STARTING A PROTOCOL WITH THE UF CLINICAL RESEARCH CENTER
TIP SHEET FOR INVESTIGATORS AND COORDINATORS
Updated 5/26/2023

These guidelines are designed to facilitate your research experience in the UF Clinical Research Center (UF CRC).

UF CRC Protocol Review Process

Protocol Submissions:

- Include:
    1. Completed UF CRC Request for Services Form (COS)
    2. Complete Protocol
    3. Draft/Approved Informed Consent Form (ICF)
    4. Current PI CV
        a. If available; laboratory manual, pharmacy manual and any regulatory documents.
- Submit the above documents to: CTSI-CRC_Budget_Req@ad.ufl.edu

RN Protocol Liaison

Once we receive your Request for Service you will receive an email with the name of your Nurse Liaison. The liaison will serve as your primary contact for CRC.

Roberta "Robyn" Brunson brunsr@shands.ufl.edu will be creating orders worksheets and assist at setting up an inservice for the staff on the UF CRC.

Protocol Review:

- Peer review protocols that have received the CRC Managers review will be forwarded to the Medical Director or Associate Medical Director of the CRC for approval.
- Industry or federally funded protocols will be administratively approved by the by the Medical Director or Associate Medical Director.

Outpatient Visits

Outpatient visit **requests are required at least 24 hours in advance** of the requested date and time.

You will receive either and approval or denial of your request within 24-72 hours. There will be an initial email indicating that we have received your request but is not approved or denied until you receive a second email confirming or denying your appointment.

Requests received after 1600 (4pm) for the following day will be denied. Last-minute scheduling requires a call to the charge nurse (294-5900) Kim Haugh, Jamie Thomas or Janet King. If approved to schedule you will need to enter your request in the scheduling system. The UF CRC hours are 0730 to 1700 Monday to Friday. Requests outside of normal business hours will require prior approval from the Nurse Manager Janet King or Kim Haugh the charge nurse.

Please do not have a participant arrive without a scheduled appointment. While it is not acceptable for us to have to turn a participant away, this could occur if we do not have a scheduled visit, orders and coordinator is not here.

All orders worksheets and R99 billing forms must be signed or have an electronic signature, dated and timed by the MD or licensed provider prior to your participant's arrival to ensure timely conduct of the study visit. Orders worksheets should be brought to the unit well in advance of there appointment by providing to the nursing staff or placing in the drop off file located in the nurse's station. If unable to bring the orders worksheet to the unit they may be faxed (352-294-5899) or emailed to the following staff; Kim Haugh garrek@shands.ufl.edu, Jamie Thomas thomjn@ufl.edu **and** Janet King jking1@ufl.edu.

If you are using a **Central lab, kits should be provided by the day before your participants visit** to facilitate accurate protocol driven laboratory activities.

Scheduling a Visit for Your Participant

To request a study visit, use the "UF CRC Online Admission Request" link on the bottom of the Clinical Research Center home webpage: http://www.ctsi.ufl.edu/research/uf-clinical-research-center/. You will also find a tutorial on scheduling requests on this same page.

Please provide participant demographics when scheduling visits. This information is used in reporting to the National Institutes of Health (NIH).

If your participant does not have a Medical Record Number, use the "Request for Medical Record Number Form" (page 5 of this document) to obtain a Shands medical record number if your subject does not have one. Email the form to Becki Mullins in admissions, mullib@shands.ufl.edu.

Consents:

All research participants must be consented prior to initiating protocol activities. One signed copy of the informed consent form (ICF) is given to the research participant and a copy of the title page and signature page(s) are placed in the UF CRC chart. You will retain the original ICF for your subject files.

Parking:

Participant parking is located adjacent to the Clinical and Translational Research Building (CTRB) on the first floor of the parking garage. There are reserved spaces with "Blue" signage for participant parking. White parking passes can be obtained from the UF CRC to be given/sent to your participant prior to their appointment. The passes are to be placed on the dash of their vehicle with the date of the visit in bold marker.

Link to Google Maps Parking and directions map

UFCRC Dietician:

Plan to meet with the UF-CRC Dietician, Jean Michelson @ jmichelson@ufl.edu , if your study requires any special dietary needs.
The coordinator is responsible for informing participants where to obtain food. "Jimmy Johns" and frozen meals available if budgeted for your study.

