Guidelines for Emergency Use

From time to time, clinicians at RowanSOM may find themselves in a position where they are in a life or death situation with a patient. And the only way to help this patient is with the use of an investigational drug, biologic and/or device. The Office of Institutional Review Board has provided the following guidelines to assist clinicians with submission of an emergency use of an investigational drug, biologic and/or device for patients with consent, process, and sponsor acknowledgement.

PLEASE NOTE: Emergency permission is granted on a one-time, one-usage basis. If the clinician wishes to treat other subjects, they must complete and submit an IRB application with a consent form. Assistance is available during the hours of 8:00 AM to 3:30 PM Monday through Friday at the following phone number: (856) 566-2712

Emergency Use is defined as the use of a test article (e.g. investigation drug/biologic or device) on 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 IRB approval for the use. The clinician is still required to obtain informed consent under these circumstances.

FDA exempts from IRB review the emergency use of a test article so long as the emergency use is reported to the IRB within five working days of its occurrence.

**Items needed from the clinician before usage:**
1. clinical condition of the patient requiring emergency permission
2. why the clinician believes it is necessary
3. information about the drug/biologic and/or device
4. consent to be used

The clinician must meet all four of the following conditions to qualify for emergency permission:

1. life threatening situation necessitating the use of the test article
2. where the subject is unable to provide effective consent.
3. there is insufficient time in which to obtain consent from the subject’s legally authorized representative (court appointed guardian for research)
4. there is no available alternative method of approved or generally recognized therapy of equal or greater likelihood of saving the subject’s life [21 CFR 50.23 (a) (1) – (4)]


http://www.fda.gov/oc/ohrt/irbs/drugsbiologics.html#emergency

For Device:
The clinician must meet all four of the following conditions to qualify for emergency permission:

- the device is intended to treat or diagnose a serious or immediately life-threatening disease condition
- there is no comparable or satisfactory alternative device or other therapy available to treat or diagnose that stage of the disease or condition in the intended patient population
- the device is under investigation in a controlled clinical trial for the same use under an approved IDE, or such clinical trials have been completed
- the sponsor of the investigation is actively pursuing marketing approval/clearance of the investigational device with due diligence [21 CFR812.36 (b) (1) – (4)]


http://www.fda.gov/oc/ohrt/irbs/devices.html#emergency

**Research consent must be obtained either by the subject or by the legally authorized representative.**(court appointed guardian for research)

If the clinician needs an acknowledgement letter from the IRB before the manufacturer/sponsor will ship the drug/biologic and/or device, the IRB will provide such a letter to the manufacturer/sponsor stating that the IRB is aware of the situation and will require a written status report from the clinician within five (5) business days from the usage of the device and/or drug. [21 CFR 56.104]