

Training Manual for **REDCap***PRO*

Manual Version: 1.6

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See the full documentation at

<https://github.com/AndrewPoppe/REDCap-PRO/tree/2.5.0#readme>

Document Revision History

Rev.	Date	By	Revision Summary
1.0	30 NOV 2021	Andrew Poppe	First draft for review
1.1	3 JAN 2022	Elinora Price	Edited main sections for clarity, added 'overview', added FAQ
1.2	5 JAN 2022	Andrew Poppe	Edited text, added FAQ item, added Known Issues section
1.3	6 APR 2022	Andrew Poppe	Updated for REDCapPRO v1.0.1
1.4	8 SEP 2022	Elinora Price	Corrected URL links
1.5	6 JAN 2023	Andrew Poppe	Added to Known Issues section
1.6	26 JUL 2024	Andrew Poppe	Updated for REDCapPRO v2.5.0

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Getting Started

What is REDCapPRO ?

- REDCapPRO is an external module for REDCap
- REDCapPRO stands for REDCap Patient Reported Outcomes
 - This means it is meant for patients in clinical trials (and study participants generally) to report their own study data
- REDCapPRO allows for the creation of an auditable login for the participant to complete surveys. This single login can be used across REDCap projects.

REDCap already has surveys. Why do I need REDCapPRO ?

- Surveys in REDCap do not meet FDA's guidelines for auditable and attributable electronic data collection (*see FDA 21 CFR Part 11.10*)
 - In the project's *Logging* application, the identity of the person entering data into the electronic record is not recorded, only "Survey Respondent".
 - If your study protocol needs 21 CFR Part 11 compliance and you need to collect surveys, REDCapPRO is your solution.
- REDCapPRO provides a log-in interface for surveys in REDCap which does two things:
 - Verifies it's the participant that is saving the data
 - Records the participant username into the project's *Logging* application for audit purposes

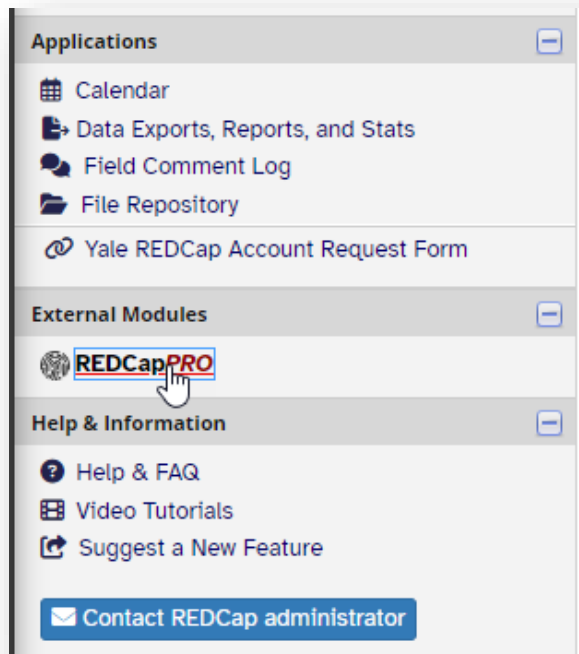
Overview

- 1) **Request** REDCap Administrator to add REDCapPRO to your project
- 2) **Register** participant in REDCapPRO, providing name and email
 - a. The participant is sent an email with their username (an 8 digit code ###-##-###) and a link to set their password
- 3) **Enroll** participant to your REDCap project
 - a. Participant uses the same login credentials across all REDCap projects
 - b. Participants can be enrolled in multiple projects at the same time.
- 4) **Send** participant their survey link or 'open survey and logout' from participant's project record.
 - a. When the participant opens survey link they will be prompted to provide their username ID or email address and their password
 - b. Participant will stay logged in for the duration of their browser session, as long as they are inactive in the surveys for less than X minutes. (*default logout time is 5 minutes*)
- 5) Survey participants' responses will be attributed to their username in the project Logging application:

Time / Date	Username	Action	List of Data Changes OR Fields Exported
10-22-2021 17:21	197-48-897	Created Record 1	dob = '2021-10-22', participant_id = '1', prescreening_survey_complete = '2'

How do I get started with REDCapPRO in my project?

- Ask your REDCap Administrator to enable REDCapPRO in your project
- After REDCapPRO is enabled in your project, it will add a link in the External Modules section of the project's left-side menu



- Click the link to open the REDCapPRO project menu.



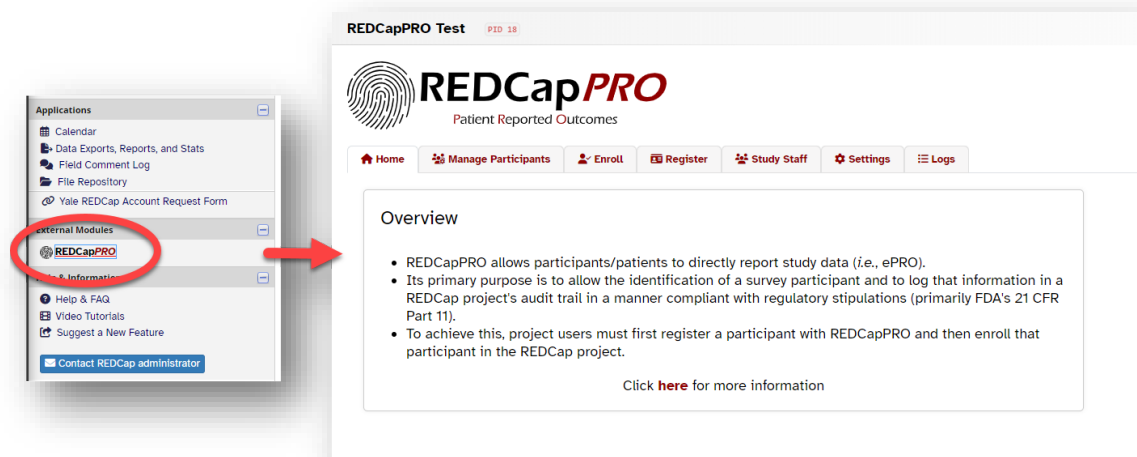
- When the REDCap Administrator has added you as a “Manager” in the REDCapPRO ‘Study Staff’, you should see the REDCapPRO menu above.
- In the “Settings” tab, set up study options, if desired:

Setting	Description	Default
Language	The language that participant-facing text in the module will appear in. (<i>Only English is fully support at this time</i>)	English
Prevent Email Login	If checked, this prevents participants from using their email address to log in to surveys. Instead, they must use their REDCapPRO username to log in.	Off
Timeout Time	The number of minutes of inactivity before participant is logged out of REDCapPRO survey	10
Study Contact Name	The name of the study staff member that study participants should contact with questions/problems. This contact info will appear in the body of emails REDCapPRO sends.	N/A
Study Contact Email	Email address for participants to contact.	N/A
Study Contact Phone	Phone number for participants to contact.	N/A

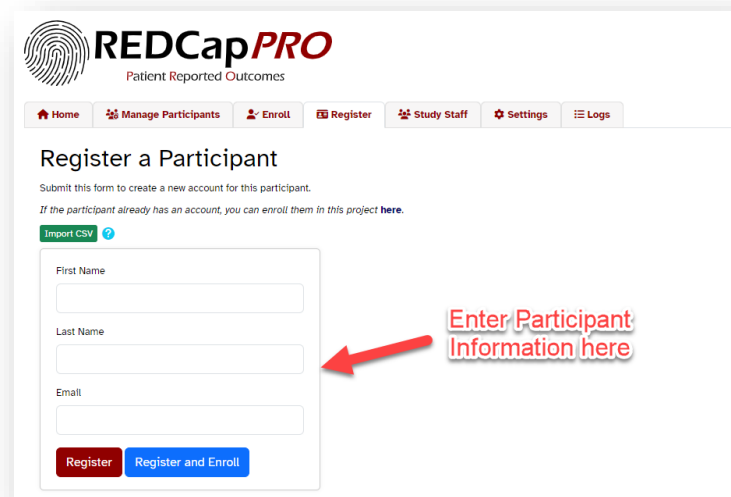
- See **Setting Study Staff Roles** section for how to setup additional project ‘Study Staff’ to be able to enroll, manage, and monitor participants in REDCapPRO. All project users have ‘no access’ to the REDCapPRO module, by default. Their access must be updated in the “Study Staff” tab of REDCapPRO.

Registering a Participant

1. First, open the REDCapPRO project menu



2. Click the *Register* tab



The screenshot shows the 'Register a Participant' form in the REDCapPRO interface. The form is titled 'Register a Participant' and includes instructions: 'Submit this form to create a new account for this participant.' and 'If the participant already has an account, you can enroll them in this project here.' Below the instructions is an 'Import CSV' button. The form contains three input fields: 'First Name', 'Last Name', and 'Email'. A red arrow points to the 'Last Name' field with the text 'Enter Participant Information here'. At the bottom of the form are two buttons: 'Register' and 'Register and Enroll'.

3. Fill out and Submit the Registration Form

First Name


Last Name

Email

Register

Register and Enroll

Register the participant but do not enroll


REDCapPRO
 Patient Reported Outcomes

[Home](#)
[Manage Participants](#)

Register a Participant

Submit this form to create a new account for this participant.

If the participant already has an account, you can edit their profile.

[Import CSV](#) ?

First Name

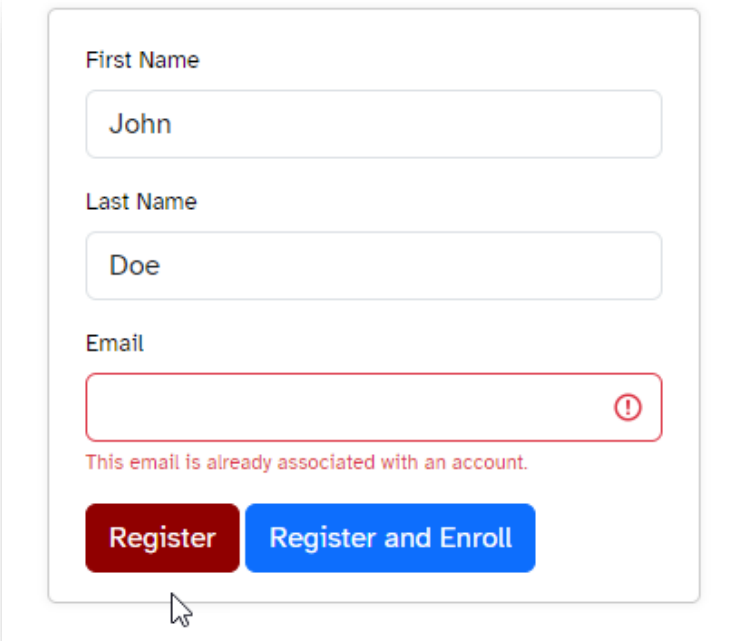
Last Name

Email



Participant Registered

4. If the Participant has already been registered, you will receive a message indicating that.



The screenshot shows a registration form with the following fields and elements:

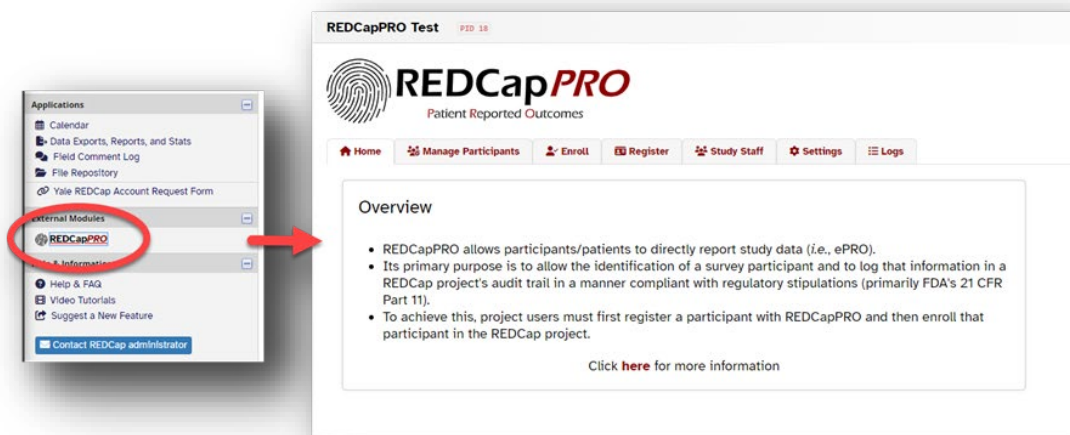
- First Name:** A text input field containing "John".
- Last Name:** A text input field containing "Doe".
- Email:** An empty text input field with a red border and a red exclamation mark icon on the right, indicating an error.
- Error Message:** Below the email field, a red text message states: "This email is already associated with an account."
- Buttons:** Two buttons are located at the bottom: a red "Register" button and a blue "Register and Enroll" button.
- Cursor:** A mouse cursor is pointing at the bottom left of the form.

