1. Purpose:

1.1. To describe the process for initiating clinical trials that utilizes Clinical Research Center (CRC).

2. Scope:

2.1. This procedure applies to all clinical research protocols that utilizes CRC.

3. Procedures:

3.1. After receiving applicable regulatory and administrative approval, a member of the team (PI, study coordinator, or research nurse) contacts the CRC Nurse Manager to schedule the in-service.

3.2. The CRC Nurse Manager notifies attendees of meeting date and time. Attendees may include, but are not limited to:

   - CRC Nurse Manager
   - CRC Nursing staff
   - Co-Investigators
   - Research Coordinator
   - Research Pharmacist
   - Research Dietitian

3.3. New protocol in-service will include the following items, review of the study orders, flowsheets, and a presentation of the items listed in the Clinical Trial Nursing Information Sheet as appropriate to the study.

   - Name of Protocol
   - Principal Investigator
   - Study Coordinator
   - Phase of Study
   - Aim of Study
   - Subject Population
   - Drug Information
   - Potential Side Effects
   - Nursing Interventions Required
   - Points of Special Attention
   - Pharmacokinetics

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3.4. Following the in-service, documents may be edited according to the feedback received from the reviewers and resubmitted to the original reviewer.

3.5. The Clinical Trial Nursing Information Sheet, signed by the PI is uploaded into the CRC Database to complete the study activation following the in-service.

4. MATERIALS AND REFERENCES:

4.1. Clinical Trial Nursing Information Sheet

5. VERSION/REVISION HISTORY:

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