

Castor

Castor eConsent Study Admin User Guide

Version 2022.5

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1. Register an account

Before you are able to access your eConsent study you will first need to be invited and create an account for eConsent.

Invited users will receive an email with a link.

You've received a new Castor eConsent invitation



Castor eConsent <no-reply@castorconsent.com>



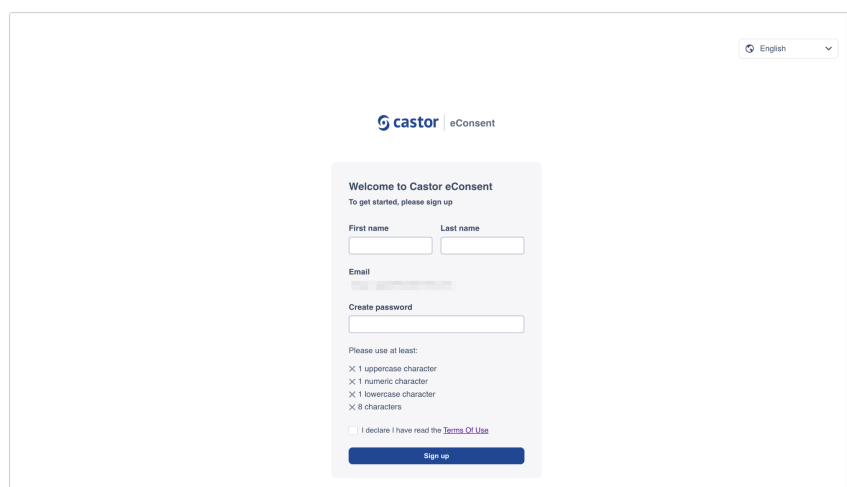
You've received a new Castor eConsent invitation

You have been invited to join the study team for 'Castor eConsent' in Castor eConsent.

To join the study please click the button below.

[Join the study](#)

By clicking the 'Join the Study' link provided in the email, you will be directed to the registration page:



The screenshot shows the Castor eConsent registration page. At the top right, there is a language dropdown menu set to 'English'. The main heading is 'Welcome to Castor eConsent' with the subtext 'To get started, please sign up'. Below this, there are input fields for 'First name' and 'Last name', followed by an 'Email' field. A 'Create password' field is also present. Underneath the password field, there are requirements: 'Please use at least: 1 uppercase character, 1 numeric character, 1 lowercase character, and 8 characters'. At the bottom, there is a checkbox for 'I declare I have read the Terms Of Use' and a 'Sign up' button.

You will need to accept the Terms of Use and provide the following details when registering the account:

- First name
- Last name
- Email will be automatically pre-filled
- Create password

After filling out the details and accepting the Terms of Use, click on the 'Sign up' button to complete the registration.

Should you already have an account registered in eConsent, you will be directed to the eConsent login page where you can log in with your eConsent credentials.

2. Log In

In order to access your eConsent study after registration has concluded you will need to access the following url's bases on the location of your study, US or Europe:

- US eConsent - <https://us.castorconsent.com/>
- EU eConsent - <https://eu.castorconsent.com/>

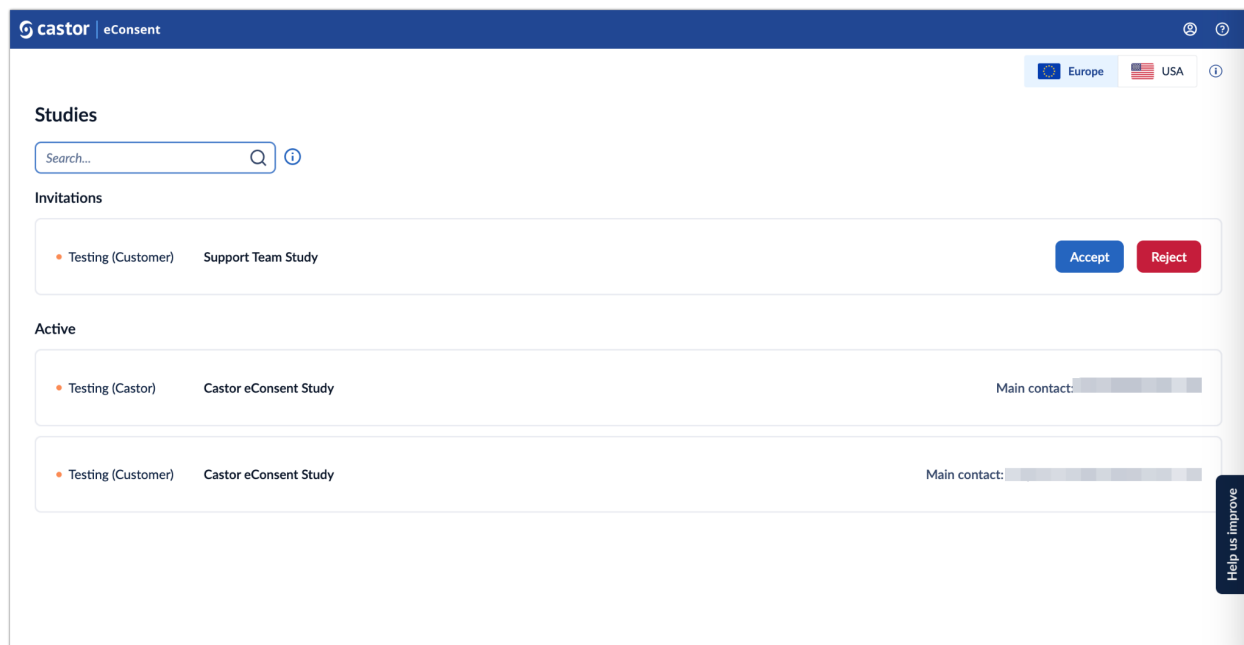
Study data is only stored on one of these servers and only one server location can be accessed at a time. If you don't see any studies listed please make sure to check our other server location.

You can toggle between the two study locations by selecting the Europe or USA icons at the top of the page.

3. Open a study

After logging in, the 'Studies' overview will be displayed with two sections, 'Invitations' and 'Active'. The 'Invitations' section will only appear if you have been sent an invitation and have not yet accepted or rejected the invitation.

Before accessing any studies you will first need to accept the invitation by pressing the 'Accept' button. Rejecting the invitation cannot be undone and you will need to contact the study admin to request a new invite.

