

<b>SOP Number:</b> SOP CW AHC 222	<b>SOP Name:</b> IRB Formation
<b>Location:</b> *Company-Wide Policies	<b>Responsible Department:</b> Research Services
<b>Executive Owner:</b> Executive Director of Research Services	<b>Original Creation Date:</b> 01/18/2022
<b>Effective Date:</b> 04/04/2022	<b>Review Date:</b> 04/04/2022

- I. SCOPE:** This standard operating procedure (SOP) applies to the Organization Official.
- II. PURPOSE:** This procedure establishes the process to form an Institutional Review Board (IRB). This procedure begins when the Organization Official has decided to form a new IRB. This procedure ends when the new IRB has been formed.
- III. QUALIFIED PERSONNEL:** A designee of the Organization Official carries out these procedures under the authority of the Organization Official.
- IV. TRAINING:** Not applicable
- V. SUPPLIES & EQUIPMENT:** Not applicable
- VI. PROCESS/PROCEDURE:**
  - A. AdventHealth maintains a roster of IRBs.
  - B. For external IRBs:
    1. Ensure that the IRB meets the criteria in CW AHC 108 Human Research Protection Program.
    2. Arrange for an agreement or contract and file the agreement or contract.
    3. Update the roster of IRBs.
  - C. For internal IRBs:
    1. Select at least five individuals to serve as IRB members and an IRB Executive Chair. One or more IRB vice-chairs may be designated.
    2. Follow SOP CW AHC 224 IRB Member Addition for each IRB member.
    3. Use HRP-430 WORKSHEET – IRB Composition to evaluate whether the IRB is appropriately constituted.
    4. Revise the membership as needed.
    5. Complete a new IRB roster.
    6. Register the IRB with OHRP at <http://ohrp.cit.nih.gov/efile/> before the IRB convenes.
- VII. DEFINITION(S):** For capitalized terms not defined in this policy, refer to CW AHC 107 Definitions in Human Research.

For capitalized designations not defined in this policy, refer to CW AHC 103 Designations in Research.

**VIII. EXCEPTION(S):** See CW AHC 101 Research Oversight

**IX. REFERENCE(S):**  
21 CFR §56.106 and §56.107

45 CFR §46.107 and 45 CFR §46 Subpart E

**X. RELATED DOCUMENT(S) / ATTACHMENT(S):**

- CW AHC 107 Definitions in Human Research
- CW AHC 103 Designations in Research
- CW AHC 101 Research Oversight
- CW AHC 108 Human Research Protection Program
- SOP CW AHC 224 IRB Member Addition
- WORKSHEETS are located on the AdventHealth Research Institute website
  - HRP-430 WORKSHEET – IRB Composition