1. Trained Clinical Research Coordinators (CRCs) will oversee all device studies conducted at Maine Medical Center (MMC).

2. For studies being conducted by an Investigator that involves the implantation of a device using Maine Medical Center’s Operating Room facilities, a MMC CRC may be assigned to:
   - Oversee the ordering, tracking and sequestering of the device.
   - Other details that ensure the safety of the subject and compliance with federal regulations and institutional policy.
   - Provide clear guidelines to the Operating Room (OR) staff necessary for the appropriate use of the device.
   - Provide oversight of proper billing procedures necessary to ensure that billing occurs according to federal guidelines.

Please contact the Clinical Trials Unit Manager who will assist in the facilitation of this process.

The IRB will not approve any investigational device study that does not comply with these guidelines.

**Ordering and Tracking of Investigational Devices**

In most cases, the study sponsor will provide the investigational device. In cases where this does not happen, the MMC CRC will provide oversight of the ordering process.

- All aspects of the investigational device handling will be recorded on a tracking document either supplied by the device company or created by MMC (*See Attachment A as sample*)

All associated purchase orders and shipping documents will be kept with the tracking document.

**Labeling of Investigational Devices**

For all investigational devices to be used in the operating room, the MMC CRC will ensure the device is clearly identified as investigational. If the device is not clearly identified as investigational, the MMC CRC will store the device in a specific container that has “Investigational Use Only” visible on the outside.
Storage/Sequestering of Investigational Devices

All items will be secured in a locked cabinet that identifies the study device. No investigational devices will be stored in the operating room. Per the study delegation log the device will be supplied to the OR for its scheduled use. Unused devices will be returned to locked storage and returned to the sponsor or manufacturer per protocol.

Staff Training and Communication

At the onset of any new approved protocol, the CRC assigned to the study will provide in-service training to the appropriate OR staff on the use and handling of the device. This will be documented on the study specific training log. Additional training to OR staff will be documented on the study specific training log.

The CRC will communicate with the OR staff when a patient is scheduled for surgery and when items are ordered.

Per the delegation log, a member of the study staff may be required to be in the operating room at the time of surgery to discuss investigational device status with the surgical team.

The CRC responsible for device inventory, per the delegation log, will ensure that the appropriate communication occurs to document device accountability.