ORLANDO HEALTH®

1414 Kuhl Ave.
Orlando, Florida 32806
321.843.7000

Type of Policy:	***PROTECTION OF HUMAN RESEARCH PARTICIPANTS***	Category:	**Orlando Health Institutional Review Board (IRB)**

Title:	***Emergency Use of Investigational Drugs, Biologics and Devices***	Policy #:	**0330-1010**
		Replaced #:	MDACCO IRB#1000-0001 ORMC IRB #6000-201
Page **1** of **6**		Issued By:	Orlando Health Institutional Review Board (IRB)
Issue Date:	**7/19/95**	Approved By:	Philip Giordano, MD Institutional Official
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Revision Dates:	1/1/01, 3/20/02, 4/1/04, 5/14/04, 11/23/07, 9/23/13, 10/7/14, 8/3/15, 8/16/17, 4/21/20, 7/12/23		

I. PURPOSE:

This policy outlines the process for the emergency use of an investigational drug, biologic or device.

II. DEFINITIONS:

A. Test article: an investigational drug, device or biologic for human use that is not approved by the FDA.

B. Emergency use: the use of a test article on a human subject (patient) in a life-threatening situation in which no standard acceptable treatment is available and in which there is insufficient time to obtain IRB approval for the use of the test article.

C. Life-threatening, for the purposes of 21 Code of Federal Regulations (CFR) 56.102(d): includes the scope of both "life-threatening" and "severely debilitating", as defined below:

1. Life-threatening: 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 endpoint 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 (patients) must be in a life-threatening situation requiring intervention before review at a convened meeting of the IRB is feasible.
2. Severely debilitating: 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.

D. Unapproved medical device: a device that is utilized for a purpose, condition, or use for which the device requires, but does not have, an approved application for premarket approval under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e) or an approved IDE under section 520(g) of 21 U.S.C. 360j(g).

III. POLICY:

It is Orlando Health IRB policy that emergency use of an investigational drug, biologic or device shall be done only in accordance with federal regulations.

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IV. PROCEDURE:

A. Emergency use of an investigational drug or biologic:

1. All of the following criteria must be met in order for a physician to treat their patient with an investigational drug or biologic without prospective IRB approval:
   a. The patient is in a life-threatening situation (as defined above);
   b. No standard acceptable treatment is available; and
   c. There is not sufficient time to obtain IRB approval for the IND.
2. The physician must contact the Investigational New Drug (IND) supplier (i.e., drug manufacturer) and obtain their agreement to provide the IND for emergency use for a specific patient under the company's IND. Should the company elect not to name the physician as an investigator, the physician can contact the FDA directly for an IND.
3. FDA contacts for obtaining an Emergency IND:
   a. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-investigational-drug-or-biologic
4. Informed Consent requirement: The investigator (physician) is required to obtain informed consent of the subject (patient) or the subject's (patient's) legally authorized representative unless the exception from the informed consent requirement applies. The consent form does not need to be a research consent form, but it must include a description of the investigational product being used, information that the product is not yet FDA approved, and the known risks of the product.
5. The physician must follow the required reporting procedures as outlined below.

B. Emergency use of an unapproved medical device:

1. Emergency use of an unapproved medical device is permitted in any of the following situations:
   a. When an IDE for the device does not exist,
   b. When a physician wants to use the device in a way not approved under the IDE, or
   c. When a physician is not an investigator under the IDE.
2. If all of the following criteria is met, then an unapproved device may be used in an emergency situation without prior approval by the FDA and the IRB:
   a. The patient has a life-threatening or serious disease or condition that needs immediate treatment including sight-threatening and limb-threatening conditions as well as other situations involving risk of irreversible morbidity;
   b. No general acceptable alternative treatment for the condition exists; and

c. Because of the immediate need to use the device, there is no time to use existing procedures to obtain FDA approval for the use.

3. FDA conditions and requirements:
   a. The FDA expects the physician to:
      1) make the determination that the patient's circumstances meet the above criteria
      2) to assess the potential for benefit from the use of the unapproved device
      3) to have substantial reason to believe that benefits will exist
      4) follow as many patient protection procedures as possible which include the following:
         a) Informed consent from the patient or legal representative.
         b) Clearance from the hospital. Contact the Corporate Office of Research Operations (CORO) for guidance on how to obtain clearance.
         c) Concurrence of the IRB chairperson.
         d) An independent assessment from an uninvolved physician.
         e) Authorization from the device manufacturer, if an approved IDE for the device exists.
   b. The physician may not conclude that an "emergency" exists in advance of the time when treatment may be needed based solely on the expectation the IDE approval procedures may require more time than is available.
4. 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.
5. The physician must follow the required reporting procedures as outlined below.

