Instructions for Completing the Executive Summary

The Research Identifiable (RIF) Executive Summary is required to be filled out to obtain RIF data and will be reviewed by the CMS Privacy Board.

General Instructions

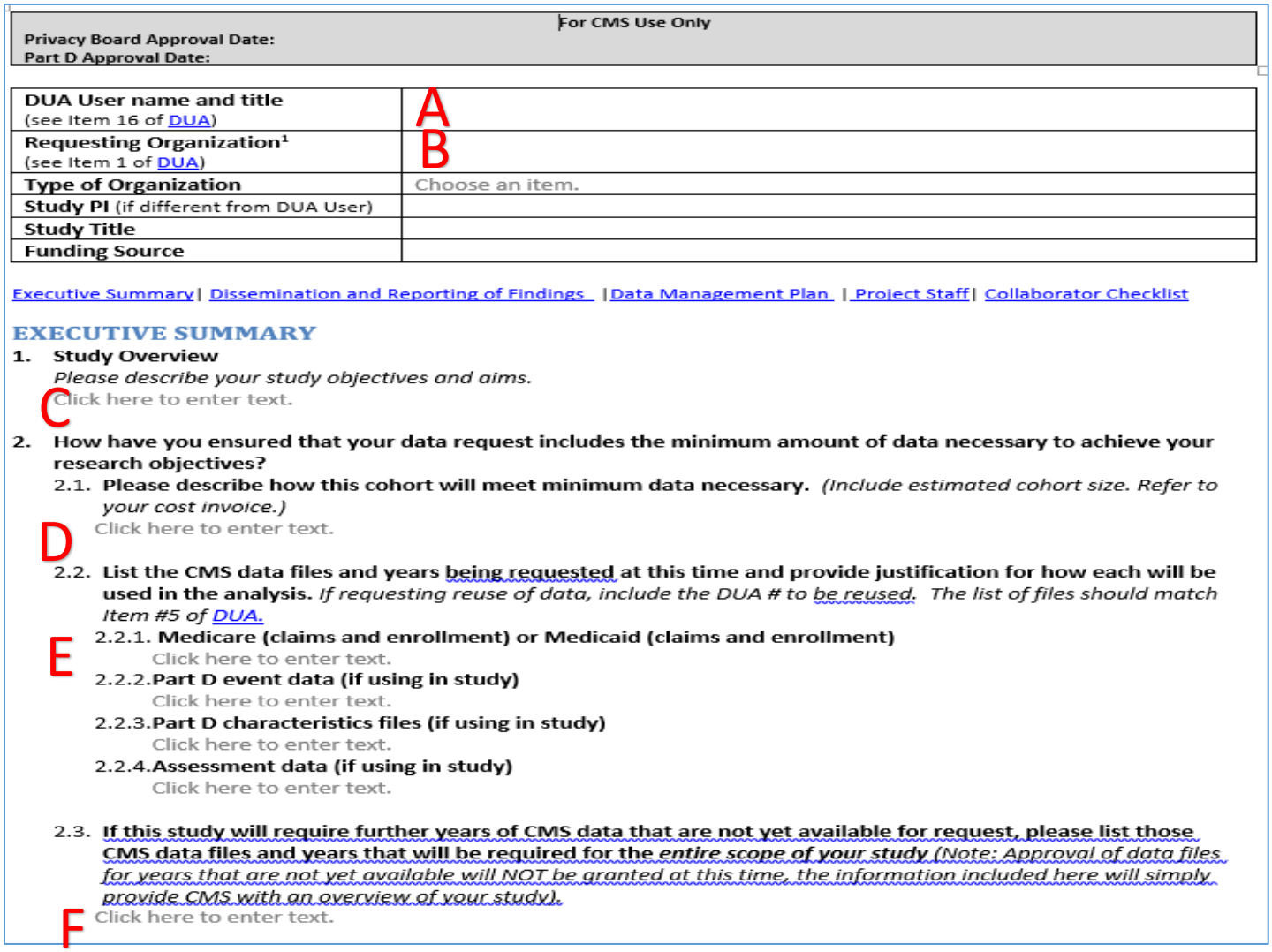
1. This document is used for a research identifiable request with physical receipt of data.
    - If data are used in the Virtual Research Data Center (VRDC) environment, use the VRDC Executive Summary.
    - If a state agency is making the request, use the State Executive Summary.

