Welcome to the Clinical Research Center

A Guide for PIs and Coordinators

THE UNIVERSITY OF ILLINOIS AT CHICAGO CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE

ccts.uic.edu

Welcome to the Clinical Research Center (CRC). As a component of the Center for Clinical and Translational Science (CCTS) it is our mission to assist the UIC Research community, supporting high quality, safe, and efficient research by providing an integrated, intentional approach for reviewing and monitoring clinical protocols, linking investigators to appropriate services, providing regulatory support, and assisting with recruitment and dissemination. We provide a core of clinical research professionals with the necessary specialized training to provide various clinical research services. The CRC nursing staff is comprised of registered nurses and advanced practice nurses with expert clinical knowledge and skills in vast areas of clinical practice. CRC clinical research coordinators also provide hands on clinical and laboratory support. This document is a brief guide on how to request, access and schedule CRC services. No document replaces individual consultation or discussion with CRC Leadership and staff. We welcome all inquiries and questions in person, via phone or email.

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Requesting CRC Services and Letters of Support

Contact CRC leadership directly with requests for CRC services by completing the CRC Service Request Form.

CRC leadership will compile the cost structure of the CRC services for your research needs and provide you with a detailed account of service fees. We recommend review of budget details in the early phases of grant submission. All services are subject to an annual 3% increase (which is implemented in quarter 3). Service needs can be re-assessed at any time and only those services actually provided are invoiced to the PI once the research begins. CRC leadership will need a copy of your research protocol or research strategy. If not yet available, a protocol summary or synopsis is helpful in our planning. If applicable, the CRC will also request laboratory instructions and case report forms specific to your project.

The information on the CRC Service Request Form is also necessary to create a Letter of Support.

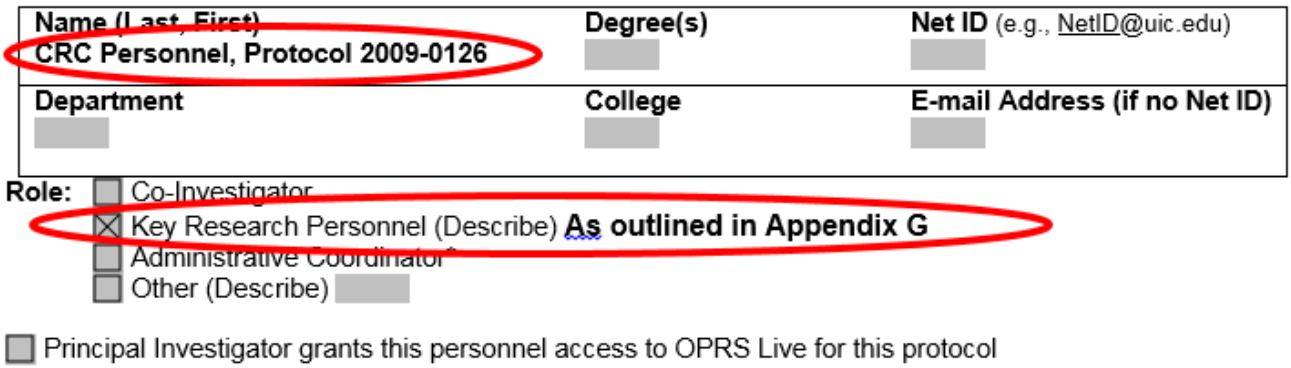
Cite It

Please acknowledge Clinical Research Center – Center for Clinical and Translational Sciences support by referencing grant number UL1TR002003 in any publications resulting from direct or indirect support.

What you'll need to submit to the IRB

The UIC IRB will require you to submit an Appendix G indicating which CRC services you will be utilizing. This form will be provided to you by CRC leadership upon approval of your research study (after submitting the CRC Service Request Form).

