



## **IRB Composition and Membership**

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Approved by: Human Protections Administrator,  
Director of OPRS,  
and Executive IRB Chair  
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### **POLICY:**

- I. The UIC IRBs are composed according to the DHSS and FDA regulations (45 CFR 46.107 and 21 CFR 56.107).
  - A. Each IRB has at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.
  - B. Each IRB includes one or more members who are knowledgeable about and experienced in working with the vulnerable categories of participants, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, involved in research regularly reviewed by the Board.
  - C. Each IRB includes at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
  - D. Each IRB includes at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
  - E. Each IRB includes at least one member representing the perspective of research participants.
  - F. Non-scientist and non-affiliated members are designated to represent the perspective of research participants for each board. The non-scientist, non-affiliated member representing the perspective of research participants may be the same or different individuals.
  - G. When the convened IRB reviews research involving prisoners, a prisoner representative is present.
  - H. When the IRB reviews research that involves categories of participants vulnerable to coercion or undue influence (e.g., children, impaired capacity to consent, mentally disabled, educationally or economically compromised, pregnant women, neonates, fetuses), one or more members or *ad hoc* consultants who are knowledgeable about or experienced in working with such participants are present.
- II. The ethical criteria at 45 CFR 46.107 and 21 CFR 56.107 guide the selection of members.



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- A. The IRB is sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human participants.
  - B. To assist in fulfilling its role, the IRB includes persons knowledgeable about the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.
  - C. Every nondiscriminatory effort is made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.
  - D. No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. The member with the conflicting issue is recused from the meeting during this time.
- III. Additional Requirements for CHAIRb
- UIC IRB #7, Chicago Area IRB (CHAIRb), has been charged with reviewing human subjects research under the scope of the Chicago Area Patient Centered Outcomes Research Network (CAPriCORN). In addition to the requirements outlined in this policy, the following requirements are in place for CHAIRb:
- A. Each institution participating in CAPriCORN research assigns a full member and, when desired, an alternate member to CHAIRb;
  - B. Each participating VA assigns a minimum of two voting members to CHAIRb;
  - C. CHAIRb follows VHA Handbook 1200.05 and VA regulations 38 CFR 16 when VA research is being conducted.
  - D. Additional criteria and IRB composition are described in the CHAIRb policy *CHAIRb Operations SOP*.
- IV. The membership includes not only voting members but alternates. The alternates are designated as replacements for specific members with comparable qualifications. Alternates replace designated voting members who are unable to attend the meeting or are recused due to a conflict and the alternate provides necessary expertise. When an alternate replaces a regular member, the alternate is provided the same material that the regular member received or would have received. Alternates adhere to the same conflict of interest and confidentiality standards as members.
- 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.
- VI. Voting members as indicated on the IRB roster provided to OHRP who are present at the meeting either in person or via tele- or videoconference for the discussion of the protocol and do not have a conflict of interest are eligible to vote. This includes both the Chair and Vice Chairs. Voting members may be replaced by their designated alternate when they are unable to attend or vote. When the voting



member and their alternate both attend the meeting, only one may participate in the voting for a given study.

## PROCEDURE:

### I. IRB Members

#### A. Recruitment and Appointment

The appointment and re-appointment processes are outlined in UIC HSPP SOP *Standard Operating Procedure - IRB Member Recruitment and Appointment Process*.

#### B. Responsibilities

1. understand the ethical principles of the Belmont Report (i.e., respect for persons, beneficence and justice);
2. participate in initial and ongoing education and training sessions;
3. ensure that the rights and welfare of research participants are protected;
4. develop a working knowledge of the criteria for IRB approval of research (45 CFR 46.111 or 21 CFR 56.111 for FDA regulated; these are posted in the IRB meeting room and copies provided members) and the IRB Review Guides;
5. attend IRB meetings on a regular basis (expectation is for each member to attend 75% of meetings);
6. serve as primary reviewers for research within their areas of expertise;
7. serve as general reviewers on all research being reviewed;
8. understand to the extent needed vote to approve, require modifications, defer, table or disapprove research submitted to the IRB; and
9. acknowledge and recuse themselves from the discussions and voting when a potential conflict of interest exists with the research being reviewed.

#### C. Non-affiliated members and members representing the perspective of participants

1. These members serve an essential and unique role for the IRB. Therefore, while their presence at the meeting is not mandated by DHHS or FDA to meet quorum, UIC strives to ensure their attendance at every meeting.
2. Measures implemented to accomplish this goal include:
  - a. reimbursement for time and travel,
  - b. assignment of two members meeting this criteria to each board,
  - c. expectation to attend 75% of meetings,
  - d. and documentation that at least 1 member meeting these criteria has attended each board meeting in the last 12 months.

#### D. Conflict of Interest

Refer to UIC HSPP policy [\*IRB Member, Ad Hoc Consultant, and OPRS Staff Conflict of Interest Policy\*](#).

#### E. Confidentiality

The IRB reviews documents that contain personal, confidential and proprietary information. Members of the IRB are responsible for maintaining all committee proceedings and documents in strict confidence. Such



information may not be used for any purpose other than the IRB review and may not be disclosed to anyone outside of the IRB unless permission is granted in writing by the Vice Chancellor for Research. Members, alternates, *ad hoc* consultants and visitors sign a UIC confidentiality agreement.

