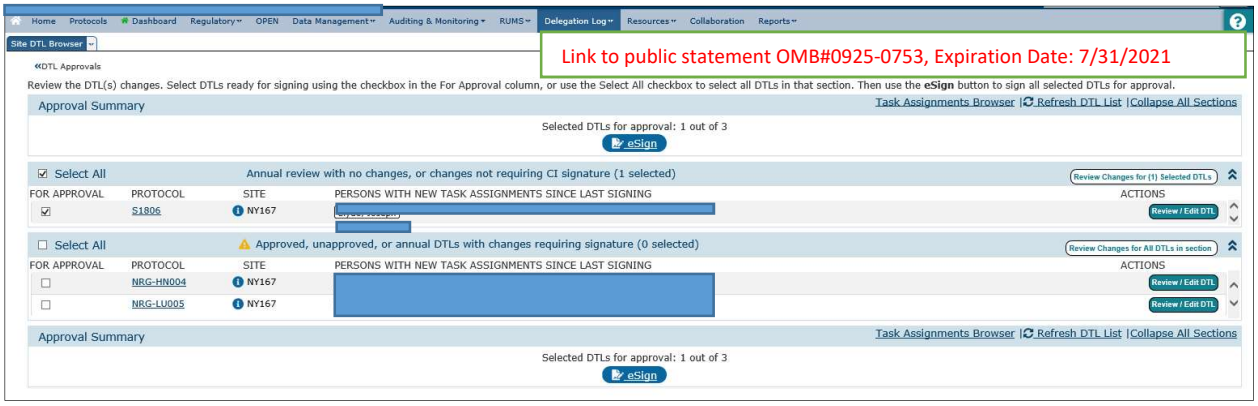
Delegation of Tasks Log (DTL) – Signing Multiple and Single DTL Options

