HUD/HDE Checklist

HUD/HDE (21 CFR 814.126(a)) submissions to TriHealth IRB must include the following:

1. ☐ **TriHealth New Study Submission Form**
2. ☐ **Conflict of Interest Questionnaires from PI, all physicians who may use the HUD device, and research coordinator/specialist(s)**
3. ☐ **CV and Medical License from PI, all physicians who may use the HUD device, and research coordinator/specialist(s)**
4. ☐ **Documentation of completion of a CITI HUD/HDE module from PI, all physicians who may use the HUD device, and research coordinator/specialist(s)**
5. ☐ **Protocol** ☐ **Not applicable**
6. ☐ **Informed consent document** ☐ **Not applicable**
7. ☐ **FDA approval letter describing HUD device approval**
8. ☐ **Letter from physician PI requesting approval to deploy the device at TriHealth, rationale for use of the device, procedures for tracking the device, process for reporting to the IRB when the device is deployed and when an adverse event occurs, and explanation of patient follow-up, tests, and/or procedures**
9. ☐ **List of physicians who may use the HUD device at TriHealth (list must be signed by the physician PI who is providing oversight of the use of the HUD at TriHealth) (list may be included in letter from physician PI)**
10. ☐ **Product brochure, device labeling, and/or instructions for use**
11. ☐ **Patient information packet (patient brochure or leaflet), including hospital/surgical consent used**

HUD/HDE submission notes to IRB: