1. PURPOSE
   1. This procedure establishes the process to add an IRB member to an IRB.
   2. This procedure begins when the Organizational Official selects a new IRB member.
   3. This procedure ends when the member has been added and the IRB’s registration has been updated.
2. POLICY
   1. The IRB Executive Chair should normally be an IRB member who is a respected individual with knowledge of research ethics, regulations, guidance, and HRPP policies and procedures.
   2. IRB chairs and vice-chairs:
      1. Discharge the IRB Executive Chair’s responsibilities when the IRB Executive Chair is unable to do so
      2. Discharge the responsibilities assigned by the IRB Executive Chair
      3. Assist in the operation of the IRB
3. RESPONSIBILITY
   1. The HRPP Administrator carries out these procedures.
4. PROCEDURE
   1. Determine whether the individual will be a regular IRB member, alternate IRB member, IRB chair, or IRB vice-chair.
   2. Obtain a copy of the individual’s résumé or curriculum vitae.
   3. Provide the résumé or curriculum vitae to the Organizational Official for review and approval.
   4. If not approved by the Organizational Official stop processing.
   5. If the individual requires training, have the individual undergo training.
   6. Upon successful completion or verification of training, appoint the IRB member, and update the IRB roster.
   7. Obtain information from the individual to complete the roster.
   8. Prepare an appointment letter, have it signed by the Organizational Official, and send to the individual.
   9. Have the individual sign the IRB member agreement.
   10. Use “WORKSHEET: IRB Composition (HRP-430)” to evaluate whether the IRB is appropriately constituted.
       1. Revise the membership as needed.
   11. If the new member is a chair, update the IRB’s registration at <http://ohrp.cit.nih.gov/efile/> within 90 days.
5. REFERENCES
   1. 21 CFR §56.106 and §56.107
   2. 45 CFR §46.107 and 45 CFR §46 Subpart E