Manual 48

ARIC REDCap Data Use Tracking Procedures

For Use by Data Access Administrators

Version 1.0

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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.
- 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annually for sIRB reporting; therefore, administrators should review their list periodically for any data users who are no longer active or who do not match local records.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 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):

Public-facing REDCap form link for distribution to data users/requestors:
https://rc2.redcap.unc.edu/surveys/?s=94JAMTEWJDPPFXENP

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.
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:

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’: 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.

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.
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’.
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.
The Excel file will look similar to this:

<table>
<thead>
<tr>
<th>Record ID</th>
<th>Event Name</th>
<th>Site / Institution Providing ARIC Data:</th>
<th>First Name</th>
<th>Last Name</th>
<th>Emails</th>
<th>Date:</th>
<th>What type of data will you need access to?</th>
<th>Complete?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial DUA</td>
<td>2 Registration</td>
<td>University of Minnesota (Field Center)</td>
<td>Test</td>
<td>User</td>
<td><a href="mailto:testuser@email.com">testuser@email.com</a></td>
<td>5/16/2023</td>
<td>De-identified Data</td>
<td>Incomplete</td>
</tr>
<tr>
<td>Initial DUA</td>
<td>12 Registration</td>
<td>University of Minnesota (Field Center)</td>
<td>John</td>
<td>Doe</td>
<td>johndoe@gi</td>
<td>7/28/2023</td>
<td>De-Identified Data</td>
<td>Complete</td>
</tr>
</tbody>
</table>

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 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.

<table>
<thead>
<tr>
<th>Record ID</th>
<th>Event Name</th>
<th>Site / Institution Providing ARIC Data</th>
<th>First Name</th>
<th>Last Name</th>
<th>Email</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Initial DUA Registration</td>
<td>University of Minnesota (Field Center)</td>
<td>Test</td>
<td>User</td>
<td><a href="mailto:reuser@email.com">reuser@email.com</a></td>
<td>05-10-2023</td>
</tr>
</tbody>
</table>

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

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).
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 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 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.