Instructions for completing the RIF Data Use Agreement (DUA)

This document: All Research Identifiable File (RIF) requests must include a completed RIF Data Use Agreement (DUA). The DUA delineates the applicable privacy and security requirements and CMS data release policies and procedures.

General Instructions

1. Do not alter the layout or content of the document.
2. Submit to ResDAC an unsigned, editable draft in PDF format.
3. The DUA is not finalized until end of the ResDAC review process. Do not sign until directed by ResDAC.
4. This is a three-page document with items to be completed on pages 1 and 3.

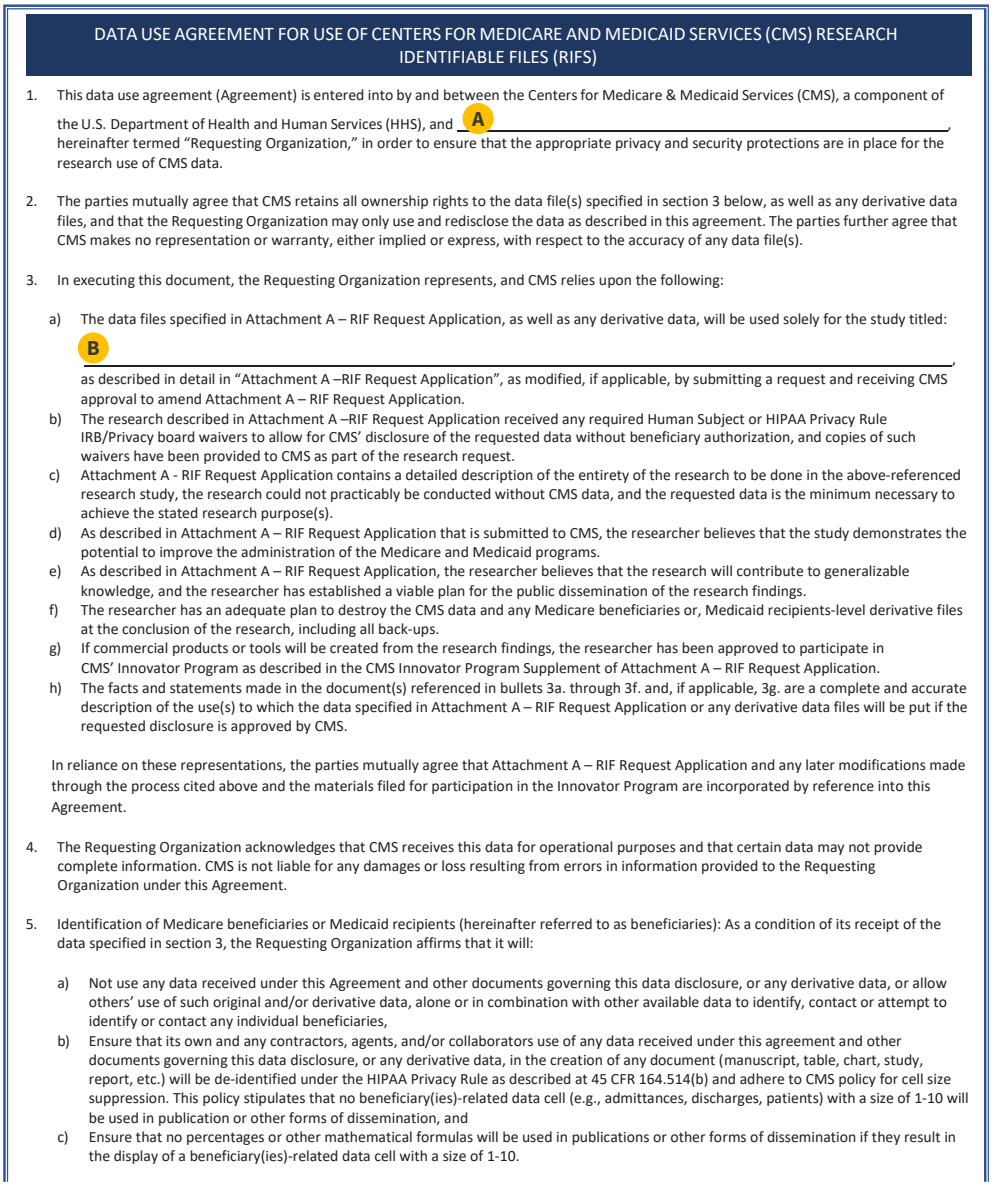
Specific Instructions

A

Enter the legal name of the Requesting Organization. The **Requesting Organization** is the organization with which the DUA is established.

B

Enter the exact Study Title. This will be the official title for CMS records.



DATA USE AGREEMENT FOR USE OF CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) RESEARCH IDENTIFIABLE FILES (RIFS)

1. This data use agreement (Agreement) is entered into by and between the Centers for Medicare & Medicaid Services (CMS), a component of the U.S. Department of Health and Human Services (HHS), and A, hereinafter termed "Requesting Organization," in order to ensure that the appropriate privacy and security protections are in place for the research use of CMS data.

