**US-Latin American-Caribbean HIV/HPV-Cancer Prevention Clinical Trials Network (ULACNet)**

**Guidance on the Initiation, Completion, and Maintenance of Delegation of Tasks Logs (DTLs) and the Registration and Credential Repository (RCR)**

This document serves as a guidance for the completion of Delegation of Tasks Logs (DTLs) and the Registration and Credential Repository (RCR) for ULACNet studies. Completion of DTLs and RCR registration are two separate requirements that must be met before ULACNet studies can open at accruing sites. DTLs document the personnel working on a ULACNet study at each accruing site (as discussed in section 1.1.), while RCR is a system used to collect the documentation needed to fulfill Good Clinical Practice (GCP), Food and Drug Administration (FDA), and National Cancer Institute (NCI) clinical trial requirements.

Delegation of Tasks Logs should be completed during or shortly after the Site Initiation Visit and updated every time there is a change in personnel or personnel delegated study tasks. Accruing sites should send their completed DTLs to their respective Lead Academic Organization (LAO), which will then send them to the DCP Regulatory Contractor to ensure that they have been completed correctly. The DTLs should include only those personnel who have been delegated significant study tasks (see section 2.3).

The Registration and Credential Repository should be completed as soon as personnel know that they will be included on a DTL and/or ULACNet protocol face sheet. Accruing sites should send their completed RCR Registration Tool documents to their respective Lead Academic Organization (LAO), which will then send them to the DCP Regulatory Contractor to ensure that all RCR registrations have been completed correctly. RCR registrations should be completed by all personnel who are listed on a DTL and/or ULACNet protocol face sheet; however, it is the responsibility of the LAOs to ensure that RCR registrations are completed for any other personnel who have significant roles in the study but are not included on a DTL or ULACNet protocol face sheet.

## Instructions for Completing DTLs and RCR Registration

## (For personnel included on a DTL)

1. Complete Initial RCR Registration
	1. Accruing sites complete the RCR Registration Tool as soon as they know the personnel who will be included in the DTL.
	2. Personnel use the RCR Registration Tool to determine whether they need to register as Investigators (IVRs), Non-Physician Investigators (NPIVRs), or Associate Pluses (APs)
	3. Personnel begin registering as IVRs, NPIVRs, or APs
2. Ensure that RCR Registration is Correct
	1. Accruing sites send the completed RCR Registration Tool to their respective LAO (the LAO will then send the document to the DCP Regulatory Contractor for quality assurance reviews)
	2. Accruing sites receive the DCP Regulatory Contractor’s quality assurance findings from their respective LAO
	3. Accruing sites ensure that all quality assurance findings are corrected
3. Complete the Initial DTL
	1. Accruing sites send their completed DTLs to their respective LAO once the site is close to opening (the LAO will then send the document to the DCP Regulatory Contractor for review of both the DTL and the RCR registrations of all personnel included on it). Accruing sites who need guidance while completing their DTLs may send drafts of their DTLs to their respective LAOs 1-2 weeks before the study opens at the site (the LAO will also send this document to the DCP Regulatory Contractor for review of the DTL and the RCR registrations of all personnel included on it). However, drafts should not contain any signatures, initials, or un-official start dates.
	2. Accruing sites receive the DCP Regulatory Contractor’s quality assurance findings from their respective LAO
	3. Accruing sites ensure that all quality assurance findings are corrected. Minor corrections should be made by the time the DTL is next updated. Major corrections should be made by the time of site activation or within the timeframe listed on the DCP site activation letter.

## Instructions for Completing RCR Registration

## (For personnel included on a ULACNet protocol face sheet)

1. Complete Initial RCR registration
	1. Personnel included on a ULACNet protocol face sheet register as IVRs, NPIVRs, or APs (investigators and sub-investigators must register as IVRs or NPIVRs)
2. Ensure that RCR registration is correct
	1. The DCP Regulatory Contractor uses the protocol to ensure that all RCR registrations are correct
	2. The DCP Regulatory Contractor contacts the LAOs with any needed corrections
	3. The LAOs contact personnel to ensure that all needed corrections are made

## Frequently Asked Questions (FAQs)

## Section 1 Introduction to Delegation of Tasks Logs (DTLs)

* 1. **What is a DTL?**

A Delegation of Tasks Log (DTL) is a document used to show which study tasks a site principal investigator has delegated to the personnel working on a clinical research study at a specific accruing clinical research site at any given time. The DTL must be updated every time there is a change in personnel or personnel delegated study tasks; accruing sites should send updated DTLs to their respective LAOs (the LAOs will then send the DTLs to the DCP Regulatory Contractor for quality assurance). This will ensure that there is documentation showing not only who worked on the study at the site, but when. Additionally, the DTL serves as a record of the names, signatures, and initials of personnel involved in collecting, reviewing, and updating key clinical study data under the supervision of a site principal investigator.

