Registration and Credential Repository (RCR) Review

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PMB, CTEP, NCI

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Goals and Objectives

• Describe why the Registration and Credential Repository was implemented

• Explain requirements and how to access the RCR system
  • IAM: https://ctepcore.nci.nih.gov/iam/
  • RCR: https://ctepcore.nci.nih.gov/rcr/
NCI’s Registration and Credential Repository and Delegation of Tasks Log Applications - Timelines

- **July 31, 2017**: RCR released to production
- **August 24, 2017**: CTEP DTL released to production
- **September 2017**: Begin DTL Pilot Phase
- **October 2017**: Enhanced reporting capabilities
Registration and Credential Repository

• Collects information that is used to verify the qualifications of personnel conducting research activities on NCI-sponsored clinical trials (e.g., FDA Form 1572, NCI Biosketch, Financial Disclosure Form, Agent Shipment Form)

• FIVE registration types

• All documents signed electronically (IAM credentials)
RCR Capabilities

• GCP training documents

• License verification

• Enhanced Turnaround time for requests

• System integration

• Automated 60 day and 30 day warning notifications

• Maintain historical documents and produce reports documenting study team members
New Registration Types

Five Registration Types

- Investigator (IVR)
- Non-Physician Investigator (NPIVR)
- Associate Plus (AP)
- Associate (A)
- Associate Basic (AB)

NOTE: All registration types will require a CTEP Identity and Access Management (CTEP-IAM) account. IVR, NPIVR, and AP registration types will use their CTEP-IAM username and password to access RCR and to electronically sign and submit registration credentials captured in RCR.
### New Registration Types

#### Five Registration Types: Definitions

- **Investigator (IVR)** – MD, DO, or international equivalent
- **Non-Physician Investigator (NPIVR)** – advanced practice provider (e.g., NP or PA) or graduate level researcher (e.g., PhD)
- **Associate Plus (AP)** – clinical site staff (e.g., RN or CRA) with data entry access to CTSU applications (e.g., RUMS, RAVE, TRIAD)
- **Associate (A)** – other clinical site staff involved in the conduct of NCI-supported research
- **Associate Basic (AB)** – individuals (e.g., pharmaceutical company employees) with limited access to NCI-supported systems
## New Registration Types – Documentation Requirements

<table>
<thead>
<tr>
<th>Documentation Required</th>
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CTEP Cancer Therapy Evaluation Program

NCI Registration and Credential Repository (RCR)

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).

RCR utilizes FIVE person 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

RCR requires the following registration documents:

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<tr>
<th>Documentation Required</th>
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RCR Related Links

- Identity and Access Management (IAM)
- Registration and Credential Repository (RCR)
- RCR Help Desk

RCR Presentations and Checklists

RCR WebEx presentation

Introduction to CTEP’s Registration and Credential Repository (RCR)

RCR Quick Reference Guide

RCR Registration Type Checklists:

- IVR
- NPIVR
- AP

RCR FAQs

How do I prepare for creating a Registration and Credential Repository (RCR) profile?

When do I have to re-register in RCR?

I have a new clinical site staff person (IVR, NPIVR, AP, or A). Where do I start?

I have my CTEP Person ID; but, I need to register as an IVR, NPIVR, or AP. What next?

I’m unable to add my Investigator to one of our clinical sites. What do I do?

I’m trying to enroll a patient in OPEN and the investigator I need to select as the credit, treating, or drug shipment investigator does not have the IRB of record on their FDA Form 1572. What do I do?
CP-CTNet Instructions, Forms and Templates

CP-CTNet Organizational Rosters

- CP-CTNet Roster Management System

Protocol Development

- CP-CTNet Consent Submission Form (DOC, 52 KB)
- CP-CTNet Consent Budget Template (DOC, 22 KB)
- CP-CTNet Protocol Submission Worksheet (DOC, 21 KB)
- DCP CP-CTNet Chemoprevention Protocol Template (DOC, 217 KB)
- DCP CP-CTNet Informed Consent Template (DOC, 151 KB)
- Additional Study Related Documents
  - Recruitment, Retention and Adherence Plan Outline Form (DOC, 125 KB)
  - Pharmacokinetic and Biomarker Method Development Report (DOC, 54 KB)

