POLICY

Any individual who consents to an NIH protocol will need to have a medical record number prior to signing the consent document. For some protocols, the IRB will approve a phone consenting process as the participant may not initially, or ever, travel to the NIH. For these situations, the NIH Clinical Center (CC) allows for off-site research participant registration. 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 telephone consenting.
- Eligibility criteria that require NIH/NCI pathology confirmation or review of scans. This would include requesting blocks/slides from an outside pathology department or requesting a CD for review from an outside radiology department.

PURPOSE

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

RESOURCES

- Patient Travel Toolkit
- MAS Policy M08-1: Reimbursement of Travel and Subsistence Expenses for NIH Clinical Research Protocol Participants
- Admissions, Travel and Vouchers (ATV) website and Quick Reference Guides

PROCEDURES

Step 1: Gather the required forms

Note: These forms cannot be modified. No crossing out of words or phrases or rewriting language on the form.
SOP#: APCR-13

Adults

- Research Participant Off-Site Registration Form
  - Obtain from the CC Admissions Office
- General Admission Consent Form (NIH-1225-1); Spanish version (NIH-1225-1SP)
- Information Practices Form (NIH-2753); Spanish version (NIH-2753-SP)

Pediatrics

- Research Participant Off-Site Registration Form
- General Admission Consent Form (NIH-1225-1), Spanish version (NIH-1225-1SP)
- General Admission Consent Addendum Form (patient name and legal guardian certification sections only) (NIH-1225-2); Spanish version (NIH-1225-2SP)
- Information Practices Form (NIH-2753); Spanish version (NIH-2753-SP)
- Statement of Relationship to Child (Required to determine relationship to child and if there is a sole or joint custody arrangement or person is not a legal guardian) (NIH-2812); Spanish version (NIH-2812-SP)

**NOTE: See step 1a before completing off-site registration**

**Step 1a: For pediatric participants: Determining Parent/Legal Guardian**

- The research nurse/team needs to determine what the family structure is before off site registration can proceed.
- Scenario 1: If the biological or adoptive parents are divorced or legally separated and if there is sole or joint custody court document for medical decision making, the court documents will need to be sent via secure email to CC Admissions at CCAdmissionsLeadership@cc.nih.gov.
  - CC Admissions will forward to NIH Office of General Counsel (OGC) to determine if only one or both parents have to sign the General Admission Consent and Information Practices Form.
- Scenario 2: If patient has a legal guardian, the court guardianship documents will need to be sent via secure email to CC Admissions at CCAdmissionsLeadership@cc.nih.gov.
  - CC Admissions will send an e-mail with the documents attached to the NIH OGC and will copy the member of the team that contacted them.
- Once it is clear who the appropriate Legally Authorized Representative(s) (LAR) is, proceed to step 2.

**Note:** Allow at least 3 days for review by OGC
Step 2: Form Review and Completion

- Send the forms to the participant via fax, email or mail.
- Once the participant has received the documents, the research nurse or patient care coordinator (PCC) should review all the forms with them and instruct them on how to complete and return the forms. Forms may be returned via secure fax #, by mail, or by email using the Medical Secure Email application.
  - Off-Site Registration Form may be completed by the research nurse/PCC. Patient doesn’t need to sign this form. **Note:** Only * items are required fields. All information on this form is entered into the CRIS Admission fields.
  - Review with participant/LAR the General Admission Consent form and Addendum form (pediatrics only):
    - Participant is to provide his/her legal name, i.e. no nicknames. Please include middle name and if none, write none.
    - Remind the participant/LAR to sign all appropriate places and their signatures must be legible.
    - The participant/LAR does not need to obtain a witness to his/her signature.
    - Once the form has been returned (via fax or mail), the witness information must be completed by an NIH employee (federal or contractor):
      - The witness signature line can be completed as follows: “Consent obtained by phone.”
      - The person who informed the participant about the consents should sign/date and print his/her name and write the Institute. **Note:** The date is the date of the phone conversation not that date forms are received.
  - Statement of Relationship to Child form (for pediatrics only)
  - Review the Information Practice consent form:
    - Review with potential participant who will have access to medical record information.
    - Discuss email communication and if they would like to do that, make sure they know to check the box and the bottom of the page and provide their email address and they will then have to sign one more time. At the bottom of the form they can select to have secure communication via email.
    - Remind the participant/LAR to sign all appropriate places and that all signatures must be legible. The participant/LAR needs to provide a witness to his/her signature.
• All forms are to be reviewed for completeness; work with the participant to ensure completeness.

Step 3: Admission Travel Voucher (ATV) Entry
• Once all forms are complete, enter an ATV Admission request to obtain a MRN. Note: insert in Remarks Section “off-site registration”
• Print the Electronic Admission Request from the Admission/Travel/Voucher (ATV) system.
• See Admissions, Voucher and Travel (ATV) website for more information

Step 4: Informing CC Admissions Office
• Once the ATV request has been submitted, provide the ATV request and all the completed/signed forms/consents to Cheryl Swinson, Sue Parada or Karen Kaczorowski. This can be done either via secure fax (301-402-0664) or hand delivery. If sending by fax, please notify, Cheryl, Sue or Karen that you are sending the information by fax.

   **NOTE:** If this step is not done, patient stays in pre-admit status.

• If the ATV form is sent electronically prior to Admissions receiving the packet of completed forms, please write in the Remarks Section “Off-site labs only – consents will be sent to Admissions”.

• The participant’s information will be entered into CRIS that evening and placed in a pre-admit status. The research participant will not be activated or officially admitted in CRIS until all the completed forms have been given to Admissions.

• The date of Admission (Outpatient Registration) will be the date the consent forms are received by CC Admissions.

Step 5: Protocol specific consent process
• Obtain the informed consent document for the specific study
• Consent via phone as per IRB approved protocol
• Remind the participant/LAR to legibility print name and sign all appropriate places. Note: Signatures must be legible.
• The participant/LAR needs to provide a witness to their signature.
• Once the signed consent is returned, the Investigator can print, sign and date (using the date of the discussion).
• Send the signed protocol consent documents to medical records for upload into CRIS
Step 6: Documentation Consent in CRIS

- Document the consent process using the Informed Consent structured progress note entitled “Documentation of Consent”.

Step 7: Obtain samples/records

- Obtain/request samples per protocol
- Document sample acquisition in CRIS using “First Registration Outpatient Report: Tissue Specimen Only”.
  - This note can be found under the “Prescribers notes”.
  - This allows you to document information about the sample/records and will keep the patient active in CRIS.
- Route to a care provider LIP (i.e., MD, DO, NP, PA) for co-signature.