LSU Health NEW ORLEANS Human Research Protection Program	EMERGENCY USE NOTIFICATION AND REPORTING PROCEDURES			
	P & P	VERSION DATE	REPLACES P & P	PREVIOUS VERSION DATE
	4.08	02.08.2020	5.18	03.25.2019

Introduction

The FDA has recognized circumstances where a test article (an investigational drug, biologic or device) may be used in patients with life-threatening or other serious diseases, for which no alternative treatment exists.

Under certain circumstances, a test drug or device may need to be administered to a human subject in a life-threatening situation, where there is no standard acceptable treatment available, or the standard treatments have failed. Such emergency use exemption is allowed under 21CFR56.104(c).

Under FDA regulations, the emergency use of a test article, other than a medical device, is a clinical investigation, the patient is a participant, and the FDA may require data from an emergency use to be reported in a marketing application.

DHHS regulations do not permit data obtained from patients to be classified as human participants research, nor permit the outcome of such care to be included in any report of a research activity subject to DHHS regulations.

If the research involves an investigational drug, the FDA has issued an IND.

Requirements

Each of the following conditions must exist to justify the emergency use of an unapproved investigational drug, biologic or device:

- The patient must have a life-threatening condition that requires immediate treatment
- There must be no generally-acceptable or available alternative for treating the patient
- Because of the immediate need to use the drug or device, there is not sufficient time to obtain IRB (i.e., Full Board) approval

All LSUHSC-NO employees must report any usage allowed under 21CFR56.104(c). This report must be received in writing by the LSUHSC IRB within five working days. This exemption allows for one (1) emergency use of a test article by the institution (LSUHSC-NO) without prospective IRB review. The IRB requires that any subsequent use of the investigational product by any LSUHSC-NO employee must have prospective IRB review and approval.

Informed Consent Requirements

Even for emergency use, informed consent must be obtained from the subject or the subject's legally authorized representative (LAR). Informed consent is sought from each prospective participant or the participant's legally authorized representative, in accordance with and to the extent required by 21 CFR 50 and informed consent is appropriately documented, in accordance with and to the extent required by 21 CFR 50.27. Informed consent may be waived if all the following conditions are met, and if the

investigator and a physician not otherwise participating in the investigation certify in writing before the use of the test article that all of these conditions are met:

- The subject is confronted with a life-threatening situation necessitating the use of the test article.
- Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from, the subject.
- Time is not sufficient to obtain consent from the subject's legal representative.
- No alternative method of approved or generally-recognized therapy is available that provides an equal or greater likelihood of saving the subject's life.

When there is not time to obtain certification of another physician prior to the emergency use of the test article informed consent is not required because all of the following are true:

- Immediate use of the test article is, in the investigator's opinion, required to preserve the life of the participant.
- Time is not sufficient to obtain the independent determination of a physician who is not otherwise participating in the clinical investigation.

If time does not allow for such certification prior to use of the investigational product then the investigator should obtain such certification in writing from an independent physician and forward it to the IRB within five days of use of the article.

The Chair of the IRB or the Chair's designee will review reports submitted by investigators that are related to Emergency Use.

Planned Emergency Use

LSUHSC-NO HRPP does not participate in exception from informed consent for planned emergency research as noted in 21CFR50.