1. PURPOSE
   1. This procedure establishes the process to add an IRB member to an IRB.
   2. This procedure begins when a potential IRB member has been identified.
   3. This procedure ends when the individual is not offered IRB membership, or the member has been added and the IRB’s registration has been updated.
2. POLICY
   1. IRB members will be selected based on qualifications, education, and experience.
   2. The [IRB Chair] should normally be an IRB member who is a respected individual with knowledge of research ethics, regulations, guidance, and HRPP policies and procedures.
   3. Vice-chairs:
      1. Discharge the [IRB Chair]’s responsibilities when the [IRB Chair] is unable to do so.
      2. Discharge the responsibilities assigned by the [IRB Chair].
      3. Assist in the operation of the IRB.
3. RESPONSIBILITY
   1. The [Human Protections Administrator] carries out these procedures.
4. PROCEDURE
   1. Obtain a copy of the individual’s résumé or curriculum vitae.
   2. Provide the résumé or curriculum vitae to the [Organizational Official] for review.
   3. If the [Organizational Official] and [IRB Chair] agrees that the background of the potential member is a good fit with the current membership of the IRB, telephone or in-person discussion about the IRB Member expectations will be held
   4. The potential IRB member may also attend and observe an IRB meeting.
   5. Upon successful completion or verification of training, the [HRPP Administrator] notifies the [Organizational Official] that the individual has completed training and assesses whether they have completing the training in a satisfactory manner to be appointed as a board member.
   6. If the training has been satisfactory and the [Organizational Official] agrees, appoint the IRB member, and update the IRB roster. If the training has not been satisfactory, the IRB Chair and [Organizational Official] will either agree on a plan for additional training or will decline to proceed with IRB membership for the potential IRB member.
   7. Prepare an appointment letter, have it signed by the [Organizational Official]], and send to the individual.
   8. Have the individual sign the IRB member agreement.
   9. Obtain information from the individual to complete the roster.
   10. Use “WORKSHEET: IRB Composition (HRP-430)” to evaluate whether the IRB is appropriately constituted.
   11. Revise the membership as needed.
   12. Update the IRB’s registration at http://ohrp.cit.nih.gov/efile/ within 90 days.
5. APPROVAL AND REVISIONS
   1. 02/28/20: Human Research Protections Office Director, Carley Emerson, originally created and approved
6. REFERENCES
   1. 21 CFR §56.106 and §56.107
   2. 45 CFR §46.107 and 45 CFR §46 Subpart E