* 1. **Why are DTLs used?**

DTLs are used because they allow those involved in clinical research studies to fulfill the below International Conference on Harmonization (IHC) Good Clinical Practice (GCP) Guidelines *ICH GCP E6 R2*

*Section 4.1.5 “The investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties”*

*Section 8.3.24 “Signature sheets” should be used “to document signatures and initials of all persons authorized to make entries and/or corrections on CRFs”*

Additionally, DTLs allow those involved in clinical research studies to fulfill the FDA’s *Guidance for Industry Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects*

*Section III.A.1. “The investigator should maintain a list of the appropriately qualified persons to whom significant trial-related duties have been delegated. This list should also describe the delegated tasks, identify the training that individuals have received that qualifies them to perform delegated tasks (e.g., can refer to an individual’s CV on file), and identify the dates of involvement in the study. An investigator should maintain separate lists for each study conducted by the investigator”*

* 1. **What is the US-Latin American-Caribbean HIV/HPV-Cancer Prevention Clinical Trials Network (ULACNet) DTL requirement?**

Each accruing ULACNet clinical research site is required to maintain its own DTL throughout the course of the study, using the most updated version of the ULACNet DTL template.

* 1. **Where can I find the ULACNet DTL template and “RCR Registration Tool” document?**

The ULACNet DTL template and “RCR Registration Tool” document can be found on the ULACNet website under “[ULACNet Instructions, Forms and Templates](https://prevention.cancer.gov/clinical-trials/clinical-trials-management/ulacnet-instructions-forms).”

**Section 2 Introduction to the Completion of Delegation of Tasks Logs (DTLs)**

1. **Who should complete a DTL?**

Each accruing ULACNet site should complete, and maintain, a DTL for each ULACNet protocol throughout the course of the study.

1. **Who should be listed as the Principal Investigator (PI) on the DTL?**

The person who will be responsible for the oversight of the clinical research study at a specific clinical research site should be listed as the PI on the DTL. The person listed as the PI should be able to speak to both the overall conduct of the study at the site and of all personnel listed on the site’s DTL during an auditing or monitoring visit.

1. **Which personnel should be included on the DTL?**

Only accruing site personnel who have been delegated significant study tasks by the site principal investigator should be included on the site’s DTL, as stated in *ICH GCP E6 R2* (see the list below for examples of significant study tasks). There is not currently any Good Clinical Practice (GCP) guidance or Food and Drug Administration (FDA) regulation defining “significant study tasks”; however, they can generally be thought of as study tasks that involve study-related contact with participants or participant protected health information (PHI). Additionally, they can generally be thought of as study tasks that require protocol-specific training.

* Assessing eligibility
* Screening participants
* Obtaining informed consent
* Randomizing participants
* Obtaining medical history
* Performing physical exams
* Performing study related procedures
* Administering study agents
* Assessing AEs/SAEs
* Completing source documentation
* Maintaining essential documents
1. **Which personnel should not be included on the DTL?**

Personnel whose work is independent of the study principal investigator, does not directly contribute to the care or protection of participants or participant protected health information (PHI), and does not require study specific training should not be included on the site’s DTL (see the list below for examples). These personnel may have some, minimal study-related contact with participants or participant PHI (e.g., administrative or office assistants). Additionally, these personnel may need to know some study-specific information (e.g., laboratory manuals, pharmacy manuals, statistical analysis plan), but generally do not require protocol-specific training.

* Administrative assistants who do not work directly with participants and who have limited access to participant PHI
* Biostatistician/Statisticians
* Data analysts
* Data core directors
* Laboratory core directors
* Laboratory managers
* Laboratory technicians
* Laboratory supervisors
* Office assistants who do not require study-protocol specific training
* Patient/Participant transporters
* Pharmacists who do not require overall protocol-specific training, who perform study agent accountability as part of their daily job, who are not involved in administering the study agent, etc.
* Phlebotomists who do not require protocol-specific training
* Regulatory specialists
1. **How should the DTL be signed?**

The DTL can be signed either by hand or electronically. However, all electronic signatures must be 21 CFR Part 11 compliant. Information about [21 CFR Part 11 compliance](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application) can be found on the FDA website.

