1 PURPOSE
1.1 This procedure establishes the process to either form or rely on a new IRB.
1.2 The process begins when the Organizational Official determines the need for a new IRB.
1.3 The process ends when the IRB is registered, the federalwide assurance is updated, and all members have completed training.

2 REVISIONS FROM PREVIOUS VERSION
2.1 Minor revisions for AAHRPP accreditation; replaces version dated 09/23/2009.

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

4 RESPONSIBILITIES
4.1 IRB staff members carry out these procedures.
4.2 The Organizational Official appoints IRB members, alternate members, and IRB chairs.

5 PROCEDURE
5.1 Determine from the Organizational Official whether the IRB will conduct all reviews without limitation or will be limited to certain types of reviews. Indicate this on the “IRB Scope” tab of the “IRB Roster.”
5.2 For external IRBs:
   5.2.1 Ensure that one or more of the following are true:
      5.2.1.1 The IRBs are part of an AAHRPP accredited organization.
      5.2.1.2 The organization’s investigator is a collaborator on Human Research primarily conducted at another organization and the investigator’s role does not include interaction or intervention with subjects.
      5.2.1.3 The organization is engaged in the Human Research solely because it is receiving federal funds. (Employees and agents of the institution do not interact or intervene with subjects, gather or possess private identifiable information about subjects, nor obtain the consent of subjects.)
   5.2.2 If the research is federally funded or the relied upon organization requires an agreement or contract, arrange for an agreement or contract.
   5.2.3 Update the federalwide assurance (FWA) with the new IRB.
   5.2.4 File the federalwide assurance (FWA).
   5.2.5 File the agreement or contract if one exists.
5.3 For internal IRBs:
   5.3.1 Select membership for the new IRB, including each of the following:
      5.3.1.1 At least five individuals to serve as IRB members.
      5.3.1.2 Additional individuals to serve as alternate IRB members, if needed.
      5.3.1.3 At least one of the individuals to be the IRB chair.
   5.3.2 Have each individual complete the “WORKSHEET: IRB Member Information.”
   5.3.3 Obtain a copy of each individual’s résumé or curriculum vitae.
   5.3.4 Complete the “WORKSHEET: IRB Composition” and revise the selected individuals as needed to ensure that the IRB is appropriately constituted.
   5.3.5 Prepare a “TEMPLATE LETTER: IRB Member Appointment” for each individual.
   5.3.6 For each new member, alternate, or chair, provide the following information for review and approval by the Organizational Official:
5.3.6.1 “WORKSHEET: IRB Member Information.”

5.3.6.2 Résumé or curriculum vitae.

5.3.6.3 “TEMPLATE LETTER: IRB Member Appointment.”

5.3.7 Revise the list of individuals if the Organizational Official does not approve one or more individual.

5.3.8 Once the appointment letters are signed:

5.3.8.1 Send each individual the “TEMPLATE LETTER: IRB Member Appointment” letter.

5.3.8.2 Schedule each previously untrained individual for training.

5.3.8.3 Register the IRB.¹

5.3.8.4 Update the federalwide assurance with the new IRB.²

5.3.9 Update the “IRB Roster.”

5.3.10 Print and file the “IRB Roster,” the federalwide assurance, and all worksheets, résumés or curriculum vitae, and appointment letters.

5.3.11 Notify the IRB manager when all individuals have completed training.

6 MATERIALS

6.1 WORKSHEET: IRB Member Information.

6.2 WORKSHEET: IRB Composition.

6.3 IRB Roster.

6.4 TEMPLATE LETTER: IRB Member Appointment.

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)
