1. PURPOSE
   1. This procedure establishes the process to communicate the review of:
      1. Emergency use of a drug, biologic, or device in a life-threatening situation.
      2. Non-emergency individual patient/small group expanded access for an unapproved medical device (commonly known as Compassionate Use).
   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.
   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
   1. None
3. POLICY
   1. None.
4. RESPONSIBILITIES
   1. IRB staff carry out these procedures.
5. PROCEDURE
   1. If the Designated Reviewer has indicated that the proposed use will follow FDA regulations:
      1. Complete a “TEMPLATE LETTER: Pre-Review of Emergency Use - Criteria Met (HRP-570)” and send to the physician.
      2. Set a 5 day deadline for receipt of the 5 day report.
   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.
   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.
   4. If the Designated Reviewer has indicated that the proposed use did NOT follow FDA regulations:
      1. Complete a “TEMPLATE LETTER: Review of Emergency Use - Criteria Not Met (HRP-573)” and send to the physician.
      2. Manage under “SOP: New Information (HRP-024)” as Non-Compliance.
6. MATERIALS
   1. SOP: New Information (HRP-024)
   2. TEMPLATE LETTER: Pre-Review of Emergency Use - Criteria Not Met (HRP-571)
   3. TEMPLATE LETTER: Review of Emergency Use - Criteria Met (HRP-572)
   4. TEMPLATE LETTER: Review of Emergency Use - Criteria Not Met (HRP-573)
   5. TEMPLATE LETTER: Pre-Review of Emergency Use - Criteria Met (HRP-570)
7. REFERENCES
   1. 21 CFR §50.23; 21 CFR §50.24; 21 CFR §56.102(d); 21 CFR §56.104(c).
   2. 21 CFR §812.36; 21 CFR §812.47.
   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>.