	University of Puerto Rico Medical Sciences Campus Human Research Subjects Protection Office	Effective: 9/1/2008
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EMERGENCY USE OF EXPERIMENTAL DRUGS OR DEVICES

Purpose:

To describe the policies and procedures for the emergency use of experimental drugs or devices at UPR MSC.

Source:

21 CFR 50.24, 56.109
21 CFR 312.36

Applicability:

Investigators, IRB Members, IRB Staff

Background:

The emergency use of an investigational drug or biologic or unapproved medical device provision in FDA regulations allows for a single use of an investigational drug or biologic or unapproved medical device for a human subject in a life-threatening situation for which no standard acceptable treatment is available and when there is not sufficient time to obtain IRB approval.

Planned emergency research conducted in life-threatening situations must be differentiated from the "emergency use" of an investigational drug or biologic or unapproved medical device. For this policy **Planned Emergency Research** defines studies designed for human subjects who are in need of

emergency medical intervention but who cannot give informed consent because of their life-threatening medical conditions and who do not have an available legally authorized representative to provide consent.

Policy:

The use of an experimental drug or device for the benefit of a single patient may be approved without delay by the Chair of the IRB provided an emergency situation exists.

Planned Emergency Research is not permitted at UPR Medical Sciences Campus.

Procedure:

The following conditions should exist for a situation to be considered an emergency:

(1) The patient is suffering from a life-threatening condition that needs immediate treatment.

(2) No acceptable alternative for treating the patient is available.

(3) Because of the immediacy of the need to use the drug or device, there is not time to use existing procedures to obtain FDA or IRB (full board) approval.

Requests for emergency use of a drug or device can be made when an IRB- approved protocol exists, but the patient does not meet all eligibility criteria for enrollment (i.e., protocol deviation).

When an approved research protocol does NOT exist, an experimental drug or device can be used on this basis only once and a protocol must be submitted to the IRB within five days. If an investigator anticipates the need to use the drug or device additional times, a protocol must be submitted to the IRB for approval. Data from these activities may only be counted toward research to the extent required by FDA regulations.

Approval to provide emergency medical care for one patient does not

constitute IRB approval of the protocol. All research protocols must receive full IRB review and approval prior to implementation.

To request approval for a **one-time** emergency use, send a letter to the IRB, detailing the following:

(1) The patient's name and age

(2) Physical condition

(3) Justification for use of the experimental drug or device (e.g., documentation that no available alternative therapy exists)

(4) Therapeutic plan (e.g., dose, mode of administration, duration of planned therapy)

(5) IND (investigational new drug)/IDE (investigational device exemption) and the name of the sponsor that is providing the drug or device

(6) The name of a physician uninvolved in the patient's care who concurs that the drug or device is needed for a life-threatening situation

(7) The name of the hospital in which the patient is to be treated, and

(8) A proposed consent document that meets the criteria described in the informed consent section.

In extreme emergencies (minutes or hours), an investigational drug or device may be used without IRB approval provided:

(1) The investigator and an uninvolved physician certify in writing in the patient's medical record that the drug or device is needed for a life threatening situation;

(2) The patient or the patient's legal representative signs a consent document that meets the criteria, except when the subject is unable to communicate consent and there is no time to obtain consent from the subject's legal representative;

(3) If an IND/IDE exists, the sponsor is notified of the emergency use of the drug or device;

(4) If an IND/IDE does not exist, the FDA is notified of the emergency use of the drug or device; and

(5) A letter describing the situation and a copy of the signed consent document are submitted to the IRB within five days.

Following the emergency use of a drug or device, a written report of the patient's status should be submitted in one week to the IRB.