Getting started at MHealth CRU

1) Enter Request for Services through CTSI Portal.
    a. Be sure to use assigned protocol number if already registered in Portal/Oncore
    b. Protocol is required to be uploaded. Does not have to be IRB approved yet, but will eventually need to upload IRB approval and approved ICFs
2) Once approved (usually within a week) study staff will receive a confirmation email containing templates for source docs and lab processing instructions and instructions for next steps.
3) If study staff is new to CRU, may set up a meeting to discuss needs of the study and provide a tour of the clinic
4) Study staff will create source docs and lab processing instructions and send to CRU contact provided in confirmation email. For sponsored studies, study staff may send lab manual and CRU MLT will make processing instructions in preferred format.
    a. Once drafts have been shared with CRU, a 30-day turnaround period may be needed
5) Two CRU nurses will review the documents, make edits, ask questions, and send the edited source docs back to study staff for approval.
    a. CRU staff will check the source docs against the protocol, but it is ultimately the responsibility of the study staff to ensure we are being asked to perform the appropriate services at the appropriate visits
6) Once all documents are finalized, a training inservice will be held for CRU staff. This should be led by PI or CRC, usually lasts 15-60 minutes depending on complexity of services needed.
    a. Powerpoints are welcome but not required. The CRU conference room is equipped for easy connection to laptops for projection. *Currently held virtually.*
    b. The CRU will provide copies of all finalized source docs, lab processing instructions, and Protocol Training Summary
7) Scheduling access will be requested for the CRU calendar by CRU contact
    a. Only those listed as “scheduler” on the portal under Personnel tab will be able to schedule
    b. As a study member, you can add more staff to the Personnel tab. “Scheduler” role must be approved by PI.
8) Before first subject visit, the following documents must be uploaded on the Portal:
    a. Current protocol
    b. IRB application if external IRB used, site supplement to ETHOS if applicable
    c. IRB approval letter (initial + for current protocol version)
    d. IRB-approved ICFs
9) Staff training logs can be provided upon request
    a. DOA logs can be signed by Clinic Manager to cover all staff
10) For every subject visit, the following is required:
    a. MRN listed for each subject, entered in subject profile in the Portal (needed for billing)
    b. Signed consent uploaded to subject profile in Portal
    c. Visit-specific source doc (personalized to subject) uploaded to visit in calendar at least 2 business days prior to visit

Frequently Asked Questions

- All of my regulatory documents are in OnCore, why do they need to be on the Portal?
    - The Portal cannot pull documents from OnCore and CRU staff do not have OnCore access. We must be able to see the protocol and consent for reference and know that the services we are providing have IRB-approval.
- What are the clinic hours? Can I schedule a visit on the weekend?
    - The clinic is fully staffed 7a-3:30 M-F, with minimal staff until 5:30p if subjects are present. Visits beyond these hours can usually be accommodated with at least 2 week notice.
- What services can the CRU provide? What cannot be done at the CRU?
    - Yes: Vital signs, anthromopetrics, blood draws, timed PKs, drug administration (including oral, injection, IV) and monitoring, OGTT/MMTT, insulin clamps, IVGTTs, EKG, urine/sputum/stool collection, spirometry, biopsy assistance, overnight visits, short-term freezer storage (<1 month), processing/packaging/shipping (dedicated MLT 0630-1500 M-F), provide meals from Fairview during visits, transport specimens to Fairview acute care lab
    - New: SOC procedures (must be ordered in Epic)
    - Not at this time: long-term freezer storage (available on Westbank through BioNet); off-site visits
- Can you give me an estimate for my study visit cost?
    - The rates are listed on the CRU website. We don't provide quotes or estimates, but if a study needs help walking through an example of charges, please contact the clinic manager.
- Can I get a copy of my completed visit source documents?
    - Yes, we return the originals after making copies for our records and scanning it in to our secure shared drive. The originals are filed in a cabinet in a secure room.
- My subject is not a patient of MHealth, how do I get an MRN?
    - If your participant does not currently have a medical record number (MRN) or if you are uncertain if a medical record exists for your participant, you will need to call 612-263-9104 and indicate that you need to register a ***RESEARCH*** patient/participant. [NOTE: the registration staff are available, 7 am-4:30 pm M-F; off hours please leave a voicemail, if appropriate.] To register a new participant for an Epic medical record you will need the individual's: Full name, date of birth, gender, address, and phone number. A field to enter the MRN has been established in the CTR Portal Scheduling System.