Registration and Credential Repository (RCR) Update and Demo

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November 2-3, 2017

Goals and Objectives

- Describe why the Registration and Credential Repository was implemented
- Explain how to access the RCR system
- Provide a live system demonstration
- Demonstrate how documents are signed and submitted to the NCI

NCI's Registration and Credential Repository and Delegation of Tasks Log Applications - Timelines

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)
- Registration process changed from paper-based to on-line
- Change from two to FIVE registration types
- All documents signed electronically (IAM credentials)

FDA 1572 Guidance document

- *https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf*
- *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
  - Integration with CTEP CORE applications to control downstream access

- Biosketch
  - Education, training, employment
  - Collects GCP and HSP training certificates
  - Integration with license verification service

Summary of Registration Types

Registration Type	Abb.	Registration Requirements	Business Rules
Investigator	IVR	Electronic annual registration using RCR • FDA Form 1572 • Financial Disclosure Form • NCI Biosketch • Agent Shipment Form (if applicable) • Human Subjects Protection* • Good Clinical Practice* • Optional CV*	• Practice Site must be on the 1572 to be claimed on a roster • IRB number on site registration must be on the Site - Protocol PI's 1572 • IRB number covering the treating, consenting, credit, drug shipment, receiving (transfer to) investigator must be listed on their 1572
Non-Physician Investigator	NPIVR	Electronic annual registration using RCR • FDA Form 1572 • Financial Disclosure Form • NCI Biosketch • Human Subjects Protection* • Good Clinical Practice* • Optional CV*	• Practice Site must be on the 1572 to be claimed on a roster • IRB number on site registration must be on the Site - Protocol PI's 1572 • IRB number covering the treating, consenting, credit, receiving (transfer to) non-physician investigator must be listed on their 1572
Associate Plus	AP	Electronic annual registration using RCR • Financial Disclosure Form • NCI Biosketch • Human Subjects Protection* • Good Clinical Practice* • Optional CV*	• 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 • May be selected as the Consenting Person in OPEN
Associate	A	Electronic annual registration using IAM	May access CTSU website and systems including view access to OPEN and RAVE
Associate Basic	AB	Electronic annual registration using IAM	Cannot access CTEP, DCP, CIRB, or CTSU systems

* Upload hardcopy document

https://ctep.cancer.gov/investigatorResources/default.htm

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- Clinical Grants and Contracts Branch
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- Clinical Trials Operations and Informatics Branch
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Investigator Resources

Last Updated: 09/08/17

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:

Documentation Required	IVR	NPIVR	AP	A	AB
FDA Form 1572	✓	✓			
Financial Disclosure Form	✓	✓	✓		
NCI Biosketch (education, training, employment, license, and certification)	✓	✓	✓		
HSP/GCP training	✓	✓	✓		
Agent Shipment Form (if applicable)	✓				
CV (optional)	✓	✓	✓		

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?

RCR Challenges

- *GCP / HSP training documents*
- *“not applicable” sections – APs*
- *License verification*
- *Turnaround time for requests*
- *System integration*
- *60 day and 30 day warning notifications - APs*

Registration and Credential Repository Demo

QUESTIONS ???

RCR Reference Slides

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

RCR: Weblinks and Help Desk

- CTEP Registration Website
  - https://ctep.cancer.gov/investigatorResources/default.htm
- CTEP Identity and Access Management **(IAM)**
  - https://ctepcore.nci.nih.gov/iam
- CTEP Registration and Credential Repository **(RCR)**
  - https://ctepcore.nci.nih.gov/rcr
- RCR Help Desk
  - RCRHelpDesk@nih.gov

Registration Documents: NCI Biosketch

Human Subjects Protection (HSP) Training

- Required one time for all IVRs, NPIVRs, and APs
  - https://humansubjects.nih.gov/resources
  - https://humansubjects.nih.gov/requirement-education
- Must provide Training Provider, Course Title, Completion Date, and Expiration Date (if applicable) and ***must upload certificate***
- If NIH training, no expiration date; otherwise, the expiration date set by course provider applies
- Common options include (but are not limited to):
  - NIH Office of Extramural Research Protecting Human Research Participants < https://phrp.nihtraining.com/users/login.php > (no charge, no expiration date)
  - Collaborative Institutional Training Initiative (CITI) Biomedical Basic < https://about.citiprogram.org/en/series/human-subjects-research-hsr/ > and < https://about.citiprogram.org/en/course/biomedical-biomed-basic/ > (charges apply, CITI expiration date applies)

Registration Documents: NCI Biosketch

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
  - https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html
- 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

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)
- Collaborative Institutional Training Initiative (CITI) GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus) < https://about.citiprogram.org/en/series/good-clinical-practice-gcp/ > and < https://about.citiprogram.org/en/course/good-clinical-practice-basic-ich/ > (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/ >