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

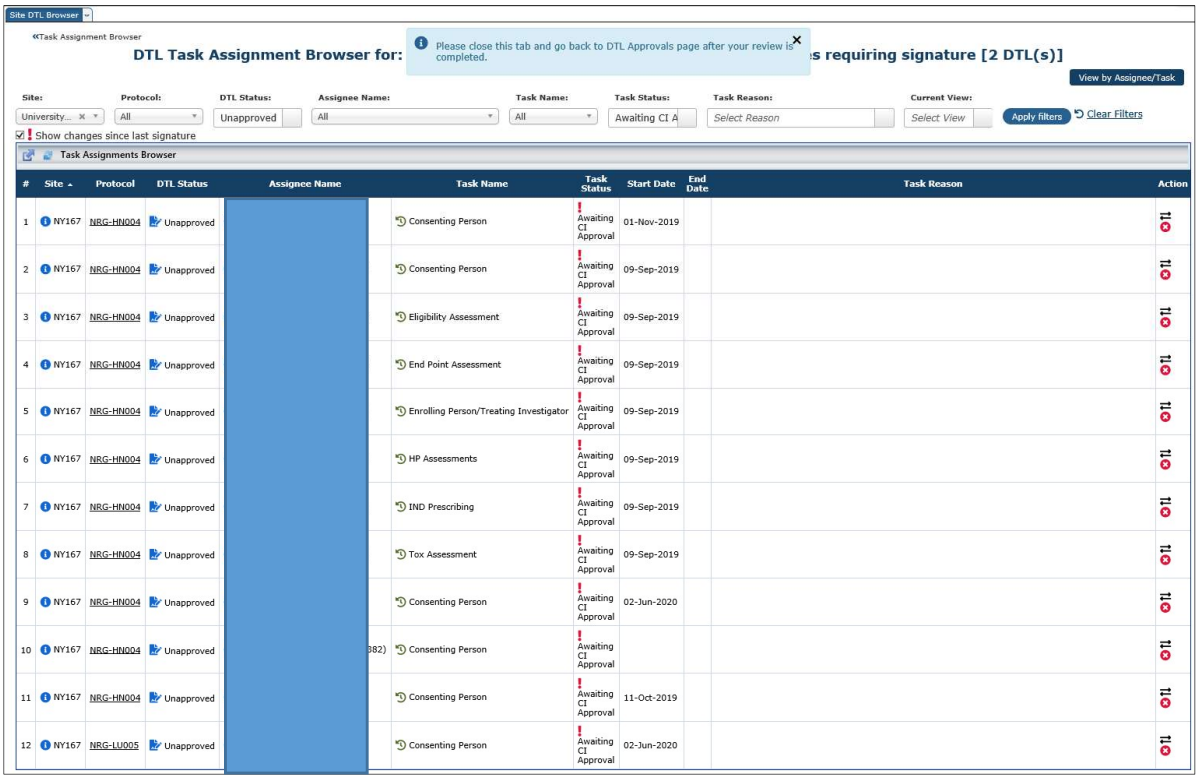


Link will take the user to the public statement:

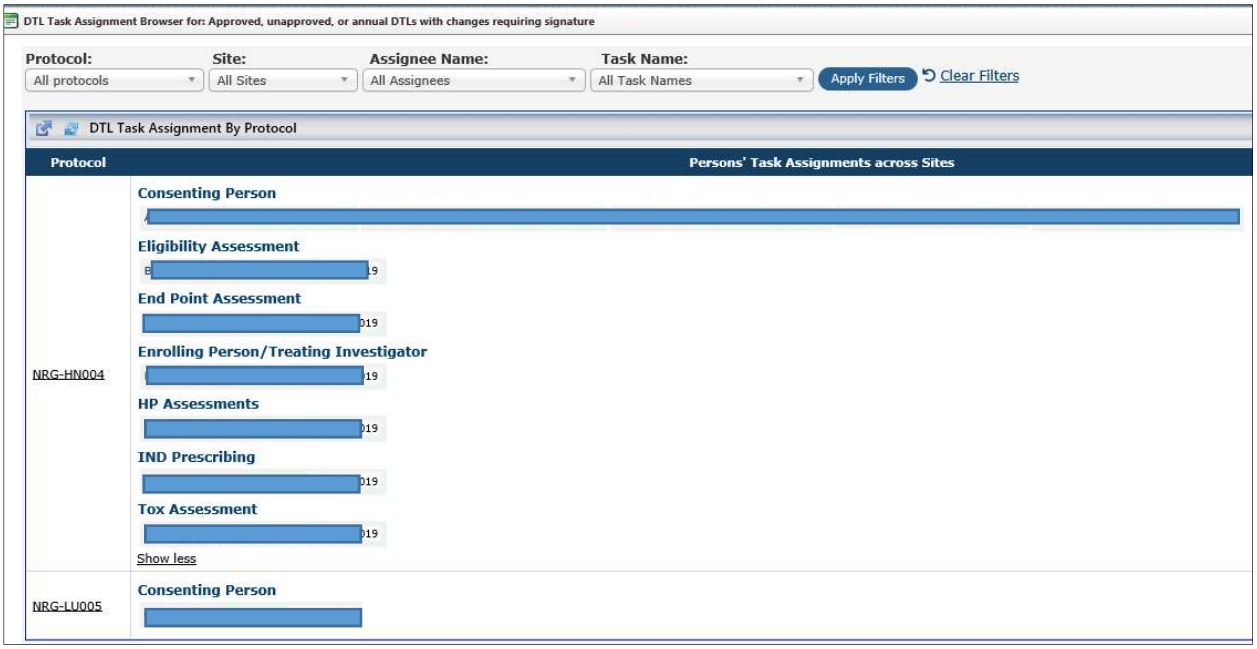
OMB #0925-0753
Expiration Date: 07/31/2021

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 many 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.

