Title: Emergency Use Review of a Test Article and Compassionate Use of an Unapproved Device

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Reviewed/Recommended for Approval: Mark Holdsworth, Pharm.D., Executive Chair HRRC
Richard Larson, MD PhD, Vice Chancellor for Research

Date: 3/6/15

Approved:

Date: 3/5/15

1 PURPOSE

1.1 This procedure establishes the process to review notifications of:

1.1.1 Emergency use of a drug, biologic, or device by a physician 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 HRRC receives a notification of a proposed or actual use.

1.3 The process ends when a Designated Reviewer has:

1.3.1 Determined whether the proposed or actual use will follow or has followed FDA-regulation and guidance; and

1.3.2 Notified the physician and HRPO staff of the determination.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Changed title of SOP to be consistent with the purpose.

2.2 Section 3.1.2: Clarified subsequent usage terms.

3 POLICY

3.1 Whenever possible physicians are to notify the HRRC of a proposed emergency use of a drug, biologic, or device in a life-threatening situation in advance of the use.

3.1.1 In rare cases, notification may be received after the use of the test article, but must be received by the HRPO no later than 5 working days after the use of the test article.

3.1.2 HRPO staff will verify that there has not been a previous report or request for the emergency use of the same test article. Subsequent usage of the test article must be reviewed by the HRRC. Physicians are to notify the HRRC of a proposed compassionate use of an unapproved device without an IDE for a serious condition.

3.2 Whenever possible, the request must be accompanied by an independent written assessment for use by an uninvolved physician, a copy of the protocol (if available at the time of request or within 30 days), an informed consent and HIPAA authorization form.

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 and a Designated Reviewer carries out these procedures.
5 PROCEDURE
5.1 HRPO staff use the "WORKSHEET: Emergency Use (HRP-322)" or equivalent to evaluate whether the circumstances will meet the regulatory and guidance criteria and will communicate the results of this determination to the reviewer.

5.1.1 Requests for emergency use are reviewed by an IRB/HRRC Chair. The Chair has the option to concur with (approve) or deny use of the drug/device/biologic.

5.1.2 If approved, HRPO staff will inform the physician that he/she can proceed with the use.

5.1.3 If approval is denied, HRPO staff will inform the physician that if the physician proceeds with the use, the IRB/HRRC will consider that action to be Non-Compliance.

5.1.4 HRPO staff will inform the PI of his/her responsibility to provide written documentation of use to the HRPO within 5 calendar days of using the drug/device/biologic.

5.1.4.1 Reminders to the HRPO staff will be set in an electronic calendar (or equivalent) to ensure that the HRPO is tracking on a daily basis all activity related to the submission during this 5 day window.

5.1.5 An electronic tracking tool (e.g. spreadsheet) will be utilized to document and track Emergency Use Submissions to ensure that regulatory requirements are met including:

5.1.5.1 Receipt of follow-on documentation of the Emergency Use outcomes within 5 days

5.1.5.2 Approvals for Emergency Use for the same drug/device/ biologic are not occurring

5.1.6 Upon receipt of documentation regarding the outcome, the information is reviewed by an IRB/HRRC Chair. HRPO staff will contact the PI if follow-up information is not received within 5 working days of the request for use, including information that the PI has decided not to proceed with use and has requested a withdrawal of the submission.

5.1.7 A summary of the request and the outcome of use will be presented by the reviewing IRB/HRRC Chair at the next fully convened IRB/HRRC meeting. If further information is requested by the fully convened committee, a letter detailing the request will be sent to the PI by HRPO staff.

5.1.8 Each Emergency Use submission and all related correspondence are maintained under a unique HRPO study number.

5.2 For notifications after the emergency use of a test article in a life-threatening situation use the "WORKSHEET: Emergency Use (HRP-322)" to determine whether the circumstances met the regulatory and guidance criteria.

6 MATERIALS
6.1 SOP: Definitions (HRP-001)
6.2 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)