Instructions for completing the State Agency Supplement

This document: This document is required for all state agencies that receive physical data. The document collects information about the agencies' data sharing plans and obligations to communicate with CMS about the plans.

General Instructions

1. Answer every item in the document.
2. Do not alter the layout or content of the document.
3. Submit to ResDAC in PDF format.
4. This is a three-page document with items to be completed on pages 1 and 3.

Specific Instructions

A

Enter the name of the Requester listed on the Research Identifiable File (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

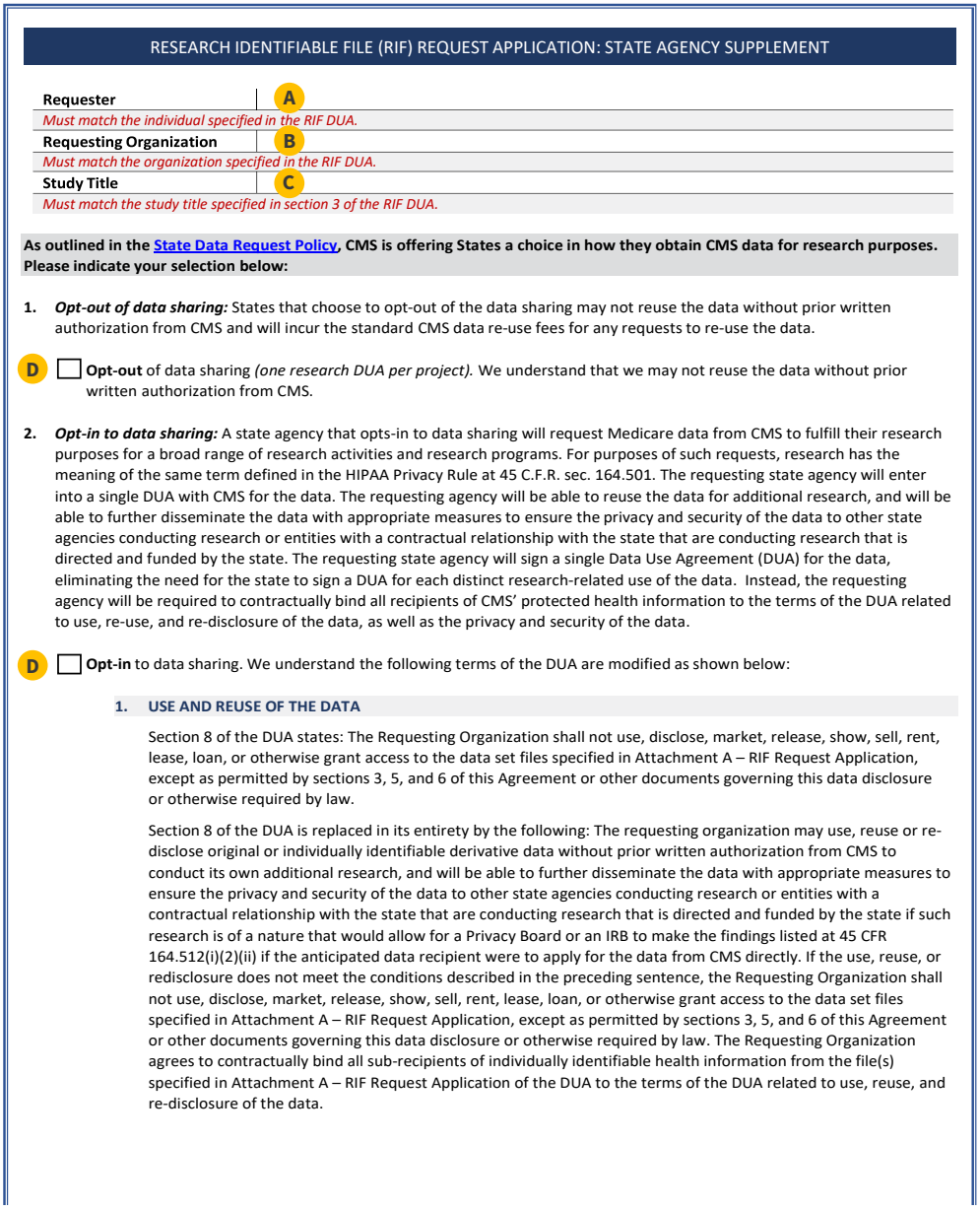
Enter the exact legal name of the Requesting Organization listed on the RIF DUA in section 1.

