11 OpenClinica Consent

OpenClinica Consent allows users to get 21 CFR Part 11-compliant signatures from participants and countersignatures from Investigators and CRCs through electronic means. It also provides tools for tracking the consent status of participants and an audit trail of all informed consent activity. PDF copies of signed eConsent forms can also be downloaded by Participants as needed. The Consent module must be activated from the Modules page before any eConsent functionality is available.

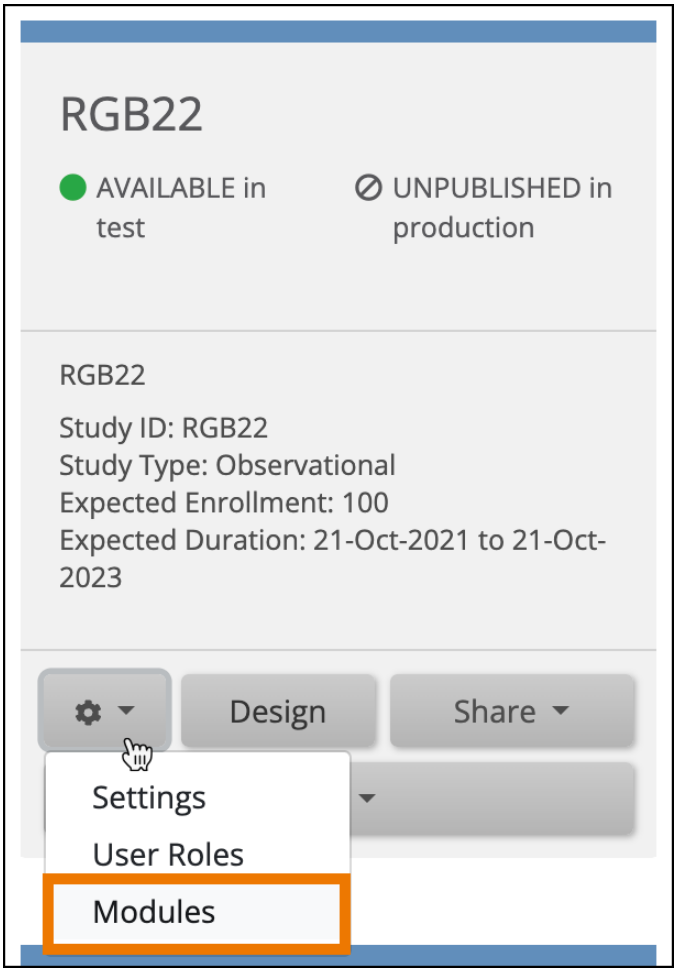
For Information on OpenClinica Consent, See the Following Sections:

11.1 Activate Consent

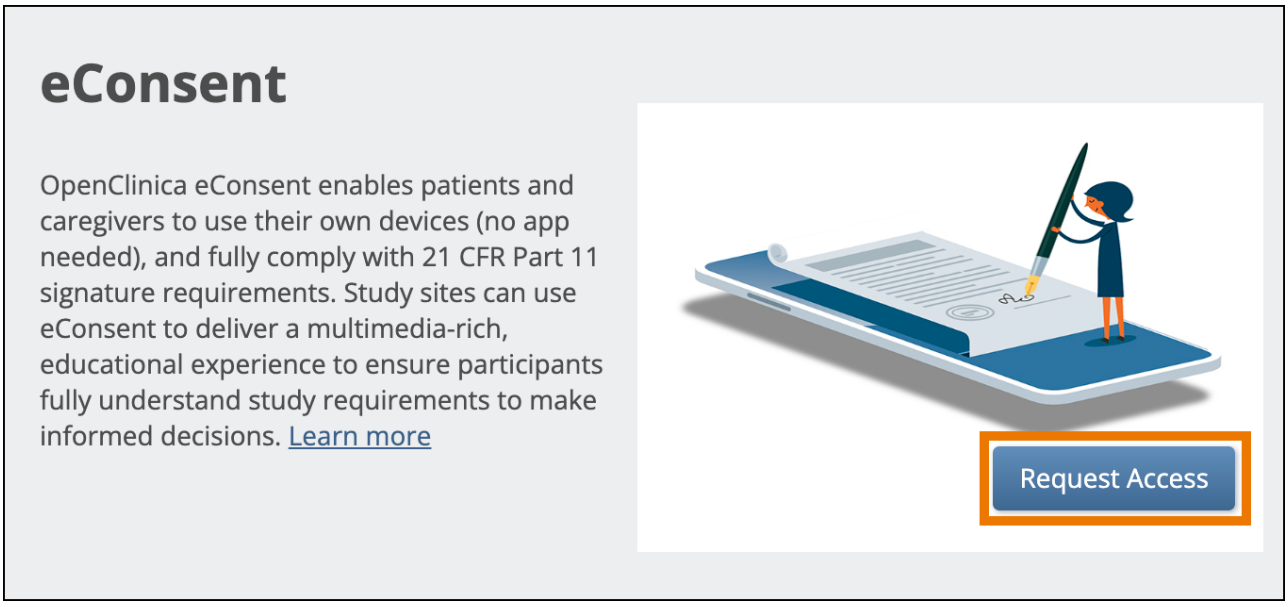
Study-level Data Managers and Administrators can request the OpenClinica Consent module for activation. Consent allows users to get signatures from participants and countersignatures from Investigators and CRCs through electronic means.

Request Consent

1. On the **My Studies** screen, in Study Designer, or the on the **Share** screen, click the **Settings (Gear)** button, and select **Modules**.

