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.
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