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

The RCR and DTL applications are often spoken of in the same breath, but they are separate applications with a common goal of improving regulatory documentation and ensuring individuals essential to the conduct of NCI-supported research have adequate training to conduct a study.

The RCR is an online self-service person registration application that will allow users to electronically sign and upload documents. It will expand the current investigator registration (IR) process managed by the Pharmaceutical Management Branch (PMB) under the Cancer Therapy Evaluation Program (CTEP).

The DTL is an application on the CTSU members' website which allows the investigator responsible for conduct of the study at the site (termed as Clinical Investigator [CI]) to delegate study-related tasks to qualified individuals at the site on designated studies.

Registration and Credential Repository (RCR)

RCR will be released on Monday, July 31st, 2017 and will replace the current paper-based IR process.
With RCR, the current two "person types" (i.e., Investigator and Associate) will be replaced with five "registration types."

REGISTRATION TYPE	ABBREVIATION	DESCRIPTION
Investigator	IVR	Licensed MD, DO, or equivalent
Non-Physician Investigator	NPIVR	Advanced practice clinical staff who may act as study principal investigators (PI), site-protocol PIs, or enrolling PIs in OPEN for select studies
Associate Plus	AP	Clinical site staff integral to the conduct of NCI-supported studies
Associate	A	Other clinical or administrative staff that require access to NCI-supported applications but act in a supporting role (ordering designees, regulatory submissions, etc.)
Associate Basic	AB	Individuals that require limited access to select NCI-supported applications or are tracked for administrative purposes (e.g., industry contacts)

All registration types must have a CTEP Identify and Access Management (CTEP-IAM) account, and CTEP-IAM credentials will be required to access the RCR application. IVRs, NPIVRs, and APs will complete their annual registration in RCR. Associates and Associate Basics will continue to complete their annual registration requirement in CTEP-IAM. The table to the right outlines RCR documentation requirements.

Documentation Required	IVR	NPIVR	AP
FDA Form 1572	X	X	
Financial Disclosure Form (FDF)	X	X	X
NCI Biosketch (including education, training, employment, license, and certification as applicable)	X	X	X
Human Subject's Protection (HSP) and Good Clinical Practice (GCP) Training Certificates	X	X	X
Agent Shipment Form (if applicable)	X		

RCR and the DTL, *continued*

As part of the Agent Shipment Form, IVRs will provide information on their shipping address, Shipping Designee (SD), Ordering Designees (ODs), and may assign a Registration Coordinator (RC) and a backup RC. *The use of an RC is strongly encouraged as RCR will have several features to allow the RCs to assist investigators with the population of their profiles and the completion of their forms.*

It is important to note that the practice site information will influence many downstream processes including:

- IVRs and NPIVRs may only be rostered at practice sites listed on their FDA Form 1572;
- IVRs and NPRIVRs may only act as the Site Protocol PI (listed on the IRB approval) for IRBs listed on their FDA Form 1572;
- IVRs and NPRIVRs may only act as the consenting, enrolling, treating, credit, drug shipment (IVRs only), or transfer investigator in OPEN when the site and the site's IRB are listed on their FDA Form 1572;
- IVRs and NPIVRs may only hold the Rave Site Investigator role or act as the CI on the DTL at sites listed on their FDA Form 1572; and
- IVRs may only order investigational agent via the Online Agent Ordering Process (OAOP) at sites listed on their FDA Form 1572.

The AP registration type is the minimal registration type required to hold the following roles in the Regulatory Support System (RSS) and/or on the DTL:

- OPEN Registrar role
- Rave CRA Role
- CRA (Lab Admin)
- Senior Lab Administrator (Rave role)
- DTL Administrator (DTLA)
- Primary role on a roster (i.e., Administrator, Senior CRA, etc.)

Associates are not required to use the RCR for registration, and can hold the following administrative roles:

- Shipping Designee (OAOP)
- Ordering Designee (OAOP)
- Registration Coordinator (RC)

It is important to note that the AB registration type will have limited access to systems, and cannot be added to treatment sites or access the CTSU members' website.

During the transition year (August 2017 to August 2018), rules for aligning IVRs and NPIVRs with the practice sites and IRBs on their FDA Form 1572 will be relaxed until the date of their annual re-registration. During the initial RCR registration, the IVR or NPIVR will have the option of auto-populating their practice sites and IRBs based on roster and IRB data in RSS. In addition, current associates will retain their OPEN Registrar or Rave roles until the time of re-registration at which point they will need to re-register at the AP level to retain access.

The Delegation of Tasks Log (DTL)

The pilot phase of the DTL will begin in August 2017. A new tab on the CTSU members' website will house the DTL application. There will be two views, one for the Lead Protocol Organizations (LPOs) and another for sites.

As noted previously, DTLs will be required on select studies as determined by NCI with studies supporting FDA registration given initial priority. The LPO is responsible for the development of the study-specific DTL based upon a

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RCR and the DTL, *continued*

master template that includes a standard task list and required registration types. While some tasks are required for all studies, the DTL will vary from study to study. In general, DTL activation will coincide with study activation.

Information on the DTL influences several other processes such as site registration approval (a protocol-specific requirement [PSR] will be added to the study in RSS), access to OPEN and Rave, and the selection of IVRs and site staff on the credentialing screen in OPEN. Upon activation of the DTL by the LPO, participating sites will access the DTL application to initiate the DTL. Any person aligned with the site can initiate the DTL and assign tasks. With few exceptions, there is no limit on the number of individuals assigned to a task. Exceptions include the DTLA (maximum of two individuals) and one CI for a given site/study combination. Tasks on the DTL are either optional or mandatory; at least one person must be assigned to all mandatory tasks. In addition, some tasks may require task-specific training.