Once registered, the participant will receive an email with a link they can click to set their REDCapPRO password.

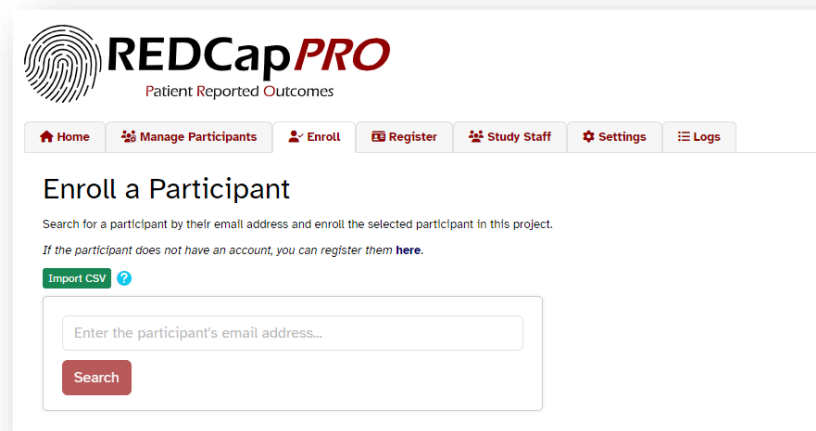
To enroll the participant in your project, click the Enroll tab and follow the instructions for enrolling a participant.

Enrolling a Participant

1. First, open the REDCapPRO project menu

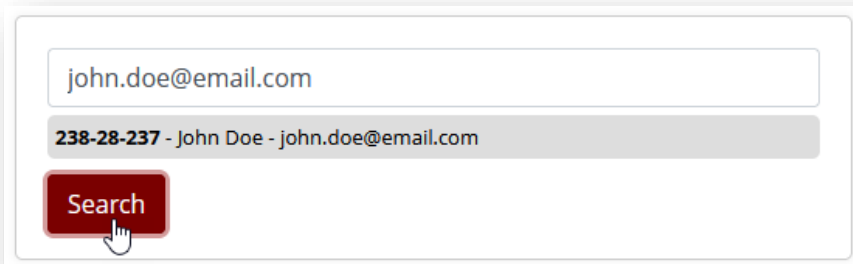


2. Click the **Enroll** tab



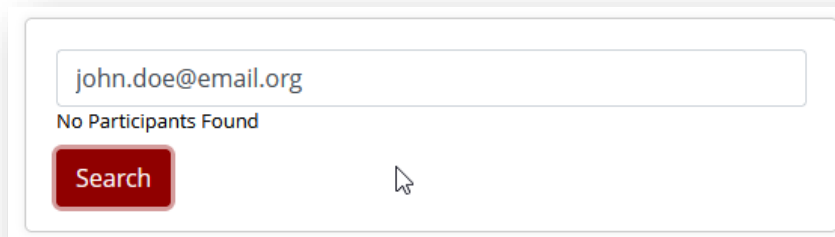
3. Enter the registered participant's email address and then click the Search button

a. If an active participant is registered with that email address, their name and username will be displayed above the Search button



A screenshot of the REDCapPRO search interface. At the top, there is a text input field containing the email address "john.doe@email.com". Below this field, a grey bar displays the search results: "238-28-237 - John Doe - john.doe@email.com". At the bottom of the interface is a red button labeled "Search". A mouse cursor is pointing at the "Search" button.

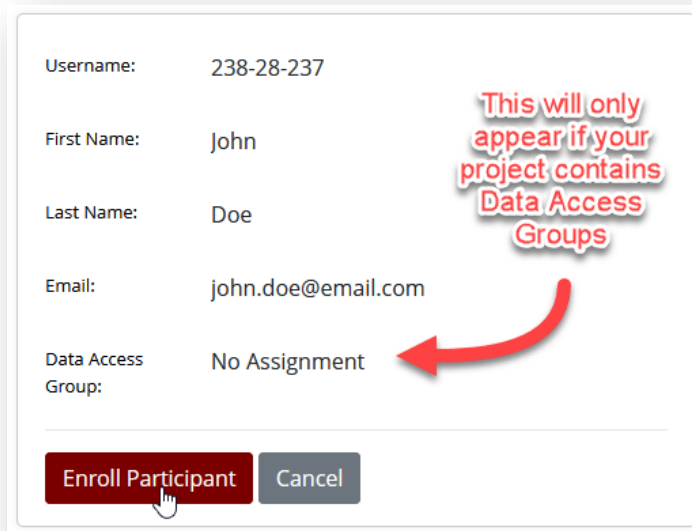
b. If no participant is registered with that email address, you will see the message "No Participants Found"



A screenshot of the REDCapPRO search interface. At the top, there is a text input field containing the email address "john.doe@email.org". Below this field, the text "No Participants Found" is displayed. At the bottom of the interface is a red button labeled "Search". A mouse cursor is pointing at the "Search" button.

c. Check that you have typed the email address correctly. If so, you may need to register this participant.

4. Click on this search result to bring up the confirmation screen



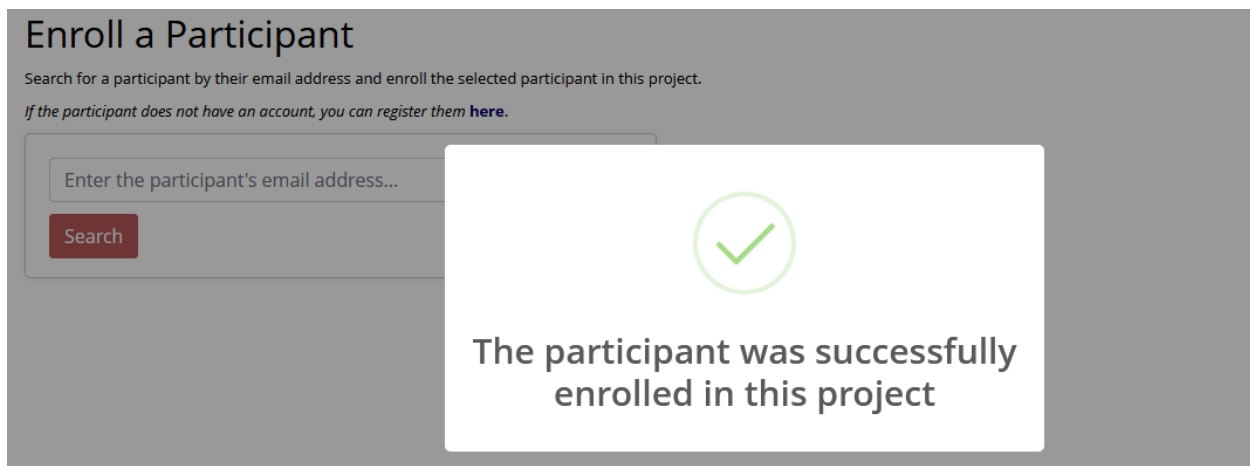
A confirmation form for enrolling a participant. It contains the following fields:

Username:	238-28-237
First Name:	John
Last Name:	Doe
Email:	john.doe@email.com
Data Access Group:	No Assignment

Below the fields are two buttons: "Enroll Participant" (red) and "Cancel" (grey). A red arrow points from a text box to the "Data Access Group" field.

This will only appear if your project contains Data Access Groups

5. If you are sure this is the correct participant, click the Enroll Participant button




Enroll a Participant

Search for a participant by their email address and enroll the selected participant in this project.
If the participant does not have an account, you can register them [here](#).

Enter the participant's email address...

Search

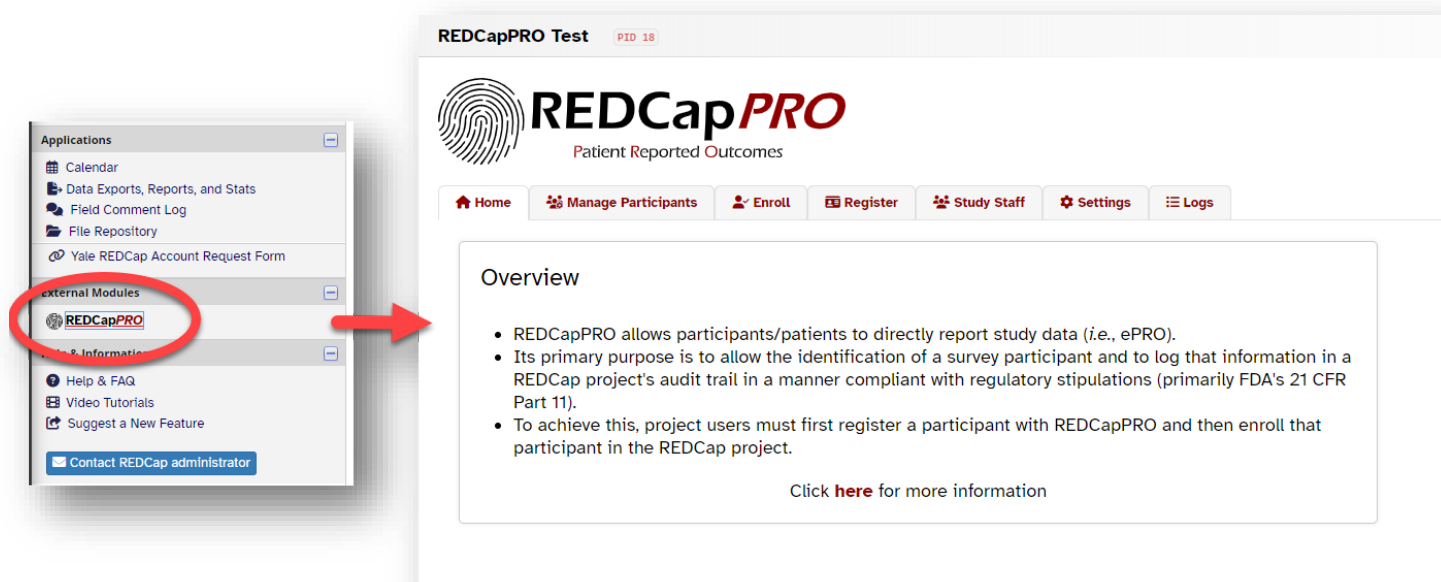


The participant was successfully enrolled in this project

If the participant is already enrolled in the project, you will receive a message indicating that.

Registering and Enrolling a Participant

1. First, open the REDCapPRO project menu



The screenshot displays the REDCapPRO Test interface. On the left, a sidebar menu lists various applications and external modules. The 'external Modules' section is expanded, and 'REDCapPRO' is highlighted with a red circle. A red arrow points from this circle to the main content area. The main content area shows the REDCapPRO logo and a navigation bar with links: Home, Manage Participants, Enroll, Register, Study Staff, Settings, and Logs. Below the navigation bar, the 'Overview' section contains a list of bullet points describing the system's purpose and usage.

Applications

- Calendar
- Data Exports, Reports, and Stats
- Field Comment Log
- File Repository
- Yale REDCap Account Request Form

external Modules

- REDCapPRO**
- Help & FAQ
- Video Tutorials
- Suggest a New Feature

[Contact REDCap administrator](#)

REDCapPRO Test PID 18

REDCapPRO
Patient Reported Outcomes

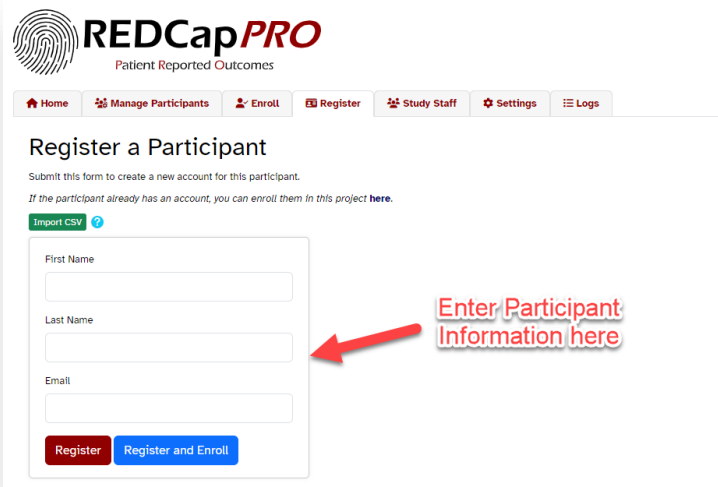
[Home](#) [Manage Participants](#) [Enroll](#) [Register](#) [Study Staff](#) [Settings](#) [Logs](#)

Overview

- REDCapPRO allows participants/patients to directly report study data (i.e., ePRO).
- Its primary purpose is to allow the identification of a survey participant and to log that information in a REDCap project's audit trail in a manner compliant with regulatory stipulations (primarily FDA's 21 CFR Part 11).
- To achieve this, project users must first register a participant with REDCapPRO and then enroll that participant in the REDCap project.

