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.

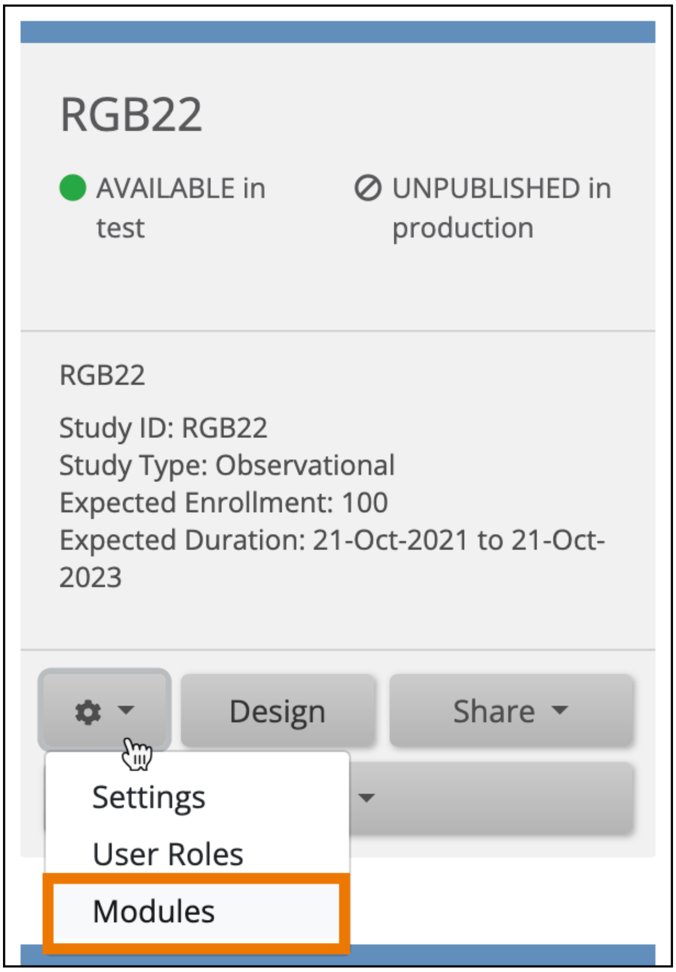
For Information on OpenClinica Consent, See the Following Sections:

11.1 Activate Consent

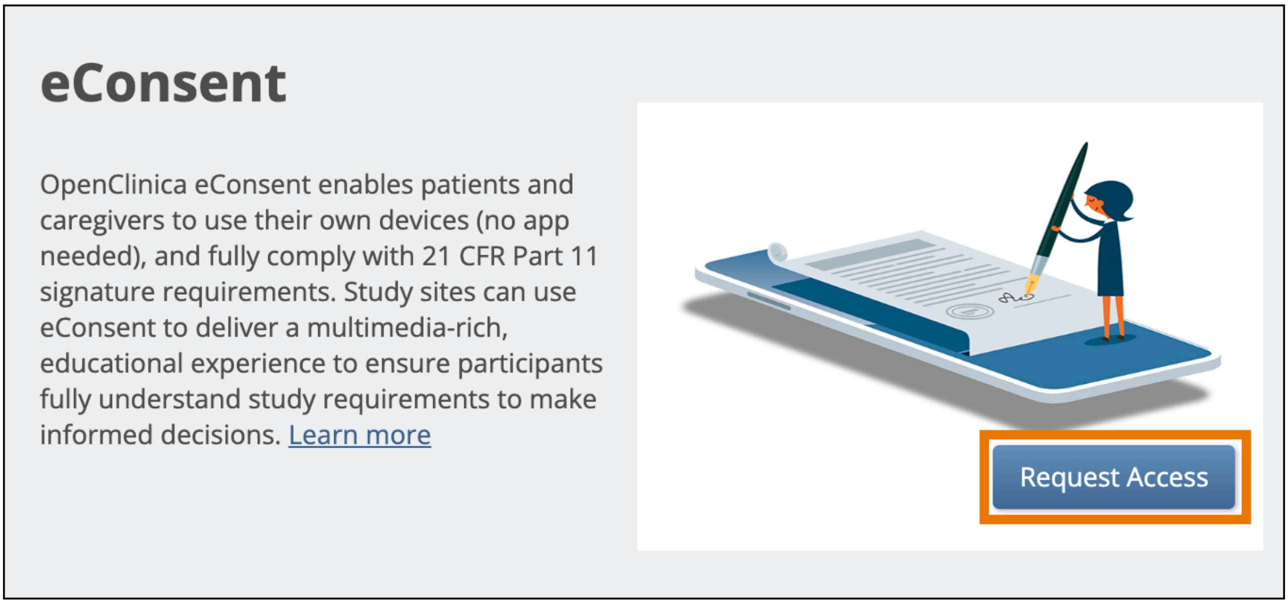
Study-level Data Managers and Administrators can request the OpenClinica Consent module for activation. Consent allows users to get signatures from participants and countersignatures from Investigators and CRCs through electronic means.

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**.