The Executive Summary is divided into 4 sections:

- Executive Summary
- Dissemination and Reporting of Findings
- Project Staff
- Data Management Plan

2. CMS uses the Executive Summary as the primary document when deciding upon approval. Please answer ALL questions and be thorough with your answers.
3. At the onset of your request, please provide a draft document in Word format.
4. Please do not alter the layout or content of the document.

Specific Instructions



For CMS Use Only
Privacy Board Approval Date:
Part D Approval Date:

DUA User name and title (see Item 16 of DUA)	A
Requesting Organization[1] (see Item 1 of DUA)	B
Type of Organization	Choose an item.
Study PI (if different from DUA User)	
Study Title	
Funding Source	

Executive Summary | Dissemination and Reporting of Findings | Data Management Plan | Project Staff | Collaborator Checklist

EXECUTIVE SUMMARY

1. **Study Overview**
   Please describe your study objectives and aims.
   C Click here to enter text.
2. **How have you ensured that your data request includes the minimum amount of data necessary to achieve your research objectives?**
   2.1. **Please describe how this cohort will meet minimum data necessary.** *(Include estimated cohort size. Refer to your cost invoice.)*
   D Click here to enter text.
   2.2. **List the CMS data files and years being requested at this time and provide justification for how each will be used in the analysis.** *If requesting reuse of data, include the DUA # to be reused. The list of files should match Item #5 of DUA.*
   E 2.2.1. **Medicare (claims and enrollment) or Medicaid (claims and enrollment)**
   Click here to enter text.
   2.2.2. **Part D event data (if using in study)**
   Click here to enter text.
   2.2.3. **Part D characteristics files (if using in study)**
   Click here to enter text.
   2.2.4. **Assessment data (if using in study)**
   Click here to enter text.
   2.3. **If this study will require further 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).*
   F Click here to enter text.

A. Enter authorized individual signing the Data Use Agreement on behalf of the requesting organization should sign as the User.
B. For Academic Institutions, please only cite the legal name of your institution-do not include names of specific schools, divisions, departments or programs within the institution.
C. Under section 1, the summary overview should be comprehensive because this is the main document the CMS Privacy Board looks at when determining approval. Include 3-4 paragraphs in length at a minimum.

D. Provide the number and criteria used to select your cohort and why this is the minimum amount of individuals needed to complete the study. Federal Regulations require CMS to release only the minimum data necessary to complete a study.
An example is found in the Part D System of Records, p. 30945, Section II. Agency Policies, Procedures, and Restrictions on Routine Uses.
http://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Privacy/Downloads/0553-DDPS.pdf

If a subpopulation is created from an existing approved project, provide the DUA number, the number of individuals and criteria used to create the original cohort. Also include the number of individuals and criteria used to create the subpopulation for the current project.
E. Under section 2.2, provide a sentence or two of justification for EACH file you are requesting under the appropriate category below. It is okay to overlap some justification if there are multiple files that are being used for the same purpose. If you are reusing data from an existing DUA, please specify reuse and provide the DUA number along with any needed crosswalk.
F. Under section 2.3, this question refers to section 10 of the DUA where it states the following: "The User agrees that, absent express written authorization from the appropriate System Manager or the person designated in section 20 of this Agreement to do so, the User shall not attempt to link records included in the file (s) specified in section 5 to any other individually identifiable source of information. This includes attempts to link the data to other CMS data files (s). A protocol that includes the linkage of specific files that has been approved in accordance with section 4 constitutes express authorization from CMS to link files as described in the protocol."

2.4. **Please list any non-identifiable or non-CMS files you are planning to use in conjunction with the above files for your analysis.** (e.g. Provider of Services (POS) file, AMA Physician Master file, etc.)

A

Click here to enter text.

3. **You are requesting Research Identifiable Files (RIF). Why can't Limited Data Set (LDS) files be used for this study?**

B

Click here to enter text.

4. **Is it feasible to obtain individual level authorization from Medicare/Medicaid beneficiaries for your research? Explain.**

C

Click here to enter text.