1. **What should I do if I need help completing the DTL?**

The principal investigators at each accruing ULACNet site may delegate one person at their site to be the DTL Administrator, who will be responsible for ensuring the timely completion of the DTL. If accruing sites need assistance completing their DTLs, the DTL Administrator may contact their respective LAOs. If additional assistance is needed, the LAO may contact the DCP regulatory contractor.

Of note, the DCP Regulatory Contractor has found that accruing sites often need assistance identifying who needs to be listed on the DTL, and therefore registered in RCR, as Investigators (IVRs), Non-Physician Investigators (NPIVRs), or Associate Pluses (APs). For this reason, the DCP Regulatory Contractor asks accruing sites to send their completed “RCR Registration Tool” document to their respective LAO at the same time their respective protocols are submitted to DCP for review. The LAO will then send the document to the DCP Regulatory Contractor so that it can provide guidance on how each person should be listed on the DTL and registered in RCR. This will allow accruing sites to begin registering in RCR as soon as possible, ensuring that site activation can occur in a timely manner, while also minimizing the DCP regulatory contractor’s DTL and RCR audit findings.

## Section 3 Completion of Delegation of Tasks Logs (DTLs) – Pre-Site Activation

1. **When should the first DTL be completed?**

The first, initial DTL should be completed when the clinical research study is close to being activated at the clinical research site and should be submitted by the LAO to the DCP regulatory contractor together with the remaining documents needed for site activation (LAO IRB approval; AO IRB approval; in-country approval, if applicable; IND status; study drugs letter, if applicable; and safety equipment letter, if applicable). The initial DTL should include only those personnel who will have completed all their study-specific training and will be ready to begin working on the study at the site once it is activated. As more personnel complete their study-specific training and are ready to begin working on the study, the DTL should be updated and sent by the LAO to the DCP regulatory contractor.

1. **When should the first DTL be sent to the Lead Academic Organization (LAO)?**

Accruing sites should send their first, initial DTLs to their respective LAOs once the accruing site is close to opening (the LAOs will send all DTLs to the DCP Regulatory Contractor). Accruing sites may send drafts of their DTLs to their respective LAO 1-2 weeks before the study opens at the site if needed (the LAOs will also send all drafts to the DCP Regulatory Contractor). However, drafts should not include any signatures, initials, or un-official start dates.

1. **What happens once the DTL is sent to the Lead Academic Organization?**

Once the completed DTL is sent to the LAO, the LAO forwards it to the DCP Regulatory Contractor. The DCP Regulatory Contractor then quality reviews the DTL against the RCR registration of each person listed on it, to ensure that all information on the DTL matches that in RCR. The DCP Regulatory Contractor’s findings are then sent back to the LAO, which shares them with the respective accruing sites and assists them in making corrections to the DTL and/or RCR registrations as needed. The DTL should be corrected and re-submitted to the DCP Regulatory Contractor by the time of site activation or within the timeframe listed on the DCP site activation letter.

## Section 4 Maintenance of Delegation of Tasks Logs (DTLs) – Post-Site Activation

1. **When do I need to update the DTL?**

The DTL is a living document that must be updated every time there is a change in personnel and/or personnel study tasks. New personnel may be added directly to the current DTL.

* 1. **What do accruing ULACNet sites need to do with updated DTLs post-site activation?**

Accruing ULACNet sites should email updated DTLs post-site activation to their respective LAOs, which will then forward them to the DCP Regulatory Contractor. The DCP Regulatory Contractor will maintain the document on behalf of the LAOs (the sponsors). The DCP Regulatory Contractor will review updated DTLs as they are received and audit the most updated version of the DTL during site auditing visits; it is therefore important for each accruing ULACNet site to maintain a copy of each version of the document in either electronic or paper format on-site.

* + 1. **Do accruing LAOs and sites need to wait for the updated version of the DTL to be reviewed before the new personnel included on it can begin working on the study?**

No, accruing sites do not need to wait for the updated DTL to be reviewed or audited before new personnel can begin working on the study. However, accruing sites should ensure that all information on the updated DTL is correct before having new personnel begin working on the study, for example the “tasks start date” (the date when all study-specific training has been completed and the new personnel can begin working on the study). The auditor will likely check that the signatures, initials, and tasks start dates on the DTL correspond with those on other documents, such as training logs.

