Instructions for amending the RIF Application

This document: CMS only requires revisions to the previously approved Research Identifiable File (RIF) Application when changing the study objectives/aims, cohort, and linkage to other files. If the instruction indicates not to make updates on this form, use the RIF Data Use Agreement (DUA): Amendment Request form to specify your amendment update. These instructions are for **amendments to approved requests only**.

General Instructions

1. Begin with your most recent, previously approved RIF application. Contact ResDAC if you need to confirm you have the most current version of your RIF application.
2. Do not delete any information from that approved document. Use ~~strikethrough~~ to note deletions and highlight all strikethroughs and insertions to denote changes.
3. Do not use tracked changes.
4. If more than one amendment has been completed for the DUA, use different color highlighting for each amendment.
5. Follow the instructions on the amendment job aid to determine whether your RIF application needs to be updated.
6. Do not alter the layout or content of the document.
7. Submit to ResDAC in Word format.

Specific Instructions

A

Do not change the Requester.

B

Do not change the Requesting Organization.

C

Do not change the Study Title.

D

Do not change the Type of Organization.

E

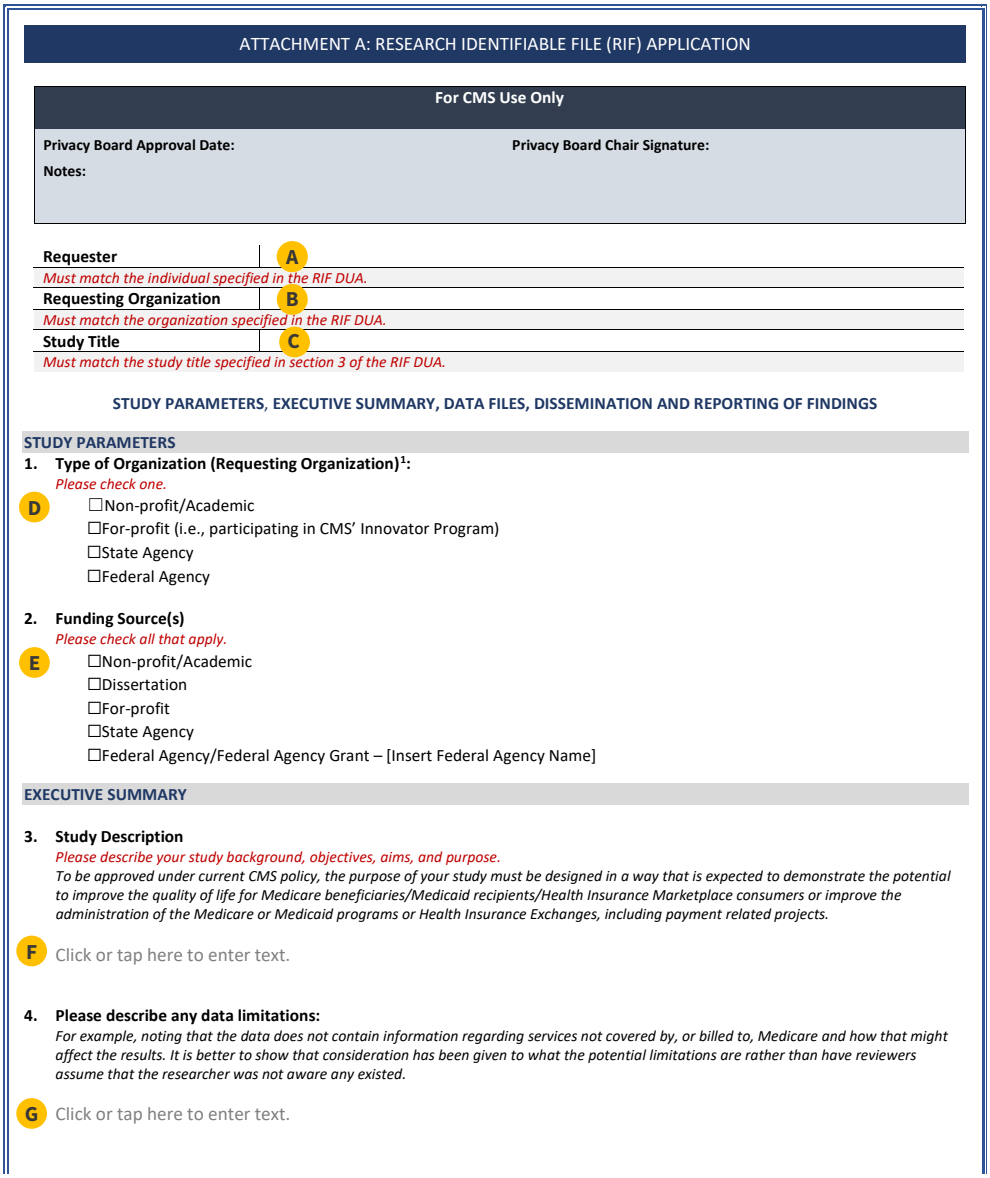
Do not change the Funding Source.

F

If appropriate, update your study objectives and aims using ~~strikethrough~~ to note deletions and highlight all strikethroughs and insertions to denote changes. Do not delete any previously approved content.

G

This section does not need to be updated.



ATTACHMENT A: RESEARCH IDENTIFIABLE FILE (RIF) APPLICATION

For CMS Use Only

Privacy Board Approval Date: **Privacy Board Chair Signature:**

Notes:

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.

