Subject: Emergency Use of FDA Regulated Products

Definitions:

1. **Emergency Use**: The use of an investigational drug, agent, biologic, or device with a human subject in an immediate serious, or life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval. “Life threatening condition” also includes sight-threatening, limb-threatening and conditions involving risk of persistent, recurrent, or irreversible morbidity.

2. **Food and Drug Administration (FDA)**: The FDA is the federal oversight agency responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation’s food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

3. **Investigational Agent**: A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial. This includes products with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, products used for an unapproved indication, or products used to gain further information about an approved use.

4. **Investigational Device Exemption**: A FDA approved investigational device exemption (IDE) permits a device that otherwise would be required to comply with a performance standard or to have pre-market approval to be shipped lawfully for the purpose of conducting investigations of that device.

5. **Investigational Device**: Any healthcare product that does not achieve its primary intended purposes by chemical action or by being metabolized. A medical device that is the subject of a clinical study designed to evaluate the effectiveness and/or safety of the device. Investigational use also includes clinical evaluation of certain modifications or new intended uses of legally marketed devices.

6. **Investigational Drugs/Investigational Biologics (Test Articles)**: A new drug or biologic that is used in a clinical investigation. The term investigational biologic also includes a biological product that is used *in vitro* for diagnostic purposes. Investigational drugs, agents, or biologics may include:
   a. Products that are not generally recognized as being safe and effective for any use under the conditions prescribed, recommended, or suggested by the FDA; or
   b. Products already approved by the FDA as safe and effective for specific indications that are being studied for new indications (or doses, strengths, or frequency).

7. **Investigational New Drug (IND)**: FDA granting of permission that a new drug, agent or biologic may be used in humans prior to FDA review of clinical data that has determined that a particular new drug, agent, or biologic is safe and effective for a specific use. This FDA permission is evidenced by the assignment of an IND number by the FDA or the granting of an IND exemption.

8. **Emergency Treatment IND**: A mechanism through the FDA for providing eligible participants with investigational drugs, agents, or biologics for the treatment of an immediate serious or life-threatening illness for which there are no satisfactory alternatives.
9. **Emergency Treatment IDE**: A mechanism through the FDA for providing eligible participants with investigational devices for the treatment of an immediate serious or life-threatening illness for which there are no satisfactory alternatives.

**Policy:**
It is the policy of the Human Research Protections Program (HRPP) to recognize the provisions found in the Food and Drug Administration (FDA) regulations for the emergency use of investigational drugs, biologics, agents, or devices.

I. Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care for patients who need such care.

II. DHHS regulations 45 CFR 46 do not permit research activities to be started, even in an emergency, without prior IRB Committee review and approval. When emergency medical care is initiated without prior IRB Committee review and approval, provisions found in the FDA regulations are used for the administration of investigational drugs, agents, biologics or devices.

III. Terms such as “interim,” “compassionate,” “temporary,” “treatment,” or other terms for an expedited approval process will not be utilized for requests for emergency use of FDA regulated products. The IRB must either grant approval at a convened full Committee meeting, or if the conditions of 21 CFR 56.104(c) are met and it is not possible to convene a quorum within the time available, the emergency use may proceed without IRB approval in accordance with FDA regulations and IRB policy.

IV. **Investigational Drugs, Agents, or Biologics (FDA Regulations).**
   A. The emergency use of investigational drugs, agents, or biologics will be handled in accordance with FDA regulations and institutional policies and procedures. Although 21 CFR 56.104(c) allows for an exemption from prior review and approval by the IRB for emergency use, the **IRB requires prior notification** of emergency use of investigational drugs, agents, or biologics.
   B. FDA regulations at 21 CFR 56.102(d), allows for one emergency use at an institution (regardless of investigator) of an investigational drug, agent, or biologic without prospective IRB review. FDA regulations require that any subsequent use of the investigational product at the institution have prospective IRB review and approval. The only exception to this provision is if the IRB has not had sufficient time to convene a meeting to review a protocol.

V. **Investigational Devices (FDA Regulations).**
   A. The emergency use of investigational (unapproved) medical devices will be handled in accordance with FDA regulations and institutional policies and procedures. Although 21 CFR 56.104(c) allows for an exemption from prior review and approval by the IRB for emergency use, the **IRB requires prior notification** of emergency use of investigational (unapproved) medical devices.
   B. Subsequent emergency use of an investigational (unapproved) medical device may not occur unless the Investigator or another person obtains approval of an IDE for the device and its use. If an IDE application for subsequent use has been filed with the FDA and the FDA disapproves the IDE application, the device may not be used even if the circumstances constituting an emergency exist.
   C. If the FDA has approved a supplement to the IDE application for compassionate use where the patient(s) has a serious condition and no alternative treatment is available, the IRB may follow HRPP Procedure XI.E.1, “Emergency Use of FDA Regulated Products” for expanded access of an unapproved medical device.

VI. Manufacturers or sponsors that agree to allow the use of the investigational drug, agent, biologic or device, but will not ship without “an IRB approval letter”, will be provided a written statement
that the IRB is aware of the proposed use and based on the information it has been provided by the Investigator that the proposed use meets the requirements of 21 CFR 56.102(d).

References:
21 CFR 814, 803.30
21 CFR 50.23(a)
21 CFR 45.104
21 CFR 312
FDA IRB Information Sheets
45 CFR 46.116(f)
45 CFR 46.103(b)
FDA: IDE Early/Expanded Access, Updated 10/23/2009