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:	***HUD (Humanitarian Use Device)***	Policy #:	**0330-1006**
		Replaced #:	ORMC IRB #6000-204 MDACCO IRB #1000-0001-R
Page 1 of 4		Issued By:	Orlando Health Institutional Review Board (IRB)
Issue Date:	**5/12/04**	Approved By:	Philip Giordano, MD Institutional Official **SIGNATURE ON FILE**
Revision Dates:	5/12/04, 11/23/07, 7/1/13, 8/29/16, 6/3/19, 11/07/22		

I. PURPOSE:

This policy outlines the process for using a Humanitarian Use Device.

II. DEFINITIONS:

When used in this policy, these terms have the following meanings:

A. Humanitarian Use Device (HUD) – a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects no more than 8,000 individuals in the United States per year.

B. Humanitarian Device Exemption (HDE) is an application that is similar to a premarket approval (PMA) application, but exempt from the effectiveness requirements of a PMA. An approved HDE authorizes marketing of a Humanitarian Use Device (HUD).

C. An unapproved medical device - a device that is used for a purpose or condition for which the device requires, but does not have, an approved application for pre-market approval under section 515 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C 360(e)].

D. Emergency use - the use of a test article 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 of the trial article.

E. 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 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 in which no standard treatment is available requiring intervention before review at a convened meeting of the IRB is feasible.

III. POLICY:

It is Orlando Health IRB's policy that the physician use of a Humanitarian Use Device shall be done only in accordance with federal regulations as noted below.

IV. HUMANITARIAN USE DEVICE:

A. An approved HDE application authorizes the applicant to market the device and local physicians to use the device to treat or diagnose a medical condition.

B. HUD policies and procedures apply to non-research use of the device ONLY.

C. Regulatory requirements and issues for the IRB to consider include:

1. FDA regulations require IRB approval before use of a HUD in facilities having oversight by an IRB. Orlando Health, Inc. prohibits outside IRB approval for use within the hospital.
2. The holder of the HDE is responsible for ensuring that the HUD is used only at facilities that have established an IRB that operates in compliance with FDA regulations.
3. The regulations do not require the facility where the HUD is used, the reviewing IRB, or the physician(s) using the HUD to document that an approved HDE application exists or that the device is to be used as specified in

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:	***HUD (Humanitarian Use Device)***	Policy #:	**0330-1006**
		Replaced #:	ORMC IRB #6000-204 MDACCO IRB #1000-0001-R
Page 2 of 4		Issued By:	Orlando Health Institutional Review Board (IRB)
Issue Date:	**5/12/04**	Approved By:	Philip Giordano, MD Institutional Official **SIGNATURE ON FILE**
Revision Dates:	5/12/04, 11/23/07, 7/1/13, 8/29/16, 6/3/19, 11/07/22		

the HDE application. However, the IRB shall grant approval of the use of a HUD contingent upon IRB review of a letter or document from the device manufacturer that documents the following 10 items:

a. the generic and trade name of the device
b. the FDA HDE number (this is a 6 digit number preceded by the letter H)
c. the date of HUD designation
d. indications for use of the device
e. a description of the device
f. contraindications, warnings, and precautions for use of the device
g. adverse effects of the device on health
h. alternative practices and procedures
i. marketing history
j. summary of studies using the device

These documents must be submitted in the same fashion as research proposals as outlined on the IRB website. Should the IRB request their presence, the physician or designee will be responsible for attending the IRB full board meeting to present the HUD and to answer any questions the IRB may have. The IRB approval of the HUD is for the approved indication only for all physicians identified in the Initial Submission Humanitarian Use Device form.

4. The IRB may check HUD information directly with FDA files utilizing the FDA website
5. There is no time limit on the FDA approval of a HDE.
6. The IRB does not have to approve each individual use of a HUD. The IRB has the discretion to determine the conditions of HUD use. The IRB may approve the use of the device in general, in a specific number of patients, or only under specific circumstances.
7. The regulations require that an IRB conduct both initial and continuing review of a HUD at least annually. The initial submission must be approved by the convened IRB. Continuing review may be approved by expedited review process, at the discretion of the IRB chair.
8. Initial review submissions are sent to the IRB via IRBNet, using the form "Humanitarian Use Device – Initial Submission". Continuing review submissions are sent to the IRB via IRBNet using the form "Humanitarian Use Device – Continuing Review – Final Report"
9. Patients must be informed of the use of the HUD either by signed consent, or by an information sheet provided or approved by the HUD's manufacturer. Signed informed consent is not required for use of a HUD used for treatment purposes. If there is no information sheet available, then signed consent must be obtained. See the IRBNet Forms and Templates library for a template HUD consent form.