[Click here](#) for more information

2. Click the *Register* tab



REDCapPRO
Patient Reported Outcomes

Home Manage Participants Enroll **Register** Study Staff Settings Logs

Register a Participant

Submit this form to create a new account for this participant.
If the participant already has an account, you can enroll them in this project [here](#).

[Import CSV](#)

First Name

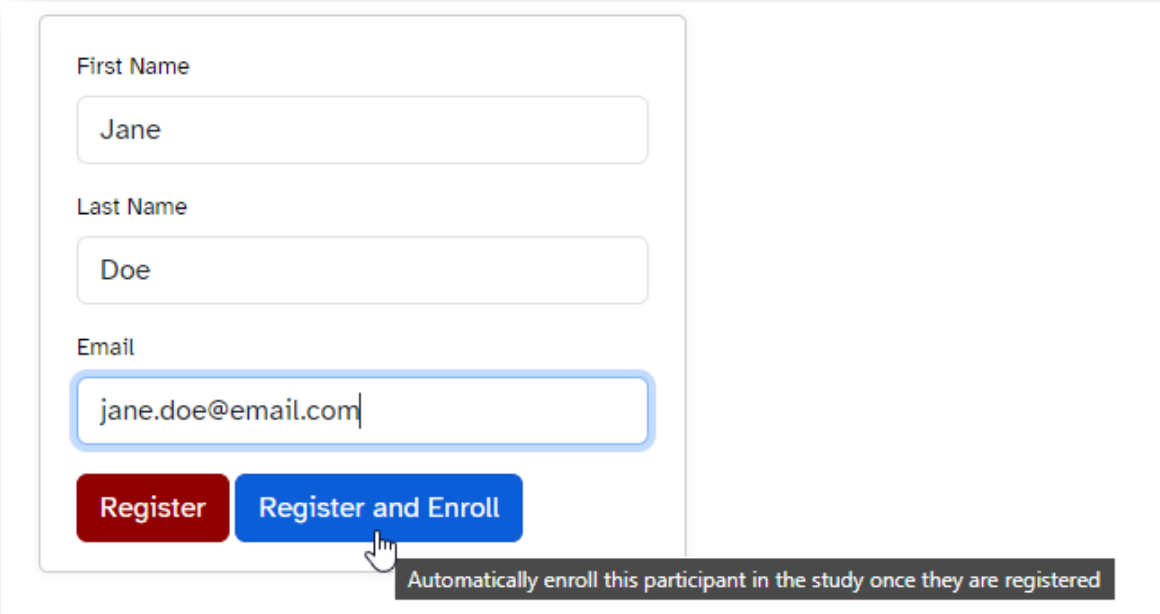
Last Name

Email

[Register](#) [Register and Enroll](#)

Enter Participant Information here

3. Fill out and Submit the Registration Form



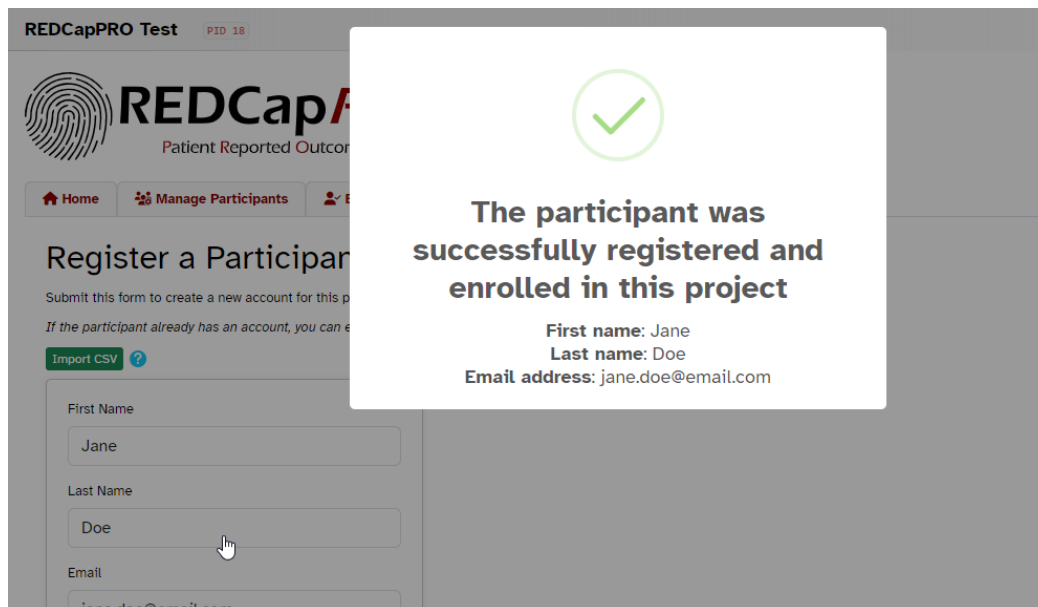
First Name

Last Name

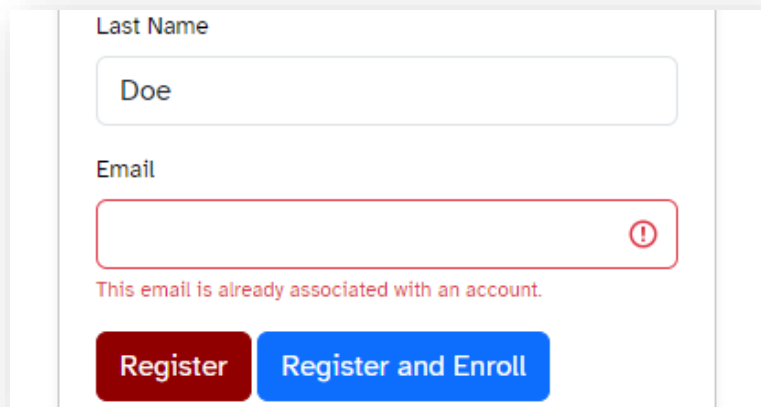
Email

[Register](#) [Register and Enroll](#)

Automatically enroll this participant in the study once they are registered



- 4. If the Participant has already been registered, you will receive a message indicating that.**


 The screenshot shows a registration form with the following fields and messages:

- Last Name:** Doe
- Email:** (Empty field with a red border and a red exclamation mark icon)
- Error message:** This email is already associated with an account.
- Buttons:** Register (red) and Register and Enroll (blue)

Once registered, the participant will receive an email with a link they can click to set their REDCapPRO password.

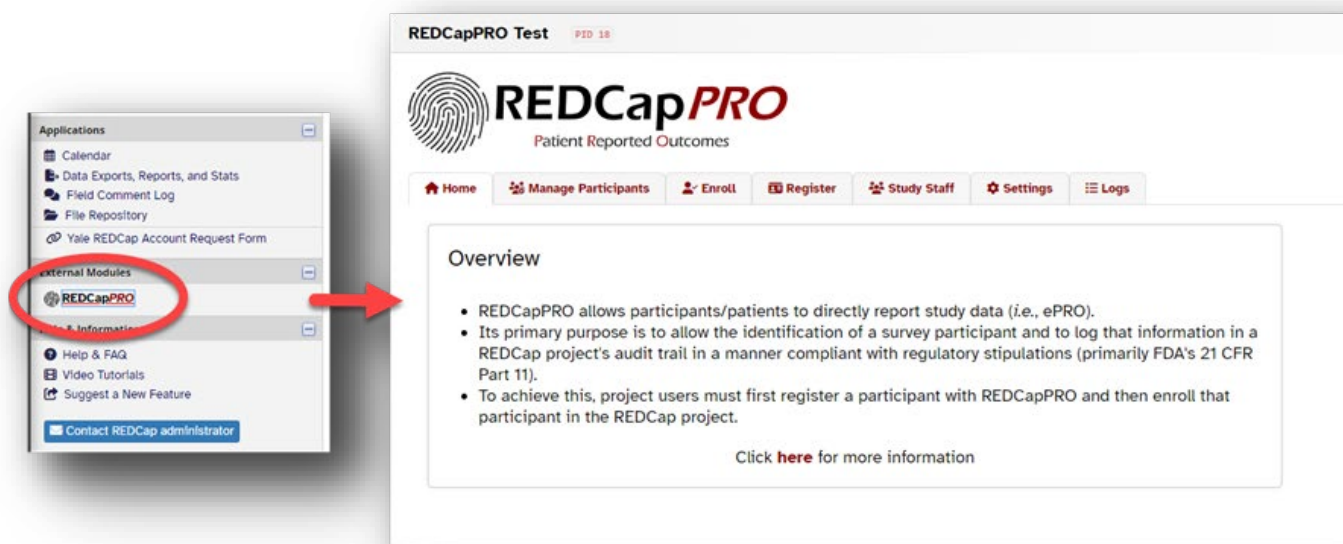
The participant is automatically enrolled into the current project.



Resetting a Participant's Password

To initiate a password reset yourself:

1. First, open the REDCapPRO project menu



2. Click the **Manage Participants** tab

Manage Study Participants
 Reset passwords, disenroll from study, etc.

Show entries Search:

Username	First Name	Last Name	Email	Data Access Group
238-28-237	John	Doe	john.doe@email.com	Unassigned <input type="button" value="v"/>

Study Participants

Showing 1 to 1 of 1 entries Previous Next

3. Locate the participant whose password you would like to reset and click that row. (You can use the search bar to find the participant.)

Manage Study Participants
 Reset passwords, disenroll from study, etc.

Show entries Search:

Username	First Name	Last Name	Email	Data Access Group
238-28-237	John	Doe	john.doe@email.com	Unassigned <input type="button" value="v"/>

Study Participants

Showing 1 to 1 of 1 entries 1 row selected Previous Next

4. Click the **Reset Password** button

Manage Study Participants
Reset passwords, disenroll from study, etc.

Show entries


Search:

Username	First Name	Last Name	Email
238-28-237	John	Doe	john.d

Study Participants


Showing 1 to 1 of 1 entries

[Reset Password](#) [Change Name](#) [Change Email](#)



**Successfully reset password
for participant.**

5. The participant will receive an email with a link to reset their password



REDCapPRO

Hello,

We have received a request to reset your account password. If you did not make this request, you can ignore this email.

To reset your password, click the link below.
This is your username: **238-28-237**

To reset your password, click [here](#)
That link is only valid for the next hour. If you need a new link, click [here](#)

If you have any questions, contact a member of the study team.

6. When they click the link in their email, they will be taken to a page to reset their password.



Reset Password

Please fill out this form to reset your password.