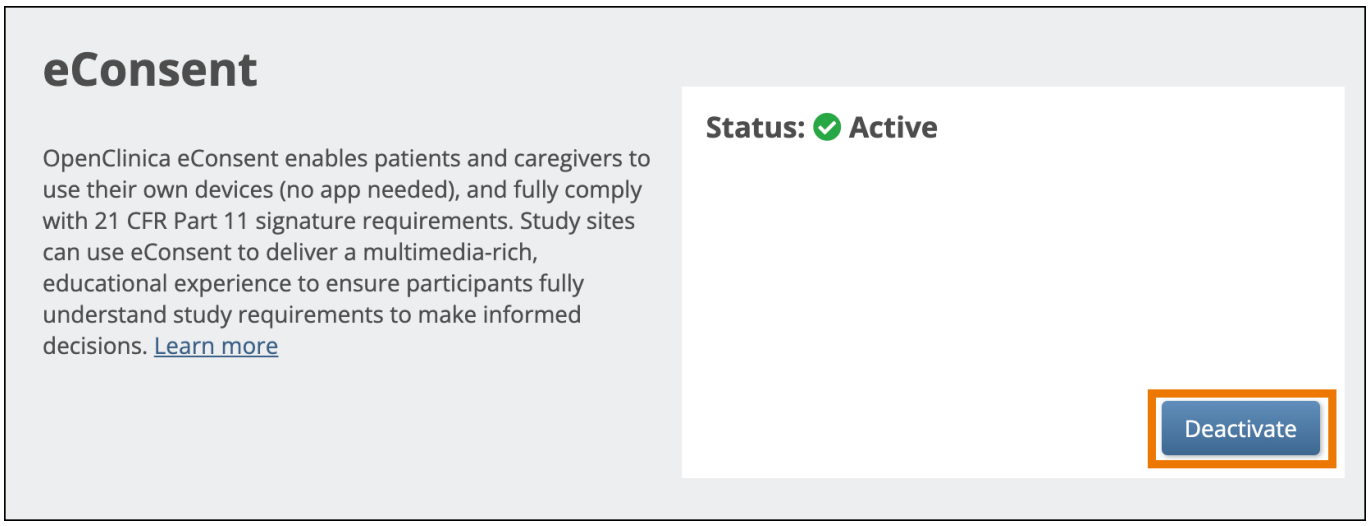


2. Click the **Request Access** button on the Consent Module card.



Note: *Once you have requested access, the status of the Consent module is set to Pending. While it is in this status, you can start designing eConsent Forms, but they are not activated for use until the request is approved and the status is set to Active. Requests are approved by OpenClinica Customer Support based on the current Consent contract with your organization.*

Once your Consent request is approved, the status is set to Active, and Consent is fully available for use in the Test and Production environments for that study.



To deactivate Consent at any time, return to the **Module Management** screen, and click the **Deactivate** button under the Consent module card. If you confirm the deactivation, this reverts all Consent Form settings and access to all Consent features and forms will be lost.

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11.2 Configure eConsent Forms

Part 11 Compliance for Electronic Signatures: Please note that in order to comply with Part 11, an electronic signature must include the participant's first and last name. Because of this requirement, for your eConsent signature to be fully compliant, your study must be designed to require first and last names to be collected prior to the signing of the eConsent form. You could do this either by including the first and last name contact fields in the informed consent form itself and only showing the eConsent form after they've been filled in, or by creating a different contact form that must be filled out by a CRC or the participant (if also using Participate) ahead of time. See **Design Participate Forms** for how to configure forms to capture first and last name in a secure manner for use in participant eConsent signatures.

Once OpenClinica Consent has been activated, Data Managers can designate Forms within non-repeating Visit Events as eConsent Forms using the **Form Template**. eConsent Forms are not available for use in Common Events or repeating Visit events.

Configure an eConsent Form:

1. Using the latest **Form Template**, configure the form to have a multi-select "signature" checkbox item type with only one response with "1" as the response name:
    a. **Survey Tab**
        i. "select_multiple EC" in the **type** column
        ii. “signature” in the **bind::oc:external** column
        iii. The item cannot have a value in the **bind::oc:itemgroup** column
        iv. Any item **name** and **label** can be used
        v. No value can be entered for **readonly**

vi. The **required** column can be used to flag the signature as required for form completion, like with other items

b. **Choices Tab**

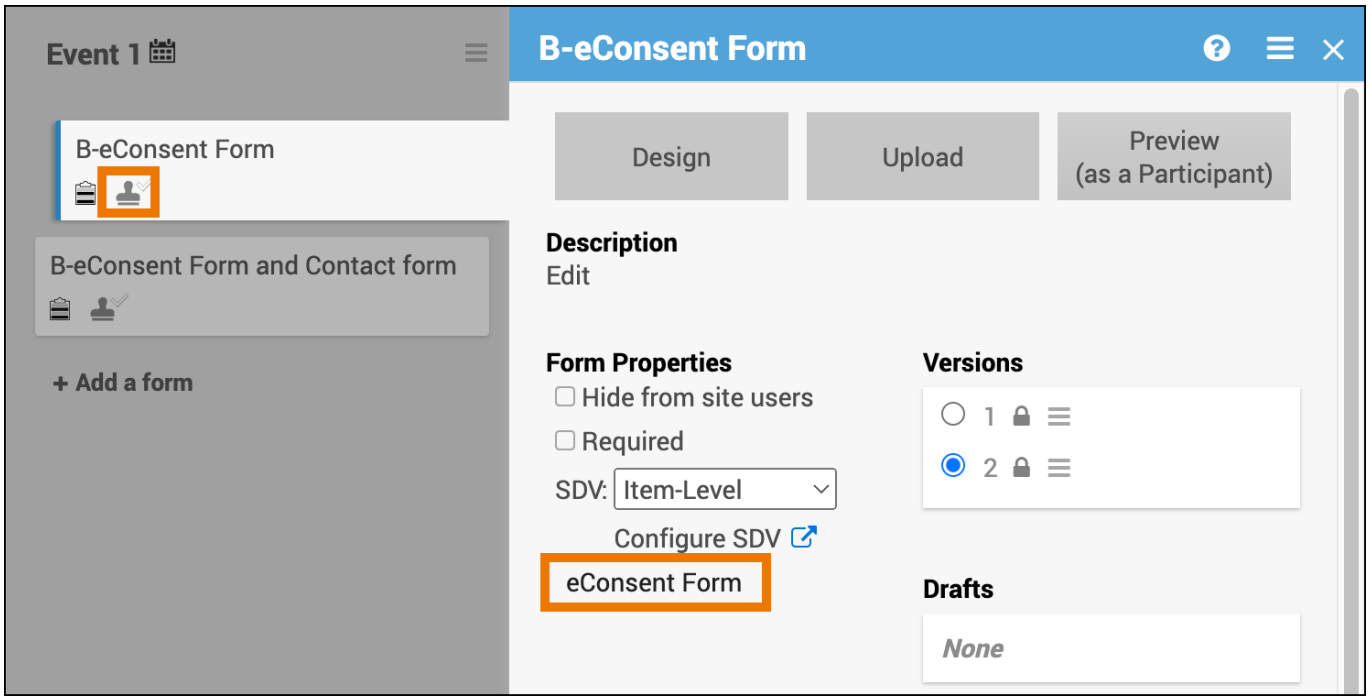
i. Use the **list_name** that matches the name defined in the Survey Tab's **type** column ("EC" in the example above)

ii. Only one choice can be added for the item because we only want one checkbox to appear.

iii. The choice **name** must be “1” (without the quotation marks)

iv. Anything can be entered for the choice **label**; this is what will appear next to the checkbox as the prompt for the participant to click and sign.

