



**Manual 48**

**ARIC REDCap Data Use Tracking Procedures**

*For Use by Data Access Administrators*

**Version 1.0**

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# ARIC REDCap Data Use Tracking Procedures

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## 1. Overview and Purpose:

With the transition to the sIRB, ARIC now needs to carefully regulate all individuals accessing ARIC data which falls into the De-identified or Limited data categories. De-identified data (non-PHI or NP data) does not contain any identifiable data. Limited data is identifiable data that includes dates. Access to Limited data will be severely restricted.

This REDCap form offers a central data user tracking mechanism that can be accessed and monitored by all ARIC participating sites. The form functions to:

- Track all data users across ARIC pSITES, Hubs, and external institutions as well as the type of data being accessed.
- Allow investigators to submit data requests to the Coordinating Center which will expedite the data request and distribution process.

## 2. Important Information

- **Under no circumstances should you edit, delete, or add fields in the REDCap form.** All desired changes to your site's page should be sent to [aricdata@unc.edu](mailto:aricdata@unc.edu).
- Data Access Administrators should only access REDCap to generate reports and/or edit records from their site. **Please do not edit records from sites outside your institution for any reason.**
- **pSITE Data Access Administrators are responsible for maintaining their list of data users in REDCap.** This tracking information will be exported at least annually for sIRB reporting; therefore, administrators should review their list periodically for any data users who are no longer active or who do not match local records.
- If at any point you are unsure how to generate a report or edit a record, please reach out to [aricdata@unc.edu](mailto:aricdata@unc.edu) and a staff member will be happy to assist you.

### 2.1 Access to Limited data:

If a data user at your site requires access to Limited data (this should be rare), your site must have additional, official documentation for that data user on file that is readily available to share if needed. This documentation includes an official signature verifying the data user's agreement to abide by the Central DUA. **For most pSITES, this means having the Central DUA form fully executed and stored at your pSITE in addition to the individual filling out the REDCap form.** For sites using separate REDCap forms to relay site-specific information, an eSignature in REDCap may suffice as 'additional, official documentation' depending on your institution's preferences regarding what constitutes a binding signature. Please note, Limited datasets must be stored in a separate location from NP datasets. Access to Limited data must be restricted only to those with a signed DUA.

## 2.2 Access to De-identified data:

If a data user at your site requests access to De-identified data (this is the majority), **the minimum requirement is the data user's affirmation in the REDCap form that they will abide by the Central DUA.** Some sites have requested that these De-identified data users also fill out 'additional, official documentation' to be sent via email to their site to track locally; while this is not required, it can be requested if preferred. All data users that submit the REDCap form will receive an option to download their responses after submission thereby giving them a copy of their affirmation to abide by the agreement.

## 3. Useful links:

Accessing the REDCap as a Data Access Administrator (requires login):

[https://rc2.redcap.unc.edu/redcap\\_v13.7.4/Design/online\\_designer.php?pid=31](https://rc2.redcap.unc.edu/redcap_v13.7.4/Design/online_designer.php?pid=31)

Public-facing REDCap form link for distribution to data users/requestors:

<https://rc2.redcap.unc.edu/surveys/?s=94JAMTEWJD PFXENP>

## 4. When to distribute the REDCap form:

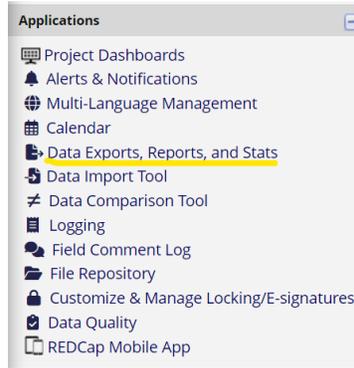
The public-facing link to the REDCap form should be distributed to any new faculty, staff, students, etc. who will be accessing data provided to them by your institution. Anyone utilizing or accessing the data on your institution's secure server, including all Data Access Administrators and Data Managers, will need to register in REDCap as a data user and accept the data use agreement. This form will capture data access going forward.

Any investigators who need to request data from the Coordinating Center for approved ancillary study- or manuscript-related activities should use the REDCap form to submit data requests. Please note that in addition to a committee-approved project, investigators will also need a fully executed DMDA and Data Request form for upload to REDCap.

