

SOP Number: SOP CW AHC 225	SOP Name: IRB Member Removal
Location: *Company-Wide Policies	Responsible Department: Research Services
Executive Owner: Executive Director of Research Services	Original Creation Date: 01/18/2022
Effective Date: 04/04/2022	Review Date: 02/12/2024

- I. **SCOPE:** This standard operating procedure (SOP) applies to the Organization Official.
- II. **PURPOSE:** This procedure establishes the process to remove a member of an IRB. This procedure begins when the Organization Official has decided to remove an IRB member. This procedure ends when the member has been removed and the IRB's registration has been updated.
- III. **QUALIFIED PERSONNEL:** The Organization Official is responsible for deciding whether to remove an IRB member. A designee of the Organization Official carries out these procedures.
- IV. **TRAINING:** Not applicable
- V. **SUPPLIES & EQUIPMENT:** Not applicable
- VI. **PROCESS/PROCEDURE:**
 - A. Notify the IRB member.
 - B. If the IRB member will no longer serve as an IRB member prepare and send a thank you letter signed by the Organization Official.
 - C. Update the IRB roster.
 1. Use HRP-430 WORKSHEET – IRB Composition to evaluate whether the IRB is appropriately constituted.
 2. Revise the membership as needed.
 - D. If the removed member was a chair, update the IRB's registration at <http://ohrp.cit.nih.gov/efile/> within 90 days
- 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

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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
- WORKSHEETS are located on the AdventHealth Research Institute website
 - o HRP-430 WORKSHEET – IRB Composition