1. PURPOSE
   1.1. This procedure establishes the process to form an IRB.
   1.2. This procedure begins when the [Organizational Official] has decided to form a new IRB.
   1.3. This procedure ends when the new IRB has been formed.

2. POLICY
   2.1. The [Organization] maintains a roster of IRBs.

3. RESPONSIBILITY
   3.1. A designee of the [Organizational Official] carries out these procedures.

4. PROCEDURE
   4.1. For external IRBs:
      4.1.1. Ensure that the IRB meets the criteria in “POLICY: Human Research Protection Program (HRP-010).
      4.1.2. Arrange for an agreement or contract and file the agreement or contract.
      4.1.3. Update the roster of IRBs.
   4.2. For internal IRBs:
      4.2.1. Select at least five individuals to serve as IRB members and an IRB chair. One or more IRB vice-chairs may be designated.
      4.2.2. Follow “SOP: IRB Member Addition (HRP-132)” for each IRB member.
      4.2.3. Use “WORKSHEET: IRB Composition (HRP-430)” to evaluate whether the IRB is appropriately constituted.
         4.2.3.1. Revise the membership as needed.
      4.2.4. Complete a new IRB roster.
      4.2.5. Register the IRB at http://ohrp.cit.nih.gov/efile/ before the IRB convenes.

5. REFERENCES
   5.1. 21 CFR §56.106 and §56.107
   5.2. 45 CFR §46.107 and 45 CFR §46 Subpart E