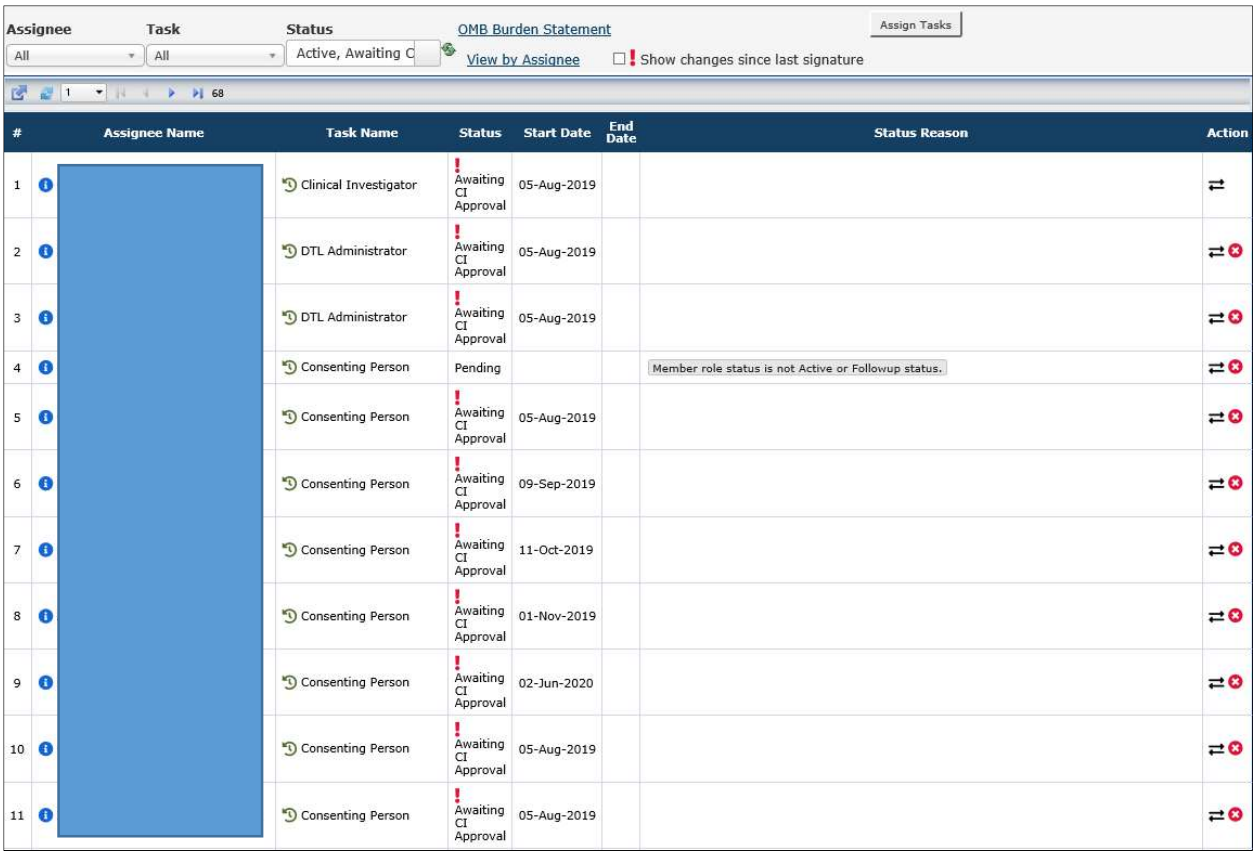
#2 – Review DTL Options for Multiple DTL Signing: Task Assignment Browser View for all selected DTLs



