SOP#: ADCR-13	**Clinical Center External Location Registration and Subsequent Activities**
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NCI Clinical Director Signature/ Effective Date:	James L. Gulley -S Digitally signed by James L. Gulley -S Date: 2023.12.10 08:42:26 -05'00'

POLICY

Some procedures for protocol eligibility and/or research may be able to take place without a participant physically coming to the Clinical Center. Any participant who consents to an NIH protocol needs to have a medical record number prior to signing the consent document. This includes field cohort participants who consent with the NIH off site consent document. For some protocols, the IRB will approve a remote consenting process as the participant may not initially, or ever, travel to the NIH. For these situations, the NIH Clinical Center (CC) allows for research participant registration from an external site.

This process is to be used for the following:

- Acquire biospecimen: This may be done as part of a separate tissue acquisition protocol or as part of an intervention protocol that allows remote consenting.
- Eligibility criteria that require NIH/NCI pathology confirmation or official radiology read of scans: This would include requesting blocks/slides from an outside pathology department or requesting a CD for official read from an outside radiology department.
- Any other procedure that will take place prior to a research participant coming to the Clinical Center.
- Telehealth consults

The external location registration process may be completed by the Clinical Research Coordinator (CRC) or Patient Care Coordinator (PCC).

After the external location registration process is completed, the research informed consent process may take place. An External Location Registration Note must be completed in CRIS within 30 days of external location registration per Clinical Center policy.

PURPOSE

The purpose of this standard operating procedure is to provide instructions for external site research participant registration with the NIH Clinical Center including appropriate documentation of the process.

RESOURCES

- Health Information Management Department (HIMD) External Location Registration Resources and Forms
- Secure Electronic Communications Methods with Patients (on the bottom left of the HIMD website)
- Admissions, Travel and Vouchers (ATV) website and Quick Reference Guides
    - Patient Travel Toolkit
- EXT-LOC Process webinar recording – located on the CCR SOP website

PROCEDURES

For the instruction on the external location registration process, please refer to Health Information Management Department (HIMD) External Location Registration Resources and Forms.

Subsequent Activities:

- Protocol Specific Informed Consent Process/Documentation
    - For the information on the informed consent process, please see CCR SOP PM-2: *Obtaining and Documenting the Informed Consent Process (Adult and Pediatric)*
- Document Sample(s)/Scans Received
    - Obtain/request samples/scans per protocol.
    - Document sample/scan acquisition in CRIS using "External Location Registration Note"
        - This note can be found under the "Documents."
        - This allows you to document information about the sample(s) received. Participant will remain in EXT LOC status.
        - You do NOT need a co-signature on this note.