## 5. How to access your site's Data User Report:

Please note, report settings should NOT be modified by Data Access Administrators. If you want to modify your site's report to include additional information captured by the REDCap form, please email [aricdata@unc.edu](mailto:aricdata@unc.edu).

To access your site's report, select 'Data Exports, Reports, and Stats' on the left side bar under 'Applications'



This will take you to the following page:

My Reports & Exports	
Report name	View/Export Options
A All data (all records and fields)	<a href="#">View Report</a> <a href="#">Export Data</a> <a href="#">Stats &amp; Charts</a>
B Selected instruments and/or events (all records)	<a href="#">Make custom selections</a>
1 DUA Respondents - All Sites	<a href="#">View Report</a> <a href="#">Export Data</a> <a href="#">Stats &amp; Charts</a>
2 Data User Profile - WFU	<a href="#">View Report</a> <a href="#">Export Data</a> <a href="#">Stats &amp; Charts</a>
3 Data User Profile - UMMC	<a href="#">View Report</a> <a href="#">Export Data</a> <a href="#">Stats &amp; Charts</a>
4 Data User Profile - UMN	<a href="#">View Report</a> <a href="#">Export Data</a> <a href="#">Stats &amp; Charts</a>
5 Data User Profile - JHU	<a href="#">View Report</a> <a href="#">Export Data</a> <a href="#">Stats &amp; Charts</a>
6 Data User Profile - BCM	<a href="#">View Report</a> <a href="#">Export Data</a> <a href="#">Stats &amp; Charts</a>
7 Data User Profile - UTHSC	<a href="#">View Report</a> <a href="#">Export Data</a> <a href="#">Stats &amp; Charts</a>
8 Data User Profile - BWH	<a href="#">View Report</a> <a href="#">Export Data</a> <a href="#">Stats &amp; Charts</a>
9 Data User Profile - CVD Epi	<a href="#">View Report</a> <a href="#">Export Data</a> <a href="#">Stats &amp; Charts</a>
10 External Data User Profile - CSCC	<a href="#">View Report</a> <a href="#">Export Data</a> <a href="#">Stats &amp; Charts</a>
11 Data Requests - CSCC	<a href="#">View Report</a> <a href="#">Export Data</a> <a href="#">Stats &amp; Charts</a>
12 Data User Profile - ARIC Hubs	<a href="#">View Report</a> <a href="#">Export Data</a> <a href="#">Stats &amp; Charts</a>

Find the report that corresponds with your site and select 'View Report'. The UMN report will be used as an example.

### Data User Profile - UMN

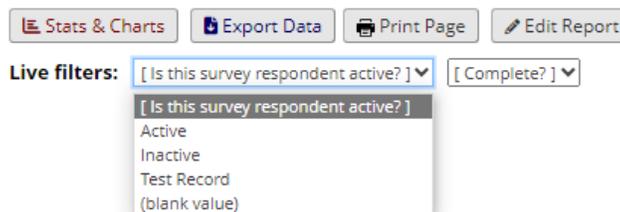
Please use the live filters to sort by active status or completion status. Leaving the filters blank will result in all records being shown.

Record ID record_id	Event Name redcap_event_name	Site / Institution Providing ARIC Data: Please read all possibilities ... unc.edu for more information. dua_site	First Name: dua_firstname	Last Name: dua_lastname	Email: email	Date: dua_date	What type of data will you need access to? Please note, Limited data ... is strict and rarely provided. data_archetype	Complete? aric_data_use_agreement_complete
2 -- [name]	Initial DUA Registration	University of Minnesota (Field Center) (3)	Test	User	testuser@mail.com	05-16-2023	De-Identified Data (1)	Incomplete (0)

