

Delegation of Tasks Log (DTL) – Signing Multiple and Single DTL Options

#1 – Summary Landing Page for Multiple DTL Signing: Shows all DTLs that require Clinical Investigator signature. (Note – names are blocked out.)

Link to public statement OMB#0925-0753, Expiration Date: 7/31/2021

Review the DTL(s) changes. Select DTLs ready for signing using the checkbox in the For Approval column, or use the Select All checkbox to select all DTLs in that section. Then use the eSign button to sign all selected DTLs for approval.

Approval Summary Task Assignments Browser | Refresh DTL List | Collapse All Sections

Selected DTLs for approval: 1 out of 3

Select All Annual review with no changes, or changes not requiring CI signature (1 selected) Review Changes for (1) Selected DTLs

FOR APPROVAL	PROTOCOL	SITE	PERSONS WITH NEW TASK ASSIGNMENTS SINCE LAST SIGNING	ACTIONS
<input checked="" type="checkbox"/>	S1806	NY167	[Redacted]	<input type="button" value="Review / Edit DTL"/>

Select All Approved, unapproved, or annual DTLs with changes requiring signature (0 selected) Review Changes for All DTLs in section

FOR APPROVAL	PROTOCOL	SITE	PERSONS WITH NEW TASK ASSIGNMENTS SINCE LAST SIGNING	ACTIONS
<input type="checkbox"/>	NRG-HN004	NY167	[Redacted]	<input type="button" value="Review / Edit DTL"/>
<input type="checkbox"/>	NRG-LU005	NY167	[Redacted]	<input type="button" value="Review / Edit DTL"/>

Approval Summary Task Assignments Browser | Refresh DTL List | Collapse All Sections

Selected DTLs for approval: 1 out of 3

Link will take the user to the public statement:

OMB #0925-0753
Expiration Date: 07/31/2021

Public reporting burden for the collection of information is estimated to average 10 minutes per site/protocol Delegation of Tasks Log (DTL). Including the time to review changes to existing DTLs and review new DTLs as applicable. An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (OMB#0925-0753). Do not return the completed form to this address.

#2 – Review DTL Options for Multiple DTL Signing: Task Assignment Browser View for all selected DTLs

Task Assignment Browser for: [2 DTL(s)] requiring signature [2 DTL(s)]

Please close this tab and go back to DTL Approvals page after your review is completed.

Site: University... x Protocol: All DTL Status: Unapproved Assignee Name: All Task Name: All Task Status: Awaiting CI Approval Task Reason: Select Reason Current View: Select View

Show changes since last signature

#	Site	Protocol	DTL Status	Assignee Name	Task Name	Task Status	Start Date	End Date	Task Reason	Action
1	NY167	NRG-HN004	Unapproved	[Redacted]	Consenting Person	Awaiting CI Approval	01-Nov-2019			<input type="button" value="Review"/> <input type="button" value="Edit"/>
2	NY167	NRG-HN004	Unapproved	[Redacted]	Consenting Person	Awaiting CI Approval	09-Sep-2019			<input type="button" value="Review"/> <input type="button" value="Edit"/>
3	NY167	NRG-HN004	Unapproved	[Redacted]	Eligibility Assessment	Awaiting CI Approval	09-Sep-2019			<input type="button" value="Review"/> <input type="button" value="Edit"/>
4	NY167	NRG-HN004	Unapproved	[Redacted]	End Point Assessment	Awaiting CI Approval	09-Sep-2019			<input type="button" value="Review"/> <input type="button" value="Edit"/>
5	NY167	NRG-HN004	Unapproved	[Redacted]	Enrolling Person/Treating Investigator	Awaiting CI Approval	09-Sep-2019			<input type="button" value="Review"/> <input type="button" value="Edit"/>
6	NY167	NRG-HN004	Unapproved	[Redacted]	HP Assessments	Awaiting CI Approval	09-Sep-2019			<input type="button" value="Review"/> <input type="button" value="Edit"/>
7	NY167	NRG-HN004	Unapproved	[Redacted]	IND Prescribing	Awaiting CI Approval	09-Sep-2019			<input type="button" value="Review"/> <input type="button" value="Edit"/>
8	NY167	NRG-HN004	Unapproved	[Redacted]	Tox Assessment	Awaiting CI Approval	09-Sep-2019			<input type="button" value="Review"/> <input type="button" value="Edit"/>
9	NY167	NRG-HN004	Unapproved	[Redacted]	Consenting Person	Awaiting CI Approval	02-Jun-2020			<input type="button" value="Review"/> <input type="button" value="Edit"/>
10	NY167	NRG-HN004	Unapproved	[Redacted]	Consenting Person	Awaiting CI Approval				<input type="button" value="Review"/> <input type="button" value="Edit"/>
11	NY167	NRG-HN004	Unapproved	[Redacted]	Consenting Person	Awaiting CI Approval	11-Oct-2019			<input type="button" value="Review"/> <input type="button" value="Edit"/>
12	NY167	NRG-LU005	Unapproved	[Redacted]	Consenting Person	Awaiting CI Approval	02-Jun-2020			<input type="button" value="Review"/> <input type="button" value="Edit"/>

#2a – Review DTL Options for Multiple DTL Signing: View by Assignee/Task option for all selected DTLs

DTL Task Assignment Browser for: Approved, unapproved, or annual DTLs with changes requiring signature

Protocol: All protocols | Site: All Sites | Assignee Name: All Assignees | Task Name: All Task Names | [Apply Filters](#) | [Clear Filters](#)

