OHSU Policy

I. Policy

A. Emergency use of a test article may not be used to circumvent the general requirement for prior IRB review and approval. The exemption allows for one emergency use of a test article without prospective IRB review, however, OHSU not deny treatment to a second individual if the IRB has not had sufficient time to convene.

B. The emergency use exemption of an investigational drug, biologic or device is permitted only if each of the following conditions exist as outlined in 21 CFR 56.102(d):
   1. A life-threatening or severely debilitating situation exists necessitating the use of the investigational drug, biologic or device;
   2. No generally acceptable alternative treatment is available; and
   3. Because of the immediate need to use the drug, biologic or device, there is not sufficient time to use existing procedures to obtain IRB approval for the use.

C. When emergency treatment is initiated without prior IRB review and approval, the patient data may not be included as research data in a prior or subsequent IRB-approved project.

D. An unapproved device may be used in human subjects only if it is approved for clinical testing under an approved application for an Investigational Device Exemption (IDE) under section 520(g) of the Act [21 U.S.C. 360(j)(g)] and 21 CFR part 812.

E. The physician may not conclude that an "emergency" exists in advance of the time when treatment may be needed based solely on the expectation that IDE approval procedures may require more time than is available. Physicians should be aware that FDA expects them to exercise reasonable foresight with respect to potential emergencies and to make appropriate arrangements under the IDE procedures far enough in advance to avoid creating a situation in which such arrangements are impracticable.

Effective: 4/21/2008