Standard Operating Procedure (SOP)

SOP Number: SOP CW AHC 237	**SOP Name:** Process and Required Elements of Consent for Exempt Research
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 Research Personnel and Institutional Review Board (IRB) staff members, chair, and committee members at AdventHealth.

II. PURPOSE: The purpose of this SOP is to describe the required process and provide the required elements of informed consent for studies determined by the IRB to meet exempt criteria.

III. QUALIFIED PERSONNEL: IRB Executive Chair, IRB members, IRB staff members, Investigators, and Research Personnel.

IV. TRAINING: Not Applicable

V. SUPPLIES & EQUIPMENT: Not Applicable

VI. PROCESS/PROCEDURE:

A. An IRB member determines whether a study meets the criteria of exempt research and whether consent is required.

B. The consent process must provide sufficient opportunity for the participant to consider whether to participate and minimize the possibility of coercion or undue influence.

C. The consent may not include exculpatory language. Exculpatory language is language through which the participant is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

D. The consent must disclose sufficient information in understandable language, using plain terms when appropriate for the participant to make a decision, and must include:

1. The activity involves research
2. The purpose of the research
3. The procedures to be followed
4. That participation is voluntary
5. The expected duration of participation
6. The confidentiality of the responses or anonymity of the process
7. Whom to contact for questions about the research

VII. DEFINITION(S): For capitalized terms not defined in this SOP, 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):

45 CFR 46.101(b)(1)-(6) Pre-2018 Requirements
45 CFR 46.104(d)(1)-(8) 2018 Requirements
DOD: 32 CFR 219

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

- CW AHC 101 Research Oversight
- CW AHC 107 Definitions in Human Research
- CW AHC 103 Designations in Research
- CW AHC 108 Human Research Protection Program
- FORMS and TEMPLATES are located in IRBNet
  - HRP-423 WORKSHEET – Exemptions
  - HRP-508 TEMPLATE: Consent for Exempt Research