



Tips for Completing the Data Use Agreement and Signature Addendum and Special Instructions for Dissertation Students

Data Use Agreement (CMS-R-0235)

Note: These instructions apply to form [CMS-R-0235](#). This form should be used when applying for CMS identifiable data where a new Data Use Agreement (DUA) is required or when adding Part D data to an existing DUA for the first time. Those who are looking to update an existing DUA should use form [CMS-R-0235U](#).

Also, all sections requiring signature (sections 16, 17, and 19) MUST be submitted with all blocks complete (i.e., email address, phone number, etc.). CMS can now accept pdf versions of the DUA.

DUA #

The DUA form includes an empty box in the upper right hand corner of the form. If you are applying for a new DUA either through the purchase of new data OR reuse, you will leave this box empty. However, if you are applying for an amendment to an existing DUA that involves adding *Part D data for the first time*, please enter your DUA number here. Reuse requests should *not* list the reuse DUA number here as you will be assigned a new DUA number for your study.

DATA USE AGREEMENT

DUA #

**(AGREEMENT FOR USE OF CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)
DATA CONTAINING INDIVIDUAL IDENTIFIERS)**

Section 1 – Requestor

List the requesting *organization* on these two lines.

Important: If you are funded by an external entity (versus internal funding), the organization listed as the awardee must be the Requestor. Sub-contractors may not submit the request as Requestor/User, but may sign as the Custodian of the data.

Accountability Act. In order to secure data that reside in a CMS Privacy Act System of Records; in order to ensure the integrity, security, and confidentiality of information maintained by the CMS; and to permit appropriate disclosure and use of such data as permitted by law, CMS and University XYZ enter into this agreement to comply with the following specific paragraphs. (Requestor)

- 1. This Agreement is by and between the Centers for Medicare & Medicaid Services (CMS), a component of the U.S. Department of Health and Human Services (HHS), and University XYZ, hereinafter termed "User." (Requestor)

NOTE: Only the requesting organization may be allowed to request reuse of the data listed on this DUA in the future.

Section 4 – Name of Study/Project

The name of the study should **match** the study title listed on the other documents included with your request packet. The CMS Contract No. (if applicable) line should not be completed.

Section 5 – Data Files

List all files you are requesting in this section. Leave the System of Record column blank. If your request involves the **reuse of data**, please list separately from new use, if applicable, and specify the DUA number under which you will request reuse. You may list multiple files on the same row if the years are the same and there are not enough rows. If you are requesting Part D event (PDE) data, please specify the number of variables (1-15 or 16+). Please specify whether your request is for a 5% sample, 100% file, or a cohort. Please list beginning and ending year(s). If you are requesting a crosswalk file, please list the year the crosswalk file is being outputted. Only currently available files and years can be listed on the DUA.

- 5. The following CMS data file(s) is/are covered under this Agreement.

File	Years(s)	System of Record
Reuse of DUA XXXXXX:		
5% Beneficiary Summary File	2002-2007	
5% Carrier SAF; 5% Outpatient SAF	2002-2007	
New Use:		
5% Beneficiary Summary File	2008-2009	
5% Carrier SAF; 5% Outpatient SAF	2008-2009	
5% PDE (1-15 variables)	2006-2009	

Section 6 – Retention Date

The retention date should be listed as a complete date (MM/DD/YYYY). The retention date can be no more than 1 year from the time of your request. (If after 1 year, your study is not completed, you may at that time apply for an extension to your DUA.)

6. The parties mutually agree that the aforesaid files(s) (and/or any derivative file(s)), including those files that directly identify individuals or that directly identify bidding firms and/or such firms' proprietary, confidential or specific bidding information, and those files that can be used in concert with other information to identify individuals, may be retained by the User until 1/31/2016, hereinafter known as the "Retention Date." The User agrees to notify CMS within 30 days of the completion of the purpose specified in section 4 if the purpose is completed before the aforementioned retention date. Upon such notice or retention date, whichever occurs sooner, the User agrees to destroy such data. The User agrees to destroy and send written certification of the destruction of the files to CMS within 30 days. The User agrees not to retain CMS files or any parts thereof, after the aforementioned file(s) are destroyed unless the appropriate Systems Manager or the person designated in section 20 of this Agreement grants written authorization. The User acknowledges that the date is not contingent upon action by CMS.

