POLICY

Research participants who sign an informed consent document for any Center for Cancer Research (CCR) protocol, including multi-site studies, are considered enrolled in that clinical research study at the time of consent.

Participants that sign an informed consent document for a research protocol at the CCR are required to be registered via the CCR Central Registration Office (CRO). Registration notification is required to be completed within 24 hours of the participant signing the consent document and will be completed by the CCR Study Coordinator. Registrations received after 5pm ET will not be processed until the following business day. If written consent is obtained via telephone, registration is required within 24 hours of the receipt of the signed consent document.

Participants MUST have a Medical Record Number (MRN) prior to registration and this number MUST be included on the registration form. See SOP ADCR-13 “Off-Site Patient Registration” for more information on how to obtain an MRN for patients who may not be coming to the Clinical Center (CC).

There will be two options associated with CRO registration: 1-step or 2-step:

- A 1-step registration process will be used when ALL eligibility is assessed under one screening protocol (e.g., 01-C-0129).
- A 2-step registration process will be used when a screening protocol will not be used solely to determine eligibility (i.e., two consents for treatment protocol where one of the consent documents is assessing partial screening in addition to a screening protocol OR one consent is used for both screening and treatment).

The protocol will specify the registration procedures required for the study. If the protocol requires registration via OPEN, IRSW, or other sponsor-specific system, the external registration process MUST occur prior to CRO registration; this will allow the CRO to obtain the accurate unique study-specific subject ID.

Participants must be registered for each protocol for which consent is signed.

For treatment protocols, treatment should begin within 72 hours (or three business days) of participant registration, unless otherwise specified in protocol.

The CRO must be notified of a change in a registered participant’s status within 5 business days of the study team becoming aware of the change. Examples of change in status include: screen failure, meets off treatment criteria, meets off study criteria, or death.

For multi-site protocols when CCR is the Coordinating Center see SOP: MI-3.
PURPOSE
To describe the steps required to register a research participant on a CCR protocol via the CRO using a protocol-specific eligibility checklist.

RESOURCES
- Center for Cancer Research Central Registration Office homepage
- CRO Help Line 240-760-6080
- Email “NCI Central Registration Office” (located in the global address book).
- CRO hours of operations: 8:30am-5:00pm, Monday-Friday, excluding federal holidays.

PROCEDURE: PARTICIPANT REGISTRATION

Step 1: Access CCR Central Registration Office (CRO) homepage
Enter the following URL in a browser (Internet Explorer or Firefox) to access the CCR Central Registration Office homepage: http://intranet.cancer.gov/ccr/welcome.htm

Step 2: Access protocol registration Eligibility Checklist
- Click on branch to access an index of open protocols per branch.
- Click on the desired protocol number to access the registration Eligibility Checklist.

Note: The Expanded Access IND registration Eligibility Checklist is found on the CRO homepage.

Step 3: Complete the registration Eligibility Checklist

Step 3a: One-step Registration Process:
- Verify that the registration Eligibility Checklist has the same amendment version letter as the current informed consent document.
- Open the protocol registration Eligibility Checklist and do one of the following:
  - Complete the checklist online, print and scan
  - Complete the checklist online and print to Adobe to save as a pdf
  - Insert the checklist in an email and complete – see Appendix A

Step 3b: Two-step Registration Process:
- Verify that the registration Eligibility Checklist has the same amendment version letter as the current informed consent document version letter.
  Registration Step 1:
  - Open the registration Eligibility Checklist, complete as above Step 3a.
  - Complete the top portion of the registration Eligibility Checklist through Registration step 1 and indicate that the participant is being registered for screening.

Registration Step 2: Once eligibility is confirmed after completion of screening procedures, open a new registration Eligibility Checklist for the protocol and complete as above Step 3a.
  - Complete the entire form and indicate that the participant is being registered for treatment.
  - Participants that do not meet the eligibility criteria should be removed from the study following procedure for Participant Status Updates (see below). This second step of registration is not necessary.
IMPORTANT: Regardless if the registration process is one-step or two-step:

- All responses must be complete and accurate for the registration to be processed by the CRO Staff.
- The registration Eligibility Checklist must contain a MRN or the form will be returned by the CRO.
- Research team member name on bottom of registration Eligibility Checklist signifies that the information has been verified by the team member.
- Registration must occur within 24 hours of the participant signing the informed consent document. If using the telephone consent process, registration must occur within 24 hours of receiving the signed informed consent.

