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 01/21/2019.

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 a 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, consider as Non-Compliance
      and use the "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 have 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 as 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 emergence 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 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 a 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 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 to the physician.

5.3.3.3.2 The Investigator will be instructed to submit a 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.