1 PURPOSE

1.1 This procedure establishes the process to communicate the notification and review of:

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

1.2 The process begins when the IRB receives a notification of a proposed or actual use.

1.3 The process ends when the IRB staff has communicated the results to the physician.

2 PREVIOUS VERSION

2.1 Revised from previous version 03/04/2019.

3 POLICY

3.1 None.

4 RESPONSIBILITIES

4.1 IRB Office staff and a Designated Reviewer carry out these procedures.

5 PROCEDURE

5.1 The proposal should be submitted via New Project submission in eIRB. The Emergency Use of Investigational Drug, Device, or Biologic Form (HRP-1203) should be submitted with all Emergency Use proposals.

5.2 Procedures are to be carried out by a Designated Reviewer who determines if the notification/request is one of the following:

5.2.1 Emergency use of a drug, biologic, or device in a life-threatening situation. If so:

5.2.1.1 **For notifications BEFORE the emergency use of a test article**: use the "WORKSHEET: Emergency Use (HRP-322)" to determine whether the circumstances will meet the regulatory and guidance criteria for emergency use, and indicate the results of this determination to the IRB Office staff (or directly to the physician if time sensitive).

5.2.1.1.1 If the circumstances meet the criteria in HRP-322, with the help of IRB Staff, inform the physician that the physician can proceed with the use or work with the physician to identify what additional information/procedures the physician needs to follow. 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 an RNI submission.

5.2.1.1.2 If not met, with the help of IRB Staff, inform the physician that if the physician proceeds with the use, the IRB will consider that action to be Non-Compliance.

5.2.1.1.3 If the actual emergency use described in the 5-day report did not follow FDA requirements, manage under "SOP: New Information (HRP-024)" as Non-Compliance.

5.2.1.2 **For notifications AFTER the emergency use of a test article:** use the "WORKSHEET: Emergency Use (HRP-322)" to determine whether the use described in the 5-day report has met the regulatory and guidance criteria for emergency use and indicate the results of this determination to the IRB Office staff (or directly to the physician if time sensitive).

5.2.1.2.1 If the actual emergency use described in the 5-day report did not follow FDA requirements, consider it Non-Compliance and use the "SOP: New Information (HRP-024)."

5.2.1.2.2 Inform IRB staff of the results of the evaluation.

5.3 Procedures to be Carried out by IRB Office Staff post review:

5.3.1 **For notifications BEFORE the emergency use of a test article**: If the Designated Reviewer has indicated that the proposed use will follow USFDA regulations:

5.3.1.1 Complete a "TEMPLATE LETTER: Pre-Review of Emergency Use - Criteria Met (HRP-570)" and send it to the physician.

5.3.2 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 an RNI submission. If the Designated Reviewer has indicated that the proposed use will NOT follow USFDA regulations:

5.3.2.1 Complete a "TEMPLATE LETTER: Pre-Review of Emergency Use - Criteria Not Met (HRP-571)" and send to the physician.

5.3.3 **For notifications AFTER the emergency use of a test article**: If the Designated Reviewer has indicated that the actual use followed USFDA regulations

5.3.3.1 Complete a "TEMPLATE LETTER: Review of Emergency Use - Criteria Met (HRP-572)" and send it to the physician.

5.3.3.2 For uses of drugs and biologics, the Investigator will be informed that with the second use of a drug in Emergency Use, they will have to submit a full protocol to the IRB for approval.

5.3.3.3 If the Designated Reviewer has indicated that the proposed use did NOT follow USFDA regulations:

5.3.3.3.1 Complete a "TEMPLATE LETTER: Review of Emergency Use - Criteria Not Met (HRP-573)" and send it to the physician.

5.3.3.3.2 The Investigator will be instructed to submit an RNI for an Emergency Use that does not meet the criteria. Manage under "SOP: New Information (HRP-024)" as Non-Compliance.

6 MATERIALS

6.1 WORKSHEET: Emergency Use (HRP-322)
6.2 SOP: Reportable New Information (HRP-024)
6.3 TEMPLATE LETTER: Pre-Review of Emergency Use - Criteria Not Met (HRP-571)
6.4 TEMPLATE LETTER: Review of Emergency Use - Criteria Met (HRP-572)
6.5 TEMPLATE LETTER: Review of Emergency Use - Criteria Not Met (HRP-573)
6.6 TEMPLATE LETTER: Pre-Review of Emergency Use - Criteria Met (HRP-570)

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 §312.310
7.3 21 CFR §812.36; 21 CFR §812.47
(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.