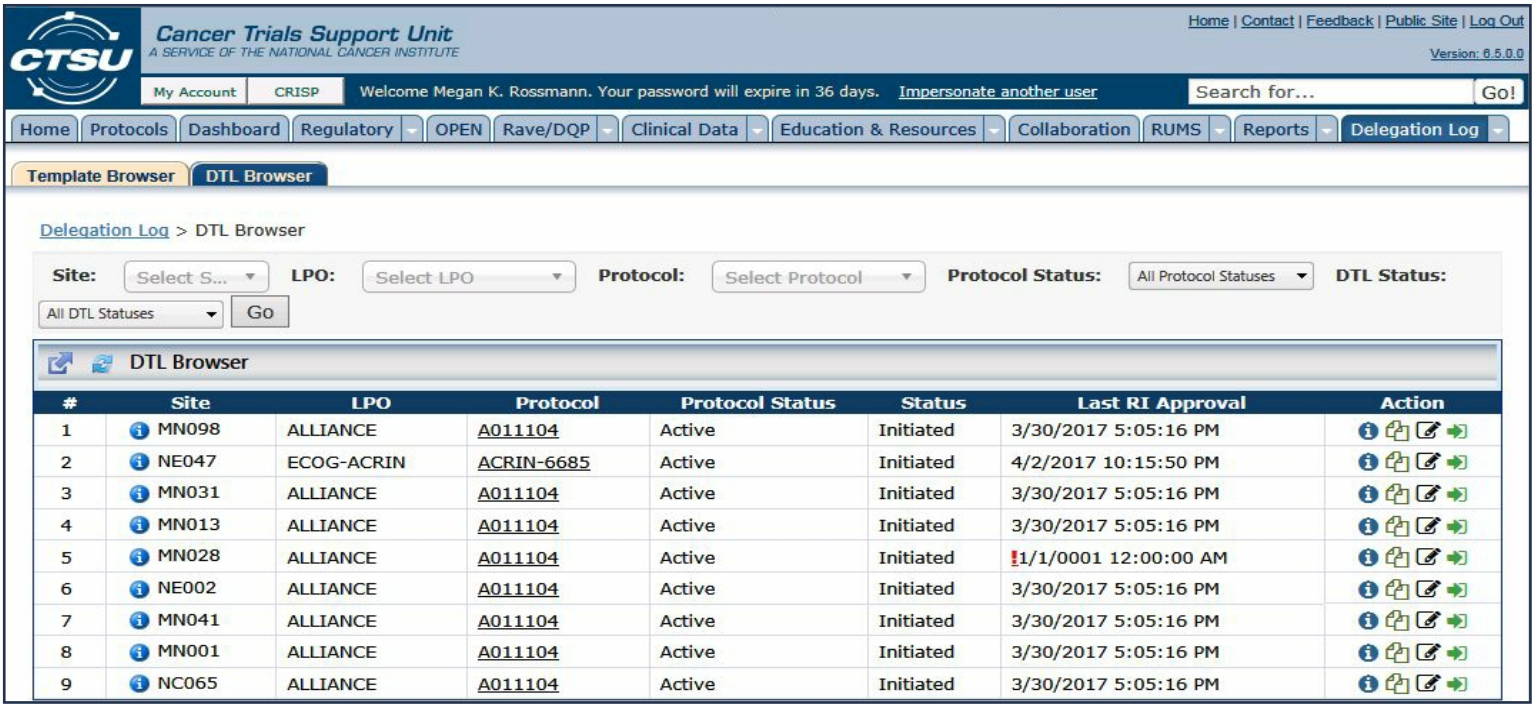
Once the DTL is complete, it can be submitted to the CI for sign-off, and receive an 'approved' status, thereby complying the DTL PSR for site registration. Once approved, only the DTLA or CI can make further changes. Updates to mandatory tasks will require the CI to re-sign the DTL, and the CI must re-sign the DTL at least annually. Failure to have at least one staff member assigned to each mandatory task, or failure of the CI to provide annual verification, will cause the DTL to go to an 'unapproved' status and the site registration status to go to 'pending'.

In addition to the overall DTL status, each task will have a task status. The task status will be 'active' when the staff member retains an active NCI registration status, active roster status, and completes task-specific training.

Several tools will be available to support sites in managing their DTLs including:

- On-screen instructions for completing and managing DTLs;
- DTL browser displaying information on the study, DTL status, and alerts for task status changes and annual CI sign-off; and
- Several planned CTSU Reporting and Information Subscription Portal (CRISP) notifications to which site staff can subscribe.

Be on the lookout for additional information and trainings on the RCR and DTL during the spring and summer NCTN Group meetings.



#	Site	LPO	Protocol	Protocol Status	Status	Last RI Approval	Action
1	MN098	ALLIANCE	A011104	Active	Initiated	3/30/2017 5:05:16 PM	
2	NE047	ECOG-ACRIN	ACRIN-6685	Active	Initiated	4/2/2017 10:15:50 PM	
3	MN031	ALLIANCE	A011104	Active	Initiated	3/30/2017 5:05:16 PM	
4	MN013	ALLIANCE	A011104	Active	Initiated	3/30/2017 5:05:16 PM	
5	MN028	ALLIANCE	A011104	Active	Initiated	!1/1/0001 12:00:00 AM	
6	NE002	ALLIANCE	A011104	Active	Initiated	3/30/2017 5:05:16 PM	
7	MN041	ALLIANCE	A011104	Active	Initiated	3/30/2017 5:05:16 PM	
8	MN001	ALLIANCE	A011104	Active	Initiated	3/30/2017 5:05:16 PM	
9	NC065	ALLIANCE	A011104	Active	Initiated	3/30/2017 5:05:16 PM	