NCI Person Registration Quick RCR Reference Guide for Investigator (IVR), Non-Physician Investigator (NPIVR), and Associate Plus (AP) Registration Types

The following provides high-level instructions to obtain a CTEP-IAM account, access the RCR system, and complete your annual NCI Person Registration.

Obtain your CTEP-IAM Account

To submit your registration documents through the RCR system, all persons with a Registration Type of *Investigator* (IVR), *Non-Physician Investigator* (NPIVR), and *Associate Plus* (AP) will require a CTEP Identity and Access Management (CTEP-IAM) account. The CTEP-IAM username and password are used to access RCR and to electronically sign your registration documents prior to submission to CTEP.

For IVRs without a CTEP-IAM account:

- Access CTEP-IAM https://ctepcore.nci.nih.gov/iam/
- Select "Request New Account".
- Answer the "Have you ever registered with CTEP?" question by selecting "Yes" and "Proceed".
- Enter your < CTEP Person ID >, < First Name >, and < Last Name > (check your registration notification email) and select "Continue".
- Answer the "Does the above information identify you?" question by selecting "Yes" and "Proceed".
- Answer the "Would you like to request for an IAM Account?" question by selecting "Yes" and "Continue".
- Complete the new account request and select "Continue".

For IVRs, NPIVRs, and APs with a CTEP-IAM account and uncertain of username and password or needing to update their primary organization, address, and contact information:

- Access CTEP-IAM https://ctepcore.nci.nih.gov/iam/
- Select "Request New Account".
- Answer the "Have you ever registered with CTEP?" question by selecting "Yes" and "Proceed".
- Enter your < CTEP Person ID >, < First Name >, and < Last Name > (check your registration notification email) and select "Continue".
- Answer the "Does the above information identify you?" question by selecting "Yes" and "Proceed".
- Answer the "Would you like to update your CTEP-IAM Account?" question by selecting "Yes" and "Continue".
- Complete the account request and select "Continue".

For questions, please contact the CTEP Registration Help Desk at CTEPRegHelp@nih.gov

Follow the RCR instructions below after receiving or reactivating your CTEP-IAM username and password.

Access the RCR system

This applies for IVR, NPIVR, and AP users.

1. Enter the URL for RCR: https://ctepcore.nci.nih.gov/rcr in your browser.
2. Enter your CTEP-IAM username and password.
3. Click "I Agree and Logon".

Complete Form FDA 1572

This section is mandatory for IVR and NPIVR users only.

1. Select one of the following to access the **Form FDA 1572** workflow:
   a. From the Message Board on the Home page, select "Update Form FDA 1572" from the "Would you like to" drop-down field and click "Go!".
   b. Select "Form FDA 1572" from the left "Jump To" menu from any workflow page.
2. To add Practice Sites to your 1572:
   a. Click "***Populate Sites***" to automatically add sites that you are rostered to and sites at which you are the Site-Protocol PI.
   b. Click "Add New Record" to search for and manually add sites.
3. Click "Save and Continue" to move to the **Labs** page, or select "Labs" from the left menu.
4. To add Labs to your 1572, click "Add New Record" to search for and manually add labs.
5. Click "Save and Continue" to move to the **IRBs** page, or select "IRBs" from the left menu.
6. To add IRBs to your 1572:
   a. Click "***Populate IRBs***" to automatically add the IRBs that are associated to your practice site(s).
   b. Click "Add New Record" to search for and manually add an IRB.
7. Click "Save and Continue" to move to the final **Form FDA 1572 Completed** page.

Complete NCI Biosketch

This section is mandatory for IVR, NPIVR, and AP users.

1. Select one of the following to access the **NCI Biosketch** workflow:

a. From the Message Board on the Home page, select "Update NCI Biosketch" from the "Would you like to" drop-down field and click "Go!".

b. If you have completed the Form FDA 1572 workflow, click "Continue" from the **Form FDA 1572 Completed** page.

c. Select "NCI Biosketch" from the left "Jump To" menu from any workflow page.