5. **If you intend on requesting the National Death Index segment of the Master Beneficiary Summary File, please complete the NDI Supplement.**

☐ YES, I've included the NDI Supplement ☐ NO, I'm not requesting the NDI

6. **If this research project is funded by a commercial entity, the (primary) lead investigator attests that they will limit data sharing with the funding entity to aggregated analytic results and will retain the right to independently prepare publications of the study results.** ☐ I attest

D

Signature of (Primary) Lead Investigator	**Date**

DISSEMINATION AND REPORTING OF FINDINGS

From the CMS DUA, "The User agrees that any use of CMS data in the creation of any document (manuscript, table, chart, study, report, etc.) concerning the purpose specified in section 4 (regardless of whether the report or other writing expressly refers to such purpose, to CMS, or to the files specified in section 5 or any data derived from such files) must adhere to CMS' current cell size suppression policy. **This policy stipulates that no cell (e.g. admittances, discharges, patients, services) 10 or less may be displayed.** Also, no use of percentages or other mathematical formulas may be used if they result in the display of a cell 10 or less."

☐ I agree.

Please describe your plans for disseminating the findings from your analysis, including specific media through which you will report results.

Click here to enter text.

E

A. Include any non-CMS data files or CMS Public use files that will be linked to the research identifiable data. Also include the variable(s) that will link the data together.

B. There are some components that RIF files have or can be used for that LDS data cannot. CMS wants to know that you have considered LDS but have concluded that RIF is the more feasible option.
   - Medicaid data is only available as a RIF file o Part D data is only available as a RIF file o Assessment data is only available as a RIF file.
   - LDS data can only be requested as 5% or 100% files. (Note: Carrier and DME can only be requested as 5% files as LDS).
   - LDS files only have beneficiary county level information
   - LDS files cannot be linked to Non-CMS data using an identifier
   - LDS does not include Beneficiary Date of Birth
   - Dates of Service ARE included in LDS files from 2009 forward.

C. If Authorization is obtained, list here, if not then explain why.

D. Check the box above and sign/date below ONLY if your study is funded by a commercial (FOR PROFIT) organization.

E. Include a description of how you will make the findings available to the public. Include the names of the scientific journals or details on how and where the study findings will be made available to the public.

As referenced on the CMS privacy page: http://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Privacy/Researchers.html

PROJECT STAFF

This section specifically identifies the project staff, organization, and the role of individuals in this project. The requestor and custodian should be named in this section at a minimum.

A

	B
1. Name & Title of Requestor /User	
Organization	
Role in this Study	
Will this individual have access to raw data, analytic files, or output with cell sizes less than 11? C	☐ NO. ☐ YES, this individual will be directly supervised by DUA signatory, [Name] . ☐ YES, this individual has signed the DUA.

	D
2. Name & Title of Custodian	
Organization	
Role in this Study	
Will this individual have access to raw data, analytic files, or output with cell sizes less than 11?	☐ NO. ☐ YES, this individual will be directly supervised by DUA signatory, [Name] . ☐ YES, this individual has signed the DUA.

3. Name & Title	
Organization	
Role in this Study	
Will this individual have access to raw data, analytic files, or output with cell sizes less than 11?	☐ NO. ☐ YES, this individual will be directly supervised by DUA signatory, [Name] . ☐ YES, this individual has signed the DUA or signature addendum.

4. Name & Title	
Organization	
Role in this Study	
Will this individual have access to raw data, analytic files, or output with cell sizes less than 11?	☐ NO. ☐ YES, this individual will be directly supervised by DUA signatory, [Name] . ☐ YES, this individual has signed the DUA or signature addendum.

*** If more individuals need to be added to this section, please copy and paste above fields.*

Page 3

A. Please list ALL individuals involved in the study and select only one option to indicate whether or not that person will have access to the raw data (Requestor/User and Custodian sign the DUA regardless).

> Note: If the "Requestor/User" is an authorized signatory who has no involvement in the research project itself, please change the response to "No" for access to the raw data (the Requestor/User still signs the DUA).

For any Project Staff in addition to the Requestor/User and Custodian who will have access to the raw data, please indicate if he/she will sign a Signature Addendum to the DUA (i.e. person will be formally listed on and bound by the DUA) OR will be supervised by another DUA signatory. If the person will be supervised, then he/she does not need to sign a Signature Addendum.

Please be sure to include each individual's formal title within the organization in addition to applicable credentials.

For academic institutions, if you are citing a specific college, school, department, center, etc., for an individual then please include that information in the "Name & Title" field. Only the legal name of the institution itself is to be entered in the "Organization" field, such as "University of _____," "Regents of the University of _____," etc.

B. Enter Requestor /User name. This person should match the person listed on DUA item 16.
C. Answer whether or not this individual will have access to raw data, analytic files, or output with cell sizes less than 11.
D. Please enter Custodian name and title. This person should match the person listed on DUA item 17.