SOP#: ADCR-2	**CCR Participant Registration & Status Updates**
Version #: 5.2	**Next Review Date: 09/2026**
Approved Date: 09/2024	**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: 2024.09.23 10:29:12 -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 that clinical research study when both the participant (or legally authorized representative) and the Investigator have signed the consent document. This includes field cohort participants who consent with the NIH offsite consent document.

Patient Registration and Enrollment System (PRES) is the system used for participant registration and status updates. This system is integrated with other databases, so it is important to have accurate information in PRES (e.g., cohort, arm, disease name). Prior to accessing the system, training must be completed, and the user must sign a confidentiality agreement.

Participants that sign an NIH protocol informed consent document (including field cohort participants that sign an NIH offsite consent) are required to be registered within 2 business days of the participant signing the consent document If written consent is obtained via telephone using a paper consent document, registration is required within 2 business days of the receipt of the signed consent document. Registration will be completed by the CCR Clinical Research Coordinator (CRC) or an Investigator.

Part of PRES includes information about embedded agreements for storage and future use of research samples/data. These must be completed at the time of registration and updated if needed during the re-consent process.

Participants that are seen, or use services, at the Clinical Center **MUST** have a Medical Record Number (MRN) in order to be registered via PRES. See SOP ADCR-13 *Clinical Center External Location Registration* for more information on how to obtain an MRN for participants who may not be coming to the Clinical Center (CC). Field cohort participants who sign an NIH offsite consent document will also need a medical record number. This will ensure that the following can be used as needed: iMed consenting process, telehealth via NIH approved platform, and the Cryacom language line for non-English speaking participants.

If the protocol requires registration via OPEN, IRSW, or other sponsor-specific system, the external registration process MUST occur prior to PRES registration; this will allow PRES to obtain the accurate unique study-specific subject ID assigned by the external system.

Participants must be registered for <u>each</u> protocol for which a consent is signed.

When the participant's status changes, the status change needs to be entered within **5 business days** of the research team becoming aware of the change.

For multi-site protocols when CCR is the Coordinating Center see SOP: MI-3.

PURPOSE

To describe the process used to register a research participant on a CCR protocol using the Patient Registration and Enrollment System (PRES).

RESOURCES

- Patient Registration and Enrollment System (PRES)
  - PRES User Manual
  - PRES Login
- PRES support email: ncipres@nih.gov
- CCR Standard Operating Procedures
  - ADCR-13: *Clinical Center External Location Registration*
  - MI-3: *Multi-Institutional: Participating Site Participant Registration & Status Update*

PROCEDURE: Training and Accessing the Patient Registration and Enrollment System (PRES)

1. Initial users will review the PRES training video and the PRES User Manual
2. Review and sign the confidentiality agreement located below this SOP.
3. Request access to system via email ncipres@nih.gov and attach the signed confidentiality agreement.
4. Refer to the support link at the bottom of every PRES form, or email ncipres@nih.gov for the questions and support.

PROCEDURE: Participant Registration

1. CRC or investigator will register the participant within 2 business days of consenting. Refer to PRES User Manual for details.

Note: If unsure about how to complete the embedded agreement information, please contact CCR OEC for assistance.

PROCEDURE: Participant Status Updates

1. Patient registration must be updated in PRES by the CRC or investigator within 5 business days when the following events of significance occur:
   a. Re-Consent
   b. Crossover
   c. Off-Treatment
   d. Off-Study
2. Refer to the PRES User Manual for instructions.
3. Email ncipres@nih.gov for questions and support.