NCI Registration and Credential Repository (RCR) Links and Delegation of Tasks Log

- Identity and Access Management (IAM)
- Registration and Credential Repository
- RCR Help Desk
- DCP Delegation of Tasks Log (DOC, 24 KB)
- DCP Delegation Task Log Master Task List (DOC, 24 KB)

Protocol Status and Amendments

- Protocol Status Update Form (DOC, 37 KB)
- Revision or Amendment Submission Checklist for DCP Chemoprevention Studies (DOC, 20 KB)

Agents/Drugs

- DCP Returned Agents List (DOC, 17 KB)
- Investigational Agent Request (DOC, 21 KB)
FDA 1572 Guidance document

- Code of Federal Regulations < 21 CFR Part 312 >

- Agreement between investigator and Sponsor
  - Provide study information to Sponsor
  - Comply with FDA regulations
  - Provides information to evaluate qualifications of investigator (completed fields plus BioSketch)
  - Informs investigator of obligations and collects commitment to conduct study per FDA regulations (attestations)
Registration and Credential Repository

• **1572**
  • Practice sites pulled from RSS ("populate sites" button)
  • Integration with OHRP (IRBs) and CLIA/CAP (Labs) databases for real-time verification
  • CP-CTNet – IVR data may not be connected through RSS

• **Biosketch**
  • Education, training, employment
  • Collects GCP training certificates
  • Integration with license verification service
Registration Documents: FDA Form 1572

Registering individual will populate their RCR profile with:

- **Practice Sites (box 3)** queried from CTEP’s Enterprise Core Module (ECM) application
- **Labs (box 4)** queried from Clinical Laboratory Improvement Amendments (CLIA) and College of American Pathologists (CAP) data
  - *At a minimum, the main lab covering each Practice Site should be listed*
- **IRBs (box 5)** queried from Office for Human Research Protections (OHRP) data
  - *Will define IRBs that can be referenced for site registrations (Site-Protocol PI), patient registrations (consenting and “enrolling” [i.e., credit, treating, drug shipment] investigator), and patient transfers (receiving investigator)*
- Electronic signature (CTEP-IAM username and password) and date
Form FDA 1572

**Practice Sites**

Confirm that the institutions, clinical centers or cancer centers where you participate on NCI-sponsored clinical research trials are accurate.

Click **Populate Sites** to add practice sites to your 1572 form based on the sites at which you are rostered or the sites at which you are the Site-Protocol PI. Click **Add New Record** to manually select sites from the **Advanced Search** for Practice Sites screen, or you can remove existing sites by clicking **Delete** from the **Actions** column.

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Click **Previous** to return to the previous page, **Save** to save your entries and remain on the page, **Save and Continue** to advance to the next page or **Back to Home** to access your home page.
Enter the clinical lab facilities that provide medical testing and services to the NCI-sponsored clinical research trials on which you participate. Collect CLIA, CAP, or Provider Numbers, in advance, from your local lab or lab manager to use in the lab search fields.

Click Add New Record to manually select labs from the Advanced Search for Labs screen or you can remove existing labs by clicking Delete from the Actions column.

Click Previous to return to the previous page, Save to save your entries and remain on the page, Save and Continue to advance to the next page, or Back to Home to access your home page.
Enter the IRBs that oversee the NCI-sponsored clinical trials on which you participate. Collect the OHRP IRB numbers, in advance, from your local IRB to use in the IRB search fields. Note that the NCI IRB is currently composed of four IRBs, which are added or removed as a package. Also note that selecting multiple FWAs with the same IRB only adds the IRB once to the 1572 form. Click Populate IRBs to add IRBs that are associated to your selected Practice Site(s). Click Add New Record to manually select IRBs from the Advanced Search for IRBs screen or you can remove existing IRBs by clicking Delete from the Actions column.