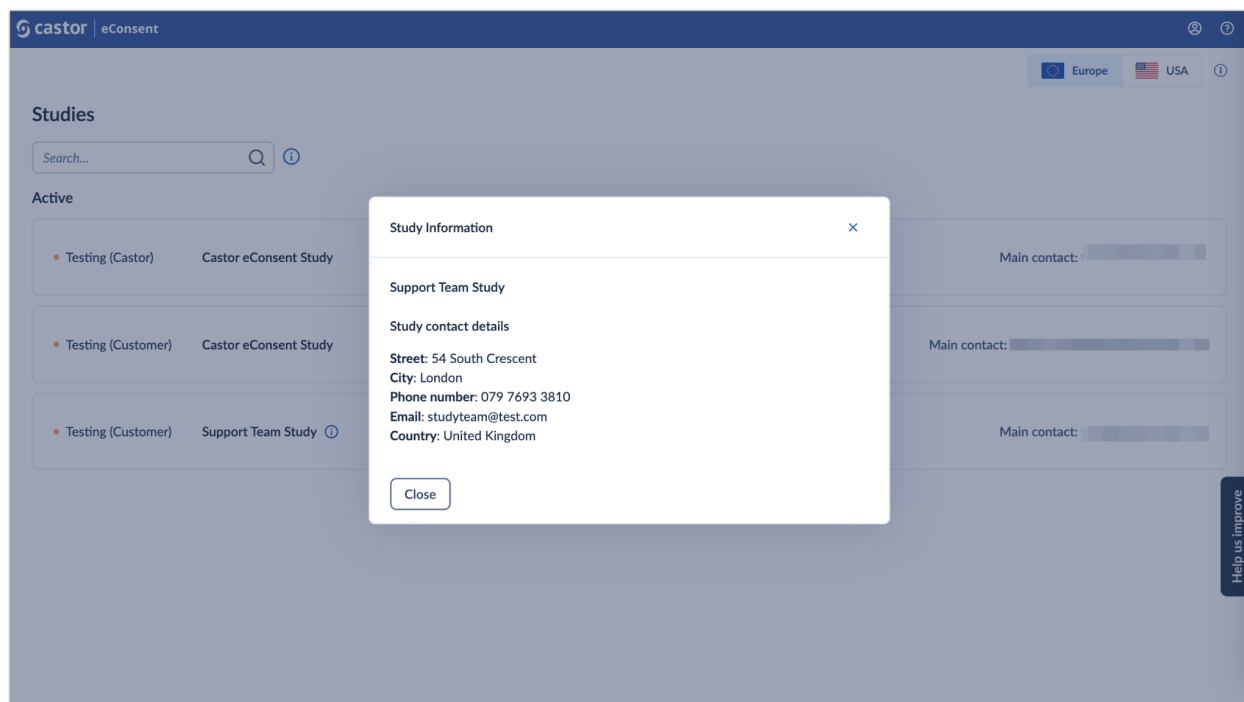


Studies overview consists of the following elements:

- **Servers:** Here the data storage locations are displayed. There are two server locations available: Europe and the United States. Study data is only stored on one of our servers and only one server location can be accessed at a time. If you don't see any studies please make sure to check a different server location.
- **Search bar:** it is possible to search by organization name, study contact email address or study name
- **Invitations:** If you are invited to a study, but you have not accepted the invite yet, the study will be listed in the top panel. It is possible to either accept or reject an

invitation to a study. Once you have accepted the invitation, you will be able to open a study.

- **Active:** once you have accepted an invitation to a study, it will appear in the 'Active' list. The list displays all studies you have access to. For each study, the following information is shown:
 - **Status:** Testing (Castor), Testing (Customer), Live. Read more about what each status means in the article: [Study status in eConsent](#)
 - **Study title:** name of the study
 - **Main contact:** main contact of the study. If the main contact has been invited to the study, but have not accepted the invitation yet, the status will be 'Main contact invited'
 - **Study information:** by clicking on the(i) icon, it is possible to view additional study information



Studies for which an invitation has been accepted will appear in the 'Active' section and it is possible to access the study by clicking on the study row.

4. Study Settings

After opening the study, on the left hand side of the screen you will see the navigation panel.

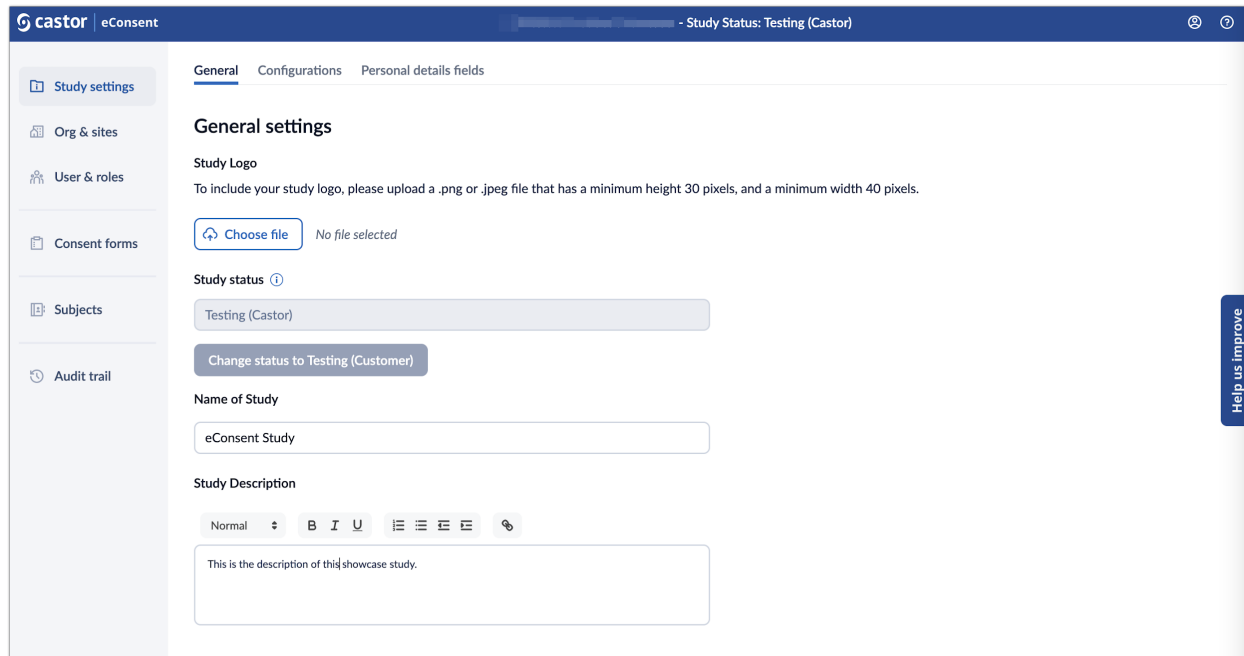
The 'Study settings' tab allows configuring the main study details. The tab contains the following sub-tabs:

- General
- Configurations
- Personal details fields

Below we will go into detail about each sub-tab's options.

4.1 General settings

Use the General settings to **configure settings that cover basic aspects of your study**, for example the study title and logo, study description. This is also the tab that you see when you open your study.



General settings

Study Logo
To include your study logo, please upload a .png or .jpeg file that has a minimum height 30 pixels, and a minimum width 40 pixels.

[Choose file](#) No file selected

Study status ⓘ
Testing (Castor)

[Change status to Testing \(Customer\)](#)

Name of Study
eConsent Study

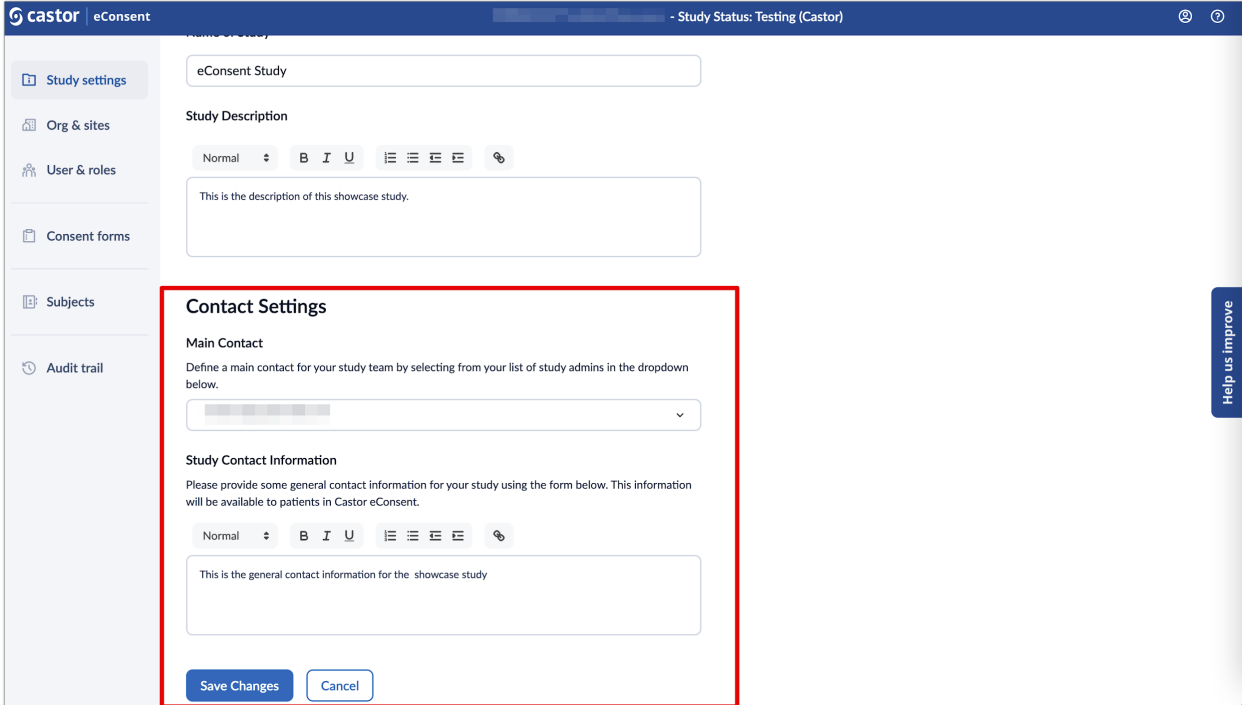
Study Description
Normal ⓘ B I U ☰ ☷ ☹ ☲ ☳ ☴ ☵ ☶ ☷ 🔗