C

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

D

Check either the box for "opt-out of data sharing" or "opt-in to data sharing". If you check "opt-out of data sharing", all reuse of data will require CMS permission. If you check "opt-in to data sharing", you are responsible for maintaining CMS data security safeguards.



RESEARCH IDENTIFIABLE FILE (RIF) REQUEST APPLICATION: STATE AGENCY SUPPLEMENT

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.	

As outlined in the State Data Request Policy, CMS is offering States a choice in how they obtain CMS data for research purposes. Please indicate your selection below:

1. ***Opt-out of data sharing:*** States that choose to opt-out of the data sharing may not reuse the data without prior written authorization from CMS and will incur the standard CMS data re-use fees for any requests to re-use the data.

D ☐ **Opt-out** of data sharing *(one research DUA per project).* We understand that we may not reuse the data without prior written authorization from CMS.

2. ***Opt-in to data sharing:*** A state agency that opts-in to data sharing will request Medicare data from CMS to fulfill their research purposes for a broad range of research activities and research programs. For purposes of such requests, research has the meaning of the same term defined in the HIPAA Privacy Rule at 45 C.F.R. sec. 164.501. The requesting state agency will enter into a single DUA with CMS for the data. The requesting agency will be able to reuse the data for additional research, and will be able to further disseminate the data with appropriate measures to ensure the privacy and security of the data to other state agencies conducting research or entities with a contractual relationship with the state that are conducting research that is directed and funded by the state. The requesting state agency will sign a single Data Use Agreement (DUA) for the data, eliminating the need for the state to sign a DUA for each distinct research-related use of the data. Instead, the requesting agency will be required to contractually bind all recipients of CMS' protected health information to the terms of the DUA related to use, re-use, and re-disclosure of the data, as well as the privacy and security of the data.

D ☐ **Opt-in** to data sharing. We understand the following terms of the DUA are modified as shown below:

1. USE AND REUSE OF THE DATA

Section 8 of the DUA states: The Requesting Organization shall not use, disclose, market, release, show, sell, rent, lease, loan, or otherwise grant access to the data set files specified in Attachment A – RIF Request Application, except as permitted by sections 3, 5, and 6 of this Agreement or other documents governing this data disclosure or otherwise required by law.

Section 8 of the DUA is replaced in its entirety by the following: The requesting organization may use, reuse or re-disclose original or individually identifiable derivative data without prior written authorization from CMS to conduct its own additional research, and will be able to further disseminate the data with appropriate measures to ensure the privacy and security of the data to other state agencies conducting research or entities with a contractual relationship with the state that are conducting research that is directed and funded by the state if such research is of a nature that would allow for a Privacy Board or an IRB to make the findings listed at 45 CFR 164.512(i)(2)(ii) if the anticipated data recipient were to apply for the data from CMS directly. If the use, reuse, or redisclosure does not meet the conditions described in the preceding sentence, the Requesting Organization shall not use, disclose, market, release, show, sell, rent, lease, loan, or otherwise grant access to the data set files specified in Attachment A – RIF Request Application, except as permitted by sections 3, 5, and 6 of this Agreement or other documents governing this data disclosure or otherwise required by law. The Requesting Organization agrees to contractually bind all sub-recipients of individually identifiable health information from the file(s) specified in Attachment A – RIF Request Application of the DUA to the terms of the DUA related to use, reuse, and re-disclosure of the data.

You do not need to complete anything on this page.

2. DATA LINKING

Section 7 of the DUA states: Absent express written authorization from CMS, the Requesting Organization agrees not to link or attempt to link beneficiary-level records included in the file(s) listed in Attachment A – RIF Request Application to any other source of information. A RIF Request Application that includes the linkage of specific files that has been approved in accordance with section 3 constitutes express authorization from CMS to link files as described in the protocol.

Section 7 of the DUA is replaced in its entirety by the following: As long as the resulting data files are only used for research projects as described in paragraph 1 above, nothing in the DUA, including, but not limited to Section 7, shall prohibit the Requesting Organization from linking records included in the file(s) specified in Attachment A – RIF Request Application of the DUA to other sources of individually identifiable information in accordance with applicable law and other legally controlling documents.

3. DATA STORAGE

Section 11 of the DUA states: The Requesting Organization agrees to maintain a data security plan with CMS if housing CMS data that is not aggregate and de-identified as described in 5b and c above that ensures they adhere to the appropriate administrative, technical, and physical safeguards to protect the confidentiality of the data set file(s) and to prevent unauthorized use or access to it in accordance with applicable law.

