1 PURPOSE
1.1 This procedure establishes the process to add a new IRB member.
1.2 The process begins when the Organizational 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 roster is updated with OHRP.

2 REVISIONS FROM PREVIOUS VERSION
2.1 Replaces the version dated November 30, 2012.

3 POLICY
3.1 IRB rosters are maintained using the “DATABASE: IRB Roster.”

4 RESPONSIBILITIES
4.1 IRB staff members carry out these procedures.
4.2 The Organizational Official or designee appoints, and may remove, IRB members, alternate members, and IRB Chairpersons.

5 PROCEDURE
5.1 Determine from the Organizational Official or designee whether the individual will be a regular IRB member, alternate IRB member, or IRB Chairperson.
5.2 Obtain a copy of the individual’s résumé or curriculum vita.
5.3 Have the individual sign the Confidentiality Agreement.
5.4 Have the individual sign the IRB Member Form.
5.5 Have the individual complete the CITI training requirements listed in the Investigator Manual.
5.6 The individual must attend one IRB meeting as a guest before becoming a voting Board member.
5.7 Update the IRB roster.
5.8 Complete “WORKSHEET: IRB Composition” and revise the membership as needed to ensure that the IRB is appropriately constituted.
5.9 Prepare a “TEMPLATE LETTER: IRB Member Appointment” for the individual.
   5.9.1 The letter provides the following information:
      5.9.1.1 A Board membership term of three years.
      5.9.1.2 Members may be reappointed at the end of their term to additional three year terms at the discretion of the Organizational Official or designee.
      5.9.1.3 Board members who were appointed prior to the adoption of this policy will have a three year term limit, which begins in 2013. These members may also be reappointed at the end of their term to additional three year terms at the discretion of the Organizational Official or designee.
5.10 Provide to the Organizational Official or designee for review and approval:
   5.10.1 Résumé or curriculum vita.
   5.10.2 TEMPLATE LETTER: IRB Member Appointment
5.11 If not approved, select another individual and restart at 5.2.
5.12 Once the appointment letter is signed:
   5.12.1 Send “TEMPLATE LETTER: IRB Member Appointment” to the individual.
5.12.2 Update the registration of all affected IRBs.¹

5.13 File the IRB roster, the individual’s résumé or curriculum vita, the Confidentiality Agreement, IRB Member form, and “IRB Member Appointment” letter.

5.14 Follow “SOP: IRB Records.”

6 MATERIALS

6.1 DATABASE: IRB Roster

6.2 TEMPLATE LETTER: IRB Member Appointment

6.3 WORKSHEET: IRB Composition

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).