- CRC personnel will also need to be included on the Appendix P listing all key research personnel. To streamline the process and avoid you having to make changes when CRC staff adjustments are made, you will include CRC staff as follows:



(Note: The Administrative Coordinator role is limited to management of submission documents and IRB correspondence. Personnel who will be interacting with subjects or accessing identifiable data must be listed as Co-Investigators or Key Research Personnel and must meet the applicable investigator training requirements.)

- If you are utilizing the CRC for space only you do NOT need to include the CRC staff on the Appendix P form. You will only need to submit the Appendix G form to the IRB which will be provided to you by CRC management.

- If the advanced practice nurse will be completing a Physical Exam or tissue biopsy you will list the CRC advanced practice nurse individually for these services.

Name (Last, First)	Degree(s)	Net ID (e.g., NetID@uic.edu)
Holtcamp, Maryann	**APN, MSN**	**mholt**
Department	**College**	**E-mail Address (if no Net ID)**
CCTS	**Medicine**	

Role:
- ☐ Co-Investigator
- ☐ Key Research Personnel (Describe)
- ☐ Administrative Coordinator*
- ☒ Other (Describe) **Performance of physical exams and tissue biopsy**

☐ Principal Investigator grants this personnel access to OPRS Live for this protocol

**(Note: The Administrative Coordinator role is limited to management of submission documents and IRB correspondence. Personnel who will be interacting with subjects or accessing identifiable data must be listed as Co-Investigators or Key Research Personnel and must meet the applicable investigator training requirements.)*

Study start up in the CRC

Once your project is IRB approved, funded, and you are preparing to begin recruitment, you will want to check back in with CRC Leadership. At that time, we will review the services and make any necessary adjustments. The PI will be asked to sign a Memorandum of Understanding (MOU) which outlines the agreed upon services and their corresponding costs. All services are subject to an annual 3% increase (which is implemented in quarter 3). Any training needs can be discussed and CRC staff training will be completed and documented. A copy of the training log will be made available to you to include in your regulatory binder.

Other items for review will include:

- ***Laboratory Services***: where will specimens be sent for analysis? Is the account established? Provide the CRC a copy of the study-specific lab requisition and any processing instructions. Alverno and Quest pick up Monday—Friday from the CRC.
- ***Investigational Drug Service***: If medications are being dispensed from UIC Investigational Drug Service (IDS), a signed MD order will be required and the mechanism to obtain medication will be established specific to the research study.
- ***Supplies***: A review of study supplies will occur at this time as well. Any supplies not provided by the CRC or specific to the research study will need to be ordered at this time. The CRC does not maintain sponsor/research study provided supplies.

- ***Shipping***: The CRC does not have accounts with FedEx or UPS or supply shipping materials. If specimens will be shipped by CRC staff, courier information and shipping supplies will need to be provided by the PI or study sponsor.

The CRC will require a copy of your IRB approval, research protocol, informed consent document, FOAP (for billing purposes), source documents (if provided/available) and study provided equipment. This is also a good time to complete the Delegation of Authority Log.

Scheduling Participants

All appointments are made and maintained in the CRC scheduling platform, CROSSPAD. Study staff (PI and coordinators) will be granted access to CROSSPAD for scheduling and billing review. CROSSPAD can be accessed from any computer but requires installation of the AnyConnect VPN. When installing AnyConnect VPN on UIC computers, administrative assistance through your departmental IT may be required. Once installed, the CROSSPAD platform will be accessible at https://ccts-crosspad.ihrp.uic.edu/.

Specific scheduling instructions will be provided to the PI and staff. Any study team member that will be using CROSSPAD to schedule research participants should complete a brief training with a member of CRC Leadership.

Always make sure to search to see if your participant is already in our system.

When searching for a time for an appointment we would suggest always putting the time at 7:00am that way you can see everything that is available for the day. CROSSPAD can take a while to process the requests when looking for an appointment so be patient – it is working unless you are getting an error message.

