STARTING A PROTOCOL WITH THE UF CLINICAL RESEARCH CENTER
TIP SHEET FOR INVESTIGATORS AND COORDINATORS
Updated 06/30/17

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

RN PROTOCOL LIAISON:
Once your protocol is approved by both the IRB and SAC, you will need to set up a time to meet with Robyn Brunson (294-5900 or brunsr@shands.ufl.edu) to discuss the protocol, order worksheets, and set up an in-service for the staff on the UF CRC.

UF CRC Protocol Review Process

Protocol Submissions:

- Include:
  - Complete Protocol
  - Draft/Approved ICF (Informed Consent Form)
  - UF CRC Request for Services Form
    - https://www.ctsi.ufl.edu/files/2010/12/CRC-Request-for-Services-form_FINAL_02.03.2017.pdf
- Submit to April Braxton, abraxton@ufl.edu or Janet Wood, janetksherwood@ufl.edu

Protocol Review Process:

- Pilot Protocols receiving CTSI, department or private funding will be referred for Scientific Advisory Committee review, including a biostatistics review
  - The SAC meets the third Thursday of each month
- Peer review protocols that have received an acceptable CRC Mangers review and a prior scientific review, such as an industry or federally funded protocol, will be administratively approved by the SAC Chairman

OUTPATIENT VISIT:

Scheduling outpatient visits is required at least 24 hours in advance.

Approval of scheduling request is 24-72hrs. You will receive an email confirmation of receipt of your request and a follow-up email of approval or denial of your request once it has been processed. Requests received after 4 p.m. for visits the following day will be denied. Last-minute scheduling should be done by phone (294-5900) to Kim Garrett, Charlie Church, or Janet King in addition to on-line scheduling.

All worksheets and orders must be signed, including date and time, by the MD for your study and be available (faxed is ok) 24 hours prior to your patient's visit. FAX: 352-294-5899. If your study uses blood collection kits from a central lab, we ask that these are brought to the CRC lab the day before as well.

CRC hours are 7:30 a.m. to 5 p.m. Monday to Friday.

SCHEDULING YOUR PARTICIPANTS:

To request a study visit, use the "UF CRC Online Admission Request" link on this page: http://www.ctsi.ufl.edu/research/uf-clinical-research-center/. You will also find a link to a tutorial for making these requests on the same page.

To view subjects you have scheduled, visit: https://webcamp.ctsi.ufl.edu/SourceCode/Login.cfm. Log into WebCAMP with a temporary password that will be sent to your email.

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.

Please include race and ethnicity when scheduling participants. This information is included in our NIH reporting.

CONSENTS:

All research subjects must be consented prior to initiating protocol activities. One signed copy of the informed consent is given to the research subject and another copy is placed in the UF CRC chart. You will retain the original for your subject files.

RESEARCH SUBJECT ADVOCATE

The role of the Research Subject Advocate is to maximize the safety and promote the rights and welfare of all research subjects on the UF CRC. Our Research Subject Advocate, Robert Kolb RN, is available Monday thru Friday 8 a.m. to 4 p.m. He can be reached at kolbhr@ufl.edu or 352-273-8882

Parking:

Participant parking is located adjacent to the Clinical and Translational Research Building (CTRB) on the first floor of the parking garage. Spaces reserved for participant parking are marked with light-blue signs. 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. (Maps and directions are available in the UF CRC if needed).

UF CRC 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 if the standard "Jimmy Johns" meal was not budgeted.

UF CRC 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 Connie Prats in lab administration at LabCustomerService@shands.ufl.edu. You will need to provide a list of tests,
PI, contact name and contact information. This information will be needed for your RAC submission.

UF-CRC-SPL - 01: POLICY AND PROCEDURE FOR SPECIMEN PROCESSING AND RETRIEVAL

PURPOSE: To assure accurate and consistent collection and retrieval of patient specimen and data.

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 CRC Protocol numbers
    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.

2. Specimens stored in the -80^{o} C freezer will be stored in 2cc, 3cc and 30cc cryotubes and labeled with Freezerworks Unlimited labels (We are transitioning to OnCore labeling used by biorepository). Storage on the CRC is intended for short-term storage up to two weeks.

3. Specimens stored in the refrigerator can be stored in their original tubes or urine specimen container however; their original label will be removed and replaced with a Freezerworks Unlimited label (OnCore).

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 insure 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.
    a. At the time of specimen retrieval, we will print a list of the samples you are receiving with the appropriate information to link the barcode to the patient. If you are blinded, again, please notify us so that we can print a special report that contains no identifying information except your study assigned number.

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 insure 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 8 a.m. to 4 p.m. There is no exception to this policy as there is no one available to log the specimens out and print reports.
    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 and print a list of the samples you will be picking up.

8. If there are any questions regarding the processing, storage or retrieval of your samples, please contact any of the above named persons at 294-5896 or 294-5900 prior to the start of your study so that we may make this an accurate and straightforward process.

INVESTIGATIONAL DRUG SERVICE:

The Investigational Drug Service serves the drug accountability needs of the UF CRC. The Pharmacists are Susan Beltz and Melissa Johnson. 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 first 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 number or CRC number. 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)