PurPOSE

1.1 Emergency use of a drug, biologic, or device in a life-threatening situation.

1.2 Non-emergency individual patient/small group expanded access for an unapproved medical device (commonly known as Compassionate Use).

1.3 The process begins when the Designated Reviewer has notified IRB staff or whether an actual or proposed use has followed or will follow FDA regulations or guidance.

1.4 The process ends when the IRB staff has communicated the results to the physician and if necessary initiated the non-compliance process.

PREVIOUS VERSION

2.1 Revised from previous version 01/25/2018.

POLICY

3.1 None.

RESPONSIBILITIES

4.1 IRB Office staff carry out these procedures.

PROCEDURE

5.1 If the Designated Reviewer has indicated that the proposed use will follow FDA regulations:

5.1.1 Complete a “TEMPLATE LETTER: Pre-Review of Emergency Use – Criteria Met (HRP-570)” and send to the physician.

5.1.2 The Investigator will be informed in the letter that they are obligated to submit a follow-up report within 5 days of the emergency use. This follow-up should be submitted as a RNI submission.

5.2 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.

5.3 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.

5.4 If the Designated Reviewer has indicated that the actual use did NOT follow FDA regulations:

5.4.1 Complete a “TEMPLATE LETTER: Review of Emergency Use – Criteria Not Met (HRP-573)” and send to the physician.

5.4.2 Manage under “SOP: New Information (HRP-024)” as Non-Compliance.

MATERIALS

6.1 SOP: Reportable 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)

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: 