The CRC – Everything you wanted to know but were afraid to ask.

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Objective for today

To (re)Introduce you to the Clinical Research Center (CRC) and all of the great things happening there.

Where is the CRC located?

- The CRC is located on the ground floor of the Multi-Disciplinary Research Center (MRC).

So what's happening now at the CRC?

- The CRC has 12 study coordinators currently assisting with 20 studies ranging in size and scope from New-Hope (a 10 patient phase II study) to MECA (400 participants) to the upcoming All of Us project.

- If you have time, please stop by. We would love to show you our facility.

What makes the CRC so special?

CRC – Capabilities

- State of the art outpatient facility
- Five fully equipped exam rooms
- Shared use laboratory
- 12-bed study participant observation unit (can be used for Phase I trials)
- Metabolic kitchen and DEXA scanner (Bionutrition Core)
- Fully equipped mobile unit (Recruitment Core)
- Research Design and Biostatistics support (Biostatistics Core)
- Ultrasound capabilities
- Joint Commission for Accreditation of Healthcare Organizations (JCAHO) accredited facility

What are the CRCs capabilities?

- The CRC provides support in the following functional areas:
  - Nursing
  - Recruitment/Community Outreach
  - Investigational Drug Services
  - Bionutrition
  - Ultrasound
  - Laboratory
  - Regulatory
  - Study Coordination/study management

What about other types of support?

- The CRC also provides support regarding:
  - Confidentiality Agreements
  - Study Feasibility assessments
  - Study Budget development and negotiation
  - Contract negotiations
  - QI/QA
  - Bioinformatics
  - Training and education (e.g. CRECD, ACTSI KL2)
  - Clinical Research workforce development and Resident research rotations

Now that I know what the CRC is and what you can do, how do I get started?

- If you are in contact with a Sponsor (or Contract Research Organization - CRO) regarding MSM as a clinical site for a clinical trial, it is imperative that you contact the Clinical Research Center (CRC) at clinicaltrialsoffice@msm.edu.
- The CRC will ensure the appropriate Confidentiality Disclosure Agreement (CDA) is in place.
- Please do not discuss any confidential information with the Sponsor (or CRO) until a CDA is in place. Be aware that you as an Investigator cannot sign the CDA. This document must be reviewed by legal and signed by OSP.

Once my CDA is in place, what's next?

