

Centers for Medicare & Medicaid Services

Enterprise Privacy Policy Engine Cloud (EPPE)

Limited Data Set (LDS) Approval Workflow Training Module-New LDS DUA Request with Re-Use Data Files

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CMS Overview

Overview 1.

This Training Guide will cover the following:

- How to add a Collaborating Organization
- How to add Main Information
- How to add Data Users/VRDC Users
- How to select Re-Use Data Files
- How to select New Data Files

1.1 **EPPE Access Prerequisites**

Before continuing this training, please complete the following:

- Obtain Identity Management (IDM) Credentials, Multi-Factor Authentication (MFA), and EPPE Access: https://www.cms.gov/files/document/eppeidm.pdf
- Access CMS Portal: https://portal.cms.gov/

1.2 Icons Used Throughout the EPPE System



A red asterisk denotes that a field is required to be entered.



The question mark icon, when selected, will display field specific help.

2. Create a New LDS DUA

Login to EPPE to begin a new DUA.

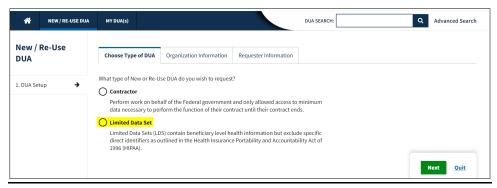
Figure 1: EPPE Welcome Screen: DUA(s) Menu



1. Click **NEW / RE-USE DUA**.

The DUA Set Up screen for New / Re-Use DUA Request is displayed.

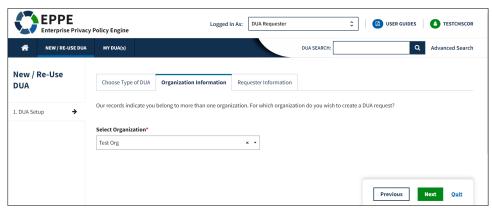
Figure 2: DUA Type Selection



- 2. Select the **Limited Data Set** radio button.
- Click Next.

Your Organization is pre-populated. A dropdown will appear for you to select your organization if you are a Requester for multiple organizations.

Figure 3: Organization Selection



4. Click Next.

2.1 Main Information Screen

The DUA Number is displayed on the Main Information screen.

Figure 4: New / Re-Use DUA Request: Main Information

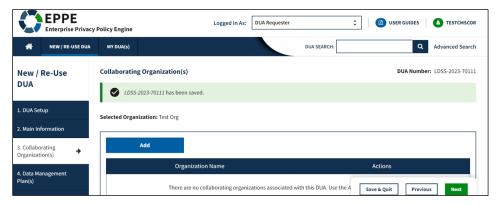


- Enter Project Name.
- 2. Enter Project Aim (Optional).
- Click Next.

2.2 Add Collaborating Organization(s)

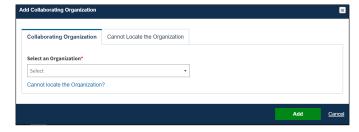
The Collaborating Organizations screen with the selected Primary Organization is displayed.

Figure 5: Collaborating Organization



 Select the Add Button if a Collaborating Organization is needed. If no Collaborating Organization is needed, click Next.

Figure 6: Collaborating Organization Select

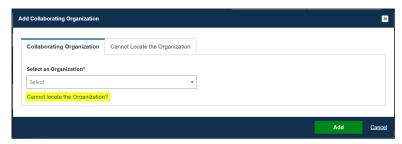


- 2. Enter the Collaborating Organization name.
- 3. Select the Collaborating Organization from the dropdown list.

4. Click Add.

If you cannot locate your organization, you can add it.

Figure 7: Add New Collaborating Organization



6. Click the "Cannot locate the Organization?" link to add an Organization.

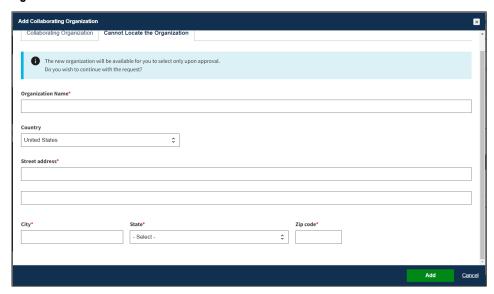
The message, "You can submit a request for a new organization; however, it will be available for you to select only upon approval. Do you wish to request a new organization?" is displayed at the top of the Cannot Locate the Organization tab.

