



NEW IRB MEMBER IDENTIFICATION, TRAINING AND MEMBER EVALUATION

11/20/2023

The purpose of this document is to describe the processes by which new IRB members are identified, nominated, trained, and added as members to the IRB and how all members are evaluated. A member of one IRB is automatically an alternate for all other IRBs. No separate appointment process for alternate members exists.

Members are selected based on their experience, expertise, and ties to the local community to ensure diversity of membership, including considerations of race, gender, and cultural backgrounds and sensitivity to community attitudes. Their term of appointment is indefinite. The diversity and expertise of the members promotes respect for the IRB's advice and counsel in safeguarding the rights and welfare of human research subjects. In addition to possessing the professional competence necessary to review specific research activities, the membership includes persons who are knowledgeable of, and who are able to ascertain the acceptability of, the proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. Since the IRB regularly reviews research that involves vulnerable participants, such as children, imprisoned people, pregnant people, or persons with diminished capacity, the membership includes one or more individuals who are knowledgeable about and experienced in working with such people.

Process:

1. Identify need and contact Department Chair for nominations
 - IRB Chairs, Vice-Chairs and staff notify the Executive Director and/or Lead Chair or designee of membership requirements on their board, such as resignations, poor attendance, lack of sufficient alternates, or need for specific expertise.
 - Members from within DUHS are nominated for IRB membership by their respective Department Chair or Director, whether the department is an academic department or a clinical department within Duke.

- The Executive Director, Lead Chair or designee will contact the respective Department Chair to discuss identifying new members or if the individual is unaffiliated will contact the prospective member directly.
- Members who are unaffiliated with DUHS or Duke University are recommended for IRB membership by current members of the Duke community or by community leaders who are knowledgeable of the qualifications of the nominee and the requirements of DUHS IRB service.
- In addition, a prospective member who is interested in joining the IRB may send an email containing their qualifications and availability to the Executive Director, Lead Chair, or designee.

2. Prospective Member contact:

- The Compliance Specialist or designee requests a CV from the prospective member. When the Executive Director, Lead Chair or designee determines that the prospective member would be a suitable IRB member, scheduling new member orientation and meeting observations begins.
- The Compliance Specialist or designee sends a letter of welcome with orientation/meeting observation information. The Compliance Specialist or designee posts a copy of the new member's CV on the shared drive so it will be accessible to the IRB Staff and Chairs.

3. Orientation

- The Compliance Specialist or designee schedules an orientation with the new member(s) for an iRIS and protocol review tutorial and to discuss the administrative organization of the meetings, staff and office.
- The Compliance Specialist or designee provides new members with orientation materials that include information on how to review and present a protocol as a primary reviewer.
- With orientation complete, the Compliance Specialist schedules new members to observe one or two full board IRB meetings, depending upon the board members' research experience and familiarity with iRIS. Following the meeting(s), they are encouraged to meet briefly with the Chair &/or Vice Chair to discuss any questions they have about what they observed in the meeting.

- The Compliance Specialist and Board Specialists offer ongoing help to orient new members to the iRIS system and explain navigation within the iRIS system.

4. CITI Training

- New members joining the IRB are required to complete the same set of CITI modules that Duke researchers complete, as per the Duke Health DOCR policy entitled “Collaborative Institutional Training Initiative (CITI) Module Requirements for Duke Health Human Subject Protection (HSP).” This policy is available on the DOCR web site.
- All IRB members are required to maintain a current CITI module certification by renewing their certification every three years, just as Duke researchers are required to do.
- The Compliance Specialist or designee will verify that all members have completed their required CITI module training.

5. Assignment to a Board

- The Compliance Specialist determines if they will replace a departed member representing that department. Typically, board assignment is based on which of the board meeting times will best fit their schedule.
- If the department has a rotation schedule for its members/alternates, the departmental administrator will incorporate the new member into that schedule.
- The Compliance Specialist forwards all new member information to the IRB Specialist and enters it into the IRB Membership Database. If there is a department rotation schedule, the Compliance Specialist or designee stores it on the IRB’s shared drive.

6. The Compliance Specialist or designee adds the member to the roster and submits the roster to OHRP

- The Compliance Specialist or designee will update the IRB Membership Database. The OHRP rosters are updated online quarterly or more often if there is a change to Board Chairs. A separate file, with a copy of the confirmation email, is kept for each roster sent to OHRP and is labeled by the date of the submission to OHRP.

- Members are not shown in the membership database until they observe the IRB meeting(s).
- The member is shown as active in the membership database once they have been added to the IRB roster. Once this is done, the member is considered a voting member of the IRB.

7. The Compliance Specialist or designee adds the revised roster to IRB website

- New members are added to the roster at the beginning of the month following their meeting observation(s).
- The Compliance Specialist or designee saves the new roster on the IRB's shared drive.
- The Compliance Director or designee posts the new roster on the IRB website monthly.

8. Evaluation of Each IRB Member

- Annually an online evaluation of each IRB member is conducted by the applicable Chair/Vice-Chair. Results of the evaluations are provided to each individual member. In addition, members are requested to complete a self-assessment.
- Evaluation results for members who are also Duke employees are sent to applicable CRU directors, upon request.

Previous Version Date(s): 8/20/2008, 8/18/2011, 3/2/2016, 4/14/2021, 4/28/2023