

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 Updated the processes for onboarding a new member to better align with current practice.

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 Arrange for the member to attend a meeting with the committee on which they intend to serve
- 5.2 Have the member sign a nondisclosure agreement before attending an observation meeting.
- 5.3 If the member confirms their interest in joining the IRB after the observation meeting, ensure that they have appropriate access to the electronic submission system to conduct reviews.
- 5.4 Obtain a copy of the member's résumé or curriculum vitae.
- 5.5 Have the member complete the online "FORM: IRB Member Information (HRP-202)."
- 5.6 Complete "WORKSHEET: IRB Composition (HRP-304)" and revise the membership as needed to ensure that the IRB is appropriately constituted.
- 5.7 Schedule the member for New IRB Member training.
 - 5.7.1 Ensure the member has completed the required CITI training, the online New IRB Member training, and the committee analyst orientation. Do not move forward with the appointment letter until all training has been completed.
 - 5.7.2 Provide the individual with the IRB Member Compensation Handout.
- 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 vitae.
 - 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 Within 30 days of appointment, update the registration of all affected IRBs.¹
 - 5.11.3 Update "DATABASE: IRB Roster (HRP-601)" or equivalent
- 5.12 Upload to the Member File:
 - 5.12.1 Signed "TEMPLATE LETTER: IRB Member Appointment (HRP-560)"
 - 5.12.2 Completed "FORM: IRB Member Information (HRP-202)"
 - 5.12.3 Résumé or curriculum vitae

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

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5.12.4 Signed nondisclosure agreement

5.13 Notify the IRB staff when the individual has been accepted as a new member and completed all requirements.

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).