Centers for Medicare & Medicaid Services

Executive Summary for Research Identifiable Data

Version 4/2015

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

DUA User name and title (see Item 16 of DUA)	Authorized individual signing the Data Use Agreement on behalf of the requesting organization.
Requesting Organization[1] (see Item 1 of DUA)	For academic institutions, please only cite the legal name of your institution here – do not include names of specific schools, divisions, departments or programs within the institution.
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.

This summary should be comprehensive because this is the main document the CMS Privacy Board looks at when determining approval. Please try to aim for a 3-4 paragraph minimum in length.

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.)*

Please explain why you chose the files you are requesting and how they will meet your study needs. CMS wants to know that you chose them specifically for your cohort and your study.

Federal Regulation on Minimum Data Necessary:
http://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Privacy/Downloads/0553-DDPS.pdf

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.*

In this section, please 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.

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.

[1] Throughout this document, "organization" can be interpreted as the company, agency, or group or team within a company, depending on which makes more sense in context with the research study for which CMS data files are being used. For example, large companies may defer to a CMS data file inventory for just their team; whereas smaller companies may keep a single CMS data file inventory for the entire company.

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).*
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 file(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.)
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?**
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
- Part D data is only available as a RIF file
- 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.

4. **Is it feasible to obtain individual level authorization from Medicare/Medicaid beneficiaries for your research?**
If Authorization is obtained list here, if not then explain why.

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

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.

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

Click here to enter text.

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.

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.

1. Name & Title of Requestor /User (DUA item 16)	
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] . X YES, this individual has signed the DUA.

2. Name & Title of Custodian (DUA item 17)	
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] . X 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.

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

DATA MANAGEMENT PLAN[2]

A response is required for every item in the Data Management Plan (DMP) with the exception of 3.5 which applies only to requests including Part D Event data. CMS will not accept "N/A" as a response for any items, nor can one response reference another (for example, "See response to item 1.5" as the response for item 1.7).

Please review the DMP Review Checklist Evaluation Guide for question-by-question instructions for completing the DMP. This document and other DMP resources are available on the "RIF Executive Summary Template" page of the ResDAC website at http://www.resdac.org/cms-data/request/materials/rif-executive-summary-template.

For research studies involving researchers from another organization that will have access to RIF or non-identifiable files, please refer to the Collaborator Checklist (pages 8-9) for guidance and considerations to include in the Data Management Plan.

For collaborating organizations that will be receiving a physical copy of the CMS data files, a full Data Management Plan should be completed by the collaborating organization.

1. **PHYSICAL POSSESSION AND STORAGE OF CMS DATA FILES**

1.1. Who will have the main responsibility for organizing, storing, and archiving the data? Please provide name(s) and job title(s).
Click here to enter text.

1.2. Describe how your organization maintains a current inventory of CMS data files.
Click here to enter text.

1.3. Describe how your organization binds all members (i.e., organizations, individual staff) of research teams to specific privacy and security rules in using CMS data files.
Click here to enter text.

1.4. Provide details about whom and how your organization will notify CMS of any project staffing changes.
Click here to enter text.

1.5. Describe your organization's training programs that are used to educate staff on how to protect CMS data files.
Click here to enter text.

1.6. Explain the infrastructure (facilities, hardware, software, other) that will secure the CMS data files.
Click here to enter text.

1.7. Describe the policies and procedures regarding the physical possession and storage of CMS data files.
Click here to enter text.

1.8. Explain your organization's system or process to track the status and roles of the research team.

[2] Note that CMS is specifically asking for reference to written policies and procedures related to your organization's administrative, technical and physical safeguards. If policies and procedures have not been developed, please explain any ongoing activities your organization is taking to document and make them available to staff. Organizations selected for DPSP reviews will be asked to provide copies of written policies and procedures. Please note that an explanation of the process is not sufficient.

Click here to enter text.

1.9. Describe your organization's physical and technical safeguards used to protect CMS data files (including physical access and logical access to the files).
Click here to enter text.

2. DATA SHARING, ELECTRONIC TRANSMISSION, DISTRIBUTION

2.1. Describe your organization's policies and procedures regarding the sharing, transmission, and distribution of CMS data files.
Click here to enter text.

2.2. If your organization employs a data tracking system, please describe.
If this does not apply to your organization then please respond "Our organization does not employ a data tracking system."
Click here to enter text.

2.3. Describe the policies and procedures your organization has developed for the physical removal, transport and transmission of CMS data files.
Click here to enter text.

2.4. Explain how your organization will tailor and restrict data access privileges based on an individual's role on the research team.
Click here to enter text.

2.5. Explain the use of technical safeguards for data access (which may include password protocols, log-on/log-off protocols, session time out protocols, and encryption for data in motion and data at rest).
Click here to enter text.