Figure 8: Add New Organization Dialogue



The Cannot Locate the Organization tab is displayed.

Figure 9: Add New Location



- 7. Enter the Organization information:
 - Organization Name

- Street Address (1 and 2)
- City
- State
- Zip Code
- 8. Click the Add button or click Cancel to exit the window without requesting.

The Confirmation message displays: "<Organization Name> was created and is pending approval. Once approved, you will be able to add them to this DUA.

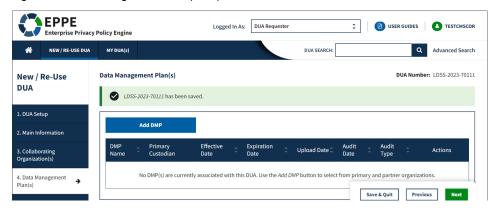
Figure 10: New Collaborating Organization Confirmation



Note: A new Organization requires EPPE Administrator approval. The DUA will not be saved and the DUA Requester will have to restart the DUA once the organization is approved.

2.3 Data Management Plan (DMP)

Figure 11: Data Management Plan (DMP)



1. Click Add DMP. If not DMP is needed, click Next.

Figure 12: Add Data Management Plan (DMP)

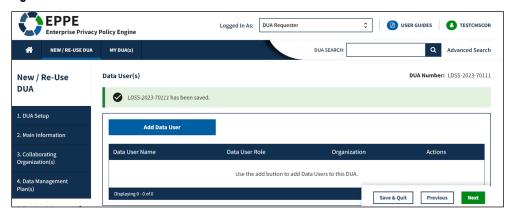


- 2. Select the **Organization** from the drop-down menu.
- 3. Select the **DMP** from the drop-down menu.
- 4. Click Add.
- 5. Click Next.

2.4 Add Data User

When adding Main Information, the Data User(s) screen is displayed. There must be at least one (1) Data User on the DUA which can include the Requester.

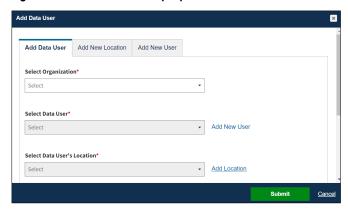
Figure 13: Add Data User



1. Click the Add Data User button to add Data Users/VRDC users.

The Add Data User pop-up is displayed.

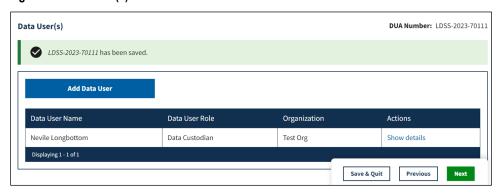
Figure 14: Add Data User: Pop-Up Window



- 2. Select Organization.
- 3. Select User Location.
- 4. Select Data User's Location from the dropdown menu.
- 5. Attach Signature Addendum.
- 6. Click the **Submit** button.

The Data User/VRDC User is displayed in the table.

Figure 15: Data User(s) Table

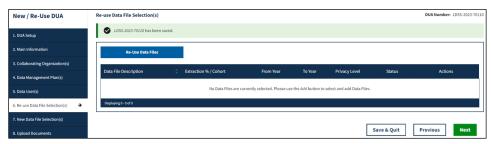


- 7. Enter additional users, as needed.
- 8. Click Next

2.5 Re-Use Data File(s) Selection

The Re-Use Data File(s) Selection screen displays.

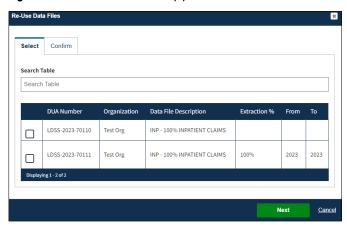
Figure 16: Re-Use Data File(s)



Select the Select Re-Use Data Files button.