2. The parties mutually agree that CMS retains all ownership rights to the data file(s) specified in section 3 below, as well as any derivative data files, and that the Requesting Organization may only use and redisclose the data as described in this agreement. The parties further agree that CMS makes no representation or warranty, either implied or express, with respect to the accuracy of any data file(s).

3. In executing this document, the Requesting Organization represents, and CMS relies upon the following:

   a) The data files specified in Attachment A – RIF Request Application, as well as any derivative data, will be used solely for the study titled: B, as described in detail in "Attachment A –RIF Request Application", as modified, if applicable, by submitting a request and receiving CMS approval to amend Attachment A – RIF Request Application.
   b) The research described in Attachment A –RIF Request Application received any required Human Subject or HIPAA Privacy Rule IRB/Privacy board waivers to allow for CMS' disclosure of the requested data without beneficiary authorization, and copies of such waivers have been provided to CMS as part of the research request.
   c) Attachment A - RIF Request Application contains a detailed description of the entirety of the research to be done in the above-referenced research study, the research could not practicably be conducted without CMS data, and the requested data is the minimum necessary to achieve the stated research purpose(s).
   d) As described in Attachment A – RIF Request Application that is submitted to CMS, the researcher believes that the study demonstrates the potential to improve the administration of the Medicare and Medicaid programs.
   e) As described in Attachment A – RIF Request Application, the researcher believes that the research will contribute to generalizable knowledge, and the researcher has established a viable plan for the public dissemination of the research findings.
   f) The researcher has an adequate plan to destroy the CMS data and any Medicare beneficiaries or, Medicaid recipients-level derivative files at the conclusion of the research, including all back-ups.
   g) If commercial products or tools will be created from the research findings, the researcher has been approved to participate in CMS' Innovator Program as described in the CMS Innovator Program Supplement of Attachment A – RIF Request Application.
   h) The facts and statements made in the document(s) referenced in bullets 3a. through 3f. and, if applicable, 3g. are a complete and accurate description of the use(s) to which the data specified in Attachment A – RIF Request Application or any derivative data files will be put if the requested disclosure is approved by CMS.

   In reliance on these representations, the parties mutually agree that Attachment A – RIF Request Application and any later modifications made through the process cited above and the materials filed for participation in the Innovator Program are incorporated by reference into this Agreement.

4. The Requesting Organization acknowledges that CMS receives this data for operational purposes and that certain data may not provide complete information. CMS is not liable for any damages or loss resulting from errors in information provided to the Requesting Organization under this Agreement.

5. Identification of Medicare beneficiaries or Medicaid recipients (hereinafter referred to as beneficiaries): As a condition of its receipt of the data specified in section 3, the Requesting Organization affirms that it will:

   a) Not use any data received under this Agreement and other documents governing this data disclosure, or any derivative data, or allow others' use of such original and/or derivative data, alone or in combination with other available data to identify, contact or attempt to identify or contact any individual beneficiaries,
   b) Ensure that its own and any contractors, agents, and/or collaborators use of any data received under this agreement and other documents governing this data disclosure, or any derivative data, in the creation of any document (manuscript, table, chart, study, report, etc.) will be de-identified under the HIPAA Privacy Rule as described at 45 CFR 164.514(b) and adhere to CMS policy for cell size suppression. This policy stipulates that no beneficiary(ies)-related data cell (e.g., admittances, discharges, patients) with a size of 1-10 will be used in publication or other forms of dissemination, and
   c) Ensure that no percentages or other mathematical formulas will be used in publications or other forms of dissemination if they result in the display of a beneficiary(ies)-related data cell with a size of 1-10.

You do not need to complete anything on this page.

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6. Identification of Providers or Suppliers: As a condition of its receipt of the data specified in section 3 the Requesting Organization further affirms that it will:

   a) Comply with the terms and conditions of this and any other agreement relevant to the information at issue, including ensuring that provider- or supplier-identifiable information (including individual physician-level data) that is published or otherwise disseminated will be patient de-identified data as that concept is understood under the HIPAA Privacy Rule's definition of de-identified data at 45 CFR 164.514(b) and CMS policy reflected in section 5b. of this Agreement.
   b) Ensure that no Tax Identification Numbers (TINs) will be used in publications or other forms of dissemination.

7. Linking Data. 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.

8. Use and Disclosure of Data. 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.

9. Retention of Data. The parties mutually agree that the data file(s) specified in Attachment A – RIF Request Application (and/or any derivative file(s)) including those files that directly or indirectly identify beneficiaries and those that can be used in concert with other available information to identify beneficiaries may only be retained by the Requesting Organization for one year from the date the DUA is finalized, hereinafter known as the "Expiration Date." However, should the purpose specified in section 3 be completed prior to that date, the Requesting Organization affirms that it will notify CMS within 30 days of such completion, at which time the Expiration Date of the DUA shall become the date specified in such notice. The Requesting Organization may request to extend the Expiration Date of the DUA, but each request may only be to extend the DUA by up to one year. Such extension must be approved by CMS and will only allow continued use of the data files specified in section 3 of this agreement and any derivative data for the purposes specified in section 3 of this Agreement.