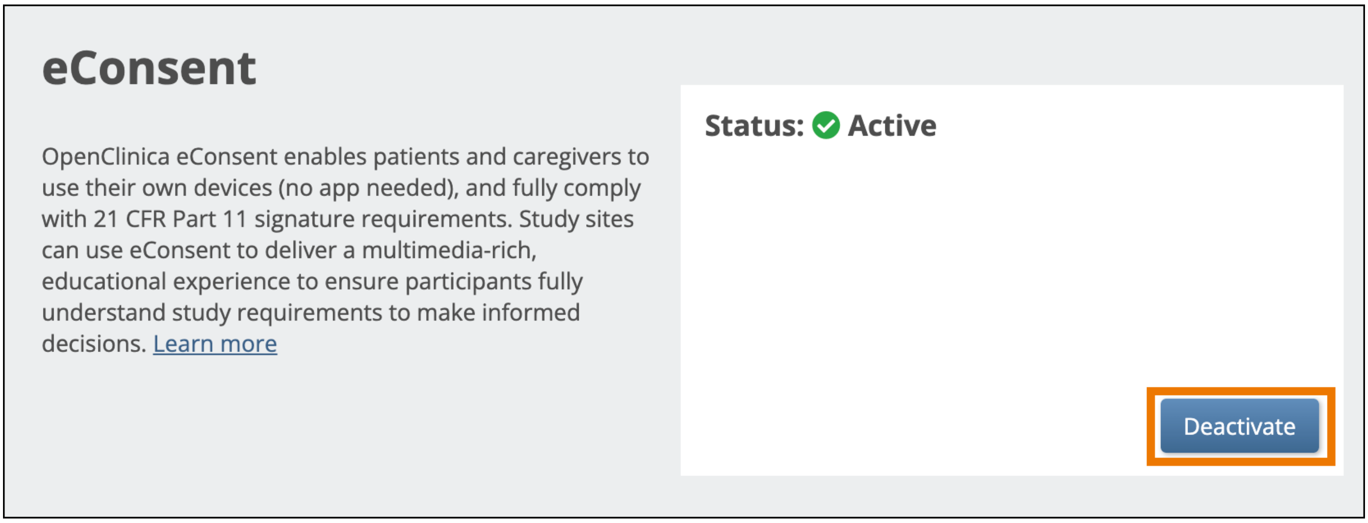


2. Click the **Request Access** button on the Consent Module card.



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.

Approved for publication by Kate Lambert. Signed on 2025-05-20 3:25PM

Not valid unless obtained from the OpenClinica document management system on the day of use.

11.2 Configure eConsent Forms

Guidance for 21 CFR Part 11 Compliance with OpenClinica Consent:

This section describes how OpenClinica supports **21 CFR Part 11 compliance** for electronic signatures in eConsent forms. Key Requirements:
• An electronic signature must include the participant's **first and last name.**
• To achieve compliance, your study must be designed to collect this information before the participant signs the **eConsent form.**
You can meet this requirement by:
• **Include first and last name fields in the eConsent form** and require these fields to be completed before the participant can submit the form.
• Creating a **separate contact form** (completed by either the CRC or the participant via Participate) that must be filled out prior to eConsent.
For more information on configuring forms to capture first and last name in a secure manner for use in participant eConsent signatures, refer to **Designing Contact Data Forms**.

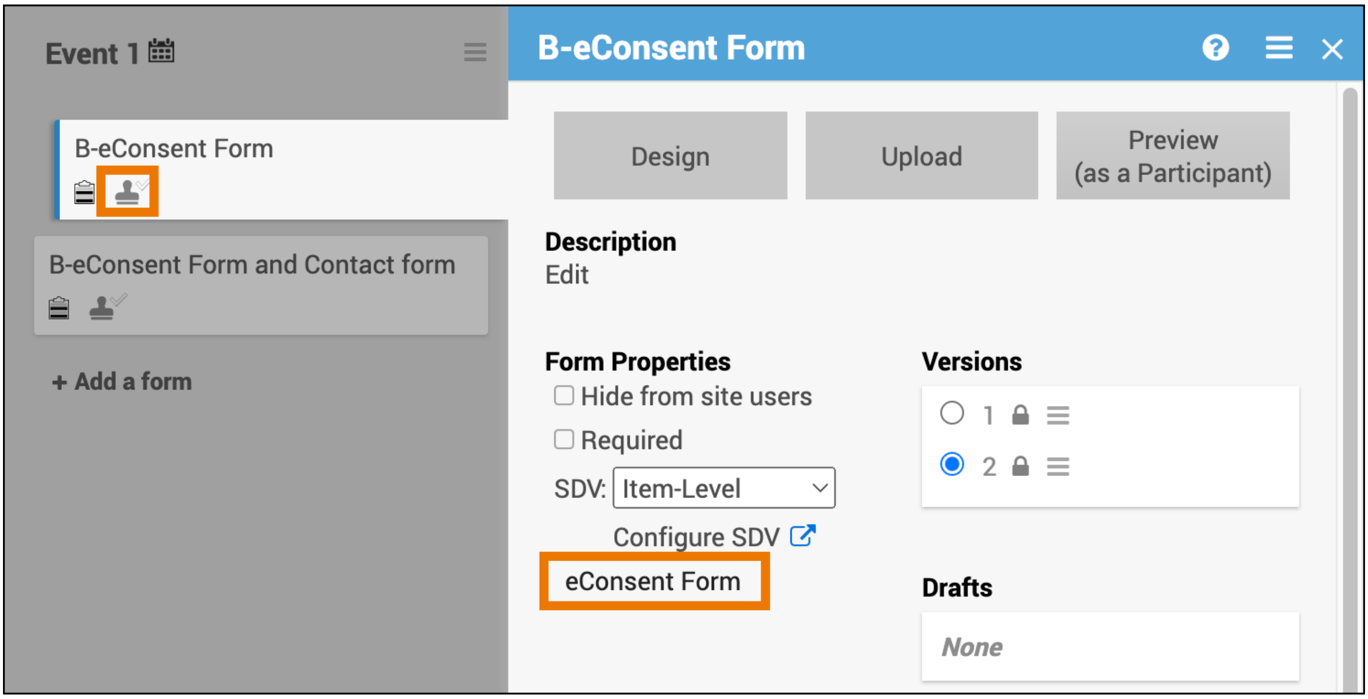
Once OpenClinica Consent has been activated, Data Managers can designate Forms within non-repeating Visit Events as eConsent Forms using the **Form Template**.

 Limitation: eConsent forms are not available for common events or repeating visit events.