2. To complete the **Personal Information** page, ensure that all the information is accurate, and modify the "Signature Display" and/or "Correspondence Display" fields, if necessary.

   Click "Save and Continue" to move to the **Education** page.

3. Complete the following mandatory sections or select the "Not Applicable" checkbox if the section doesn't apply to you:

   a. **Education**
   b. **Professional Training**
   c. **Employment**
   d. **Professional Certification**
   e. **Professional License**
   f. **ABMS Board Certification**

   To complete these sections, click "Add New Record" to add a new record (line item), or click "Edit" to update an existing record.

   To move to the next section, click "Save and Continue" or select the next section from the left menu.

4. To complete the **NCI Required Training** page, click "Edit" to add the required details and upload the Good Clinical Practice (GCP) and Human Subject Protection (HSP) training certificates. Click "Update" to save.

   See page 4 for GCP and HSP training information.

   To move to the next section, click "Save and Continue" or select the section from the left menu.

5. The following sections are optional for NCI registration:

   a. **CV**
   b. **Personal Statement**
   c. **Professional Memberships**
   d. **Honors**
   e. **Publications**
   f. **Research Support**

6. Click "Save and Continue" to move to the final **NCI Biosketch Completed** page.

Complete Financial Disclosure Form

This section is mandatory for IVR, NPIVR, and AP users.

1. Select one of the following to access the **Financial Disclosure Form (FDF)** workflow:

   a. From the Message Board on the Home page, select "Update FDF" from the "Would you like to" drop-down field and click "Go!".

   b. If you have completed the NCI Biosketch workflow, click "Continue" from the **NCI Biosketch Completed** page.

   c. Select "FDF" from the left "Jump To" menu from any workflow page.

2. Answer all four questions on the page. If "Yes" is selected for any question, add the name of the pharmaceutical company/companies by clicking "Add New Record" from the grid that displays.

3. Click "Save and Continue" to move to the final **Financial Disclosure Form Complete** page.

Complete Agent Shipment Form

This section is mandatory only for IVR users who require NCI-supplied agent shipments.

1. Select one of the following to access the **Agent Shipment Form** workflow:

   a. From the Message Board on the Home page, select "Update Agent Shipment Form" from the "Would you like to" drop-down field and click "Go!".

   b. If you have completed the Financial Disclosure Form workflow, click "Continue" from the **Financial Disclosure Form Complete** page.

   c. Select "Agent Shipment Form" from the left "Jump To" menu from any workflow page.

2. From the **Agent Shipment Form Welcome** page, click 'Yes' to confirm your need to order investigational agents. Note: This page does not display if you have existing shipment information.

3. Complete the summary components by selecting the following information:

   a. Shipping Site
   b. Shipping Address
   c. Shipping Designee (SD)
   d. Shipping Contact Information
   e. Ordering Designee(s) (OD)

4. Click "Save and Continue" to move to the final **Agent Shipment Summary Completed** page.

Complete Practice Preferences

This section is required for IVR, NPIVR, and AP users.

1. Select one of the following to access the **Practice Preferences** page:
    a. From the Message Board on the Home page, select "Update Practice Preferences" from the "Would you like to" drop-down field and click "Go!".
    b. If you are a NPIVR or AP and have completed the Financial Disclosure Form workflow, click "Continue" from the **Financial Disclosure Form Complete** page.
    c. If you are a IVR and have completed the Agent Shipment Summary workflow, click "Continue" from the **Agent Shipment Summary Completed** page.
    d. Select "Practice Preferences" from the left "Jump To" menu from any workflow page.
2. Add your preferences for **Medical / Professional Specialty** and **Areas of Interest**.
3. Click "Save and Continue" to move to the **Sign and Submit Welcome** page.

Validate, Sign and Submit Registration Documents

This section is mandatory for IVR, NPIVR, and AP users.

