

SOP: All Emergency Use, Compassionate Use (Device Only) and IRB Waiver for Individual Patient Expanded Access (Drug Only) Post-Review

1 PURPOSE

- 1.1 This procedure establishes the process to communicate the review of:
 - 1.1.1 Emergency use of a drug, biologic, or device in a life-threatening situation.
 - 1.1.2 Non-emergency individual patient/small group expanded access for an unapproved medical device (commonly known as Compassionate Use).
 - 1.1.3 Non-emergency individual patient expanded access use of an investigational drug for which an IRB waiver is requested.
- 1.2 The process begins when the Designated Reviewer has notified IRB staff of whether an actual or proposed use has followed or will follow FDA regulations and guidance.
- 1.3 The process ends when the IRB staff has communicated the results to the physician and if necessary initiated the non-compliance process.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 None

4 RESPONSIBILITIES

- 4.1 IRB staff carry out these procedures.

5 PROCEDURE

- 5.1 For emergency use of a drug, biologic, or device in a life-threatening situation:
 - 5.1.1 If the Designated Reviewer has indicated that the proposed use will follow FDA regulations:
 - 5.1.1.1 Complete HRP-570 - LETTER - Pre-Rev EU - Crit Met and send to the physician.
 - 5.1.1.2 Set a 5 day deadline for receipt of the 5 day report.
 - 5.1.2 If the Designated Reviewer has indicated that the proposed use will NOT follow FDA regulations, complete HRP-571 - LETTER - Pre-Rev EU - Crit Not Met and send to the physician.
 - 5.1.3 If the Designated Reviewer has indicated that the actual use described in the 5-day report followed FDA regulations, complete HRP-572 - LETTER - Review of EU - Crit Met and send to the physician.
 - 5.1.4 If the Designated Reviewer has indicated that the proposed use did NOT follow FDA regulations:
 - 5.1.4.1 Complete HRP-573 - LETTER - Review of EU - Crit Not Met and send to the physician.
 - 5.1.4.2 Manage under HRP-024 - SOP - New Information as Non-Compliance.

- 5.2 For compassionate use of a device, complete HRP-574 - LETTER - Device Compassionate Use.
- 5.3 For non-emergency individual patient expanded access use of an investigational drug for which an IRB waiver is requested, complete HRP-575 - LETTER - Rev of IRB Waiver for Indiv Pt Drug Exp Access.

6 MATERIALS

- 6.1 HRP-024 - SOP - New Information
- 6.2 HRP-570 - LETTER - Pre-Rev EU - Crit Met
- 6.3 HRP-571 - LETTER - Pre-Rev EU - Crit Not Met
- 6.4 HRP-572 - LETTER - Review of EU - Crit Met
- 6.5 HRP-573 - LETTER - Review of EU - Crit Not Met
- 6.6 HRP-574 - LETTER - Device Compassionate Use
- 6.7 HRP-575 - LETTER - Rev of IRB Waiver for Indiv Pt Drug Exp Access

7 REFERENCES

- 7.1 21 CFR §50.23; 21 CFR §50.24; 21 CFR §56.102(d); 21 CFR §56.104(c).
- 7.2 21 CFR §812.36; 21 CFR §812.47.
- 7.3 (FDA Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors) Frequently Asked Questions About Medical Devices:
<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf>..
- 7.4 AAHRPP element I.7.C