2. Make additional changes to the form definition as necessary, then upload the file to a Non-repeating Visit event. (Other event types do not support eConsent forms).
3. After the form is successfully uploaded, the system will automatically update the Form Card to show that the form is an eConsent form.
    a. This cannot be edited within the Form Card or Study Designer, but would need to be changed by editing the form definition and re-uploading the form version



Note: Contact Data items and permission tags will work as normal, with the only exception being that all users will be able to see the eConsent status on the Participant Matrix. Queries cannot be added to signature checkbox items.

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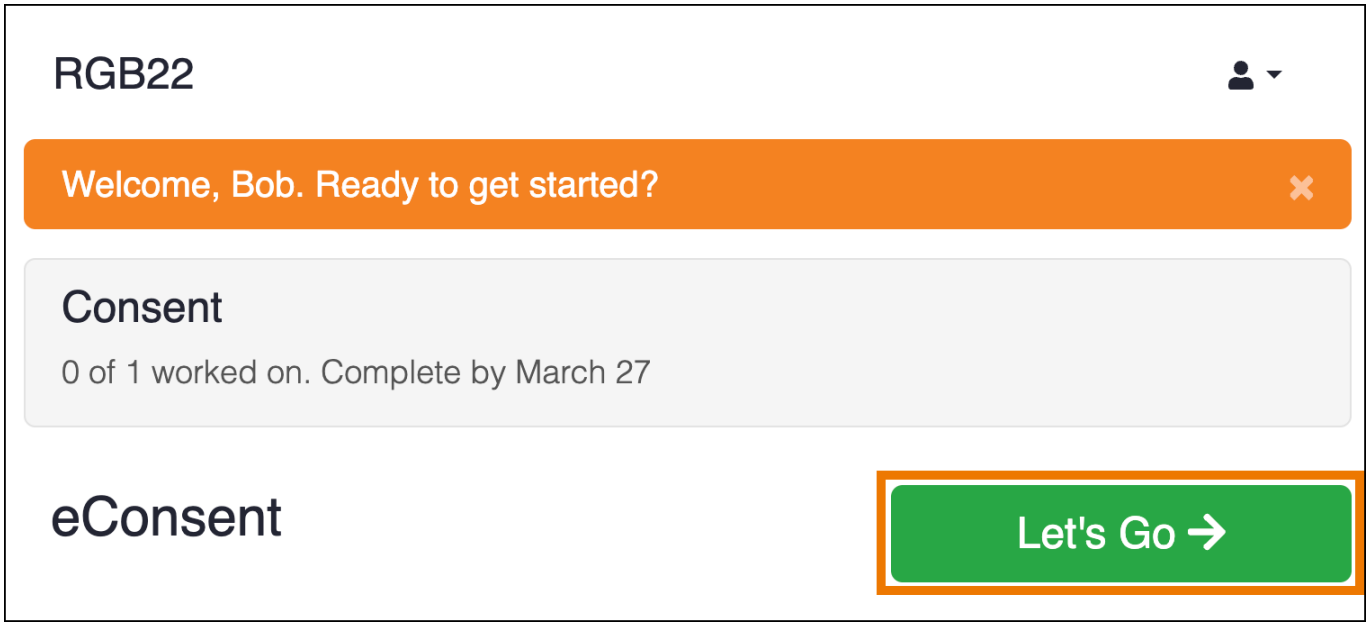
11.3 eConsent for Participants

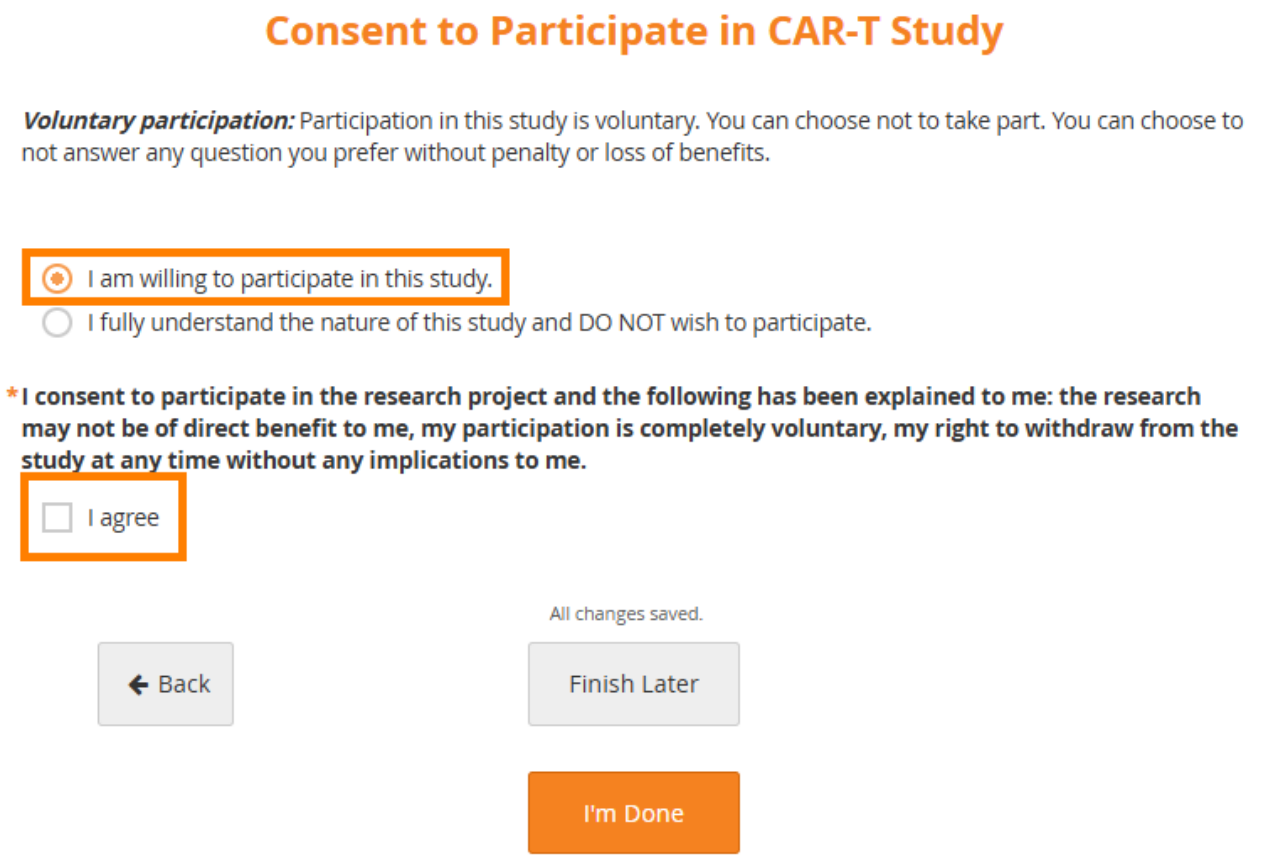
After a Visit including an eConsent form has been scheduled and the participant has been invited to the study, the participant can electronically sign the eConsent form.

