



## *Tips for Completing a Research Identifiable Data Request Packet*

A new data use agreement (DUA) is required when researchers are requesting data for a **new study**. Each DUA is study specific. Therefore, a new DUA is required whether a researcher will be purchasing new CMS data or will be reusing CMS data already at their institution under another DUA. In order to apply for a new DUA, researchers must complete a request packet. A list and examples of the required materials are provided on the [ResDAC website](#) on the New Study request page. Please note that if your data request involves reuse of data, there are additional documents required, which are also outlined on the ResDAC New Study request page.

While many of the materials are self-explanatory, this document is intended to provide additional instructions and tips for completing the request packet materials. If you have any questions while completing your documents, please contact ResDAC at [resdac@umn.edu](mailto:resdac@umn.edu) or 1-888-973-7322.

To begin the review process, please email all documents to ResDAC in **draft** form (i.e. no signatures / no letterhead). Details regarding the request process timeline are outlined [here](#).

**Important:** If you are funded by an external entity (versus internal funding), the organization listed as the awardee must be the Requestor/User on the request. All documents therefore must be on the awardee institution's letterhead and a representative from that institution must sign as the User on the DUA. Sub-contractors may not submit the request as Requestor/User, but may sign as the Custodian of the data.

## **Required Documents**

### Written Request Letter

- The data files, years and study title listed in the request letter should match exactly across all documents of the request packet.
- The request letter must be signed by the same individual that signs as "User" on the Data Use Agreement. 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.

- Be sure that the final (signed) version of the request letter is submitted on institution letterhead; this is not required for draft versions.
- If you are requesting any custom extract (i.e. not a standard 5% or 100% sample), please briefly describe in the letter and include your estimated cohort size.
- CMS will **not** accept electronic/digital signatures; the final version of the letter should be printed, signed, scanned, and emailed back to ResDAC.

## Executive Summary

- The data files, years and study title listed in the executive summary should match exactly across all documents of the request packet.
- If you plan to request future years of data for this study, please include a mention of that in the executive summary. You will not officially be approved for these files, but it is important that CMS understands the full scope of your study.
- Be sure to complete all sections.
- The information you provide in the data management section should be specific to this request.

## Study Plan or Protocol

Researchers that have a federally approved protocol may submit their approved grant proposal in lieu of the study plan/protocol.

## Data Use Agreement (DUA)

- Detailed instructions for completing the DUA are found in this [document](#).

## IRB Documentation

- IRB review must come from the institution that received the funding (i.e. University of MN researcher receives the grant, then the IRB review must come from UMN.) If the organization that receives the funding doesn't have an IRB, then the researcher can select the IRB of his/her choice.
- See information about the necessary IRB documentation [here](#).

## Evidence of Funding

- Evidence of funding is usually a copy of the face sheet of the grant, contract, or cooperative agreement.
- If the study is funded **internally**, you may provide a signed letter from someone in your organization that can verify you have sufficient funds to cover the cost of the data. For example, the letter may come from the chair of your department or a financial staff member at your institution.
- If you are a dissertation student requesting a sole reuse request (i.e. no new data), you do not need to include this document as the reuse fee is waived.

## Specification Worksheet

- This document provides instructions to the data processor (Buccaneer) on how to complete your data request.
- There are several tabs contained in this worksheet and not all will necessarily apply to your request, however, please do **not** delete any tabs.
  - *Contact Request Info*
    - **This tab is required for all New Study requests (new use and reuse).**
    - In the Data Extract Specification section, be sure to list all files, all years, how the files will be created (i.e. custom cohort versus standard 5% or 100% files), and any other special instructions for Buccaneer; this should match the files listed on the other request packet documents.
    - The Requestor Information section (starting on row 39) should match who has signed as the User and Custodian on the DUA.
    - If the request involves a new extract of data, please include shipping account information or specify that you will provide a pre-paid label at time of shipping.
    - Under Method of Payment, "Interagency Agreement Number" can only be selected for federal agencies.
  - *Disclaimer*
    - **It is important that all researchers read this disclaimer.**
    - Nothing needs to be filled out on this tab.
  - *Extract Summary*
    - **This tab only needs to be filled out if your request involves new use.**
    - Please select how the data will be constructed and all the files you are requesting.
    - The "indicate percent" columns (K,L) is where you will indicate whether you would like your cohort pulled against the 5% sample or against the full 100% sample.

