries to subjects and others, any reports of serious or continuing noncompliance.
- B. Continuing Reviews - Records of continuing review activities.
- C. Amendments/Modification Requests - Records of minor and significant changes to research activities.
- D. Suspension or termination of IRB approval – Per 45 CFR 46.113: An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.
- E. Correspondence with Lead Researchers - Copies of correspondence between the IRB and the Investigators.
- F. New Findings - Statements of significant new findings developed during the course of the research, which may relate to the participant's willingness to continue participation that will be provided to the participants. This information may be provided in the Re-consent Cover memo. The cover memo will be attached to the revised Consent Form.
- G. IRB Minutes - The minutes of all IRB Committee meetings.
- H. IRB Rosters - Changes in membership are updated quarterly and maintained electronically.
- I. IRB Policies and Procedures - The IRB will maintain written policies and procedures that will be reviewed at least every three years.

References:

45 CFR 46.115

UC Records Retention Schedule, Research Administration Records, B.5. - IRB Records including Human Studies Exempted from IRB Review records; Approved 2015-11-20

Procedure Number 5.A

Title: Procedure for IRB Records and Documentation

Procedure:

This procedure outlines the necessary maintenance of IRB office records associated with research activities under the jurisdiction of the UC Irvine (UCI) Institutional Review Board (IRB).

- I. IRB Administration Responsibilities are assumed by the Office of Research Administration. Human Research Protections (HRP) staff prepares and/or maintains adequate documentation of IRB activities, including the following:
 - A. **Protocol File** – The following documentation is retained in the relevant protocol file:
 1. *New Submission* - All available documents related to the submission of a research protocol including but not limited to:
 - a. the original IRB application
 - b. the Protocol Narrative
 - c. Scientific Evaluations, if any
 - d. Consent and Assent Forms
 - e. Recruitment Advertisements
 - f. the Master Protocol, if applicable
 - g. the Sponsor's Brochure, if applicable
 - h. DHHS-approved sample informed Consent Form, if applicable
 - i. DHHS-approved protocol, if applicable
 2. *Continuing Review* – records of Continuing Review activities including but not limited to:
 - a. Continuing Review application
 - b. the most current Protocol Narrative
 - c. the most current Consent/Assent Forms
 - d. Data Monitoring reports, if available
 - e. List of unanticipated problems, and any serious or continuing noncompliance submitted to the IRB since initial approval (generated by the HRP staff).
 3. *Amendment/Modification Request* - records of requests for revisions to protocol including but not limited to
 - a. Modification request form
 - b. the revised Protocol Narrative
 - c. the revised Consent/Assent Forms, if applicable
 - d. recruitment advertisements, as applicable
 - e. the Sponsor's Amendment, if applicable
 4. *IRB Approval letter* for each of the above IRB activities. The approval letter will document:
 - a. The specific permissible Exempt or Expedited category(ies);
 - b. Determinations required by the regulations for:
 - (1) Waiver or alteration of the consent process;
 - (2) Research involving pregnant women, fetuses, and neonates;

- (3) Research involving prisoners;
 - (4) Research involving children; and
 - c. The initial and continuing reviews, the frequency (approval period) for the next continuing review.
 - 5. *Individual Reports of New Information* including reports of noncompliance submitted by the Lead Researcher via the "New Information Report" are maintained in the protocol file.
 - 6. *IRB/HRP documentation* – copies of all review activity documentation such as materials provided by the HRP staff to the IRB reviewer(s), reviewer checklist(s) and commentary, etc. The reviewers checklists document:
 - a. The specific permissible Exempt or Expedited category(ies);
 - b. Determinations required by the regulations and protocol-specific findings supporting those determinations including:
 - (1) Waiver or alteration of the consent process;
 - (2) Research involving pregnant women, fetuses, and neonates;
 - (3) Research involving prisoners;
 - (4) Research involving children; and
 - c. The frequency (approval period) for the next continuing review.
 - 7. *Correspondence* - HRP staff maintain copies of all correspondence between the IRB, HRP staff and Investigators. Correspondence (letters, e-mail) related to a research protocol are kept in the protocol file.
- B. ***IRB Minutes*** - The minutes of all IRB Committee meetings must be in sufficient detail to demonstrate:
- 1. The specific IRB Committee;
 - 2. The approval of previous meeting minutes;
 - 3. The review of a summary of exempt and expedited reviews and determinations made by the Subcommittee since the last IRB meeting;
 - 4. Attendance at the meeting, to include:
 - a. The name of the alternate voting;
 - b. An account in the voting block of all the members present in the room at the time of the vote. This will include documentation of the following:
 - 1. When a member is present for the discussion and vote or leaves the room;
 - 2. When a member absents themselves during the vote due to a conflict of interest and
 - 3. Initial and continued presence of a majority of members, including at least one nonscientist.
 - 5. IRB Committee Members absent due to conflicting interest are identified and documented on a per protocol basis. Members' absent due to conflicting interest are not counted towards quorum.
 - 6. For each protocol discussed at the meeting, the minutes should detail:
 - a. The assigned reviewers and their scientific or non-scientific status as indicated on the IRB Committee rosters [e.g. NS (non-scientist), OS (other scientist), and PS (physician scientist), and/or a non-voting member, including the use of any expert consultants and their scientific or nonscientific status and specialty;
 - b. If a consultant is used and attends the meeting in person or by