DTL Task Assignment By Protocol

Protocol: **Persons' Task Assignments across Sites**

NRG-HN004

- Consenting Person
- Eligibility Assessment
- End Point Assessment
- Enrolling Person/Treating Investigator
- HP Assessments
- IND Prescribing
- Tox Assessment

Show less

NRG-LU005

- Consenting Person

#2b – Review DTL Options for single or multiple DTL Signing: View by Manage Site DTL for single DTL

Assignee: All | Task: All | Status: Active, Awaiting C | [View by Assignee](#) | Show changes since last signature

Assign Tasks

#	Assignee Name	Task Name	Status	Start Date	End Date	Status Reason	Action
1		Clinical Investigator	Awaiting CI Approval	05-Aug-2019			↑
2		DTL Administrator	Awaiting CI Approval	05-Aug-2019			↑ ×
3		DTL Administrator	Awaiting CI Approval	05-Aug-2019			↑ ×
4		Consenting Person	Pending			Member role status is not Active or Followup status.	↑ ×
5		Consenting Person	Awaiting CI Approval	05-Aug-2019			↑ ×
6		Consenting Person	Awaiting CI Approval	09-Sep-2019			↑ ×
7		Consenting Person	Awaiting CI Approval	11-Oct-2019			↑ ×
8		Consenting Person	Awaiting CI Approval	01-Nov-2019			↑ ×
9		Consenting Person	Awaiting CI Approval	02-Jun-2020			↑ ×
10		Consenting Person	Awaiting CI Approval	05-Aug-2019			↑ ×
11		Consenting Person	Awaiting CI Approval	05-Aug-2019			↑ ×

#3 – Multiple DTL Signing Page: Attestation text will vary depending if the site is a U.S. site or other country that can sign attesting to U.S. or ICH/GCP regulations. This example shows the U.S. regulatory language.

Electronic Signing

You have selected 3 out of 3 total site DTLs to approve

I agree to conduct the study in accordance with the relevant, current protocol and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

I agree to personally conduct or supervise the described investigation(s).

I agree to inform any patients, or any persons used as controls, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review and approval in 21 CFR Part 56 are met.

I agree to report to the sponsor adverse experiences that occur in the course of the investigation(s) in accordance with 21 CFR 312.64.

I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for inspection in accordance with 21 CFR 312.68.

I will ensure that an IRB that complies with the requirements of 21 CFR Part 56 will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

I agree that my registration documents (FDA Form 1572, NCI Biosketch, Financial Disclosure Form) on file with the NCI's Registration and Credential Repository (RCR) will be applied to this protocol and site-specific Delegation of Tasks Log.

AGREEMENT: *By signing this Electronic Signature Acknowledgment Form, I attest to the accuracy and integrity of this document and agree that my electronic signature is the legally binding equivalent to my handwritten signature. Whenever I execute an electronic signature, it has the same validity and meaning as my handwritten signature. I will not, at any time in the future, repudiate the meaning of my electronic signature or claim that my electronic signature is not legally binding.*

By checking, I agree to all commitments stated above

CTSU e-Sign

Please enter your CTEP-IAM Credentials

Username:

Password:

IAM-SSo

#4: Single DTL Signing – PDF Generation: Attestation text will vary depending if the site is a U.S. site or other country that can sign attesting to U.S. or ICH/GCP regulations. This example shows the ICH/GCP language.



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Attachment A21_Elec_Sig_Page

OMB# 0925-0753 Expiration Date: 07/31/2021

Example DTL Signed on 20-Feb-2020

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (OMB#0925-0753). Do not return the completed form to this address.

Protocol Information			
Protocol Title			
Phase	CTEP Document Number	Lead Protocol Organization	
Site Information			
Research Site Name	Site ID	Address	
Clinical Investigator Information			
Person ID	Name of Clinical Investigator		
IRB of Record			
IRB #	IRB Name	Address	
Laboratory Information			
Delegation of Tasks Log			
#	CTEP Person ID	Person	Research Task
Clinical Investigator			



Sub-Investigators			
Delegation of Tasks Log (Site Added Tasks Not Mandatory for this Protocol)			
#	CTEP Person ID	Person	Research Task
Commitments			
<ul style="list-style-type: none"> I agree to conduct the study(ies) in accordance with the relevant, current protocol(s) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects. I agree to personally conduct or supervise the described investigation(s). I agree to inform any patients, or any persons used as controls, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and independent Ethics Committee(IEC) review and approval in ICH E6, national and regional legislation, and the Declaration of Helsinki are met. I agree to report to the sponsor adverse experiences that occur in the course of the investigation(s) in accordance with ICH E6, national and regional legislation, and the Declaration of Helsinki. I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug. I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments. I agree to maintain adequate and accurate records and to make those records available for inspection in accordance with ICH E6, national and regional legislation, and the Declaration of Helsinki. I will ensure that an IEC that complies with the requirements of ICH E6, national and regional legislation, and the Declaration of Helsinki will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IEC all changes on the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IEC approval, except where necessary to eliminate apparent immediate hazards to human subjects. I agree to comply with all other requirements, regarding obligations of clinical investigators and all other pertinent requirements in ICH E6, national and regional legislation, and the Declaration of Helsinki. 			



Signature		
Signature	Date	Printed Name
<i>I have acknowledged and agree that my electronic signature is the legally binding equivalent to my handwritten signature. Whenever I execute an electronic signature, it has the same validity and meaning as my handwritten signature. I will not, at any time in the future, repudiate the meaning of my electronic signature or claim that my electronic signature is not legally binding.</i>		