Step 4: Send the completed registration Eligibility Checklist to the CRO

- Send completed registration checklist via encrypted email to “NCI Central Registration Office” (located in the global address book)
  
  NOTE: Encrypted emails can be sent from any computer in the Clinical Center using a PIV card with an active encryption certificate.
- Any emails received by the Central Registration Office after 5pm will be processed the next business day.
- The CRO prefers that completed registration Eligibility Checklists be sent via email. This will allow for registrations to be processed in a timely fashion.

Step 5: CRO Review of registration Eligibility Checklist for completeness and accuracy

- The CRO will:
  
  o Review the registration Eligibility Checklist for completeness and accuracy.

  Note: The CRO has the responsibility of protocol assignment in CRIS.
- For treatment protocols, if the registration Eligibility Checklist is complete and accurate, the CC pharmacy will be informed of the registration by the CRO and investigational product(s) will be released.
- If the registration Eligibility Checklist is incomplete or inaccurate, the CRO will contact the person registering the participant to resolve the issue(s). NOTE: The CC Pharmacy will not be notified of registration until the issues are resolved. No investigational product(s) will be released until that time.

Step 6: Confirmation of registration will be sent to the study team member

- A confirmation e-mail will be sent to the team member who registered the patient acknowledging the patient has been registered and the CC pharmacy has been informed, if applicable.
  
  o For treatment studies, a Verification of Registration form will be sent which will include the participant’s unique study ID number. Note: For studies in C3D, this number will be the number to use in C3D.
  
  o For non-treatment studies, the confirmation email will contain the participant’s accrual number.
- Randomized Studies: The randomized treatment assignment will be provided on the Verification of Registration form.
- Masked studies: The sequence number will be provided on the Verification of Registration form.
PROCEDURE: PARTICIPANT STATUS UPDATES
When there is a change in a registered participant’s status (i.e., screen failure, meets off treatment criteria, meets off study criteria, or death), the CRO must be notified within 5 business days of the study team becoming aware of the change.

Step 1: Access and complete Participant Status Update Form
Enter the following URL in a browser (Internet Explorer or Firefox) to access the CCR Central Registration Office homepage: [http://intranet.cancer.gov/ccr/welcome.htm](http://intranet.cancer.gov/ccr/welcome.htm)
- Form is located on the left side of the CRO homepage.
- Open form and do one of the following:
  - Complete the checklist online, print and scan
  - Complete the checklist online and print to Adobe to save as a pdf
  - Insert the checklist in an email and complete – see Appendix A

Step 2: Send completed Participant Status Update Form
- Send completed form via encrypted email to “NCI Central Registration Office” (located in the global address book)
- Any emails received by the Central Registration Office after 5pm will be processed the next business day.
Appendix A

Sending Eligibility Checklists Directly to CRO via Email

Instead of printing and scanning completed registration Eligibility Checklist to send to CRO via email, there is an option to insert the registration Eligibility Checklist into an email, complete the checklist and send to the CRO via encrypted email. To do this, the correct toolbar options must be set on Internet Explorer browser.

Step 1:

If Internet Explorer browser does not have “File”, “Edit”, “View”, etc. listed at the top, right click in that area and click “Menu Bar” as option.

Step 2:

Open correct protocol registration Eligibility Checklist as in Step 2 above. Once open, Click on “File”, select “Send”, then “Page by Email.”
Step 3:
The registration *Eligibility Checklist* will be inserted into the text of an email. The *Checklist* can be completed in the email and sent encrypted to “NCI Central Registration Office”.

![Image of email process]

Protocol: 12-C-0807G
P.I.: Mark Buckner, M.D.
Lymphoid Malignancy Branch (LMB)

**Eligibility Checklist**

- **Patient Information**
  - Last Name [ ], First Name [ ]
  - Patient Medical Record Number [ ]
  - Date of Birth [ ]

- **Race**
  - [ ] White
  - [ ] Black or African American
  - [ ] Asian
  - [ ] Native Hawaiian or Other Pacific Islander
  - [ ] American Indian or Alaskan Native
  - [ ] Hispanic
  - [ ] Multi Race

- **Time Procurement Questions**
  - [ ] Did the participant consent to Time Procurement for cancer research? [Y] Yes [N] No
  - [ ] Did the participant consent to Time Procurement for non-cancer research? [Y] Yes [N] No
  - [ ] Did the participant consent to having someone contact them in the future for new research not included in this consent? [Y] Yes [N] No

*Patient declined to answer questions pertaining to the Time Procurement.*