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

Before subjects can be scheduled for visits on the CRC unit, an informational meeting needs to occur with CRC staff to communicate general information about the CRC and 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 before 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 a 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 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 before protocol submission to work out potential issues and reduce time to approval.

APPLICATION PROCESS:

New Protocol Submissions

1. Protocols reviewed by the RSRB
   a. When filling out the protocol application in the Click IRB system, indicate that the study will use the resources of the CRC. This will provide the CRC with access to the study documents, IRB

approval documents, and future amendments.

b. After RSRB approval has been received, submit the CRC Protocol Submission Application. If you did not indicate at the initial RSRB submission that the study will use the resources of the CRC, attach the required study documents detailed in the table below, as well as the departmental scientific review of the study.

2. Protocols reviewed by an IRB external to the University of Rochester – submit the CRC Protocol Submission Application.
   a. CRC Protocol Submission Application
   b. IRB approval
   c. IRB-approved consent form(s)
   d. Departmental scientific review of the study
   e. Required study documents detailed in the table below

Once the required documents are received, the CRC feasibility review will begin.

The table below details the components required for CRC protocol review. The required components are based on the involvement of the CRC in the study. Incomplete submissions may result in delay of review.

CRC Involvement	Protocol	IRB-Approved Consent Form	IRB Documentation of Approval	Manual or the Portion thereof that Relates to the Tests Conducted on the CRC	Measures/ Assessments to be Conducted in the CRC
Nursing	yes	yes	yes	yes	yes
Nutrition Services	yes	yes	yes	no	no
Blood draw and processing (blood drawn on the CRC)	yes	yes	yes	yes	no
Blood processing (blood draws not conducted on the CRC)	yes	yes	yes	yes	no
Vital signs only	yes	yes	yes	no	no
DXA	yes	yes	yes	no	no
CRC Use (no services required)	yes	yes	yes	no	no

Adding Use of CRC Resources or Services to a Study that has Already Received IRB Approval

Submit the CRC Protocol Submission Application.

Protocol Amendments

- When a protocol amendment impacts the CRC, a CRC Amendment Submission Form and supporting documentation need to be submitted to CTSI for CRC review. It is the responsibility of the study team to communicate protocol changes that impact the CRC.

Regardless of whether or not an amendment directly impacts the CRC, if the protocol or consent form is revised, a copy of the protocol or consent form needs to be forwarded to CTSI.

PROTOCOL INITIATION

After the protocol is approved and a CRC protocol number has been given, the study team is required to give an in-service to the CRC staff.

In-service for CRC staff:
The purpose of this meeting is for the study staff to inform the CRC staff of the study details and procedures to ensure a smooth protocol initiation. The PI of the study needs to attend this meeting.

This in-service needs to be conducted for CRC studies occurring on the unit so study staff and appropriate CRC staff can discuss the protocol procedures, and answer questions/clarify issues prior to study implementation. If flow sheets are to be used for a study, please contact the CRC Nurse Manager for assistance, if necessary, and to review the finalized flow sheet prior to the first subject visit.

The in-service needs to occur before subjects can be scheduled for visits on the unit.

STUDY VISITS

Once the above meeting has taken place and all issues have been addressed, then the study staff can schedule subjects. Information and instructions regarding scheduling, physician orders, administrative and other issues are detailed below.

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. **Please call for availability BEFORE informing the subject of the visit date.**

Patient Care Orders/Physician Orders:
Patient care orders/physician orders need to be **received by the CRC at least 48 hours prior to a study visit**. This will allow time to resolve any questions, and for any study blood tubes to be labeled prior to the visit. Templates for orders are located on the CRC website at https://www.urmc.rochester.edu/clinical-translational-science-institute/resources/clinical-research-center/forms.aspx. At this time, we are not part of the electronic medical record.

