CONDUCTING RESEARCH STUDIES ON THE
CLINICAL RESEARCH CENTER (CRC)
Information Sheet

The CRC application and information about protocol submission are located on the CRC website at https://www.urmc.rochester.edu/clinical-translational-science-institute/resources/clinical-research-center/forms.aspx.

There are several steps to starting a study on the CRC. Following these steps will help to ensure a well-planned study and a smooth initiation.

SUBMITTING A PROTOCOL USING THE CRC APPLICATION

You are encouraged to contact CRC personnel early on in the process of developing your protocol to address questions regarding the services the CRC can provide. Please see the table below for contact information for key CRC personnel.

Spencer Rosero, MD	Program Director	275-4775
Mary Little	CTSI Administrative Manager	275-0653
Ann Miller, RN	Nurse Manager	275-2907
Nellie Wixom, RD	Research Dietitian	275-3918

Well before subjects can be scheduled for visits on the CRC unit, an informational meeting needs to take place with CRC staff for the purpose of communicating general information about the CRC and to understand your needs for the study, including equipment, supplies, tools, and forms. This meeting will occur with the CRC Nurse Manager and other pertinent CRC staff to discuss the CRC unit's general policies, scheduling process, and physician order requirements, as well as becoming familiar with the unit. This meeting most often takes place before protocol approval, and can take place even before protocol submission.

PROTOCOL APPROVAL:

The CRC must approve a protocol prior to conducting research procedures on study subjects on the CRC or using CRC resources. The CRC approval process involves a review of the protocol for the feasibility of the requested use of CRC services or resources. This feasibility review will take place **after** IRB (RSRB, single IRB, or central IRB) approval has been given. The CRC is committed to prompt review of the protocol for feasibility. Please note the following:

- The review process starts upon receipt of the CRC application, IRB approval, and all required study documents.
- If there are no questions or issues needing clarification arise during the review process, the protocol can be approved and a CRC protocol number provided by the fifth business day after CRC receipt of the protocol.
- If the PI responds promptly to any questions or items of clarification arising from the review, it is estimated that the turnaround time for the feasibility review would be a total of two weeks from CRC receipt of the complete protocol package.
- The CRC strongly encourages study teams to work with the CRC staff prior to protocol submission to work out potential issues and reduce time to approval.

CRC Involvement Protocol

Scheduling:
Please call 275-2907 as soon as you know you would like to bring in a subject. The CRC needs advance notice to ensure there are available staff, equipment, and space the day you would like to schedule your study visit.

Note: If CRC resources were used during multiple timeframes above, then cite each of the grant numbers that supported the work.

Thank you for using the Clinical Research Center. We welcome any feedback that will make using the CRC as convenient as possible!