C. Exception from the informed consent requirement –
1. A physician is required to obtain the informed consent of the patient, or a legally authorized representative, for the emergency use of an investigational product unless both the physician and a physician who is otherwise not involved in the care of the patient certify, in writing, that the emergency situation fulfills the following criteria:
   a. The subject (patient) is confronted by a life-threatening situation necessitating the use of the test article.
   b. Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from, the subject (patient)

c. Time is not sufficient to obtain consent from the subject's (patient's) legally authorized representative.

d. No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject's life.

2. If, in the investigator's (physician's) opinion, immediate use of the test article is required to preserve the subject's life, and if time is not sufficient to obtain an independent physician's determination that the four conditions above apply, the investigator (physician) should make the determination to use the test article and, within 5 working days after the use of the article, have the determination reviewed and evaluated by an independent physician who is not involved with the use of the test article.

D. **Required reporting procedures** for after the emergency use of investigational drugs, devices, or biologics:

1. IRB reporting procedures:

a. For IRB Chair concurrence of an unapproved drug, biologic or device is used in an emergency, the physician must submit to the IRB Emergency Use Initial Notification Form in IRBNet, this may be done concurrently when submitting to the FDA and comply with provisions of the IRB regulations [21 CFR part 56]. The report should include a description of the patient's response, if available, to the test article. This should be done using the "Emergency Use Initial Notification Form" in IRBNet.

b. For investigational drugs, a follow up report must also be sent to the IRB within 5 working days [21 CFR 56.104(c)] from the completion of treatment using the "Emergency Use – Follow Up Progress Report Form". The report should include a description of the patient's response, if available, to the test article. If the treatment lasts beyond one year, ask the IRB for further assistance.

c. If the treatment is ongoing and the drug becomes commercially available, a follow up report must also be sent to the IRB within 5 working days from the day the patient transitions to commercially available drug. The report should be done using the "Emergency Use – Follow Up Progress Report Form".

d. When the IRB receives a report by a physician of an emergency use, the IRB Chair and/or designee will review and acknowledge the submission. The submission will be reviewed and acknowledged by other Board members at the next convened meeting.

e. This process should not be construed as IRB "approval", but an acknowledgement by the IRB.

f. Should a situation arise, which would require subsequent use of the test article, every effort should be made either to become an investigator or to develop a protocol for future use of the article and submit to the IRB for approval.

2. FDA and/or Sponsor reporting procedures:

a. For *unapproved devices*:

1) If an IDE for the use exists, then the physician must immediately notify the sponsor of the emergency use (who will notify the FDA of the emergency use within 5 days of the use through submission of an IDE report), or

2) If an IDE does not exist, then the physician must notify FDA of the emergency use with a follow up report and provide the FDA with a written summary of the conditions constituting the emergency, description of device used, details of the case, and the patient protection measures that were followed and the patient's results. For assistance, see the FDA website at: https://www.fda.gov/medical-devices/investigational-device-exemption-ide/expanded-access-medical-devices or by e-mailing CDRHExpandedAccess@fda.hhs.gov.

b. For *investigational drugs or biologics:*

1) If a single-use IND was issued for an individual patient only, then this IND must be closed with the FDA, per policy/procedures of the sponsor and the FDA, once treatment has completed.

2) If the subject was enrolled under a sponsor-held IND, then the sponsor must be notified of the completion of treatment. The IRB should be notified via IRBNet submission of such actions taken with the sponsor and/or the FDA.

E. Subsequent uses of investigational drugs, devices, or biologics:

1. The physician should evaluate the likelihood of a similar need for the investigational drug, device, or biologic occurring again with another patient. If future use is likely, the physician (or another person) should begin the process to obtain approval of either an IND for the drug and its use, or, an IDE for the device and its use.

2. It is important to remember that for situations meeting the definition of emergency use, as defined above, a physician is allowed one emergency use of a test article without prospective IRB review. However, the FDA acknowledges that it would be inappropriate to deny emergency treatment to a second individual if the only obstacle is that the IRB has not had sufficient time to convene a meeting to review the issue.

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3. If an IDE application for subsequent use has been filed with FDA and FDA disapproves the IDE application, the device may not be used even if the circumstances constituting an emergency exist. Developers of devices that could be used in emergencies should anticipate the likelihood of emergency use and should obtain an approved IDE for such uses.

V. DOCUMENTATION:

Emergency Use Initial Notification form and its supporting documentation must be submitted for review by the IRB Chairperson.

Actions of concurrence by the IRB Chair shall be documented in the IRB meeting minutes.

VI. REFERENCES:

A. Code of Federal Regulations - 21 CFR 56.102(d), 21 CFR 56.104(c), 21.CFR 50.23 and 21 CFR 56.108(a)(3)
B. FDA guidance document: Emergency Use of an Investigational Drug or Biologic – Information Sheet, last updated on 1/19/2016
C. "Expanded Access for Medical Devices", FDA website: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm051345.htm#emergency

VII. ATTACHMENTS:

None.