Username: **238-28-237**

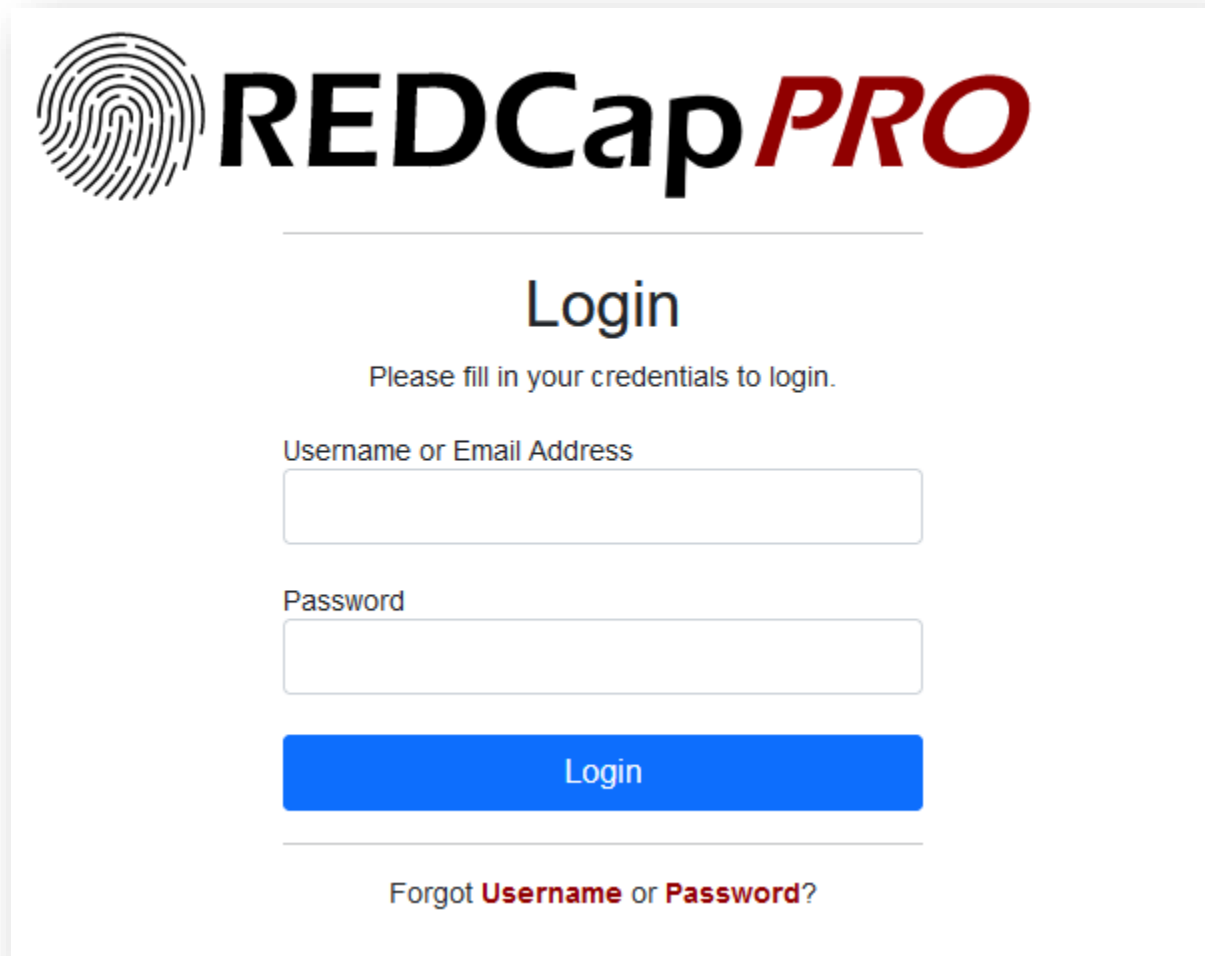
New Password

Confirm Password

Submit

Participant-Initiated Password Reset

1. The participant must first access the login screen for a survey.



The image shows a login screen for REDCapPRO. At the top left is a fingerprint icon. To its right is the text "REDCapPRO" in a large, bold font, with "PRO" in red. Below this is a horizontal line. Under the line is the word "Login" in a large, black font. Below "Login" is the text "Please fill in your credentials to login." in a smaller, black font. Below this text are two input fields. The first is labeled "Username or Email Address" and the second is labeled "Password". Below the input fields is a blue button with the word "Login" in white. Below the button is a horizontal line. Below the line is the text "Forgot **Username** or **Password**?" in a smaller, black font, with "Username" and "Password" in red.

 **REDCapPRO**

Login

Please fill in your credentials to login.

Username or Email Address

Password

Login

Forgot **Username** or **Password**?

2. They should click the Forgot Password link and then enter their username or email address on the Forgot Password screen.

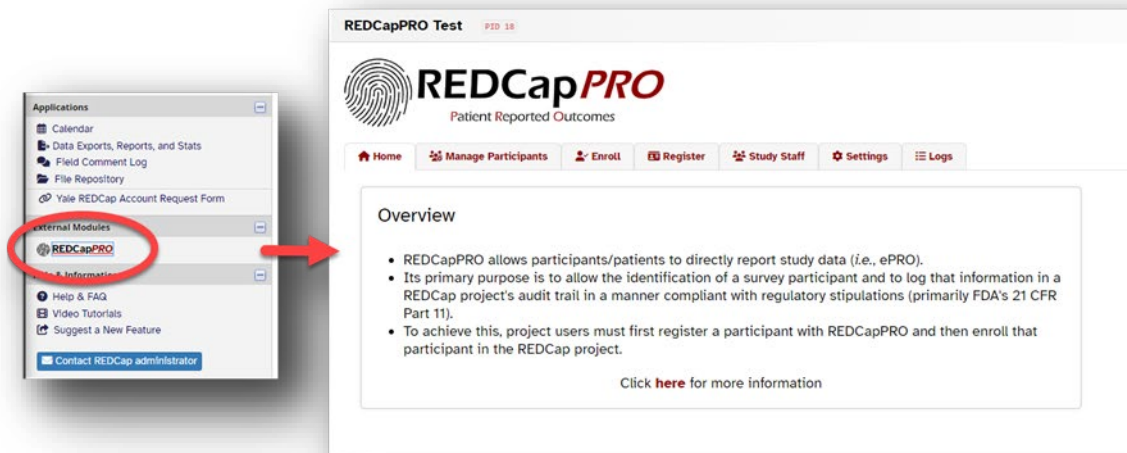


The screenshot shows the REDCapPRO 'Forgot Password' interface. At the top is the REDCapPRO logo. Below it, the heading 'Forgot Password?' is centered. A subtext prompt asks the user to 'Provide the username or email address associated with your account.' Below this is a text input field labeled 'Username or Email Address' containing the email 'john.doe@email.com'. A blue 'Submit' button is positioned below the input field, with a hand cursor icon pointing at it. At the bottom of the form, there is a red link labeled 'Forgot Username?'.

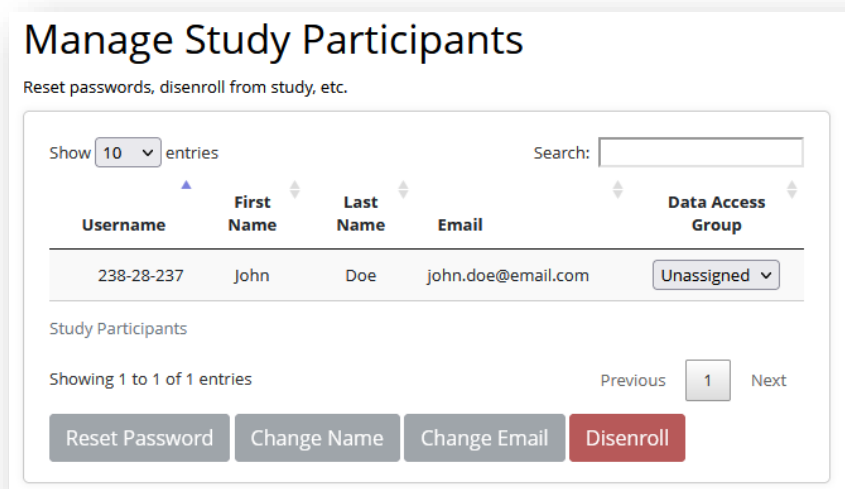
3. A password-reset email will be sent to the participant as described in the previous section.

Updating a Participant's Email Address

1. First, open the REDCapPRO project menu



2. Click the **Manage Participants** tab



Manage Study Participants

Reset passwords, disenroll from study, etc.

Show 10 entries Search:

Username	First Name	Last Name	Email	Data Access Group
238-28-237	John	Doe	john.doe@email.com	Unassigned

Study Participants

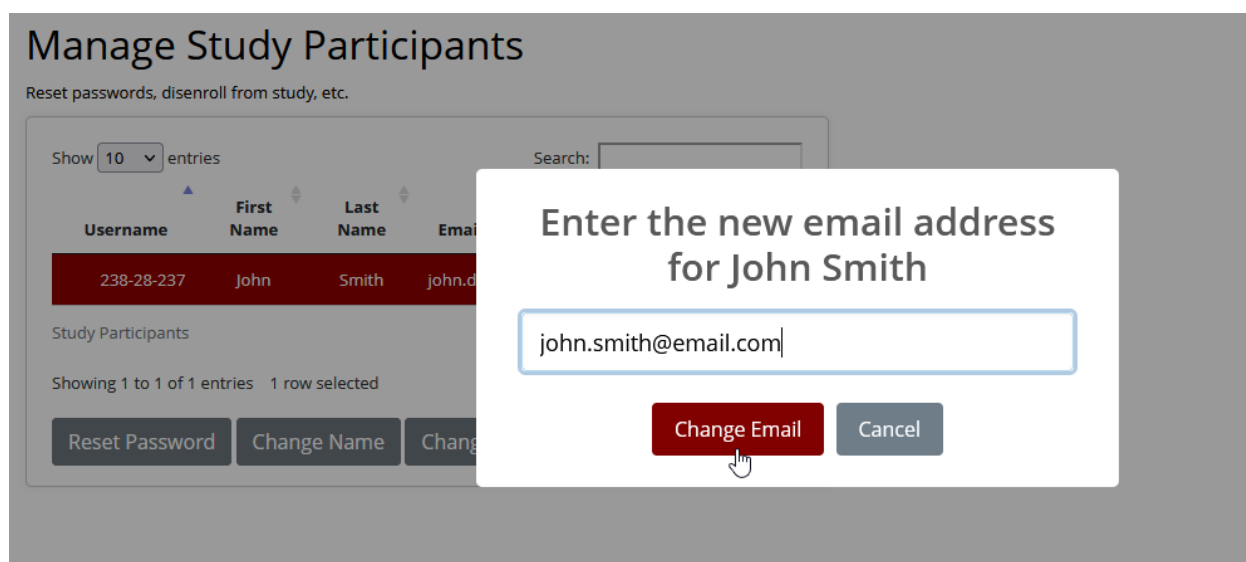
Showing 1 to 1 of 1 entries Previous 1 Next

Reset Password Change Name Change Email Disenroll

3. Locate the participant whose email you would like to reset and click that row.

(You can use the search bar to find the participant.)

4. Click the **Change Email** button and enter the new email.



Manage Study Participants

Reset passwords, disenroll from study, etc.

Show 10 entries Search:

Username	First Name	Last Name	Email
238-28-237	John	Smith	john.d

Study Participants

Showing 1 to 1 of 1 entries 1 row selected

Reset Password Change Name Change

Enter the new email address for John Smith

Change Email Cancel

5. Click the *Change Email* button

6. The participant will receive an email at both the old and new addresses notifying them of the change

Manage Study Participants
Reset passwords, disenroll from study, etc.


Show entries

Search:

Username	First Name	Last Name	Email
238-28-237	John	Smith	john.smith@yale.edu

Study Participants

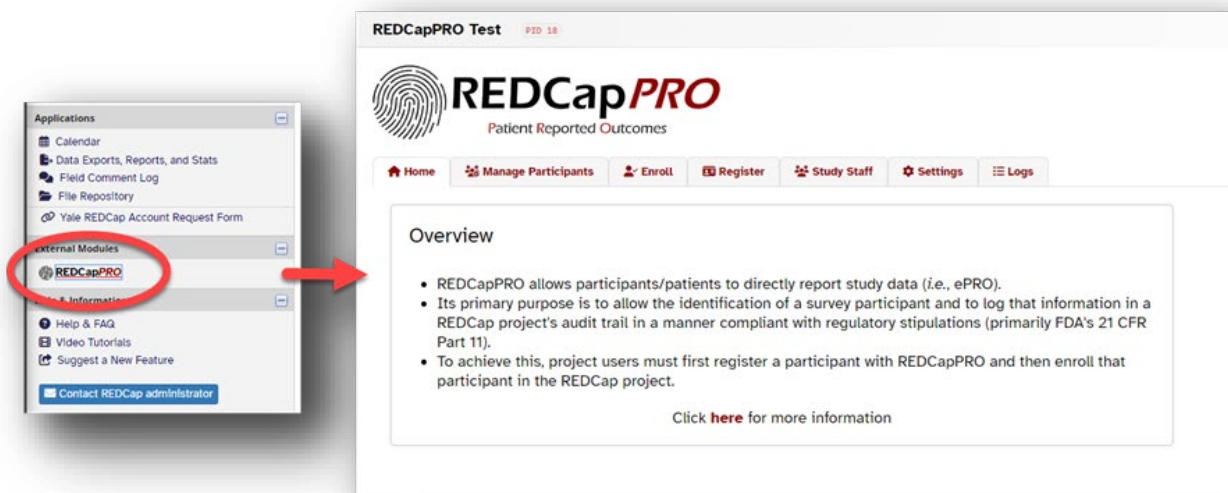
Showing 1 to 1 of 1 entries



**Successfully changed
participant's email address.**

Updating a Participant's Name

1. First, open the REDCapPRO project menu



2. Click the **Manage Participants** tab

Manage Study Participants
Reset passwords, disenroll from study, etc.

Show **10** entries Search:

Username	First Name	Last Name	Email	Data Access Group
238-28-237	John	Doe	john.doe@email.com	Unassigned

Study Participants

Showing 1 to 1 of 1 entries Previous **1** Next

Reset Password Change Name Change Email Disenroll

3. Locate the participant whose name you would like to reset and click that row.

Manage Study Participants
Reset passwords, disenroll from study, etc.

Show **10** entries Search:

Username	First Name	Last Name	Email	Data Access Group
238-28-237	John	Doe	john.doe@email.com	Unassigned

Study Participants

Showing 1 to 1 of 1 entries 1 row selected Previous **1** Next

Reset Password Change Name Change Email Disenroll

(You can use the search bar to find the participant.)

4. Click the *Change Name* button and enter the new name.

Manage Study Participants

Reset passwords, disenroll from study, etc.

