1 PURPOSE
1.1 This procedure establishes the process to review and communicate the notifications 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 IRB receives a notification of a proposed or actual use.
1.3 The process ends when a Designated Reviewer and IRB Office has:
   1.3.1 Determined whether the proposed or actual use will follow or has followed USFDA-regulation and guidance; and
   1.3.2 Notified the physician of the determination.

2 PREVIOUS VERSION
2.1 Revised from previous version 11/22/2018

3 POLICY
3.1 Whenever possible physicians are to notify the IRB of a proposed emergency use of a drug, biologic, or device in a life-threatening situation in advance of the use.
3.2 Physicians are to notify the IRB of a proposed compassionate use of an unapproved device, for the purpose of obtaining concurrence from an IRB Chair.
3.3 Emergency uses and device compassionate uses cannot be claimed as research.
3.4 Investigators are to notify the IRB of a non-emergency individual patient expanded access use of an investigational drug “Request for Authorization to Use Alternative IRB Review Procedures” identified on FDA Form 3926 (field 10.b.) or a separate waiver request included with FDA Form 1571 for the purpose of obtaining concurrence from an IRB Chair or designee.

4 RESPONSIBILITIES
4.1 As specified, 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. Procedures are to be carried out by a Designated Reviewer who determines if the notification/request is one of the following:
   5.1.1 Emergency use of a drug, biologic, or device in a life-threatening situation. If so:
     5.1.1.1 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).
      5.1.1.1.1 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.

5.1.1.1.2 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.

5.1.1.1.3 If the actual emergency use described in the 5-day report did not follow FDA requirements, manage use “SOP: New Information (HRP-024)” as non-compliance.

5.1.1.2 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).

5.1.1.2.1 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).”

5.1.1.2.2 Inform IRB staff of the results of the evaluation.

5.1.1.3 Compassionate use of a device. If so, use “WORKSHEET: Compassionate Use of a Device (HRP-325)” to determine whether the circumstances will meet the regulatory and guidance criteria and indicate the results of this determination to the physician.

5.1.1.4 Non-emergency individual patient expanded access use of an investigational drug for which an IRB waiver is requested. If so, use “WORKSHEET: Criteria for Approval (HRP-314)” to determine whether the proposed use meets the requirements under 21 CFR 50 and 56.1111 and indicate the results of this determination to the IRB staff.

5.1.1.5 Execute the “Submit Designated Review” activity. In the “Notes” section document that the decision is to concur (or not) is in lieu of review and approval at a convened IRB meeting at which a majority of the members are present per the request for a waiver under 21 § 56.105 of the requirements in § 56.108(c).

5.1.1.6 If none of the above, stop processing the request and the IRB Office Staff will inform the physician or submitter.

5.1.2 Inform IRB Office staff of the results of the evaluation.

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

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

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

5.2.2 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:

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

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

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1 “The IRB chairperson (or designated IRB member) would consider the same information that the full IRB would consider to determine whether to approve the treatment when reviewing and concurring for individual patient expanded access use.” Per FDA correspondence dated 10/10/17
5.2.3.1 Complete a "TEMPLATE LETTER: Review of Emergency Use - Criteria Met (HRP-572)" and send to the physician.

5.2.3.2 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.

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

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

5.2.3.3.2 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 WORKSHEET: Compassionate Use of an Unapproved Device (HRP-325)
6.3 TEMPLATE LETTER: Pre-Review of Emergency Use - Criteria Met (HRP-570)
6.4 TEMPLATE LETTER: Pre-Review of Emergency Use - Criteria Not Met (HRP-571)
6.5 TEMPLATE LETTER: Review of Emergency Use - Criteria Met (HRP-572)
6.6 TEMPLATE LETTER: Review of Emergency Use - Criteria Not Met (HRP-573)
6.7 FORM: Emergency Use of Investigational Drug, Device, or Biologic (HRP-1203)

7 REFERENCES

7.1 21 CFR §50.23; 21 CFR §50.24; 21 CFR §50.25(d)
7.2 21 CFR §56.102(d); 21 CFR §56.104(c)
7.3 21 CFR §312.310