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Registration Documents: Biosketch

Registering individual will populate their RCR profile with:
- Education, Professional Training, and Employment
- Professional License / Certifications
- Board Certifications
- **Good Clinical Practice (GCP) training**, including a scanned copy of the certificate
- Electronic signature (CTEP-IAM username and password) and date

**NOTE:** Attachment of a CV will be optional; but completion of the NCI Biosketch will be required to ensure a standardized collection of the required information.
Your NCI Biosketch = Your representation to the NCI and FDA

- CTEP recognizes the variability in the education, training, professional certification, and employment credentials of the individuals who will utilize RCR and provides the option to select “not applicable” for some sections of the NCI Biosketch sections.

- However, “abusing” this option by selecting “not applicable” for all NCI Biosketch sections will result in your registration request being returned for update.

- Please realize that your NCI Biosketch is the single representation of your qualifications to all of the NCI as well as to the FDA. If you check all sections as “not applicable”, NCI has no information to evaluate your qualifications to participate in the research process and will deny your registration request.
Registration Documents: Financial Disclosure Form

Completed at time of registration packet submission (i.e., information not part of NCI Profile in RCR)

▪ Four questions regarding potential financial conflicts

▪ If any question answered “yes”, source of potential conflict (e.g., pharmaceutical company) must be identified

▪ Electronic signature (CTEP-IAM username and password) and date
Registration Documents: Agent Shipment Form

NOTE: Only available for IVR registration type and only required for investigators requesting shipment of investigational agent from the Pharmaceutical Management Branch (PMB).

Registering investigator will populate their NCI Profile in RCR with:

- Shipping Site
- Shipping Address
- Shipping Designee (SD) and contact information
- Ordering Designees (OD)
- Standardized suggestions (e.g., “Primary Shipping Designee (PSD)” address or “Preferred Shipping Address (PSA)”)) will be offered based on Practice Sites selected
- Electronic signature (CTEP-IAM username and password) and date
Roles (application)

- Protocol PI for CTEP- or DCP-sponsored protocols Site-Protocol PI (i.e., IRB PI) for CTEP- or DCP-sponsored studies (Regulatory Support System [RSS])
- Consenting or “Enrolling” (Credit, Treating, Drug Shipment, Receiving [transfer to]) investigator for CTEP- or DCP-sponsored studies
- Drug Shipment investigator for CTEP-sponsored protocols
- Site Investigator for CTEP- or DCP-sponsored studies (RAVE)

NOTE: MD, DO, or international equivalent
Registration Type – Non-Physician Investigator (NPIVR)

Roles

- Protocol PI for select DCP- or CTEP-sponsored protocols
  - Protocol flagged by sponsor as “NPIVR eligible as Protocol PI”
- Site-Protocol PI for select DCP-sponsored studies (RSS)
  - Protocol flagged by sponsor as “NPIVR eligible as Site-Protocol PI”
- “Enrolling” (Credit, Treating, Receiving [transfer to]) investigator for select DCP-sponsored studies
  - Protocol flagged by sponsor as “NPIVR eligible as Enrolling Investigator"
- Consenting Person for CTEP- or DCP-sponsored protocols
- Site Investigator for select DCP-sponsored studies (RAVE)
Degrees that might be expected to register as an NPIVR

- NP (Nurse Practitioner)
- ONP (Oncology Nurse Practitioner)
- APRN (Advanced Practice Registered Nurse)
- CNS (Clinical Nurse Specialist)
- MSN (Master of Science in Nursing)
- DNP (Doctor of Nursing Practice)
- DNS (Doctor of Nursing Science)
- PA (Physician Assistant)
- PhD (Doctor of Philosophy)
- EdD (Doctor of Education)
- ScD (Doctor of Science)
- DrPH (Doctor of Public Health)
- MPH (Master of Public Health)
- PharmD (Doctor of Pharmacy)
- DPT (Doctor of Physical Therapy)
Registration Type – Associate Plus (AP)

