1. PURPOSE
   1. This procedure establishes the process to form an IRB.
   2. This procedure begins when the [Organizational Official] has decided to form a new IRB.
   3. This procedure ends when the new IRB has been formed.
2. POLICY
   1. The [Organization] maintains a roster of IRBs.
3. RESPONSIBILITY
   1. A designee of the [Organizational Official] carries out these procedures under the authority of the [Organizational Official].
4. PROCEDURE
   1. For external IRBs:
      1. Ensure that the IRB meets the criteria in “POLICY: Human Research Protection Program (HRP-010).
      2. Arrange for an agreement or contract and file the agreement or contract.
      3. Update the roster of IRBs.
   2. For internal IRBs:
      1. Select at least five individuals to serve as IRB members and an IRB chair. One or more IRB vice-chairs may be designated.
      2. Follow “SOP: IRB Member Addition (HRP-132)” for each IRB member.
      3. Use “WORKSHEET: IRB Composition (HRP-430)” to evaluate whether the IRB is appropriately constituted.
         1. Revise the membership as needed.
      4. Complete a new IRB roster.
      5. Register the IRB at <http://ohrp.cit.nih.gov/efile/> before the IRB convenes.
5. REFERENCES
   1. 21 CFR §56.106 and §56.107
   2. 45 CFR §46.107 and 45 CFR §46 Subpart E