Remember that when scheduling appointments, all appointments are first come, first serve. No appointment slots are held or blocked. The CRC is open Monday through Friday from 7am to 4pm. Any requests for appointments outside of normal business hours should be addressed to CRC Leadership.

When searching for an appointment in CROSSPAD, if the designated time or date is not provided as an option, it likely is already booked or staff or room space is not available.

CROSSPAD will not allow you to schedule an appointment less than 24 hours in advance. For less than 24 hour or any last minute requests, please call the CRC at 312-996-2937 and email CRC staff. Be prepared to provide your name, the study name, the date and time you are seeking to schedule. A member of the CRC staff will also request the participant's full name, DOB and any study-specific identification number to complete the scheduling process if the desired appointment is available.

If you need to make any changes to a scheduled appointment (change the date, participant, visit, etc), please inform CRC staff as soon as possible. This information is necessary to prepare the clinic and staff for your scheduled study visit.

Check in and Check out procedures

Research staff are required to sign in upon arrival to the CRC and sign out when they depart the CRC.

Upon arrival to the CRC, participants are requested to "check in" at the front desk. At the time of check in, CRC staff will collect any necessary information to complete the process in CROSSPAD (race, ethnicity, DOB if not provided) and alert a CRC staff member assigned to the participant visit.

For the *initial visit in the CRC*, a copy of the fully signed informed consent document will be required prior to CRC staff completing any assessments or procedures. A copy machine is available in the CRC work room if you need to make a copy of the consent document or upload (for REDCap charting). A copy of the "documentation of informed consent" is not required by the CRC. It is highly recommended that documentation of informed consent be completed by the staff member completing the process and kept with the original consent document. If you or your staff have questions regarding obtaining or documenting informed consent, please discuss with CRC Leadership.

Upon completion of the study visit, the participant and study staff should "check out" at the front desk. This is particularly helpful when the study team has the final contact with the participant and allows CRC staff the opportunity to clean the room in preparation for the next appointment.

How to set up your study if utilizing any hospital services (including UIC Pathology/Lab Services)

You will need to reach out to Rockell Moore to get your study set up with a hospital account number (FIN#). You will send her a completed grants and contracts registration form as well as the signed MOU form. If you will utilize any hospital services that should be charged to the grant you will also need to complete the link patient to grant account form.

Once you complete the grants and contracts registration form and the MOU and send those to Rockell to set up your study you will get a FIN number (ends in 9517). Getting the FIN number takes about 3-5 days but it can take up to 2 weeks for your account to be put into production mode in the system.

Once you have your FIN number and the study is in production you can contact Anita Patel to set up a lab requisition form if you are utilizing UIC Pathology/Lab services. She will need to know the study name and FIN number, if you will be using Study IDs or medical record #'s (MRs). If you are using medical record numbers she will need to know if the results will be going into Cerner. She will also need a study contact person and number if any issues arise with the samples. She will also need to know what test(s) to put on the requisition. You will also need to provide a short study title to be used for the requisition form.

To request information on hospital service costs including costs for using UIC Pathology/Lab services you can contact Scott Kennedy.

CRC Laboratory

The following services are available within the CRC Laboratory: sample processing, short-term storage and specimen shipping. The CRC laboratory houses a, refrigerator, small -20°C freezer, and full size -80°C freezer for temporary storage of biological samples drawn as part of CRC investigators' studies.

- The CRC staff can ship samples for you. CRC staff has the required IATA certification to ship biological specimens. We observe the following guidelines:
- The investigator must provide all packing material (e.g. styrofoam and cardboard boxes).

- The investigator must also provide the CRC staff with a courier service account. This includes courier airbills (filled with the recipient address and the account number to be billed). Federal Express (1-800-GOFEDEX) is the preferred courier for biological specimens. Please contact them directly to set up an account. If the specimens to be shipped are known to present an increased risk to the carrier (i.e. blood containing HIV), we suggest you call the above numbers and talk to the hazardous material manager to assess your particular needs.
- The CRC lab provides wet and/or dry ice for shipping of samples that are temperature-sensitive.
- The CRC lab will pack the specimens in the provided material, arrange for pick up by the courier service, and -upon request- track the package delivery.

