



Review of Research by the Convened IRB

<http://research.uic.edu/human-subjects-irbs/>

Version: 1.5; Date: 01/21/2019

Approved by: Human Protections Administrator and
Director of OPRS

AAHRPP REF#: 130

AAHRPP Elements: II.2.C, II.2.D, II.2.D.1-3., II.2.E.,
II.2.E.1.-3.

POLICY:

- I. In accordance with federal regulations, initial and continuing reviews of research must be conducted by the IRB at convened meetings at which a simple majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas (i.e., a quorum), except where expedited review is allowed under HHS regulations at [45 CFR 46.110](#).
- II. The IRB Chair may expand the required member representation for quorum on a protocol-specific basis secondary to the scope of the research being reviewed or involvement of vulnerable groups in the study. The presence of an unaffiliated member and member representing the perspective of the participant at the meeting is highly desirable but not mandatory per UIC policy. Refer to UIC HSPP policy [IRB Composition and Membership](#).
- III. Review of amendments (i.e., proposed changes to previously approved research) must be conducted by the IRB at convened meetings, except when changes are minor (refer to UIC HSPP policy [Amendment to Previously Approved Research](#)).
- IV. The UIC IRBs use a reviewer system with two reviewers having scientific expertise and/or research experience relevant to the study assigned as primary reviewers. The exception is initial review as a nonscientific reviewer is generally assigned as well. The review by this individual focuses on the viewpoint of research participant, acceptability of the consent process and understandability of the consent document. However, all agenda materials are provided to all members, and the final determination is made by a vote of all members present following the discussion.
- V. An IRB panel may, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

PROCEDURE:

- I. Application Materials
 - A. Materials required for submission are outlined on the [Initial Review Checklist](#), [Continuing Review Checklist](#), and [Amendment Checklist and Instructions](#) located on the UIC OPRS website.



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- B. The required materials for other submissions (e.g., Prompt Reporting to the IRB, Humanitarian Devices, and Emergency Use) are listed within the associated UIC HSPP policy.

II. Convened Meeting Schedule

- A. In general each of the IRBs meet twice monthly with the exception of CHAIRb which meets monthly. Meetings may be cancelled if there is a lack of submissions or quorum, or if the meeting falls within a UIC-mandated holiday. Whenever possible, cancelled meeting are re-scheduled. Schedules for the board meetings are posted on the UIC OPRS website or the CHAIRb Portal.
- B. The Chair in consultation with the OPRS Director may convene an IRB to conduct an unscheduled meeting as needed. Examples of reasons for this include but are not limited to: emergency use of an investigational drug or device, treatment IND, humanitarian use device, or sponsor deadline or pending expiration of IRB approval for a protocol of high institutional importance.
- C. IRB meetings last until determinations have been made for all items of business on the agenda or until quorum is no longer maintained.
- D. Submission deadlines for convened review by the IRB are provided on the OPRS website and typically are two weeks before the meeting. Items may be added to the agenda after this date with the approval of the Chair and OPRS Director provided adequate time for evaluation exists (generally > 48 hours before the meeting).

III. Pre-meeting Review Procedures

- A. Assignment of Submissions to an IRB
 - 1. Submissions for convened review are assigned to an IRB based on:
 - a. next available IRB meeting date,
 - b. type of research (Health and Biological Sciences [IRBs 1 or 3] or Social, Behavioral, and Educational Sciences [IRB 2]),
 - c. vulnerable populations (e.g, prisoner research [IRBs 1 or 2]),
 - d. IRB conducting the initial review, as continuing reviews and amendments are typically assigned to the IRB that conducted the initial review, and
 - e. performance site (i.e., CHAIRb when research conducted at CAPriCORN institutions).
 - f. Protocols may be transferred to another board due to considerations of expertise and workload with agreement of both IRB Chairs.
 - 2. A protocol that has been disapproved by one IRB may not be submitted or transferred to another IRB.
- B. OPRS Staff Pre-Review
 - 1. OPRS staff perform a pre-review as time permits. The pre-review is guided by a pre-review checklist, and serves as a mechanism to assist with the following functions:



