Clinical Research Center (CRC)
CRC Approval Process
(C-02-01)

1. **Purpose:**

1.1. To describe the process for approving clinical research protocols for Clinical Research Center (CRC) support.

2. **Scope:**

2.1. This procedure applies to clinical research protocols submitted for CRC support.

3. **Procedures:**

3.1. CRC Nurse Manager contacts study team within 2 weeks of receiving CRC service request via electronic Office of Clinical Research (OCR) service portal.

3.2. All protocols will undergo a feasibility review by the CRC Nurse Manager prior to CRC utilization.

3.3. Prior to CRC feasibility meeting, study team sends study documents such as protocol, pharmacy manual, lab manual, study budget, etc. as applicable to CRC nurse manager.

3.4. The following attendees are required to attend CRC feasibility meeting.

- Principle Investigator
- CRC nurse manager
- Study coordinator or representative
- Investigational pharmacy for study requires investigational product
- Baylor St Luke's Medical Center (BSLMC) Research staff for studies requires BSLMC support

3.5. CRC nurse manager emails CRC feasibility meeting minutes along with any pending items to the study team.

3.6. CRC nurse manager presents study to internal feasibility meeting.

3.7. CRC feasibility meeting minutes/checklist, protocol, and finalized budget is required to conduct internal feasibility review.

3.8. CRC nurse manager sends PI agreement for review/signature

3.9. CRC nurse manager draft nursing orders and flowsheet and sends to study team for approval.

3.10. Study conducted at McNair 7th floor also requires approval from Nurse Director of the clinic/infusion suite.

3.11. CRC nurse manager verifies the following.

3.11.1. Study set up in Clinical Trial Management System (CTMS)
3.11.2. Study budget finalized in CTMS
3.11.3. CRC utilization box is checked in CTMS
3.11.4. Study set up in Electronic Medical System (EMR) system
3.11.5. Study Drug is profiled in EMR as applicable
3.11.6. Principal investigator is added to CRC Epic department as applicable.

3.12. CRC nurse manager adds study to the following internal portal.

3.12.1. Project Activity Tracker (PAT)
3.12.2. OCR regulatory system
3.12.3. Clinical Research Resource (CRR)

3.13. Once study team receives all regulatory and administrative approval, CRC in-service is scheduled/conducted before seeing first subject in CRC.

3.14. Mock visit is also scheduled for complex study visit.

4. MATERIALS AND REFERENCES:

4.1. Office of Clinical Research (OCR) service portal
4.2. Clinical Trial Management System (CTMS)
4.3. CRC Approval Flowchart

5. VERSION/REVISION HISTORY:

Approval Date	Version	Revision Summary
10/10/22	1	