



# 5.1 Signing Participant Records

Use this page to learn how to apply electronic signatures to Participant records in OpenClinica.

**Roles: Investigators** (a site-level role) and **Data Specialists** (a study-level role) can sign Participant records. Custom roles based on these roles may also sign records.

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## Overview

You can sign Participant records at the following levels:

- Study Event level
- Participant level
- Bulk level (multiple Participants at one time)

Signing confirms that data entry and review are complete according to protocol and regulatory requirements.

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## Eligibility Requirements for Signing

**Event Eligibility** A Study Event is eligible for signature only when all of the following conditions are met:

- All **required Forms** in the Event are marked **Complete**.
- All **non-required Forms** are marked **Complete** or **Not Started**.
- The Study Event is in a final state: **Not Scheduled, Complete, Stopped, or Skipped**.

**Archived** or **Removed** records cannot be signed. **Participant Eligibility** A Participant record is eligible to be signed (individually or in bulk) only if **all Events** for that Participant meet the Event eligibility criteria listed above.

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## Electronic Signatures with SAML Single Sign-On (SSO)

**Note:** Behavior differs depending on whether SAML SSO is enabled in your OpenClinica environment.

- **SAML SSO enabled:** You sign records using a **Signature Code** and your OpenClinica username.
  - **SAML SSO not enabled:** You sign records using your OpenClinica username and password.
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## Signature Codes (SAML SSO Enabled)

When SAML SSO is enabled, Investigators, Data Specialists, and custom roles based on those roles must use a Signature Code. **Generate a Signature Code**

1. On the **Electronic Signature** screen, click **Send a new signature code to my email**.
2. OpenClinica generates a unique Signature Code and sends it to the email address associated with your user account.

## Signature Code Rules A Signature Code:

- Is never displayed within OpenClinica.
- Cannot be retrieved after it is sent.
- Can be reused for subsequent signings.
- Can be replaced at any time by generating a new code.

□ **Warning:** You are responsible for securely storing your Signature Code.

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## Sign a Study Event

You can initiate signing from multiple locations. **Option 1: From the Participant Matrix**

1. On the **Participant Matrix**, select the Event you want to sign.
2. From the drop-down list, select **Sign**. *The Sign option appears only if the Event is in a final state.*

The screenshot shows the 'Participant Matrix for New Test Site' interface. At the top, there are navigation icons, a page size selector set to '50', a 'Show More' button, a 'Select An Event' dropdown menu, and an 'Add New Participant' button. Below this is a table with columns: Sign, Participant ID, Eligibility & Consent, Exam, Treatment, Daily, Final Treatment, and Actions. The table contains several rows of participant data. A modal window is open over the row for participant 'a12345', showing details for the event 'Eligibility & Consent' which is '30-Nov-2021 completed'. The modal includes buttons for 'View', 'Edit', 'Remove', and 'Sign', with the 'Sign' button highlighted by a red rectangle.

Sign	Participant ID	Eligibility & Consent	Exam	Treatment	Daily	Final Treatment	Actions
<input type="checkbox"/>	a123	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> x4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Apply Filter Clear Filter
<input type="checkbox"/>	a1234	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> x2	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Search X Add
<input type="checkbox"/>	a12345	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> x2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Search X Add
<input type="checkbox"/>	DF-001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Search X Add
<input type="checkbox"/>	site001	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Search X Add

## Option 2: From the Participant Details Screen

1. Click the **View** icon for the Participant.
2. Locate the Event and select **Sign** from the **Actions** drop-down list.

## Participant Matrix for New Test Site

50 Show More Select An Event Add New Participant

Sign	Participant ID	Baseline	Exam	Treatment	Follow up	Final Treatment	Actions
<input type="checkbox"/>	a123	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/> <input type="checkbox"/>
<input type="checkbox"/>	a1234	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

Visits

Sort by Date Search form or visit name Add New

Treatment (1)	Exam (1)	Baseline
02-Nov-2021 Pre-Treatment Evaluation 18-Nov-21 by rbianchi+PI (1)	01-Nov-2021 Exam Vitals 18-Nov-21 by rbianchi+PI (1)	01-Nov-2021 Vitals 18-Nov-21 by rbianchi+PI (1)

Adverse Event

View Edit Remove Sign

### Option 3: From the Update Study Event Screen

1. Select **Edit** from the Event Actions menu.
2. On the **Update Study Event** screen, click **Sign Event** at the bottom of the page.

## Update Study Event

Participant ID: a1234

Event: Exam

Start Date/Time: 01-Nov-2021 \* [ ] : [ ] (DD-MMM-YYYY HH:MM)

End Date/Time: [ ] [ ] : [ ] (DD-MMM-YYYY HH:MM)

Status: completed

Submit Changes

Cancel

### Other Actions

Sign Event:

For **Common Events**, click the **Sign** icon in the **Actions** column on the Participant Details screen.

