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Owner	Stephanie Madrigal: Dir Clin Rsrch Admin/Ops
Category/ Chapter	Compliance
Applicability	OSF All Operating Units
Areas/Depts	Research

Humanitarian Use Device (HUD): Non-Investigational

DEFINITIONS:

1. **Device User Facility:** hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility, which is not a physician's office. School nurse offices and employee health units are not device user facilities.
2. **Humanitarian Use Device (HUD):** medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 8,000 individuals in the United States per year. HUD designations are issued by the FDA.
3. **Facility Research Executive (FRE):** person delegated by the President of the facility who is responsible for research conducted within and/or involving the facility, for addressing in collaboration Research Administration and the Institutional Official (IO) any matters relating to compliance with research policies, regulatory compliance, and/or research misconduct, and for granting or denying permission for investigators to initiate application to an Institutional Review Board (IRB) and/or initiate study related activities. The FRE serves as member of the Research Oversight Council (ROC).
4. **Humanitarian Device Exemption (HDE):** premarket approval application granted by the FDA to the manufacturer of an HUD. FDA approval of an HDE authorizes the applicant to market a Humanitarian Use Device (HUD), subject to certain profit and use restrictions.
5. **New Product Committee:** committee under Ministry Supply Chain Material Resource Utilization that evaluates all new product requests
6. **Reportable Event:** event that user facilities become aware of that reasonably suggests that a device has or may have caused or contributed to a death or serious injury.
7. **Serious Injury:** injury or illness that:
    a. is life-threatening,

b. results in permanent impairment of a body function or permanent damage to a body structure, or

c. necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

8. **Use/Clinical Use:** use of an HUD according to its approved labeling and indication(s) to treat or diagnose patients.

PURPOSE:

1. To describe how OSF HealthCare (OSF) complies with the Food, Drug & Cosmetic Act (FD&C Act) as amended by 21st Century Cures Act) and FDA regulations related to the Clinical Use of Humanitarian Use Devices in clinical treatment or diagnosis (i.e., use that does not constitute human subject research).
2. This policy applies only to the non-investigational, on-label use of an HUD. Investigational or off-label use of HUDs is not authorized by this policy, and is subject to other research policies pertaining to the conduct of clinical trials.
3. This Policy applies to any OSF facility or department under which an HUD is used, and to all OSF Mission Partners and any other clinician (whether OSF employed or not) involved in the use of the HUD.

POLICY:

1. OSF requires that clinicians comply with all applicable regulations pertaining to HUD, and that all uses of HUDs be reviewed and approved by an IRB as defined by Federal regulations.
2. If a clinician in an emergency situation determines that IRB approval cannot be obtained in time to prevent serious harm or death to a patient, an HUD may be administered without prior approval by the IRB. Emergency use of the HUD is reported to the IRB within 5 business days.
3. The Facility/Department under which a clinician will use an HUD is responsible for ensuring appropriate storage, inventory and use tracking, and reporting processes are in place and met.

PROCESS:

Clinician Responsibilities

1. Obtain New Product Committee approval by submitting a new product request through the Lumere intake system: https://app.lumere.com/providers/osf/requests/add/
2. Complete and submit a Humanitarian Use Device (HUD) for Clinical Use Only (Not Research) application to the OSF Research Administration Office.
3. Obtain IRB approval for clinical use of the HUD at the device user facility.
4. Comply with local inventorying and reporting requirements as described under Facility/ Department requirements.
5. When making use of an HUD after all approvals are secured, provide patient information packets and any other IRB required materials to patients prior to their receiving the HUD.

6. Comply with requirements for continuing review at the intervals determined by the IRB.
7. Fulfill respective reporting requirements upon becoming aware of a Reportable Event, or of a malfunction that would be likely to cause a Reportable Event if the malfunction were to reoccur, and submit such reports to the appointed person as described under Facility/ Department responsibilities. Separate reporting requirements may be required by:
    a. the FDA (see References for Guidance and required Forms),
    b. the IRB, and
    c. the HUD manufacturer.

Facility/Department Responsibilities

Upon notice from a clinician of IRB approval to use an HUD, the Facility Research Executive of the Facility and/or Department under which the HUD will be used will appoint the appropriate Mission Partner (e.g. Manager of the Cath Lab or Angio Suite) to be responsible for:

1. Establishing a separate storage and inventory process by which to track use of the HUD (separate from on-label use).
2. Notifying the IRB of record and Research Administration of any Reportable Events or use of the HUD by unauthorized clinicians.
3. Ensuring the authorized clinician completes respective reporting requirements upon becoming aware of a Reportable Event, or of a malfunction that would be likely to cause a Reportable Event if the malfunction were to reoccur.
4. Submitting completed reports of Reportable Events to the appropriate recipient as noted in item 7 under Clinician Responsibilities.