- teleconference, a statement that the consultant received all pertinent study material before the meeting, a statement that the consultant was able to actively and equally participate in all study-related discussions and the key information provided by the consultant.
- c. If a Committee Member is excused from the meeting due to a conflict of interest during the discussion or vote of the study;
 - d. Actions taken by the IRB Committee;
 - e. Separate deliberations for each action
 - f. Discussion of any controverted issues and resolutions;
 - g. If discussing a suspension or notification of expiration, issues that arise where treatment may be continued for safety purposes; and
 - h. The vote on these actions including the number of votes "for", "against," or "abstain" in order to document the continued existence of a quorum.
7. When a protocol is approved, the minutes reflect that the criteria for approval found in regulations 45 CFR 46.111 and if applicable, 21 CFR 56.111 were discussed and that the protocol was approved based on the criteria.
 8. When a protocol is approved, the level of risk (e.g., minimal or greater than minimal) and the approval period (review interval) appropriate to the level of risk are determined.
 9. When protocol revisions are requested or a proposal is disapproved, the basis for the revisions or the disapproval is included.
 10. For Continuing Review.
 - a. The minutes reflect the IRB Committee's determination regarding which protocols require continuing review more often than annually, as appropriate to the risk, and the approval period; and
 - b. The minutes reflect the criteria for approval found in regulations 45 CFR 46.111 and if applicable, 21 CFR 56.111 have been discussed and documented.
 - c. The minutes reflect the level of risk (e.g., minimal or greater than minimal) and the approval period, appropriate to the level of risk.
 11. For DHHS-Supported Study - When the IRB Committee reviews DHHS-approved informed consent documents for DHHS-supported studies, the minutes reflect the justification of any deletions or substantive modifications of information concerning risks or alternative procedures contained in the DHHS-approved sample informed consent document.
 12. Specific IRB Findings. When specific findings on the part of the IRB Committee are required, these findings are fully documented in the minutes and include protocol-specific information justifying each determination. For example:
 - a. Alteration or Waiver of Informed Consent. When approving a procedure that alters or waives the requirements of informed consent, the minutes document that the Committee made the determination.
 - b. Waiver of Documentation of Informed Consent. When approving a procedure that waives the requirements for obtaining a signed informed consent document, the minutes document that the Committee made the determination.
 - c. Significant/Non-significant risk device. When the sponsor or the

investigator claims that the device is not significant risk a determination of whether the device is non-significant or significant risk and a rationale for the determination is documented.

13. Research Involving Prisoners. When approving research involving prisoners, the minutes will document that the Committee made the seven additional findings and indicate the specific category, which authorizes the research, required in accordance to IRB policy.
 - a. Additionally, the minutes must reference that a majority of the IRB Committee (exclusive of prisoner member/representative) has no association with the prison(s) involved, apart from their membership on the IRB; and
 - b. At least one member of the IRB Committee is a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except where a particular research project is reviewed by more than one IRB, only one IRB need satisfy this requirement.
14. Research Involving Children. When approving research involving children, the minutes will document that the Committee made the findings in accordance with federal; regulations and IRB policy.
15. Wards of the State or Other Agency. When reviewing research involving children who are wards of the state or any other agency, institution, or entity, the IRB must determine documents in the minutes that such research is:
 - a. Related to the child's status as wards; or
 - b. Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as participants are not wards.
16. Research Involving Pregnant Women, Human Fetuses and Neonates. When approving research involving fetus, pregnant women, neonates the minutes document that the Committee made the findings in accordance with IRB policy.
17. Research Involving Cognitively Impaired Individuals. When reviewing research involving individuals who are determined to be cognitively impaired and/or lack decision capacity, the IRB must find and document in the minutes that the use of a Surrogate Decision-Maker is appropriate.
18. Alternates. Meeting minutes document when an alternate Committee member replaces a voting Committee member. Alternates should have the same scientific or non-scientific status as the Committee Member (e.g. NS, OS, and PS).
19. Minority Report. IRB Members may file a minority report at their discretion. The report will be included with the minutes.