Sign an eConsent form (Participants):

When a participant opens their dashboard, they will see the eConsent form on their dashboard with the date that the Visit event was scheduled.



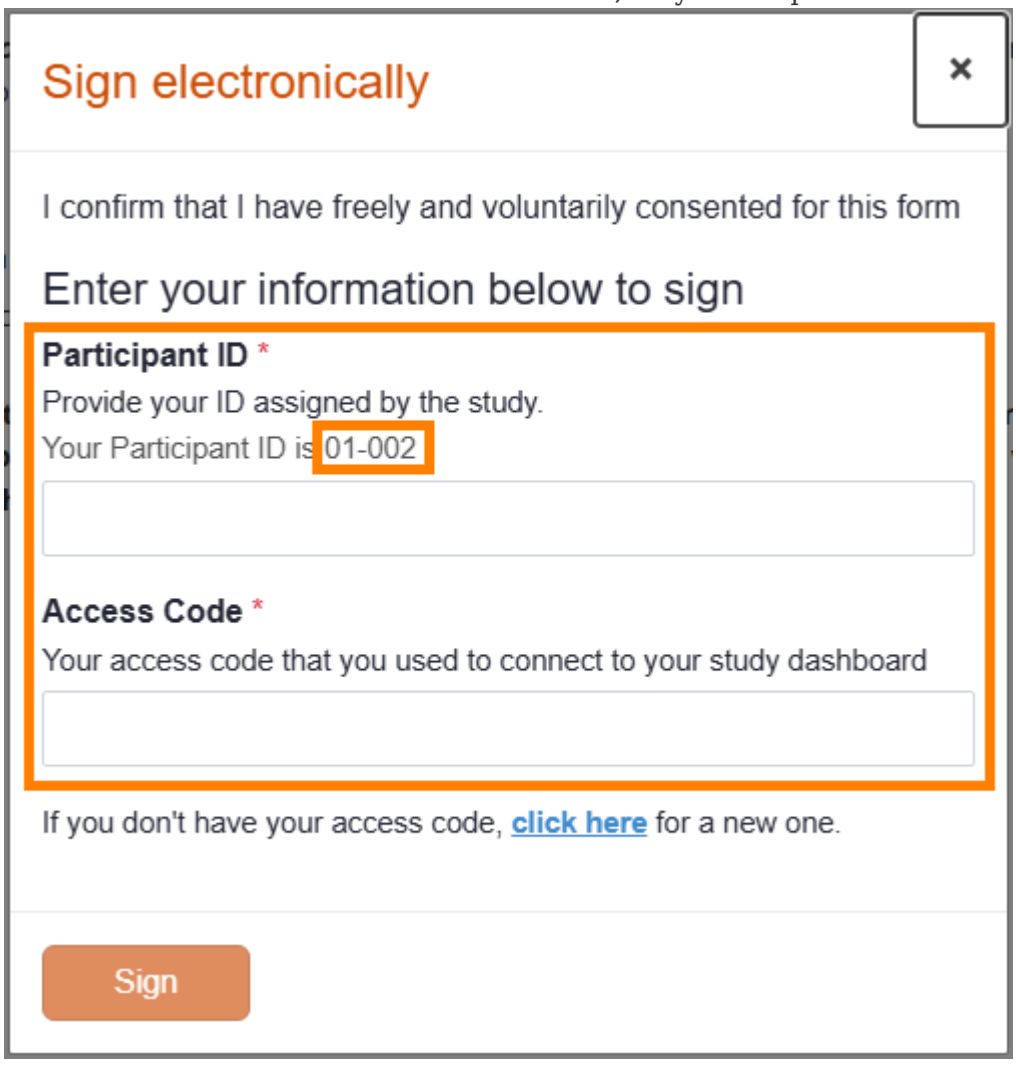
After the participant clicks **Let's Go**, they will see the form to fill out. For the eConsent form, in addition to any other text or input items in the form definition, the Participant will see the consent checkbox to indicate they are ready to add their formal signature. The text on the form will vary based on your study configuration. In the image below, the question asking whether the Participant is willing to participate in the study is an example of a question configured during study design.



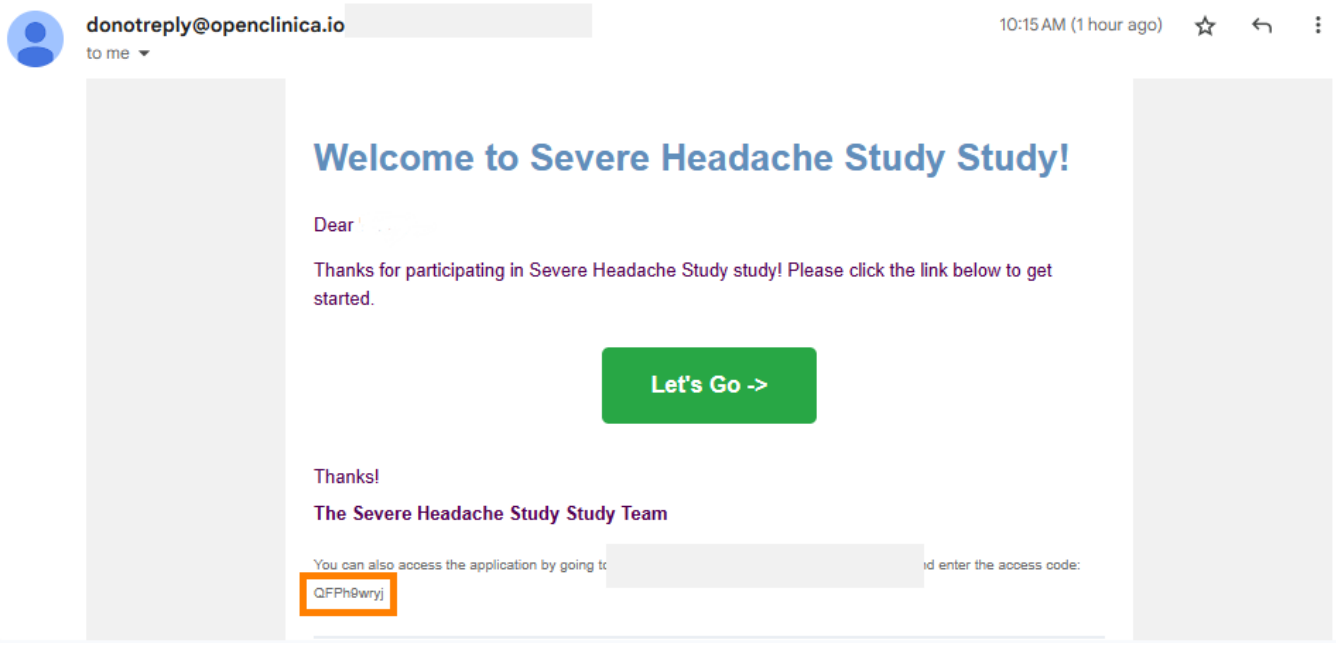
Once the participant has answered the study-specific questions, they can click the checkbox to confirm their agreement to participate in the study. To proceed, they must enter:

- **Participant ID:** This will be displayed on the screen.
- **Access Code:** This is provided in the email they received alerting them that the eConsent visit was available for signature.

If they don't remember or have lost their access code, they can request a new one by clicking **"click here"**.

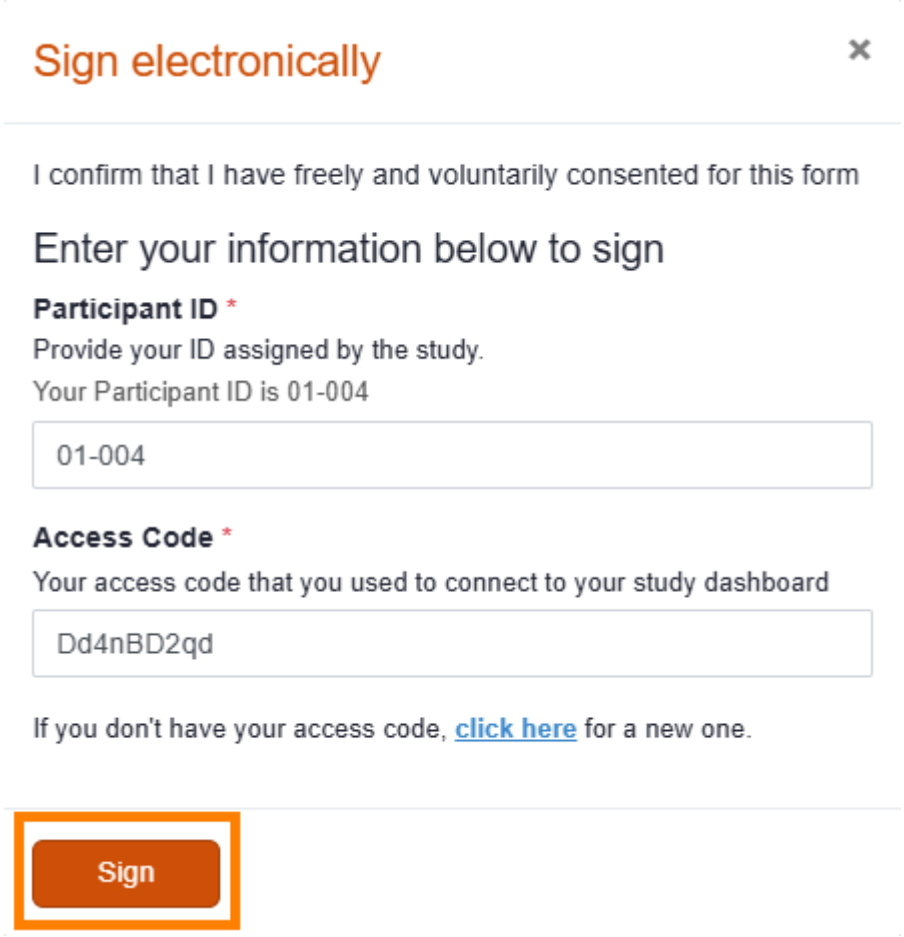


The new access code will be sent to their email address, mobile phone number, or both (if both are available).