If the manufacturer provides or approves an information sheet, this may be used in lieu of a signed informed consent form. However, this information sheet must inform the patient:

1. that the device is a Humanitarian Use Device
2. that the FDA has determined the device is safe to use

ORLANDO HEALTH®
1414 Kuhl Ave.
Orlando, Florida 32806
321.843.7000

3. that there is not enough data to determine whether or not the device will be effective at treating the patient's condition.

10. The IRB should confirm that the HUD is not being used as part of a research or clinical investigation designed to collect data to support a FDA premarket approval application.
11. If the HUD is being used for research purposes, the policies and procedures for research submissions shall apply.

V. OFF-LABEL USE OF A HUMANITARIAN USE DEVICE

A. HUDs may be used off-label for treatment purposes, just as any FDA approved device may be used off-label for non-research, treatment only purposes. Some HUD manufacturers request that the IRB be notified of off-label uses. In such a situation, the physician shall, within 5 days after the use of the device, provide written notification to the chairman of the IRB of such use. This is done via IRBNet, using the form "HUD Off-Label Use Form". Such written notification shall include the study ID/medical record number of the patient involved, the date on which the device was used, and the reason for the use.

B. When the device is used off label:

1. Call Device company and receive approval to use the device off label if required by the company
2. Inform the patient or legally authorized representative of the off-label use.
3. Notify the IRB with in five working days of the off label use if required by manufacturer.

VI. EMERGENCY USE OF A HUMANITARIAN USE DEVICE THAT IS NOT YET IRB APPROVED

A. In accordance with 21 CFR 814.124(a), if a physician in an emergency situation determines that approval for the use of a HUD cannot be obtained from the IRB in time to prevent serious harm or death to a patient, a HUD may be administered without prior approval by the IRB.
B. The IRB must be notified of the emergency use within 5 working days of the use of the device, following the same procedures as for emergency use of an investigational device, and using the Emergency Use Initial Notification Form posted in the IRBNet Forms and Templates library.
C. The physician should ensure that appropriate patient protection measures are addressed before the device is used.
D. In addition to addressing the patient protection measures, prior FDA approval of the HUD for emergency use may be required just as it is for emergency use of an investigational device.
E. A physician who wishes to use a device for emergency use should provide the IDE sponsor with the following:
   1. A description of the patient's condition and the circumstances necessitating treatment with the device,
   2. A discussion of why alternative therapies are unsatisfactory,
   3. Information to address the patient protection measures.
F. For emergency use of a HUD, the physician should provide this information to the HDE holder, who may need to submit a HDE amendment for FDA approval before the use occurs.

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:	***HUD (Humanitarian Use Device)***	Policy #:	**0330-1006**
		Replaced #:	ORMC IRB #6000-204 MDACCO IRB #1000-0001-R
Page 4 of 4		Issued By:	Orlando Health Institutional Review Board (IRB)
Issue Date:	**5/12/04**	Approved By:	Philip Giordano, MD Institutional Official **SIGNATURE ON FILE**
Revision Dates:	5/12/04, 11/23/07, 7/1/13, 8/29/16, 6/3/19, 11/07/22		

G. If the request is approved, the physician should follow the instructions of the device manufacturer for an appropriate schedule for monitoring the patient, based on the recommendations for approved use of the HUD.
H. Submission of a follow-up report to the sponsor and/or the FDA may be required.
I. The physician should submit a request for full IRB approval of the HUD for future use, following the instructions above in section IV, as soon as possible to avoid the need for emergency use in the future.

VII. DOCUMENTATION:

Documentation shall be maintained by the IRB Office via IRBNet.

VIII. REFERENCES:

A. Code of Federal Regulations – 21 CFR 814.124
B. 21st Century Cures Act, effective December 13, 2016
C. Federal Register, Volume 82, Number 108, *June 7, 2017*
D. Institutional Review Board Management and Function,, Robert Amdur, M. D., and Elizabeth Bankert, MA, Jones and Bartlett Publishers, 2002.
E. IRBNet Forms and Templates Library

IX. ATTACHMENTS:

None