Roles

- Registrar role
- RAVE CRA, CRA (Lab Admin), SLA roles (RAVE)
- Primary site roles such as Site Administrator, Data Administrator, LAPS Administrator, NCTN lead CRA, LAO Administrator
- Auditor role
- Consenting Person for CTEP- and DCP-sponsored protocols
Registration Type – Associate (A)

**Roles**

- Administrative roles (RSS / NCI CIRB / TRIAD)
- Shipping Designee
- Ordering Designee
- Registration Coordinator (RCR)
- RAVE Read-Only (RAVE)

- **NOTE:** No change to the current CTEP-IAM registration process.
Roles

- Personnel (e.g., pharmaceutical company employees) who need to register; but, who cannot be granted system or web access
- Administrative roster (RSS)
- Biospecimen protocol PI
- Biospecimen proposal PI

NOTE: No change in the current CTEP-IAM registration process.
NOTE: CTEP-IAM account will not be authenticated for system access.
# Summary of Registration Types

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<th>Registration Type</th>
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<th>Registration Requirements</th>
<th>Business Rules</th>
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<td>Investigator</td>
<td>IVR</td>
<td>Electronic annual registration using RCR</td>
<td>• Practice Site must be on the 1572 to be claimed on a roster&lt;br&gt;• IRB number on site registration must be on the Site - Protocol PI’s 1572&lt;br&gt;• IRB number covering the treating, consenting, credit, drug shipment, receiving (transfer to) investigator must be listed on their 1572</td>
</tr>
<tr>
<td>Non-Physician Investigator</td>
<td>NPIVR</td>
<td>Electronic annual registration using RCR</td>
<td>• Practice Site must be on the 1572 to be claimed on a roster&lt;br&gt;• IRB number on site registration must be on the Site - Protocol PI’s 1572&lt;br&gt;• IRB number covering the treating, consenting, credit, receiving (transfer to) non-physician investigator must be listed on their 1572</td>
</tr>
<tr>
<td>Associate Plus</td>
<td>AP</td>
<td>Electronic annual registration using RCR</td>
<td>• Must have an AP, NPIVR, or IVR registration type to hold the OPEN Registrar role, RAVE CRA role, TRIAD Site User role, primary site roles, or the CTMB-AIS Auditor role&lt;br&gt;• May be selected as the Consenting Person in OPEN</td>
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<tr>
<td>Associate</td>
<td>A</td>
<td>Electronic annual registration using IAM</td>
<td>May access CTSU website and systems including view access to OPEN and RAVE</td>
</tr>
<tr>
<td>Associate Basic</td>
<td>AB</td>
<td>Electronic annual registration using IAM</td>
<td>Cannot access CTEP, DCP, CIRB, or CTSU systems</td>
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</table>
RCR: Process Changes for IVR, NPIVR, AP

- All users must have a CTEP-IAM account
- Once an CTEP-IAM account has been approved study personnel will be able access RCR using their CTEP-IAM credentials
- All users will complete their re-registration on an annual basis within RCR
- GCP training details and certificate will be required for registration and for annual re-registrations
- Information related to education, training, employment, professional license, and board certification required and electronically captured
- Practice Sites, Labs, and IRBs electronically captured (IVR, NPIVR only)
- Electronically sign (no wet signatures) and submit (no mailing) registration packet to NCI
RCR: Business Rule Changes

- IVRs and NPIVRs must list all Practice Sites at which NCI-supported studies are conducted on their FDA Form 1572
  - To be claimed at a site on a roster, the CTEP Site Code must be listed as a Practice Site on the FDA Form 1572
  - Site-Protocol PI (IRB PI) must have all Practice Sites covered by the IRB approval listed on their FDA Form 1572
- IVRs and NPIVRs must list all IRBs providing coverage for NCI-supported studies at the Practice Sites listed on their FDA Form 1572
  - IRB number on site registration must be listed on the Site-Protocol PI’s FDA Form 1572
  - IRB number covering the consenting and “enrolling” (credit, treating, drug shipment, receiving [transfer to]) investigator(s) must be listed on the respective investigator’s FDA Form 1572
RCR: Where to Start?