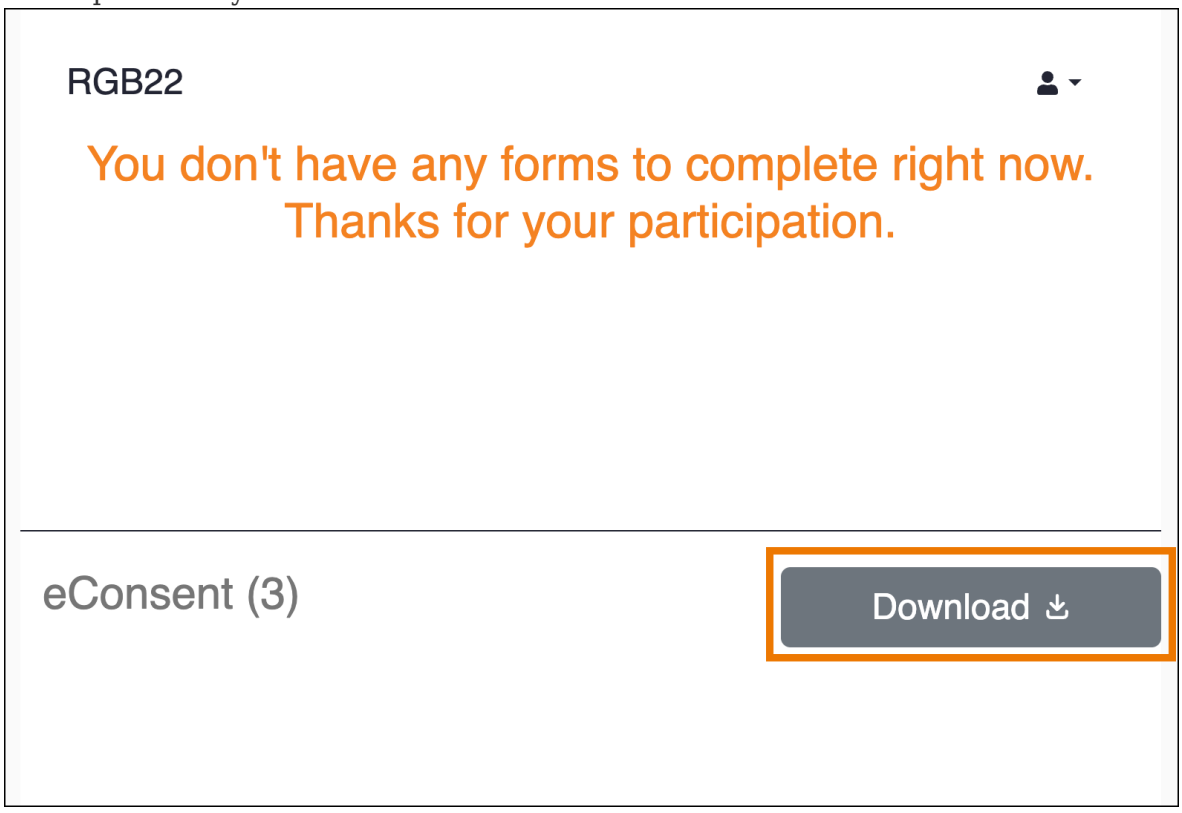


After the participant enters their Participant ID and access code, they will click Sign. The Sign

button becomes clickable only after both the Participant ID and access code have been entered.

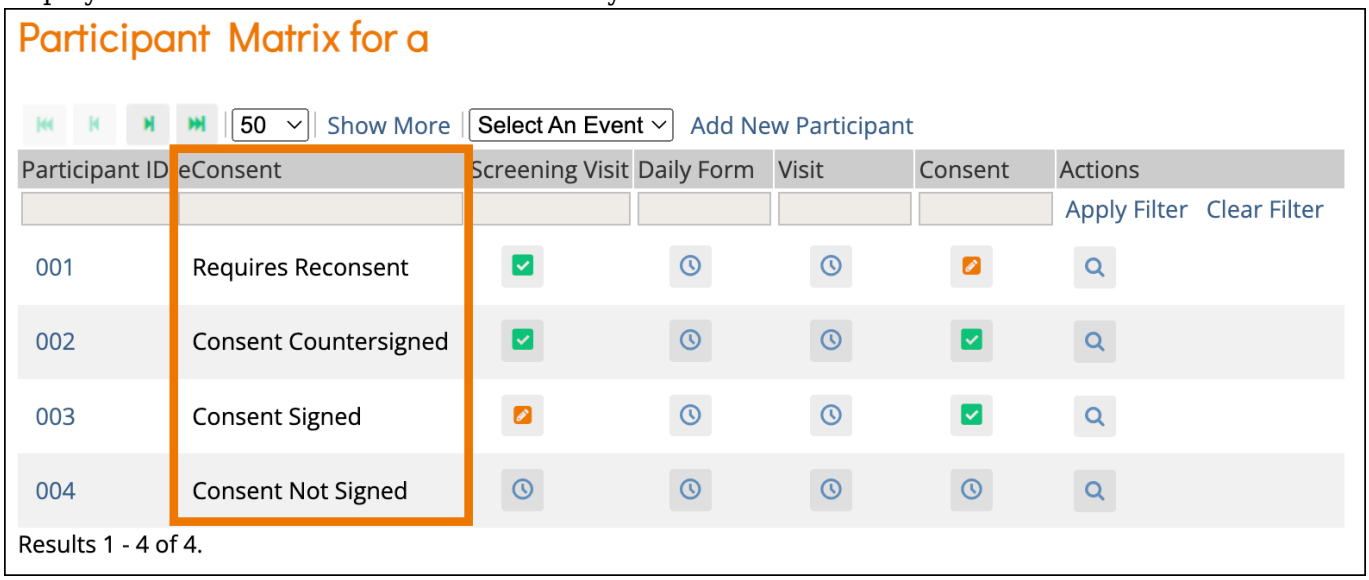


With the eConsent signed, the form will automatically be marked complete. When the participant returns to their dashboard, they will notice the eConsent form will appear at the bottom with a grey download button which allows them to download a copy of their eConsent form. This download option will remain available to the Participant if they return to the dashboard in the future.

