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., RUMS, 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*** 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., OPEN, 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

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 by site administrators or claimed in RSS by NCTN roster owners***
- 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

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 (CTEP-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: 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 Investigators (IVRs), Non-Physician Investigators (NPIVRs), Associate Plus (APs)
  - 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

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
- 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/ >

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

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” address or “Preferred Shipping Address”) will be offered based on Practice Sites selected
- Electronic signature (CTEP-IAM username and password) and date

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

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

NOTE: MD, DO, or international equivalent

Registration Type – Non-Physician Investigator (NPIVR)

Roles (application)

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

NOTE: NPIVR cannot “order” study agent in OAOP or be a drug shipment investigator in OPEN and cannot “prescribe” study agents on CTEP-sponsored protocols.

Registration Type – Non-Physician Investigator (NPIVR)

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

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 – Non-Physician Investigator (NPIVR)

“Ordering” and “Prescribing” for CTEP-sponsored clinical trials

- “**Ordering**” is defined as entering a request for the shipment of a CTEP investigational agent for a specific investigator on a specific protocol using PMB’s OAOP application.
- “**Prescribing**” is defined as writing an order for a specific patient (e.g., your doctor gives you a prescription for Amoxicillin 250mg and tells you to take one capsule four times a day for 7 days OR an oncologist writes an order in the patient’s chart for 1000mg of chemo agent X to be administered IV over one hour).
- “**Protocol directed therapy**” is defined as any “treatment” involving CTEP investigational agents or commercial agents, specified by the protocol.
- NPIVRs may ***NOT*** “order” a CTEP IND agent from PMB or “prescribe” “protocol directed therapy” for patients on CTEP-sponsored clinical trials.

Registration Type – Associate Plus (AP)

Roles (application)

- Registrar role (OPEN)
- RAVE CRA, CRA (Lab Admin), SLA roles (RAVE)
- TRIAD access
- Primary site roles such as Site Administrator, Data Administrator, NCORP Administrator, LAPS Administrator, NCTN lead CRA (RSS/RUMS)
- Auditor role (CTMB-AIS)
- Consenting Person for CTEP- and DCP-sponsored protocols (OPEN)

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 CTEP-IAM registration process.

Registration Type – Associate Basic (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 (START)
- Biospecimen proposal PI (NCI NAVIGATOR)

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

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 status to hold the OPEN Registrar role, RAVE CRA 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

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 (beginning with < 600000 > 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, individuals with a "Primary Site Role", and individuals with the CTMB-AIS "Auditor" 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., Monday, July 31st, 2017) 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 for IVR, NPIVR, AP

- All users must have a CTEP-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 CTEP-IAM account)***
- HSP/GCP training details and certificates will be required for initial 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 and ***control downstream processes*** (IVR, NPIVR only)
- Electronically sign (no wet signatures) and submit (no mailing) registration packet to NCI

RCR: Business Rule Changes (very important)

- 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: Business Rule Changes (very important)

- Persons requiring write access to OPEN, RAVE, or TRIAD 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, NCTN Lead CRA) will require a minimum AP Registration Type
- Persons holding the CTMB-AIS Auditor role (i.e., serving on a site audit team) will require a minimum AP Registration Type
- Persons consenting patients on CTEP or DCP-sponsored protocols will require a minimum AP Registration Type
- Persons reverting to an Associate or AB Registration Type will have their OPEN, RAVE, and TRIAD 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: Easing the Burden of First RCR Registration

- Registration Coordinator (RC) and “Backup RC” assignments
- RC templates for FDA Form 1572 (Practice Sites, Labs, and IRBs) and Agent Shipment Form (Shipment Site, Shipping Address, Shipping Designee and contact information, and Ordering Designees)
- 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
- Electronic signature on all forms using CTEP-IAM credentials

RCR: Rolling Implementation of Business Rules

- Rolling implementation of new business rules 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 FDA Form 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 FDA Form 1572 IRB must match site's IRB approval
  - **OPEN Enrollments:** "enrolling" investigator's FDA Form 1572 IRB must match site's IRB approval

RCR: Final Thoughts

- Online registration for all “Registration Types”, via CTEP-IAM for AB and A and via RCR, including electronic signature using CTEP-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/NCORP-SYS), 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)

RCR: What Can I Do Now?

