

**SOP#: ADCR-2**

**CCR Participant Registration & Status Updates**

**Version #: 5.0**

**Next Review Date: 12/2025**

**Approved Date: 12/2023**

**Review Interval Period: Biennial**

**NCI Clinical Director Signature/**

**Effective Date:**

## **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 off site consent document. Participant registration and status update is completed via Patient Registration and Enrollment System (PRES).

Participants that sign an NIH informed consent document for a research protocol conducted by the CCR are required to be registered within 2 business days of the participant signing the consent document, including signing the informed consent via iMedConsent™ Process. 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 **MUST** have a Medical Record Number (MRN) prior to registration and this number **MUST** be included on the registration form. 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).

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 each protocol for which a consent is signed.

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

When the participant's status changes, the status change needs to be entered within **5 business days** of the study 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 Guide](#)
  - [PRES Login](#)
- PRES support email: [ncipres@nih.gov](mailto:ncipres@nih.gov)
- Center for Cancer Research [Standard Operating Procedures](#)
  - ADCR-13: *Clinical Center External Location Registration*
  - MI-3: *Multi-Institutional: Participating Site Participant Registration & Status Update*

## PROCEDURE: PARTICIPANT REGISTRATION USING THE PATIENT REGISTRATION AND ENROLLMENT SYSTEM (PRES)

1. Initial users, will review the [PRES training video](#).
2. Review the PRES instruction manual for the appropriate processes for:
  - a. Searching and selecting a patient
  - b. Searching and selecting a protocol
  - c. Creating a registration
  - d. Entering embedded agreement information for storage and future use of research samples/data.

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

3. Refer to the support link at the bottom of every PRES form, or email [ncipres@nih.gov](mailto:ncipres@nih.gov) for the questions and support

## PROCEDURE: PARTICIPANT STATUS UPDATES

1. Patient registration must be updated in PRES when the following events of significance occur:
  - a. Re-Consent
  - b. Off-Treatment
  - c. Off-Study
  - d. Crossover
2. Refer to the PRES manual for instructions.
3. Email [ncipres@nih.gov](mailto:ncipres@nih.gov) for the questions and support.