This is the description of this showcase study.

- **Study logo:** To include your study logo, please upload a .png or .jpeg file that has a height between 30 and a minimum width 40 pixels. To remove the logo, click on the 'Clear' button.
- **Study status:** This field displays the study status information. A study goes through the following statuses: Testing (Castor), Testing (Customer), Live. To learn more about what each status means, read the article 'Study status'.
- **Name of the study:** The title of your study.
- **Study description:** Description of the study. The study description will be displayed to patients in Castor eConsent.

4.1.1 Contact settings

In the 'Contact Settings' section, you can add some general contact information for your study. This information will be available to patients in Castor eConsent.



Study settings

eConsent Study

Study Description

Normal B I U [List Bulleted] [List Numbered] [List Task] [Link]

This is the description of this showcase study.

Contact Settings

Main Contact
Define a main contact for your study team by selecting from your list of study admins in the dropdown below.

[Dropdown menu]

Study Contact Information
Please provide some general contact information for your study using the form below. This information will be available to patients in Castor eConsent.

Normal B I U [List Bulleted] [List Numbered] [List Task] [Link]

This is the general contact information for the showcase study

Save Changes **Cancel**

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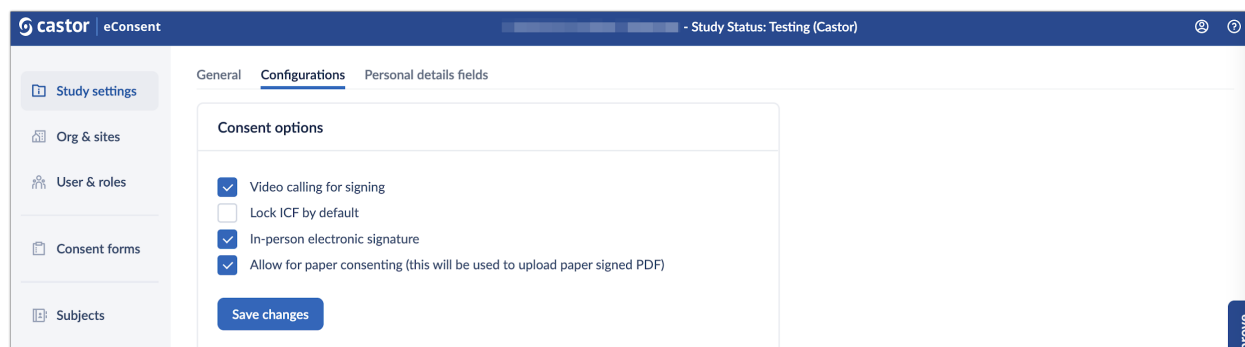
- **Main contact:** This field allows you to add a main contact for your study team by selecting them from your list of study admins in the dropdown. The main contact is visible for study team members only.
- **Study contact information:** This field allows adding some general contact information for your study. This information will be visible to patients in Castor eConsent when they login and access your study.

4.2 Configurations

By accessing the 'Configurations' tab, you are able to define properties related to consent, screening and subject ID's for your study.

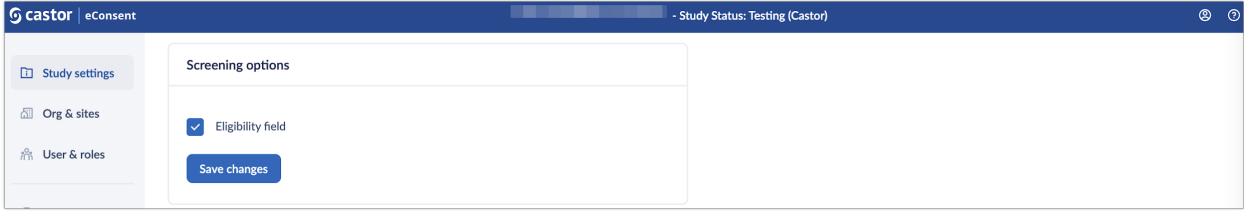
4.2.1 Consent options

The 'Consent options' section allows to enable the following features:



- **Video calling for signing:** This will activate the possibility to perform a video call.
- **Lock ICF by default:** When the ICF is locked by default, it will first have to be unlocked by a study team member to allow for the participant to sign. To enable or disable these features, check the checkbox accordingly and click the button 'Save changes' to apply the changes.
- **In-person electronic signature:** This feature allows signing of the consent forms in-person.
 - The in-person signing process is started by the user that is conducting the consent procedure by selecting the 'Sign in-person' ICF option from the subject.
 - The study team member that is conducting the consent procedure first has to confirm the subject's identity before the in-person signing could kick off. This identity confirmation step is logged in the audit trail.
 - When handing over the device to the subject, the subject can directly sign the ICF without having to create an eConsent account.
- **Allow for paper consenting (this will be used to upload paper signed PDF):** when this setting is enabled, study admins can create paper ICFs which will allow for uploading of a signed PDF.