Configure an eConsent Form:

1. Use the latest **[Form Template]**
2. In the **Survey** tab, configure a multi-select checkbox item as follows:
    - **type** column: "select_multiple EC"
    - **bind::oc:external** column: “signature”
    - **bind::oc:itemgroup** column: *(must be blank)*
    - **readonly** column: *(must be blank)*
    - **required column:** Optional – flag as required if needed for completion
    - **item name/label:** Any name or label may be used
3. In the **Choices Tab:**
    - Use the **list_name** that matches the Survey Tab type ("EC" in the example above).
    - Add **only one choice** (to display a single checkbox).
    - The choice **name** must be “1” (without the quotation marks)
    - The **choice label** can be any text prompt (this is what the participant sees).
4. Make any additional changes needed in the form definition.
5. Upload the form to a **non-repeating visit event**.
    - After upload, the **Form Card** automatically indicates that the form is an eConsent form

 Important: The eConsent designation cannot be changed in the **Form Card** or **Study Designer**. To update, you must edit the form definition and re-upload the form.



Behavior and Limitations

The following behaviors and limitations apply specifically to eConsent forms within OpenClinica:

- Contact data items and permission tags work as usual.
- All users can view eConsent status on the **Participant Matrix.**
- Queries cannot be added to signature checkbox items.

Replacing a Form Definition (eConsent ↔ Non-eConsent

In limited cases, you can replace a form with another that has a different eConsent designation. This is only allowed when **all** conditions are met

- The form has exactly **one version** (active or archived).
- The form has **not been published** to production (draft or test environments only).
- The replacement form uses the **same version number** as the existing form.

Outcomes

- **From eConsent → non-eConsent**: All eConsent-specific features (icons, consent statuses) are removed from the **Participant Details Page (PDP)**, **Participant Matrix**, and form cards
- **From non-eConsent → eConsent**: The eConsent features are added to those areas

 Note: If you attempt to change a form's eConsent status without meeting the required conditions, the system will display a standard error message indicating that the form type cannot be changed.

Approved for publication by Kate Lambert. Signed on 2025-12-12 12:11PM

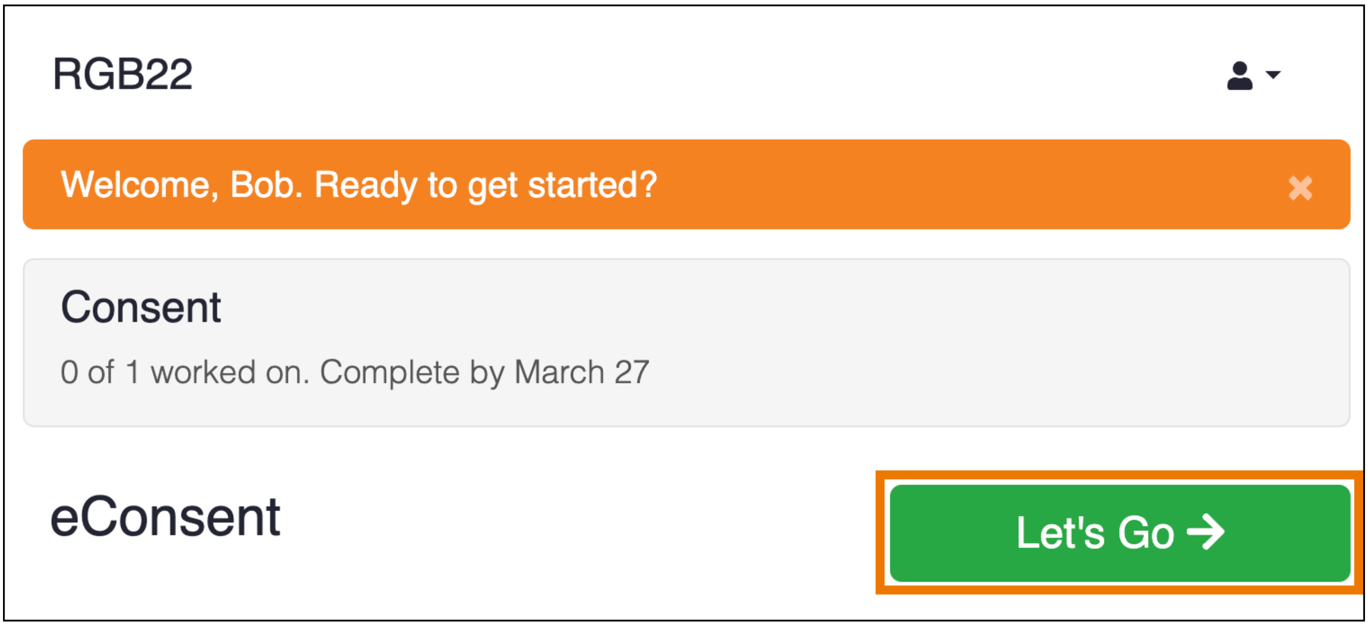
Not valid unless obtained from the OpenClinica document management system on the day of use.