10. Destruction of Data. By the Expiration 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 Expiration 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 Expiration Date.

11. Security Requirements. 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.

12. The Requesting Organization shall contractually bind any contractors, agents, and/or collaborators to the terms and conditions of this Agreement and other documents governing this data disclosure prior to granting them access to the data files specified in Attachment A – RIF Request Application or any derivative data, and limit such access to that required to carry out the project described in Attachment A – RIF Request Application. The Requesting Organization further agrees that, within the Requesting Organization and the organizations of its agents and collaborators, access to the data covered by this Agreement shall be limited to the minimum amount of data and minimum number of individuals necessary to achieve the purpose stated in this section (i.e., individual's access to the data will be on a need-to-know basis).

13. Violation of the Terms of this Agreement. The Requesting Organization agrees that in the event CMS determines or has a reasonable belief that the Requesting Organization or its agents, contractors, or collaborators have made or may have made a use, reuse, or disclosure of the aforesaid file(s) that is not authorized by this Agreement or other documents governing this data disclosure, the Requesting Organization will cease use of all data files specified in section 3 including any derivatives files, while CMS investigates the potential incident or violation. As part of its investigation, the Requesting Organization agrees that CMS, at its sole discretion, may require the Requesting Organization to: (a) promptly investigate and report to CMS the Requesting Organization's determinations regarding any alleged or actual unauthorized use, reuse or disclosure, (b) promptly resolve any problems identified by the investigation; (c) if requested by CMS, submit a formal response to an allegation of unauthorized use, reuse or disclosure; (d) if requested by CMS, submit a corrective action plan with steps designed to mitigate the ill-effects of and prevent any future unauthorized uses, reuses or disclosures; and (e) if requested by CMS, return or destroy the data files specified in section 3 and any derivative data. The Requesting Organization understands that as a result of CMS's determination or reasonable belief that unauthorized uses, reuses or disclosures have taken place, CMS may refuse to make future releases of CMS data to the Requesting Organization.

C

Do not sign and date until advised by ResDAC during the review process.

D

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

E

Enter the name of the Data Custodian. 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). For VRDC data requests, no data custodian is required and this may be left blank.

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Furthermore, should the Requesting Organization discover any use, reuse or disclosure of the aforesaid file(s) that may be in violation of this Agreement, Requesting Organization affirms that it will report the incident or breach by email to both the CMS IT Service Desk (cms_it_service_desk@cms.hhs.gov) and the CMS DUA Mailbox (DataUseAgreement@cms.hhs.gov) within one hour of discovery, and cooperate fully in the federal security incident response. While CMS retains all ownership rights to the data file(s), as outlined above, the Requesting Organization agrees to bear the cost of and liability for any incidents involving or breaches of PII or PHI from the data file(s) specified in section 3 or any derivative data while they are entrusted to the Requesting Organization. Furthermore, if CMS determines that the risk of harm requires notification of affected individual persons of the security incident or breach and/or other mitigation activities, the Requesting Organization affirms as a condition of receiving the data files specified in section 3 that it will carry out those CMS-defined notifications and/or mitigation activities without cost to CMS or its beneficiaries.

14. Penalties. The Requesting Organization acknowledges that penalties under § 1106(a) of the Social Security Act [42 U.S.C. § 1306(a)], including possible imprisonment, may apply with respect to any disclosure of information in the data files(s) that is inconsistent with the terms of the Agreement. The Requesting Organization further acknowledges that criminal penalties under the Privacy Act [5 U.S.C. § 552a(i)(3)] apply if it is determined that the Requesting Organization, or any individual employed or affiliated therewith, knowingly and willfully obtained the data file(s) under false pretenses. In addition, the Requesting Organization acknowledges criminal penalties under the 42 U.S.C. 290dd-2(f). The Requesting Organization also acknowledges that criminal penalties may be imposed under 18 U.S.C. § 641.

The undersigned individual hereby attests that he or she is authorized to enter into this Agreement on behalf of the Requesting Organization and agrees to all the terms specified herein.

C

Requester Signature **Date**

D

Requester Printed Name

The parties mutually agree that the following named individual is designated as Data Custodian of the data file(s) on behalf of the Requesting Organization and shall oversee and monitor Requesting Organization's and any agents, contractors, or collaborators compliance with the terms and condition established in this Agreement. The Requesting Organization agrees to notify CMS fifteen (15) days prior to any change of custodianship. The parties mutually agree that CMS may disapprove the appointment of a data custodian, or may require the appointment of a new data custodian at any time.

C

Data Custodian Signature **Date**

E

Data Custodian Printed Name