

Standard Operating Procedure (SOP)

SOP #: 401.130	HRP-130 IRB Formation
Executive Owner: Vice President Research Operations	Effective Date: 6/11/2018
	Review Date: 09/23/2019

Scope	This SOP applies to the [Organizational Official].
Purpose	This procedure establishes the process to form an IRB. This procedure begins when the [Organizational Official] has decided to form a new IRB. This procedure ends when the new IRB has been formed.
Qualified Personnel	A designee of the [Organizational Official] carries out these procedures under the authority of the [Organizational Official].
Training	Not applicable.
Supplies & Equipment	Not applicable.
Procedure	<ol style="list-style-type: none"> 1. The [Organization] maintains a roster of IRBs. 2. For external IRBs: <ol style="list-style-type: none"> 2.1. Ensure that the IRB meets the criteria in “POLICY: Human Research Protection Program (HRP-010). 2.2. Arrange for an agreement or contract and file the agreement or contract. 2.3. Update the roster of IRBs. 3. For internal IRBs: <ol style="list-style-type: none"> 3.1. Select at least five individuals to serve as IRB members and an IRB chair. One or more IRB vice-chairs may be designated. 3.2. Follow “SOP: IRB Member Addition (HRP-132)” for each IRB member. 3.3. Use “WORKSHEET: IRB Composition (HRP-430)” to evaluate whether the IRB is appropriately constituted. <ol style="list-style-type: none"> 3.3.1. Revise the membership as needed. 3.4. Complete a new IRB roster. 3.5. Register the IRB at http://ohrp.cit.nih.gov/efile/ before the IRB convenes.
Definition(s)	IRB: Institutional Review Board
Reference(s)	21 CFR §56.106 and §56.107 45 CFR §46.107 and 45 CFR §46 Subpart E
Related Documents	Not applicable.
Keywords	IRB, institutional review board, IRB member