11.3 eConsent for Participants

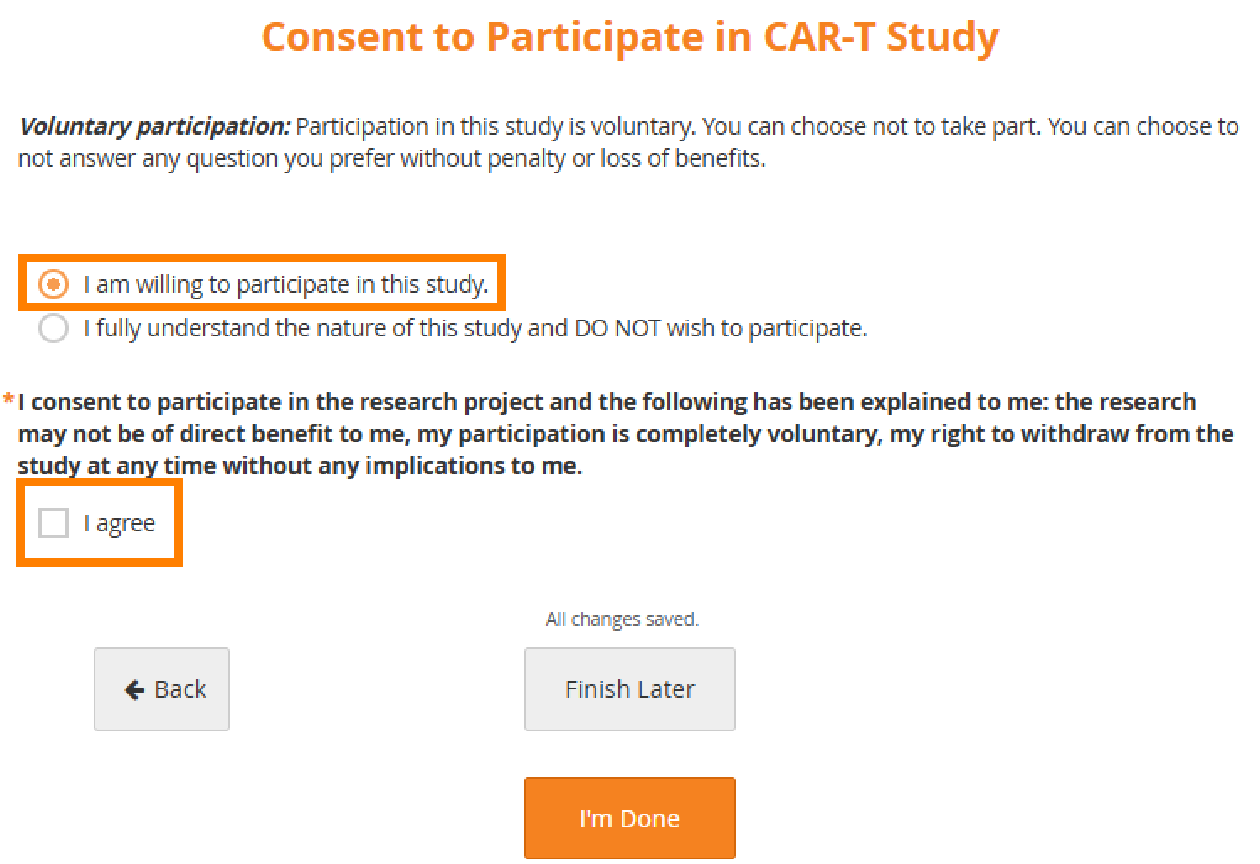
After a Visit including an eConsent form has been scheduled and the participant has been invited to the study, the participant can electronically sign the eConsent form.

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.



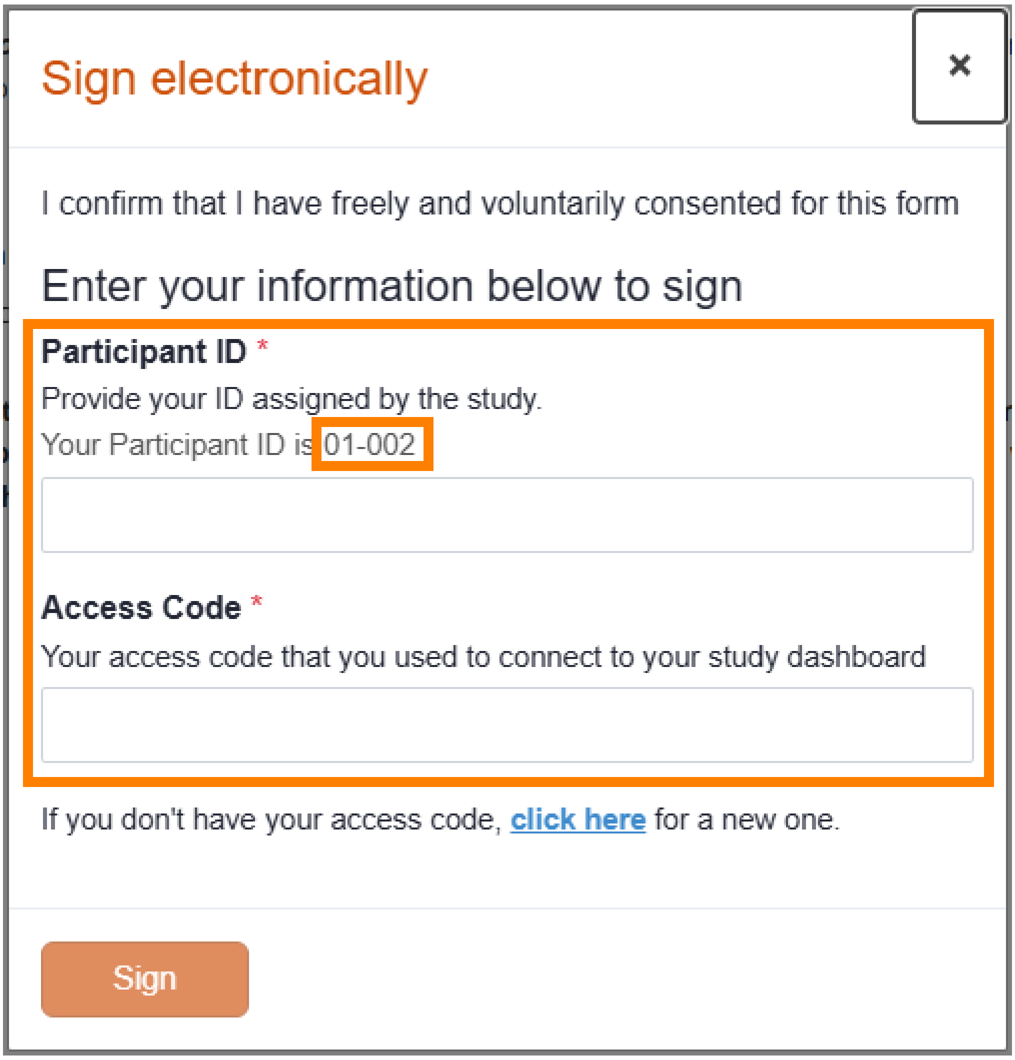
After the participant clicks **Let's Go**, they will see the form to fill out. For the eConsent form, in addition to any other text or input items in the form definition, the Participant will see the consent checkbox to indicate they are ready to add their formal signature. The text on the form will 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.



