

DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR MEDICARE & MEDICAID SERVICES

For CMS Use only:

Privacy Board Approval Date

Form Approved OMB No. xxxx-xxxx

STATE EXECUTIVE SUMMARY FOR RESEARCH IDENTIFIABLE DATA

Part D Approval Date

Requesting State Agency (see Item 1	of <u>DUA</u>)		
DUA User name and title (see Item 16	5 of <u>DUA</u>)		
Study/Project Title			
DATA SHARING			
research purposes. States that cho to opt-out of the data sharing ma	uest Memo from June 2012, CMS is offering States a choice in how pose to opt-in to data sharing will only sign one research DUA per ay not use or reuse the data without prior written authorization from rany requests to re-use or re-disclose the data.	State. States that choose	
Please indicate your selection belo	ow.		
We have signed and included	☐ Opt-in to data sharing (one research DUA per State) We have signed and included Attachment A to the DUA and will supply the log of users on a quarterly basis. ☐ Opt-out of data sharing (one research DUA per project) We understand that we may not use or reuse the data without prior written authorization from CMS.		
This section specifically identifies results. If a State chooses to opt-in	er organizations using CMS data each state agency or organization that will be using the data or so n to data sharing (and signs Attachment A to the DUA) this log mo) on a quarterly basis. States that do not opt-in to data sharing do	ust be supplied to CMS	
STATE DEPARTMENT	SUMMARY OF RESEARCH PLANS USING	ACCESS	
(OR CONTRACTOR)	MEDICARE DATA	METHOD*	

*If the data will be housed in a separate location from that identified in the DUA, please note the separate location here.

State Executive Summary for Research Identifiable Data (02/14)

 Study Overview Please describe your study objectives and aims. How have you ensured that your data request includes the minimum amount of data necessary to achieve your research objectives? Please describe how this cohort will meet minimum data necessary. (Include estimated cohort size. Refer to your cost invoice.) 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 the #5 of DUA. List the Medicare (claims and enrollment) or Medicaid (claims and enrollment) being requested as this time and provide justification for how each file 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. List the Part D event data (if using in study) being requested as this time and provide justification for how each file 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. List the Part D characteristics files (if using in study) being requested as this time and provide justification for how each file 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. List the Assessment data (if using in study) being requested as this time and provide justification for how each file 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. 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 cope of your study (Notex Approval of data files for years that are not yet available will NOT be granted at this time, the inf	EXECUTIVE SUMMARY
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3. You are requesting identifiable files. Why can't Limited Data Set (LDS) files be used for this study? Please check all that are applicable to this request.	
☐ I'm requesting data that are only available as identifiable data (Medicaid, Assessments, Medicare Part D event)	
☐ My research requires personal beneficiary identifiers (in order to link to other datasets or to contact Medicare be	eneficiaries)
☐ My research requires beneficiary DOB, zip code, or physician identifiers.	
Other (please explain):	
4. Is it feasible to obtain individual level authorization from Medicare/Medicaid beneficiaries for your research? Explain	in.
5. If you intend on requesting the National Death Index segment of the Master Beneficiary Summary File, please comp NDI Supplement.	plete the
\square YES, I've included the NDI Supplement \square 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 d funding entity to aggregated analytic results and will retain the right to independently prepare publications of the I attest	
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 (manusc study, report, etc.) concerning the purpose specified in section 4 (regardless of whether the report or oth refers to such purpose, to CMS, or to the files specified in section 5 or any data derived from such files) me current cell size suppression policy. This policy stipulates that no cell (e.g. admittances, discharges, patient may be displayed. Also, no use of percentages or other mathematical formulas may be used if they result cell 10 or less."	ner writing expressly nust adhere to CMS' ts, services) 10 or less
□ I agree.	
Please describe your plans for disseminating the findings from your analysis, including specific media through which yo	ou will report results.

DATA MANAGEMENT PLAN

Please reference the <u>Data Management Plan Guidelines</u>, <u>Data Management Plan Review Checklist Evaluation Guide</u>, <u>Collaborator Checklist</u>, and/or the <u>FAQ document</u> for more information on completing this section. These materials are found under the Executive Summary section of the New Study Requesting Data page of the website.

1. PH	TYSICAL 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).
1.2.	Explain the infrastructure (facilities, hardware, software, other) that will secure the CMS data files.
2. DA	ATA SHARING, ELECTRONIC TRANSMISSION, DISTRIBUTION
2.1.	Describe your organization's policies and procedures* regarding the sharing, transmission, and distribution of CMS data files.
2.2.	Please indicate how you will allow other state agencies (and/or contractors) to 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:
2.3.	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 data management under the appropriate subsections of the data management plan.)
2.4.	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.
safegu proced	hat CMS is specifically asking for references to written policies and procedures related to your organization's administrative, technical and physical ards. If policies and procedures have not been developed, please explain any ongoing activities your organization is taking to document policies and lures and make them available to staff. Organizations selected for DPSP reviews will be asked to provide copies of written policies and procedures. Please hat an explanation of the process is not sufficient.

S. COMPLETION OF RESEARCH TASKS AND DATA DESTRUCTION
3.1. In the event that the state is required by CMS to stop all research activities with CMS data, describe your organization's process to complete the Certificate of Disposition form and policies and procedures* to destroy data files.
3.2. In the event that the state is required by CMS to stop all research activities with CMS data, describe your organization's policies and procedures* to ensure original data files are not used following notice from CMS.
Note that CMS is specifically asking for references to written policies and procedures related to your organization's administrative, technical and physical afeguards. If policies and procedures have not been developed, please explain any ongoing activities your organization is taking to document policies and procedures and make them available to staff. Organizations selected for DPSP reviews will be asked to provide copies of written policies and procedures. Pleas note that an explanation of the process is not sufficient.

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