1 PURPOSE
1.1 This procedure establishes the process to communicate the review of:
1.1.1 Emergency use of a drug, biologic, or device in a life-threatening situation.
1.1.2 Compassionate use of an unapproved device without an IDE for a serious
condition.
1.2 The process begins when the Designated Reviewer has notified HRPO staff of
whether an actual or proposed use has followed or will follow FDA regulations and
guidance.
1.3 The process ends when the HRPO staff has communicated the results to the
physician and if necessary initiated the non-compliance process.

2 REVISIONS FROM PREVIOUS VERSION
2.1 Changed title of SOP to be consistent with the purpose.

3 POLICY
3.1 Whenever possible physicians are to notify the HRPO 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 HRPO of a proposed compassionate use of an
unapproved device without an IDE for a serious condition.
3.3 Data obtained from uses covered by this procedure cannot be used in a non-
exempt systematic investigation designed to develop or contribute to generalizable
knowledge.

4 RESPONSIBILITIES
4.1 HRPO staff carry out these procedures.

5 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 Determine the date of the 5 day deadline for receipt of the report.
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 followed FDA
regulations
5.3.1 Complete a “TEMPLATE LETTER: Review of Emergency Use - Criteria Met (HRP-572)” and send to the physician.
5.3.2 For uses of drugs and biologics, determine the date of the 30 day deadline for receipt of a protocol.
5.4 If the Designated Reviewer has indicated that the proposed 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.

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

7 REFERENCES
7.1 21 CFR 56.102 (d): Definition of Emergency Use
7.2 21 CFR 56.104 (c): Exemption from IRB requirement; emergency use of a test article
7.3 21 CFR 50.23 (a-c): Exception from General Requirements (Informed Consent of Human Subjects)