* + - 1. **What should accruing sites do with previous versions of their DTLs?**

All previous versions of the DTL should be maintained in either electronic or paper format, with dates indicating when each version was updated. Personnel who have signed and initialed the previous versions of the DTL do not need to re-sign or re-initial the updated version of the DTL unless the document needs to be re-started (due to change in PI, damage to original document, etc.). Accruing sites should make note of when each version of the DTL was completed; if an accruing site sends a draft of its DTL to its respective LAO without signatures or initials, it should also make note that the version was sent as a draft. All signed and initialed (i.e., non-draft) versions of the DTL should be archived with other study data after the end of the study. These are files that may be reviewed by an auditor, monitor, and/or FDA inspector (if applicable).

## Section 5 NCI Registration and Credential Repository (RCR)

5.1 **What is RCR?**

RCR is a system used by the National Cancer Institute (NCI) to maintain many of the documents needed for clinical research studies. These documents include the NCI version of the FDA Form 1572, NCI Biosketch (used by NCI in place of CVs), GCP training certificates, financial disclosure forms, and study agent shipment forms. For this reason, DCP will not issue its Final Approval for a study to open at a site until all personnel listed on that site’s DTL have correctly registered in RCR.

RCR Registration Types (from <https://ctep.cancer.gov/investigatorresources/default.htm>)

* Investigator (IVR) — MD, DO, or international equivalent
* Non-Physician Investigator (NPIVR) — Advanced practice providers (e.g., NP or PA) or graduate level researchers (e.g., PhD)
* Associate Plus (AP) — Clinical site staff

**Documents Required to be Completed in RCR per Registration Type** (from <https://ctep.cancer.gov/investigatorresources/default.htm>)

|  |  |  |  |
| --- | --- | --- | --- |
| **Documentation Required** | IVR | NPIVR | AP |
| NCI version of FDA Form 1572 (includes practice sites, labs, and IRBs/IECs) | ✓ | ✓ |  |
| NCI Biosketch (includes education, professional training, employment, professional certification, professional licenses) | ✓ | ✓ | ✓ |
| GCP Training | ✓ | ✓ | ✓ |
| Financial Disclosure Form | ✓ | ✓ | ✓ |
| Agent Shipment Form | ✓ |  |  |
| CV (Optional; the NCI uses the NCI Biosketch in place of CVs) | ✓ | ✓ | ✓ |

5.2 **Why is RCR used?**

RCR is used to maintain many of the documents needed for clinical research studies, as stated in section 5.1, including those outlining the qualifications of the study development team. The DCP regulatory contractor will access these documents directly in RCR as needed, such as during an FDA inspection. The LAO will send the DCP regulatory contractor other essential documents needed for the initiation of the study, including the LAO IRB approval; AO IRB approval; in-country approval, if applicable; IND status; study drugs letter, if applicable; and safety equipment letter, if applicable.

5.3 **Who should be registered in RCR?**

All those listed on a ULACNet DTL or protocol face sheet should register in RCR. The DCP Regulatory Contractor will audit RCR registrations of those listed on ULACNet DTLs and protocols to ensure that they are registered as Investigators (IVRs), Non-Physician Investigators (NPIVRs), or Associate Pluses (APs) as appropriate (all investigators and sub-investigators must register as IVRs or NPIVRs). However, it is the responsibility of the LAOs to ensure that any other personnel who have significant roles in the study but who are not included on a ULACNet DTL or protocol face sheet complete their registration in RCR (e.g., sub-investigators).

5.4 **When should personnel begin registering in RCR?**

Personnel should begin registering in RCR as soon as they know they have or will be included on either a ULACNet DTL or protocol face sheet. Each accruing site should complete the “RCR Registration Tool” document as thoroughly as possible, on which they should list the study tasks that each person will most likely be delegated once the PI and/or DTL administrator begin working on the DTL. These delegated study tasks will determine whether these personnel will need to register in RCR as APs, NPIVRs, or IVRs. Accruing sites should then send the document to their respective LAO (the LAO will then send it to the DCP Regulatory Contractor for quality assurance).

5.5 **What should I do if I need help completing RCR?**

If accruing sites need help completing RCR, then they should first contact the LAO’s RCR Registration Coordinator or Point of Contact. If LAOs need help completing RCR, they should contact the DCP regulatory contractor. Both LAOs and accruing sites can contact the DCP regulatory contractor as needed.