- **‘Record ID’:** An ID number assigned to every form respondent by REDCap. The IDs are assigned in sequential order with each new respondent.
- **‘Event Name’:** ‘Initial DUA Registration’ means it is the first time the individual has responded to the form. A secondary response would be noted by ‘DUA Renewal’. Most users likely will not need to register in REDCap more than once.
- **‘Site / Institution Providing ARIC Data’:** The respondent has selected that they are accessing or will access data provided by your site.
- **‘Date’:** Site reports are sorted by date in chronological order.
- **‘What type of data will you need access to?’:** In most cases, the respondent will have access to only de-identified data. Since this is a checkbox field, it is possible for the respondent to report access to both De-identified and Limited data. The report cannot be filtered by data type since this form question is set up as a checkbox field. The report will need to be exported into Excel in order to sort by data type. If a data user needs to change their data access level, see directions [here](#).
- **‘Complete?’:** This column states whether the record submission by the respondent is complete. In cases where the submission is incomplete, the record should be reviewed for missing information. See directions [here](#).
- If there is another field you would like included in your site’s report (such as the data user’s ‘Role’ in ARIC), please send the request to [aricdata@unc.edu](mailto:aricdata@unc.edu).

All site reports can be filtered by data user active status or record completion.

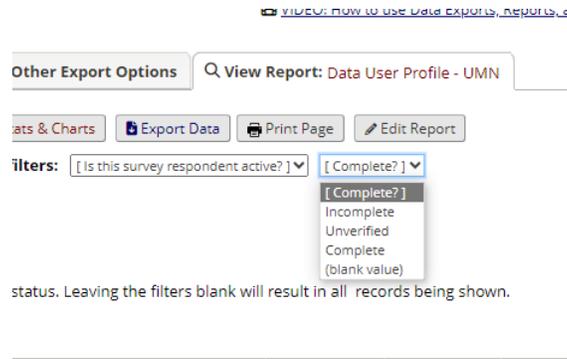
To filter by active status, select the filter drop down and select the status you want to see all results for. If you want to see all active data users, select ‘Active’ and this will only populate the list with all active data users.



or completion status. Leaving the filters blank will result in all records being shown.

on Providing ARIC Data:Please read all inc.edu for more information.	First Name: dua	Last Name: dua
---	-----------------------	----------------------

To filter by record completion, select the filter drop down and select the status you want to see all results for. If you want to see all remaining incomplete records, select 'Incomplete' and this will only populate the list with all incomplete records.

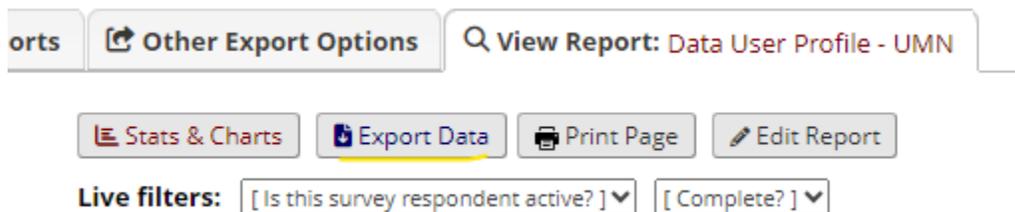


If you want to search for a specific data user, use the search bar to the right of the screen.



## 6. Exporting Reports:

To export your site's report to an Excel file for easy viewing and sorting, select the 'Export Data' button on the 'View Report' page.



This will result in a page popup. Select 'CSV / Microsoft Excel (Labels)' as the export format and then select 'Export Data'.

**Exporting "Data User Profile - UMN"**

Select your export settings, which includes the export format (Excel/CSV, SAS, SPSS, R, Stata) and if you wish to perform de-identification on the data set.

**Choose export format**

-  CSV / Microsoft Excel (raw data)
-  **CSV / Microsoft Excel (labels)**
-  SPSS Statistical Software
-  SAS Statistical Software
-  R Statistical Software
-  Stata Statistical Software
-  CDISC ODM (XML)

**De-identification options (optional)**

The options below allow you to limit the amount of sensitive information that you are exporting out of the project. Check all that that apply.

**Known Identifiers:**

- Remove All Identifier Fields (tagged in Data Dictionary)
- Hash the Record ID field (converts record name to an unrecognizable value)

**Free-form text:**

- Remove unvalidated Text fields (i.e. Text fields other than dates, numbers, etc.)
- Remove Notes/Essay box fields

**Date and datetime fields:**

- Remove all date and datetime fields
- OR —
- Shift all dates by value between 0 and 364 days (shifted amount determined by algorithm for each record) [What is date shifting?](#)
- Also shift all survey completion timestamps by value between 0 and 364 days (shifted amount determined by algorithm for each record)

[Deselect all options](#)

**Advanced data formatting options**

**Export blank values for gray Form Status?**

All Form Status fields with a gray status icon can be exported either as a blank value or as "0" (Incomplete). Hint: Blank values are recommended if the data will be imported back into REDCap, in which this preserves the gray status icons for all the imported records.