Show 10 entries

Username	First Name	Last Name	Email
238-28-237	John	Doe	john.d

Study Participants

Showing 1 to 1 of 1 entries 1 row selected

Reset Password Change Name Change

Enter the new name for this participant

John

Smith

Change Participant Name Cancel

5. Click the *Change Participant Name* button

Manage Study Participants

Reset passwords, disenroll from study, etc.


Show 10 entries Search:

Username	First Name	Last Name	Email
238-28-237	John	Smith	john.d

Study Participants

Showing 1 to 1 of 1 entries

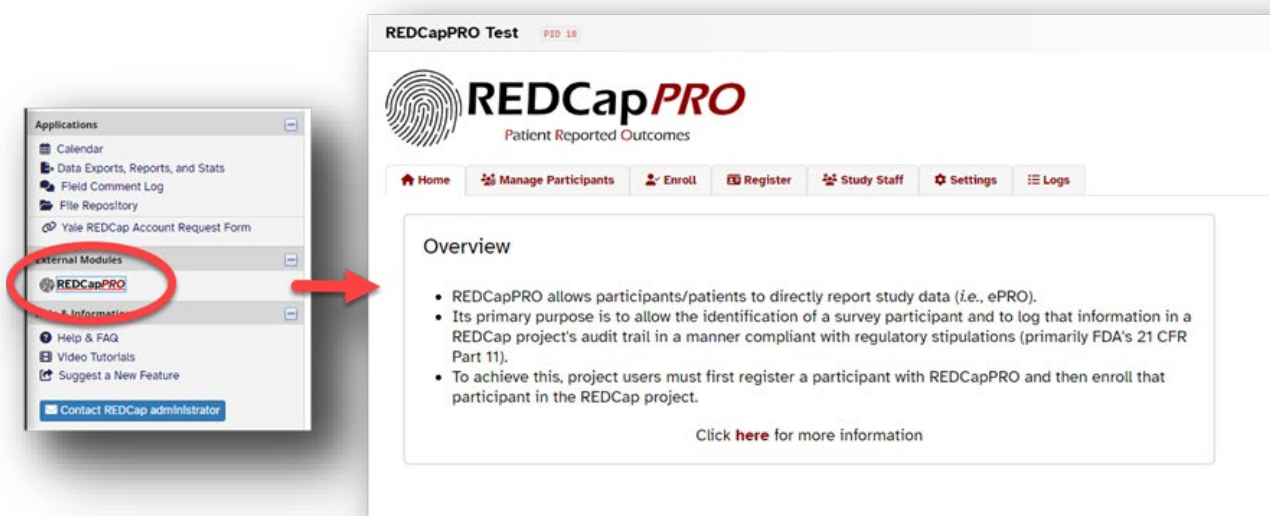
Reset Password Change Name Change



Successfully updated participant's name.

Updating a Participant's Data Access Group (DAG)

1. First, open the REDCapPRO project menu





2. Click the **Manage Participants** tab

Manage Study Participants

Reset passwords, disenroll from study, etc.

Show entries Search:

Username	First Name	Last Name	Email	Data Access Group
238-28-237	John	Doe	john.doe@email.com	Unassigned ▼

Study Participants

Showing 1 to 1 of 1 entries Previous Next

Reset Password Change Name Change Email Disenroll

3. Locate the participant whose DAG you would like to reset and click the Data Access Group dropdown in that row. (You will only have this option if you are not in a DAG)

Manage Study Participants

Reset passwords, disenroll from study, etc.

Show entries Search:

Username	First Name	Last Name	Email	Data Access Group
238-28-237	John	Doe	john.doe@email.com	Unassigned ▼

Study Participants

Showing 1 to 1 of 1 entries Previous Next

Reset Password Change Name Change Email Disenroll

4. Select the DAG you'd like to switch the Participant to.



Manage Study Participants

Reset passwords, disenroll from study, etc.

Show 10 entries

Username	First Name	Last Name	Email
238-28-237	John	Doe	john.d

Study Participants

Showing 1 to 1 of 1 entries

Reset Password

Change Name

Change



Switch Data Access Group for John Doe?

From Unassigned to DAG 1

Switch DAG

Cancel

5. Click the *Switch DAG* button

Manage Study Participants

Reset passwords, disenroll from study, etc.

Show 10 entries

Username	First Name	Last Name	Email
238-28-237	John	Doe	john.d

Study Participants

Showing 1 to 1 of 1 entries

Reset Password

Change Name

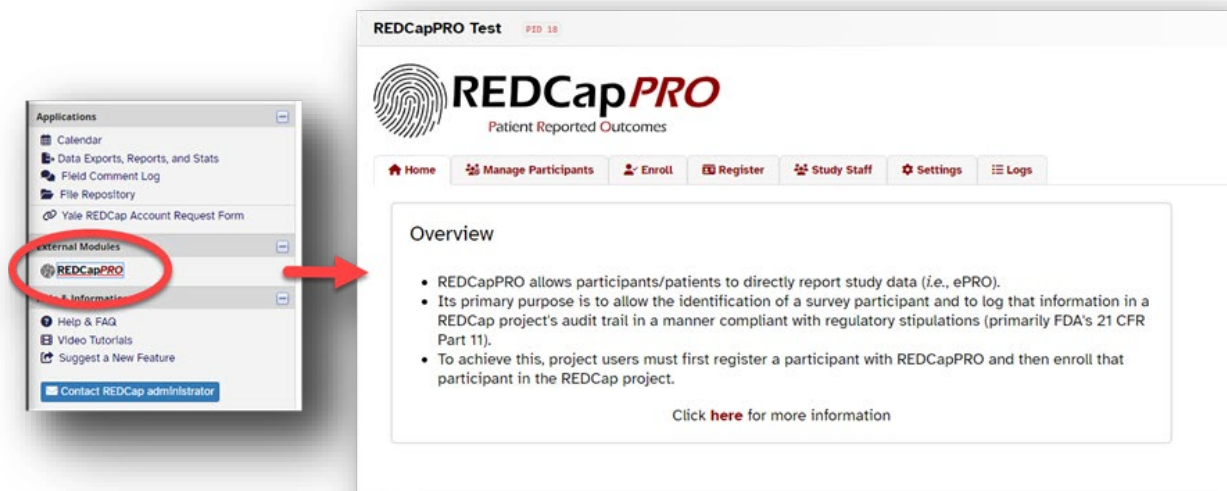
Change



Successfully switched participant's Data Access Group.

Disenrolling a Participant

1. First, open the REDCapPRO project menu



2. Click the **Manage Participants** tab

Manage Study Participants

Reset passwords, disenroll from study, etc.

Show 10 entries Search:

Username	First Name	Last Name	Email	Data Access Group
238-28-237	John	Doe	john.doe@email.com	Unassigned

Study Participants

Showing 1 to 1 of 1 entries Previous 1 Next

Reset Password Change Name Change Email Disenroll

3. Locate the participant whom you would like to disenroll and click that row.

(You can use the search bar to find the participant.)

Manage Study Participants

Reset passwords, disenroll from study, etc.

Show 10 entries Search:

Username	First Name	Last Name	Email	Data Access Group
238-28-237	John	Doe	john.doe@email.com	Unassigned

Study Participants

Showing 1 to 1 of 1 entries 1 row selected Previous 1 Next

Reset Password Change Name Change Email Disenroll

4. Click the *Disenroll* button

Manage Study Participants

Reset passwords, disenroll from study, etc.


Show 10 entries

Username	First Name	Last Name	Email
238-28-237	John	Doe	john.d

Study Participants

Showing 1 to 1 of 1 entries 1 row selected

Reset Password Change Name Change



Are you sure you want to remove John Doe from this project?


Remove Participant Cancel

5. Click the *Remove Participant* button

Manage Study Participants

Reset passwords, disenroll from study, etc.

No participants have been enrolled in this study



Successfully disenrolled participant from project.



Registering Multiple Participants via CSV Import

1. First, open the REDCapPRO project menu

The screenshot illustrates the process of opening the REDCapPRO project menu. On the left, a sidebar menu is shown with the 'REDCapPRO' option under the 'external Modules' section circled in red. A red arrow points from this option to the main interface on the right. The main interface, titled 'REDCapPRO Test PID 18', displays the REDCapPRO logo and a navigation bar with links: Home, Manage Participants, Enroll, Register, Study Staff, Settings, and Logs. Below the navigation bar, the 'Overview' section contains the following information:

Overview

- REDCapPRO allows participants/patients to directly report study data (i.e., ePRO).
- Its primary purpose is to allow the identification of a survey participant and to log that information in a REDCap project's audit trail in a manner compliant with regulatory stipulations (primarily FDA's 21 CFR Part 11).
- To achieve this, project users must first register a participant with REDCapPRO and then enroll that participant in the REDCap project.

Click [here](#) for more information



2. Click the *Register* tab

Register a Participant

Submit this form to create a new account for this participant.

If the participant already has an account, you can enroll them in this project [here](#).

Import CSV ?

First Name

Last Name

Email

Register

Register and Enroll



3. Click the ? icon to see instructions

Import Participants via CSV

You can register (and optionally enroll) many participants at once by importing a CSV file. The file must be formatted with the following columns.

[Click here](#) to download an import template.

Column name	Description	Possible values	Required	Notes
fname	First name of the participant	Any text	Required	
lname	Last name of the participant	Any text	Required	
email	Email address of the participant	Valid email	Required	The email address must not match the email address of a registered participant. If so, you will receive an error message and the import will be cancelled.
enroll	Whether or not to enroll the participant into this study once they are registered	Y to enroll <Blank> not to enroll	Optional	You can omit the column entirely if you do not want to enroll any of the newly registered participants.
dag	Data Access Group to enroll the participant into	Integer value representing the Data Access Group ID number	Optional	This value can be found on the DAGs page in the project. If enroll is not "Y" for a row, then the DAG value is ignored for that row. The usual DAG rules apply, so you can only assign a participant to a DAG if that DAG exists in the project. If you are assigned to a DAG yourself, you can only assign participants to that DAG. If you are not assigned to a DAG, you can assign the participant to any DAG.

Registration Import File Format

4. Download the import template and add the names and emails for all the participants you would like to register. Save the file.



5. Click the “Import CSV” button and select the file you just saved.

Register a Participant

Submit this form to create a new account for this participant.

If the participant already has an account, you can enroll them in this project [here](#).

Import CSV ?

First Name

Last Name

Email

Register **Register and Enroll**

Confirm Participants to Import

Examine the table of proposed changes below to verify it is correct.

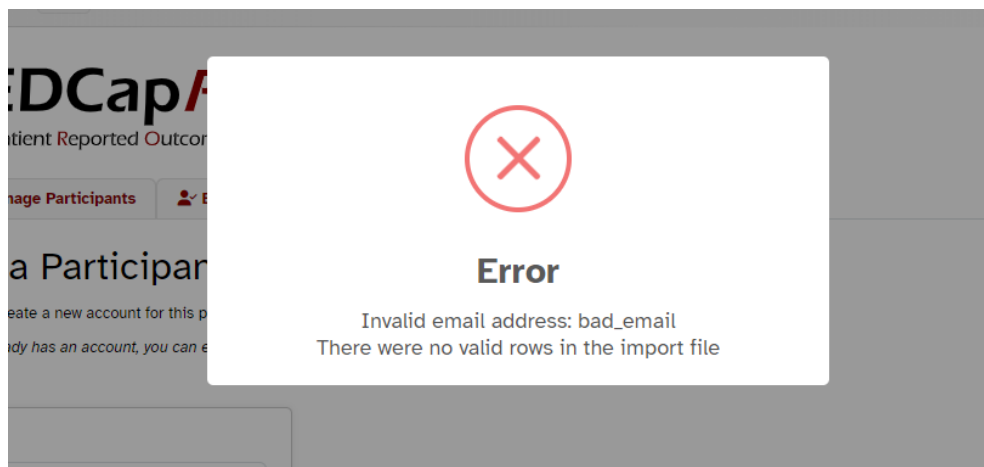
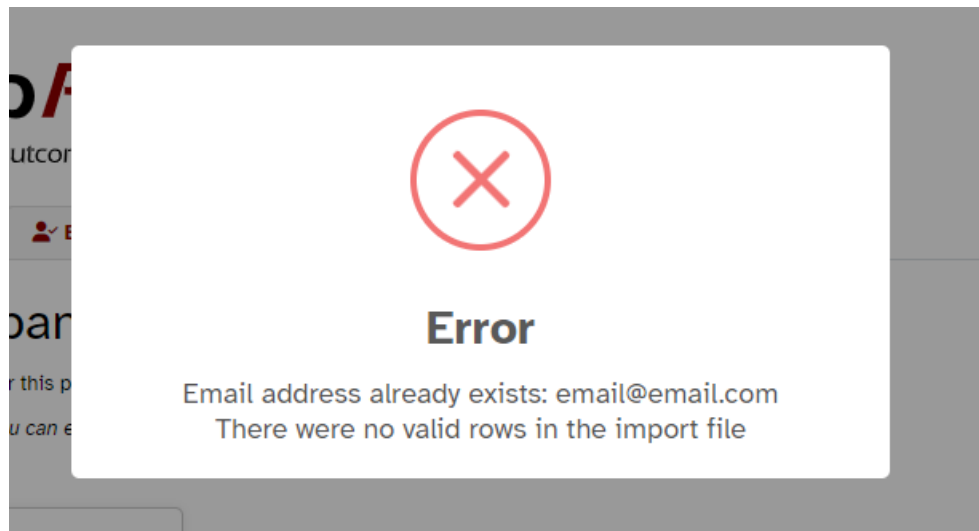
First Name	Last Name	Email	Enroll
Test	User	email@email.com	No