Note: Re-Use Data File(s) Selection page with available Re-Use data files from the Primary or Collaborating Organization(s) is displayed. Files from active LDS DUAs as well as Researcher DUAs with "Limited Data Set" Privacy Level will be displayed.

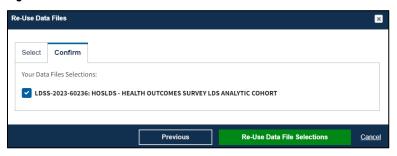
Figure 17: Add Re-Use Data File(s)



2. Select the file(s) for re-use.

3. Click Next.

Figure 18: Confirm Re-Use Files



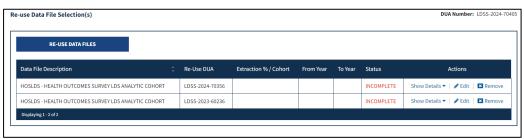
4. Click the Re-Use Data File Selections button.

Notes:

- To narrow the list, you can use Search Table to enter the DUA number or the file name.
- You may need to Re-Use from multiple entries to get a complete set of years you want.

The selected Re-Use data files are displayed in the table below.

Figure 19: Add Re-Use Data File(s): Edit Re-Use Data File(s)

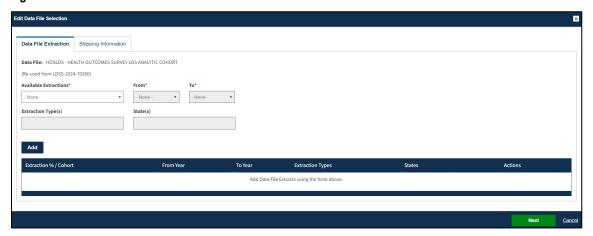


- 5. The file(s) status displays "INCOMPLETE."
- 6. Select the **Edit** action to complete required file attributes.

Note: Use the Remove action to remove the file(s) from the table. Remove does not delete the file from the system. It only removes the file from the update table and places it back in the list of re-use data files to be selected.

The Data File Information screen is opened with the Data File Extraction tab in focus.

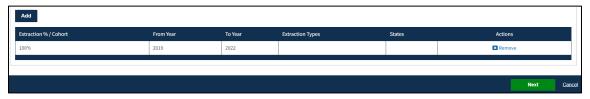
Figure 20: Edit Re-Use Data File Selection



- 7. Select the **Data File Extraction/Cohort** percentage.
- 8. Select the **From** and **To** Year.
- Extraction Type and States are optional fields.
- 10. Click Add.

Note: Some future file years in the year range may not be available yet.

Figure 21: Re-Use Data File(s) Extraction Criteria Displays in Table

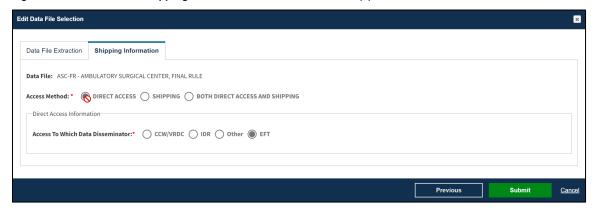


The selected data file extraction attributes display in the table below.

11. Click Next.

Shipping Information from the original DUA is view-only in the table below.

Figure 22: Direct Access/Shipping Information for Re-Use Data File(s)



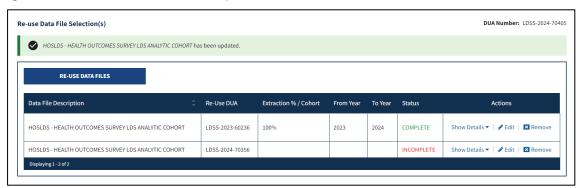
- 12. Select the **Data Disseminator**.
- 13. Select the **Primary Recipient.**
- 14. Select the Location.
- 15. Carrier and Carrier Account Number are optional.
- 16. Click Add.
- 17. Click Submit.

Note: The Shipping Information for Re-Use File(s) are read only screens.

Re-Use data files will not be re-shipped.

The Status of the first re-use file is Complete. If multiple files were selected for re-use, as in this example, each file's attributes must be edited to a status of Complete.

