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.

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).