**POLICY**

Food and Drug Administration (FDA) regulations require IND sponsors to select qualified investigators. NCI policy requires all persons participating in any NCI-sponsored clinical trial to register and renew their registration annually. Registration is accomplished via the NCI Registration and Credential Repository (RCR).

**RESPONSIBILITY**

All persons participating in any NCI-sponsored clinical trial

**GUIDELINES**

The RCR is available for the electronic submission of NCI registration documents by clinical research personnel participating on NCI-sponsored clinical trials. The RCR system, in combination with other NCI Clinical Oncology Research Enterprise (CORE) applications, ensures real-time updates to control trial activities and system access. The RCR meets FDA regulatory requirements while maintaining an annual registration submission cycle to allow investigators to quickly participate on research trials, increase efficiency and lower the cost of conducting clinical trials.

RCR utilizes **FIVE** registration types.

* **Investigator (IVR)**— MD, DO, or international equivalent
* **Non-Physician Investigator (NPIVR)**— advanced practice providers (e.g., NP or PA) or graduate level researchers (e.g., PhD)
* **Associate Plus (AP)**— clinical site staff (e.g., RN or CRA) with data entry access to CTSU applications (e.g., RUMS, OPEN, RAVE, TRIAD)
* **Associate (A)**— other clinical site staff involved in the conduct of NCI-sponsored trials
* **Associate Basic (AB)**— individuals (e.g., pharmaceutical company employees) with limited access to NCI-supported systems

**PROCEDURES**

**All users:**

1. Obtain your CTEP-IAM Account
2. The CTEP-IAM can be accessed at: [**https://ctepcore.nci.nih.gov/iam**](https://ctepcore.nci.nih.gov/iam)
3. Follow the RCR instructions below after receiving or reactivating your CTEP-IAM username and password.

## Additional Steps for IVR users\*

## Access the RCR system

* + Enter the RCR URL or click <https://ctepcore.nci.nih.gov/rcr> to access RCR from your browser.
	+ Enter your CTEP-IAM credentials.

## Complete Form FDA 1572

## Complete NCI Biosketch

## Complete Financial Disclosure Form

## Complete Agent Shipment Form

## Validate, Sign and Submit Registration

Additional Steps for NPIVR users\*

## Access the RCR system

* 1. Enter the RCR URL or click <https://ctepcore.nci.nih.gov/rcr> to access RCR from your browser.
	2. Enter your CTEP-IAM credentials.

## Complete Form FDA 1572

## Complete NCI Biosketch

## Complete Financial Disclosure Form

## Complete Agent Shipment Form

## Validate, Sign and Submit Registration

## Additional Steps for AP users

## Access the RCR system

* + Enter the RCR URL or click <https://ctepcore.nci.nih.gov/rcr> to access RCR from your browser.
	+ Enter your CTEP-IAM credentials.

## Complete NCI Biosketch

## Complete Financial Disclosure Form

## Validate, Sign and Submit Registration

\* IVR and NPIVR users may be assisted by a registration coordinator. This is staff at the consortium or at the affiliate that edits user profiles and tracks registration requirements. To facilitate this, investigators will be required to submit a CV annually that provides the following information necessary for RCR completion:

* Education
* Professional Training (Internship, Residency, etc.)
* Employment with start and end dates
* Professional Certification, if applicable
* Professional License, if applicable
* ABMS Board Certification with start and expiration dates

**REFERENCE:**

Cancer Therapy Evaluation Program (CTEP)

Division of Cancer Treatment and Diagnosis (DCTD)

National Cancer Institute (NCI)

National Institutes of Health (NIH)

Home Page: <http://ctep.cancer.gov/default.htm>

**ASSOCIATED FORMS:** N/A

**COMMITTEE APPROVAL:** UC Policy and Procedure Committee