Cancel **Confirm**

Successfully registered participants

OK

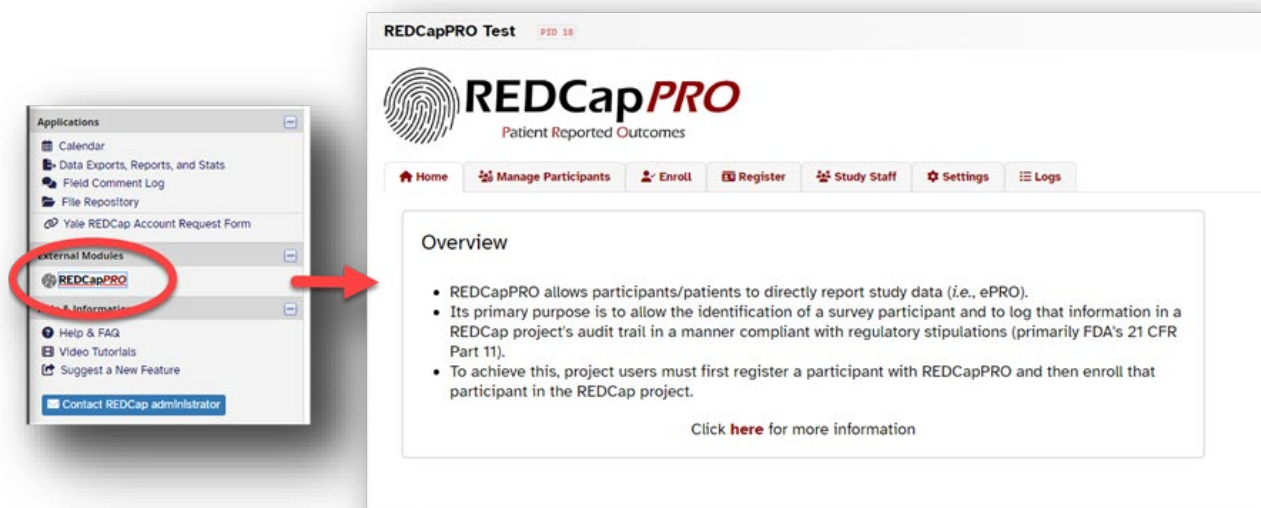
6. If any Participant has already been registered or your CSV file was not formatted correctly, you will receive a message indicating that.



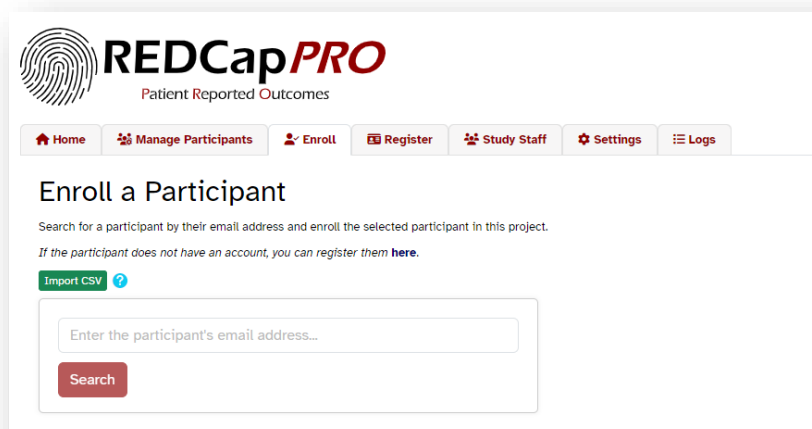
Once registered, the participants will receive an email with a link they can click to set their REDCapPRO password.

Enrolling Multiple Participants via CSV Import

1. First, open the REDCapPRO project menu



2. Click the **Enroll** tab





3. Click the ? icon to see instructions

Import Participants via CSV

You can register (and optionally enroll) many participants at once by importing a CSV file. The file must be formatted with the following columns.

[Click here](#) to download an import template.

Column name	Description	Possible values	Required	Notes
username	REDCapPRO username of the participant	Any text	Required	Either this column or the email column must be present in the import file. NOT BOTH
email	Email address of the participant	Valid email	Required	Either this column or the username column must be present in the import file. NOT BOTH
dag	Data Access Group to enroll the participant into	Integer value representing the Data Access Group ID number	Optional	This value can be found on the DAGs page in the project. If enroll is not "Y" for a row, then the DAG value is ignored for that row. The usual DAG rules apply, so you can only assign a participant to a DAG if that DAG exists in the project. If you are assigned to a DAG yourself, you can only assign participants to that DAG. If you are not assigned to a DAG, you can assign the participant to any DAG.

Registration Import File Format


4. Download the import template and add the information for all the participants you would like to enroll. Save the file.

5. Click on “Import CSV” and select the file you just saved.

Enroll a Participant

Search for a participant by their email address and enroll the selected participant in this project.

If the participant does not have an account, you can register them [here](#).

Import CSV ? 

Enter the participant's email address...

Search

Confirm Participants to Enroll

Examine the table of proposed changes below to verify it is correct.

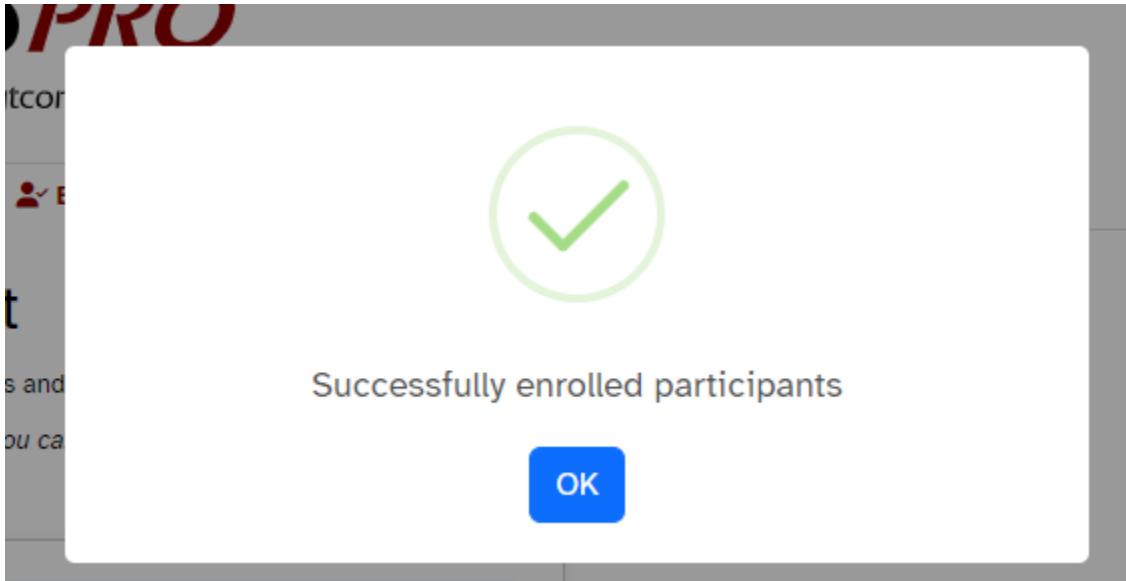
Username	First Name	Last Name	Email	DAG ID
892-22-954	Jackie	Jormp-Jomp	jackie@email.com	[No Assignment]

Cancel **Confirm**

- If no participant is registered with that email address, you will see the message “Email address is not associated with a REDCapPRO participant”
- Check that you have typed the email address correctly. If so, you may need to register this participant.



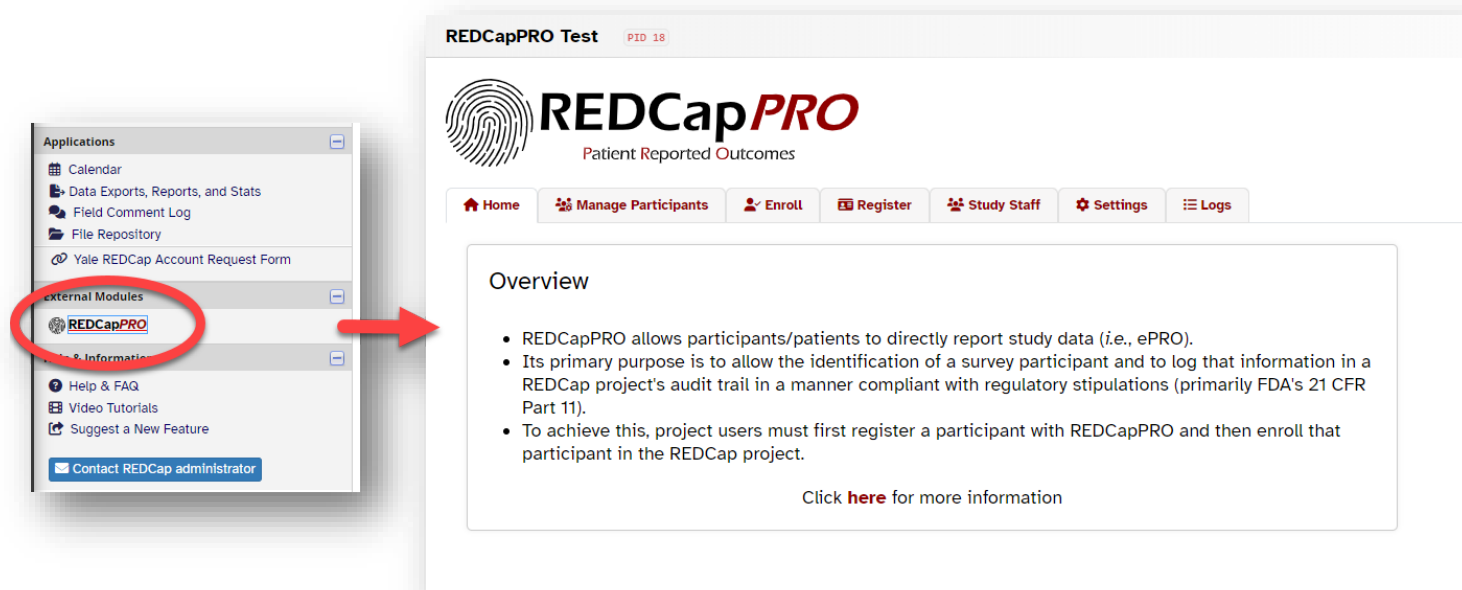
6. Click Confirm to import the participants



If the participant is already enrolled in the project, you will receive a message indicating that.

Registering and Enrolling Multiple Participants via CSV Import

1. First, open the REDCapPRO project menu



The screenshot displays the REDCapPRO Test interface. On the left, a sidebar menu lists various applications and external modules. The 'REDCapPRO' module is highlighted with a red circle, and a red arrow points from it to the main content area. The main content area shows the REDCapPRO logo and a navigation bar with links: Home, Manage Participants, Enroll, Register, Study Staff, Settings, and Logs. Below the navigation bar, an 'Overview' section provides information about REDCapPRO, including its purpose and how to use it. A link labeled 'here' is provided for more information.

Applications

- Calendar
- Data Exports, Reports, and Stats
- Field Comment Log
- File Repository
- Yale REDCap Account Request Form

External Modules

- REDCapPRO**
- Help & FAQ
- Video Tutorials
- Suggest a New Feature
- Contact REDCap administrator

REDCapPRO Test PID 18

REDCapPRO
Patient Reported Outcomes

Home Manage Participants Enroll Register Study Staff Settings Logs

Overview

- REDCapPRO allows participants/patients to directly report study data (i.e., ePRO).
- Its primary purpose is to allow the identification of a survey participant and to log that information in a REDCap project's audit trail in a manner compliant with regulatory stipulations (primarily FDA's 21 CFR Part 11).
- To achieve this, project users must first register a participant with REDCapPRO and then enroll that participant in the REDCap project.

Click [here](#) for more information



2. Click the *Register* tab

Register a Participant

Submit this form to create a new account for this participant.

If the participant already has an account, you can enroll them in this project [here](#).

Import CSV ?

