Shared Responsibilities of Research Administrators: Humanitarian Use Devices (HUDs)

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Introduction

- 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." Although these products are not considered investigational, the FDA requires IRB approval before it can be available for use.
- This was a quality improvement project that sought to improve the current system of how our hospitals maintain accountability of Humanitarian Use Devices (HUDs).
- This was done by conducting routine quality assurance review of HUDs; identifying barriers in device accountability; engaging a student intern to provide a comprehensive tool to improve patient safety oversight in HUDs; and developing a checklist to help improve clinical best practice guidelines.

Concerns

- Two (2) routine reviews out of two (2) approved HUDs had poor accountability.
- Rutgers University (RU) HUD Shared Responsibilities Guidance was not being followed.
- Device accountability unavailable.
- Inventory logs unavailable.
- No documentation of patients receiving labelling information.

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Action

A Checklist was developed for clinicians, hospital staff and IRBs to help navigate and improve HUD processes. This tool was also used by the Human Subjects Protection (HSP) analyst in conducting routine HUD reviews.

RU HUD Shared Responsibilities Guidance

Clinicians

- Obtain IRB approval/Institutional clearances prior to HUD first use.
- Maintain IRB approval.
- Document patient receipt of labeling information.
- Device used by ONLY designated clinicians approved for the use.
- HUD within scope of labeling.
- Report to HDE holder/FDA any serious injury, death or malfunction caused by HUD.

Institutions

- Access: only used by individuals credentialed and approved to use the HUD.
- Credentialing: providers are qualified through training and expertise.
- Accountability: Device Accountability is maintained and reported as required.

Institutional Review Board (IRB)

- Conduct initial (full board), and Continuing Reviews of the HUD.
- Ensure Clinicians document patient receipt of labeling information.
- Ensure approved informed consent obtained for Safety and effectiveness data collected for PMA.

Checklist Element	Resources	Check
1. IRB Approval	21 CFR 814.124: FDA Guidance:	☐
2. Patient Information Packet/Informed Consent	FDA Guidance:	☐
3. Summary of Protocol	FDA Guidance:	☐
4. Device Accountability Plan	21 CFR 814.20: FDA Guidance:	☐
5. Labeling Information	21 CFR 814.104: FDA Guidance:	☐
6. Off-label Use	21 CFR 814.110: FDA Guidance: FDA Webcast:	☐
7. Training & Certification	FDA Guidance:	☐
8. Post marketing surveillance	21 CFR 814.126:	☐
9. Device Report	21 CFR 814.126:	☐
10. IRB Continuing Review	21 CFR 814.124: §520(m)(4), SMDA (1990):	☐

Improvements

After implementation of the checklist, the HSP Analysts conducted routine reviews on five (5) out of eight (8) HUDs approved by the IRB. Four (4) out of five (5) investigators showed 100% compliance.

Research administrators, clinicians and hospital staff demonstrated a shared responsibility by utilizing the checklist to improve patient safety and oversight of HUDs.