1. PURPOSE
   1. This procedure establishes the process to appoint and re-appoint IRB member.
   2. The process begins when an individual expressed interest, is nominated, or applies to join the IRB. (This may be a completely new IRB member, or 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. The appointment or re-appointment of an IRB member, including their designation as either a scientist or non-scientist, affiliation status, and representative capacity is vetted and approved by the Institutional Official or designee.
4. RESPONSIBILITIES
   1. IRB staff members carry out these procedures.
   2. The Institutional Official or designee appoints IRB members, alternate members, IRB chairs, and if used, other officers (e.g., vice chairs.).
5. PROCEDURE
   1. Have the individual complete the “FORM: IRB Member Information (HRP-202)” or otherwise gather the similar information.
   2. Obtain a copy of the individual’s résumé or curriculum vita.
   3. Interview the individual to assess suitability and availability.
      1. Determine from the Institutional Official 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 Institutional Official or designee will be consulted before proceeding with the appointment.
   4. Schedule a time for the applicant to attend and observe IRB meeting, as applicable.
   5. Add the individual to the “Committee” database in IRB Manager and ensure that the IRB is appropriately constituted.
   6. Prepare a “TEMPLATE LETTER: IRB Member Appointment (HRP-560)” for the individual.
   7. Provide to the Institutional Official or designee for review and approval:
      1. FORM: IRB Member Information (HRP-202) or similar information.
      2. Résumé or curriculum vita.
      3. Completed “TEMPLATE LETTER: IRB Member Appointment (HRP-560).”
   8. If not approved, select another individual and restart at 5.1.
   9. Once the appointment letter is signed:
      1. Send the signed “TEMPLATE LETTER: IRB Member Appointment (HRP-560)” to the individual.
      2. If the individual requires training, schedule the individual for training.
      3. Update the registration of all affected IRBs.[[1]](#footnote-1)
   10. File:
       1. ”Committee” database in IRB Manager
       2. TEMPLATE LETTER: IRB Member Appointment (HRP-560)
       3. Signed IRB appointment letter
       4. FORM: IRB Member Information (HRP-202) or similar information
       5. Resume or curriculum vita.
   11. Notify the IRB Chair when the individual has completed training.
       1. If the individual is eligible to conduct non-committee reviews, update the system to reflect that.
6. MATERIALS
   1. FORM: IRB Member Information (HRP-202)
   2. TEMPLATE LETTER: IRB Member Appointment (HRP-560)
   3. WORKSHEET: IRB Composition (HRP-304)
7. REFERENCES
   1. 45 CFR §46.107, 45 CFR §46.103(b)(3), 45 CFR §46.115(a)(5).
   2. 21 CFR §56.107, 21 CFR §56.115(a)(5).

1. See <http://www.hhs.gov/ohrp/assurances/>. Use Web site: <http://ohrp.cit.nih.gov/efile/>. [↑](#footnote-ref-1)