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

2 REVISIONS FROM PREVIOUS VERSION
2.1 None

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

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 Determine from the Institutional Official or designee 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 “DATABASE: IRB Roster (HRP-601)” or equivalent.
5.2 For external IRBs:
5.2.1 Ensure that one or more of the following are true:
   5.2.1.1 The HSRBs are part of an AAHRPP accredited institution.
   5.2.1.2 The institution’s investigator is a collaborator on Human Research primarily conducted at another institution and the investigator’s role does not include interaction or intervention with subjects.
   5.2.1.3 The institution 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 institution 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:
   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 Follow “SOP: IRB Member Addition” for each IRB member.
5.3.3 Use “WORKSHEET: IRB Composition (HRP-304)” and revise the selected individuals as needed to ensure that the IRB is appropriately constituted.
5.3.4 Notify the Institutional Official or designee and IRB director when all individuals have completed training.

6 MATERIALS
6.1 DATABASE: IRB Roster (HRP-601)
6.2 FORM: IRB Member Information (HRP-202)
6.3 SOP: IRB Member Addition (HRP-082)
6.4 TEMPLATE LETTER: IRB Member Appointment (HRP-560)
6.5 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).