



SOP: IRB Formation

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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