SOP: Emergency Use Post-Review				
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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 IRB staff of whether an actual or proposed use has followed or will follow USFDA regulations and guidance.

1.3 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

2.1 None

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 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 IRB staff carry out these procedures.

5 PROCEDURE

5.1 If the Designated Reviewer has indicated that the proposed use will follow USFDA 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 Set a 5 day deadline for receipt of the 5 day report.

5.2 If the Designated Reviewer has indicated that the proposed use will NOT follow USFDA 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 USFDA 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, set a 30 calendar day deadline for receipt of a protocol.

5.4 If the Designated Reviewer has indicated that the proposed use did NOT follow USFDA 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)

6.3 TEMPLATE LETTER: Review of Emergency Use - Criteria Met (HRP-572)

6.4 TEMPLATE LETTER: Review of Emergency Use - Criteria Not Met (HRP-573)

6.5 TEMPLATE LETTER: Pre-Review of Emergency Use - Criteria Met (HRP-570)

6.6 WORKSHEET: Emergency Use (HRP-322)

7 REFERENCES

7.1 21 CFR §50.23; 21 CFR §56.104(c).