Instructions for completing the RIF Data Use Agreement: Extension Request

This document: All Research Identifiable File (RIF) 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. Submit to ResDAC signed in PDF format.

Specific Instructions

A

Enter the name of the Requester listed on the RIF 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 RIF DUA in section 1.

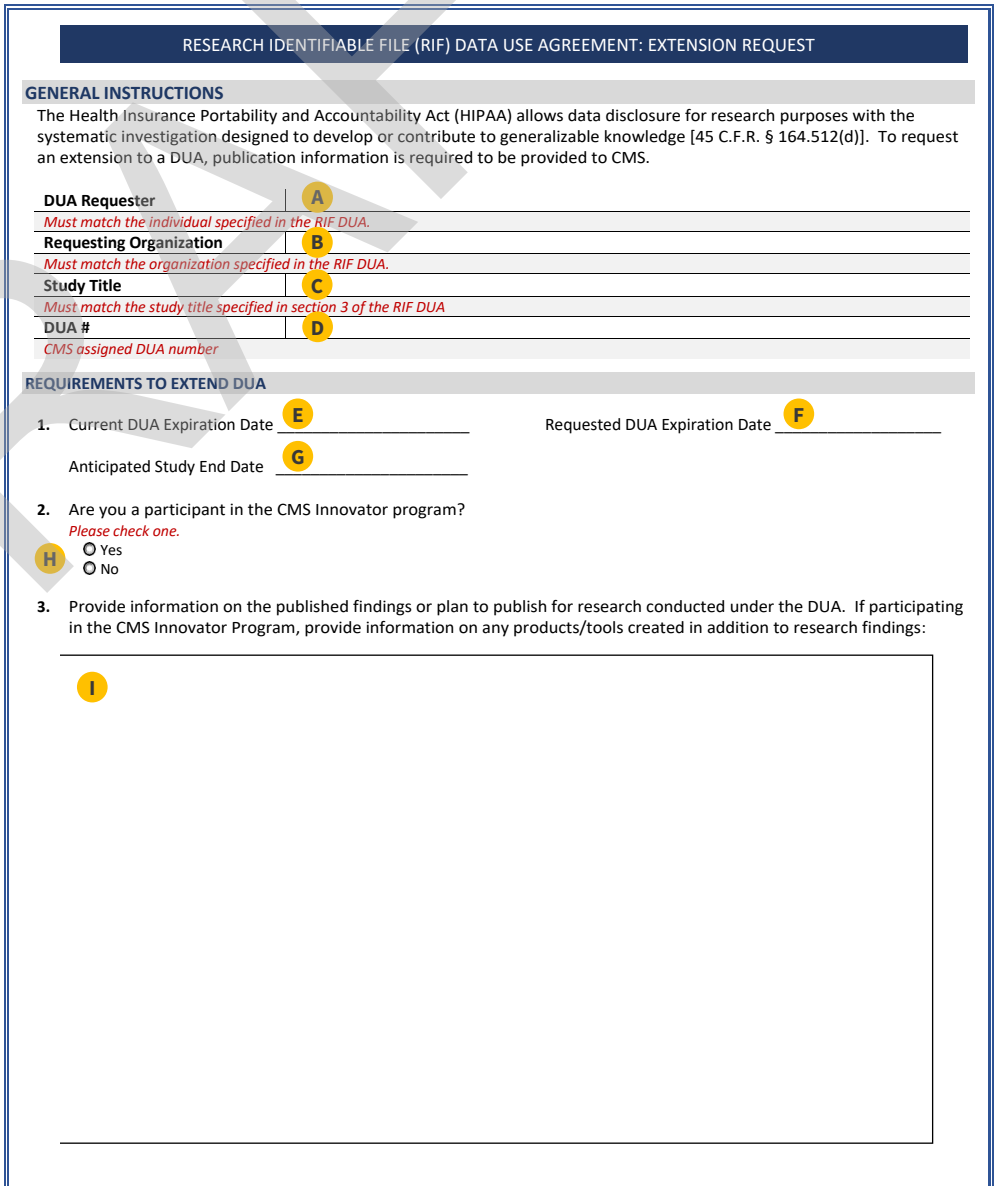
C

Enter the exact Study Title listed on the RIF DUA in section 3.

D

Enter the DUA number of the DUA you are extending.

(Instructions continue on page 2)



RESEARCH IDENTIFIABLE FILE (RIF) DATA USE AGREEMENT: EXTENSION REQUEST

GENERAL INSTRUCTIONS

The Health Insurance Portability and Accountability Act (HIPAA) allows data disclosure for research purposes with the systematic investigation designed to develop or contribute to generalizable knowledge [45 C.F.R. § 164.512(d)]. To request an extension to a DUA, publication information is required to be provided to CMS.

DUA Requester A
Must match the individual specified in the RIF DUA.

Requesting Organization B
Must match the organization specified in the RIF DUA.

Study Title C
Must match the study title specified in section 3 of the RIF DUA

DUA # D
CMS assigned DUA number

REQUIREMENTS TO EXTEND DUA

1. Current DUA Expiration Date E _____ Requested DUA Expiration Date F _____

   Anticipated Study End Date G _____

2. Are you a participant in the CMS Innovator program?
   Please check one.
   H ○ Yes ○ No

3. Provide information on the published findings or plan to publish for research conducted under the DUA. If participating in the CMS Innovator Program, provide information on any products/tools created in addition to research findings:

   I

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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.