- a. confirmation that all documents required by the IRB have been submitted by the investigator;
 - b. assessment as to whether the protocol was submitted for the appropriate level of review;
 - c. assessment as to whether supplemental reviews from other committees are required and their status;
 - d. (at continuing review) confirmation that the approved documents (e.g., informed consent documents and protocol, when applicable) submitted by the investigator match the current IRB-approved documents; and
 - e. Identification of potential regulatory and/or administrative issues and concerns that the IRB may wish to consider.
 2. Pre-review comments are provided to IRB members in advance of the meeting.
 3. OPRS staff members may contact researchers following the pre-review in an attempt to resolve any outstanding issues before the meeting as time permits and dependent upon the nature of the pre-review comments.
- C. Committees Supplementing the IRB Review
 1. Depending on the protocol, committees providing supplemental reviews for initial review, continuing review, or amendment submissions to the IRB may include: the Cancer Center-Protocol Review Committee, Conflict of Interest Resolution Committee, Clinical Research Center, Institutional Biosafety Committee, Investigational Drug Service, Embryonic Stem Cell Research Oversight Committee, Radiation Safety Committee, Radioactive Drug Review Committee, CAPriCORN Steering Committee, and CAPriCORN Patient-Clinician Advisory Committee. Separate policies and procedures describe the interactions and communication timelines between the IRB and these committees.
 2. Once completed, the written reviews from these committees are provided to the IRB members. While the goal is to have these reviews and/or approvals completed at the time of submission, the IRB may initiate their review of the research before reviews from the other committees are completed, except for the Investigational Drug Service and Radiation Safety Committee. IRB approval may not occur until final committee reports have been reviewed and considered by the IRB.
- D. Preparation of Meeting Agenda
 1. The Assistant Director or IRB Coordinator determines the review type (convened vs expedited) of the submissions and constructs the agenda.
 - a. The Assistant Director or IRB Coordinator consults with the Chair (or designee) to verify the assignment of reviewers and verification of appropriate representation at the meeting for any vulnerable groups.



- b. The Assistant Director or IRB Coordinator consults with the Chair (or designee) to determine whether a need exists for *ad hoc* reviewers.
 2. IRB members, alternates, and *ad hoc* consultants are notified of their assignments and submissions to review through the agenda. The agenda, submissions, review materials, and other relevant meeting materials (e.g., policies and articles for discussion, meeting minutes, etc.) are available via OPRS Live approximately one week before the meeting and remain accessible throughout the meeting discussion.
 3. The agenda also informs IRB members of the research protocols approved by expedited procedures since the last IRB meeting, emergency use of a test article, unanticipated problems or allegations of serious or continuing noncompliance, protocols closed or suspended, protocols whose IRB approval has expired, past meeting minutes to be reviewed or minutes approved since the last meeting, continuing education or policy discussions, and other pertinent information related to the meeting and review of the submissions.
- E. Materials Provided to Reviewers
 1. Primary reviewers are expected to perform an in depth review of the complete set of documents submitted by the investigator via the OPRS Live system. Their review includes all materials submitted in conjunction with the IRB application.
 2. If the IRB members or *ad hoc* consultants require additional information, clarification, or guidance, they may contact OPRS staff for assistance. They may also contact the investigator directly. The IRB members or *ad hoc* consultants should upload any information received from the investigator to OPRS Live as part of their review.

IV. IRB Meeting Procedures

A. Attendance

1. Attendance at convened meetings is captured in the minutes via the signature sheet and within the discussion, as applicable:
 - a. IRB members (voting, alternates) in attendance,
 - b. IRB members not in attendance,
 - c. Replacement of a member in voting by an alternate,
 - d. Continued presence of quorum for all votes, including a member whose primary concern is in a nonscientific area,
 - e. Attendance of members and alternate members who participate through tele- or videoconference,
 - f. IRB members who are recused due to a conflicting interest,
 - g. Others present (e.g., invited guests, investigators invited to address the IRB, *ad hoc* consultants, OPRS/OVCR administration).