1. Select one of the following to access the **Sign and Submit** workflow:
    a. From the Message Board on the Home page, select "Update Validate, Sign and Submit" from the "Would you like to" drop-down field and click "Go!".
    b. If you have completed the Practice Preferences workflow, click "Save and Continue".
    c. Select "Validate and View Documents" from the left "Jump To" menu from any workflow page.
2. From the **Validation** page:
    a. Select "Start Complete Registration!".
    b. Click "Go To Page" to make necessary corrections. Use the left "Jump To" menu to return to the **Validation** page. Repeat if needed.
    c. Click "Continue" to move to the **Electronic Signature Acknowledgement** page.
3. From the **Electronic Signature Acknowledgement** page, select the checkbox and click "Save and Continue".
4. To electronically sign each registration document:
    a. Select the Acknowledgment checkbox.
    b. Click "Sign" and enter CTEP-IAM credentials in pop-up eSignature window.
    c. Click "Continue" to move to and sign your next registration document.
5. From the **Review and Submit the Packet** page, click "Submit the Packet" to submit your registration documents after all documents have been signed.

For questions, please contact the CTEP Registration and Credential Repository Help Desk at RCRHelpDesk@nih.gov

Good Clinical Practice (GCP) and Human Subject Protection (HSP) Training Information

The following provides an overview of the GCP and HSP training requirements and provides training resources.

Good Clinical Practice Training

Required at least every three years for all persons assigned to the Investigator, Non-Physician Investigator, and Associate Plus Registration Types.

See the Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials:

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

The **Training Provider**, **Course Title**, **Completion Date**, and **Expiration Date**, if applicable, and the provider's **training certificate** must be uploaded in the NCI Required Training subsection of the NCI Biosketch.

The GCP Expiration Date can be set to either a) an expiration date set by course provider; or b) three years from course completion date, whichever occurs first.

Current acceptable training options are provided below.

- Collaborative Institutional Training Initiative (CITI) - GCP for Clinical Trials with Investigational Drugs and Medical Devices (US FDA Focus) (charges apply, CITI completion and expiration dates apply):

  https://about.citiprogram.org/en/series/good-clinical-practice-gcp/

  https://about.citiprogram.org/en/course/good-clinical-practice-basic-fda/

- Collaborative Institutional Training Initiative (CITI) GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus) (charges apply, CITI completion and expiration dates apply):

  https://about.citiprogram.org/en/series/good-clinical-practice-gcp/

  https://about.citiprogram.org/en/course/good-clinical-practice-basic-ich/

- National Institute of Allergy and Infectious Diseases (NIAID) Good Clinical Practices course (free of charge, NIAID completion date applies, default three year expiration date applies):

  https://gcplearningcenter.niaid.nih.gov/

- National Institute on Drug Abuse (NIDA) Good Clinical Practice Course (free of charge, NIDA completion and expiration dates apply)

  https://gcp.nidatraining.org/

- TransCelerate GCP Mutual Recognition Program

  http://www.transceleratebiopharmainc.com/gcp-training-attestation/

  http://www.transceleratebiopharmainc.com/wp-content/uploads/2017/03/GCP-MR-Minimum-Criteria-R2_FINAL.pdf

Human Subjects Protection Training

One-time training required for all persons assigned to the Investigator, Non-Physician Investigator, and Associate Plus Registration Types.

https://humansubjects.nih.gov/resources

https://humansubjects.nih.gov/requirement-education

The **Training Provider**, **Course Title**, **Completion Date**, and **Expiration Date**, if applicable, and the provider's **training certificate** must be uploaded in the NCI Required Training subsection of the NCI Biosketch.

Note: If the NIH training course is taken, then there will be no expiration date (select "not applicable"); otherwise enter the expiration date set by course provider when applicable.

Training options are provided below (but are not limited to the following).

- NIH Office of Extramural Research (free of charge, no expiration date):

  https://phrp.nihtraining.com/users/login.php

- Collaborative Institutional Training Initiative (CITI) Biomedical Basic (charges apply, CITI expiration date applies):

  https://about.citiprogram.org/en/series/human-subjects-research-hsr/

  https://about.citiprogram.org/en/course/biomedical-biomed-basic/