Research Data Authorization

Site Coordinator - Withdrawal Process

Overview

When a participant's authorization is withdrawn, the Site Coordinator processes the withdrawal in the Research Data Authorization (RDA) tool. This QRC outlines the withdrawal options and the steps the Site Coordinator takes in RDA.

Understanding Withdrawal Options

Participants can choose to withdraw their authorization for Duke to gather their Medicare data, or they can withdraw from the study completely. Each choice has options.

Withdrawing Authorization for Duke to Gather Participant's Medicare Data (participant is still enrolled in the study)

There are *two considerations* for this option:

1. Stop gathering Medicare data, but *keep* Medicare data already gathered for the purpose of the study
   - Site Coordinator changes participant **Status** in RDA to ***Withdrawn Consent*** (see *Withdrawing the Participant in RDA* below)
   - RDA application automatically stops collecting new participant data
   - Site Coordinator notifies Study Coordinator/Team, letting them know participant no longer providing Medicare data
   - Study Coordinator responsible for removing participant from study, if needed
2. Stop gathering Medicare data, and *delete* all Medicare data already gathered for the study
   - Site Coordinator changes participant **Status** in RDA to ***Revoked*** (see *Withdrawing the Participant in RDA* below)
   - RDA application automatically stops collecting new participant data
   - Site Coordinator notifies Study Coordinator/Team, letting them know participant removing *all* Medicare data from study
   - Study Coordinator responsible for removing participant from study, if needed

Withdrawing Authorization from the Study Completely

- Site Coordinator changes participant **Status** in RDA to ***Withdrawn Consent*** or ***Revoked***, depending on whether or not the participant opts to allow Duke to keep Medicare data already gathered (see *Withdrawing the Participant in RDA* below)
- RDA application automatically stops collecting new participant data
- Site Coordinator notifies Study Coordinator/Team, letting them know participant completely withdrawing from study
- Study Coordinator responsible for removing participant from study

  Note: RDA Audit Trail maintains information about any participants who were ever enrolled in studies

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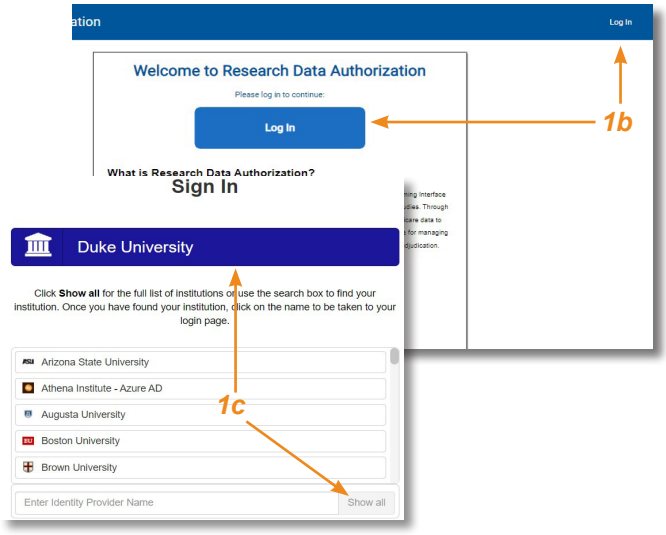
Withdrawing the Participant in RDA

1 Log into the **Research Data Authorization** tool:
   - **a** Go to https://rda.dcri.duke.edu
   - **b** Click either the **Login** link or the **Log In** button
     You are routed to the **Duke Sign In** page
   - **c** Click your organization's button to connect and log in using your organization credentials
     Note: You might need to click the **Show all** button to find and click on your organization.



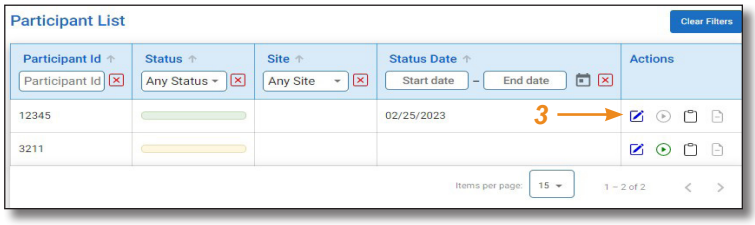
2 On the **Home** or **Participants** screen, locate the participant who is withdrawing in the **Participant List**

3 Click the participant's **Edit** button

4 Select the correct **Status**:
   - ***Withdrawn Consent*** *(keeps data gathered so far)*
   - ***Revoked*** *(removes all data gathered for the study)*
     This option will automatically appear if the participant chose to revoke their authorization (see box below), or the Site Coordinator can select it here

5 Click **Save**

6 Notify the Study Coordinator/Team accordingly

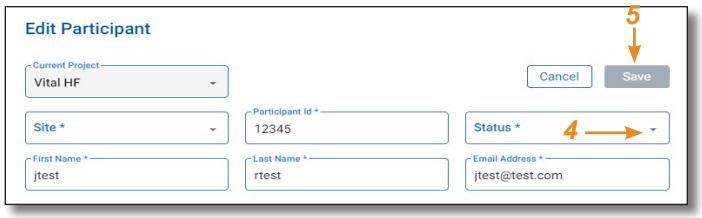


Participants have three ways to revoke their authorization:

1 Select the revoke option on **Medicare.gov**

2 Call **1-800-Medicare**

3 Contact the **RDA Support** team via phone, **919-668-0014**, or email, **RDAuth@duke.edu**



Considerations for Withdrawing Participant Authorization

- The participant always has the ability to manage their authorization (see box above)
- If a withdrawal was done in error, the participant can reauthorize
- The Study Coordinator works with the participant, if needed, to determine level of withdrawal.

Getting Help

If you have questions or comments about the content of this QRC, please email Technology Training [**dcriittrain@dm.duke.edu**]. If you experience any technical problems working with **Research Data Authorization** that you are unable to resolve, contact the **RDA Support** team via phone, **919-668-0014**, or email, **RDAuth@duke.edu**.

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