# Registration and Credential Repository (RCR) and Delegation of Tasks Log (DTL)

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# Background – Joint FDA / EMA Audit

## Gaps Identified in Current System

- FDA Form 1572 documentation
  - Missing practice sites, labs, IRBs
- No record of study-specific responsibilities assigned at the practice site level
- Failure to verify that personnel conducting research activities were qualified to do so on the protocol
- Lack of protocol-specific training

# NCI's Solutions and Enhancements

- **Registration and Credential Repository (RCR)**
  - Provide a self-service online person registration application with electronic signature and submission capability
  - Define specific Registration Types – Investigator (IVR), Non-Physician Investigator (NPIVR), Associate Plus (AP), Associate (A), and Associate Basic (AB)
  - Registration Type will dictate person-specific regulatory documentation requirements – FDA Form 1572, Financial Disclosure Form (FDF), NCI Biosketch, Agent Shipment Form, and enhanced training requirements (i.e., HSP and GCP training)
  - Registration Type will permit assignment of roles for access to CTEP CORE applications (e.g., OPEN, RAVE) and task assignments for performance of study activities (i.e., DTL)

# NCI's Solutions and Enhancements

- **Delegation of Tasks Log (DTL)**
  - Define and maintain an online DTL for designated studies conducted at a site
  - Define a standard list of NCI research tasks to be part of the DTL
  - Delegate research tasks based on qualifications and Registration Type
  - Utilize the protocol and site specific DTL, in combination with registration documents from RCR, to construct a Study Site Registration Packet

# Registration and Credential Repository

# 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*** an Identity and Access Management (IAM) account. IVR, NPIVR, and AP registration types will use their IAM username and password to access RCR and to ***electronically sign*** and submit registration credentials captured in RCR.

# New Registration Types – Documentation Requirements

| 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) | ✔ | ✔ | ✔ | | |

# 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
  - ***will define sites at which an IVR or NPIVR can be requested to be claimed in RUMS or NCORP-SYS or claimed in RSS by NCTN roster owners***
- Labs (box 4) queried from Clinical Laboratory Improvement Amendments (CLIA)  and College of American Pathologists (CAP) web service
  - ***at a minimum, the main lab covering each practice site should be listed***
- IRBs (box 5) queried from Office for Human Research Protections (OHRP) web service
  - ***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 [transfer to] investigator)***
- Electronic signature (IAM username and password) and date

# Registration Documents:  NCI Biosketch

Registering individual will populate their RCR profile with:

- Education, Professional Training, and Employment
- Professional License / Certifications
- Board Certifications
- ***Human Subject Protection (HSP) and Good Clinical Practice (GCP) training***, including a scanned copy of the certificate(s)
- Electronic signature (IAM username and password) and date

NOTE: Information on the current Supplemental Investigator Data Form (IDF) will be separated into the “NCI Biosketch” and the “Agent Shipment Form”.

NOTE: Attachment of a CV will be optional; but, the NCI Biosketch will be required to ensure a standardized collection of the required information.

# Registration Documents:  Financial Disclosure Form

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

- Four questions regarding potential financial conflicts
- If any question answered “yes”, source of potential conflict (e.g., pharmaceutical company) must be identified
- Electronic signature (IAM username and password) and date

# Registration Documents:  Agent Shipment Form

Registering investigator will populate their RCR profile with:

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

NOTE: Only available for IVR registration type and only ***required*** for investigators requesting shipment of investigational agent from PMB.

# Registration Type – Investigator (IVR)


## Roles (application)

- Protocol PI for CTEP or DCP sponsored protocols (START)
- 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 (Oncology Patient Enrollment Network [OPEN])
- Drug Shipment investigator (Online Agent Order Processing [OAOP])
- Site Investigator (RAVE)

# Registration Type – Non-Physician Investigator (NPIVR)

IVR | **NPIVR** | AP | A | AB

## Roles (application)

- Protocol PI for select DCP or CTEP sponsored studies (START)
  - 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”
- Consenting or “Enrolling” (Credit, Treating, Receiving [transfer to]) investigator for select DCP sponsored protocols (OPEN)
  - protocol flagged by sponsor as “NPIVR eligible as Enrolling Investigator"
- Site Investigator for select DCP sponsored studies (RAVE)

NOTE: NPIVR cannot be a drug shipment investigator in OPEN or OAOP.

