SOP: All Emergency Use, Compassionate Use (Device Only) and IRB Waiver for Individual Patient Expanded Access (Drug Only) Review

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1 PURPOSE

1.1 This procedure establishes the process to review 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 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 IRB staff of the determination.

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, 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 A Designated Reviewer carries out these procedures.

5 PROCEDURE

5.1 Determine 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, use the "WORKSHEET: Emergency Use (HRP-322)" to determine whether the circumstances will meet, or if 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 staff (or directly to the physician if time sensitive).
  - 5.1.1.1 If the notice is in advance of the use, inform the IRB staff (or physician if time sensitive) that the physician can proceed with the use or work with the physician to identify what additional information/procedures the physician needs to follow. Set a 5-day reminder to request the 5-day report.
  - 5.1.1.2 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.

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5.1.2 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.

5.1.3 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 56.111[1] and indicate the results of this determination to the IRB staff.

5.1.3.1 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).

5.1.4 If none of the above, stop processing the request and inform the physician or submitter.

5.2 Inform IRB staff of the results of the evaluation.

6 MATERIALS

6.1 SOP: Definitions (HRP-001)
6.2 SOP: New Information (HRP-024)
6.3 WORKSHEET: Criteria for Approval (HRP-314)
6.4 WORKSHEET: Emergency Use (HRP-322)
6.5 WORKSHEET: Compassionate Use of a Device (HRP-325)

7 REFERENCES

7.1 21 CFR §50.23; 21 CFR §50.24; 21 CFR §56.102(d); 21 CFR §56.104(c).
7.2 21 CFR §812.36; 21 CFR §812.47.
7.3 (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.
7.4 Individual Patient Expanded Access Applications: Form FDA 3926 Guidance for Industry; https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm432717.pdf

[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

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