Expectations for use of the CRC

The CRC is a clinic utilized by multiple faculty and staff of UIC. We ask that you understand and abide by fundamental professional standards and workplace expectations as we want to ensure a positive work environment, while promoting the highest expectations of professionalism within our unit. These standards relate to several key areas including customer service, ethics, safety, communication and general professional appearance.

We ask that you do not use the phone at the front desk to make outgoing calls. There are two phones in the middle of the clinic and a phone in the back workroom that can be used by PIs and research staff. If you need to make a call from the direct CRC line the phone on the small desk in the middle of the clinic should be used.

Participant Reimbursements and Parking Validation

The CRC does offer participant reimbursement as a service. If you would like the CRC staff to reimburse your study participants you will need to provide the cash, gift cards, or appropriate information to complete a vendor information form and TEM subject payment submission.

The CRC does not provide parking validation or parking stickers. If you wish to provide parking stickers for your study participants, they can be purchased through UIC Parking Services. Parking stickers can be kept in the CRC lock box and distributed as per your instructions to your study participants. A log of distribution will be maintained for your study documentation purposes.

Source Documents and Charting of CRC assessments

The CRC maintains source documentation of all assessments or procedures completed. If you or your sponsor have case report forms available, please share with the CRC. Source data will be recorded on paper or electronically. Electronic data will be captured in REDCap. CRC staff will create a REDCap database specific to your research protocol data collection needs. The PI and study team will be granted access to the research database. If you do not currently have a REDCap account, the request for an account can be submitted at http://ccts.uic.edu/content/establishing-your-account

REDCap databases created by the CRC are backed up monthly by the CRC. Please discuss any additional access or data collection needs with CRC Leadership.

Invoicing and Billing

Visit billing is calculated in 'real time' meaning that as a study visit is completed, the bill for services is confirmed and completed. The study PI will be invoiced for all services on a quarterly basis (or more frequently if required). Quarter 1 (January-March), Quarter 2 (April-June), Quarter 3 (July-September), Quarter 4 (October-December). At the end of each quarter, the PI and study coordinator will receive an email from CRC Leadership with a detailed account of the billed services for the quarter. Any discrepancies should be brought to the attention of CRC Leadership. They will be reconciled before final approval is provided and the account FOAP is billed for services.

At any time, the PI and study coordinator may review the study invoices in CROSSPAD. Any discrepancies should be brought to the attention of CRC Leadership.

Emergency Situations and Protocols

The CRC maintains protocols to handle emergency situations. If you are having any issues with participants or if an emergency arises please communicate with the CRC staff and CRC leadership will be involved as required. Evacuations for fire, tornado, etc. are completed following the UIC/UI Health policies. Please discuss any questions regarding handling emergency procedures or difficult participants with CRC Leadership.

Contact Information

CRC Leadership

Charity Ball
Maryann Holtcamp
Amy Kennedy-Krage

CRC Staff

Email: ccts-crc@uic.edu *We are **unable to receive attachments to this email**. If you need to attach something please cc one of the CRC Leadership team.*
Phone: 312-996-2937

Directions to the CRC

Handicap Accessible Entrances
Main Entrance

CRC Study Closeout Procedures

Upon completion of your study please complete the following steps to appropriately closeout your study with the CRC.

1. Inform CRC Leadership that your study has completed – i.e., you will no longer be seeing participants in the CRC for your study protocol.
2. Ensure that you cite the Clinical Research Center – Center for Clinical and Translational Sciences support by referencing grant number UL1TR002003 in any publications resulting from direct or indirect support (i.e., any use of CRC services including space).
3. Send CRC Leadership citations for any publications or presentations resulting from CRC support.