# Registration Type – Associate Plus (AP)


## Roles (application)

- Registrar role (OPEN)
- RAVE CRA, CRA (Lab Admin), SLA roles (RAVE)
- Primary site roles such as Site Administrator, Data Administrator, NCORP Administrator, LAPS Administrator, NCTN lead CRA (RSS/RUMS)

# Registration Type – Associate (A)

IVR | NPIVR | AP | **A** | AB

## Roles (application)

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

NOTE: No change to the current IAM registration process.

# Registration Type – Associate Basic (AB)

IVR | NPIVR | AP | A | **AB**

## Roles (application)

- 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 (PATS)
- Biospecimen proposal PI (NCI NAVIGATOR)

NOTE: No change in the current IAM registration process.

NOTE: IAM account will ***not*** be authenticated for system access.

# Migration Activities: Person Types to Registration Types

- Person Types of Associate and Investigator will be replaced with the five Registration Types in CTEP, DCP, CIRB, and CTSU systems
- New persons will be given a unique CTEP ID and existing persons will retain their assigned CTEP ID
  - Updates to Registration Type will *not* change a person's CTEP ID
- Investigator records will be migrated to the IVR Registration Type
- Users currently registered as an Associate and assigned as a Protocol PI or Site - Protocol PI for nontreatment studies will be migrated to the NPIVR Registration Type
- Users currently registered as an Associate and assigned the OPEN Registrar or RAVE CRA, CRA (Lab Admin), or SLA roles as well as individuals with a "Primary Site Role" will be migrated to the AP Registration Type
- All other users will be retained at the Associate Registration Type

# Migration Activities: Profile Population

- User profiles will be prepopulated with existing practice site(s), IRB(s), and HSP/GCP training information where available
  - Practice sites aligned to IVR (and the few identified NPIVR) in RSS
  - IRB numbers from all IRB approvals associated with a listed practice site where the site registration status is pending, approved, or closed
  - NCI CIRB IRB numbers (all four) if a listed practice site is on the NCI CIRB roster
  - Share existing HSP/GCP data where available

NOTE: Users will have from the transition date (i.e., official cutover from IR to RCR) until their registration expiration date to “register up” to their migrated registration type without loss of system access or assigned roles. Will require one year to complete the initial registration cycle and obtain complete credentials for all registered persons.

# RCR: Process Changes (IVR, NPIVR, AP)

- All users must have an IAM account
- Existing users will complete their re-registration within RCR
  - Emailed re-registration notifications (no paper or electronic documents) will replace current notifications
- New users will access RCR to submit their initial registration (after ***first*** obtaining an IAM account)
- HSP/GCP training details and certificates will be required for initial registration and for annual re-registrations (IVR, NPIVR, AP)
- Information related to education, training, employment, professional license, and board certification required and electronically captured (IVR, NPIVR, AP)
- Practice sites, IRBs, and labs electronically captured and ***control downstream processes*** (IVR, NPIVR)
- Electronically sign (no wet signatures) and submit (no mailing) registration packet to NCI (IVR, NPIVR, AP)

# 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 1572
  - Site-Protocol PI (IRB PI) must have all practice sites covered by the IRB approval listed on their 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 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 1572

# RCR:  Business Rule Changes

- Persons requiring write access to OPEN or RAVE must hold a Registration Type of IVR, NPIVR, or AP
- Persons holding a primary site role (e.g., Site Administrator, Data Administrator, LAPS Administrator, NCORP administrator) will require a minimum AP Registration Type
- Persons reverting to an Associate or AB Registration Type will have their OPEN and RAVE roles automatically inactivated
- Persons with an AB role can be claimed at administrative locations only and will not have access to any systems or websites

