



EMERGENCY USE OF AN INVESTIGATIONAL PRODUCT

Clinical Research Policy/Procedure	
Approved: February 2009	Next Review: February 2012

Purpose

To ensure the safety and welfare of patients. To ensure regulatory requirements are adhered to when using an unapproved investigational product for the emergency medical treatment of a single patient.

Responsible Persons

Physicians.

Definitions

Emergency Use means the use of an investigational product on a single patient in a life-threatening or severely debilitating situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval.

Life-threatening Situation means diseases or conditions where the likelihood of the patient's death is high unless the course of the disease is interrupted, and diseases or conditions with potentially fatal outcomes, where the endpoint of clinical trial analysis is survival. The criteria for life-threatening do not require the condition to be immediately life-threatening or to immediately result in death. Rather, the patient must be in a life-threatening situation requiring intervention before review at a convened meeting of the IRB is feasible.

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.

Policy

Under unusual circumstances, the use of an investigational product (i.e., investigational drug, biologic, or device) may only occur in a controlled clinical trial that has been reviewed and approved by an IRB. However, extraordinary circumstances may arise when a physician determines it is in the best interests of a patient in an emergency situation to be treated with an investigational product.

Federal regulations permit the emergency use of an investigational product on a single patient if: (1) the situation is a life-threatening or severely debilitating situation, (2) no standard acceptable treatment is available, and (3) there is no sufficient time to obtain prospective IRB approval. A physician must use his/her professional judgment to assess whether the situation is life-threatening or severely debilitating, and whether no standard acceptable treatment is

available. ***For purposes of this policy, there is not sufficient time to obtain prospective IRB approval from a convened meeting of the IRB if the situation presents less than five (5) business days from the anticipated emergency use.*** Expedited IRB review of emergency use is prohibited.

When the aforementioned criteria are satisfied, emergency use of an investigational product is exempt from regulatory requirements requiring prior review and approval by an IRB. However, even if prospective IRB review and approval is exempt, if the proposed emergency use involves an investigational drug or biologic, the physician must obtain an emergency investigational drug application (Emergency IND) directly from the FDA or via the drug/biologic manufacturer. If the proposed emergency use involves an investigational device, the physician must notify and obtain authorization from the investigational device exemption (IDE) sponsor, if an IDE exists. If an IDE does not exist, the physician must report the emergency use directly to the FDA.

After emergency use of an investigational product, the physician must report the emergency use to the IRB within three (3) business days of the use.

Once an investigational product is utilized in an emergency use situation at Swedish, any subsequent use of the same investigational product requires prospective IRB review and approval. If a physician anticipates the possibility of emergency use of an investigational product for multiple patients, the physician must work with the product manufacturer to develop a protocol for such use. The protocol must be reviewed and approved by an IRB before emergency use for multiple patients can be initiated. However, emergency treatment to a subsequent patient will not be denied if the only obstacle to the treatment is a lack of time for the IRB to review and approve the protocol.

Notwithstanding the use of research-related terms in this Policy/Procedure, emergency use of an investigational product is not research. Any data generated from the emergency use medical treatment may not be included in any previously-conceived research project.

Procedure

INSTITUTIONAL NOTIFICATION OF EMERGENCY USE

1. When emergency use of an investigational product is being considered, the physician should immediately contact: (1) the Manager, Institutional Review Office, Swedish Research Center; (2) the Research Education & Compliance Officer; and (3) the appropriate Research Manager. To identify the appropriate Research Manager, refer to the Swedish Research webpage at: http://www.swedishmedical.org/research/admin/Initiating_research.html.
2. The physicians should promptly contact the investigational product manufacturer to: (i) notify the manufacturer of the proposed emergency use, and (ii) seek authorization from the manufacturer or the FDA, as described below:
 - a. If the investigational product is a drug or biologic, the physicians should contact the drug/biologic manufacturer to determine whether the product can be provided under an existing IND. If not, the physician must work together with the drug/biologic manufacturer and the Research Education & Compliance Officer to obtain an Emergency IND from the FDA prior to the emergency use. If the need for an investigational drug or biologic arises in an emergency situation that does not allow time for submission of an Emergency IND to the FDA, the FDA may

- c. If immediate emergency use of the investigational product is, in the physician's opinion, required to preserve the life of the patient, and time is not sufficient to obtain an independent determination in advance of the emergency use, the determinations described above (section 3.b) must be documented by the physician, and, within three (3) business days after the emergency use, the physician must have his/her determination reviewed and evaluated in writing by an independent physician not otherwise participating in the emergency use. The physician's written certification and the independent physician's written evaluation must be submitted to the IRB within three (3) business days of the emergency use.

PATIENT OUTCOME

7. Promptly after and no later than three (3) business days after the emergency use, the physician must provide to the IRB a written report of the patient outcome information and the patient protection measures that were followed.

Supplemental Information

N/A

Expert Consultants

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Regulatory Requirement

21CFR 50.23; 21CFR 56.102(d) and 56.104(c); 21CFR 312.36; and 21CFR 812.35(a).

References

Information Sheet Guidance for Institutional Review Boards and Clinical Investigators: "Emergency Use of an Investigational Drug or Biologic" (1998).
 Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors: "Frequently Asked Questions About Medical Devices" (2006).

Addenda

N/A