C. ***Distribution of Minutes***

1. The Administrator develops a draft of the IRB Committee meeting minutes and includes the draft in the full Committee materials for the next convened meeting.
2. The IRB Committee members review and communicate to the Administrator any necessary revisions.
3. The final version of the meeting minutes is maintained electronically. The Institutional Official has access to all final versions of minutes via a secure folder in FileNet.

- D. **List of IRB Members** - A roster of regular and alternate IRB members identified by:
1. Name;
 2. Earned degrees;
 3. Representative capacity;
 - a. Physician Scientist (PS), Other Scientist (OS), or Non-Scientist (NS)
 - b. Affiliation with UCI: Affiliated or Non-Affiliated – Individuals considered affiliated with UCI include:
 - (1) Individuals with a current employment or other relationship (e.g., full-time or part-time employee, full-time or part-time student, trainee, member of governing panel or board, or paid or unpaid consultant or agent) with UCI.
 - (2) Individuals with a former employment or other relationship UCI.
 - (3) Individuals who have an immediate family member (spouse, domestic partner or dependent children) with a current employment or other relationship UCI.
 - (4) Individuals who have an immediate family member with a former employment or other relationship UCI.
 - (5) Representatives of a vulnerable population
 4. Indications of experience and expertise sufficient to describe each regular and alternate member's anticipated contribution to the IRB's deliberations; and
 5. Employment or other relationship between each member and UCI (i.e., full-time employee, graduate student, part-time employee, emeritus faculty, unpaid consultant, unpaid IRB member).
 6. All changes in Committee membership are reported to OHRP and FDA on a quarterly basis.
- E. **Policies and Procedures** – HRP Standard Operating Policies and Procedures Manual includes the following information:
1. Policies and procedures for conducting initial and continuing review of research and for reporting findings and actions to the Lead Researcher and the Institution.
 2. Policies and procedures for determining which projects require review more often than annually and which projects need verification from sources other than the Lead Researcher that no material changes have occurred since previous IRB review.
 3. Policies and procedures for ensuring prompt reporting to the IRB of proposed changes in the research and for ensuring that such changes in approved research are not initiated without IRB review and approval except when necessary to eliminate apparent immediate hazard to a subject.
 4. Policies and procedures for ensuring prompt reporting to the IRB, Institutional Officials, the Study Sponsor, and all applicable federal agencies (e.g., OHRP, FDA) of any unanticipated problems involving risks to subjects or to others.
 5. Policies and procedures for ensuring prompt reporting to the IRB, appropriate UCI personnel, and of the appropriate Department of Agency head (e.g., OHRP, FDA) of:

- a. of any serious or continuing non-compliance with these policies and procedures or with the requirements or determinations of the IRB; and
 - b. any suspension or termination of IRB approval.
 - F. **Emergency Use Reports** – All documents related to Emergency Use of a FDA-regulated test article (i.e., investigational drug, biologic, or medical device) is maintained electronically.
 - G. **Reports of any subject complaints** – All subject complaints are followed up and resolved by the HRP staff and IRB, if necessary. Subject complaint documentation is maintained electronically.
 - H. **Regulatory non-compliance reviews** – All noncompliance reviews are followed up and resolved by the HRP staff and the IRB, if necessary. Noncompliance review documentation is maintained electronically.
 - I. **Attendance records** – the HRP staff maintains attendance lists of IRB training sessions.
 - J. **Budget and Accounting Records** – The Assistant VCR and Directors prepare an annual budget for OR which include resource allocation for Human Research Protections. Resource allocations are based on cost analysis of expenses in previous fiscal year and projections of necessary resources and factors these expenses into the budget proposed to the VCR.
- II. **The Human Research Protections (HRP) Team Responsibilities**
- A. The HRP team (Administrator, Senior Analyst, and Analyst) under the direction of the Administrator is responsible for the retention of all research documents and required documentation in the IRB file.
 - B. The HRP team will maintain the collation of all IRB documents into the protocol file following the HRP Administrative Procedures.
 - C. The IRB Administrator will be responsible for electronically retaining the final approved copy of all IRB Committee meeting minutes.

