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 a "TEMPLATE LETTER: Pre-Review of Emergency Use - Criteria Met (HRP-570)" 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 a "TEMPLATE LETTER: Pre-Review of Emergency Use - Criteria Not Met (HRP-571)" 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 a "TEMPLATE LETTER: Review of Emergency Use - Criteria Met (HRP-572)" 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 a "TEMPLATE LETTER: Review of Emergency Use - Criteria Not Met (HRP-573)" and send to the physician.
  - 5.1.4.2 Manage under "SOP: New Information (HRP-024)" as Non-Compliance.

5.2 For compassionate use of a device, complete a "TEMPLATE LETTER: Review of Device Compassionate Use (HRP-574)."

5.3 For non-emergency individual patient expanded access use of an investigational drug for which an IRB waiver is requested, complete "TEMPLATE LETTER: Review of IRB Waiver for Non-Emergency Individual Patient Expanded Access Use of an Investigational Drug (HRP-575)."

6 MATERIALS

6.1 SOP: New Information (HRP-024)

6.2 TEMPLATE LETTER: Pre-Review of Emergency Use - Criteria Not Met (HRP-571)

6.3 TEMPLATE LETTER: Review of Emergency Use - Criteria Met (HRP-572)

6.4 TEMPLATE LETTER: Review of Emergency Use - Criteria Not Met (HRP-573)
6.5 TEMPLATE LETTER: Pre-Review of Emergency Use - Criteria Met (HRP-570)
6.6 TEMPLATE LETTER: Review of Device Compassionate Use (HRP-574)
6.7 TEMPLATE LETTER: Review of IRB Waiver for Non-Emergency Individual Patient Expanded Access Use of an Investigational Drug (HRP-575)

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.