First Name

Last Name

Email

Register

Register and Enroll

3. Click the ? icon to see instructions

Import Participants via CSV

You can register (and optionally enroll) many participants at once by importing a CSV file. The file must be formatted with the following columns.

[Click here](#) to download an import template.

Column name	Description	Possible values	Required	Notes
fname	First name of the participant	Any text	Required	
lname	Last name of the participant	Any text	Required	
email	Email address of the participant	Valid email	Required	The email address must not match the email address of a registered participant. If so, you will receive an error message and the import will be cancelled.
enroll	Whether or not to enroll the participant into this study once they are registered	Y to enroll Blank not to enroll	Optional	You can omit the column entirely if you do not want to enroll any of the newly registered participants.
dag	Data Access Group to enroll the participant into	Integer value representing the Data Access Group ID number	Optional	This value can be found on the DAGs page in the project. If enroll is not "Y" for a row, then the DAG value is ignored for that row. The usual DAG rules apply, so you can only assign a participant to a DAG if that DAG exists in the project. If you are assigned to a DAG yourself, you can only assign participants to that DAG. If you are not assigned to a DAG, you can assign the participant to any DAG.

Registration Import File Format

4. Download the import template and add the names and emails for all the participants you would like to register. Save the file.



5. Click the “Import CSV” button and select the file you just saved.

Register a Participant

Submit this form to create a new account for this participant.

If the participant already has an account, you can enroll them in this project [here](#).

Import CSV ?

First Name

Last Name

Email

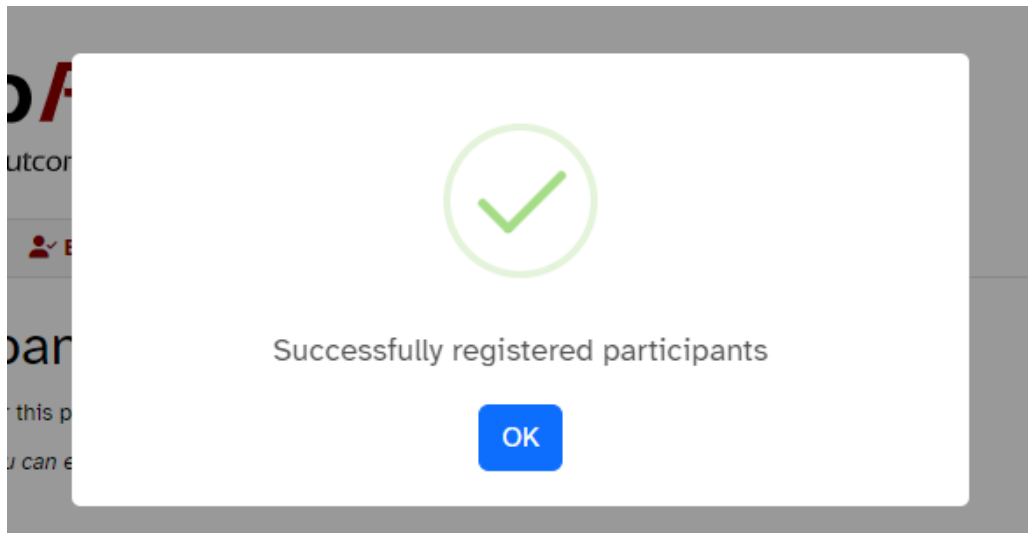
Register **Register and Enroll**

Confirm Participants to Import

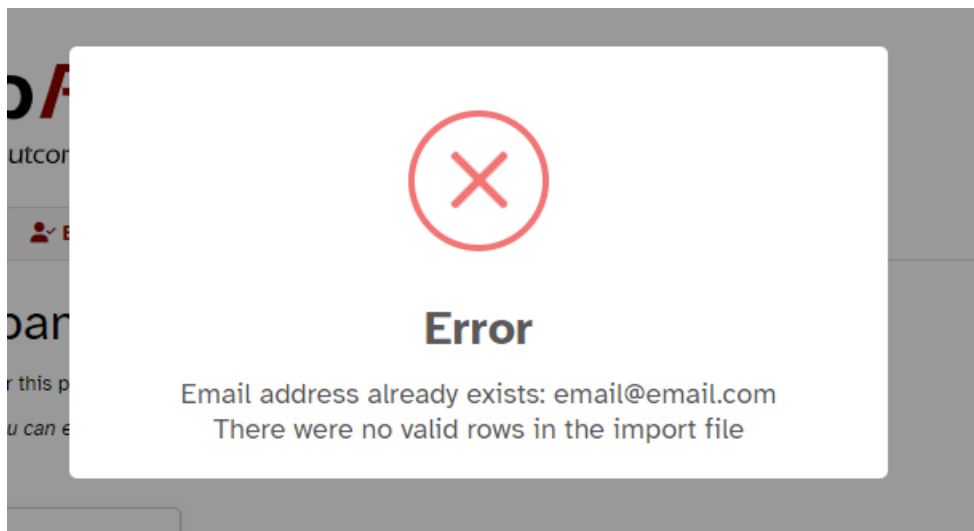
Examine the table of proposed changes below to verify it is correct.

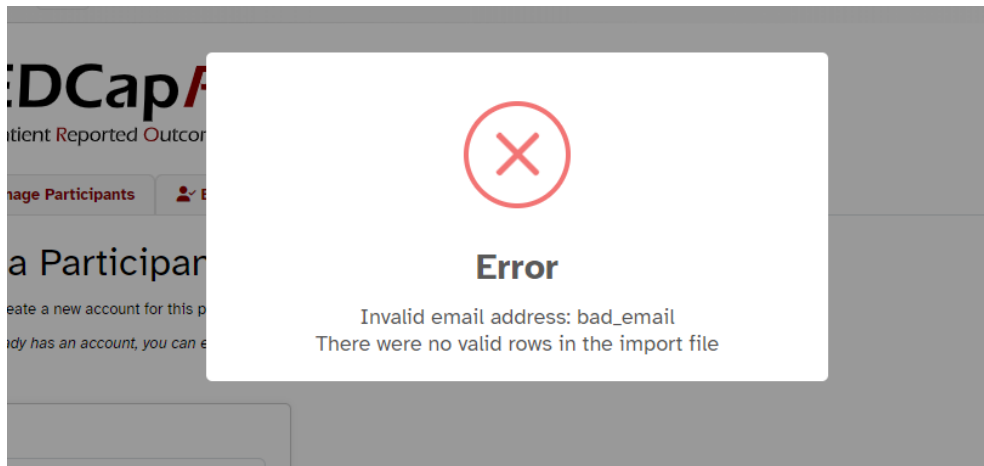
First Name	Last Name	Email	Enroll	DAG ID
Test	User2	email2@email.com	Yes	[No Assignment]

Cancel **Confirm**



6. If any Participant has already been registered or your CSV file was not formatted correctly, you will receive a message indicating that.





Once registered, the participants will receive an email with a link they can click to set their REDCapPRO password.

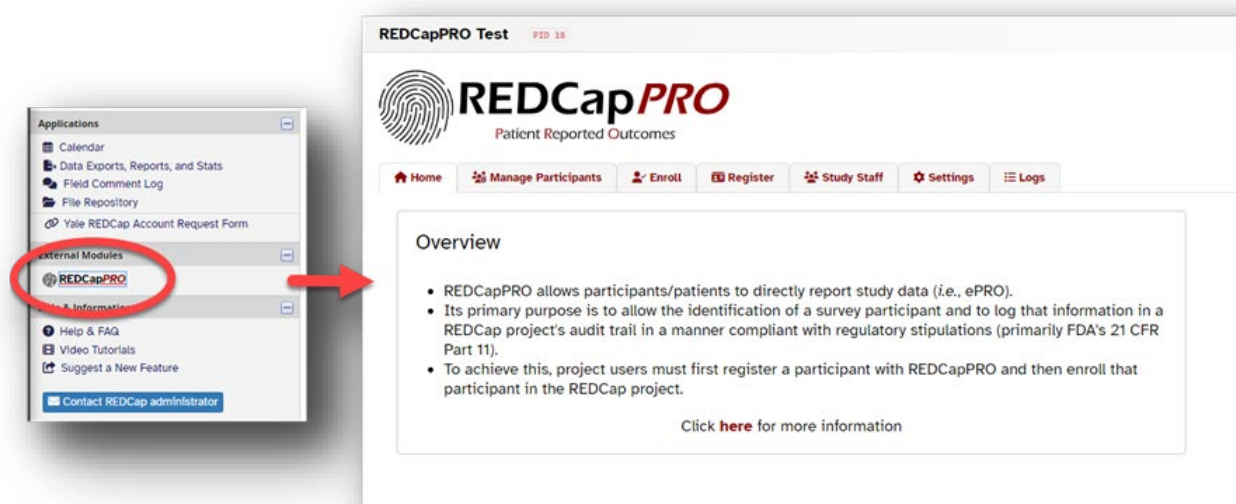
The participants will be automatically enrolled in the project.

Setting Study Staff Roles

Roles determine what a staff member sees and what they can do in REDCapPRO. In general, you should grant the lowest role required for the staff member to complete their duties. If a study staff is not enrolling participants, sending surveys to participants, or overseeing participant enrollment and contact activities, then “no access” is typically appropriate.

To update a staff role:

1. First, open the REDCapPRO project menu





2. Click the **Study Staff** tab

Manage Study Staff

Set [staff permissions](#) to REDCapPRO

Show entries Search:

Username	Name	Email	User Role
admin	joe admin	andrew.poppe@yale.edu	Manager
alice	alice manager	andrew.poppe@yale.edu	No Access
bob	bob user	andrew.poppe@yale.edu	Normal User

Showing 1 to 3 of 3 entries Previous Next

3. Find the staff member whose role you would like to update and click the dropdown in the User Role column.

4. Select the role you would like to change to, and then click the *Save Changes* button


Manage Study Staff

Set [staff permissions](#) to REDCapPRO

Show entries Search:

Username	Name	Email
admin	joe admin	andrew.poppe@yale.edu
alice	alice manager	andrew.poppe@yale.edu
bob	bob user	andrew.poppe@yale.edu

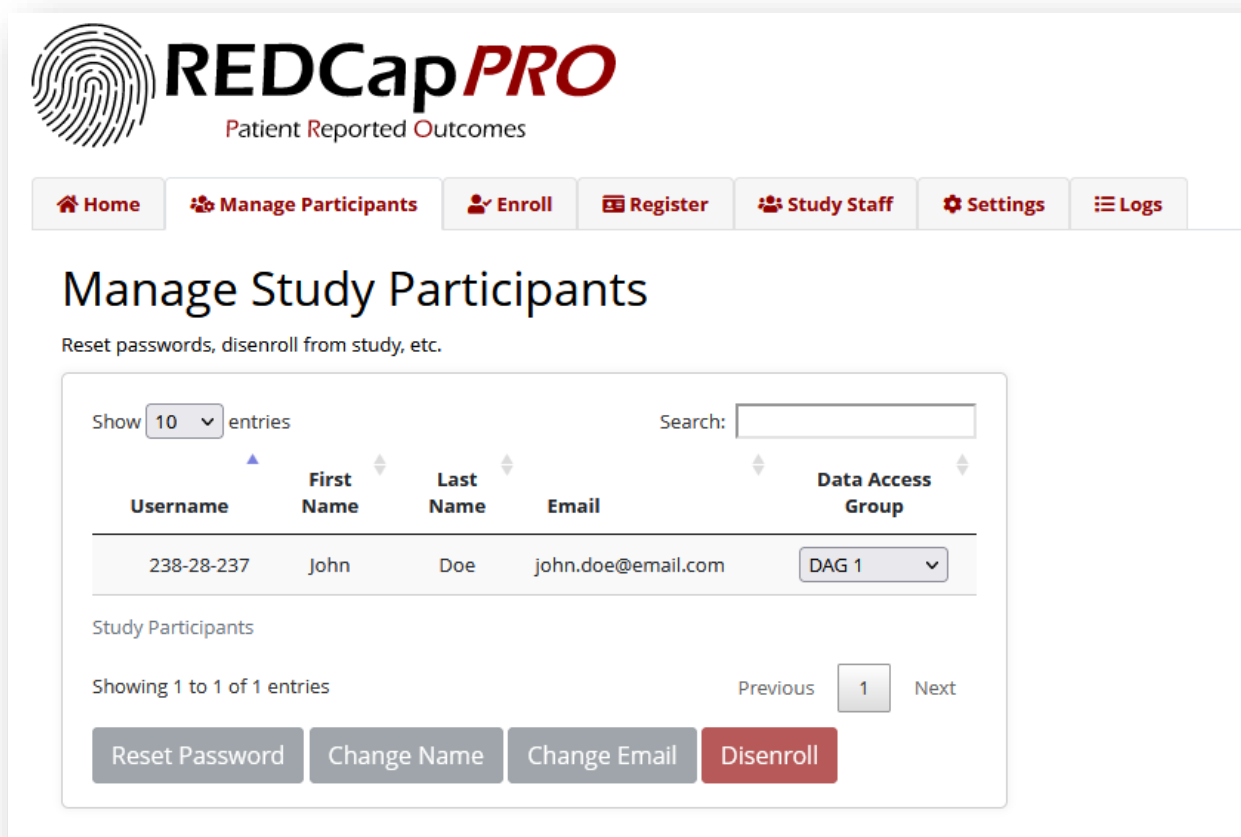
Showing 1 to 3 of 3 entries Previous 1 Next



