# Standard Operating Procedure (SOP)

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| **SOP Number:** SOP CW AHC 233 | **SOP Name:** IRB Review of Emergency and Compassionate Uses |
| **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 IRB Executive Chair, IRB staff, and Designated Reviewers.

**II. PURPOSE:** This procedure establishes the process to assist treating physicians to comply with FDA requirements for Emergency Uses, Compassionate Uses, and Single Patient Expanded Access. This procedure begins when an IRB staff member notifies a Designated Reviewer of a situation that might involve an Emergency Use or a Compassionate Use. This procedure ends when the Designated Reviewer informs the submitter and IRB staff members of whether the use complies or complied with FDA requirements.

**III. QUALIFIED PERSONNEL:** IRB Executive Chair carries out these procedures for Compassionate Use when conducted before the use. IRB staff carry out these procedures for Emergency Use. A Designated Reviewer carries out these procedures for Single Patient Expanded Access.

**IV. TRAINING:** Not Applicable

**V. SUPPLIES & EQUIPMENT:** Not Applicable

**VI. PROCESS/PROCEDURE:**

A. Whenever possible, physicians are to notify the AdventHealth IRB in advance of a proposed Emergency Use.

B. Physicians are to notify the AdventHealth IRB in advance of a proposed Compassionate Uses.

C. Data obtained from uses covered by this SOP cannot be used in a non-exempt systematic investigation designed to develop or contribute to generalizable knowledge.

D. Designated Reviewers can inform submitters of whether a proposed use, if carried out as described, will meet FDA requirements or whether a use already carried out met FDA requirements.

E. The IRB has no authority to prospectively or retrospectively approve or disapprove a use.

F. IRB staff members follow SOP CW AHC 211 Post Review to provide written notification to the submitter of the results of this SOP.

G. The Emergency Use of a drug or biologic and Single Patient Expanded Access are "research" as defined by FDA, the patient is a "subject" as defined by FDA, and the FDA may require data from an Emergency Use to be reported in a marketing application.

H. Both initial and continuing review of Single Patient Expanded Access may follow this procedure. Initial, continuing review, and amendments of Single Patient Expanded Access may receive IRB Executive Chair concurrence.

I. Review the information provided and if needed contact the submitter or physician.

J. Determine whether the situation is:

1. Emergency Use of a drug or biologic. If so use, HRP-451 WORKSHEET – Emergency Use Drugs and Biologics.
2. Emergency Use of a device. If so use, HRP-452 WORKSHEET – Emergency Use Devices.
3. Compassionate Use. If so use, HRP-453 WORKSHEET – Compassionate Use Devices.
4. Single Patient Expanded Access. If so:

   a) Use, HRP-454 WORKSHEET – Single Patient Expanded Access.
   b) Assign an approval interval (not to exceed one year) based on risk.

5. None of the above. If so, stop all processing under this SOP and notify the submitter and the IRB staff member.

K. Determine whether the use meets or met FDA requirements.

L. Notify the submitter of the determination or work with the submitter to have the use comply with FDA requirements.

1. If a use was carried out and did not meet FDA requirements, handle this as Noncompliance under SOP CW AHC 212 New Information.
2. Notify the IRB staff member handling the submission of the decision and the reasons.

## 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.

For abbreviations not defined in this policy, refer to CW AHC 102 Abbreviations in Research.

## VIII. EXCEPTION(S):

See CW AHC 101 Research Oversight

## IX. REFERENCE(S):

21 CFR §56.102(d) 21 CFR §56.104(c)
FDA Guidance: IDE Early/Expanded Access

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

- CW AHC 107 Definitions in Human Research
- CW AHC 103 Designations in Research
- CW AHC 102 Abbreviations in Research

- CW AHC 101 Research Oversight
- CW AHC 108 Human Research Protection Program
- SOP CW AHC 211 Post Review
- SOP CW AHC 212 New Information
- WORKSHEETS are located on the AdventHealth Research Institute website
  - HRP-451 WORKSHEET – Emergency Use Drugs and Biologics
  - HRP-452 WORKSHEET – Emergency Use Devices
  - HRP-453 WORKSHEET – Compassionate Use Devices
  - HRP-454 WORKSHEET – Single Patient Expanded Access