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| The purpose of this checklist is to allow Clinicians to conduct a quality improvement self-assessment of their Humanitarian Use Device (HUD) Project and is indicative of what the Rutgers HSPP Quality Assurance Team would expect to see when performing on site monitoring or auditing of your HUD Project.  As defined in 21 CFR 814.3(n), a Humanitarian Use Device (HUD) is a “medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year”. FDA grants approval for physicians to use HUDs in clinical treatment or a clinical investigation through its Humanitarian Device Exemption (HDE) Program. Although the use of a HUD within its approved labeling does not constitute research, the FDA requires IRB approval be obtained before a HUD can be used in an institution. Therefore, a healthcare professional wishing to use an HDE approved HUD to treat or diagnose a patient *must obtain IRB approval before use of the HUD (except for emergency use)*.  The responsibilities of Clinicians, IRBs and the Institution (where clinical care with HUD will occur), when clinical use of a HUD is proposed, are listed below. | | |
| HUD Project Details | | |
| Clinician | |  |
| IRB Protocol Number | |  |
| Name of Diagnostic or Device | |  |
| Device Manufacturer | |  |
| HDE Holder | |  |
| Name of Person Completing Checklist | |  |
| Date Checklist Completed | |  |
| **Device Information And Use** | | |
| Use Status  [as of MM/DD/YYYY] | | Number of Patients Which have received device:  Number of devices used: |
| Date of Initial IRB Approval: | | Date: |
| Date First HUD Administered: | | Date: |
|  | | |
| 1. PROJECT DOCUMENTATION | | |
| Yes  No  N/A | 1. The following documents are included in the Project Files: | |
| Yes  No  N/A | Protocol |
| Yes  No  N/A | Humanitarian Device (HDE) Exemption approval order issued by FDA |
| Yes  No  N/A | Description of the Device |
| Yes  No  N/A | Product Labeling |
| Yes  No  N/A | Patient Information Packet that may accompany the HUD |
| Yes  No  N/A | Informed Consent Form or Consent Process Letter |
| Yes  No  N/A | Device Accountability Plan |
| Yes  No  N/A | Evidence of Training & Certification |
| Yes  No  N/A | Hospital/Clinic approval for use of HUD at the location where the clinical service will be provided, if required. |
| Yes  No  N/A | 1. Obtained and documented informed consent in a manner approved by the IRB. | |
| Yes  No  N/A | 1. Documented that patients received the product labeling information prepared by the HDE holder. | |
| Yes  No  N/A | 1. The project documentation specifies which designated Clinicians are approved for specific HUD use (i.e., individuals listed in the IRB protocol and approved by the institution for HUD use). | |
| Yes  No  N/A | 1. The HUD is used within the scope of its labeling (i.e., indication listed in the Directions for Use). | |
| Yes  No  N/A | 1. Maintain a Device Accountability Plan. | |
| Yes  No  N/A | 1. Maintain IRB approval (continuing review) for as long as the HUD continues to be used at the institution. | |
| Yes  No  N/A | 1. Provided copies of safety information at continuing review. | |
| Yes  No  N/A | 1. If a physician used a HUD outside of its approved indication(s), additional approval from the IRB was obtained. | |
| Yes  No  N/A | 1. Secured IRB approval before off-label use, except in emergency situations. If used off-label for emergency use, IRB was notified the of such use as soon as practicable. | |
| Yes  No  N/A | 1. Reported to the HDE holder/FDA and to the IRB whenever a HUD may have caused or contributed to the death or serious injury, or has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur (21 CFR 814.126(a), see also 21 CFR 803.10). | |
| Yes  No  N/A | 1. When safety & effectiveness data is being collected for a Pre-Market Approval for the HUD, it is considered research and another e-IRB application must be submitted for approval of the research. | |
| 1. DEVICE ACCOUNTABILITY | | |
| Yes  No  N/A | 1. First HUD administered on or after effective date of IRB approval. | |
| Yes  No  N/A | 1. Number of Patients Which have received device: Amount: \_\_\_\_\_\_, as of [Date]. | |
| Yes  No  N/A | 1. Number of devices used \_\_\_\_\_\_\_\_\_\_ as of \_\_\_\_\_\_, as of [Date]. | |
| Yes  No  N/A | 1. Device has been used only by designated Clinicians approved for specific HUD use (i.e., individuals listed in the IRB approved protocol for HUD use and approved by the institution). | |
| Yes  No  N/A | 1. For protocols outlining additional HUD Training, designated Clinicians received such training prior to HUD use (Health care providers are qualified through training and expertise to use the device as required in the HDE Approval Order). | |
| Yes  No  N/A | 1. Device Accountability is maintained for each HUD use and is reported as required by protocol. | |
| Yes  No  N/A | 1. Serial numbers/lot numbers are being tracked for use and any other situation which renders the device used. | |
| Yes  No  N/A | 1. Device inventory log is maintained (received and returned from manufacturer). | |
| Comments: | | |

**MATERIALS:**

HRP-502g – TEMPLATE – Humanitarian Use Device Consent

HRP-503f – TEMPLATE – Humanitarian Use Device Protocol