

<b>DEPARTMENT:</b> Research Compliance		<b>Reference#</b> IRB.013
<b>Effective Date:</b> 6/23/06	<b>Page</b> 1 of 3	<b>Replaces Policy Dated:</b> 1/23/2006
<b>Description:</b>	Emergency Use of a Test Article	

**A. Emergency Use of an Investigational Drug or Biologic**

The Sunrise Health IRB (SHIRB) allows the emergency use of an investigational drug or biologic if the FDA requirements for emergency use are met. Whenever possible, the IRB Chair should be notified of the intent to use the investigational drug or biologic to ensure that the FDA requirements for emergency use are met.

*Emergency use of an investigational drug or biologic* is defined as 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 approval from the IRB.

The emergency use provision in the FDA regulations is an exemption from prior review and approval by the Institutional Review Board and may not be used unless each of the following conditions exist:

- The patient is in a life-threatening or severely debilitating situation;
- There is no standard acceptable treatment available; and
- There is not sufficient time to obtain approval from the IRB.

*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. The criteria for life-threatening do not require the condition to be immediately life-threatening or to immediately result in death. Rather, the subjects 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.

Even in emergency situations, the investigator is required to obtain informed consent from the subject or the subject's legally authorized representative unless both the investigator and an independent physician certify in writing all of the following:

<b>DEPARTMENT:</b> Research Compliance		<b>Reference#</b> IRB.013
<b>Effective Date:</b> 6/23/06	<b>Page 2 of 3</b>	<b>Replaces Policy Dated:</b> 1/23/2006
<b>Description:</b>	Emergency Use of a Test Article	

- The subject is confronted by a life-threatening (or severely debilitating) situation necessitating the use of the investigational drug;
- 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 legally authorized representative; and
- No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the life of the subject.

Although the SHIRB does not have to prospectively review the emergency use of an investigational drug in a life-threatening situation, whenever possible, investigators are required to contact the SHIRB Office and complete a form to document that an emergency exists.

Investigators are required to submit a report on the emergency use to the IRB within 5 working days. The report is reviewed by the IRB Chair to ensure that the emergency use meets FDA regulations. The investigator is informed that if s/he anticipates the need to use the investigational drug in additional subjects, prospective review by the IRB is required.

**B. Emergency Use of an Unapproved Device**

The SHIRB allows for the emergency use of an unapproved device if the FDA requirements for emergency use are met. Whenever possible, the IRB Chair should be notified of intent to use an unapproved device.

*Emergency use of an unapproved device* is defined as the use of an unapproved device for the purpose or condition for which the device requires, but does not have, an approved application for premarket approval (FDA approval for marketing) with a human subject in a life-threatening situation where the unapproved device may offer the only possible life-saving alternative, but an IDE for the device does not exist, or the proposed use is not approved under an existing IDE, or the physician or institution is not approved under the IDE.

Using its enforcement discretion, FDA has not objected if a physician chooses to use an unapproved device in such an emergency, provided that the physician

<b>DEPARTMENT:</b> Research Compliance		<b>Reference#</b> IRB.013
<b>Effective Date:</b> 6/23/06	<b>Page 3 of 3</b>	<b>Replaces Policy Dated:</b> 1/23/2006
<b>Description:</b>	Emergency Use of a Test Article	

later justifies to FDA that an emergency actually existed. Each of the following conditions must exist to justify emergency use:

- The patient is in a life-threatening condition that needs immediate treatment;
- No generally acceptable alternative for treating the patient is available; and
- Because of the immediate need to use the device, there is no time to use existing procedures to get FDA approval for the use.

Even in emergency situations, the investigator is required to obtain informed consent from the subject or the subject's legally authorized representative unless both the investigator and an independent physician certify in writing all of the following:

- The subject is confronted by a life-threatening situation necessitating the use of the investigational device;
- 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; and
- No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the life of the subject.

Although the SHIRB does not have to prospectively review the emergency use of an unapproved device in a life-threatening situation, whenever possible, investigators are required to contact the IRB Office and complete a form to document that an emergency exists.

Investigators are required to submit a report on the emergency use to the IRB within 5 working days. The report is reviewed by the IRB Chair to ensure that the emergency use meets FDA regulations. The investigator is informed that if s/he anticipates the need to use the investigational device in additional subjects, prospective review by the IRB is required.