1. PURPOSE
   1. This procedure establishes the process to appoint and re-appoint an IRB member.
   2. The process begins when an individual expresses interest, is nominated, or applies to join the IRB. This may be a new IRB member or a re-appointment of a previous member.
   3. The process ends when the IRB roster is updated, and the new member has completed training.
2. REVISIONS FROM PREVIOUS VERSION
   1. None.
3. POLICY
   1. IRB rosters are maintained using HRP-601 - DATABASE - IRB Committee Member Profile (in eIRB).
   2. IRB members /alternates are appointed for a one-year term. Members/alternates are eligible for re-appointment at the end of their term.
4. RESPONSIBILITIES
   1. IRB staff members carry out these procedures.
   2. The Institutional Official (IO) or designee appoints/re-appoints IRB members, alternate members, IRB chairs, and if used, other officers (e.g., vice chairs).
5. PROCEDURE
   1. Have the individual complete the IRB Committee Member Profile in eIRB.
   2. Obtain a copy of the individual’s résumé or curriculum vitae.
   3. Use the information in the completed profile and the individual’s résumé or curriculum vitae to determine if the individual qualifies as a scientist or nonscientist and affiliated or nonaffiliated.
   4. Interview the individual to assess suitability and availability.
      1. Determine from the IO or designee whether the individual will be a regular IRB member, alternate IRB member, or IRB chair.
      2. In any instance for which the scientific or non-scientific status or affiliation status of a newly appointed or re-appointed IRB member may be questionable, the IO or designee will be consulted before proceeding with the appointment.
   5. Schedule a time for the applicant to attend and observe IRB meetings, as applicable.
   6. Schedule the individual for orientation and CITI training.
   7. After orientation and training are completed, add the individual to the IRB Roster.
   8. Complete HRP-304 - WORKSHEET - IRB Composition and revise the membership as needed to ensure that the IRB is appropriately constituted.
   9. Update the registration of all affected IRBs.
   10. Prepare HRP-560 - LETTER - IRB Appointment or equivalent for the individual.
   11. Provide the letter to the IO or designee for review, approval, and signature, including electronic.
   12. If not approved, select another individual and restart at 5.1.
   13. Once the appointment letter is signed:
       1. Send the signed appointment letter to the individual.
       2. Assign individual the ‘Committee Member’ role in the system.
       3. If the individual is designated to conduct non-committee reviews, e-IRB will automatically update the ‘Eligible Designated Reviewers’ List.
6. MATERIALS
   1. HRP-202 - FORM - IRB Member Information
   2. HRP-304 - WORKSHEET - IRB Composition
   3. HRP-560a, b & c - LETTER - IRB Appointment
   4. HRP-561 - LETTER - IRB Thank You
   5. HRP-601 - DATABASE - IRB Committee Member Profile (in e-IRB)
7. REFERENCES
   1. 45 CFR §46.107, 45 CFR §46.108(a)(2), 45 CFR §46.115(a)(5)
   2. 21 CFR §56.107, 21 CFR §56.115(a)(5)