- Make sure your study personnel have a CTEP-IAM account
- Begin creating a “cheat sheet” for your IVRs and NPIVRs
  - Practice Sites (CTEP Site Codes)
  - Labs (CLIA/CAP Lab numbers) >>> check with your hospital lab manager
  - IRBs (OHRP IRB numbers) >>> check with your local IRB
- Begin collecting GCP training documentation including course provider, course title, completion date, expiration date, and an e-copy of the training certificate for your IVRs, NPIVRs, and Aps (GCP training maximum 3 year expiration)
- Setup a “Registration Coordinator(s)” for your sites
- Establish a “Primary Shipping Designee(s)” for your sites (for PMB supplied agents ONLY)
RCR Registration Tips

- Registration Coordinator (RC) and “Backup RC” assignments
- RC templates for FDA Form 1572 (Practice Sites, Labs, and IRBs)
- Warning and error indicators for complete and accurate registration information
- Instructional message boards, online notifications, and emails
- Workflow-driven
- Checklists available for AP, NPIVR, and IVR
- Quick Reference Guide available for AP, NPIVR, and IVR
- Electronic signature on all forms using CTEP-IAM credentials
QUESTIONS ???
RCR Reference Slides
RCR: Weblinks and Help Desk

**CTEP Identity and Access Management (IAM)**
- [https://ctepcore.nci.nih.gov/iam](https://ctepcore.nci.nih.gov/iam)

**CTEP Registration and Credential Repository (RCR)**
- [https://ctepcore.nci.nih.gov/rcr](https://ctepcore.nci.nih.gov/rcr)

**RCR Help Desk**
- [RCRHelpDesk@nih.gov](mailto:RCRHelpDesk@nih.gov)
To setup a Registration Coordinator (RC):

Send an email to <CTEPRegHelp@ctep.nci.nih.gov> with Subject: Make Me a Registration Coordinator

• Include CTEP Person ID, full name, and CTEP Site Code for the proposed RC as well as a list of investigators (with their CTEP Person IDs) to be added to the RCs portfolio
To setup a Backup Registration Coordinator (Backup RC):

Send an email to <CTEPRegHelp@ctep.nci.nih.gov> with Subject: Add Backup Registration Coordinator

- Include CTEP Person ID and full name of the current RC as well as the CTEP Person ID and full name of the proposed Backup RC
To setup a Primary Shipping Designee (PSD):

Send an email to <CTEPRegHelp@ctep.nci.nih.gov> with Subject: Establishing a Primacy Shipping Designee for <CTEP Site Code / CTEP Site Name>

- Include CTEP Person ID and full name for the proposed PSD (Note: pharmacist with pharmacy address strongly preferred)

- CTEP Registration Team will contact the proposed PSD to complete a “PSD Worksheet” identifying the shipping CTEP Site Code, shipping address, shipping contact information, and ordering designees
**Good Clinical Practice (GCP) Training**

- Required at least every three years for all Investigator (IVR), Non-Physician Investigator (NPIVR), and Associate Plus (AP) registration types
- Must provide Training Provider, Course Title, Completion Date, and Expiration Date (if applicable) and **must upload certificate**
- Expiration date equals either (1) expiration date set by course provider OR (2) three years from course completion date, whichever occurs first

