

SOP: IRB Membership Appointment

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1 PURPOSE

- 1.1 This procedure establishes the process to appoint and re-appoint an IRB member.
- 1.2 The process begins when an individual expresses interest, is nominated or applies to join the IRB. (This may be a completely new IRB member, or re-appointment of a previous member.)
- 1.3 The process ends when the IRB roster is updated and the new member has completed training.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 IRB rosters are maintained using the “DATABASE: IRB Roster (HRP-601).”
- 3.2 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

- 4.1 IRB staff members carry out these procedures.
- 4.2 The Organizational Official or designee appoints IRB members, alternate members, IRB chairs, and if used, other officers (e.g., vice chairs.).

5 PROCEDURE

- 5.1 Have the individual complete the “FORM: IRB Member Information (HRP-202).”
- 5.2 Obtain a copy of the individual’s résumé or curriculum vita.
- 5.3 Interview the individual to assess suitability and availability.
 - 5.3.1 Determine from the IO/OO or designee whether the individual will be a regular IRB member, alternate IRB member, or IRB chair.
 - 5.3.2 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.
- 5.4 Schedule a time for the applicant to attend and observe IRB meeting, as applicable.
- 5.5 Add the individual to the “DATABASE: IRB Roster (HRP-601).”
- 5.6 Complete “WORKSHEET: IRB Composition (HRP-304)” and revise the membership as needed to ensure that the IRB is appropriately constituted.
- 5.7 Prepare a “TEMPLATE LETTER: IRB Member Appointment (HRP-560)” for the individual.
- 5.8 Provide to the IO/OO or designee for review and approval:
 - 5.8.1 FORM: IRB Member Information (HRP-202).
 - 5.8.2 Résumé or curriculum vita.
 - 5.8.3 Completed “TEMPLATE LETTER: IRB Member Appointment (HRP-560)”
- 5.9 If not approved, select another individual and restart at 5.2.
- 5.10 Once the appointment letter is signed:
 - 5.10.1 Send the signed “TEMPLATE LETTER: IRB Member Appointment (HRP-560)” to the individual.
 - 5.10.2 If the individual requires training, schedule the individual for training.
 - 5.10.3 Update the registration of all affected IRBs.¹
- 5.11 File:
 - 5.11.1 DATABASE: IRB Roster (HRP-601)
 - 5.11.2 Signed IRB appointment/re-appointment letter
 - 5.11.3 FORM: IRB Member Information (HRP-202).
 - 5.11.4 Résumé or curriculum vita.
 - 5.11.5 Any other signed agreements

¹ See <http://www.hhs.gov/ohrp/assurances/>. Use Web site: <http://ohrp.cit.nih.gov/efile/>.

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- 5.11.6
- 5.12 Notify the IRB manager when the individual has completed training.
 - 5.12.1 Assign individual the “Committee Member” role in the system.
 - 5.12.2 If the individual is designated to conduct non-committee reviews, update the “Update Eligible Designated Reviewers” activity.

6 MATERIALS

- 6.1 DATABASE: IRB Roster (HRP-601)
- 6.2 FORM: IRB Member Information (HRP-202)
- 6.3 TEMPLATE LETTER: IRB Member Appointment (HRP-560)
- 6.4 TEMPLATE LETTER: IRB Member Thank You (HRP-561)
- 6.5 WORKSHEET: IRB Composition (HRP-304)

7 REFERENCES

- 7.1 45 CFR §46.107, 45 CFR §46.108(a)(2), 45 CFR §46.115(a)(5).
- 7.2 21 CFR §56.107, 21 CFR §56.115(a)(5).