RUTGERS UNIVERSITY
Office for Research

CHECKLIST: Post Approval Monitoring Self-Assessment - Humanitarian Use Device (HUD)		
NUMBER	EFFECTIVE DATE	PAGE
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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 HRPP Quality Assurance and Evaluation (QA&E) 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	2. Obtained and documented informed consent in a manner approved by the IRB.	
☐ Yes ☐ No ☐ N/A	3. Documented that patients received the product labeling information prepared by the HDE holder.	

☐ Yes ☐ No ☐ N/A	4. 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	5. The HUD is used within the scope of its labeling (i.e., indication listed in the Directions for Use).
☐ Yes ☐ No ☐ N/A	6. Maintain a Device Accountability Plan.
☐ Yes ☐ No ☐ N/A	7. Maintain IRB approval (continuing review) for as long as the HUD continues to be used at the institution.
☐ Yes ☐ No ☐ N/A	8. Provided copies of safety information at continuing review.
☐ Yes ☐ No ☐ N/A	9. If a physician used a HUD outside of its approved indication(s), additional approval from the IRB was obtained.
☐ Yes ☐ No ☐ N/A	10. 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	11. 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	12. 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.
13. DEVICE ACCOUNTABILITY	
☐ Yes ☐ No ☐ N/A	1. First HUD administered on or after effective date of IRB approval.
☐ Yes ☐ No ☐ N/A	2. Number of Patients Which have received device: Amount: _____, as of [Date].
☐ Yes ☐ No ☐ N/A	3. Number of devices used _____ as of _____, as of [Date].
☐ Yes ☐ No ☐ N/A	4. 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	5. 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	6. Device Accountability is maintained for each HUD use and is reported as required by protocol.
☐ Yes ☐ No ☐ N/A	7. Serial numbers/lot numbers are being tracked for use and any other situation which renders the device used.
☐ Yes ☐ No ☐ N/A	8. Device inventory log is maintained (received and returned from manufacturer).
Comments:	

MATERIALS:
16.319 (HRP-502g) – TEMPLATE – Humanitarian Use Device Consent