UNIVERSITY OF MIAMI

SOP: All Emergency Use, Compassionate Use (Device Only) and 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.

1.2 The process begins when the IRB receives a notification of a proposed or actual emergency use or an initial review submission for an actual use.

1.3 The process ends when a convened IRB has:
- 1.3.1 Determined whether the actual use has followed FDA-regulation and guidance; the proposed use is consistent with applicable regulatory requirements; and
- 1.3.2 Notified the individuals as outlined in HRP-303 – WORKSHEET – Communication of Review Results.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Updated to include new regulatory provisions and to include pre- and post-review.

2.2 Updated to remove the requirement for specific template letters.

2.3 Revised for clarity

2.4 Revised to include all emergency use, compassionate use device, and individual expanded access investigational drug use.

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, for the purpose of obtaining concurrence from an IRB Chair.

3.2 Emergency uses and device compassionate uses cannot be claimed as research.

3.3 Investigators are to notify the IRB of a non-emergency individual patient expanded access use of an investigational drug via an eProst Submission for Initial Review

4 DEFINITIONSRESPONSIBILITIES

4.1 IRB chairs, committees, Investigators, and HRSO staff members carry out these procedures.

5 PROCEDURE

5.1 Determine if the notification/request is one of the following:
- 5.1.1 Advance notice of emergency use of a drug, biologic, or device in a life-threatening situation. If so, and time permits, contact an IRB Chair or refer the physician to an IRB Chair for discussion.
  - 5.1.1.1 Use HRP-322 - WORKSHEET - Emergency Use to determine whether the circumstances will meet the regulations and guidance for emergency use.
    - 5.1.1.1.1 Notify the physician of the determination verbally or via email that the requirements are met.
    - 5.1.1.1.2 The treating physician will report the use to the IRB within 5 working days with documentation supported in HRP-322-WORKSHEET - Emergency Use
- 5.1.2 Post – Use Notice of emergency use
  - 5.1.2.1 Require the physician to submit a Report of New Information with the following information:

5.1.2.1.1 Information about patient's condition supporting need for emergency use; and

5.1.2.1.2 Copy of unsigned consent document used to obtain consent for the use; or

5.1.2.1.3 Statement explaining that informed consent was not obtained in advance, providing justification found in 21 CFR 50.23 (a) or (b).

Follow HRP – 20 SOP – Incoming Items for additional actions.

5.1.3 If the report is advance notice of expanded access use of a drug, biologic, or medical device, notify the physician that they need to submit an initial review submission through eProst.

5.1.3.1 If the request is for single patient treatment use (expanded access), the physician must submit the following in the initial review submission:

5.1.3.1.1 Description of patient's condition with support for using the investigational product

5.1.3.1.2 Investigator Brochure or other information about the investigational product that demonstrates the background, foreseeable risks and information relating to efficacy.

5.1.3.1.3 IND or IDE

5.1.3.1.4 Informed consent document

5.1.3.2 If the request is for treatment use (expanded access) of an investigational product for multiple patients expanded access, the physician must submit the documents required for initial review of a protocol as outlined in HRP 103 – Investigator Manual.

5.1.3.2.1 Follow HRP-020 – Incoming Items

6 MATERIALS

6.1 HRP-020 – SOP – Incoming Items
6.2 HRP-021 - SOP - Pre-Review
6.3 HRP-024 - SOP - New Information
6.4 HRP-314 - WORKSHEET - Criteria for Approval
6.5 HRP-322 - WORKSHEET - Emergency Use
6.6 HRP-325 - WORKSHEET - Device Compassionate Use

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 21 CFR § 56.105; 21 CFR § 56.108(c).
7.4 (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.
7.5 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
7.6 AAHRPP element 1.7.C