- Make sure your IVRs have an CTEP-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 your 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

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 (very important)

- 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

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

- CTEP Identity and Access Management (IAM)
  - https://ctepcore.nci.nih.gov/iam
  - Select < Request New Account >
  - Have you ever registered with CTEP? >>> Select < No > and < Proceed >
  - Complete and submit new account request
  - Receive CTEP Identity and Access Management, New Account Request email
  - Receive CTEP Identity and Access Management, Account Approved email >>> change temporary password to permanent password and answer security question
  - Receive CTEP Identity and Access Management, Account Activated >>> CTEP Person ID assigned

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

- CTEP Registration and Credential Repository (RCR)
  - < https://ctepcore.nci.nih.gov/rcr >
  - Enter IAM Username and Password
  - To change your Registration Type, select “Change Registration Type” from “Would you like to” menu
  - To begin registering as your selected “Registration Type”, select “Update FDA Form 1572” (for IVR or NPIVR) or “Update NCI Biosketch” (for AP) from the “Would you like to” menu
  - Follow the onscreen prompts to complete your profile, generate and sign your documents, and submit your registration packet to CTEP

RCR: When do I have to re-register in RCR?

- 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
- 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

NCI Delegation of Tasks Log (DTL)

Delegation of Tasks Log (DTL) Goals

- Improve compliance with federal regulations governing oversight of human subjects research
- Allow the site Clinical Investigator (CI) to delegate study-related tasks and track assignments throughout the protocol life-cycle
- Improve ability to document appropriate GCP/HSP and study-specific training of individuals assigned to study-specific tasks
- Ensure delegation of tasks is complete prior to study enrollment at the site
- Provide a complete list of the investigators AND sub-investigators who make a direct and significant contribution to the clinical data

DTL Summary Information

- Scope
  - Select NCI-supported trials, with the priority given to FDA Registration trials
  - Pilot is with a limited number of NCTN studies
  - NCI will determine when a study-specific DTL is required, generally at the concept or letter of intent (LOI) phase
- Access
  - The DTL application will be under a separate tab on the CTSU website
  - Two views of the DTL: LPO-facing and Site-facing
  - Users will be able to see DTLs for their associated sites and organizations
- Pilot Schedule
  - Initial pilot studies August 2017 with the remainder of the pilot studies about a month later

DTL Business Rule (1)

- DTL protocol-specific templates are based upon a Master DTL template
- The LPO is responsible for setup and submission of the protocol-specific template to NCI for review and approval prior to study activation
- The DTL protocol-specific template will include
  - Primary tasks: CI and DTLA
  - Required Tasks
  - Required registration type per task (IVR, NPIVR, AP. A)
  - Roster requirements
  - CI signature requirements
  - Training requirements

DTL Business Rules (2)

- Any individual on a participating roster at the site can initiate the DTL
- Mandatory assignment of a Clinical Investigator (CI) responsible for the overall conduct of the study at the site and one or two DTL Administrators (DTLAs)
- The CI must have the IRB documented on the IRB approval listed on their FDA Form 1572 to approve the DTL
- After the CI approves the DTL, only the CI or DTLAs can make changes to the DTL
- The CI is required to sign the site DTL initially, when new task assignments require CI sign-off, and at least annually

DTL Business Rules (3)

- Studies with a DTL will have a DTL Protocol Specific Requirement (PSR) in RSS that will automatically comply when the CI signs the DTL
- All mandatory tasks on the DTL must have at least one qualified (required registration type and “active” registration status) site staff person assigned for the CI to approve the DTL
- The site must maintain an approved DTL to retain an approved site registration status in RSS
- Task assignments on the DTL will control site access to Rave and OPEN and the selection of investigators in OPEN

DTL Application

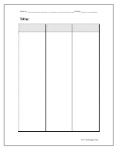
Protocol

Approved

DTL Protocol

Protocol Documents

Approved DTL Template [1.0]



Protocol Specific Requirements

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

Site Registration [Approved]

Site

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 Pilot Protocols

- ALLIANCE
  - A051301
  - A021502
- ECOG-ACRIN
  - EA8143
  - EA514
- NRG
  - NRG-GY005
  - NRG-GI004
- SWOG
  - S1605
  - S1418
- COG
  - AEWS1221
  - AALL1331

DTL Summary

- CTEP works 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 (IVR, NPRIVR, AP, A)
- 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 >>> reviewable on audit)

DTL, RCR, and Study Site Registration (FDA) Packet

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

Application Release Schedule

- Monday, July 31st, 2017 – RCR released
- September 2017 – Pilot testing of DTL application begins
- 3rd Quarter 2018 – Initial RCR registration cycle complete (i.e., complete credentials for all registered persons)

Questions?

For further questions or feedback, please send email to:

< NCIPMBRCRDTL@mail.nih.gov >

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