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> 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.
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> to be reported in a marketing application.
2.8. <Single Patient Expanded Access> and <Compassionate Use> require continuing review
2.9. 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:
  - 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