4.2.2 Screening options

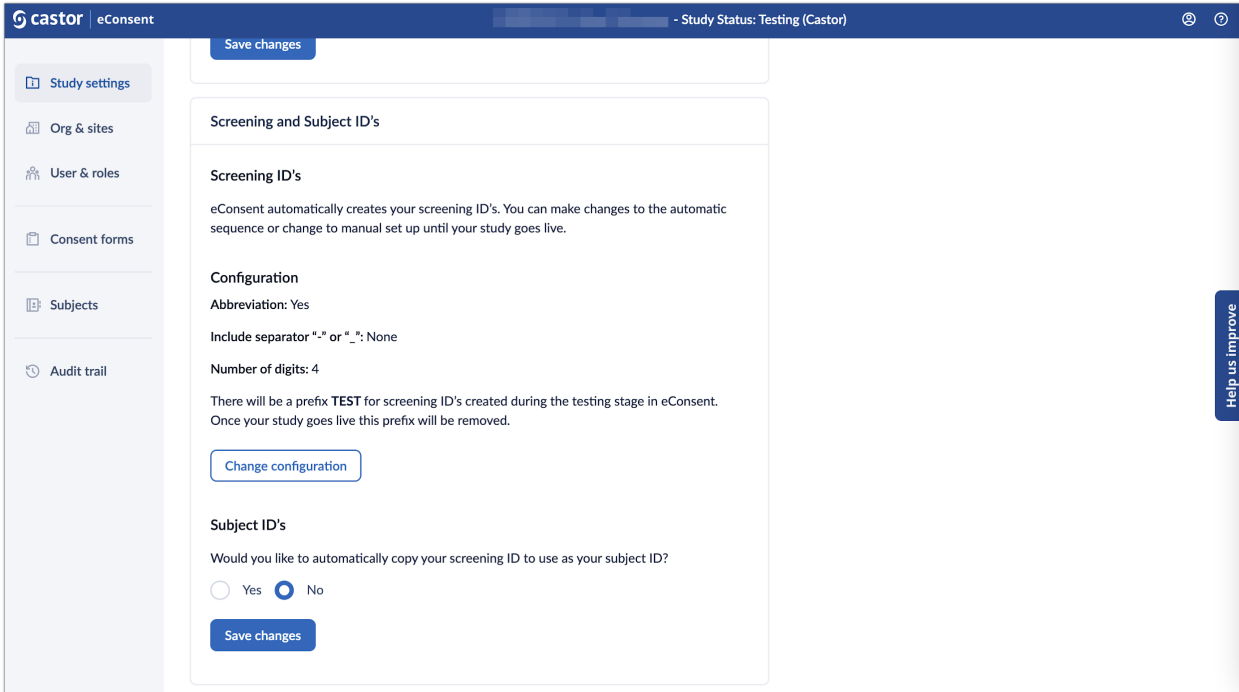


Subject eligibility can be captured in eConsent using the 'Screening options' section:

- A study setting '**Eligibility field**' allows the collection of your subject eligibility status (available statuses are: pending, pass, and fail) including the timestamp of when this was updated.
- The eligibility status can be updated manually, or automatically based on the outcome of a screening survey that is filled in by the subject.

4.2.3 Screening and Subject ID's

It is possible to configure screening ID and subject ID for your study.

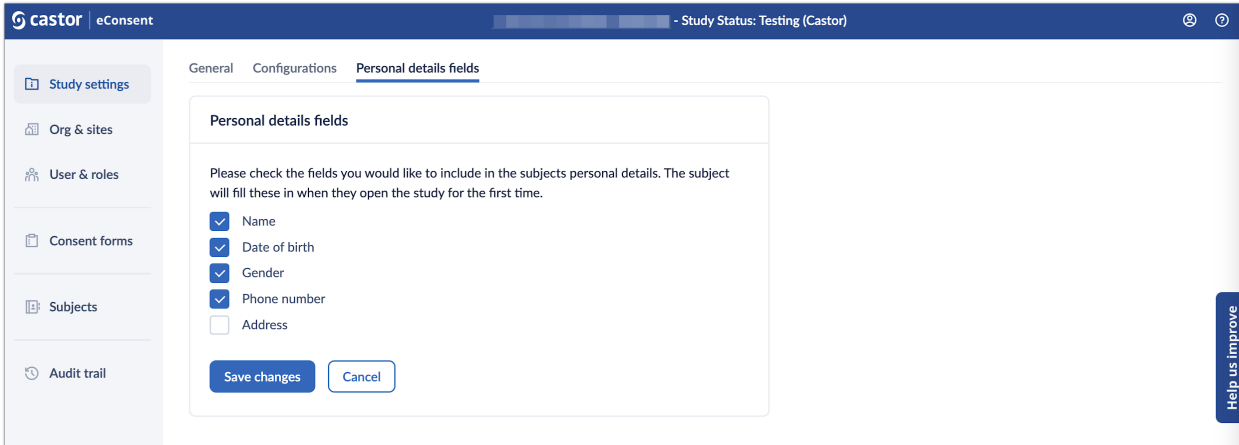


- **Screening ID's:**
 - eConsent automatically creates your screening ID's. You can make changes to the automatic sequence or change to manual set up until your study goes live.
 - To configure the Screening ID's, click on the 'Change configuration' button, set the field 'Set up automatic eConsent screening ID sequence?' to 'Yes' and define how the ID's should be configured.
 - Site abbreviation, a separator, and the number of digits are configurable when enabling automatic screening ID generation. When this feature is enabled, no manual entry of screening ID's is allowed.
 - Click on the 'Set screening ID' button to save the changes.

- **Subject ID's:**
 - A study setting to let eConsent automatically generate screening ID's is added. Site abbreviation, a separator, and the number of digits are configurable when enabling automatic screening ID generation. When this feature is enabled, no manual entry of screening ID's is allowed.
 - It is possible to copy over the screening ID into the subject ID for studies that do not make a distinction between these two identifiers by setting the field 'Would you like to automatically copy your screening ID to use as your subject ID?' to 'Yes'.

4.3 Personal details fields

Additional personal details of the subjects can be collected. Data to be collected can be configured in the section 'Personal details fields'. This data is collected on a per study level, and subjects will be prompted to fill in the data. You can also add and edit this information.



castor | eConsent - Study Status: Testing (Castor)

General Configurations **Personal details fields**

Personal details fields

Please check the fields you would like to include in the subjects personal details. The subject will fill these in when they open the study for the first time.

- ☒ Name
- ☒ Date of birth
- ☒ Gender
- ☒ Phone number
- ☐ Address

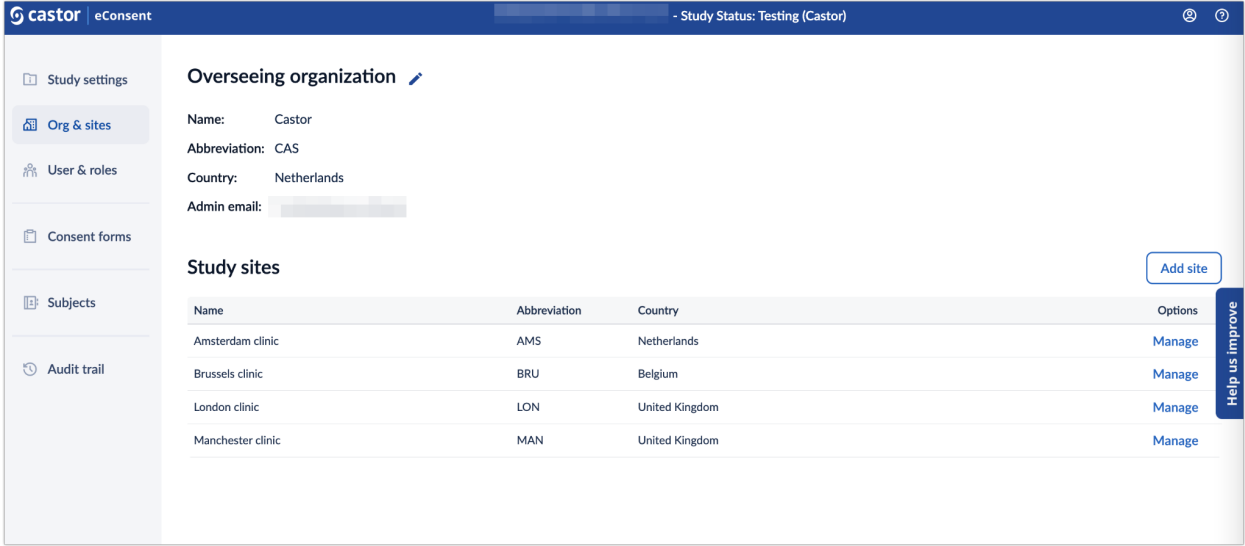
[Save changes](#) [Cancel](#)

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- The following subject information can be collected: Name, Date of birth, Gender, Phone number, Address.
- When opening the study as a subject, and there are personal details requested, the subject is prompted to fill in and submit their data before continuing. Subjects can always review their submitted data via the 'Study Profile' tab.
- Changes concerning the subject's personal details are logged in the audit trail.

