

Policy Memorandum No. 7

Subject: Individual Membership Process

Departments Affected: All

Page 1 of 2 pages

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NEW INVESTIGATOR/INDIVIDUAL MEMBERSHIP PROCESS

All investigators and associates/clinical site staff involved in the conduct of NCI-sponsored clinical trials must register and create an account through the Cancer Therapy Evaluation Program (CTEP) Identity and Access Management (IAM) registration system and ID.me (which incorporates Identity Proofing (IP) and Multi-Factor Authentication (MFA) into the registration process). This CTEP-IAM user account is also required to access the Cancer Trials Support Unit (CTSU) website (<https://www.ctsuo.org/>) and other CTEP functions (e.g., CTEP-AERS). To participate in NCI clinical trials supported by the CTSU, all investigators must obtain a Cancer Therapy Evaluation Program (CTEP) — Identity and Access Management (IAM) account and register in the Registration and Credential Repository (RCR) system. The RCR is a self-service online person registration application with electronic signature and document submission capability.

CTEP-IAM Registration: <https://ctepcore.nci.nih.gov/iam/index.jsp>

CTEP-IAM Helpdesk: ctepreghelp@ctep.nci.nih.gov

~~CTEP~~ Help Desk Phone #: 703-738-9171 (Monday-Friday, 8:30am - 4:30pm Eastern Time)

Investigators and associates/clinical site staff who are significant contributors to research must also register in the Registration and Credential Repository (RCR) system. The RCR is a self-service online person registration application with electronic signature and document submission capability. A CTEP-IAM account must be obtained before accessing the RCR system.

RCR Registration: <https://ctepcore.nci.nih.gov/rcr/>

RCR Helpdesk: RCRHelpDesk@nih.gov

Help Desk Phone #: (703) 738-9171 (Monday-Friday, 8:30 am - 4:30 pm Eastern Time)

Each person registering with the NCI is assigned a Registration Type. The Registration Type that you're assigned is based on the activities that you perform while participating on NCI-sponsored clinical trials. The CTEP/RCR system utilize the following 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) who may act as study principal investigators (PI), site-protocol PIs, or enrolling PIs in OPEN for select studies
- **Associate Plus (AP)** — clinical site staff (e.g., RN or CRA) integral to the conduct of NCI-supported studies with data entry access to CTSU applications (e.g., RUMS, OPEN, RAVE, TRIAD)
- **Associate (A)** — other clinical or administrative site staff involved in the conduct of NCI-sponsored trials that require access to NCI-supported applications but act in a supporting role (ordering designees, regulatory submissions, etc.)
- **Associate Basic (AB)** — individuals that require limited access to select NCI-supported applications or are tracked for administrative purposes (i.e., industry contacts). ABs will not have access to the CTSU website or systems.

Your Registration Type will define the required information and documents that you will need to submit during the NCI registration process (i.e., FDA Form 1572; Financial Disclosure Form; NCI Biosketch; Agent Shipment Form;; Good Clinical Practice; and Optional Human Subjects Protection and CV).

Once individuals have registered in these two systems, as applicable, institutions can submit credentialing requests to add investigators to their sites through one of the following systems.

- **For NCORP institutions:** Please submit a request through the DCP NCORP-SYS Management System (<https://applications.prevention.cancer.gov/ncorp-sys/>).
- **For all other institutions:** Please submit a request through the CTSU Roster Update Management System (RUMS) application (<https://www.ctsuo.org/>). To access the RUMS application, logon to the CTSU member's

website and click the RUMS tab.

~~IVRs must complete an annual registration in RCR and electronically submit the following: FDA Form 1572; Financial Disclosure Form; NCI Biosketch; Agent Shipment Form (if applicable); Good Clinical Practice and Optional CV. Business rules require that the following information be listed on the FDA Form 1572: All practice sites by CTEP institution code; all laboratories; and all Institutional Review Boards (IRBs) responsible for reviewing NCI-supported research at the listed practice sites.~~

~~Once investigators have registered in these two systems, institutions can submit credentialing requests to add investigators to their sites through RUMS (Members, Affiliates) or NCORPSYS (NCORPs).~~