



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 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).
- 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
- 2.2 Included provision for use of alternative to template letters.
- 2.3 Added requirement to notify applicable Associate Directors and Supervisors of changes and requirement to update and HSRO website.
- 2.4 Reconciliation to Huron HRPP Toolkit 4.5, dated 12/10/2021

3 GUIDING PRINCIPLES

- 3.1 IRB rosters are maintained using HRP-601 - DATABASE - IRB Roster.
- 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 HSRO staff members carry out these procedures.
- 4.2 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

- 5.1 Have the individual complete or update HRP-202 - FORM - IRB Member Information.
- 5.2 Obtain a copy of the individual's résumé or curriculum vita (CV).
- 5.3 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, their expertise with vulnerable subjects, and if they are affiliated or unaffiliated.
- 5.4 Interview the individual to assess suitability and availability.
 - 5.4.1 Determine from the IO/OO or designee whether the individual will be a regular IRB member, alternate IRB member, or IRB chair.
 - 5.4.2 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.
- 5.5 Have the member sign a confidentiality agreement.
- 5.6 Schedule a time for the applicant to attend and observe an IRB meeting, as applicable.
- 5.7 Add the individual to HRP-601 - DATABASE - IRB Roster.
- 5.8 Complete HRP-304 - WORKSHEET - IRB Composition and revise the membership as needed to ensure that the IRB is appropriately constituted.
- 5.9 Prepare HRP-560 - LETTER - IRB Appointment, or equivalent, for the individual.
- 5.10 Provide to the IO/OO or designee for review and approval:
 - 5.10.1 HRP-202 - FORM - IRB Member Information.
 - 5.10.2 Résumé or curriculum vita.
 - 5.10.3 Completed HRP-560 - LETTER - IRB Appointment.
- 5.11 If not approved, select another individual and restart at 5.1.
- 5.12 Once the appointment letter is signed:
 - 5.12.1 Send the signed HRP-560 - LETTER - IRB Appointment, or equivalent, to the individual.



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- 5.12.2 If the individual requires training, schedule the individual for training.
- 5.12.3 Update the registration of all affected IRBs using HRP-080 - SOP - IRB Formation and Registration.
- 5.13 File:
 - 5.13.1 HRP-601 - DATABASE - IRB Roster
 - 5.13.2 Signed IRB appointment/re-appointment letter
 - 5.13.3 HRP-202 - FORM - IRB Member Information.
 - 5.13.4 Résumé or curriculum vita.
 - 5.13.5 Any other signed agreements
- 5.14 Notify the IRB manager when the individual has completed training.
 - 5.14.1 Assign individual the "Committee Member" role in the system.
 - 5.14.2 If the individual is designated to conduct non-committee reviews, update the "Update Eligible Designated Reviewers" activity.

6 MATERIALS

- 6.1 HRP-080 - SOP - IRB Formation and Registration
- 6.2 HRP-202 - FORM - IRB Member Information
- 6.3 HRP-304 - WORKSHEET - IRB Composition
- 6.4 HRP-560 - LETTER - IRB Appointment
- 6.5 HRP-601 - DATABASE - IRB Roster

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).
- 7.3 AAHRPP elements I.1.E, II.1.A-C