

SOP: Emergency and Compassionate Uses

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1. PURPOSE

- 1.1. This procedure establishes the process to assist treating physicians to comply with FDA requirements for <Emergency Uses> and <Compassionate Uses>.
- 1.2. This procedure begins when an HRPP staff member notifies a <Designated Reviewer> of a situation that might involve an <Emergency Use> or a <Compassionate Use>.
- 1.3. This procedure ends when the <Designated Reviewer> informs the submitter and HRPP staff members of whether the use complies or complied with FDA requirements.

2. POLICY

- 2.1. Whenever possible, physicians are to notify the IRB in advance of a proposed <Emergency Use>.
- 2.2. Physicians are to notify the IRB in advance of a proposed <Compassionate Uses>.
- 2.3. 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.
- 2.4. <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. The IRB has no authority to prospectively or retrospectively approve or disapprove a use.
- 2.5. HRPP staff members follow "SOP: Post Review (HRP-111)" to provide written notification to the submitter of the results of this SOP.
- 2.6. The emergency use of a drug or biologic is "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.

3. RESPONSIBILITY

- 3.1. A <Designated Reviewer> carries out these procedures.

4. PROCEDURE

- 4.1. Review the information provided and if needed contact the submitter or physician.
- 4.2. Determine whether the situation is:
 - 4.2.1. <Emergency Use> of a drug or biologic. If so use, "WORKSHEET: Emergency Use Drugs and Biologics (HRP-451)."
 - 4.2.2. <Emergency Use> of a device. If so use, "WORKSHEET: Emergency Use Devices (HRP-452)."
 - 4.2.3. <Compassionate Use>. If so use, "WORKSHEET: Compassionate Use Devices (HRP-453)."
 - 4.2.4. None of the above. If so, stop all processing under this SOP and notify the submitter and the HRPP staff member.
- 4.3. Determine whether the use meets or met FDA requirements.
- 4.4. Notify the submitter of the determination or work with the submitter to have the use comply with FDA requirements.
 - 4.4.1. If a use was carried out and did not meet FDA requirements, handle this as <Noncompliance> under "SOP: New Information (HRP-112)."
- 4.5. Notify the HRPP staff member handling the submission of the decision and the reasons.

5. REFERENCES

- 5.1. 21 CFR §56.102(d) 21 CFR §56.104(c)
- 5.2. FDA Guidance: IDE Early/Expanded Access