

**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>, <Compassionate Uses>, and <Single Patient Expanded Access>.
- 1.2. This procedure begins when an HRPP staff member notifies a <Designated Reviewer> of a situation that might involve an <Emergency Use>, a <Compassionate Use>, or a <Single Patient Expanded Access>.
- 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 Use>.
- 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.
- 2.5. The IRB has no authority to prospectively or retrospectively approve or disapprove an <Emergency Use>.
- 2.6. HRPP staff members follow “SOP: Post Review (HRP-111)” to provide written notification to the submitter of the results of this SOP.
- 2.7. 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> or a <Single Patient Expanded Access> to be reported in a marketing application.
- 2.8. The <Emergency Use> of a device and <Compassionate Use> are not “research” as defined by FDA. However, the FDA may require data from an <Emergency Use> or a <Single Patient Expanded Access> to be reported in a marketing application.
- 2.9. <Single Patient Expanded Access> and <Compassionate Use> require continuing review
- 2.10. Initial and continuing review of <Single Patient Expanded Access> and <Compassionate Use> follow this procedure.

## 3. RESPONSIBILITY

- 3.1. An IRB chair carries out these procedures for <Compassionate Use> when conducted before the use.
- 3.2. HRPP staff carry out these procedures for <Emergency Use> for both pre-use notifications and post-use reports.
- 3.3. A <Designated Reviewer> carries out these procedures for <Single Patient Expanded Access>.

## 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. <Single Patient Expanded Access> to a drug. If so:

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- 4.2.3.1. Use, "WORKSHEET: Expanded Access Drugs and Biologics (HRP-454)."
- 4.2.3.2. Assign an approval interval (not to exceed one year) based on risk.
- 4.2.4. <Compassionate Use> of a device. If so:
  - 4.2.4.1. Use, "WORKSHEET: Compassionate Use Devices (HRP-453)."
  - 4.2.4.2. Assign an approval interval (not to exceed one year) based on risk.
- 4.2.5. 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 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, 21 CFR §56.104
- 5.2. FDA Guidance: Emergency Use of an Investigational Drug or Biologic - Information Sheet
- 5.3. FDA Guidance: IDE Early/Expanded Access
- 5.4. FDA Guidance: Expanded Access: Information for Physicians
- 5.5. FDA Guidance: Expanded Access to Investigational Drugs for Treatment Use — Questions and Answers
- 5.6. FDA Guidance: Expanded Access for Medical Devices