5. Managing overseeing organization and sites

The 'Overseeing Organization & Sites' overview allows changing the details of the main organization, adding new study sites and managing existing ones.



Overseeing organization ✎

Name: Castor
 Abbreviation: CAS
 Country: Netherlands
 Admin email: [redacted]

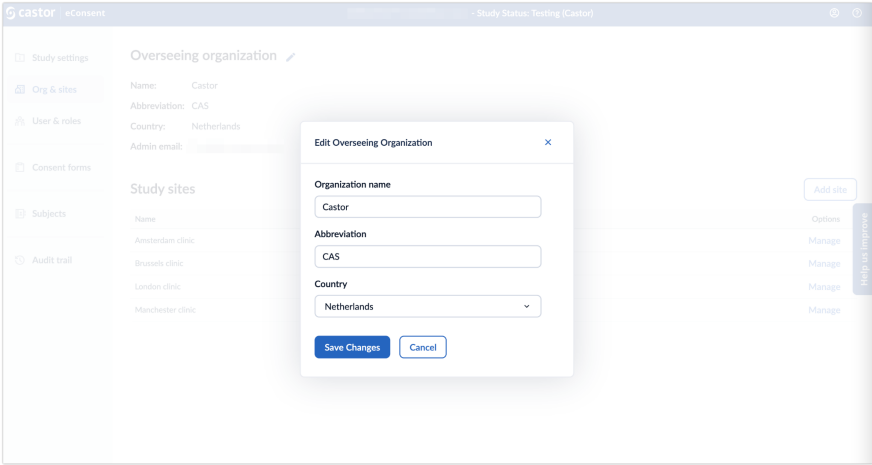
Study sites Add site

Name	Abbreviation	Country	Options
Amsterdam clinic	AMS	Netherlands	Manage
Brussels clinic	BRU	Belgium	Manage
London clinic	LON	United Kingdom	Manage
Manchester clinic	MAN	United Kingdom	Manage

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5.1 Overseeing Organization

In this section, you can view the following details related to the overseeing organization: Name, Abbreviation, Country, Admin email. It is possible to edit these details, with the exception of the admin email, by clicking on the pencil icon to the right of the Overseeing organization header.



Overseeing organization ✎

Name: Castor
 Abbreviation: CAS
 Country: Netherlands
 Admin email: [redacted]

Study sites Add site

Name	Abbreviation	Country	Options
Amsterdam clinic	AMS	Netherlands	Manage
Brussels clinic	BRU	Belgium	Manage
London clinic	LON	United Kingdom	Manage
Manchester clinic	MAN	United Kingdom	Manage

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Edit Overseeing Organization ✕

Organization name

Abbreviation

Country

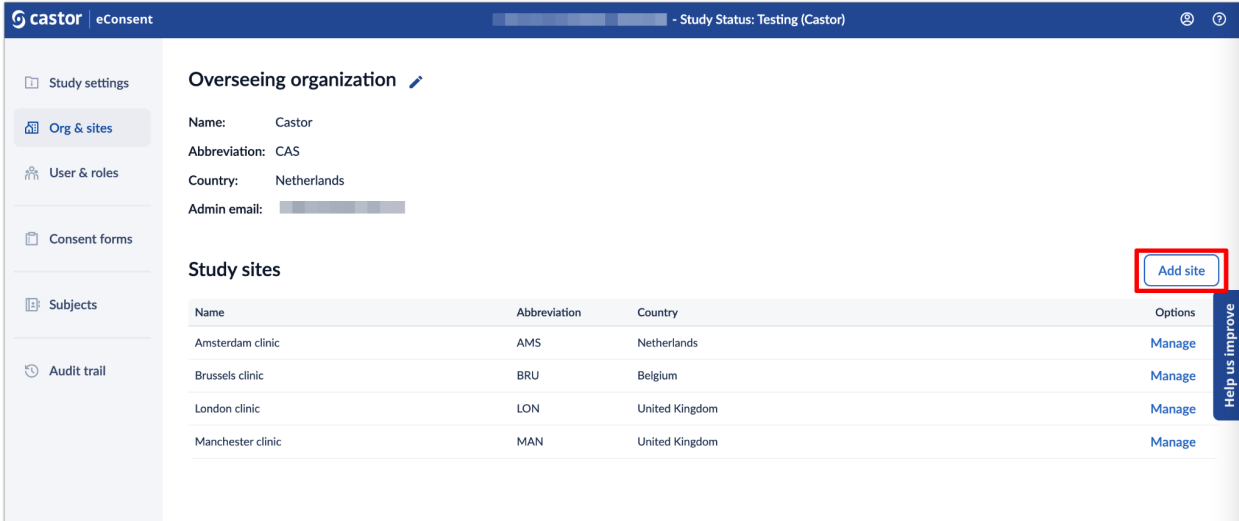
[Save Changes](#) [Cancel](#)

5.2 Adding and editing study sites

In the 'Org & sites' section, it is possible to manage existing sites and add new sites in the study. Please make sure that you have the 'Study Admin' rights before proceeding.

To add a site:

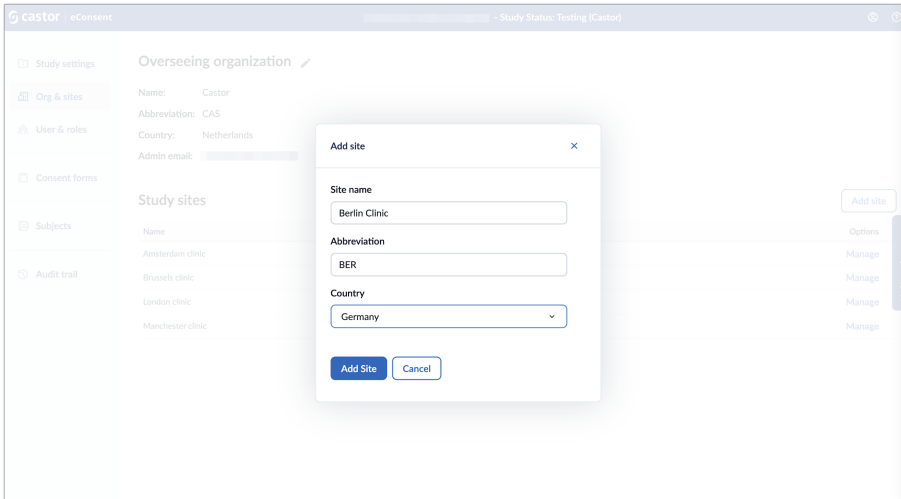
1. Click the 'Add site' button:



The screenshot shows the 'Org & sites' section of the Castor eConsent interface. The left sidebar contains navigation links: Study settings, Org & sites (selected), User & roles, Consent forms, Subjects, and Audit trail. The main content area is divided into two sections: 'Overseeing organization' and 'Study sites'. The 'Overseeing organization' section displays fields for Name (Castor), Abbreviation (CAS), Country (Netherlands), and Admin email. The 'Study sites' section contains a table with columns: Name, Abbreviation, Country, and Options. The table lists four existing sites: Amsterdam clinic (AMS, Netherlands), Brussels clinic (BRU, Belgium), London clinic (LON, United Kingdom), and Manchester clinic (MAN, United Kingdom). Each site has a 'Manage' link in the Options column. A red box highlights the 'Add site' button located at the top right of the 'Study sites' section.

