Standard Operating Procedure (SOP)

SOP Number: SOP CW AHC 226	**SOP Name:** Designated Exempt Reviewers
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:** 04/04/2022

I. SCOPE: This standard operating procedure (SOP) applies to the IRB Executive Chair and IRB staff.

II. PURPOSE: This procedure establishes the process to designate or remove individuals from the list of IRB members who can review and approve exempt Human Research. This procedure begins when IRB Executive Chair considers adding or removing an individual designated to review and approve exempt Human Research. This procedure ends when the IRB Executive Chair notifies HRPP staff of a new individual designated to review and approve exempt Human Research or the removal of a previously designated individual.

III. QUALIFIED PERSONNEL: The IRB Executive Chair carries out these procedures. IRB staff maintain a list of individuals designated to review and approve exempt Human Research and the category of exemption each individual is authorized to grant.

IV. TRAINING: Not applicable

V. SUPPLIES & EQUIPMENT: Not applicable

VI. PROCESS/PROCEDURE:

A. AdventHealth may designate one or more individuals to review and approve exempt Human Research.

B. Individuals designated to review and approve exempt Human Research do not need to be IRB members.

C. In general, individuals designated to review and approve exempt Human Research are granted authority for only one exemption category.

D. To designate an individual to review and approve exempt Human Research in one category or a limited number of categories:

1. Train the individual to approve exempt Human Research in one or more categories using the following documents.
   a) HRP-204 FORM – Promptly Reportable Information
   b) HRP-421 WORKSHEET – Human Research
   c) HRP-423 WORKSHEET – Exemptions, modified to limit the exemption category or categories to those authorized.
   d) CW AHC 112 Investigator Obligations
   e) CW AHC 111 Prompt Reporting Requirements

2. Notify IRB staff to update the list of individuals designated to review and approve exempt Human Research to include the name of the individual and the categories of exemption on which the individual has been trained.

E. To remove an individual's designation to review and approve exempt Human Research:
   1. Notify IRB staff to update the list of individuals designated to review and approve exempt Human Research to remove the name of the individual.
   2. Inform the individual that he or she may no longer review and approve exempt Human Research.

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):
45 CFR §46.101(b)

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
- CW AHC 112 Investigator Obligations
- CW AHC 111 Prompt Reporting Requirements
- WORKSHEETS are located on the AdventHealth Research Institute website
  - HRP-421 WORKSHEET – Human Research
  - HRP-423 WORKSHEET – Exemptions
- FORMS are located in IRBNet
  - HRP-204 FORM – Promptly Reportable Information