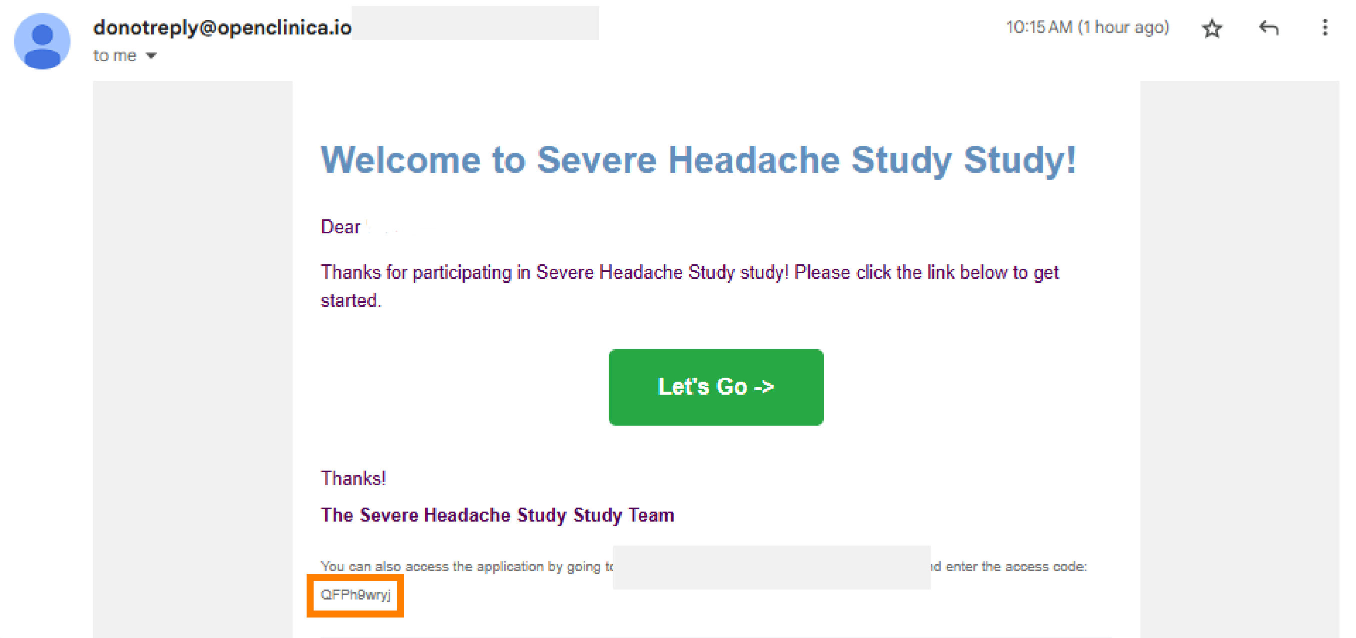
Once the participant has answered the study-specific questions, they can click the checkbox to confirm their agreement to participate in the study. To proceed, they must enter:

- **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.

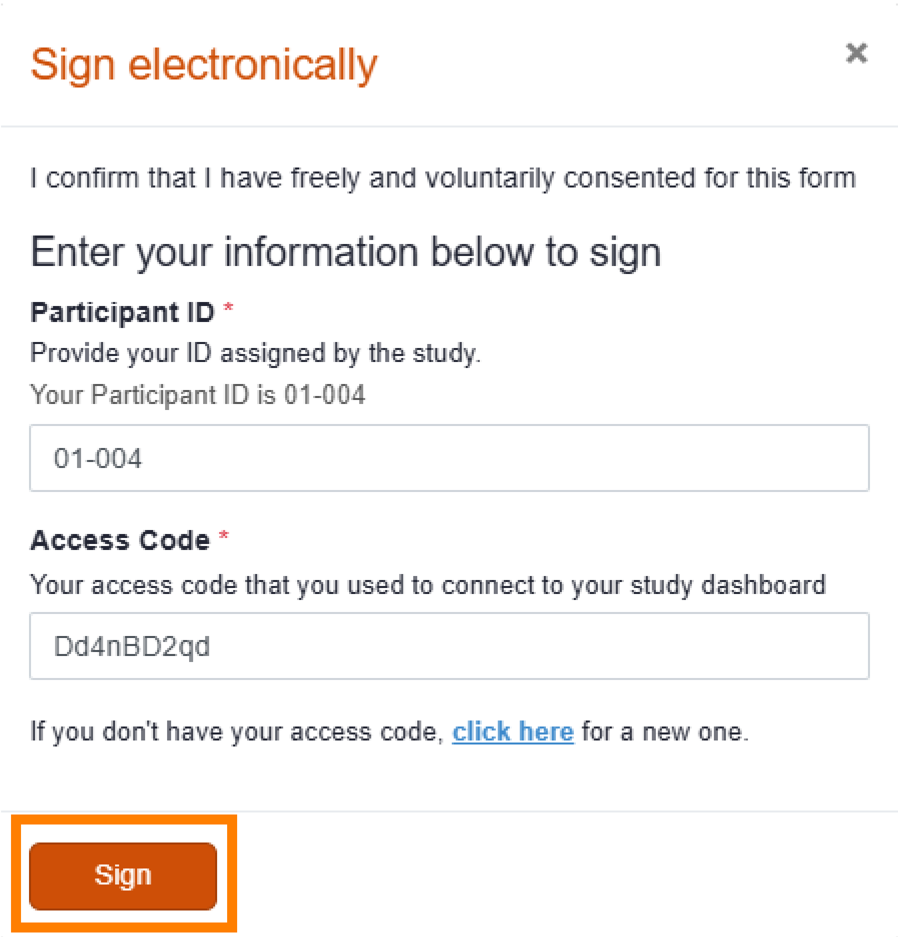
If they don't remember or have lost their access code, they can request a new one by clicking **"click**



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.

