

OPERATING PROCEDURES/POLICIES

Committee: Institutional Review Board
Policy Number: IRB-29
Effective Date: September 4, 2007

POLICY TITLE:

EMERGENCY USE OF INVESTIGATIONAL DRUGS, BIOLOGICS OR MEDICAL DEVICES

POLICY:

The IRB Chair or designate shall be notified of any single-patient emergency use of an investigational drug, biologic or medical device prior to its use. Under the U.S. Food and Drug Administration (FDA) regulations prospective IRB review is not required for the use of an investigational new drug, biologic or medical device when a bona fide life-threatening situation exists, where no standard acceptable treatment is available, and when there is not sufficient time to obtain IRB approval in advance. The physician responsible for the emergency use of the investigational product is still required to obtain informed consent under these circumstances.

PROCEDURE:

- 29.1 The emergency use of an unapproved investigational drug or biologic requires an IND and unapproved investigational device requires an IDE. If the intended subject does not meet the criteria of an existing research study protocol, or if an approved study research protocol does not exist, the treating physician is to contact the manufacturer and determine if the investigational drug, biologic, or device can be made available for emergency use under the company's IND or IDE.
- 29.2 Emergency use is defined in the FDA regulations as the use of a test article (investigational drug, biologic or device) in a patient 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 [21 CFR 56.102 (d)]. Under the FDA regulations an exemption from prior review and approval by the IRB is allowed for the use of the investigational product in a single patient in a life-threatening situation. Any subsequent uses of the

investigational drug, biologic, or device in life-threatening, emergency situations must have prospective IRB review and approval. [21 CFR 56.104(c)]

- 29.3 Children's institutional policy requires the treating physician to verbally notify the IRB Chair *prior to* any single-patient emergency use of an investigational product. If the IRB Chair is not available, the physician must notify the Coordinator of the Investigational Drug Service in Children's Pharmacy. If neither the IRB Chair nor the Coordinator of the Investigational Drug Service is available, the physician must notify Children's Medical Director. In addition to notifying the IRB Chair, the physician must notify the hospital's Medical Device Committee if the emergency involves the use of an investigational medical device (IDE) and the hospital's Investigational Drug Services, when the emergency involves the use of an investigational drug or biologic.
- 29.4 At the time of notification, the IRB Chair shall determine that a bona fide emergency situation exists and to remind the treating physician that they must obtain signed written consent from the patient or their legally representative before the investigational device, drug or biologic is used. The IRB Chair shall also remind the treating physician of their requirements to provide a written report of this emergency use and to submit an IRB application for prospective review and approval if future uses of the investigational product are possible.
- 29.5 The IRB has a sample Emergency Use Consent Form Template available on the IRB web site to assist physicians in quickly preparing a written consent form for the patient or their legal representative. Alternatively, the manufacturer of the investigational product may have a sample Emergency Use Consent Form available that can be modified by the treating physician to include information specific to the local setting, e.g., the names and contact information for the treating physician(s).
- 29.6 The treating physician must report the use of an investigational product under emergency circumstances in writing to the Chair of the IRB within 5 working days [21 CFR 56.104(c)]. The principal investigator shall describe in sufficient detail the emergency situation, the outcome for the patient (at the time of reporting) from this emergency use, and a copy of the consent form signed by the subject or their legally authorized representative.
- 29.7 All emergency uses of investigational products shall be reported to the full IRB at the next scheduled IRB meeting following receipt of the written report from the principal investigator. A description of the emergency use shall be documented in the IRB minutes for the meeting at which the emergency use is reported. The emergency use report shall be filed in the IRB Notebook for Emergency Uses and entered as an Emergency Use application in the IRB