Export gray Form Status fields with value of "0" ▼

**Set CSV delimiter character**

Set the delimiter used to separate values in the CSV data file (only valid for CSV Raw Data and CSV Labels export formats):

, (comma) - default ▼

**Force all numbers into a specified decimal format?**

You may choose to force all data values containing a decimal to have a specified decimal character (comma or period/full stop). This will be applied to all calculations and number-validated text values in the export file.

Use fields' native decimal format (default) ▼

NOTE: Your data formatting selections above will be remembered in the future and will be pre-selected upon your next export.

**Export Data** Cancel

If the data export was successful, you will see the following screen. Click the Excel Icon in the bottom right of the screen to download the file.

**✓ Data export was successful!**

The data export was successful, and your data is now ready to be downloaded. Click the download icon(s) below on the right to download your data file. If exporting to a specific statistical analysis package, you will additionally need to download the syntax file that is provided for that stats package. For more details, follow the instructions in the box below.

**How to cite publications and grants**

When publishing manuscripts relating to this REDCap project, we ask that in your publication you please cite the items listed below that have been utilized in this project. Thank you!

1. Please cite your institution/organization's grant: **UL1TR002489 from the Clinical and Translational Science Award program of the National Center for Advancing Translational Sciences, National Institutes of Health.**
2. Please cite the **official REDCap publications.** [View citation and template methods language](#)

 **CSV / Microsoft Excel (labels)**

You may download the survey results in CSV (comma-separated) format, which can be opened in Excel. You have the choice of downloading the data either with the full headers and answer labels or just with the answer codes (i.e. raw data).

NOTE: If you are using a version of Microsoft Excel prior to Excel 2007, due to limitations the data will only be read to 255 columns when opened.

Click icon(s) to download:



Send file?

Close

The Excel file will look similar to this:

Record ID	Event Name	Site / Institution Providing ARIC Data:	First Name:	Last Name:	Email:	Date:	What type of data will you need access to?	Complete?
	Initial DUA 2 Registration	University of Minnesota (Field Center)	Test	User	testuser@e mail.com	5/16/2023	De-Identified Data	Incomplete
	Initial DUA 12 Registration	University of Minnesota (Field Center)	John	Doe	johndoe@g	7/28/2023	De-Identified Data	Complete

This file can then be sorted by any of the column headers such as data type, name, date, etc. Please make sure this list of users and their data access is correct.

## 7. When to edit a record:

As a Data Access Administrator, you will need to edit a respondent's record under any of the following circumstances:

- The record is incomplete.
- The respondent is no longer an active data user at your site (i.e., change of employment, etc.).
- A new level of data access is needed by a respondent (i.e., no longer needs Limited data access, etc.). See directions [here](#).
- If you believe any information provided by a respondent to be incorrect, please email the concern to the respondent's email address provided in the report.
  - If they confirm the error, please edit and save the record (directions provided [here](#)).
- If there is someone listed as a data user in your site's report that does not match any local training or data use records, please email the respondent to obtain any missing documentation.
  - If it is the case that the individual is not a true data user at your site, please edit the record to be 'inactive' (directions provided [here](#)). If it appears they are an ARIC data user at a different institution, please email [aricdata@unc.edu](mailto:aricdata@unc.edu) specifying your concern and the Record ID # of the individual.

## 8. How to edit a record:

From the report page, click on the record ID # of the respondent's record that you want to edit.

Record ID record_id	Event Name redcap_event_name	Site / Institution Providing ARIC Data:Please read all possibilities ... unc.edu for more information. dua_site	First Name: dua_firstname	Last Name: dua_lastname	Email: email	Date: dua_date
2 -- [name]	Initial DUA Registration	University of Minnesota (Field Center) (3)	Test	User	testuser@email.com	05-16-2023

After clicking on the record ID #, REDCap will take you to the following page:

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event. If you wish, you may modify the events below by navigating to the [Define My Events](#) page.