Procedure Number: 5.B**Title: Procedure for Planning and Implementing IRB Committee Meeting Agendas****Procedure:**

This procedure provides guidance on the purpose, development, and implementation of the UC Irvine (UCI) Institutional Review Board (IRB) Committee meeting agendas.

I. IRB Committee Responsibilities

- A. At a convened IRB Committee meeting, the following items will be placed on the agenda for review:
1. New IRB Applications submitted for Review. All newly proposed research involving human participants, excluding those projects that meet one or more of the exemption categories as authorized in 45 CFR 46.104(d) and 21 CFR 56.104(d) or one or more of the expedited categories as authorized in 45 CFR 46.110;
 2. Continuing Review Applications. Continuing review of all human participants research at intervals appropriate to the degree of risk, but not less than once per year, excluding those projects that meet one or more of the exemption categories as authorized in 45 CFR 46.101(b) and 21 CFR 56.104(d) or one or more of the expedited categories as authorized in 45 CFR 46.101(b) (8) or (9);
 3. Significant Modifications. All major amendments to currently approved human participants research activities that materially affect an assessment of the risk/benefit profile of the study or substantially change the specific aims or design of the study; and
 4. Unanticipated Problems Involving Risk to Participants or Others. All unanticipated problems involving risks to participants or others. Factors that help determine the need for review at a convened meeting are:
 - a. The seriousness of the event;
 - b. Whether the event is described in the study protocol and informed consent document;
 - c. Whether the event occurred at a location for which the UCI IRB is the IRB of record; and
 - d. The Investigator's recommendations as to whether the problem was a direct result of a participant's participation in the research study.
 5. Expedited Review Determinations. A report documenting approval of research per expedited review procedures for the previous month is provided to the IRB Committee as an item on the next convened IRB Committee meeting agenda.
 - a. This documentation must include a citation to the specific permissible category or categories justifying the expedited review.
 - b. This documentation advises all Committee members of research proposals that have been approved under the expedited review procedure.
 6. Noncompliance. The HRP reports promptly to the IRB Committee any serious or continuing noncompliance with the Federal regulations or

requirements of the IRB as an item on the next convened IRB Committee meeting agenda.

7. Education. As necessary, education will be placed on the agenda for IRB Committee members, which may include:
 - a. Federal regulations;
 - b. Local policies and procedures;
 - c. Any changes in Federal regulations;
 - d. Any changes in local policies and procedures; or
 - e. Other items as requested by the IRB.
- B. Agendas and review materials will be distributed via an electronic agenda to Committee members one week prior to scheduled Committee meeting, allowing ample time for adequate review and preparation.
- C. Addendums and review materials will be distributed to Committee members via e-mail in a timely manner that allows ample time for adequate review of the addendum item. Consideration of the complexity and the scope of the research will be given in determining the appropriate time required for adequate review. The Committee member will notify the IRB Administrator if additional time will be required, to allow for prioritization and reassignment of the addendum item.

II. **IRB Administrator Responsibilities**

- A. It is the responsibility of the Administrator to place all scheduled items for Committee review on the next available agenda. In general, there is a review cap of 25 items per meeting - 10 new IRB applications and 15 other items (i.e., combination of continuing review applications, modification requests, and may include reports of unanticipated problems involving risk to participants or others).
- B. The Administrator will assure that the agenda includes all relevant sections to be discussed during the Committee meeting.
- C. It is the responsibility of the Administrator to include the reports of all approvals that have occurred since the previous Committee meeting by either expedited means or registered determinations of exempt status with the agenda for notification to the Committee.
- D. When an addendum to a finalized agenda is warranted, the Administrator will assemble materials and assure distribution via e-mail in a timely manner that allows ample time for adequate review of the addendum item. Consideration of the complexity and the scope of the research should be given in determining the appropriate time for adequate review.
- E. If a Committee member notifies the Administrator that additional time will be required for an adequate review, the Administrator will evaluate the addendum item for prioritization and reassignment of the addendum item.

References:

45 CFR 46
21 CFR 50
21 CFR 56