**Hospital Review of Clinical Trial Devices**

**Which Involve a New Supply or Device Required by the Sponsor of a Clinical Trial**

Purpose: To specify the additional requirements for clinical trials where the Hospital/Health System is purchasing a new supply and/or device or where the supply/device to be used in the clinical trial is provided at no cost by the sponsor and will be used in any ancillary area of the Health System.

1. Submits to CBR for Coverage Analysis: PI/Coordinator

a. In addition to currently required documents, include:

i. Separate agreement or contract for purchase of the supply or device, if provided by the sponsor {this is not the clinical trial agreement}

ii. Complete ***Hospital Review of Device Trials tab in the CBR Submission Workbook.***

2. Compiles required documents and submits to SC and HRI via email: CBR

3. Conducts initial review of device: SC

a. Supply Chain personnel are responsible for coordinating/communicating with contacts in the ancillary units (i.e. Fred Horton in OR and Marla Jones/Jennifer Evans in HVC)

4. Notifies HRI if review is required: SC

5. Coordinates timely placement on the appropriate PRT agenda: SC

a. HRI will use financial analysis completed by PRT, if review is required.

6. Initiates purchase agreement: SC

a. Purchase agreement does NOT need to be executed for step 8 to be completed and routed to CBR; This process can occur concurrently with negotiation/execution of clinical trial agreement.

7. Initiates and completes financial analysis, if not completed by PRT: HRI

8. Completes ***Device Trial Analysis Form*** *{formerly known as the Hospital Letter of Agreement}* using outcome of PRT reviews and the associated financial analysis, if applicable: HRI

9. Obtains approval from appropriate Hospital executives: HRI

10. Signs ***Device Trial Analysis Form*** and distributes a copy of the approved form to Clinical Billing Review and the PI/Coordinator: HRI

NOTE: Hospital supply chain may not initiate purchasing process for the device until the study has received OIRB approval. However, OIRB approval is NOT required for the Hospital approval form to be completed.

CBR – Clinical Billing Review HRI-Hospital Revenue Integrity, Ron Evans/Jeffrey Byars

PRT – Product Review Team {OR, HVC, etc.)

SC – Supply Chain, Jeffrey Byars, and Ragan Manning {resourceutilization@uabmc.edu}

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