- *CCW Chronic Conditions*
  - **This tab is only required if you are requesting Medicare data pulled by one of the CCW pre-defined chronic conditions.**
- *Optional Addntl Criteria*
  - **This tab is only required if you are requesting new use of Medicare data where the cohort will be limited by sex, age, date of death, race, residence, or Medicare status.**
- *MAX Data*
  - **This tab is only required if you are requesting new use of Medicaid (MAX) data.**
- *PDE Justification*
  - **This tab is only required if you are requesting Part D data and must be completed for both new use and reuse.**
  - Even if you are requesting **reuse** of Part D data, you must select and justify *only* the variables needed for your *current* study.
  - Provide brief justification for each variable under column C ("Reason for Requesting PDE Element"); the justification should be specific for each variable.

## Formal CMS Cost Invoice

- If your New Study request **only involves reuse**, ResDAC will provide you with a reuse fee invoice and you will only need to complete the following sections of the cost invoice form:
  - To/From/Date/Re: ([page 1](#))
  - Study Description ([page 1](#))
  - Data extract description with a brief mention of your plans to reuse data ([page 1](#))
  - Requests involving reuse section ([page 3](#))
- If your request involves requesting new data, ResDAC will review your cost invoice, submit it to Buccaneer for processing, and will forward the completed invoice back to you.

## Additional Documentation for Assessment Data (MDS, OASIS, IRF-PAI, or Swing Bed Assessments)

- Variable selection and justification worksheets are **only** required if you are requesting assessment data (i.e. MDS, OASIS, IRF-PAI, or swing bed).

- Even if you are requesting **reuse** of assessment data, you must select and justify *only* the variables needed for your current study.
- Please place a “X” in column A for each variable that you would like.
- Provide brief justification for each variable under the appropriate column (“Use in Analysis” for MDS worksheets and “Justification” for other assessment worksheets).

## Additional Documentation for Part D Requests

- The only additional documentation required for Part D requests is the PDE justification tab of the specification worksheet.
- See [above for instructions](#) on completing that tab.

## Additional Documentation for Name & Address Requests

- Beneficiary name and address information is **only** made available to researchers who must contact beneficiaries directly in order to conduct their study (e.g. to enroll survey participants)
- Researchers must supply the full study survey, any study brochure/information letter, a CMS beneficiary notification letter, and a cost estimate from the University of Minnesota Beneficiary Contact Service.

## Statement of Support from Federal Project Officer

- This document is **only** required if your study has a federally approved protocol.
- If there is any significant change in the request (e.g. types of files, years of files, extract methodology) listed in the study proposal used in the grant application and the current request packet, please note them here.
- As outlined on the ResDAC website, this statement may be provided either as a letter (signed and on institutional letterhead) or via email. If submitted by email, the statement of support should be emailed to the requestor directly and then forwarded to ResDAC along with your full packet.

## **Additional Documents Required for Reuse Requests**

### Statement of Support from Original Requestor

- This document is **only** required if your study involves the reuse of data within your institution (cross-institutional reuse of data is not allowed).
- If the individual who signed as User on the original DUA is the same person signing the current DUA, this letter is not required. Please describe the situation in the request letter.

### Statement of Support from Original Federal Project Officer

- This document is **only** required if the original study had a federally approved protocol. .
- As outlined on the ResDAC website, this statement may be provided either as a letter (signed and on institutional letterhead) or via email. If submitted by email, the statement of support should be emailed to the requestor directly and then forwarded to ResDAC along with your full packet.