2.6. Are additional organizations involved in analyzing the data files provided by CMS? Click here to enter text.

If so, please review the Collaborator Checklist for guidance and considerations to include in the Data Management Plan, and indicate below how these organizations' analysts will access the data files:

- ☐ VPN connection
- ☐ Will travel to physical location of data files at requesting organization
- ☐ Request that a copy of the data files be housed at second location
- ☐ Other: Click here to enter text.

2.7. If an additional copy of the data will be housed in a separate location, please describe how the data will be transferred to this location. (Also, please ensure you have included information on this organization's database management under the appropriate subsections of the database management plan.)
If this does not apply to your organization then please respond "An additional copy of the data will not be housed in a separate location."
Click here to enter text.

3. DATA REPORTING AND PUBLICATION

3.1. Who will have the main responsibility for notifying CMS of any suspected incidents wherein the security and privacy of the CMS data may have been compromised? Please describe and identify your organization's policies and procedures for responding to potential breaches in the security and privacy of the CMS data.
Click here to enter text.

3.2. Explain how your organization's data management plans are reviewed and approved.
Click here to enter text.

3.3. Explain whether and how your organization's data management plans are subjected to periodic updates during the DUA period.
Click here to enter text.

3.4. Please attest to the CMS cell suppression policy of not publishing or presenting tables with cell sizes less than 11. (see Item 9 of the DUA) ☐ I agree.

4. COMPLETION OF RESEARCH TASKS AND DATA DESTRUCTION

4.1. Describe your organization's process to complete the Certificate of Disposition form and policies and procedures to dispose of data files upon completion of its research.
Click here to enter text.

4.2. Describe your organization's policies and procedures used to protect CMS data files when individual staff members of research teams (as well as collaborating organizations) terminate their participation in research projects (which may include staff exit interviews and immediate access termination).
Click here to enter text.

4.3. Describe policies and procedures your organization uses to inform CMS of project staffing changes, including when individual staff member's participation in research projects is terminated, voluntarily or involuntarily.
Click here to enter text.

4.4. Describe your organization's policies and procedures to ensure original data files are not used following the completion of the project.
Click here to enter text.

Please do not delete the remainder of this document.

PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-XXXX . The time required to complete this information collection is estimated to average two hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

COLLABORATOR CHECKLIST

Please note –This checklist* is for guidance purposes only and for organizations that are involving an additional organization as part of their research study. The checklist identifies data safeguard practices and considerations of the collaborating organization that should be indicated in the data requestor's Data Management Plan. All questions may not apply but are dependent upon the data sharing arrangement between the organizations involved in the research study.

(Information that should be indicated for each collaborating organization that will have access to RIF or non-identifiable files.)*

A. Access to Identifiable and De-identifiable Files

1. What is the name of the collaborating organization?*
   Click here to enter text.
2. How will the collaborating organization access the CMS data (secure VPN, a physical copy on site at the collaborating organization, traveling to the DUA holder's site, etc.)?*
   Click here to enter text.
3. Who are the researchers from the collaborating organization? Indicate if each researcher will have access to raw data, analytic files, or output with cell sizes less than 11. (*Please ensure that these individuals and data access rights are listed in the Project Staff list.*)*
   Click here to enter text.
4. What binding agreements are required of the researchers from the collaborating organization?*
   Click here to enter text.
5. What training is required of researchers from the collaborating organization?*
   Click here to enter text.
6. How will the collaborating organization notify the DUA holder of changes in staff who are participating on the research team?*
   Click here to enter text.
7. Will the researchers from the collaborating organization abide by the DUA holder's project rules or the policies of their employing organization?*
   Click here to enter text.

B. Access to RIF

1. Will the collaborating organization have access to RIF?*
   Click here to enter text.

   If yes, please provide the following required details:

   a. Will the collaborating organization have the ability to download and store a copy of the CMS data?
      Click here to enter text.
   b. Does the collaborating organization intend to backup the data? If so, has the collaborating organization developed a backup arrangement and are the back-up copies maintained at a second location?
      Click here to enter text.
   c. Who is responsible for maintaining the security and distribution of the CMS data at the collaborating organization?
      Click here to enter text.

d. Does the collaborating organization maintain an inventory of the CMS data files that are maintained by the collaborating organization?
Click here to enter text.

e. How will the collaborating organization tailor and restrict data access?
Click here to enter text.

f. Please describe the collaborating organization's physical and technical safeguards used to protect CMS data files (including physical access and logical access to the files).
Click here to enter text.

g. Please describe the collaborating organization's infrastructure, operating systems, and hardware that will be used to secure the CMS data.
Click here to enter text.

h. How will the collaborating organization dispose of electronic copies of the data?
Click here to enter text.

C. Physical Copies of RIF

Please note - if the collaborating organization will maintain a separate copy of the CMS data, the collaborating organization is required to complete a full Data Management Plan.

1. Will a separate copy of the CMS data be housed at the collaborating organization's location?
Click here to enter text.

2. How will the collaborating organization receive the CMS data (shipment from the DUA holder, collaborating organization will request an additional copy directly from CMS, POC from the collaborating organization will transport the data, etc.)?
Click here to enter text.