F. Compensation

1. The UIC OVCR compensates IRB members and alternates, when appropriate, with a fixed, pre-determined amount per meeting attended for their IRB participation in acknowledgement of their efforts, including but not limited to, maintaining a current understanding of the application of relevant regulations, laws and policies and procedures involving human subjects protections. A differential is provided Vice Chairs and Chairs to account for the additional time commitments.
2. IRB member payments are coordinated by the OVCR Finance Office.
3. Members who cannot be paid via payroll (i.e., members who are not affiliated with UIC) enter into a contract with UIC which outlines the terms of the compensation.
4. The only CHAIRb members who are compensated by UIC are the UIC representatives. UIC does not compensate nor enter into contracts with other CHAIRb members.

G. Evaluation of Members

Refer to UIC HSPP SOP *Standard Operating Procedure: IRB Member Evaluation*.

II. IRB Chairs and Vice-Chairs

A. Recruitment and Appointment

1. The OPRS Director and Human Protections Administrator seek nominees from previous and current Chairs and IRB members, section chiefs, Department Heads, Associate/Assistant Deans for Research, and the senior administrators within OVCR. Research and professional expertise, IRB experience, knowledge of the federal regulations, state laws and UIC HSPP policy, and leadership skills are considered in making the selection. The Chairs and Vice Chairs are officially appointed by the Vice Chancellor of Research.
2. The appointment process follows the outline for IRB members.
3. IRB Chairs are appointed for 5 year terms and Vice Chairs for 3 year terms. The CHAIRb Chair has a 1 year term.

B. Responsibilities of Chair

1. items listed in I.B. for IRB members;
2. mentors and evaluates IRB members;
3. directs convened IRB meetings in a manner that:
  - a. identifies conflicts of interest among members and recuses them during the discussion and vote on the protocol;
  - b. allows sufficient time for discussion of each protocol;
  - c. encourages a well-rounded discussion and participation of all members;
  - d. fosters a collegial atmosphere;
  - e. guides the Board in applying the regulations; and



- f. ensures required determinations are made, approval criteria are met and voting occurs for each study.
  4. reviews and approves expedited submissions;
  5. evaluates the IRB agenda prior to distribution to ensure the required membership or necessary expertise will be available at the meeting to provide a suitable review of each protocol;
  6. seeks *ad hoc* consultants when expertise beyond that available on the IRB is needed;
  7. review adverse events, unanticipated problems, allegations of noncompliance and other events requiring prompt reporting according to regulations and UIC policy;
  8. Suspend all or parts of the research when it is suspected or determined that one of the following has occurred: unanticipated problem associated with unexpected serious harm to research participants or others, research is not being conducted in accordance with IRB requirements with possible risk of harm to participants, or serious or continuing noncompliance.
  9. review and acknowledge Protocol Exceptions and Emergency Use requests following UIC policy and procedures;
  10. attend the monthly IRB Chair meetings;
  11. provide input on the development and implementation of new or revised policies and procedures; and
  12. work with the OPRS staff and OVCR leadership to advance the mission of the HSPP.
- C. Responsibilities of Vice Chair  
The responsibilities of the Vice Chair mirror those of the Chair, with the extent of responsibilities outside the meeting dependent on the activities delegated by the Chair and ability of the Chair to perform those duties (e.g., due to vacation, illness, leave of absence).
- D. Conflict of Interest  
Refer to UIC HSPP policy [\*IRB Member, Ad Hoc Consultant, and OPRS Staff Conflict of Interest Policy.\*](#)
- E. Confidentiality  
Chairs and Vice Chairs are expected to maintain the same confidentiality as the IRB members as described in section I.E.
- F. Compensation  
A differential above the compensation for IRB members is provided to the Vice Chairs and Chairs to account for the additional time commitments.
- G. Evaluation of Chairs and Vice Chairs
1. The Vice Chairs are evaluated annually as described in UIC HSPP SOP *Standard Operating Procedure: IRB Member Evaluation.*
  2. The Chairs are evaluated annually by the OPRS Director. Input from the IRB Vice Chairs, members and OPRS staff is incorporated. The evaluation is conducted in person, and includes an assessment of the Chair's performance in leading the convened meeting, expedited review activities and the functioning of the board. Areas for improvement and resource needs are identified.



III. Expedited Review

- A. The IRB Chairs are the primary individuals, in accordance with the regulations, charged with performing expedited reviews, including expedited submissions (initial, continuing or amendments), conditions required to secure approval outside the meeting, initial review of adverse events, unanticipated problems, allegations of noncompliance, other events requiring prompt reporting according to regulations and UIC policy, Protocol Exceptions, and Emergency Use of an investigational drug, biologic or device.
- B. The Chairs formally delegate responsibility for performing all or some of the types of expedited reviews to experienced IRB members with appropriate qualifications. Experienced members are defined as individuals having at least one year of active IRB service, providing high quality reviews of submissions at convened meetings and knowledge of the regulations as assessed by the Chair and AD. Other factors considered include attendance and participation at IRB meetings, research experience, and profession. The Chair and IRB AD are responsible for training and overseeing the expedited reviewer.

REFERENCES:

45 CFR 46.107 and Subpart C 45 CFR 46.304  
 21 CFR 56.107  
 VHA Handbook 1200.05  
 38 CFR 16.107

REVISION LOG:

Version (#, date)	Replaces (#, date)	Summary of changes
1.0, 5/16/12	NA	Creation of policy.
1.1, 2/29/16	1.0, 5/16/12	Removal of items related to the Collaborative JBVAMC/NU/UIC IRB (IRB #4). Inclusion of Chicago Area Institutional Review Board (CHAIRb) requirements.
1.2, 1/3/17	1.1, 2/29/16	Correction of policy title. Addition of hyperlinks.