Roles successfully changed

Explanation of Roles:

1. **Manager:** Highest privileges
 - a. can register, enroll, unenroll, set DAGs, and reset passwords
 - b. can set study staff access to REDCapPRO,
 - c. Can view REDCapPRO logs
 - d. Can manage settings: designate a study-specific contact, turn off email login option

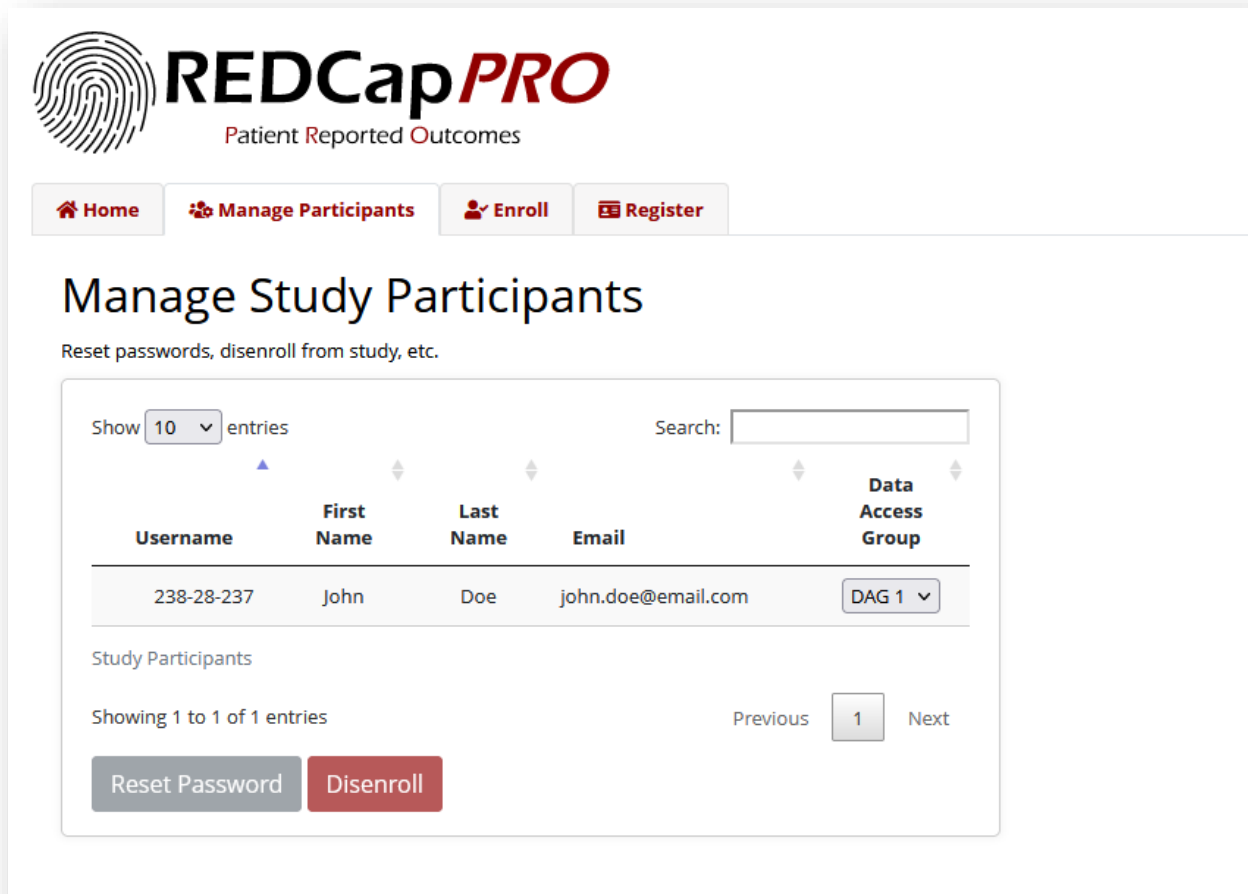


The screenshot shows the REDCapPRO web interface. At the top is the REDCapPRO logo and a navigation bar with links: Home, Manage Participants, Enroll, Register, Study Staff, Settings, and Logs. The main heading is 'Manage Study Participants' with a subtext 'Reset passwords, disenroll from study, etc.' Below this is a table of participants. The table has columns for Username, First Name, Last Name, Email, and Data Access Group. A single participant is listed: Username 238-28-237, First Name John, Last Name Doe, Email john.doe@email.com, and Data Access Group DAG 1. Below the table are buttons for 'Reset Password', 'Change Name', 'Change Email', and 'Disenroll'. There is also a search bar and a pagination control showing 'Showing 1 to 1 of 1 entries'.

Username	First Name	Last Name	Email	Data Access Group
238-28-237	John	Doe	john.doe@email.com	DAG 1

Buttons: Reset Password, Change Name, Change Email, Disenroll

- 2. Normal User:** Some user management privileges:
- a. can register, enroll, unenroll, set DAGs, and reset passwords



REDCapPRO
Patient Reported Outcomes

Home Manage Participants Enroll Register

Manage Study Participants

Reset passwords, disenroll from study, etc.

Show 10 entries Search:

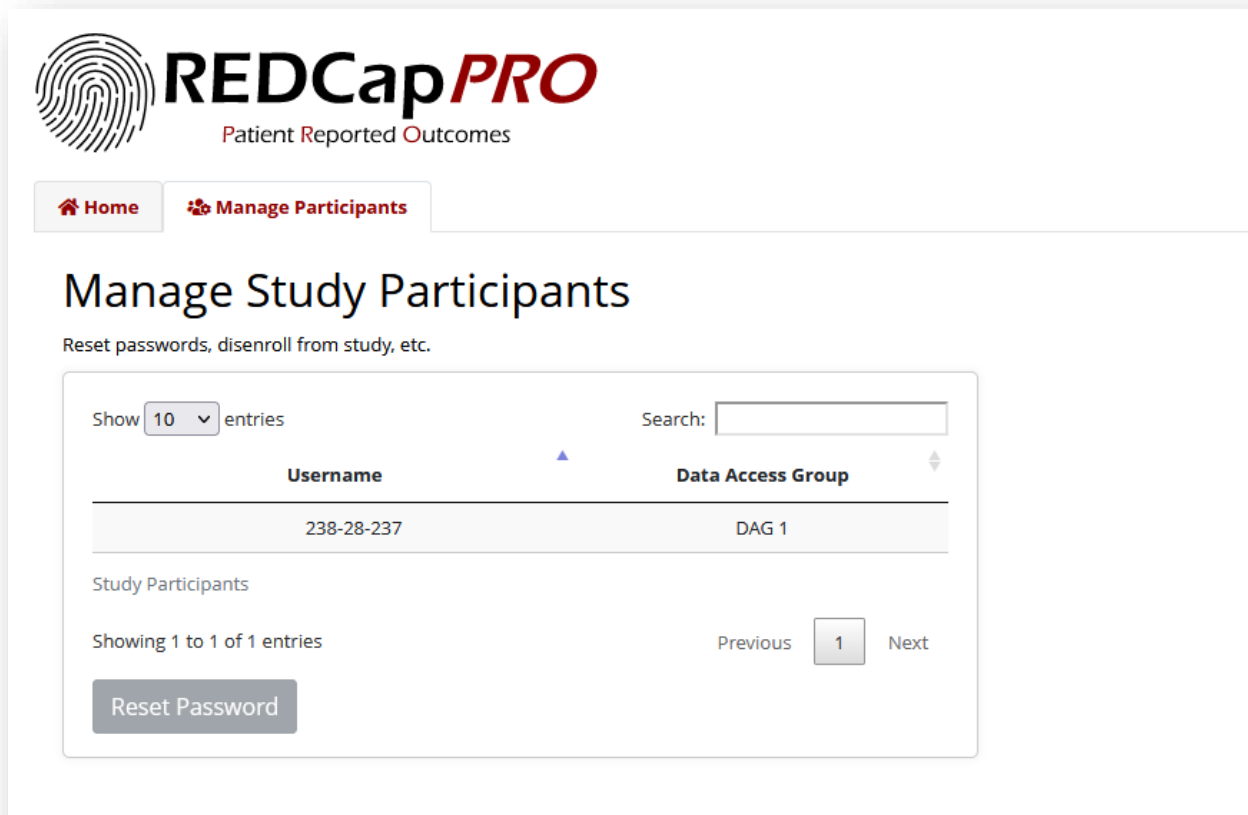
Username	First Name	Last Name	Email	Data Access Group
238-28-237	John	Doe	john.doe@email.com	DAG 1

Study Participants

Showing 1 to 1 of 1 entries Previous 1 Next

Reset Password Disenroll

3. Monitor: Restricted view – can only view the username and data access group of enrolled study participants



REDCapPRO
Patient Reported Outcomes

[Home](#) [Manage Participants](#)

Manage Study Participants

Reset passwords, disenroll from study, etc.

Show entries Search:

Username	Data Access Group
238-28-237	DAG 1

Study Participants

Showing 1 to 1 of 1 entries Previous Next

[Reset Password](#)

4. No Access: No access to REDCapPRO

FAQ

Q. Do I need to link or register my participant's project record with the participant's REDCapPRO ID?

- A. No, the REDCapPRO ID and participant record do not need to be linked in the record, the REDCapPRO ID will show up in the project logging. However, there are @Action Tags available to populate record fields with the REDCapPRO information. (See **Appendix A** for how to use REDCapPRO action tags. Or see full documentation for more details about action tags: <https://github.com/AndrewPoppe/REDCap-PRO/tree/2.5.0#readme>)

Q. I am using other External Modules in my project—will they work with REDCapPRO?

- A. REDCapPRO has not been tested for compatibility with other External Modules –we recommend testing EM combinations within your project prior to move to production. REDCapPRO is not compatible with the Survey Log Identifier EM.

Q. What browsers should participants use to log in to their survey?

- A. REDCapPRO has been tested on Chrome and Firefox. REDCap is **not** supported for Internet Explorer.



Q. My participant is completing surveys in person, do they still need to use REDCapPRO to log in?

A. Yes they still need to use REDCapPRO for P11 compliance. When conducting surveys in person, *always verify that study personnel are fully logged out of the REDCap application* before providing the survey to the participant. If a study personnel logs into the REDCap application in the same browser as the participant surveys, their login will overwrite and interfere with the REDCapPRO logging. Best practice is to conduct REDCap data entry and participant surveys on separate devices or on separate browsers. **YOU MUST ALWAYS LOG OUT OF REDCAP BEFORE PROVIDING A DEVICE TO A PARTICIPANT.** Failing to log out is a security violation that would give the participant unauthorized access to REDCap.

Q. What email address will emails come from that are sent to participants from REDCapPRO?

A. Emails sent to participants will come from noreply.REDCapPRO@ynhh.org. Please inform your participants of this fact to prevent emails from REDCapPRO inadvertently being delivered to their spam folders.

Known Issues

- **A bug was observed in which erroneous values may be inserted into fields on the REDCapPRO Settings form upon opening that page.**
 - **Description:** Erroneous values may be mistakenly inserted into the 'Primary Contact Person' Name, Email, and Phone fields on the Settings page of the REDCapPRO project menu when that page is first opened. These values are clearly not valid values and look like the following: "
Warning: ...". Attempting to save the Settings form results in an error, and the values are not saved.
Note: this bug was encountered once on our validation testing server, but our team has been unable to replicate it on that or any of our other REDCap servers.
 - **Workaround:** The workaround for this bug is for the user to delete the erroneous values should they encounter them. This allows the Settings page to be used as intended.



Appendix A

Action Tags

This module provides several action tags for populating REDCap fields with information about REDCapPRO participants. These are described below: Note: All action tags must exist on the same data collection instrument (not survey).

Action Tag	Use with field type	Validation on field type	Description
@RCPRO-USERNAME	text	none	This transforms the field into a dropdown selector. The user can select a participant and populate the field with that participant's username
@RCPRO-EMAIL	text	email	If @RCPRO-USERNAME is present on the instrument, then when it is selected the field with the @RCPRO-EMAIL tag will be populated with the participant's email address
@RCPRO-FNAME	text	none	Like @RCPRO-EMAIL, but the field will be populated with the participant's first name
@RCPRO-LNAME	text	none	Likewise, with last name