|  |
| --- |
| **For CMS Use Only** |
| **Privacy Board Approval Date:** |  |
| **Part D Approval Date:**  |  |

|  |  |
| --- | --- |
| **DUA User name and title** (see Item 16 of [DUA](http://www.cms.gov/cmsforms/downloads/cms-r-0235.pdf)) |  |
| **Requesting Organization[[1]](#footnote-1)** (see Item 1 of [DUA](http://www.cms.gov/cmsforms/downloads/cms-r-0235.pdf)) |  |
| **Type of Organization** | Choose an item. |
| **Study PI** (if different from DUA User) |  |
| **Study Title** |  |
| **Funding Source** |  |

[Executive Summary](#_EXECUTIVE_SUMMARY) | [Dissemination and Reporting of Findings](#_DISSEMINATION_AND_REPORTING) | [Project Staff](#_PROJECT_STAFF) | [Data Management Plan](#_DATA_MANAGEMENT_PLAN)

## EXECUTIVE SUMMARY

1. **Study Overview**

*Please describe your study objectives and aims.*

Click here to enter text.

1. **How have you ensured that your data request includes the minimum amount of data necessary to achieve your research objectives?**
	1. **Please describe how this cohort will meet minimum data necessary.** *(Include estimated cohort size. Refer to your cost invoice.)*

Click here to enter text.

* 1. **List the CMS data files and years being request 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*](http://www.cms.gov/cmsforms/downloads/cms-r-0235.pdf)*.*
		1. **Medicare (claims and enrollment) or Medicaid (claims and enrollment)**

Click here to enter text.

* + 1. **Part D event data (if using in study)**

Click here to enter text.

* + 1. **Part D characteristics files (if using in study)**

Click here to enter text.

* + 1. **Assessment data (if using in study)**

Click here to enter text.

* 1. **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).*

Click here to enter text.

* 1. **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.

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

Click here to enter text.

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

Click here to enter text.

1. **If you intend on requesting the National Death Index segment of the Master Beneficiary Summary File, please complete the** [**NDI Supplement**](http://www.resdac.org/cms-data/request/materials/ndi-supplemental-form)**.**

[ ]  YES, I’ve included the NDI Supplement [ ]  NO, I’m not requesting the NDI

1. **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 (*NOT APPLICABLE TO INNOVATORS*).** [ ] I attest

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

## DISSEMINATION AND REPORTING OF FINDINGS

1. 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.

1. 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.

## PROJECT STAFF

*This section specifically identifies the project staff, organization, and the role in this project. The Requestor and Custodian should be named in this section at a minimum.*

|  |  |
| --- | --- |
| 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?**  | [ ]  NO.[ ]  YES, this individual will be directly supervised by DUA signatory, [Name] .[ ]  YES, this individual has signed the DUA. |

|  |  |
| --- | --- |
| 1. **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. |

|  |  |
| --- | --- |
| 1. **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](http://www.cms.gov/cmsforms/downloads/cms-r-0235a.pdf). |

|  |  |
| --- | --- |
| 1. **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](http://www.cms.gov/cmsforms/downloads/cms-r-0235a.pdf). |

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

## DATA MANAGEMENT PLAN (for CMS VRDC Requests)[[2]](#footnote-2)

*Please reference the* [*Data Management Plan Guidelines*](http://www.resdac.org/sites/resdac.org/files/DPSP_Data%20Management%20Plan%20Guidelines.docx)*,* [*Data Management Plan Evaluation Guide*](http://www.resdac.org/sites/resdac.org/files/DMP%20Review%20Checklist%20Evaluation%20Guide.docx)*, and/or the* [*FAQ document*](http://www.resdac.org/sites/resdac.org/files/DPSP%20FAQs.docx) *for more information on completing this section. This is found under the Executive Summary section of the New Study Requesting Data page.*

# PHYSICAL POSSESSION AND STORAGE OF CMS DATA FILES

* 1. Who will have the main responsibility for organizing, storing, and archiving the data? Please provide name(s) and job title(s).

**Not applicable to the CMS VRDC user**.

* 1. Describe how your organization maintains a current inventory of CMS data files being accessed (identify how the agency tracks users and the data being accessed per project).

Click here to enter text.

* 1. 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. Provide details about who and how your organization will notify CMS of any project staffing changes.

Click here to enter text.

* 1. 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. Explain the infrastructure (facilities, hardware, software, other) that will access the CMS VRDC.

Click here to enter text.

* 1. Describe the policies and procedures regarding access to CMS data files.

Click here to enter text.

* 1. Explain your organization’s system or process to track the status and roles of the research team.

Click here to enter text.

* 1. Describe your organization’s physical and technical safeguards used to protect CMS data files (explain the safeguards used to protect user ids/passwords, ensure users comply with CMS VRDC rules of operation, only download statistical results, etc.).

Click here to enter text.

1. **DATA SHARING, ELECTRONIC TRANSMISSION, DISTRIBUTION**
	1. Describe your organization’s policies and procedures regarding the sharing, transmission, and distribution of CMS data files.

**Not applicable to the CMS VRDC user.**

* 1. If your organization employs a data tracking system, please describe.

Click here to enter text.

* 1. Describe the policies and procedures your organization has developed for the physical removal, transport and transmission of CMS data files (CMS VRDC users shall identify what will be done with any statistical files that are downloaded from the CMS VRDC).

Click here to enter text.

* 1. Explain how your organization will tailor and restrict data access privileges based on an individual’s role on the research team (CMS VRDC users shall include language to ensure they only request access to the minimum amount of data necessary for completion of their project. Additionally, if a user has access for multiple projects, language shall be included to specify that the user will only access the data files specific to each DUA).

Click here to enter text.

* 1. 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.

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

If so, please indicate 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.

* 1. 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.)

**This question is not applicable to this project as the data will be accessed within the CMS VRDC.**

1. **DATA REPORTING AND PUBLICATION**
	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.

* 1. Explain how your organization’s data management plans are reviewed and approved.

Click here to enter text.

* 1. Explain whether and how your organization’s data management plans are subjected to periodic updates during the DUA period.

Click here to enter text.

* 1. 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](http://www.cms.gov/cmsforms/downloads/cms-r-0235.pdf)). [ ]  I agree.
1. **COMPLETION OF RESEARCH TASKS AND DATA DESTRUCTION**
	1. Describe your organization’s process to notify CMS when the project is complete and access is no longer needed.

Click here to enter text.

* 1. Describe your organization’s policies and procedures for notifying CMS if a current CMS VRDC user is no longer working on the project (particularly if a project involves multiple users).

Click here to enter text.

* 1. Describe policies and procedures your organization uses to inform CMS of access changes when staff member’s participation in the research project is terminated, voluntarily or involuntarily.

Click here to enter text.

* 1. Describe your organization’s policies and procedures to ensure original data files are not used following the completion of the project.

**This question is not applicable to this project as the data will be accessed within the CMS VRDC.**

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.

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. [↑](#footnote-ref-1)
2. Note that we are specifically asking you to reference your 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. [↑](#footnote-ref-2)