STUDY PARAMETERS, EXECUTIVE SUMMARY, DATA FILES, DISSEMINATION AND REPORTING OF FINDINGS

STUDY PARAMETERS

1. **Type of Organization (Requesting Organization)[1]:**

Please check one.

D

☐Non-profit/Academic
☐For-profit (i.e., participating in CMS' Innovator Program)
☐State Agency
☐Federal Agency

2. **Funding Source(s)**

Please check all that apply.

E

☐Non-profit/Academic
☐Dissertation
☐For-profit
☐State Agency
☐Federal Agency/Federal Agency Grant – [Insert Federal Agency Name]

EXECUTIVE SUMMARY

3. **Study Description**

Please describe your study background, objectives, aims, and purpose.
To be approved under current CMS policy, the purpose of your study must be designed in a way that is expected to demonstrate the potential to improve the quality of life for Medicare beneficiaries/Medicaid recipients/Health Insurance Marketplace consumers or improve the administration of the Medicare or Medicaid programs or Health Insurance Exchanges, including payment related projects.

F Click or tap here to enter text.

4. **Please describe any data limitations:**

For example, noting that the data does not contain information regarding services not covered by, or billed to, Medicare and how that might affect the results. It is better to show that consideration has been given to what the potential limitations are rather than have reviewers assume that the researcher was not aware any existed.

G Click or tap here to enter text.

H

Do not change this table. All content from this table must remain as originally approved. Data files added as part of an amendment are listed in the RIF DUA: Amendment Request form.

I

If appropriate, update changes to the criteria you are using to define your cohort and changes to the estimated cohort size. Use ~~strikethrough~~ to note deletions and highlight all strikethroughs and insertions to denote changes. Do not delete any previously approved content.

J

This section does not need to be updated.

K

If appropriate, update changes to the non-CMS data or Public Use Files (PUF) being used in conjunction with the RIF data. Use ~~strikethrough~~ to denote deletions and highlight all strikethroughs and insertions to denote changes. Do note delete any previously approved content.

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5. Data Files Needed

H *For each file, record the data file name, justification for requesting the data file, frequency of data being requested, indicate if the data being requested can be framed as a reuse of data obtained (or a subset of such data) under an existing DUA, if so from what DUA, the cohort of the data requested (ex: 5%, 20%, 100%, custom cohort), and the method of dissemination.*

Add rows to the table as needed by clicking on the '+' in the lower right of the table.

Data File Name	Justification for how each data file will be used in the analysis	Years/Quarters Requested[2]	Cohort	DUA # (reuse only)	Dissemination

6. Please describe your cohort and how it is the minimum necessary to achieve your research objectives.
Include estimated cohort size.

I Click or tap here to enter text.

7. If this study will require future years of CMS data that are not yet available for request, please list those CMS data files and years that will be required for the *entire scope of your study*
(Note: Approval of data files for years that are not yet available will NOT be granted at this time, the information included here will simply provide CMS with an overview of your study).

J Click or tap here to enter text.

8. Please list any other data files or sources of information that you are planning to use to support your research study. (e.g., Provider of Services (POS) file, AMA Physician Master file, etc.). If you will be linking or attempting to link to the CMS files specified in section 5, please describe how you will be linking the data.

Name of additional files	Purpose for using the data file in the analysis	If linking to CMS data, describe how linkage will occur
K	K	K

L

This section should not be changed.

M

This section should not be changed.

N

This section should not be changed.

O

This section should not be changed.

P

This section should not be changed.

ATTACHMENT A: RESEARCH IDENTIFIABLE FILE (RIF) APPLICATION

9. Please check all that are applicable to your data request and ensure that the relevant supplements are completed
(Note: The supplements will be incorporated by reference into the Data Use Agreement; the Key Personnel Supplement is not listed since it is required for all Data Use Agreements):

L

- ☐ CMS Innovator Program Supplement
- ☐ State Agency Supplement
- ☐ Collaborating Organization Supplement

10. If this research project is funded by a for-profit entity, the Requesting Organization attests that they will limit data sharing with the funding entity to analytic results that meet the CMS cell suppression policy and are de-identified under the HIPAA Privacy Rule as described at 45 CFR 164.514(b) and will retain the right to independently prepare publications of the study results. Any aggregated analytic results that are shared with the for-profit entity must be limited to only interim results that support the research results that will be made publicly available.

M

- ☐ I attest
- ☐ Not applicable, the research project is not funded by a for-profit entity
- ☐ Not applicable, the research is being conducted under CMS' Innovator Program

11. If researchers from the Requesting Organization will be accessing CMS data in the Virtual Research Data Center (VRDC), the Requester attests that they understand and will adhere to the CMS VRDC Terms of Use and the CMS VRDC Output Review Policy and will submit a signed DUA Signature Addendum for Research Identifiable Files Acquired from CMS for each VRDC Seat Holder.

N

- ☐ I attest
- ☐ Not applicable, researchers will not be accessing CMS data in the Virtual Research Data Center

DISSEMINATION AND REPORTING OF FINDINGS

12. From sections 5 (b) and (c) of the CMS DUA, "As a condition of its receipt of CMS data, the Requesting Organization affirms that it will 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. The Requesting Organization will also ensure that no use of percentages or other mathematical formulas will be used in publications or other forms"

O

- ☐ I agree.

13. What are your plans for publicly disseminating the findings from your analysis, including specific media through which you will report results?

P

Click or tap here to enter text.