All overnight study visits must be signed by the primary physician investigator with SMH admitting privileges, or a physician or nurse practitioner who is listed on the protocol. Outpatient visits that include any type of medication or invasive procedure (e.g. muscle biopsy, nerve conduction studies, etc.) will need the orders signed by the primary physician investigator.

Outpatient studies that are minimal risk and do not include study medications may use the Study Visit Order form. This form may be signed by the Principal Investigator or a qualified study team member appointed by the PI. The PI maintains responsibility for oversight of the study.

Orders can be created and signed in advance and given to the CRC staff who will place them in a file on the unit.

If requested, the CRC Nursing staff will assist the study team with writing or reviewing the Patient care orders.

The orders should include: the CRC protocol number and specific protocol procedures (i.e., blood draws, DXA scan, etc.). If the procedures need to be completed in the order listed, that should be indicated. Blood draws should be as specific as possible (i.e., number and types of tubes, "bloods as per kit", or reference to flow- sheet, etc.). **Only items that have been approved by the CRC can be ordered**.

Please include a phone or pager number for the coordinator on each

order. Other Issues:
If a subject consents off the CRC unit, please bring a signed copy of the consent form to the first visit for the subject. This is required before any study procedures conducted on the unit.

All inpatient visits need to follow the usual hospital procedure for admissions (i.e., history and physical for each visit and daily notes by MD or NP). All inpatient charts are subject to an audit by the hospital.

All CRC staff will be advocates for subjects to ensure studies are conducted according to the protocol.

ADMINISTRATIVE ISSUES

Adverse Events: Submit reports of serious adverse events **(SAEs)** and locally occurring adverse events **(AEs)** to the CRC as they occur.

Protocol Amendments: Provide the CRC with copies of all protocol amendments/changes, and a copy of all IRB amendment approvals and updated consent forms. If the amendment impacts the CRC, a CRCAmendment Submission Form (located on the CRC website at https://www.urmc.rochester.edu/clinical- translational-science-institute/resources/clinical-research-center/forms.aspx) must be submitted, along with revised study documents.

Approvals/Consent Forms: Provide the CRC with copies of the updated IRB study approval and consent form. The CRC requires a copy of the renewed study approval and consent form (if applicable) each year. If the RSRB-reviewed protocol was submitted to the CRC through the Click IRB system, the CRC can obtain the reapproval and current consent forms from the Click IRB system.

Annual Report: Complete an annual report each year, as requested by the CRC for reporting to the NIH.

Publications:

Once the study has been completed and data analyzed, acknowledge the support of the CRC in applicable publications. Please keep in mind that although these publications may not be published for several years after the CRC services are utilized, the grant reference must still be included.

The wording below should be used for citing the use of CRC resources in a publication. Please note that the wording to be used is dependent upon the timeframe during which CRC resources were used.

1. Wording for Publications Resulting from Studies Using CRC Resources **only during the timeframe prior to 9/30/06**:

"This publication was made possible by Grant Number 5 MO1 RR00044 from the National Center for Research Resources (NCRR), a component of the National Institutes of Health (NIH). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of NCRR or NIH."

2. Wording for Publications Resulting from Studies Using CRC Resources **during the timeframe of 9/30/06 - 6/30/12**:

"The project described in this publication was supported by the University of Rochester CTSA award number UL1 RR024160 from the National Center for Research Resources and the National Center for Advancing Translational Sciences of the National Institutes of Health. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health."

3. Wording for Publications Resulting from Studies Using CRC Resources **during the timeframe of 7/1/12 – 8/14/16**:

"The project described in this publication was supported by the University of Rochester CTSA award number UL1 TR000042 from the National Center for Advancing Translational Sciences of the National Institutes of Health. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health."

4. Wording for Publications Resulting from Studies Using CRC Resources **on or after August 15, 2016**:

"The project described in this publication was supported by the University of Rochester CTSA award number UL1 TR002001 from the National Center for Advancing Translational Sciences of the National Institutes of Health. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health."

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!