Figure 23: Re-Use Data File Attributes Completed for First File



18. Click the **Edit** action for each file to update the data file extraction information.

Notes:

- The display of the files in this list have been expanded to show the file details.
- If there are re-use data files you are unable to select, a message will be displayed "If the files you would like to re-use are not in the re-use data files listed below, add them as new files. Please list the file names in the comment section along with the DUA number(s) from which the files would be re-used."

CMS Upload Documents

3. Upload Documents

The following are the predefined LDS document types.

Table 1: Predefined LDS Document Types

Document	Rule(s)
Attachment A Research Protocol	Required for all New DUAs.
LDS Worksheet/Re-Use Data Worksheet	 The LDS Worksheet is required when New use files are being requested. The Re-Use Data Worksheet is required when Re-Use files are being requested.
Signature Addendum	Required when adding Data Users to an LDS DUA, other than the requester, through New/Re-Use and/or Update/Amend.

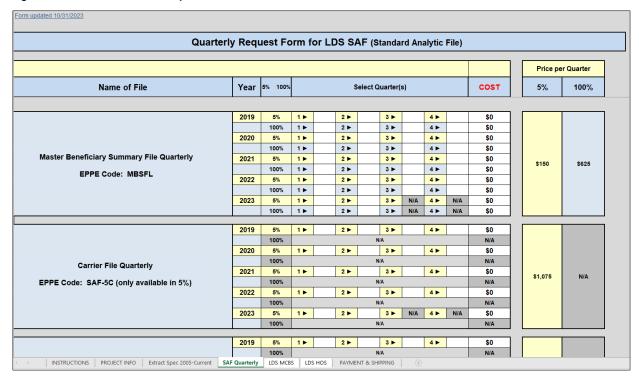
Note: An example of the LDS Worksheet is shown next.

The Standard Analytic File (SAF) Quarterly tab of the LDS Worksheet is shown in Figure 24.

Notes:

- Some future file years in the year range may not be available yet.
- You may only order files and years available on the LDS Worksheet.

Figure 24: LDS Worksheet Example

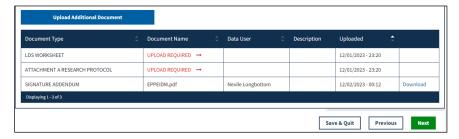


The Upload Documents screen is displayed and includes predefined document types.

Note: The page Upload Documents screen will note, "Add the required documents below & if needed use the button to add additional documents. You can find & download all documents here on CMS.gov."

CMS Upload Documents

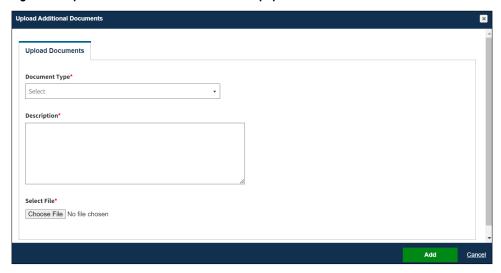
Figure 25: Upload Documents Screen



1. Click the **Upload Additional Documents** button to upload required documents, example: LDS Worksheet.

The Upload Documents pop-up opens.

Figure 26: Upload Documents: File Selection Popup



- 2. Select **Document Type** from the dropdown menu.
- 3. Enter a Description.
- 4. Click the Choose File button to choose your file from your local computer.
- 5. Click the **Add** button once the file has been selected.

The Upload Documents screen is redisplayed. In this example, Additional Supporting Documents can be added.

CMS Upload Documents

Figure 27: Upload Documents Screen: Additional Supporting Documents



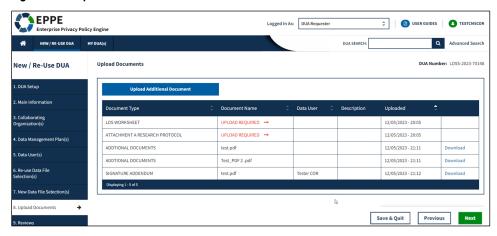
- 6. Select Additional Document as the Document Type and add a Description.
- 7. Click the **Choose File** button to choose your file from your local computer.
- 8. Click the **Add** button once the file has been selected.

Notes:

- Uploaded files can be deleted from this page prior to DUA submission.
- An upload date and time stamp will be displayed on the DUA Review screen for all uploaded files.