Name	Abbreviation	Country	Options
Amsterdam clinic	AMS	Netherlands	Manage
Brussels clinic	BRU	Belgium	Manage
London clinic	LON	United Kingdom	Manage
Manchester clinic	MAN	United Kingdom	Manage

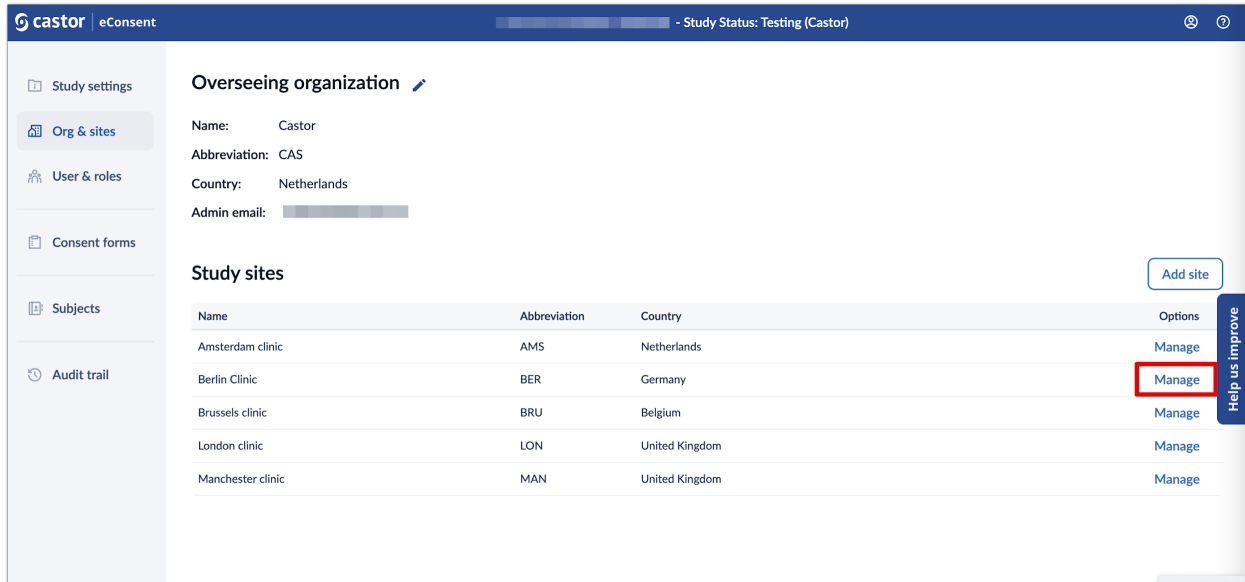
2. Enter the site details such as Site name, Abbreviation, and Country
3. Click 'Add site' to save the changes:



The screenshot shows the 'Add site' dialog box overlaid on the 'Org & sites' section. The dialog box contains three input fields: 'Site name' (with 'Berlin Clinic' entered), 'Abbreviation' (with 'BER' entered), and 'Country' (with 'Germany' selected from a dropdown menu). At the bottom of the dialog box are two buttons: 'Add Site' and 'Cancel'.

To edit the site details or to delete a site:

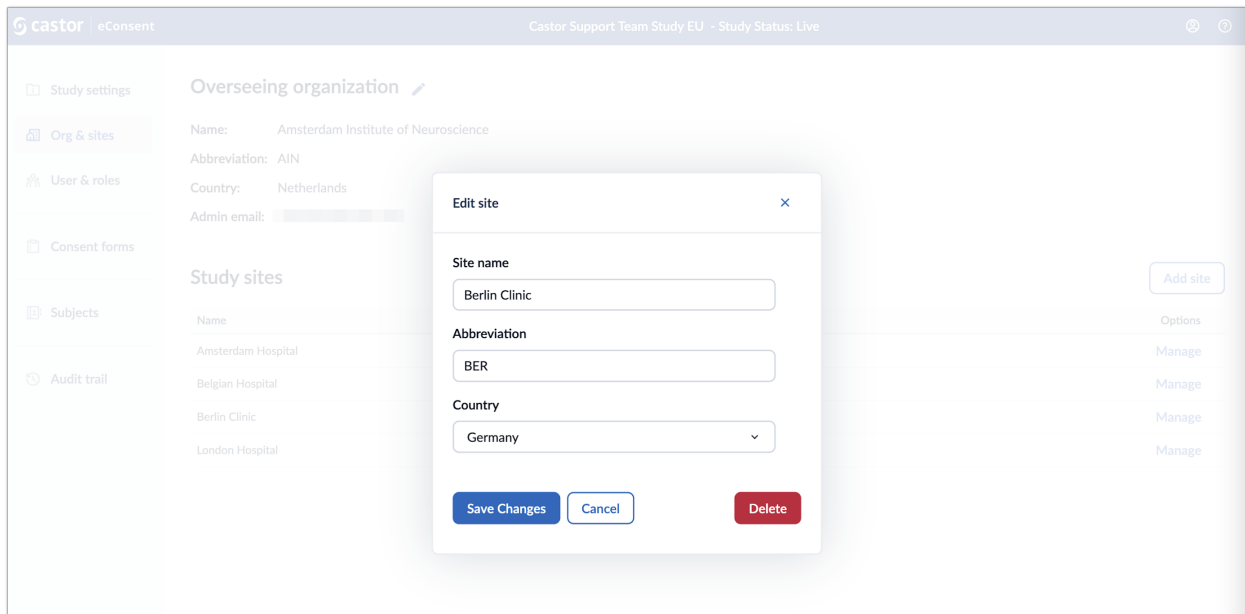
1. Click on the 'Manage' icon in the 'Options' column.



The screenshot shows the 'Study sites' section of the Castor eConsent interface. The 'Study sites' table lists several sites, and the 'Manage' link for the 'Berlin Clinic' is highlighted with a red box. The table has the following data:

Name	Abbreviation	Country	Options
Amsterdam clinic	AMS	Netherlands	Manage
Berlin Clinic	BER	Germany	Manage
Brussels clinic	BRU	Belgium	Manage
London clinic	LON	United Kingdom	Manage
Manchester clinic	MAN	United Kingdom	Manage

2. A pop-up window will appear where you can adjust the site details accordingly.



The screenshot shows the 'Edit site' pop-up window. The window contains the following fields and buttons:

- Site name:** Berlin Clinic
- Abbreviation:** BER
- Country:** Germany (dropdown menu)
- Buttons:** Save Changes, Cancel, Delete

3. After editing the site information, click on 'Save changes' to apply the changes.

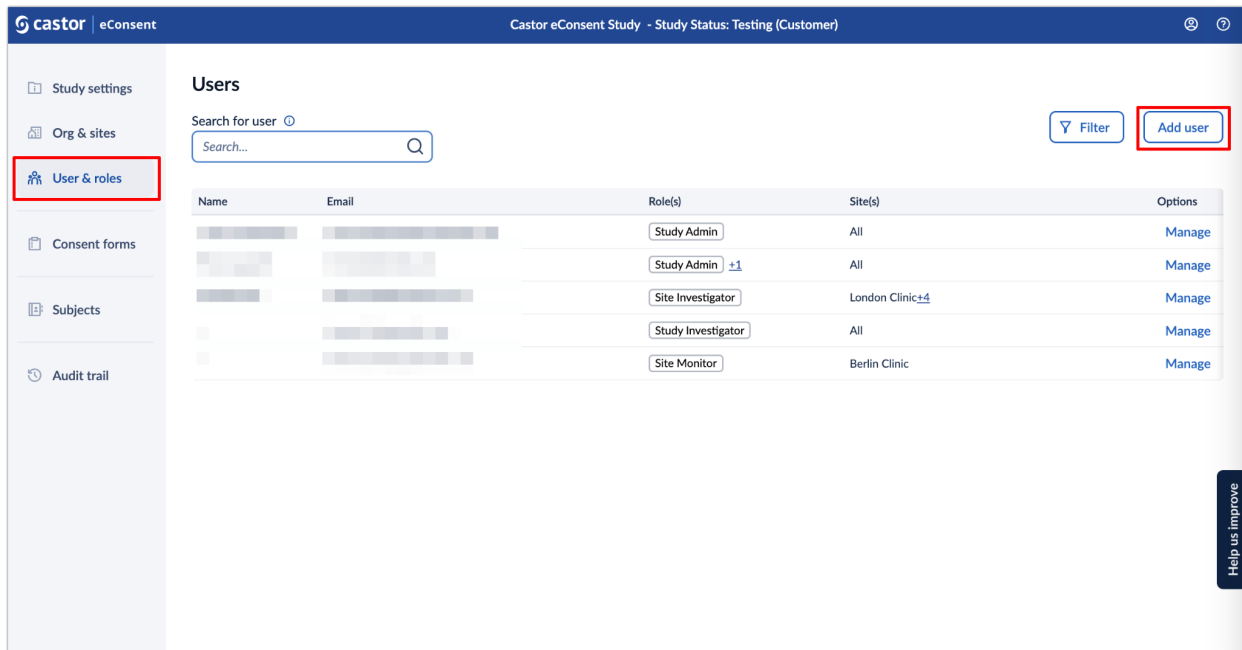
4. If you would like to delete the site, click on the 'Delete' button. A confirmation message will appear. Keep in mind that it is not possible to delete a site, if it is associated with a subject, an informed consent form or a user.