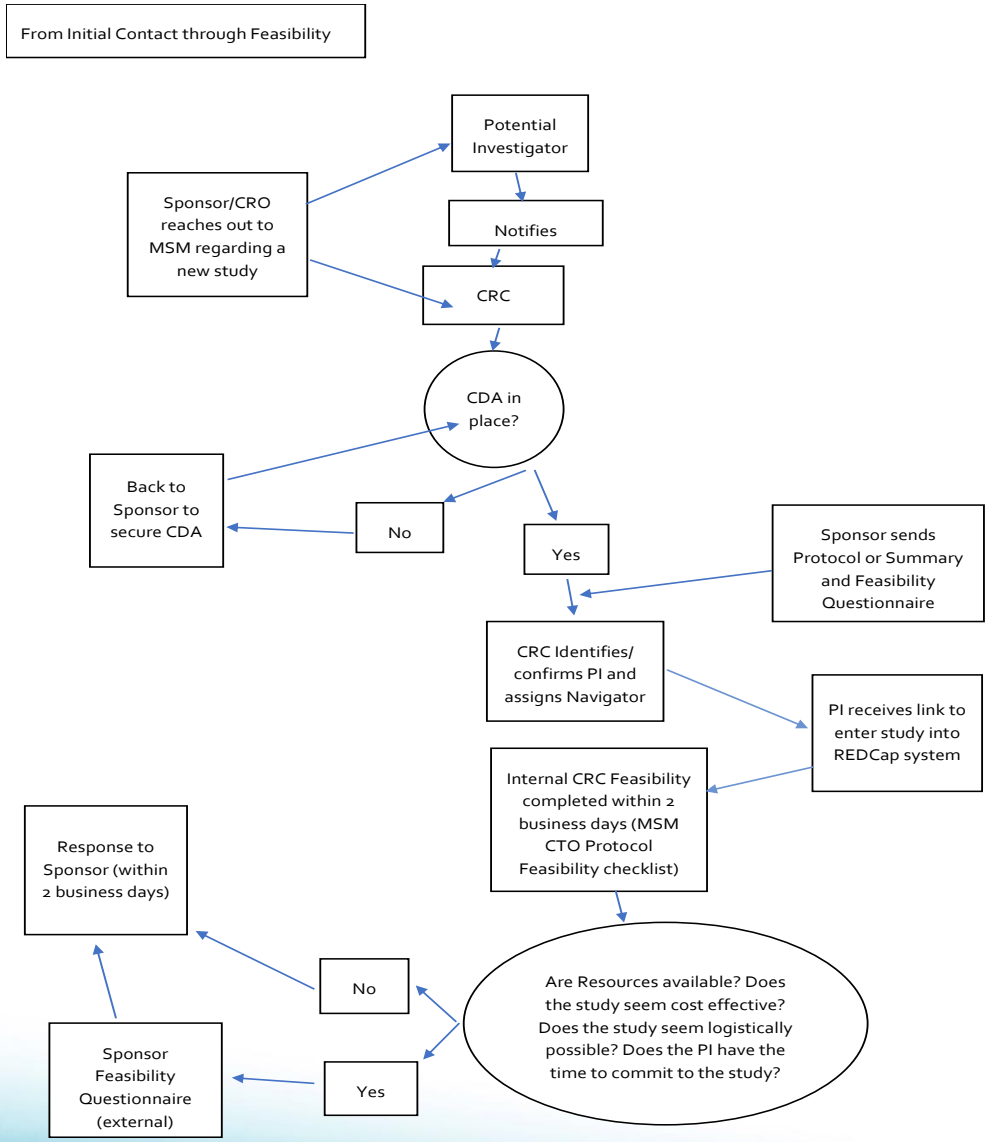
- Once the CDA is in place and you receive a protocol or protocol synopsis, a "navigator" will be assigned to you to help you with the process of getting of the necessary info into our systems.

How are resources assigned to a study?

- As part of the budget development, the CRC does a time-to-task analysis to determine the types and number of resources need to successfully conduct the study.

- Based on the information, staff is assigned based on two primary criteria: availability and therapeutic experience.

