



NEW IRB MEMBER IDENTIFICATION, NOMINATION AND TRAINING AND MEMBER EVALUATION

8/20/2008

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 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.

1. Identify need---contact Department Chair for nominations

- IRB Chairs, Vice-Chairs and staff notify the Executive Director and Senior Chairman of membership problems on their board, such as resignations, poor attendance, lack of sufficient alternates, or need for specific expertise. The Executive Director or Senior Chair will contact the respective Department Chair to discuss identifying new members.

2. Nomination letters from Department Chairs

- Department Chairs forward the letters to the IRB Executive Director, who confirms with the Senior Chair and the Institutional Official or designee that the nominee will be a suitable IRB member.
- The Executive Director forwards the letter to Education Director to start the orientation process. The original nomination letter is filed in the Master File for Members.
- The Education Director or designee sends a letter of welcome with orientation information once the specific IRB assignment is known, so that typically the new member's orientation and observations all take place with the IRB on which he/she will be serving as a member. The Education Director or designee sends a copy of this correspondence to the Chair, Vice Chair and Board Specialists for the IRB that the new member is joining and 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. Education Director schedules orientation with new member

- Whenever possible the Education Director schedules the date for orientation and first meeting observation at least 30 days after the initial IRB contact with the new member to allow time to notify staff and arrange for extra materials to be available for the new member. For orientation, whenever possible the Education Director schedules new members to attend a meeting of the IRB that they will join as a member. Their second observation will be as a voting member without

any primary reviewer assignments. The Board Specialists will track when the new member has attended two observation meetings and is ready to be added as a primary reviewer on that IRB.

- The Education Director schedules no more than 2 new members to attend as observers at any meeting.
- The Board Specialist will put the date for orientation on the office calendar in Lotus Notes, send an email to Chair, Vice Chair, board specialists, with a copy to the Executive Director and Education Director notifying them that a new member will observe.
- The Education Director updates the membership database to include these orientation dates.

4. Assignment to a board

- The Education Director and the Chair and/or Vice-Chair of the relevant board will decide if the new member will be replacing an existing or departed member representing that department, or the Education Director will ask the new member which of the board meeting times will best fit his/her schedule.
- If the department has a rotation schedule for its members/alternates, the Education Director will incorporate the new member into that schedule.
- The Education Director or designee notes in the IRB Membership Database the board on which a new member will serve. If there is a department rotation schedule, the Education Director puts that in the notes field of the database.

5. The Education Director or designee adds the member to the roster, submits the roster to OHRP.

- The Education Director or designee will update both the IRB Membership Database and the OHRP rosters on line. 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 as active until they observe one IRB meeting. The Education Director or designee updates the database to show the effective date of their membership as the date of their first IRB meeting observation.

6. The Compliance Specialist adds the revised roster to IRB website

- The Education Director or designee saves the new roster as an Acrobat .pdf file on the J drive.

- The Compliance Specialist posts the new roster on the IRB website monthly.

7. Orientation

- The Education Director schedules new members to observe two meetings of the IRB to which they will be assigned as a member. The observation will be for the full meeting. Following each meeting, they will meet briefly with the Chair &/or Vice Chair to discuss any questions they have about what they observed in the meeting.
- Prior to the first observational IRB meeting, the Education Director meets with the new member(s) to discuss the administrative organization of the meetings, staff and office.
- The Education Director provides new members with orientation materials that include a packet of information on how to review a protocol as a primary reviewer.
- The Board Specialist provides the new member with the same meeting materials that other members in attendance receive.

8. Evaluation of Each IRB Member

- Annually the IRB Chairs, Vice-Chairs, Executive Director and Education Director meet to evaluate the performance of each IRB member. The IRB chair who works closely with that member conveys the results of that evaluation to the member .
- The IRB chair conveys in writing to the member's department chairperson a summary of that evaluation. The Education Director retains a copy in the Master File for Members.