6. User and roles

The User & Roles page displays the names, emails, roles, and sites for everyone with access to your study. From this page, it is possible to revoke access, view pending study invitations, and re-send or cancel invitations.

6.1 Adding a user

1. Navigate to the 'Users' tab.
2. Click on 'Add user' to add someone to the study.



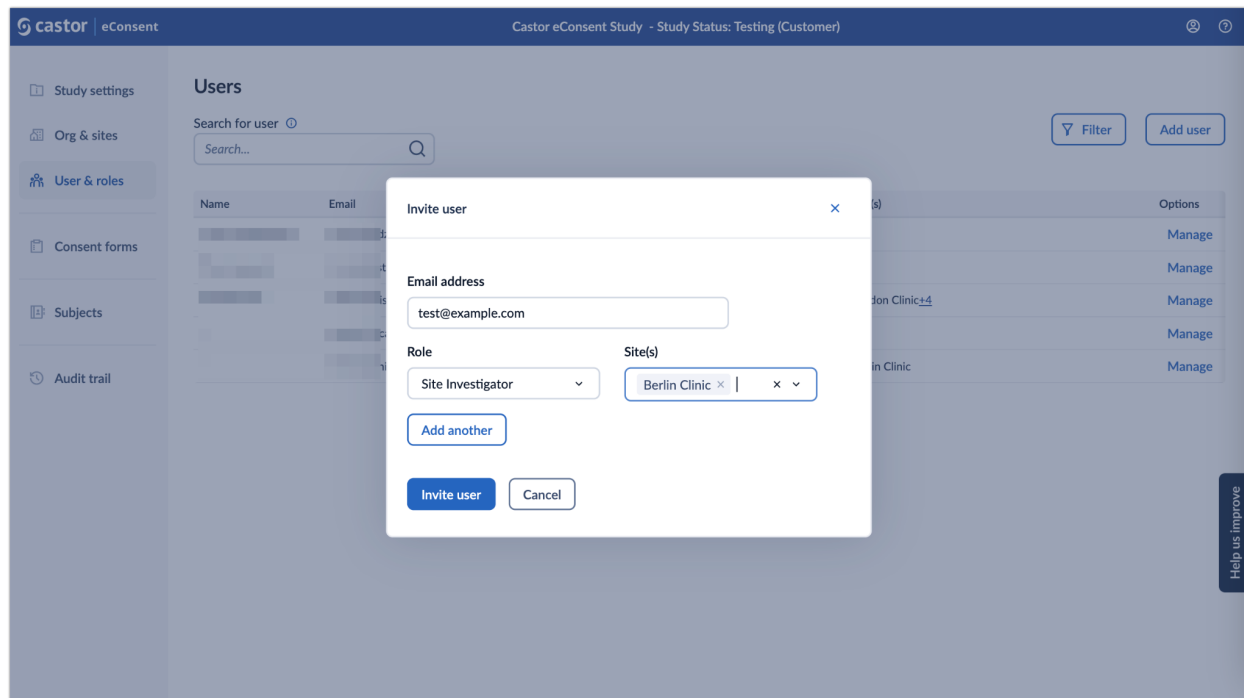
Users

Search for user

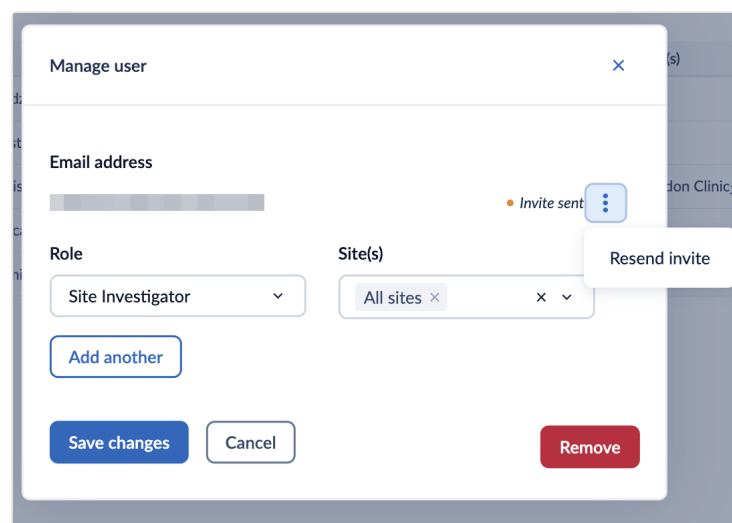
Name	Email	Role(s)	Site(s)	Options
[Redacted]	[Redacted]	Study Admin	All	Manage
[Redacted]	[Redacted]	Study Admin +1	All	Manage
[Redacted]	[Redacted]	Site Investigator	London Clinic +4	Manage
[Redacted]	[Redacted]	Study Investigator	All	Manage
[Redacted]	[Redacted]	Site Monitor	Berlin Clinic	Manage

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3. A pop-up will be shown. Fill in the user's email address and select a site to which the user belongs and assign the role. You can also click on the 'Add another' button to assign another role to the user.



4. Press 'Invite user'. The added users will be shown in the Users list.
5. To check the status of the invite, you can click on the 'Manage' button. There are two statuses available - Invite sent or Invite rejected. Click on the three dots next to the invite status to resend the invitation.



6. If you would like to remove the user, click on the 'Remove' button.

6.2 User roles

The user role(s) can be assigned at the Study level, which means that the role will be applicable for all sites in the study. This includes the role(s) of Study Admin, Study Monitor, Study Investigator, and Study Read-only. Alternatively, you can assign site-specific user roles which will only be linked to selected site(s). These include the role(s) of Site Admin, Site Investigator, and Site Monitor.