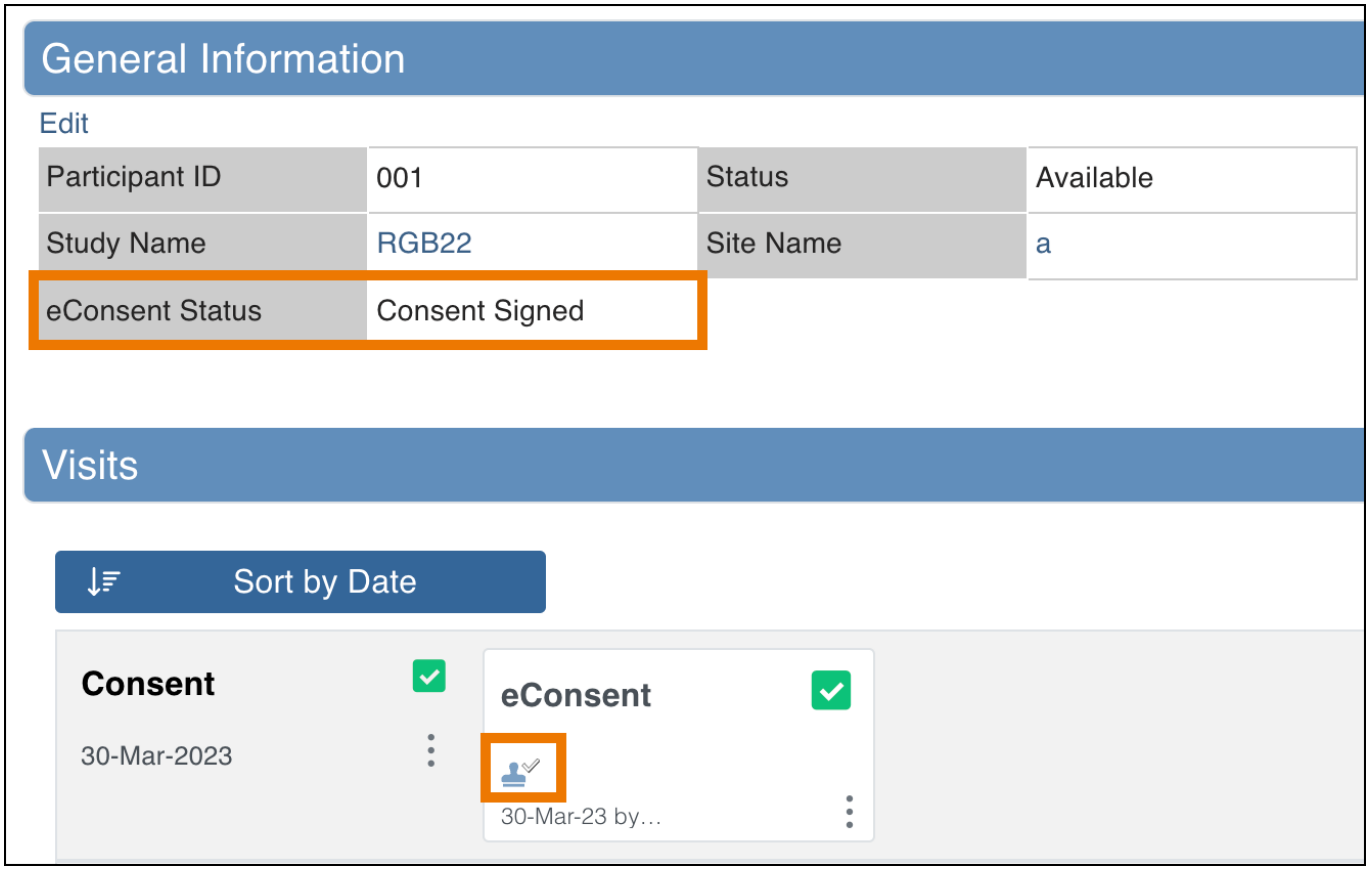


11.4 Consent in Study Runner

After the OpenClinica Consent module has been activated for your study and at least one eConsent form has been configured for it, Study Runner can be used to monitor participant consent statuses and schedule eConsent events to make the consent forms available to participants. The eConsent status for all participants can be viewed on the **Participant Matrix**. A separate column will be displayed for each eConsent form in the study.



The eConsent status for individual participants' eConsent forms can be viewed on the **Participant Details Page** both in the General Information section as well as on the form cards in the Visits section.



The eConsent statuses include the following:

Icon	Status	Description
	Consent Not Signed	The participant has not yet signed this eConsent form.
	Consent Signed	The participant has signed this eConsent form, but it has not yet been countersigned by a site user (CRC or Investigator).
	Consent Countersigned	The participant has signed this eConsent form and it has been countersigned by a site user (CRC or Investigator).
	Requires Reconsent	This eConsent form was signed by the participant (and possibly also countersigned), but a site user (CRC or Investigator) removed the consent. This might be done if a newer version of the eConsent form is being used. The participant will need to sign for consent again.

Schedule an eConsent Form:

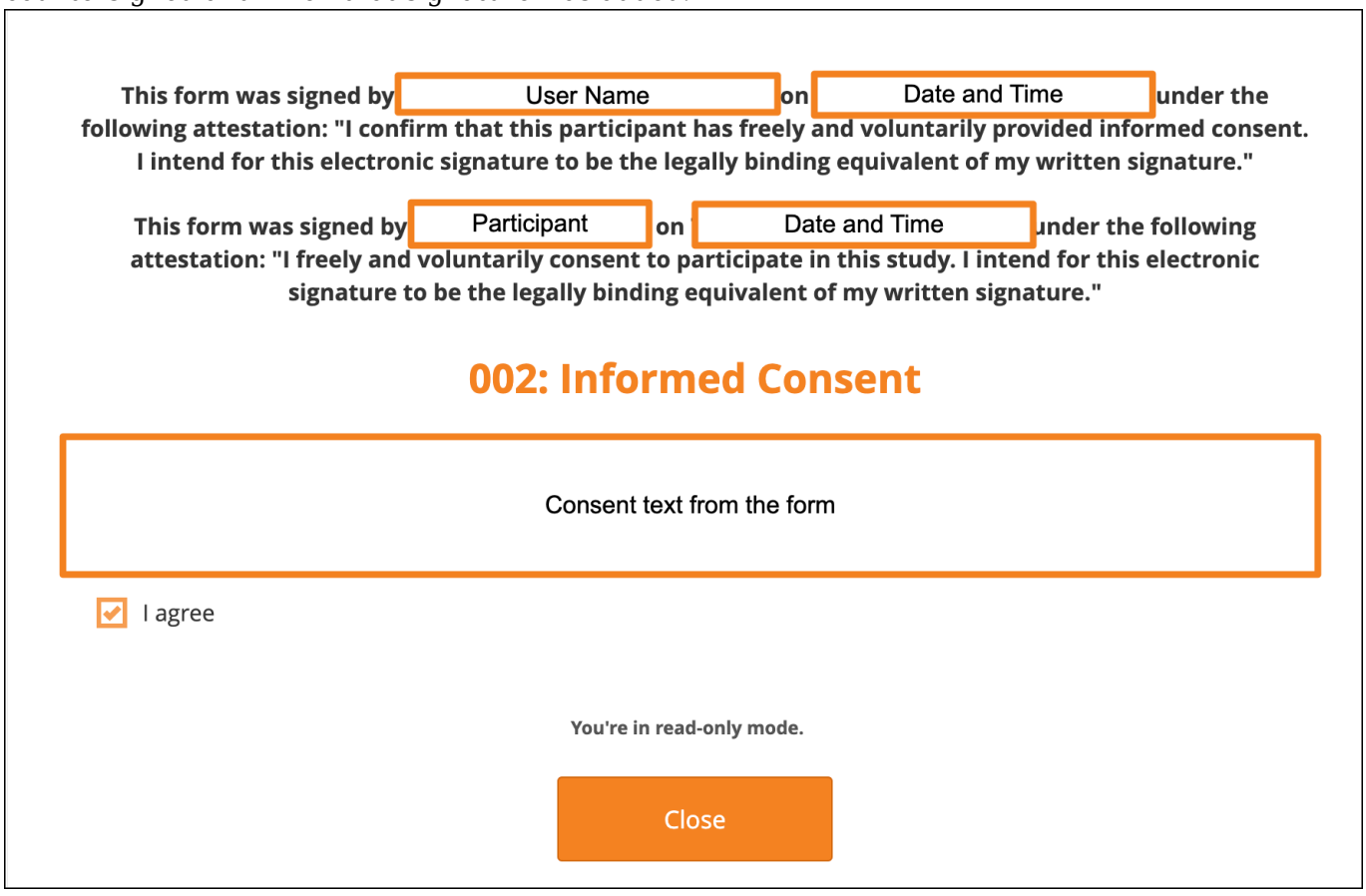
For a participant to see the eConsent form on their dashboard, the **event** with the eConsent form will need to be scheduled first. This event is scheduled in the same way as any other Visit event is scheduled and can be done from the Participant Matrix or by using the **Add New** button on the Participant Details Page.