The Document upload is required pop-up is displayed when there are missing documents. In this example, the message "UPLOAD REQUIRED→" next to all required documents.

Figure 28: Required Documents



9. Click Next.

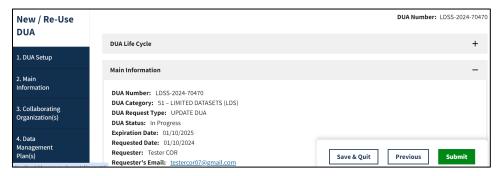
Note: You will receive additional pop-ups when specific predefined documents have not been uploaded such as an LDS Worksheet (required if New data files are added to the DUA).

4. Review and Submit New/Re-Use LDS DUA

The Review screen displays the following sections of the DUA:

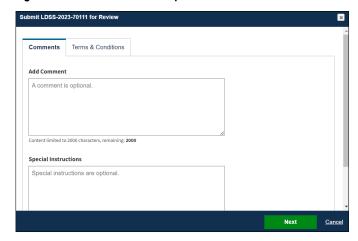
- Review: DUA Life Cycle
- Review: Main Information (click the plus sign (+) to expand any section)
- Review: Contacts
- Review: Collaborating Organizations
- Review: Data Management Plans
- Review: Data User(s)
- Review: Data File Descriptions
- Review: Documents

Figure 29: Review the DUA



- 1. Click the plus icon (+) to expand the respective section.
- 2. Click the minus icon (-) to collapse the respective section.
- 3. Click Submit.

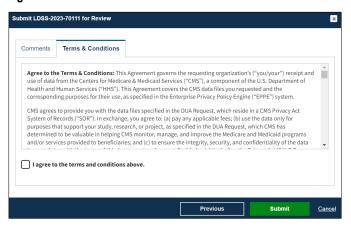
Figure 30: Add Comments or Special Instructions



- 4. Add a Comment if applicable.
- 5. Add Special Instructions if applicable.
- 6. Click Next.

The Terms & Conditions screen is displayed.

Figure 31: Terms and Conditions



- 7. Click the downward arrow to expand the Terms and Conditions.
- 8. Click the *I agree to the Terms and Conditions* checkbox.
- Click Submit.

Submission confirmation message, "Your DUA request <DUA number> seen below has been submitted for approval. You will receive a follow-up email notification." is displayed on the DUA Request Status screen.

Figure 32: DUA Submission Confirmation



Notes:

- The DUA will be placed in the Requester's Submitted Queue.
- The LDS DMT will find the DUA in their Pending Action(s) queue.
- If payment is required, the DUA will not appear in your Approved queue until the LDS DMT approves it and the Payment Coordinator has confirmed payment.
- If payment is not required, the DUA will not appear in your Approved queue until the LDS DMT approves it.

CMS Acronyms and Glossary

5. Acronyms and Glossary

The following are acronyms used within the EPPE system.

Table 2: Acronyms

Acronym	Definition
CMS	Centers for Medicare and Medicaid Services
DMT	DUA Management Team
DUA	Data Use Agreement
EPPE	Enterprise Privacy Policy Engine
EUA	Enterprise User Administration
IDM	Identity Management
LDS	Limited Data Set
MFA	Multi-Factor Authentication
PDF	Portable Document Format
VRDC	Virtual Research Data Center

The following terms are defined for EPPE users in the Glossary.

Table 3: Glossary

Term Attachment A Research Protocol	Definition Required for all New DUAs.
LDS Worksheet/Re-Use Data Worksheet	 The LDS Worksheet is required when New use files are being requested. The Re-Use Data Worksheet is required when Re-Use files are being requested.
Signature Addendum	Required when adding Data Users to an LDS DUA, other than the requester, through New/Re-Use and/or Update/Amend.

6. EPPE Help Desk Information

EPPE Help Desk Contact Information

Hours of Operation: Monday - Friday 9:00 AM to 6:00 PM EST

844-EPPE-DUA (844-377-3382)

eppe@cms.hhs.gov

Note: For information on policies, forms, and other LDS DUA related information, please refer to the <u>Limited Data Set (LDS)</u> page.