Not valid unless obtained from the OpenClinica document management system on the day of use.

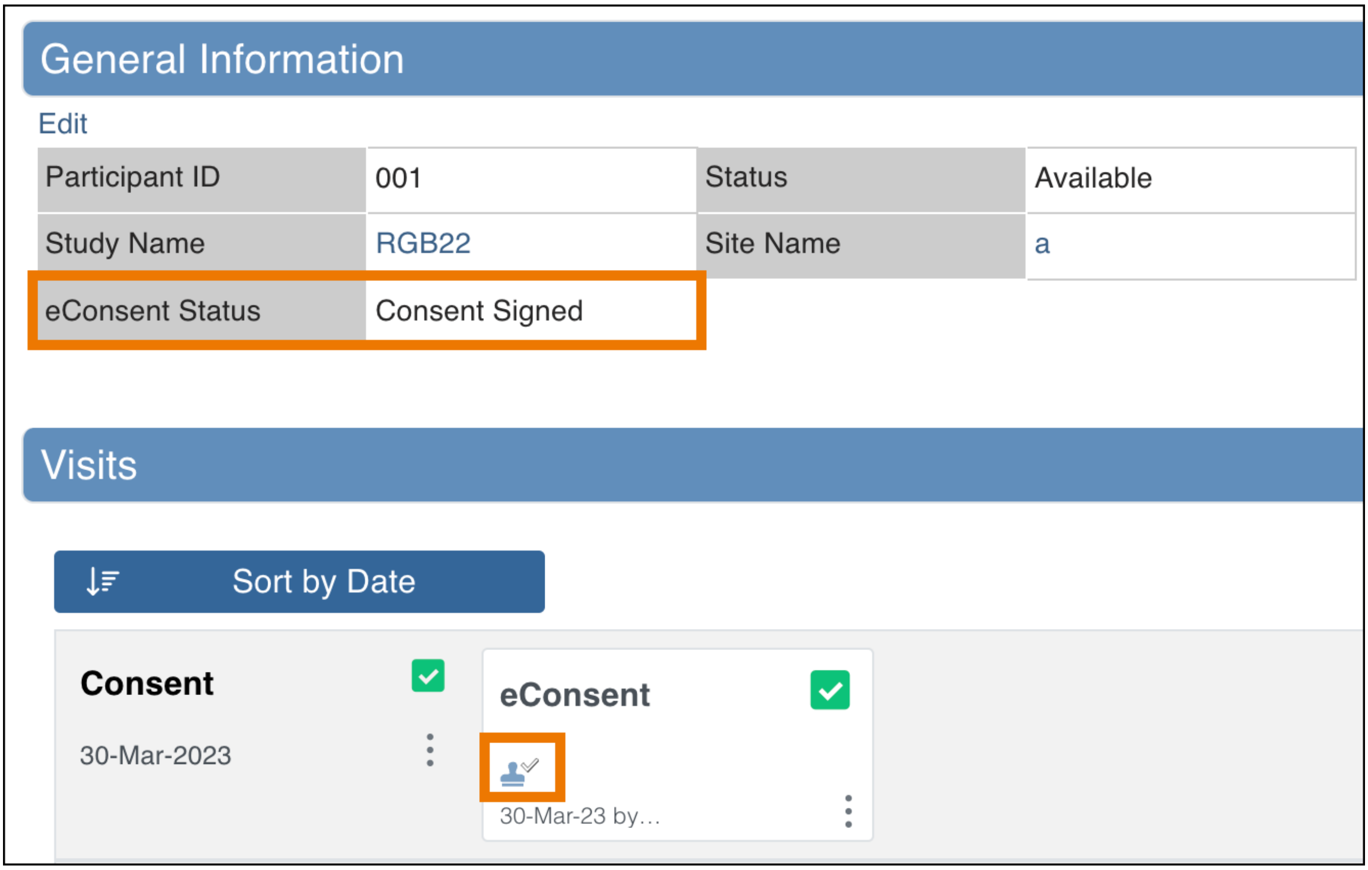
11.4 Consent in Study Runner

After the **Consent module** has been activated for your Study and at least one eConsent Form has been configured, you can use **Study Runner** to:

- Monitor Participant consent statuses
- Schedule eConsent Events to make consent Forms available to Participants

You can view eConsent statuses in two places:

- **Participant Matrix** – A separate column is displayed for each eConsent Form in the Study.
- **Participant Details Page** – Status appears in the **General Information** section and on the Form cards in the **Visits** section.



The following statuses may appear for eConsent Forms:

Icon	Status	Description
	Consent Not Signed	The Participant has not yet signed the eConsent Form.

	Consent Signed	The Participant has signed the eConsent Form, but it has not yet been countersigned by a site user (CRC or Investigator).
	Consent Countersigned	The Participant has signed the eConsent Form, and it has been countersigned by a site user (CRC or Investigator).
	Requires Reconsent	The Participant's previous consent was removed. This typically occurs when a new version of the eConsent Form is issued and a Data Manager has migrated the record to this new version, or if a site user (CRC or Investigator) has manually unconsented the form due to a process error. The Participant must provide consent again. **Note:** When an eConsent Form is set to *Requires Reconsent*, it is marked as *Data Entry Started* and reappears on the Participant's dashboard so the Participant can re-sign.

Scheduling and Managing eConsent Forms

Schedule an eConsent Form

For a Participant to see an eConsent Form on their dashboard, you must schedule the **Event** containing the Form.

Schedule the Event the same way you schedule any other Visit Event:

- From the **Participant Matrix**, or
- By clicking **Add New** on the **Participant Details** page.

For more information on scheduling events, refer to **Schedule an Event.**

Invite the Participant

To access the eConsent Form, the Participant must also be invited to the Study.

