

SOP: IRB Membership Addition

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1 PURPOSE

- 1.1 This procedure establishes the process to add a new IRB member.
- 1.2 The process begins when the Institutional Official or designee has appointed a new IRB member to an IRB. (This may be a completely new IRB member, or the addition of a previous member to another IRB.)
- 1.3 The process ends when the IRB registration is updated with OHRP and the IRB staff have been notified of the addition.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 IRB rosters are maintained using the “DATABASE: IRB Roster (HRP-601)” or equivalent.
- 3.2 IRB Members must complete New Member Training before being assigned to conduct any reviews.

4 RESPONSIBILITIES

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

5 PROCEDURE

- 5.1 Obtain a copy of the individual’s résumé or curriculum vita.
- 5.2 Have the individual complete the “FORM: IRB Member Information (HRP-202).”
- 5.3 Complete “WORKSHEET: IRB Composition (HRP-304)” and revise the membership as needed to ensure that the IRB is appropriately constituted.
- 5.4 Schedule the individual to observe a meeting with the committee they plan to serve.
- 5.5 If not approved, select another individual and restart at 5.1.
- 5.6 Schedule the individual for New IRB Member training.
- 5.7 Ensure the member has completed the required CITI training and the in-person New IRB Member training. Do not move forward with the appointment letter until the training has been completed.
- 5.8 Determine from the Institutional Official or designee whether the individual will be a regular IRB member, alternate IRB member, or IRB chair.
- 5.9 Prepare a “TEMPLATE LETTER: IRB Member Appointment (HRP-560)” for the individual.
- 5.10 Provide to the Institutional Official or designee for review and approval:
 - 5.10.1 FORM: IRB Member Information (HRP-202).
 - 5.10.2 Résumé or curriculum vita.
 - 5.10.3 Completed “TEMPLATE LETTER: IRB Member Appointment (HRP-560).”
- 5.11 Once the appointment letter is signed:
 - 5.11.1 Send the signed “TEMPLATE LETTER: IRB Member Appointment (HRP-560)” to the individual and cc all individuals listed.
 - 5.11.2 Update the registration of all affected IRBs.¹
- 5.12 Update “DATABASE: IRB Roster (HRP-601)” or equivalent:
 - 5.12.1 Set the Start Date, End Date, update the new member information and all other columns, then save.
- 5.13 File:
 - 5.13.1 Old and new DATABASE: IRB Roster (HRP-601)
 - 5.13.2 TEMPLATE LETTER: IRB Member Appointment (HRP-560)
- 5.14 Notify the IRB staff when the individual has been accepted as a new member and completed all requirements.

6 MATERIALS

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

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- 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 WORKSHEET: IRB Composition (HRP-304)

7 REFERENCES

- 7.1 45 CFR §46.107, 45 CFR §46.103(b)(3), 45 CFR §46.115(a)(5).
- 7.2 21 CFR §56.107, 21 CFR §56.115(a)(5).