CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE

CONDUCTING CLINCAL RESEARCH STUDIES IN THE CLINICAL RESEARCH CENTER (CRC)
Information Sheet

SUBMITTING A PROTOCOL USING TRACs

All protocols requesting the use of CRC resources are required to be entered into and maintained in OnCore, the UMass CTMS. If you do not have access to OnCore or have any questions about OnCore, please visit https://www.umassmed.edu/ocr/oncore/ for more information.

The CRC service requests need to be completed on the CCTS TRAcs Website .

TRAcs is designed to allow investigators/study teams to request services in support of a protocol. The request builds upon information asking some additional questions to clarify the roles and responsibilities of the study team and CRC staff. Answering the questions completely will facilitate the implementation of your protocol.

An informational meeting may need to be scheduled with CRC Nurse Manger to discuss protocol specific needs, including equipment, supplies, tools, and/or other required resources. This meeting will be scheduled by the CRC Grants & Contracts specialist and Nurse Manager, and if necessary, include a tour of the unit.

PROTOCOL APPROVAL PROCESS

The CRC must approve, in writing, any requests for CRC resources. The CRC approval process involves a review of the protocol and other study information as needed (for example: Investigator Brochures and pharmacy manuals) for the feasibility of the requested use of CRC services or resources. The CRC is committed to prompt review of the protocol for feasibility. Please note the following:

- The review process starts upon receipt of a complete CRC service request TRACs submission and after the informational meeting is held, if determined to be necessary. The CRC Grants & Contracts specialist will gather all the information and present it to the CRC nurse manager prior to the meeting.
- The table below details the current basic charges of the CRC and will be used to establish the fee schedule. The required components will be based upon the involvement of the CRC staff and resources in the study. Incomplete submissions may result in delay of review.
- If there are no questions needing clarification during the review process, a CRC service agreement will be sent to the PI/Clinical Coordinator.
- If the PI/study team responds promptly to any questions or items of clarification arising from the review, it is estimated that the turnaround time for protocol approval is a total of two to four weeks from CRC receipt of the complete protocol package.
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PROTOCOL INITIATION

After the request is approved and a CRC Service Agreement has been signed, the study team may be required to give an in-service to the CRC staff or include them in the study Site initiation visit meeting. 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 implementation. The PI of the study should attend this meeting for any services supporting a treatment clinical trial.

The UMMS IRB requires that all required CRC staff that are working on a study be added as research staff to the study in eIRB and OnCore, enabling the CRC staff access to the protocol documents and consent forms.

STUDY VISITS

Once the study is IRB approved, active in Oncore, Oncore calendar includes the CRC services and all issues have been addressed, study subjects can be scheduled.

Scheduling: To facilitate scheduling, the CRC uses the UMMS Room Scheduler (the same online system used to schedule campus conference room spaces) as the method to request all space. This allows research staff to view available space and request specific CRC rooms and resources. All requests should be submitted at least 2 business days in advance and will be reviewed by the CRC team. Please see the CRC Scheduling Job Aid for instructions.

Patient Care Orders/Physician Orders: Not all subject visits held within the CRC are recorded in the Epic medical record. It is the responsibility of the PI and study team to complete any/all medical record documentation.

Visits that include CRC RN administration of investigational product require RN review IDS prescription prior to administration.

Informed Consent If a subject is consented off the CRC unit, please bring a signed copy of the consent form to the first visit for the subject or load the signed ICF documents into OnCore. This is required prior to any study procedures conducted on the unit.

ADMINISTRATIVE ISSUES

Adverse Events: If determined to be the responsibility of the CRC staff based on the service agreement, reports of serious adverse events **(SAEs)** and locally occurring adverse events **(AEs)** will be submitted to the appropriate parties (e.g., IRB or sponsor) by the CRC staff as they occur. All SAES will also be recorded in OnCore.

Protocol Amendments/Informed Consents: Based on the service agreement, study staff will inform and 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 previously approved CRC services, a request to revise the CRC Service Agreement must be submitted, along with revised study documents.

Approvals/Consent Forms: Based upon the service agreement, study team will ensure that the CRC has access to copies of the updated IRB study approval and consent form.

Annual Report: Based upon the service request information and OnCore data, the CRC compiles information on an annual basis to report to the UMMS CCTS, as required by the NIH. CCTS staff may contact study teams if data is necessary to complete the annual report.

Updating an Existing CRC Service Agreement: Complete the CRC service request form in TRAcs and choose the "Update an existing CRC Service Agreement" option.

It should be noted that all CRC services are recorded in OnCore. Any adjustment that is made to the service agreement also needs to be made to OnCore. Changes to OnCore can also be requested by completing an "OnCore Change Request" in the TRAcs.

This should be completed whenever a protocol amendment impacts CRC services. It is the responsibility of the study team to communicate protocol changes that impact the CRC. If the CRC staff are responsible for IRB submissions, the CRC will work with the investigators and Department Administrators to ensure that the CRC Service Agreement is updated.

CRC Service Agreements will be reviewed every two years. If revisions are needed the CRC Office Manager will contact the PI/Study Team.

PUBLICATIONS

Once the study has been completed and data analyzed, the support of the CRC must be acknowledged 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. If you have any questions, please contact the CRC staff.

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 August 14, 2015**:

"The project described in this publication was supported by the University of Massachusetts CTSA award number UL1TR000161 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."

2. Wording for Publications Resulting from Studies Using CRC Resources **on or after August 14, 2015**:

"The project described in this publication was supported by the University of Massachusetts CTSA award number UL1TR001453 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.

Clinical Research Center - Recharge Fee Schedule

Type of Charge	Federal	Department or Investigator	Other Non Profit (e.g. Foundation)	Industry
CRC does - IRB submission- initial	$50/hour ($600 Max)	$50/hour ($600 Max)	$50/hour ($600 Max)	$1,250
Study Start Up	None	Variable	Variable	Variable, starts at $3,000 + overhead
Ongoing regulatory (amendments, annual renewals)	$50/hour	$50/hour	$50/hour	$75/hour
Nursing charge per hour	$75/hour	$75/hour	$75/hour	$100/hour
Room charge per hour	None	$25/hour	$40/hour	$60/hour
Clinical Research Coordinator per hour	$50/hour	$50/hour	$50/hour	$75/hour