Once the Visit with the eConsent Form is scheduled **and** the Participant has been invited:

- The Participant can log in to their dashboard.
- The Participant can sign the eConsent Form.
- After signing, the Form is marked as **Completed**, and the eConsent status is updated in **Study Runner**.

For more information on inviting participants, refer to **Invite Participants** and **Automating Participant Access.**

View an eConsent Form

After the Event with an eConsent Form has been scheduled, the Form can be viewed by any user with permission.

- **Participant users** are the only ones who can check the box to sign the Form. It is read only for all other users.

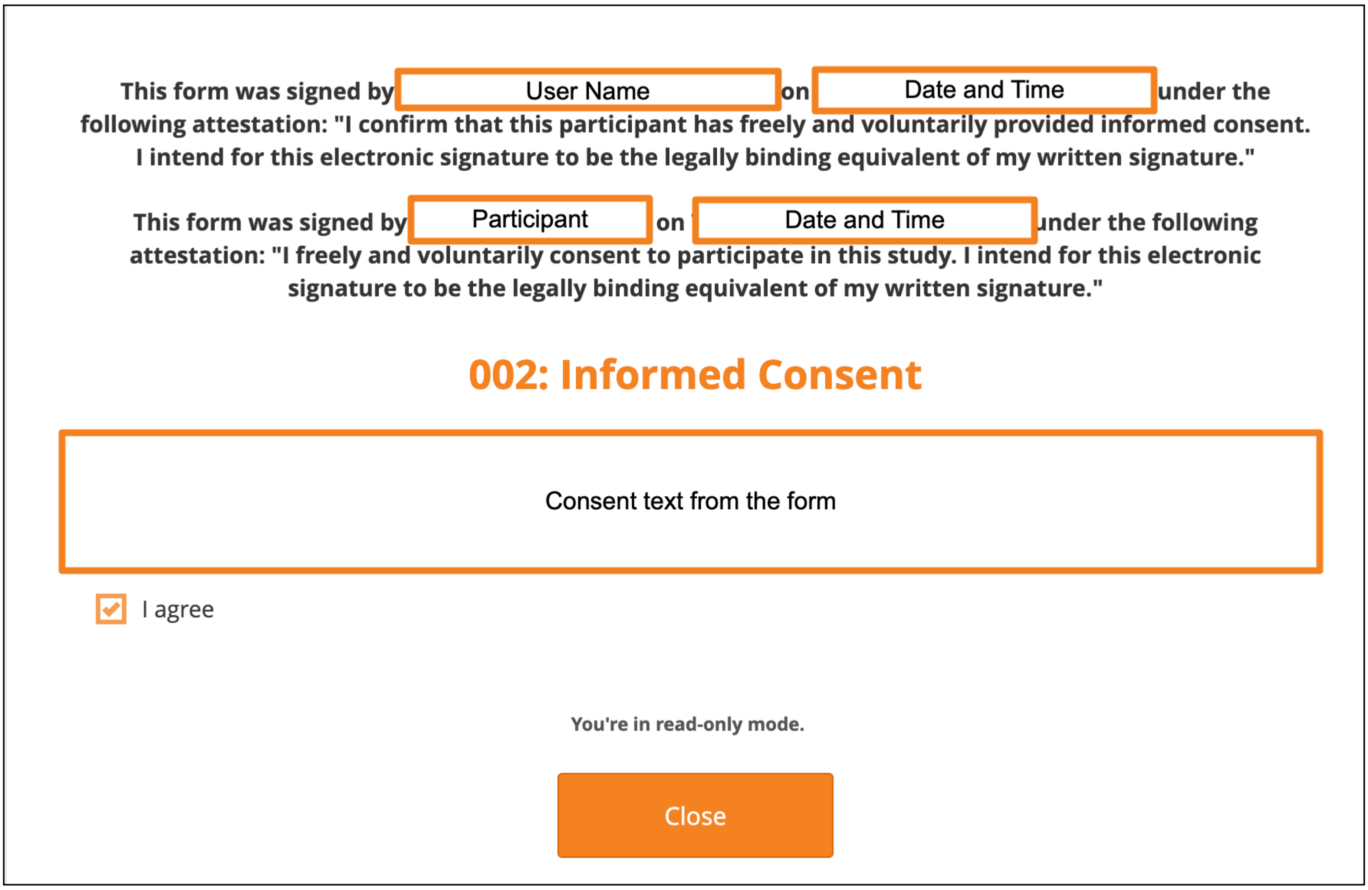
- Other users (e.g., CRCs, Investigators, Data Managers) can open the Form but cannot sign on behalf of the Participant.
- To open the Form:
  - Click the Visit Form card, or
  - Use the actions menu.

When viewing the Form, the top of the page displays signature information:

- When the Participant signed
- The Participant's name (visible only to CRCs and Investigators)
- Who countersigned and when the countersignature was added

 Note: A Form is not visible to the Participant until both conditions are met:

1. The Visit Event containing the eConsent Form is scheduled.
2. The Participant has been invited to the Study.



Countersign a Signed Consent

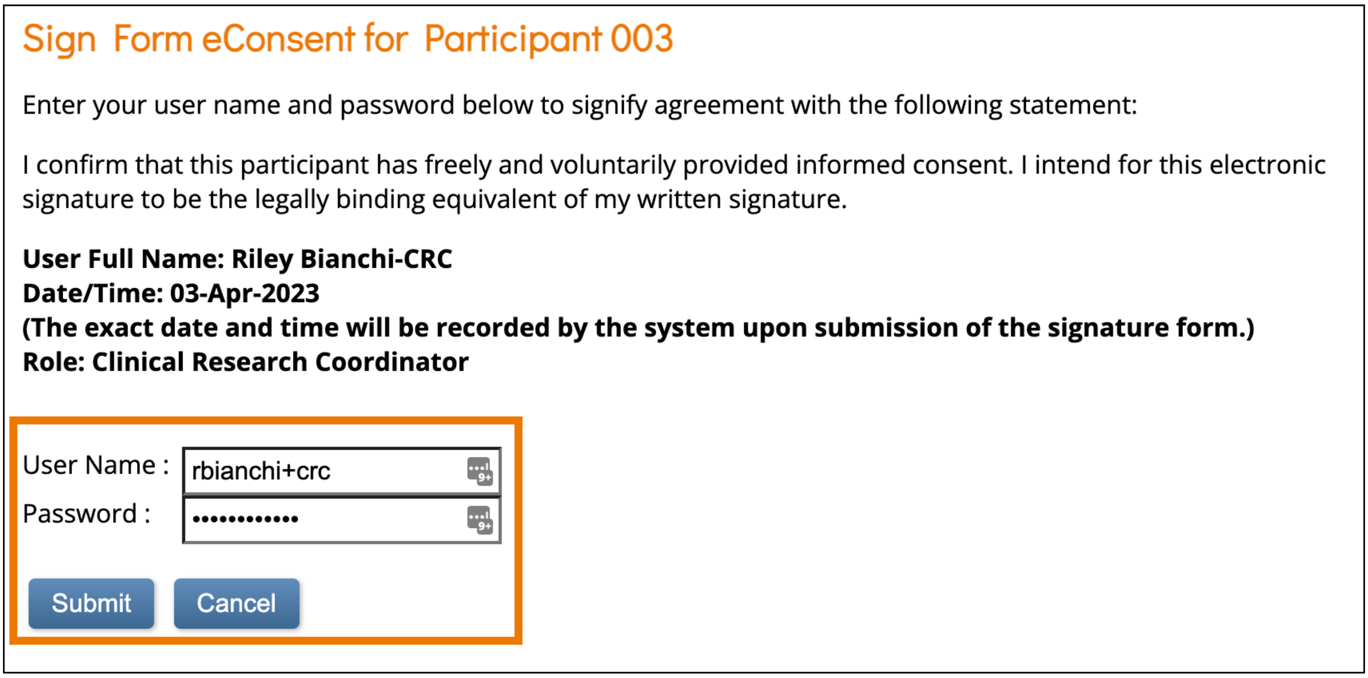
After a Participant signs an eConsent Form, its status is updated on both the **Participant Matrix** and the **Participant Details** page.
Clinical Research Coordinators (CRCs) and Investigators can then countersign.

To countersign:

1. On the signed eConsent Form card, open the **Actions** menu.
2. Select **Countersign**.

3. Enter your **Username** and **Password** to confirm.
4. Click **Submit**.

The eConsent status on the Form card updates to **Consent Countersigned**.



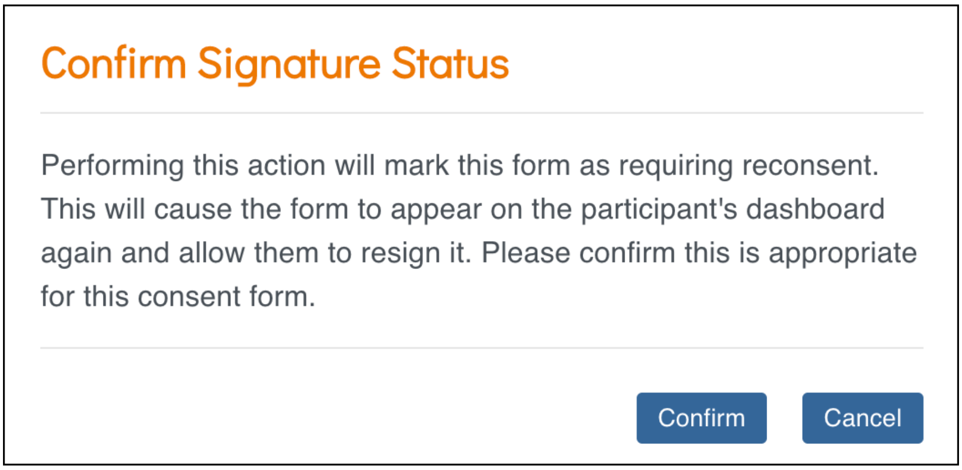
Unconsent a Signed Consent

You can also remove consent when a Participant must re-sign (for example, if the participant made a mistake completing the form).

To unconsent:

1. On the signed eConsent Form card, open the **Actions** menu.
2. Select **Unconsent**.
3. In the **Confirm Signature Status** window, review the message.
    - Performing this action will mark the Form as *Requires Reconsent*.
    - The Form will reappear on the Participant's dashboard for re-signing.
4. Click **Confirm**.

The Form's eConsent status updates to **Requires Reconsent** and the Form status changes from **Completed** to **Data Entry Started**.



 Warning: Once you unconsent a Form, the action cannot be reversed. The Participant must re-sign to restore consent.

 Note: The eConsent status in the **General Information** section of the **Participant Details** page is updated when the page is refreshed.

Migrating an eConsent Form to a New Version

When you migrate a Consent Form to a new version, OpenClinica updates the status and clears outdated data to maintain integrity and compliance.

Behavior during migration

- The Consent signature status is set to **Requires Reconsent**.
- The Form is cleared, removing all data except Participant contact fields.
- The Form status is reset to **Not Started**.
- You must enter a **Reason for Change (RFC)** to complete the migration.

Audit Log

- Both the *Migration* and *Clear* actions are recorded in the Audit Log.
- The RFC is stored with these records.
- For more details, see **Participant Audit Log**.

 Warning: Migrating to a new version permanently removes previously signed consent data. Participants must re-sign the updated Form.

Reassign

Reassigning a Participant transfers them to another site. After reassignment:

- The Participant is associated with the new site.
- Reporting, permissions, and workflow are updated.
- Existing Participant data remains intact.

Clear

Clearing a Form removes all active data. When you clear a Form:

- The Form status resets to **Not Started**.
- All associated queries are closed.
- Audit history is retained, but active data is permanently removed.