# RCR: Final Thoughts

- Online registration for all “Registration Types”, via IAM for AB and A and via RCR, including electronic signature using IAM username and password, for AP, NPIVR, and IVR
- Five “Registration Types” with differing credential collection and differing potential role and task assignment
- Enhanced, structured collection of person registration and credential data, particularly practice sites, IRBs, and HSP/GCP training, for utilization across CTEP, DCP, NCI CIRB, and CTSU systems
- Availability of a single source of electronic person registration documentation (FDA Form 1572, NCI Biosketch, HSP/GCP training) to NCI, clinical site staff (via RUMS/NCORPSYS), and grantee operations office staff (via RSS) at all times as well as to the FDA when required (i.e., a copy of all submitted documentation will always be electronically available)

# Summary of Registration Types

| Registration Type | Abb. | Registration Requirements | Business Rules |
|---|---|---|---|
| Investigator | IVR | Electronic annual registration using RCR<br>• FDA Form 1572<br>• Financial Disclosure Form<br>• NCI Biosketch<br>• Agent Shipment Form (if applicable)<br>• Human Subjects Protection*<br>• Good Clinical Practice*<br>• Optional CV* | • Practice Site must be on the 1572 to be claimed on a roster<br>• IRB number on site registration must be on the Site - Protocol PI's 1572<br>• 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<br>• FDA Form 1572<br>• Financial Disclosure Form<br>• NCI Biosketch<br>• Human Subjects Protection*<br>• Good Clinical Practice*<br>• Optional CV* | • Practice Site must be on the 1572 to be claimed on a roster<br>• IRB number on site registration must be on the Site - Protocol PI's 1572<br>• 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<br>• Financial Disclosure Form<br>• NCI Biosketch<br>• Human Subjects Protection*<br>• Good Clinical Practice*<br>• Optional CV* | Must have an AP, NPIVR, or IVR registration status to hold the OPEN Registrar role , RAVE "write" roles, or primary site roles |
| 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

# NCI Delegation of Tasks Log (DTL)

# Delegation of Tasks Log (DTL) Goals

- Identify the Clinical Investigator (CI) and Delegation of Tasks Log Administrator (DTLA) for every site participating on an identified protocol
- Identify individuals who can perform designated tasks on the protocol at the site level
- Track changes in task assignment over study lifecycle
- Provide a complete list of the investigators AND sub-investigators who make a direct and significant contribution to the clinical data

# Completion of a Protocol and Site – Specific DTL

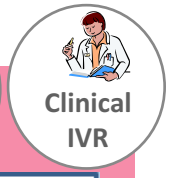
- CTEP will work with the LPOs during LOI / Concept / Protocol development to determine if a DTL is required
- Protocol specific DTL template developed by LPO, submitted to CTEP for review and approval, and released to clinical sites at protocol activation
- CI [or DTL Administrator (DTLA) on behalf of CI] assigns research tasks to registered persons based on qualifications and Registration Type
- CI reviews and signs the protocol and site–specific DTL
- Protocol/Site activation (i.e., site registration) will be based on the completion of the DTL as well as any other protocol specific requirements (PSRs)
- Signed protocol and site–specific DTL controls downstream system access (e.g., OPEN patient enrollment, RAVE data submission) as well as conduct of the protocol at the clinical site (e.g., eligibility assessment, patient treatment, response assessment)

# DTL Application

**Protocol**

Site Registration [Approved]

**Site**

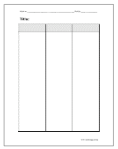




Approved

**DTL Protocol**

Protocol Documents

Approved DTL Template [1.0]



