

## **Standard Operating Procedure (SOP)**

SOP Number: SOP CW AHC 221	SOP Name: IRB Roster
Location: *Company-Wide Policies	<b>Responsible Department:</b> Research Services
Executive Owner:	Original Creation Date: 01/18/2022
Executive Director of Research Services	
Effective Date: 04/04/2022	<b>Review Date:</b> 02/12/2024

- **I.** <u>SCOPE</u>: This standard operating procedure (SOP) applies to all HRPP Personnel responsible for maintaining Institutional Review Board (IRB) rosters.
- **II. <u>PURPOSE</u>:** This SOP describes the information recorded in IRB rosters.
- **III. <u><b>QUALIFIED PERSONNEL:**</u> HRPP Personnel are responsible for carrying out these procedures.
- **IV. TRAINING:** Not applicable
- V. **SUPPLIES & EQUIPMENT:** Not applicable

## VI. <u>PROCESS/PROCEDURE</u>:

- A. Note the following on the IRB roster:
  - 1. The IRB registration number
  - 2. The IRB registration name
  - 3. Any restrictions on the IRB's scope
  - 4. Effective date of the IRB roster
  - 5. If the roster is inactive, the end effective date of the IRB roster
  - 6. If the IRB was deactivated, a note to that effect
- B. For each IRB member record:
  - 1. Name
  - 2. Earned degrees
  - 3. Gender
  - 4. Scientific status
    - a) Whether the IRB member has primary interests in scientific or non-scientific areas: S (Scientific) or NS (Non-scientific)
  - 5. Representative capacity
    - a) Populations about whom the IRB member is knowledgeable or experienced. (e.g., Children, Prisoners)
    - b) If the member represents the general perspective of subjects, note this.
  - 6. Indications of experience: Brief description of the IRB member's chief anticipated contributions to IRB deliberations, such as profession, certifications, licensure, IRB experience, research experience, or life experience

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- 7. Relationship to AdventHealth: describe any relationship between the IRB member and AdventHealth
- 8. Affiliation status:
  - a) Whether the IRB member or an Immediate Family member of the IRB member has a relationship with the AdventHealth: A (Affiliated) or NA (Non-affiliated)
  - b) Note that an IRB member may have no relationship to AdventHealth, but the IRB member may be affiliated because an Immediate Family member may have a relationship with AdventHealth.
- 9. Office: Whether the IRB member is an IRB Executive Chair, IRB vice-chair, or other appointed office
- 10. Membership status: Whether the IRB member is a regular member or an alternate member
- 11.Alternates: If the member is an alternate member, the class of IRB members for whom the member can alternate
- 12. Designated Reviewer: Whether the member is a Designated Reviewer
- **VII.** <u>**DEFINITION(S)**</u>: For capitalized terms not defined in this policy, refer to CW AHC 107 Definitions in Human Research.
- VIII. EXCEPTION(S): See CW AHC 101 Research Oversight

## IX. <u>REFERENCE(S)</u>:

Electronic Code of Federal Regulation (*e-CFR*<sup>™</sup>). (June 10, 2015). 21 CFR; §56.115(a)(5), 56.107(d): IRB Records. Retrieved from: <u>Click here</u>.

Electronic Code of Federal Regulation (*e-CFR*<sup>™</sup>). (June 10, 2015). 45 CFR, §46.107(a)(2), 46.107(d): IRB Records. Retrieved from: <u>Click here.</u>

## X. <u>RELATED DOCUMENT(S) / ATTACHMENT(S)</u>:

- CW AHC 107 Definitions in Human Research
- CW AHC 101 Research Oversight
- CW AHC 108 Human Research Protection Program