Section 11 of the DUA is replaced in its entirety by the following: The Requesting Organization agrees to maintain a data security plan with CMS that ensures they adhere to the appropriate administrative, technical, and physical safeguards to protect the confidentiality of the data set file(s) and to prevent unauthorized use or access to it in accordance with applicable law. The Requesting Organization may physically move, transmit, or disclose the file(s) specified in Attachment A – RIF Request Application of the DUA away from the site specified in its Data Management Plan provided that such action is limited to the disclosures described above in paragraph 1. The Requesting Organization agrees to ensure that each data storage site includes the appropriate administrative, technical, and physical safeguards to protect the confidentiality of, and to prevent the unauthorized use or access to the data in accordance with applicable law. The Requesting Organization also agrees to keep a record of all sites where the file(s) specified in Attachment A – RIF Request Application of the DUA or any derivative data are stored and provide such information to CMS upon request and in accordance with paragraph 5 below. The Requesting Organization agrees to contractually bind all sub-recipients to: 1) immediately report any breach of personally identifiable information to the Requesting Organization; 2) destroy the data in the event the agreement with the Requesting Organization is terminated unless CMS states in writing that the data may be retained; 3) take corrective actions for agreement violations that can be adequately mitigated to reasonably protect the privacy and security interests of the affected individual(s). The Requesting Organization agrees to report its own and all downstream data recipient violations to CMS and to abide by CMS' findings and when applicable corrective actions.

4. TERMINATION OF THE AGREEMENT

Section 10 of the DUA states: Upon expiration of the Retention Date, the Requesting Organization must destroy all files specified in Attachment A – RIF Request Application of this agreement. Such destruction shall include any original, derivative, or back-up files that directly or indirectly identify individual beneficiaries and as well as any such files that can be used in concert with other information to identify individual beneficiaries. The Requesting Organization may retain aggregate data results for its own use beyond the Retention date if such data complies with the limits in this paragraph and those in sections 5 and 6 of this Agreement. For all other data, the Requesting Organization agrees to complete the required destruction and attestation of destruction within 30 days of the Retention Date.

Section 10 of the DUA is replaced in its entirety by the following: In the event the Agreement is: 1) not renewed prior to the Retention Date specified in Section 9 of the DUA or 2) terminated for any reason, the Requesting Organization agrees to destroy or ensure the destruction of all copies of the file(s) specified in Attachment A – RIF Request Application of the DUA including any individually identifiable derivative data at sites where the Requesting Organization or a downstream data recipient has physically moved, transmitted, or disclosed the file(s) to conduct additional research as described in paragraph 1. Upon termination of the DUA, the Requester must also complete certificate of destruction to cover all sites where the file(s) specified in Attachment A – RIF Request Application of the DUA were physically moved, transmitted, or disclosed.

E

If 'Opt-In to data sharing' is selected, complete the table listing all planned projects. **Note:** On a quarterly basis, you will be submitting an updated version of this table to CMS.
All data disclosures under a state opt-in DUA are reported in the log. The department, contractor, or organization accessing the data is logged but not specific individuals.

5. ADDITIONAL REQUIREMENTS

The Requesting Organization agrees to provide CMS with a quarterly report detailing to whom the data has been disclosed and for what they are using it, as well as any sites where the data has been physically moved, transmitted, or disclosed. Notwithstanding the preceding sentence, at the request of CMS at any point in the future, the Requester agrees to notify CMS of a proposed re-disclosure of the file(s) specified in Attachment A – RIF Request Application of the DUA or any individually identifiable derivative data and allow a 30-day period for CMS to review and, if necessary, request modifications or veto the data request. If CMS does not provide an approval or denial within 30 days, then the request is automatically approved, but such automatic approval will not negate the obligations laid out in the preceding paragraphs, and will not be construed as confirmation of conformance with such paragraphs.

LOG OF STATE AGENCIES AND OTHER ORGANIZATIONS USING CMS DATA

This section specifically identifies each state agency or state-contracted organization that is, at the time of application, expected to be using the data or seeing individual level data elements or output of analyses. If a State chooses to opt-in to data sharing, updated copies of this log must be supplied to CMS (ResearcherDUA@cms.hhs.gov) on a quarterly basis (or thirty days prior to an anticipated data release if the second sentence of the preceding paragraph is triggered). States that do not opt-in to data sharing do not need to complete this log.

E

State Department (or contractor)	Summary of Research Plans Using Medicare or Medicaid Data	Access Method*

*If the data will be housed in a separate location from that identified in the DUA, please note the separate location here. If the data will be accessed via VPN at the location in the DUA, please note it.