**Protocol Specific Requirements**

- IRB Approval
- PSR #1
- PSR #2
- Approved Site DTL

**Site DTL for MN019, E1Z11** [Approved]

| Task | Primary? | Reqd? | Reg Type | Person |
|---|---|---|---|---|
| Clinical Investigator | Yes | Yes | IVR, NPIVR | |
| DTL Administrator | Yes | Yes | IVR, NPIVR | |
| Tox Assessment | No | Yes | IVR, NPIVR | |
| HP Assessments | No | Yes | IVR, NPIVR | |
| Enrolling Person / Treating Investigator | No | Yes | IVR, NPIVR | |
| Consenting Person | No | Yes | IVR, NPIVR | |
| Credit Investigator | No | Yes | IVR, NPIVR | |
| OPEN Registrar | No | Yes | IVR, NPIVR | |
| Rave CRA | No | Yes | IVR, NPIVR | |
| Eligibility Assessment | No | Yes | IVR, NPIVR | |
| Enter AE/SAE Data | No | Yes | IVR, NPIVR | |

# DTL and Study Site Registration Packet (FDA Packet)

- Produced on demand for audit or inspection purposes
- Includes:
  - General protocol details
  - DTL – current and copies of all signed version(s)
  - Study-specific information
    - Protocol CI (all annual 1572s, FDFs, NCI Biosketches, HSP and GCP training certificates)
    - Sub-investigators (FDFs, NCI Biosketches, HSP and GCP training certificates)
    - Central labs
    - CIRB/IRB information
    - Study-specific training

# RCR and DTL Launch Support

# Easing the Burden for First Time RCR Registration

- Registration Coordinator (RC) assignments
- RC templates for FDA Form 1572 (sites, labs, and IRBs) and Agent Shipment Form (drug shipment site, shipping designee, shipping address and contact information, ordering designees)
- Warning and error indicators for complete and accurate registration information
- Instructional message boards and notifications
- Workflow-driven
- Electronic signature on all forms using IAM credentials

# RCR Production Launch

- Rolling implementation based on date of registration
- "Relaxed Mode" for business rules until person re-registers
  - **Rostering of Investigators:** No verification that the investigator lists the sites on their 1572 until re-registration
  - **IRB Verification:** No verification of IRB numbers for site-protocol PI or enrolling investigator until re-registration
- All RCR rules enforced **after** re-registration
  - **Rostering of Investigators:** an investigator can only be claimed at a site if the site is listed as a practice site on the investigator's 1572
  - **Site Registrations:** site-protocol PI's 1572 IRB must match site's IRB approval
  - **OPEN Enrollments:** investigator's 1572 IRB must match site's IRB approval

# Easing Burden for DTL Set-up

- Collaborate on creation of study-specific template with LPO
  - During protocol development, but can follow separate timelines
  - Standardized tasks list
- Allow administrative changes by DTLA
- Relaxation of rules for first year while investigator / sub investigator data is compiled in RCR
- Development of site level templates
- Ability to “copy” existing DTLs

# DTL Production Launch

- Pilot (all participating sites) with a Registration Trial from each NCTN before expansion
  - Studies will be determined by CTEP and LPO
  - LPOs will need to have an approved DTL template before new studies receive CTEP approval
    - Grace period for addition of DTL to ongoing registration trials

# Application Release Schedule

- July 31st, 2017 – RCR released
- August 2017 – Pilot testing of DTL application begins
- 3rd Quarter 2018 – Re-registration cycle complete

# RCR: What Can I Do Now?

- Make sure your IVRs have an IAM account (very few do)
- Begin creating a “cheat sheet” for your IVRs and NPIVRs
  - Practice Sites (CTEP site codes) >>> check RUMS
  - Labs (CLIA/CAP lab numbers) >>> check with hospital lab manager
  - IRBs (OHRP IRB numbers) >>> check with your local IRB
- Begin collecting HSP and 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
- Setup a “Registration Coordinator(s)” for your sites
- Establish a “Primary Shipping Designee(s)” for your sites

*Questions?*

*For further questions or feedback, please send email to:*

*< NCIPMBRCRDTL@mail.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

# 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)



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