REFERENCES:

1. 21 CFR 814, Premarket Approval of Medical Devices, Subpart H - Humanitarian Use Devices. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=814&showFR=1&subpartNode=21:8.0.1.1.11.7.
2. 21 CFR 803, Medical Device Reporting. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=803.
3. FDA Guidance Document, Humanitarian Use Device (HUD) Designations. (September 5, 2019). https://www.fda.gov/media/85356/download.
4. FDA Guidance Document, Humanitarian Device Exemption (HDE) Program. (September 6, 2019). https://www.fda.gov/media/74307/download.
5. 21st Century Cures Act, SEC. 3052 Humanitarian Device Exemption. (December 13, 2016). https://www.congress.gov/114/bills/hr34/BILLS-114hr34eah.pdf.
6. Form FDA 3419, Annual Summary of Death & Serious Injury Reports. https://www.fda.gov/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities.
7. Form FDA 3500A, MedWatch Form for FDA Safety Reporting. https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting.

HYPERLINKS:

1. OSF Guidance for Investigators: Humanitarian Use Device (HUD) Decision Tree at https://www.osfhealthcare.org/media/filer_public/29/26/29269b89-e87a-4a2f-bd7b-f58913ca127c/osf_guidance_hud_decision_040320.pdf.
2. OSF Humanitarian Use Device (HUD) Application Form at https://osf-p-001.sitecorecontenthub.cloud/api/public/content/be5e4d6fa0ef4cf0b32fb35d162abf2c?v=e254ba7d.
3. Manufacturer and User Facility Device Experience (MAUDE) searchable database of medical device reports submitted to the FDA at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm.

This policy is in effect for OSF Healthcare System, OSF Healthcare Foundation and all OSF Healthcare System subsidiaries and affiliates, except as limited in the header or body of this policy. For purposes of this policy, the terms "subsidiaries" and "affiliates" mean facilities or entities wholly owned or wholly controlled by OSF Healthcare System. The hospitals covered by this policy are:

		Name as listed with Medicare:
X	OSF St. Mary Medical Center	ST MARY MEDICAL CENTER
X	OSF Saint Francis Medical Center	SAINT FRANCIS MEDICAL CENTER
X	OSF Saint James – John W. Albrecht Medical Center	SAINT JAMES HOSPITAL
X	OSF St. Joseph Medical Center	ST JOSEPH MEDICAL CENTER
X	OSF Saint Anthony's Health Center	OSF HEALTHCARE SYSTEM
X	OSF Saint Anthony Medical Center	SAINT ANTHONY MEDICAL CENTER
X	OSF Saint Francis Hospital	ST FRANCIS HOSPITAL
X	OSF Holy Family Medical Center	OSF HEALTHCARE SYSTEM
X	OSF Saint Elizabeth Medical Center	Ottawa Regional Hospital & Healthcare Center
X	OSF Saint Luke Medical Center	OSF HEALTHCARE SYSTEM
X	OSF Saint Paul Medical Center	Mendota Community Hospital
X	OSF Heart of Mary Medical Center	OSF HEALTHCARE SYSTEM
X	OSF Sacred Heart Medical Center	OSF HEALTHCARE SYSTEM
X	OSF Little Company of Mary Medical Center	OSF HEALTHCARE SYSTEM
X	OSF Saint Clare Medical Center	OSF HEALTHCARE SYSTEM

Approval Signatures

Step Description	Approver	Date
Education/Communication Step	Stephanie Madrigal: Dir Clin Rsrch Admin/Ops	10/26/2023
Executive Steering Committee	Amy Olsen: Coord Clinical Policy RN	10/26/2023
President, OSF Healthcare	Sister Diane Marie: President-Sister	10/5/2023
System Chief Medical Officer	Ralph Velazquez: System CMO	10/4/2023
Regulatory/Policies Council	Michael Theisen: Resource Document Spec	10/4/2023
Executive Director, Research Administration	Stephanie Madrigal: Dir Clin Rsrch Admin/Ops	9/22/2023
Notification	Heidi Vermillion: Coord Research Admin	9/22/2023