SOP#: MI-3	**Non-NIH Site Participant Registration & Status Update**
Version #: 3.1	**Next Review Date: 05/2026**
Approved Date: 05/2024	**Review Interval Period: Biennial**
NCI Clinical Director Signature/ Effective Date:	James Gulley, M.D., Ph.D. Digitally signed by James Gulley, M.D., Ph.D. Date: 2024.05.22 14:50:12 -04'00'

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 a clinical research study at the time of consent.

All participants at the non-NIH site(s) that sign an informed consent document for a research protocol at the CCR are required to be registered via the CCR Patient Registration and Enrollment System (PRES). When the CCR is the Coordinating Center for a multi-site study, the CCR Clinical Research Coordinator (CRC) is responsible for the registration of participants from non-NIH sites. A 2-step registration process will be used. Non-NIH sites will submit the registration form and notify the CCR CRC within **one business day** of participant signing the consent document.

Once the non-NIH site notifies the CCR CRC, the CCR CRC has **two business days** to complete the registration notification via PRES.

The CCR SC must be notified by the non-NIH site of any change in a registered participant status within **5 business days** of the non-NIH site becoming aware of the change. CCR SC must then update PRES within **5 business days** of becoming aware of the change. Examples of change in status are: screen failure, reconsent, meets off treatment criteria, meets off study criteria, death.

For Experimental Therapeutics Clinical Trials Network (ETCTN) protocols where the CCR is the corresponding organization, non-NIH sites will not register participants in PRES.

Important: Email communication between the CCR SC and non-NIH sites that contains Personally Identifiable Information (PII) must be sent encrypted via Outlook or the NIH Secure E-mail and File Transfer Service (SEFT) – see Resources.

PURPOSE

To describe the steps required to register a research participant in PRES from a participating non-NIH site when the CCR is the Coordinating Center.

RESOURCES

- CCR Policies/Standard Operating Procedures website
  - ADCR-2: *CCR Participant Registration & Status Updates*
- CCR Supplemental Guidance for the Use of NIH Secure Email File Transfer (SEFT)

PROCEDURE: PARTICIPANT REGISTRATION

STEP 1: Provide the registration and status change forms to non-NIH site

- The CCR CRC is responsible for providing all non-NIH sites with the *NCI Center for Cancer Research Participant Registration Form* and *NCI Center for Cancer Research Participant Status Change Form* located under this SOP.

STEP 2: Non-NIH site Registration Step 1

- Within one business day of the research participant signing the informed consent document, the non-NIH site will complete the *NCI Center for Cancer Research Participant Registration Form* and send to the CCR SC via **encrypted email**.
    - Signed page of the informed consent document must also be sent to verify enrollment.
    - If the consent contains any embedded questions that the research participant must answer, that page(s) containing participant responses must also be sent.

Note: Information sent by the non-NIH site must be maintained by the CCR SC as a research record on the team's protocol shared network.

- The CCR SC will send an email confirmation to the non-NIH site that the form was received. The CCR SC will register the participant in PRES within 2 business days of receipt of registration form (see ADCR-2).

  Note: The non-NIH site informed consent document signed by the participant specifies that PII will be shared with NIH; therefore, the non-NIH site can provide PII, including date of birth and local medical record number, required on the Registration Form. The participant has agreed to share PII with NIH.
- The question in PRES regarding eligibility may be answered "No" at this point.

STEP 3: Registration Step 2 - Verification of eligibility

- Once eligibility is confirmed by the non-NIH site, the site will send an email to the CCR SC indicating that the participant meets eligibility criteria.

Note: Information sent by the non-NIH site must be maintained by the CCR SC as a research record on the team's protocol shared network.

- Once the email confirming eligibility is received, the CCR SC will update PRES within 2 business days to indicate participant is eligible.
- If participant is not eligible see procedure below to remove them from the study as a screen failure.

STEP 4: Notify non-NIH site of participant's registration

- The CCR SC is responsible for providing registration information to the non-NIH site. This includes the unique participant number for the study database, if applicable.
- The non-NIH site is responsible for notifying their local pharmacy of participant registration/randomization, if applicable.

PROCEDURE: CHANGE IN PARTICIPANT STATUS

When there is a change in a registered participant's status (i.e.: screen failure, reconsent, meets off treatment criteria, meets off study criteria, death), the non-NIH site must notify the CCR SC within 5 business days of becoming aware of the status change. The CCR SC must update PRES within 5 business days of becoming aware of the change.

Non-NIH site will complete *NCI Center for Cancer Research Participant Status Change Form*

- When there is a change in participant status (fails screening, reconsent, meets off treatment criteria, meets off study criteria, death), the CCR CRC must provide *NCI Center for Cancer Research Participant Status Change Form* to the non-NIH site.
- Non-NIH site is responsible for completing the form and returning to the CCR SC via **encrypted email** within 5 business days.
- CCR SC is responsible for sending an email confirmation to the non-NIH site that the form was received.
- The CCR SC will update the participant status in PRES within 5 business days of receiving the status change form (see ADCR-2).