Getting Started



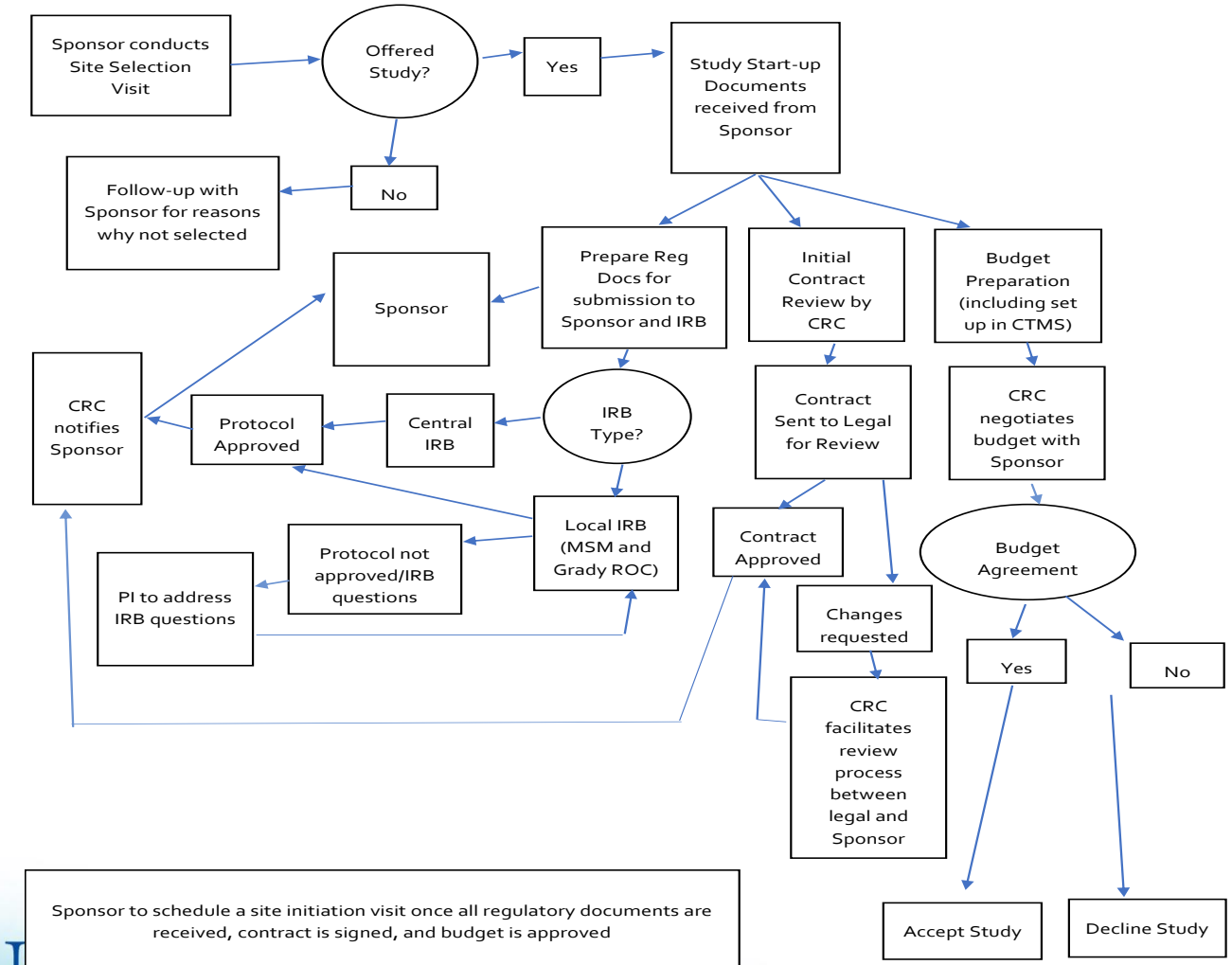
How do I know if my study is financially feasible?

- The CRC supports faculty with the pre-award phase of sponsored clinical trials.
- We will work with Investigators to develop study budgets. These budgets can be compared to those presented by the Sponsor to determine any potential financial gains or loses.
- Additionally, the CRC will help you to determine if the study is logistically feasible.

So how does the process work, determining the budget, getting a contract in place and sorting through the regulatory submission requirements?

From Site Selection to Site Initiation

Note: Once Selected by Sponsor/CRO as a potential study site, CRC will assign/confirm Study Coordinator



Sponsor to schedule a site initiation visit once all regulatory documents are received, contract is signed, and budget is approved

So tell me more about the regulatory process.

The Regulatory support staff's primary responsibilities are:

- Working with your study coordinator to ensure all study start up documents are collected.
- Getting the protocols (and other materials) submitted to the MSM Institutional Review Board (IRB).
- Assisting with other submissions as necessary (e.g. Central IRB, Grady ROC, etc.)
- Ensuring MSM faculty and staff stay current on all certifications and licenses such as HIPAA, CITI course, Medical/ Nursing license, etc.

What if the CRC is contacted directly by a Sponsor regarding a clinical trial?

- If the CRC is contacted directly regarding clinical trial, we will reach out to potential Investigators.

- We are putting together a database of potential investigators that we can quickly search on therapeutic area and areas of research interest.

How do I get on your list of potential investigators?

- As we are making our rounds to the various departments, we are sending out a link that enables you to input some research interests and basic therapeutic information. It takes about 5 minutes to complete the questionnaire.

- Note: you will be asked to upload your current cv and NIH biosketch so please have them available when you log into the system.

What if I have other questions later?

For Further information, please contact us at:

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