1. PURPOSE

1.1. This procedure establishes the process to add or remove an IRB member.
1.2. This procedure begins when the IRB Chair selects a new IRB member or decides to remove an IRB member.
1.3. This procedure ends when the member has been added or when a member has been removed, and the IRB’ roster and registration has been updated.

2. POLICY

2.1. The IRB Chair will determine that an additional member is needed on the IRB or when an IRB Member is to be removed from the IRB.

3. RESPONSIBILITY

3.1. The IRB chair with the assistance of the Assistant Director of IRBs carries out these procedures.

4. PROCEDURE

4.1. IRB Member Addition:

4.1.1. Evaluate the need to add a member, determine what expertise might be required based on current protocols being reviewed.
4.1.2. Determine whether the individual will be a regular IRB member or alternate IRB member.
4.1.3. Work with chairperson or director of the appropriate division or department to recommend a member.
4.1.4. Obtain a copy of the individual’s résumé or curriculum vitae.
4.1.5. The IRB Chair will discuss the recommendation with the proposed new member to determine commitment and desire to be a board member.
4.1.6. Have the individual undergo initial IRB member training.
4.1.7. Obtain information from the individual to complete the roster
4.1.8. Upon successful completion or verification of training, the institutional official will appoint the IRB member, and the IRB roster will be updated.
4.1.9. Prepare an appointment letter, have it signed by the Institutional Official, and send to the individual.
4.1.10. Have the individual sign the IRB member confidentiality agreement.
4.1.11. Refer to the “IRB REGULATORY GUIDANCE: IRB Composition (HRP-430)” to evaluate whether the IRB is appropriately constituted.
4.1.12. Revise the membership as needed.

4.2. IRB Member Removal:

4.2.1. Update the IRB Roster

4.2.1.1. Reference “IRB REGULATORY GUIDANCE: IRB Composition (HRP-430)” to evaluate whether the IRB is appropriately constituted.

4.2.2. If the removed member was a chair, update the IRB’s registration at http://ohrp.cit.nih.gov/efile/ within 90 days

5. REFERENCES

5.1. 21 CFR §56.106 and §56.107
5.2. 45 CFR §46.107 and 45 CFR §46 Subpart E