Adverse Events

Adverse Events [Add New](#)

Actions	Form Status <span>↑↓</span>	Last Updated <span>↑↓</span>	Updated By <span>↑↓</span>
	Completed	09-Jul-2024	klambert+crc@openclinica.com
		09-Jul-2024	klambert+crc@openclinica.com

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**Edit**  
**View**  
**Remove**  
**Sign**

Casebook

## Complete the Electronic Signature

- Review the **Electronic Signature** screen, which displays:
  - The attestation text
  - Your full name
  - A list of the records you are signing

**Sign Event** for Participant

Enter your user name and password below to signify agreement with the following statement:

"I confirm that the data for this participant are a full, accurate, and complete record of the observations recorded. I intend for this electronic signature to be the legally binding equivalent of my written signature."

**User Full Name:** XXXXXXXXXX

**Date/Time:**  
(The exact date and time will be recorded by the system upon submission of the signature form.)

**Role:** Data Specialist

- Enter your credentials:
  - SAML SSO enabled:** Enter your OpenClinica **username** and **Signature Code**.
  - Non-SSO environments:** Enter your OpenClinica **username** and **password**.
- Scroll to review the list of Forms in the Event and the query status for each Form.
- Click **Submit** to complete the signature.

**Outcome:** You are returned to the Participant Details screen, where the **Signed** icon appears on the

Event.

<b>Final Treatment</b> <span style="color: green;">✔</span>	<b>Exam</b> <span style="color: green;">✔</span>
04-Nov-2021	18-Nov-21 by rbianchi+PI (1)

## Forms Included in an Event Signature

**Note:** The attestation that appears when signing the Participant Event includes the forms listed above the User's Full Name on the Sign Event screen. The forms available to sign include all forms

for the event, except the following:

- Forms the signing user cannot access due to permission tags or the **Hidden** attribute of the form
- Forms that were started in the event occurrence but are currently **Archived** or **Removed**
- Forms in the event occurrence that were never started or have **Not Started** status

For more information about form access permissions, refer to [Managing Form Access and Permissions](#).

## Signature Errors (SAML SSO Enabled)

If a signing attempt is unsuccessful, the record remains unsigned and an error message is displayed:

- **Invalid Signature Code - If the code entered is not valid, the following message appears:** “The Signature Code you have provided is not valid. Please enter a valid code. You can use the link below to generate a new one.”
- **Expired Signature Code - If the code has expired, the following message appears:** “The Signature Code you have provided is expired. You can use the link below to generate a new one.”
- **Invalid Username** If an invalid username is entered, the record is not signed and an invalid username message is displayed.

□ **Note:** Users must correct the error by entering a valid code and/or username. Signature codes can be regenerated using the “**Send a new signature code to my email**” link.

## Sign Participant Records for All Events for a Participant

If all Events for a Participant are in a final state (**Not Scheduled, Complete, Stopped, or Skipped**), you can sign the entire Participant record.

- On the **Participant Matrix**, click **Sign** to sign all eligible Events for that Participant.

**Participant Matrix for New Test Site**

50 Show More Select An Event Add New Participant

Sign	Participant ID	Eligibility & Consent	Exam	Treatment	Daily	Final Treatment	Actions
<input type="checkbox"/>							Apply Filter Clear Filter
<input type="checkbox"/>	a123	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> x4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
<input type="checkbox"/>	a1234	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> x2	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>
<input type="checkbox"/>	a12345	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> x2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

## Bulk Sign Multiple Participant Records for All Events

When multiple Participants are eligible for signing:

- A checkbox appears in the **Sign** column.

- The **Sign** option is also available in the **Actions** column.

Select multiple Participants using the checkboxes, then complete the signing process to apply signatures in bulk.

**Participant Matrix for New Test Site**

50 Show More Select An Event Add New Participant

Sign	Participant ID	Eligibility & Consent	Exam	Treatment	Daily	Final Treatment	Actions
<input type="checkbox"/>							Apply Filter Clear Filter
<input type="checkbox"/>	a123	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> x4	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
<input type="checkbox"/>	a1234	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> x2	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
<input type="checkbox"/>	a12345	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> x2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

### Multiple User Signatures

Multiple users can sign an Event, so even if an Event has already been signed, the **Sign** action will still be available. If there are multiple signatures, all active signatures that have been added since the Event last became signed will display on the Form as well as in the Audit Log.

### When Events Become Unsigned

An Event becomes unsigned if any of the following occur:

- A user makes changes to an item on a Form after the Form was signed.
- The Event status was changed from **Completed**, **Stopped**, **Skipped** or **Not Scheduled** after being signed. (This also changes the Participant status from **Signed** to **Available** and the Event Status to **Completed**.)
- A user archives/unarchives the Form, unless the Form had a status of **Not Started**.
- A user removes/restores the Form.

**Note:** Changing the version of a Form will only unsign the Form if a user changes data.

### Cancel a Signature

You can cancel the signing process at any time. **Result:** The record remains unsigned and no signature is applied.

Approved for publication by Kate Lambert. Signed on 2026-06-04 1:56PM

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