



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](#).

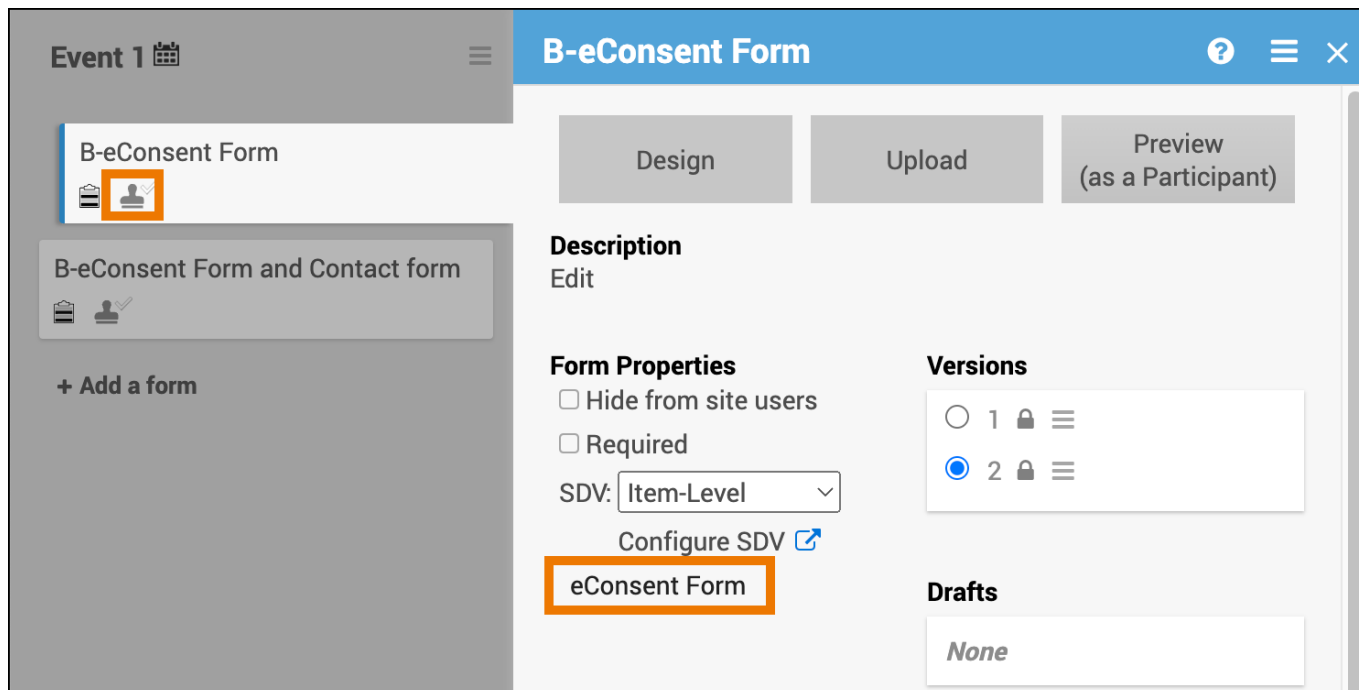
Once OpenClinica Consent has been activated, Data Managers can designate Forms within non-repeating Visit Events as eConsent Forms using the [Form Template](#).

□ **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.