[Choose action for record](#)

Record ID 9 -- [name]

Data Collection Instrument	Initial DUA Registration	DUA Renewal
ARIC Data Use Agreement (survey)		

**Legend for status icons:**

- Incomplete  Incomplete (no data saved) ?
- Unverified  Partial Survey Response
- Complete  Completed Survey Response

To edit the record, select the status icon under the 'Initial DUA Registration' event. This will take you to the form with all the person's responses for editing. If you are updating information in an already complete form, select 'Save and Exit' once you are done. If the form was incomplete prior to editing the record, see directions below.

### 8.1 Incomplete record:

As the legend in the middle of the screen indicates, this record is incomplete for the first event (Initial DUA Registration).

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event. If you wish, you may modify the events below by navigating to the [Define My Events](#) page.

[Choose action for record](#)

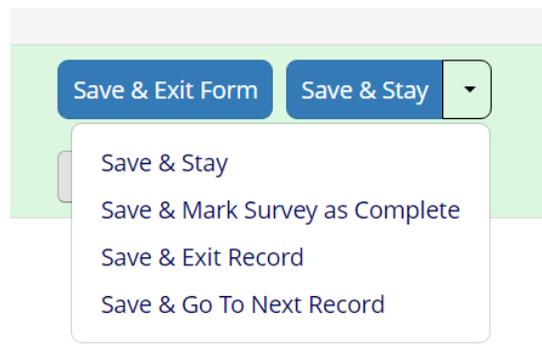
Record ID 2 -- [name]

Data Collection Instrument	Initial DUA Registration	DUA Renewal
ARIC Data Use Agreement (survey)		

**Legend for status icons:**

- Incomplete  Incomplete (no data saved) ?
- Unverified  Partial Survey Response
- Complete  Completed Survey Response

To edit the record, click on the status icon under 'Initial DUA Registration'. This directs you to the form with their responses where information can be added. *If more than half of the required fields are missing information, set the record as a 'Test Record' (see directions here).* After adding any missing information, select the arrow next to 'Save & Stay'. This will produce a drop-down menu where you can select 'Save & Mark Survey as Complete'. If you select 'Save and Exit', the form remains labeled as 'incomplete'.



## 8.2 Change in data access level:

If a data user requires a change in data access, please see the following guidance.

If the data user currently only has access to De-identified data but will soon need access to Limited data:

1. Have the data user sign the Central DUA.
2. Track and store the signed Central DUA at your site.
3. Email [aricdata@unc.edu](mailto:aricdata@unc.edu) providing the name of the data user who needs a data access change. Please confirm in the email that the Central DUA has been signed for that user. A copy of the agreement does not need to be provided.

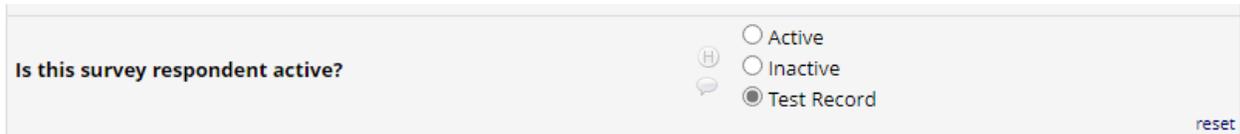
If the data user currently has access to Limited data but soon will only need access to De-identified data:

1. Email [aricdata@unc.edu](mailto:aricdata@unc.edu) providing the name of the data user who needs a data access change.

### 8.3 Setting Activity Status:

First see 'How to Edit a Record'. To change the activity status, find the section in the form that asks, 'Is this survey respondent active?'. Select the option that best describes the respondent's activity status.

- **Active:** The person is actively using or accessing ARIC data.
- **Inactive:** The person is no longer using or accessing ARIC data due to reasons such as a change in employment or job duties. If a person submits a second REDCap form response as an update to their first response (i.e., change in data type access, etc.), the first record should be marked as 'Inactive'.
- **Test Record:** This assignment is used to identify records that are not needed. Records with a large amount of missing information should be identified as 'Test Records'. This is also used for testing out the REDCap form when changes are implemented.



Is this survey respondent active?

Active  
 Inactive  
 Test Record

[reset](#)