

Instructions for completing the Limited Data Set (LDS) Data Use Agreement (DUA): Extension Request

All Limited Data Set (LDS) Data Use Agreements (DUA) are valid for up to one year. An extension request is required if a study is continuing past the DUA expiration date. Dissemination of findings into the public domain is a requirement under HIPAA for data disclosure of research. Information regarding dissemination of findings is required for an extension request.

General Instructions

1. Answer every item in the document.
2. Do not alter the layout or content of the document.
3. Upload the signed document to EPPE.

Specific Instructions

A

Enter the name of the Requester listed on the LDS Data Use Agreement (DUA). The Requester is the individual authorized to sign agreements on behalf of the requesting organization. This person is often referred to as the 'legal signatory'. This person accepts all terms and conditions in the DUA and attests that all information contained in the request is accurate.

B

Enter the exact legal name of the Requesting Organization listed on the LDS DUA.

C

Enter the exact Study Title listed on the LDS DUA.

D

Enter the DUA number of the DUA you are extending.
(Instructions continue on page 2)

RESEARCH IDENTIFIABLE FILE (RIF) AND LIMITED DATA SET (LDS) DATA USE AGREEMENT: EXTENSION REQUEST

GENERAL INSTRUCTIONS

The Health Insurance Portability and Accountability Act (HIPAA) allows data disclosure for research, which is defined as a "systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge" [45 C.F.R. § 164.501]. To request an extension to a DUA, publication information must be provided to CMS.

DUA Requester	A	
<i>Must match the individual specified in the DUA.</i>		
Requesting Organization	B	
<i>Must match the organization specified in the DUA.</i>		
Study Title	C	
<i>Must match the study title specified in the DUA</i>		
DUA #	D	
<i>CMS assigned DUA number</i>		

REQUIREMENTS TO EXTEND DUA

1. Current DUA Expiration Date **E** _____

Anticipated Study End Date **G** _____

Requested DUA Expiration Date **F** _____

(No more than one year from current expiration date)
2. Have you publicly disseminated findings from your analysis in the past year?

Please check one.

H Yes, answer #3
 No, answer #4
3. If you answered "Yes" on #2, (a) provide a link or citation to where your research is published and (b) describe why you continue to need access to CMS data under this DUA to conduct research:

I

E

Enter the current expiration date listed on the DUA. **This date must be exactly correct.** If you are not sure, see the [EPPE Training Module](#) for instructions to view your DUA.

A request for an extension can be processed no more than 60 days prior to the current expiration date.

F

Enter the requested DUA expiration date. A DUA can be extended for no more than one year.

G

Enter the end date that all anticipated work on this study will be completed.

H

Check one selection. If “Yes”, only answer #3. If “No”, skip to answer #4.

I

If you answered “Yes” on question #2, provide the link(s) or citation(s) to published research covered by this DUA. Additionally, describe your plans to continue access and use of CMS data to conduct research under this DUA.

RESEARCH IDENTIFIABLE FILE (RIF) AND LIMITED DATA SET (LDS) DATA USE AGREEMENT: EXTENSION REQUEST

GENERAL INSTRUCTIONS

The Health Insurance Portability and Accountability Act (HIPAA) allows data disclosure for research, which is defined as a “systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge” [45 C.F.R. § 164.501]. To request an extension to a DUA, publication information must be provided to CMS.

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Study Title	C
<i>Must match the study title specified in the DUA</i>	
DUA #	D
<i>CMS assigned DUA number</i>	

REQUIREMENTS TO EXTEND DUA

- Current DUA Expiration Date **E** _____ Requested DUA Expiration Date **F** _____
 (No more than one year from current expiration date)

Anticipated Study End Date **G** _____
- Have you publicly disseminated findings from your analysis in the past year?
Please check one.

H Yes, answer #3
 No, answer #4
- If you answered “Yes” on #2, (a) provide a link or citation to where your research is published and (b) describe why you continue to need access to CMS data under this DUA to conduct research:

I

J

If you answered “No” on question #2, provide any information regarding the absence of public dissemination of your research findings in the past year, including any contributing factors. Additionally, describe your plans to publish research under this DUA within the next year.

K

The **Requester, Data Custodian, or Requester Proxy** listed on the DUA must sign this form. The signatory is attesting to the four attestation statements above. CMS will accept digital signatures on this form.

The **Requester** is the individual authorized to sign agreements on behalf of the requesting organization. This person is often referred to as the ‘legal signatory’. This person accepts all terms and conditions in the DUA and attests that all information contained in the request is accurate.

A **Data Custodian** is an individual who will be responsible for ensuring that the environment in which the CMS data is stored complies with all applicable CMS data security requirements, including the establishment and maintenance of security arrangements to prevent unauthorized use.

RESEARCH IDENTIFIABLE FILE (RIF) AND LIMITED DATA SET (LDS) DATA USE AGREEMENT: EXTENSION REQUEST

- 4. If you answered “No” on #2, (a) provide information on why you haven’t publicly disseminated findings from your research in the past year and (b) describe your plans to publish findings within the next year

J

ATTESTATIONS

- 1. We are still using this data as originally requested for our Project/Study.
- 2. In accordance with the terms and conditions of the DUA, we understand that the data for this DUA may not be used in any form, or for any additional work, outside the scope of this DUA without the expressed written consent of CMS.
- 3. I have reviewed the contact information on the DUA and submitted necessary updates.
- 4. We request a one (1) year [or less, if applicable] extension for the DUA number listed above.

K

Signature

Date