

National Cancer Institute (NCI)  
Experimental Therapeutics Clinical Trials Network (ETCTN) Guidance

## DF/HCC ETCTN eDTL Guidance: the Site eDTL and eDTL Template

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### Contents

Introduction .....	1
Procedure for Site eDTL .....	2
Procedure for eDTL Template.....	2
Procedure for Note-to-File.....	3
Links .....	4

### Introduction

As of January 2020, all new ETCTN studies are required to utilize an electronic version of a “Delegation of Authority” log or eDTL available via the CTSU website. These study and site-specific logs document the study-related tasks delegated to qualified site staff by each participating DF/HCC Site Principal Investigator (PI).

The requirement for a Site eDTL is addressed within the protocol and is listed among the protocol-specific requirements (PSRs) on the CTSU protocol page for the study. Separate Site eDTLs must be submitted by our individual participating sites (DFCI, MGH, BIDMC), including when we Chair a study. An approved site log is required for an approved site registration status enabling a site to begin (and continue) enrollment to a study. If the eDTL’s approval lapses, the site’s status reverts to “pending” and the site will not be able to enroll patients until the eDTL is approved once again. Study teams can make the Site eDTL the DTL of record to avoid having to maintain multiple logs. For older studies which utilized a DF/HCC Delegation of Authority (DOA) log, teams can create a Note-to-File for the retired log when replacing the log with a Site eDTL.

In addition, when we are the Protocol Chair, the DF/HCC study team is required to create a protocol-specific eDTL Template for the study for use by participating sites as part of the study’s pre-activation activities. Approval of the template is a requirement for CTEP final approval and activation of a study. The eDTL Template serves to inform the requirements of the protocol specific Site eDTL that is to be completed by the applicable study’s participating sites.

The eDTL applications have been enhanced for bulk functionality for assignments, activations, and approvals. They also include an updated Help Topics for instructions and other resources. eDTL Help Topics are available on each screen within the application; they are loosely context specific. See the question mark icon on the right margin of the screen.

## Procedure for Site eDTL

- 1) Any rostered study team member at a participating site can create and edit a new eDTL.
- 2) **The Site PI will be referred to as the CI throughout this document to be consistent with the language used on the eDTL.**
- 3) Study Team member accesses the [eDTL application](#), selects the Site eDTL browser, initiates a Site DTL and assigns Site PI (or CI) and study staff all of the Required Tasks (or minimum tasks) based on the eDTL [Master Task List](#). This list describes each task, and includes the allowed registration requirements and whether CI signoff is required for the task. All tasks on the eDTL require the assignees to have an active CTEP registration status. Please see DF/HCC NCI and CTEP Registration Guidance for more details on CTEP registration.
  - a) Each site must assign only one (1) Site PI (or CI) and up to three (3) DTL Administrators (DTLAs)
  - b) A few tasks (OPEN Registrar, Rave CRA, Rave Investigator) are associated with corresponding institutional roles granted on the local ETCTN Roster (ie Registrar, Rave CRA, Site Investigator) . Please see DF/HCC ETCTN and CIRB Rostering Guidance for further details on being granted roster roles.
  - c) Where applicable, backup assignments are encouraged (Such as the DTLA task). All indicated Required Tasks for the eDTL must have at least one staff member with an active CTEP registration status. If there is a required task and all staff who are assigned the task have inactive CTEP registration statuses, the eDTL will revert to “unapproved” and enrollment will halt.
- 4) Study team member submits the eDTL to the CI for sign off.
  - a) Once an eDTL is signed by a CI, only the CI and DTLA can make updates.
- 5) Completed and signed Site eDTL is submitted via the eDTL application for approval.
- 6) eDTL is approved.
- 7) After initial DTL approval, CIs must sign a DTL at the following times:
  - i) When assignments requiring CI signature are added to the DTL;
  - ii) With new versions of the DTL; and
  - iii) A minimum of once annually.

## Procedure for eDTL Template

- 1) Access to the DTL Template Browser Web Application is granted to Protocol Chair staff via the CTSU administrative roster. DF/HCC ETCTN Protocol Chair staff should email Sharon Atkinson ([Sharon\\_Atkinson@dfci.harvard.edu](mailto:Sharon_Atkinson@dfci.harvard.edu)).

- 2) and Shelby Watterworth ([Shelby\\_Watterworth@dfci.harvard.edu](mailto:Shelby_Watterworth@dfci.harvard.edu)) of the DFCI ETCTN Office to request this additional roster role.
- 3) Access the CTSU Website once rostered. At the top of the CTSU webpage users need to adjust their view from the “Site User” to “LPO User” setting. Select “Delegation Log” from the navigation bar on the CTSU Website and select “DTL Template Browser” from the drop-down menu. From the Template Browser landing page, select “+DTL Template” to initiate a new protocol-specific Template DTL.
- 4) In the newly initiated eDTL Template, include all required tasks based on those described in DTL Master List and submit the draft template for CTEP-PIO approval.
- 5) CTEP’s PIO reviews and approves the Template DTL.
- 6) The Template DTL is posted to the CTSU website at the time of final CTEP Approval and Activation along with the other final protocol documents.

## Procedure for Note-to-File

- 1) Copy and paste the below onto your institutional letterhead:

### **Note-to-File**

**From:** ETCTN Office

**Date:** MM/DD/YYYY

**Re:** Delegation of Task Log (DTL)

This **Note-to-File** serves to ensure that the DOA documentation for (CTEP & local protocol numbers) used prior to (date of eDTL implementation) will not be destroyed. (Protocol numbers) is a NCI CIRB study which is now required to maintain an electronic Delegation of Tasks Log (eDTL) on CTSU. The local DOA document used prior to the implementation of the eDTL will stay within regulatory documentation for this study. End dates will not be applied to the DOA log.

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**Staff Member Name**

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**Date**

- 2) Follow your institutional procedures for documenting a Note-to-File as out line in [DF/HCC Policy DOC-100](#)

## Links

CTSU DTL Application: <https://dtl.ctsu.org/dashboard>

Compiled Site DTL Guide & Other Resources for Application Updates including FAQs, CI Quick Guides: <https://www.ctsu.org/master/simplepage.aspx?ckey=HELP-DTLMOD-ALL-RESOURCES>

DTL Master Task List: <https://www.ctsu.org/master/simplepage.aspx?ckey=DTL-TASK-LIST>

CI Sign off Guidance: <https://www.ctsu.org/master/simplepage.aspx?ckey=HELP-DTLMOD-APPROVE-DTLS-GUIDE>

DF/HCC Policy DOC-100: <https://www.dfhcc.harvard.edu/research/clinical-research-support/document-library/dfhcc-policy-and-operation-library>