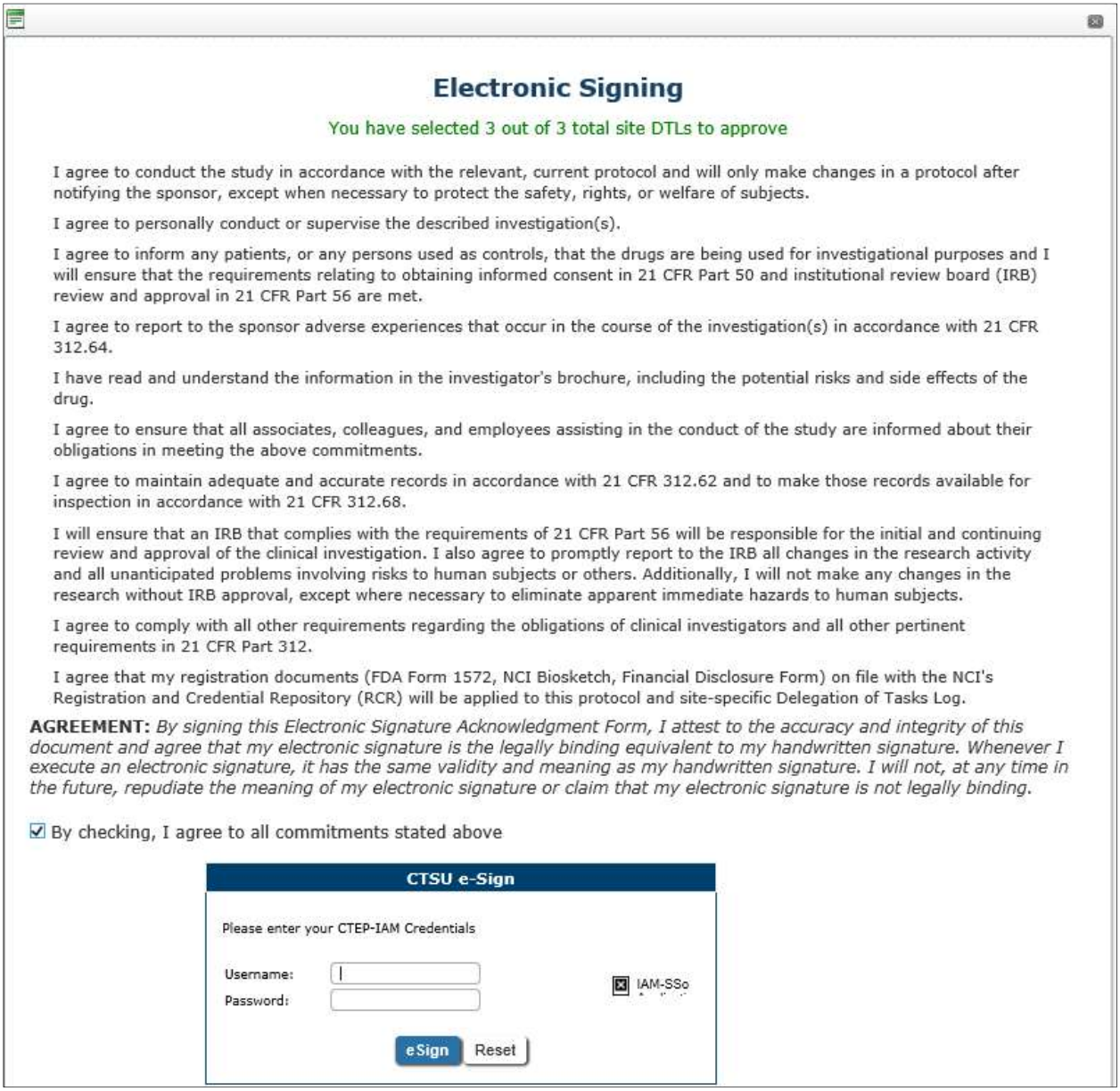
#2a – Review DTL Options for Multiple DTL Signing: View by Assignee/Task option for all selected DTLs



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



#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.



#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

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

- 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 Committe(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 repo it 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.

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Signature		
Signature	**Date**	**Printed Name**
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.		