MCW IRB Committee Procedures

EMERGENCY USE OF INVESTIGATIONAL DRUGS, DEVICES, OR BIOLOGICS

Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: Institutional Review Board Committees

PURPOSE:
To outline the process and steps the IRB Committee takes in reviewing and evaluating notification of an emergency use of an investigational drug, biologic or device by a physician.

DEFINITIONS:
Emergency Use of an Investigational Drug: The use of an investigational drug or biological product with a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval.

Emergency Use IND: In an emergency situation, the request to use an unapproved investigational drug may be made via telephone or other rapid means of communication, and authorization to ship and use the drug may be given by the FDA official over the telephone. In these situations, known as emergency IND (eIND) requests, shipment of and treatment with the drug may begin prior to FDA's receipt of the written IND submission that is to follow the initial request.

Emergency Use of an Investigational Device: Emergency use is the use of an investigational device in an emergency situation. It is intended to provide patients and physicians with access to devices intended to treat life-threatening or serious diseases or conditions when there is no available alternative and no time to obtain FDA approval. Emergency use may apply even if the investigational device is being studied in a clinical trial under an IDE: if a physician needs to use the device in a manner inconsistent with the approved investigational plan; or a physician who is not part of the clinical study, wishes to use the device to treat a patient with a life-threatening or serious disease or condition. Emergency use of an investigational device may occur before an IDE is approved and when a device is not being studied under an IDE.

Life-threatening Situation: With regards to 21 CFR 56.102(d), both life-threatening and severely debilitating, are defined below.

- **Life-threatening** means:
  - Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted; and
  - Diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival.
- **Severely debilitating** means diseases or conditions that cause major irreversible morbidity. Examples of severely debilitating conditions include blindness, loss of arm, leg, hand or foot, loss of hearing, paralysis or stroke.

PROCEDURE:

1. Under federal regulations, the IRB Committee is charged to review a physician's submission for emergency use of an investigational drug, device or biologic within 5 working days of the use. The IRB Committee or designee will conduct a review as outlined in this procedure.
2. The HRPP office will forward the submission to the IRB Chair or designee in accordance with *Staff: Assigning Primary Reviewers and Use of Consultants.*
3. For emergency use submissions of an investigational article, the IRB Chair or designee will review the event with with regards to the federal regulations, the subject's condition, the alternatives, and if consent was obtained or the subject was notified of the use appropriately.
4. Because the emergency use of an investigational article is not considered research, the IRB Chair or designee will review the submission to ensure all elements are addressed per the federal regulations. The IRB Chair or designee will complete the *IRB Member Form: Emergency Use Reviewer Checklist.*

The specific criteria are made available to all members via the HRPP website.

IRB Review

1. The IRB Chair or designee will consult with the physician and the HRPP office to determine if there have been any emergency uses of the same investigational article (device, drug or biologic) for the same indication at our institutions. FDA regulations *typically* require prospective IRB review and approval for repeated uses of the same investigational article at an institution.
2. The IRB Chair or designee will review the eBridge SmartForm and the consent form, along with the additional documentation (independent physician assessment, authorization from the FDA and/or the emergency use IDE/IND).
3. The IRB Chair or designee will acknowledge if the notification meets the federal regulations.
4. An IRB decision letter will be issued to the Investigator, along with the consent form in accordance with *Staff: Creation and Processing of IRB Meeting Minutes and Decision Letters.* The IRB Decision Letter will include instructions to the Investigator to file follow-up reports regarding the subject outcomes 30 days and 90 days post-use.
5. The IRB Chair will inform the convened Committee of the Emergency Use at their next IRB meeting.

REFERENCES:

21 CFR 56.102
21 CFR 56.104(c)
21 CFR 812.35(a)
21 CFR 312.36
FDA Guidance: Emergency Use of an Investigational Drug or Biologic Information Sheet
FDA Guidance on Investigation Device Exemption (IDE) Policies and Procedures

SUPPORTING DOCUMENTS:
IRB Member Form: Emergency Use Reviewer Checklist
Staff: Assigning Primary Reviewers and Use of Consultants.
Staff: Creation and Processing of IRB Meeting Minutes and Decision Letters

Effective Date:	06/15/2018
Version number:	4.0
Previous Version/date:	3.0, 06/07/2013
Responsible Office:	HRPP Office
Approval Date:	06/07/2018

Approved By
HRPP Authorized Official: David Clark, PhD, Director, HRPP
Human Research Protections Program (HRPP)
Office of Research
Medical College of Wisconsin