Section 12 – Attachments

If you are including a **signature addendum** ([CMS-R-0235A](#)), please list that here. If not, please leave blank. You do not need to list all the documents included in your request packet. Please see instructions later in this document to determine if you need to submit a signature addendum.

12. The parties mutually agree that the following specified Attachments are part of this Agreement:

Signature Addendum

Section 16 – User

This section will be signed by an individual who has legal authority to sign on behalf of the requesting organization. Often the Principal Investigator of the study will sign, however some organizations have a designated legal representative sign as User. Researchers should check with their organization to determine who is best to sign.

Important: The individual signing as the User should also be the person who signs the request letter included with your request packet.

NOTE: Only the person who signs as User can provide required letters of support for any future reuse requests of this data. Furthermore, only individuals from the requesting organization may be allowed to request reuse of the data listed on this DUA.

Section 17 – Custodian

This section will be completed and signed by the individual responsible for the observance of all conditions of user and for data security at the institution where the data will be held.

Section 18 – Disclosure Provision

This section will be completed by a CMS representative and should be left blank.

Section 19 – Federal agency

If your study protocol is federally approved, you will need to have your federal project officer complete and sign this section. If your protocol is not federally approved, please leave blank.

Section 20 – CMS representative

This section will be completed by a CMS representative and should be left blank.

Signature Addendum

A signature addendum is required when individuals other than those who have signed the DUA as User or Custodian will have access to individual level data. Individuals who will only have access to aggregate information, defined as cell sizes 11 or greater, as described in item 9 of the DUA, do not need to sign the DUA or an addendum. Individuals who are supervised under institutional authority by someone else who has signed either the DUA or a signature addendum do not need to submit a signature addendum. Please also list the key staff in the executive summary of your data request packet and specify who will have access to the data and how they are covered (i.e. they have signed the DUA/signature addendum or are supervised under institutional authority by someone who has signed).

On the first line of the Addendum form, please indicate both the name of the **User** (Section 16) and the study title (**abbreviated version of study name is only needed**). The DUA number should be left blank when applying for a new DUA whether through purchase of new data OR reuse.

ADDENDUM TO DATA USE AGREEMENT (DUA)

Addendum to DUA for J. Doe / AMIs in the Medicare Population . If this is an addendum to a previously approved DUA, insert the CMS assigned DUA number here: _____. The following individual(s) may/will have access to CMS data that is being requested for this agreement. Their signatures attest to their agreement to the terms of this Data Use Agreement:

Instructions for Dissertation or Thesis Students

A student completing a Data Use Agreement for dissertation or thesis purposes will follow a very similar process to what was described above, but with a few special instructions regarding who signs as User (Section 16) and as Custodian (Section 17) on the DUA.

Section 16 – User

This section will be signed by an individual who has legal authority to sign on behalf of the requesting organization. **Students cannot sign as the User.** Often the **faculty advisor** will sign, however some organizations have a designated legal representative sign as User. *Students should check with their organization to determine who is best to sign.* **Important:** The individual signing as the User should also be the person who signs the request letter included with the request packet.

Section 17 – Custodian

This section will be completed and signed by the individual responsible for the observance of all conditions of user and for data security at the institution where the data will be held. **Students can sign as the Custodian,** if they will be in charge of data security. If there is a designated IT person, this person should sign as Data Custodian, and the student should then submit a signature addendum.

Signature Addendum

If circumstances at the university require that others sign as User and Custodian, a student should sign a signature addendum. As with any other request, individuals who will have access to individual level data and did not sign the DUA should also sign a signature addendum.

If you have any questions or comments, ResDAC staff can be contacted at 1-888-9ResDAC or resdac@umn.edu

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