Registration Documents: NCI Biosketch
Common options for GCP training include …

- Collaborative Institutional Training Initiative (CITI) GCP for Clinical Trials with Investigational Drugs and Medical Devices (US FDA Focus) <https://about.citiprogram.org/en/series/good-clinical-practice-gcp/> and <https://about.citiprogram.org/en/course/good-clinical-practice-basic-fda/> (charges apply, CITI completion and expiration dates apply)


- National Institute of Allergy and Infectious Diseases (NIAID) Good Clinical Practices course <https://gcplearningcenter.niaid.nih.gov/> (free of charge, NIAID completion date applies, default three year expiration date applies)

- National Institute on Drug Abuse (NIDA) Good Clinical Practice course <https://gcp.nidatraining.org/> (free of charge, NIDA completion and expiration dates apply)

- Transcelerate GCP Mutual Recognition Program <http://www.transceleratebiopharmainc.com/gcp-training-attestation/>
IVRs, NPIVRs, and APs will be notified by email 60 days in advance of their “registration expiration date”

Notification will include a “Profile Checklist” and a “Quick Reference Guide” along with the RCR weblink

Review the “Profile Checklist” to see what information you will need to complete your profile

Use the “Quick Reference Guide” to get started in IAM or RCR

Check the status of your IAM account at https://ctepcore.nci.nih.gov/iam

Access RCR at https://ctepcore.nci.nih.gov/iam

If you encounter difficulties, contact the RCR Help Desk at RCRHelpDesk@nih.gov

IVRs, NPIVRs, and APs will also receive a reminder notification 30 days in advance of their “registration expiration date” and a suspension notification when their registration status changes to “suspended”

RCs and Backup RCs will be copied on all notifications
Your NCI Biosketch (not your CV) is your representation to the NCI, to the groups of which you are a member, and to the FDA.

To be eligible to register at the AP, NPIVR, or IVR level, which recognizes you as a “significant contributor” to CTEP-supported research, you must complete your NCI Biosketch with sufficient information (e.g., combination of education, professional certification, and employment) for CTEP, as the sponsor, to review your qualifications for credentialing at the < AP >, < NPIVR >, or < IVR > registration type.

If sufficient information is not provided (e.g., if you select all of the “not applicable” boxes), your registration will be returned to you as CTEP is unable to evaluate your credentials to be a “significant contributor” to CTEP-sponsored research.
RCR: I’m receiving a warning in RCR that I need to add additional practice sites to my FDA Form 1572. Why?

- **Practice sites are pulled from the CTSU’s Regulatory Support System (RSS) based on the sites at which ...**
  - you are rostered
  - you are a “Site-Protocol PI” (i.e., IRB PI)

- **If you are rostered at a clinical site and do not add that clinical site to your practice sites, you will be removed from that clinical site for all CTEP- and DCP-supported rosters on approval of your FDA Form 1572.**

- **If you are the “Site-Protocol PI” (i.e., IRB PI) for a clinical site and do not add that clinical site to your practice sites, the site registration status for all of your protocols at that clinical site will revert to “pending” on approval of your FDA Form 1572.**
RCR: I'm receiving a warning in RCR that I need to add additional IRBs to my FDA Form 1572. Why?

- **IRBs are pulled from the CTSU’s Regulatory Support System (RSS) based on …**
  - IRBs associated with “approved”, “pending”, or “closed” site registrations at your practice sites
  - IRBs associated with protocols for which you are the “Site-Protocol PI”
  - one or more of your practice sites are on the NCI CIRB roster (NOTE: all four NCI CIRBs will be added)
- **If the IRB of record is not listed on your FDA Form 1572, you will be unable to “enroll” a patient (i.e., be selected as the credit, treating, drug shipment, or receiving [transfer to] investigator) in OPEN.**
- **If you are the “Site-Protocol PI” (i.e., IRB PI) and do not add the IRB of record to your FDA Form 1572, the site registration status for all of your protocols at all clinical sites referencing that IRB will revert to “pending” on approval of your FDA Form 1572.**