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 IO/OO (This may be a completely new IRB member, or re-appointment of a previous member.)
   3. The process ends when the IRB registration is updated with OHRP and the new member has completed training.
2. REVISIONS FROM PREVIOUS VERSION

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| --- | --- | --- |
| **Version** | **Date** | **Revisions** |
| R00 | 3/25/14 | Original issue |
| R01 | 9/7/17 | Remove reference to multiple IRBs, Change complete worksheet to utilize worksheet, remove template letter to simply letter |
| R02 | 1/22/19 | Additions related to new Common Rule: Revised document title (formerly “IRB Membership Addition”), added procedures to selection of new and re-appointed IRB members, added required documents for member file |
| R02 | 12/17/2020 | Annual review, update logo |
| R02 | 10/14/2021 | Annual review, no changes |
| R02 | 11/28/22 | Annual review, no changes |
| R02 | 11/14/23 | Annual review, no changes |

1. POLICY
   1. IRB rosters are maintained using the “DATABASE: IRB Roster (HRP-601).”
   2. IRB members /alternates are appointed for a three-year term. Members/alternates are eligible for re-appointment at the end of their term.
2. RESPONSIBILITIES
   1. IRB staff members carry out these procedures.
   2. The Institutional Official / Organizational Official (IO/OO) or designee appoints/re-appoints IRB members, alternate members, IRB chairs, and if used, other officers (e.g., vice chairs.).
3. PROCEDURE
   1. Have the individual complete the “FORM: IRB Member Information (HRP-202).”
   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 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 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 “DATABASE: IRB Roster (HRP-601).”
   6. Complete “WORKSHEET: IRB Composition (HRP-304)” and revise the membership as needed to ensure that the IRB is appropriately constituted.
   7. Prepare an IRB Member Appointment letter for the individual.

* 1. Provide to the IO/OO or designee for review and approval:
     1. FORM: IRB Member Information (HRP-202).
     2. Résumé or curriculum vita.
     3. Completed “TEMPLATE LETTER: IRB Member Appointment (HRP-560)”
  2. If not approved, select another individual and restart at 5.1.
  3. 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-2)
  4. File:
     1. DATABASE: IRB Roster (HRP-601)
     2. Signed IRB appointment/re-appointment letter
     3. FORM: IRB Member Information (HRP-202).
     4. Résumé or curriculum vita.
     5. Any other signed agreements
  5. 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.

1. MATERIALS
   1. DATABASE: IRB Roster (HRP-601)
   2. FORM: IRB Member Information (HRP-202)
   3. TEMPLATE LETTER: IRB Member Appointment (HRP-560)
   4. TEMPLATE LETTER: IRB Member Thank You (HRP-561)
   5. WORKSHEET: IRB Composition (HRP-304)
2. 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-2)