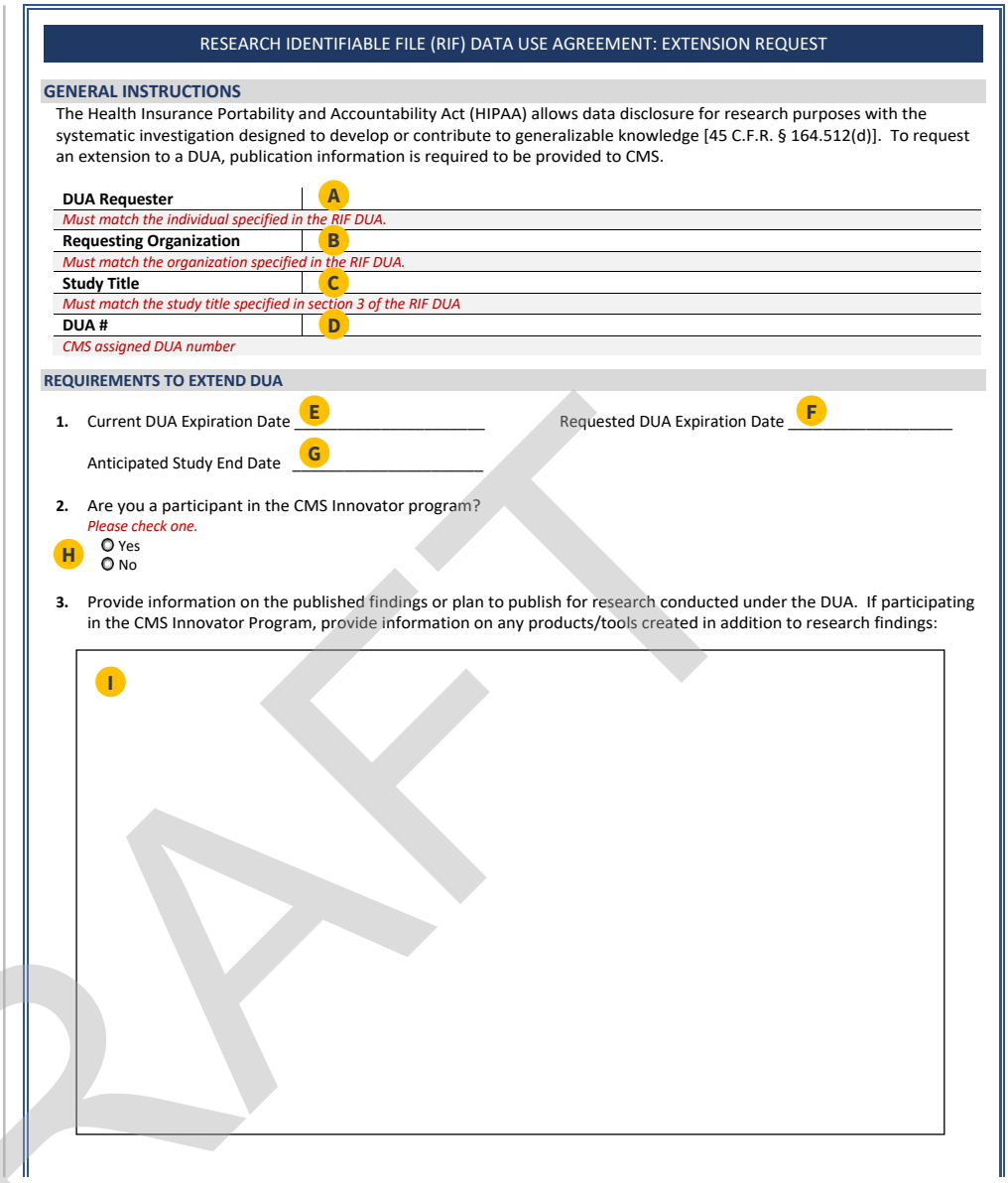
H

If the DUA being extended is part of the CMS Innovator program, you must select 'Yes'. Otherwise, select 'No'.

I

For all DUA types, provide information regarding published findings or plans of disseminating findings related to the research covered by this DUA.

If this DUA is part of the **CMS Innovator program**, provide information regarding any products or tools created or plans to create any products or tools as part of the project covered by this DUA.



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2. Are you a participant in the CMS Innovator program?
   Please check one.
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3. Provide information on the published findings or plan to publish for research conducted under the DUA. If participating in the CMS Innovator Program, provide information on any products/tools created in addition to research findings:

   I

DRAFT

J

For all DUA types, provide links to any published findings related to the research covered by this DUA.

If this DUA is part of the **CMS Innovator program**, provide links to any products or tools created as part of the project covered by this DUA.

K

The **Requester** or a **Data Custodian** 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. For physical data, this is the individual that is listed on the DMP Self-Attestation Questionnaire (SAQ).

RESEARCH IDENTIFIABLE FILE (RIF) DATA USE AGREEMENT: EXTENSION REQUEST

4. Provide links to the published findings that contribute to generalizable knowledge. If participating in the CMS Innovator Program, also include a link to any product/tool:

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

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