B. Quorum and Voting Requirements

1. The Chair and Vice Chairs are voting members of the IRB.



2. The Chair, with assistance of the Assistant Director of the IRB, determines that quorum is established and maintained. Quorum is documented in the minutes via the signature sheet and via the vote as documented in the individual minutes entry for each submission that is discussed.
3. Standards for quorum and voting are:
 - a. A majority of voting members of the IRB (or their designated alternates), including at least one member whose primary concerns are in non-scientific areas, must be present in person or via tele- or videoconference to conduct a convened meeting.
 - b. In order for research to be approved, it must receive the approval of a majority of such members present at the meeting. Voting occurs by a show of hands or voice vote. The vote count is documented in the RiSC database and reflected in the minutes. Voting by proxy is not permitted.
 - c. Members who recuse themselves due to a conflicting interest are not counted among those who have voted or abstained toward said protocol.
 - d. If quorum is lost during a meeting, due to either lack of a majority of IRB members being present or absence of a non-scientist or another required member (e.g., representative of a vulnerable group), the IRB cannot take any further actions or vote until quorum is restored. If quorum is not restored, the protocol is tabled and the meeting may not continue until quorum is achieved. If quorum cannot be achieved, the meeting is adjourned.
 - e. Presence of a non-affiliated member is desirable.
 - f. A non-scientist or non-affiliated member represents the perspective of research participants
 - g. Protocol-Specific Quorum Requirements
 - (1) When the IRB reviews research that involves participants vulnerable to coercion or undue influence, at least one member must be present who is knowledgeable about or experienced in working with these participants.
 - (2) When the IRB reviews research that involves prisoners, a prisoner representative must be present.
 - (3) In accordance with 34 CFR Parts 350 and 356, if an IRB reviews research that is supported by the U.S. Department of Education and subject to 34 CFR 97 and that purposefully includes children with disabilities or individuals with cognitive impairment and decisional impairment as research subjects, at least one member primarily concerned with the welfare of these research subjects must be present.

C. Conflict of Interest



The Chair asks at the beginning of the meeting in reference to the entire agenda or before each protocol in reference to said protocol whether any members have a conflict of interest as defined in UIC HSPP policy [IRB Member, Ad Hoc Consultant, and OPRS Staff Conflict of Interest Policy](#).

D. Protocol Review

1. IRB members are provided with review guides to assist in conducting their reviews.
2. The IRB discusses each protocol individually and applies the criteria for approval as described in the applicable review guides.
3. The primary reviewers provide a summary of the protocol and lead the discussion of the protocols assigned to them. They are expected to have a thorough understanding of the research and conduct an in-depth review using the materials submitted by the investigator and the review guides relevant to the research.
4. A primary reviewer presents a summary highlighting:
 - a. critical issues for consideration of the IRB,
 - b. when reviewing an amendment
 - (1) changes being proposed,
 - (2) impact of changes on approval criteria,
 - (3) any significant new findings that have arisen from the review process and that might relate to subjects' willingness to continue participation, and
 - (4) whether and how these finding should be provided to subjects.
 - c. when conducting a continuing review
 - (1) concerns that have arisen since the prior IRB review,
 - (2) whether adverse events are of the type or frequency expected,
 - (3) whether changes to the protocol or consent are required,
 - (4) whether verification is needed from someone other than the researcher that no material changes have occurred since the prior IRB review,
 - (5) any significant new findings that have arisen from the review process and that might relate to subjects' willingness to continue participation should be provided to subjects,
 - (6) whether and how these finding should be provided to subjects, and
 - (7) current consent documents are complete and accurate.
 - d. recommendations for action by the IRB (i.e., approval, conditions required to secure approval, deferral),
 - e. whether the criteria for approval under [45 CFR 46.111](#) (and subparts [B](#), [C](#), and [D](#), when applicable) or [21 CFR 56.111](#) and any other required determinations are met (initial review), continue to be met (continuing review) or are not



