



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 new member has completed training.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None
- 2.2 Included provision for use of alternative to template letters.

3 GUIDING PRINCIPLES

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

4 RESPONSIBILITIES

- 4.1 HSRO 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 Determine from the Institutional Official or designee whether the individual will be a regular IRB member, alternate IRB member, or IRB chair.
- 5.2 Have the individual complete the “FORM: IRB Member Information (HRP-202).”
- 5.3 Obtain a copy of the individual’s résumé or curriculum vita (CV).
- 5.4 Add the individual to the “DATABASE: IRB Roster (HRP-601).”
- 5.5 Complete “WORKSHEET: IRB Composition (HRP-304)” and revise the membership as needed to ensure that the IRB is appropriately constituted.
- 5.6 Prepare a “TEMPLATE LETTER: IRB Member Appointment (HRP-560),” or equivalent, for the individual.
- 5.7 Provide to the Institutional Official or designee for review and approval:
 - 5.7.1 FORM: IRB Member Information (HRP-202).
 - 5.7.2 Résumé or curriculum vita.
 - 5.7.3 Completed “TEMPLATE LETTER: IRB Member Appointment (HRP-560), or equivalent.”
- 5.8 If not approved, select another individual and restart at 5.2.
- 5.9 Once the appointment letter is signed:
 - 5.9.1 Send the signed “TEMPLATE LETTER: IRB Member Appointment (HRP-560),” or equivalent, to the individual.
 - 5.9.2 If the individual requires training, schedule the individual for training.
 - 5.9.3 Update the registration of all affected IRBs.¹
- 5.10 Maintain the following in Regulatory Binder: IRB Roster:
 - 5.10.1 DATABASE: IRB Roster (HRP-601)
 - 5.10.2 FORM: IRB Member Information (HRP-202).
 - 5.10.3 IRB Members CV or résumé.
 - 5.10.4 TEMPLATE LETTER: IRB Member Appointment (HRP-560)
 - 5.10.5 TEMPLATE LETTER: IRB Member Thank You (HRP-561)
- 5.11 Notify the Executive Director, HSRO when the individual has completed training.

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



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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 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).