Managing Delegation of Tasks Logs

Matthew Boron, RPh

PMB, CTEP, NCI

NATIONAL CANCER INSTITUTE

November 2, 2018

Registration and Credential Repository (RCR) Update

Registration Type	Correct Counts
A	28
AP	15717
IVR	19836
NPIVR	1215
	36796

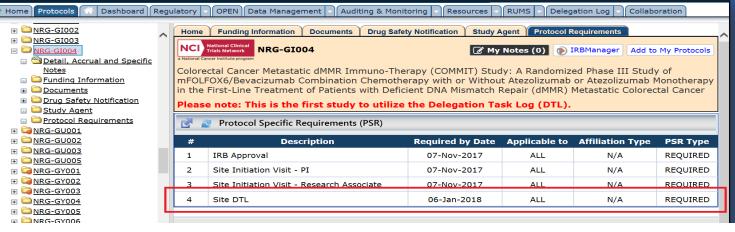# Registration and Credential Repository (RCR) … more to come

- Enhanced RC and back-up RC functionality

- Reports (site protocol reports – with DTLs, 1572 reports)

- Review of profile details (HSP / GCP / licensing)

Delegation of Tasks Log (DTL) - What is it?

- documents the delegation of tasks by the site Clinical Investigator (CI) to appropriately trained site staff at the clinical site for a protocol

- For select protocols, a signed DTL is required to obtain an approved site registration and enroll subjects in OPEN

- required for select protocols as determined by the CTEP or the Division of Cancer Prevention (DCP)

What Studies Require One?

- CTEP Investigational New Drug (IND) application, and/or that support FDA registration

- Information on DTL requirements is included in the protocol webpages [See CTSU members' website → Protocols or Regulatory Tabs →Protocol Requirements subtab]

- DTL activation notices will be in Bi-monthly Broadcasts and/or targeted broadcasts when a new DTL is activated on an existing study

ALLIANCE protocols requiring a Delegation of Tasks Log

- 15 study DTLs activated

  - **A021502**: Randomized Trial of Standard Chemotherapy Alone or Combined with Atezolizumab as Adjuvant Therapy for Patients with Stage III Colon Cancer and Deficient DNA Mismatch Repair

  - **A051301**: A Randomized Double-Blind Phase III Study of Ibrutinib During and Following Autologous Stem Cell Transplantation Versus Placebo in Patients with Relapsed or Refractory Diffuse Large B-cell Lymphoma of the Activated B-cell Subtype

  - **A021602**: Randomized, Double-Blinded Phase III Study of CABozantinib Versus Placebo IN Patients with Advanced NEuroendocrine Tumors After Progression on Everolimus (CABINET)

When does the DTL have to be Completed?

- For newly activated studies, the DTL must be complete prior to obtaining an approved site registration status

- For already active studies, registered sites have 60 calendar days to complete the DTL after activation of the amendment to retain an approved site registration status

- For new versions of the DTL on a study, registered sites have 60 calendar days to complete the DTL update to retain an approved site registration status

Requirements for Assigning Tasks

- All tasks on the DTL require the assignee to have an active CTEP registration status

- Most tasks are limited to individuals on a participating roster at the site and registered in the Registration and Credential Repository (RCR)

- While there is a core set of required tasks, optional tasks may vary between studies

- The Site DTL Browser and Master Task List provide more detail on requirements for DTL assignment

Delegation of Tasks Log – who should I add?

- **IVR (INVESTIGATOR)**

  - CTEP-Sponsored treatment trials

    - M.D., D.O., international equivalent

  - DCP-Sponsored trials / some CTEP non-treatment trials

    - Multiple different healthcare professionals

Delegation of Tasks Log – who should I add?

INVESTIGATOR ONLY

- Clinical Investigator

- Drug Shipment Investigator

- IND prescribing (investigational arm and SOC arms)

- Treating / Enrolling person

Delegation of Tasks Log – who should I add?

NPIVR (Non-Physician Investigator)

- Mid-level providers
  - Examples, not limited to:
    - APN
    - PA
    - PharmD
    - NP
    - MPH
    - Etc.

Delegation of Tasks Log – who should I add?

NPIVR (Non-Physician Investigator)

- Eligibility

- End point assessment

- Enrolling/Treating (CTEP non-treatment trials and some DCP studies)

- History and Physical

- Toxicity Assessment

- Agent Prescribing -- maybe

- Rave Investigator – maybe

Delegation of Tasks Log – who should I add?

AP (Associate Plus)

- CRA / RN / Pharmacist

- RAVE roles (also requires role assignment in RSS)

- NCTN/ETCTN/LAPS/LAO/Site Administrators

- Auditor

- Registrar – OPEN (also requires role assignment in RSS)

Delegation of Tasks Log – who should I add?

AP (Associate Plus)

- Delegation of Tasks Log Administrator

- Consenting

- Investigational Product Accountability

- OPEN Registrar

- RAVE CRA

Delegation of Tasks Log Update

- Email communications

  - CI and DTLA(s)

  - CI approval required tasks

  - Annual (30, 14 and 1 day prior to due date)

Delegation of Tasks Log Issues

- RCR registration suspended

  - Person will not be in LOVs for OPEN/DTL

  - Last person on a required task → DTL will change to unapproved and Site

    Registration status will be set to PENDING

  - Can no longer be Site Protocol PI (IRB PI)

Delegation of Tasks Log Questions

- Staff covering multiple sites – cloning

- Clinical Investigator practicing at multiple sites – What is reasonable?

- Changes to DTL – CI signature Required?

- General DTL site navigation – CI dashboard

Delegation of Tasks Log on the Horizon

- Bulk assignment / removal

- Bulk signing

- Dashboard for CI to help navigate signing of documents

- Local tasks – still looking into this

Where can I find Help?!?

Questions??

www.cancer.gov   www.cancer.gov/espanol