- met. The criteria for approval must also be assessed for amendments when the changes affect a criterion for approval, and
- f. whether the required elements of informed consent are present ([45 CFR 46.116](#) or [21 CFR 50.25](#)) or waiver or alteration granted according to the regulations and the consent process is appropriate.
- 5. The other reviewer provides any additional information and recommendations.
- 6. Other IRB members are provided the opportunity to express their views. These members are expected to have reviewed the materials provided them and have sufficient understanding of the protocol to assess its acceptability.
- 7. An IRB member who cannot attend the convened meeting in person or via tele- or videoconference may submit written feedback via OPRS Live or email to the Assistant Director so that the convened IRB may consider their comments. IRB members who do not attend the IRB meeting do not count toward quorum and cannot vote.
- 8. *Ad Hoc* Consultants are present only for the discussion involving the relevant protocol, speak to the area of knowledge in their written report, and remain present until the IRB is ready to vote to allow any questions or concerns to be addressed. *Ad Hoc* consultants are not permitted to vote and do not count toward quorum.
- 9. After the IRB completes their deliberation, the Chair (or designee) calls for a motion and vote.
- E. Documentation
 - 1. Discussions of controverted issues and actions taken by the IRB, and separate determinations and protocol specific justifications for the determinations are documented in the minutes as described in UIC HSPP policy [Documentation of IRB and OPRS Activities](#).
- F. Range of possible actions by the IRB
 - 1. Approval: An approval is granted if the research activities meet the criteria for approval ([45 CFR 46.111](#) and/or [21 CFR 56.111](#) and, if applicable Subparts [B](#), [C](#), and [D](#)) and no changes to the research are required by the IRB.
 - 2. Conditions Required to Secure Approval: The IRB requires that the investigator (a) make specified changes to the research protocol or informed consent document(s), (b) confirm specific assumptions or understandings on the part of the IRB regarding how the research will be conducted, or (c) submit additional documents, such that, based on the assumption that the conditions are satisfied, the IRB is able to make all of the determinations required for approval (under [45 CFR 46.111](#) and/or 21 CFR 56.111 and, if applicable, subparts [B](#), [C](#), and [D](#)). Under this scenario, further review of the research by the convened IRB is not necessary. The IRB may designate the Chair (or other designee) to review the written



response from the investigator, determine whether the conditions for approval have been met and, when they are met, approve the research. The date of approval is the date the Chair (or designee) determines the conditions for approval have been met.

3. Deferral: Substantial revisions, requests for more information for IRB consideration or other additional documentation are required, and preclude the IRB from making the determinations required for approval. The response to the IRB's concerns and any revisions to the protocol or consent documents must be reviewed at a convened meeting of the IRB.
4. Tabled: Criteria for a convened IRB meeting or review of the protocol are not met (e.g., loss of quorum, appropriate expertise or representation for a vulnerable group is not present). Study is reviewed at a subsequent meeting when criteria for review are met.
5. Disapproval: A study is disapproved if it is found to be unethical, without scientific or scholarly merit and/or does not meet the criteria for approval. Written notification from the IRB of a decision to disapprove a protocol is accompanied by the IRB panel's reasons for the decision and an invitation for reply by the Investigator. A protocol may not be disapproved under expedited review procedures.

- G. Approval Period. Please refer to the UIC HSPP policy [Approval Date and Approval Period](#) for more information.

V. Post meeting activities

- A. The investigator is notified in writing that a review determination has been made. A letter detailing the IRB's findings is sent to the investigator as an e-mail attachment. The notification letter is prepared by the OPRS staff based on the completed review guide and meeting discussion. The staff may request the reviewer to provide their input on the letter.
- B. The notification letter includes:
 1. date of review
 2. relevant submission information (i.e., IRB protocol number, protocol title, submission type)
 3. process of review
 4. decisions of the IRB
 5. when the IRB requires revisions to the protocol, application, and/or consent documents, and/or further information or clarifications for approval (i.e., conditions required to secure approval or deferral) the following is included:
 - a. description of revisions, information requests, or clarifications
 - b. instructions for submitting written response
 - c. notice that submission will be withdrawn in 90 days if no response
 6. When IRB disapproves research the following is included:
 - a. Description of reasons for disapproval
 - b. Description of how researcher may respond