Invite the Participant:

The participant will need to be **invited** to the study to have access to the eConsent form. Once the Visit with the eConsent form is scheduled and the participant has been invited to the study, the participant can sign the eConsent form using their dashboard. After the participant signs the eConsent form, the form will be marked as Completed and its eConsent status will be updated in Study Runner.

View an eConsent Form:

After a Visit event with an eConsent form has been scheduled for the participant, the form can be opened by any user with permission to view it, but only Participant users will be able to click the checkbox to mark the eConsent form as Signed. Open the form by clicking on the Visit form card or use its actions menu. When viewing the eConsent form, the top of the page will display the information about when it was signed with the name of the participant (name included only when viewing as a CRC or an Investigator). The form will also display the information on who countersigned and when that signature was added.

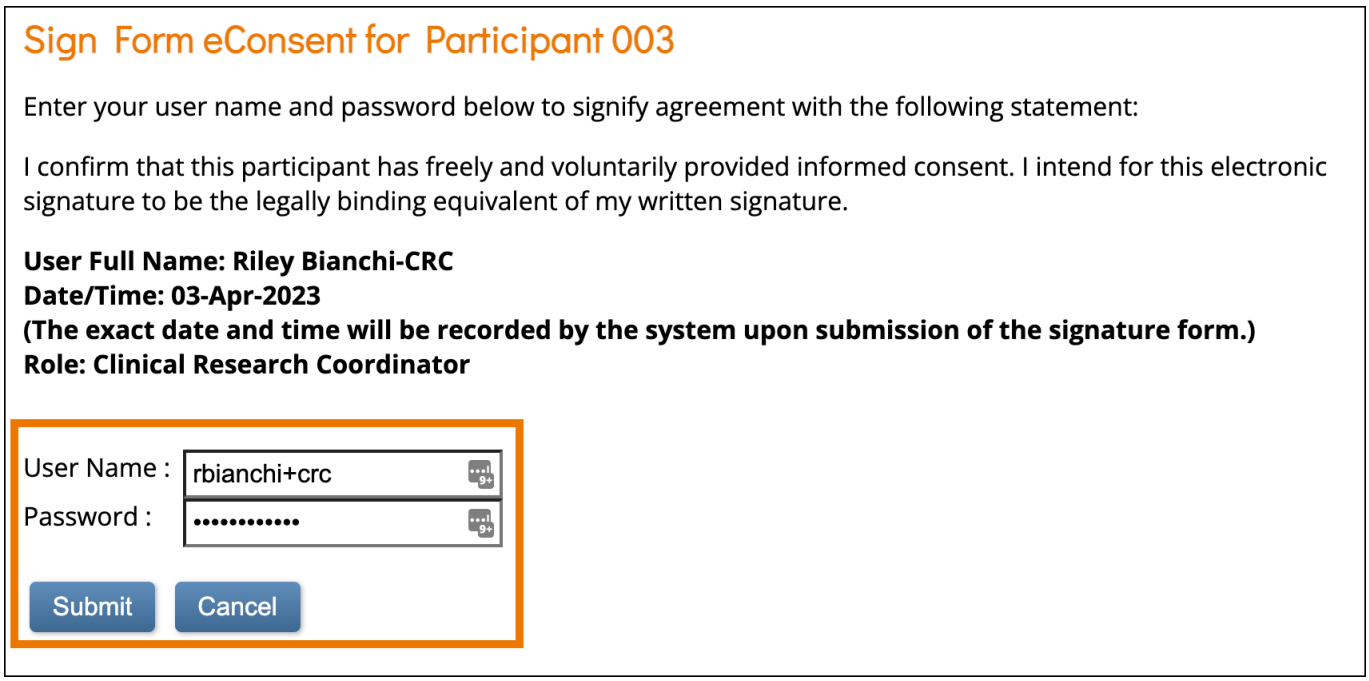


Note: The consent checkbox will be read-only. Only Participant users can click the checkbox.

Countersign a Signed Consent:

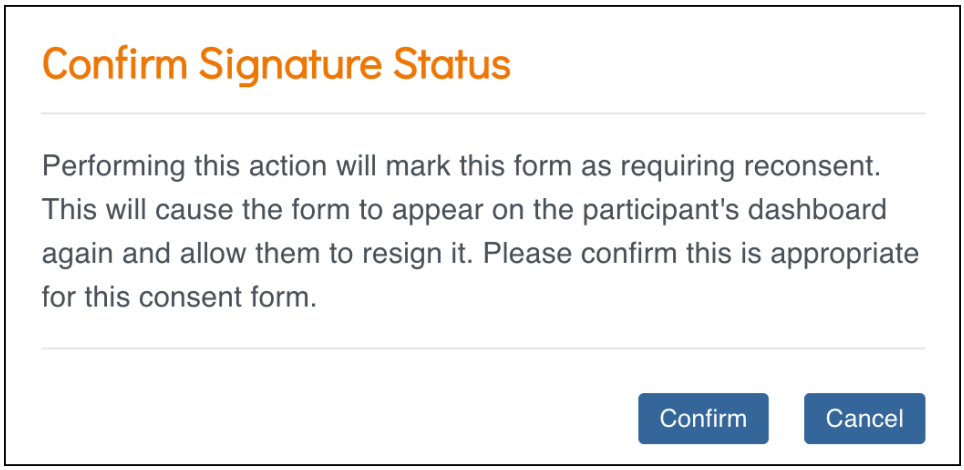
After the participant has signed their consent, the form's eConsent Status will be updated accordingly on the Participant Matrix and on the Participant Details Page. Clinical Research Coordinators and Investigators can then countersign the form.

1. Click the Actions menu on the signed eConsent form card and select **Countersign**.
2. Enter your Username and Password to confirm your countersignature and click **Submit**.
3. The eConsent status on the form card will be updated to Consent Countersigned.



Unconsent a Signed eConsent:

1. Click the Actions menu on the signed eConsent form card and select Unconsent.
2. The *Confirm Signature Status* window will open and explain:
    a. Performing this action will mark this form as requiring reconsent. This will cause the form to appear on the participant's dashboard again and allow them to re-sign it. Please confirm this is appropriate for this consent form.
3. Click Confirm to Unconsent the Signed Consent.
4. The eConsent status on the form card will update to Requires Reconsent and the form status will be changed from Completed to Data Entry Started.



Note: The eConsent status in the General Information section of the Participant Details Page will update when the page is refreshed.