SOP: IRB Membership Appointment

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 in consultation with the Institutional Official/ Organizational Official (IO/OO) (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. IRB rosters are maintained using HRP-601 - DATABASE - IRB Roster.
   2. IRB members /alternates are appointed for a three-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 IO/OO or designee appoints/re-appoints IRB members, alternate members, IRB chairs, and if used, other officers (e.g., vice chairs.).
5. PROCEDURE-IRB MEMBER APPOINTMENT
   1. Use the HRP-382 – WORKSHEET – Adding a New IRB Member to onboard a new IRB member.
   2. Have the individual complete HRP-202 - FORM - IRB Member Information.
   3. Obtain a copy of the individual’s résumé or curriculum vita.
   4. Use the information in the completed HRP-202 - FORM - IRB Member Information and the individual’s résumé or curriculum vita to determine if the individual qualifies as a scientist or nonscientist, and if they are affiliated or unaffiliated.
   5. Obtain a completed Confidentiality agreement for external IRB members.
   6. Interview the individual to assess suitability and availability.
      1. Determine from the IO/OO 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/OO or designee will be consulted before proceeding with the appointment.
   7. Schedule a time for the applicant to attend and observe an IRB meeting, as applicable.
   8. Add the individual to HRP-601 - DATABASE - IRB Roster.
   9. Complete HRP-304 - WORKSHEET - IRB Composition and revise the membership as needed to ensure that the IRB is appropriately constituted.
   10. Prepare HRP-560A - LETTER - IRB Member Appointment for the individual.
   11. Provide to the IO/OO or designee for review and approval:
       1. HRP-202 - FORM - IRB Member Information.
       2. Résumé or curriculum vita.
       3. Completed HRP-560A - LETTER - IRB Member Appointment.
       4. Confidentiality agreement, if applicable
   12. If not approved, select another individual and restart at 5.1.
   13. Once the appointment letter is signed:
       1. Send the signed HRP-560A - LETTER - IRB Member Appointment to the individual.
       2. If the individual requires training, schedule the individual for training.
       3. Update the registration of all affected IRBs.[[1]](#endnote-1)
   14. File:
       1. HRP-601 - DATABASE - IRB Roster.
       2. Signed IRB appointment letter.
       3. HRP-202 - FORM - IRB Member Information.
       4. Résumé or curriculum vita.
       5. Any other signed agreements.
   15. Notify the IRB manager when the individual has completed training.
       1. Assign individual the “Committee Member” role in the system.
       2. If the individual is designated to conduct non-committee reviews, update the “Update Eligible Designated Reviewers” activity. Indicate in HRP-601 - DATABASE - IRB Roster
6. PROCEDURE-IRB MEMBER RE-APPOINTMENT
   1. In December of each year, review HRP-601 - DATABASE - IRB Roster to IRB members that are due for re-appointment.
   2. Review list of IRB Members due for re-appointment with IRB Chairs.
   3. If an IRB Member will not be re-appointed, follow HRP-083 - SOP - IRB Membership Removal.
      1. Update the registration of all affected IRBs.[[2]](#endnote-2)
      2. Update HRP-601 - DATABASE - IRB Roster
   4. For any IRB Members that will be re-appointed:
      1. Complete HRP-304 - WORKSHEET - IRB Composition and revise the membership as needed to ensure that the IRB is appropriately constituted.
      2. Prepare HRP-560B - LETTER - IRB Member Re-Appointment for the individual.
      3. Provide to the IO/OO or designee for review, approval and signature.
      4. Once the appointment letter is signed:
         1. Send the signed HRP-560B - LETTER - IRB Member Re-Appointment to the individual.
         2. Update Appointment expiration date in HRP-601 - DATABASE - IRB Roster
   5. File:
      1. HRP-601 - DATABASE - IRB Roster
      2. Signed IRB re-appointment letter.
7. MATERIALS
   1. HRP-083 - SOP - IRB Membership Removal
   2. HRP-202 - FORM - IRB Member Information
   3. HRP-304 - WORKSHEET - IRB Composition
   4. HRP-382 – WORKSHEET – Adding a New IRB Member
   5. HRP-560A - LETTER - IRB Member Appointment
   6. HRP-560B - LETTER - IRB Member Re-Appointment
   7. HRP-601 - DATABASE - IRB Roster
8. 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).
   3. AAHRPP elements I.1.E, II.1.A-C

1. See <http://www.hhs.gov/ohrp/assurances/>. Use Web site: <http://ohrp.cit.nih.gov/efile/>. [↑](#endnote-ref-1)
2. See <http://www.hhs.gov/ohrp/assurances/>. Use Web site: <http://ohrp.cit.nih.gov/efile/>. [↑](#endnote-ref-2)