7. When IRB approves submission, information relevant to the submission as prompted by the notification template is included.
 - C. In instances where the IRB did not approve the study under review, the investigator must respond to the IRB's findings in writing. If the investigator requests an opportunity to respond to the IRB in person at a convened meeting every effort will be made to accept the investigator's request; however, the Chair in consultation with the OPRS Director make the final decision based on logistics and the IRB's findings.
 - D. Reporting Findings to Organization
 1. The investigator's department head and, if applicable, faculty sponsor are copied on all communications.
 2. The Institutional Official is informed of the IRB's review actions through the IRB minutes.
 - E. Review of Investigator's responses to the IRB
 1. The IRB Coordinator or Assistant Director reviews responses from investigators for conditions required to secure approval and notes their pre-review comments with the response as time permits. The response is then assigned to the Chair (or designee).
 2. Responses from PIs for deferrals are reviewed by the IRB Coordinator or the Assistant Director and changes are verified. The deferral responses are then assigned to the next IRB meeting for re-review by the convened IRB. The IRB that originally reviewed the protocol must review the deferral response, unless it was stipulated that a different committee is able to review the deferral response. The re-review is assigned to the original primary reviewers whenever possible.
 3. Responses and resubmissions from investigators for disapproved submissions are prepared for convened IRB review. The IRB that originally reviewed the submission reviews the response and resubmission, unless it was stipulated that a different IRB is able to review the response and resubmission.
 - F. Investigators are provided 90 days to respond to the IRB's findings. UIC HSPP policy [*Administrative Withdrawal of Research and Submissions*](#) describes the policy and procedures related to withdrawal of research due to a failure to respond.
 - G. The consequences of a failure to obtain continuing review approval by the expiration date are described in UIC HSPP policy [*Lapse in IRB Approval*](#).
- VI. Review of Research by the CHAIRb
- A. CHAIRb follows the policies and procedures regarding review process as stated within this document.
 - B. CHAIRb protocols are submitted and communications are sent via the CHAIRb Portal.
 - C. Additional post-review procedures are outlined in the *CHAIRb Operations SOP*.

REFERENCES:



21 CFR 56.108(a), 21 CFR 56.109

45 CFR 46.109

FDA Guidance for IRBs, Clinical Investigators, and Sponsors: IRB Continuing Review after Clinical Investigation Approval. US FDA, DHHS, February 2012.

OHRP Guidance on Continuing Review of Research, OHRP, DHHS, November 10, 2010

OHRP Guidance on IRB Approval of Research with Conditions, OHRP, DHHS, November 10, 2010

OHRP Guidance on Written IRB Procedures OHRP, DHHS, July 1, 2011

OHRP Frequently Asked Questions: IRB Procedures

REVISION LOG:

| Version (#, date) | Replaces (#, date) | Summary of changes |
|-------------------|--------------------|--|
| 1.1, 06/18/09 | 1.0, 10/15/08 | Revised policy to be more inclusive of both convened and expedited review. Changed title to reflect this from "Convened Review Process" to "IRB Review Process." |
| 1.2, 09/17/09 | 1.1, 06/18/09 | Included a description of the quorum requirements, a description of the calculation period, the list of items reviewed by the primary reviewer and other IRB members for continuing review. |
| 1.3, 05/18/12 | 1.2, 09/17/09 | Updated IRB review procedures, quorum requirements, and IRB actions. Method for calculating expiration date and approval period revised. |
| 1.4, 01/10/17 | 1.3, 05/18/12 | Removal of JBVAMC specific language. Removal of language regarding approval periods as a separate policy has been created. |
| 1.5, 01/21/19 | 1.4, 01/10/17 | Revised to account for review and review actions occurring via OPRS Live. Clarification regarding recused members and definition of majority. Editorial revisions to reduce duplicative information. Updated links to comply with 2018 Requirements (45CFR46). |