UFCRC Core Laboratory:

Plan to meet with the UF-CRC Laboratory Technician, Tomy Mathew 294-5896 tomathew@ufl.edu to discuss logistics of any labs sent to outside laboratories, other lab requirements and specimen retrieval. Please provide a copy of the laboratory manual for your study if available.

Shands Clinical Laboratory:

If you have blood tests that will be run at Shands Clinical Laboratory you will need an R99# form for billing of these tests to the study. You will need to email lab administration at LabCustomerService@shands.ufl.edu. You will need to provide a list of tests, PI, contact name and contact information. Please provide the filled out yellow R99 form or a printed copy of the EPIC orders at the time of blood draw.

PROCEDURE FOR SPECIMEN PROCESSING AND RETRIEVAL

1. Specimens will arrive at the UF- CRC Sample Processing Lab labeled with the following information:
    a. Patient's first and last name
    b. Patient's Medical Record number
    c. IRB # and/or CRC Protocol #
    d. Date
    e. P.I.'s Name
    f. Time (optional)
    g. Time Interval (optional)
    h. Study Assigned Number (optional-if blinded)
    i. If the study has pre-labeled kits, follow the kit instructions to label the tubes and aliquots. Please have this done prior to arrival to CRC.
2. Specimens stored in the –80^{o} C freezer on the CRC is intended for short term storage up to 2 weeks.
3. Specimens stored in the refrigerator can be stored in their original tubes or urine specimen container.
4. Should you have a need to store a specimen in a container provided by the study or by a drug company, please contact Tomy Mathew, Sr. Med. Technologist at 294-5896 to ensure that the container will fit in our storage boxes.

5. In the event that either the P.I., Study Coordinator or any study personnel are blinded to the patient identification, please contact Tomy Mathew, Sr. Med. Technologist at 294-5896 so that we may help you in any way possible to facilitate your storage of samples in the CRC Sample Processing Lab.
6. If specimen labels are provided by the study or drug company, it is your responsibility to contact any of the above name persons to ensure that these labels comply with HIPAA guidelines and CRC Policy. If they contain any unaccepted patient identifiers, they will not be used.
7. Retrieval of your specimens can be obtained in the following manner:
    a. Retrieval of specimens occurs Monday through Friday, from 0800 – 1600. There is no exception to this policy.
    b. Please notify the CRC Sample Processing Lab personnel at 294-5896 at least 24 hours prior to the desired time you wish to pick up your specimens. This will give them adequate time to retrieve the specimens accurately.
8. If there are any questions regarding the processing, storage or retrieval of your samples, please contact any of the above name persons at 294-5896 or 294-5900 prior to start of your study so that we me make this an accurate and straightforward process.

INVESTIGATIONAL DRUG SERVICE: IDS@shands.ufl.edu

The Investigational Drug Service serves the drug accountability needs of the UFCRC. Please contact the Investigational Drug Service Pharmacist pager #1-800-758-0830 office #4-4716 (Shands North Tower) or 294-5894 (CTRB) to determine how they may assist you with handling, ordering, and managing your drug/test articles. They are located in the ground floor of the main hospital building across from the main pharmacy and at the CTRB 1st floor, in the UF CRC.

- The MD orders for the investigational drug and other medications allowed per protocol are to be entered into EPIC by the MD, ARNP or placed and pended by the study coordinator (MD or ARNP will need to sign the pended order). The Investigational Drug Pharmacist will make a template for your study medications that will enable you to access your order set by Protocol name, IRB# or CRC#. The Investigational Pharmacy order does not include the subject's own medications. Please work with the Pharmacist to determine how much lead time is necessary for your particular study.
- If your study requires that any unused medication, empty medication containers or medication labels BE SAVED, please inform the RN staff, and include this important information in your MD orders.

Request for Medical Record Number

Name	
Address	
Telephone	
DOB	
Race	
Gender	
SSN	
Language	
Marital Status	
	Please email this form to Becki Mullins in admissions to obtain MRN: (mullib@shands.ufl.edu)