It is possible to choose from the following list of the default [roles](#):

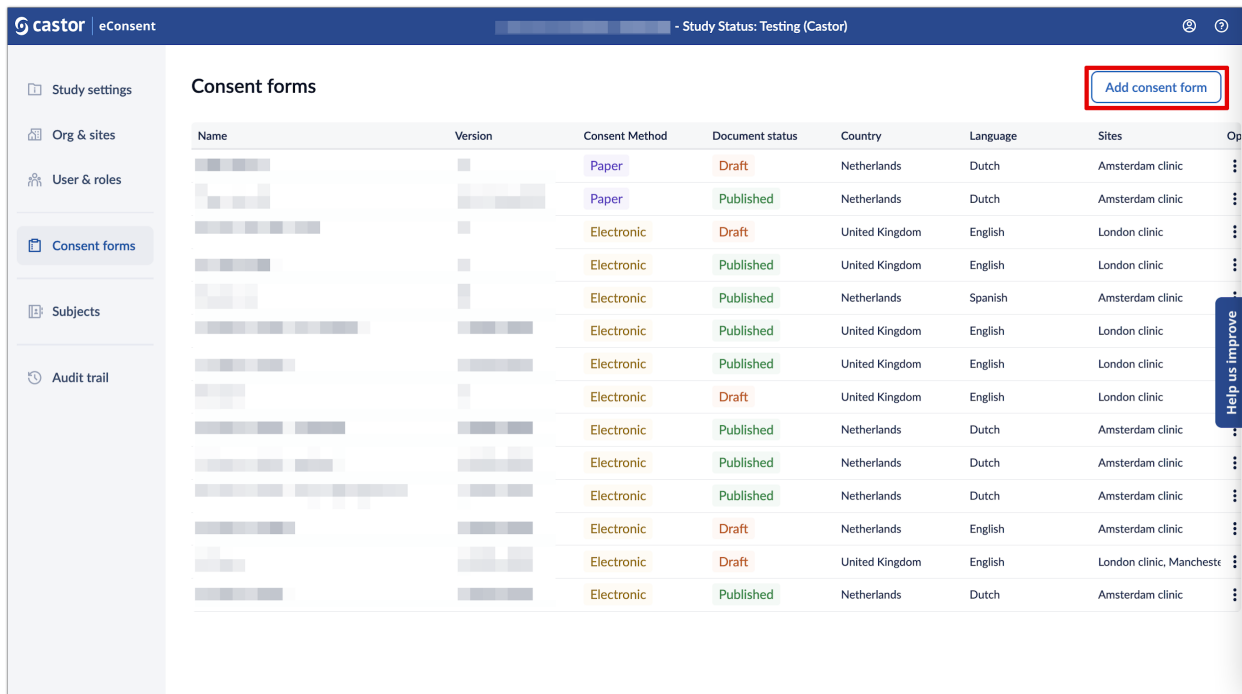
- **Study admin:** The study admin can perform all actions related to the study settings, Org & Site, User Roles, and Consent forms.
- **Site admin:** The site admin can view study settings, organization and sites, view, add and edit user & roles, consent forms, invite, view non PII and PII, edit and sign ICF, and view the audit trail.
- **Study/Site investigator:** The study and site investigator can view study settings, organization and sites, view user & roles, consent forms, invite, view non PII and PII, edit and sign ICF, and view audit trail for a study or site respectively.
- **Study/Site monitor:** The study and site monitor can view study settings, organization and sites, view user & roles, consent forms, view non PII and PII, and view audit trail for a study or site respectively.
- **Study/Site read-only:** The study and site read-only role allows to view study settings, organization and sites, view user & roles, consent forms, view non PII, and view audit trail for a study or site respectively.

7. Consent forms

The 'Consent Forms' page displays the names, versions, and other relevant details of the consent forms. From here it is possible to create new consent forms and manage existing ones.

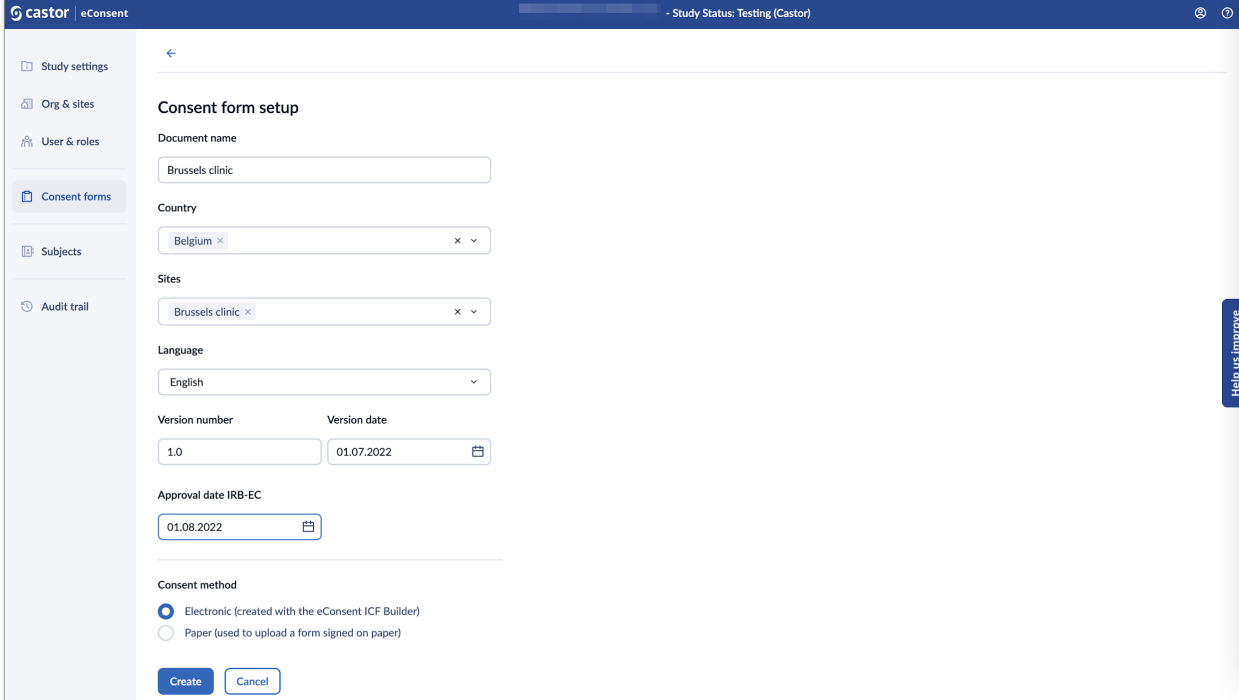
7.1 Adding a new consent form

1. Click on the 'Add consent form' button.



Name	Version	Consent Method	Document status	Country	Language	Sites	Op
[Redacted]	[Redacted]	Paper	Draft	Netherlands	Dutch	Amsterdam clinic	⋮
[Redacted]	[Redacted]	Paper	Published	Netherlands	Dutch	Amsterdam clinic	⋮
[Redacted]	[Redacted]	Electronic	Draft	United Kingdom	English	London clinic	⋮
[Redacted]	[Redacted]	Electronic	Published	United Kingdom	English	London clinic	⋮
[Redacted]	[Redacted]	Electronic	Published	Netherlands	Spanish	Amsterdam clinic	⋮
[Redacted]	[Redacted]	Electronic	Published	United Kingdom	English	London clinic	⋮
[Redacted]	[Redacted]	Electronic	Published	United Kingdom	English	London clinic	⋮
[Redacted]	[Redacted]	Electronic	Draft	United Kingdom	English	London clinic	⋮
[Redacted]	[Redacted]	Electronic	Published	Netherlands	Dutch	Amsterdam clinic	⋮
[Redacted]	[Redacted]	Electronic	Published	Netherlands	Dutch	Amsterdam clinic	⋮
[Redacted]	[Redacted]	Electronic	Published	Netherlands	Dutch	Amsterdam clinic	⋮
[Redacted]	[Redacted]	Electronic	Draft	Netherlands	English	Amsterdam clinic	⋮
[Redacted]	[Redacted]	Electronic	Draft	United Kingdom	English	London clinic, Manchestr	⋮
[Redacted]	[Redacted]	Electronic	Published	Netherlands	Dutch	Amsterdam clinic	⋮

2. You will be taken to the 'Consent form setup' page to specify the details of the new consent form:



Consent form setup

Document name
Brussels clinic

Country
Belgium

Sites
Brussels clinic

Language
English

Version number
1.0

Version date
01.07.2022

Approval date IRB-EC
01.08.2022

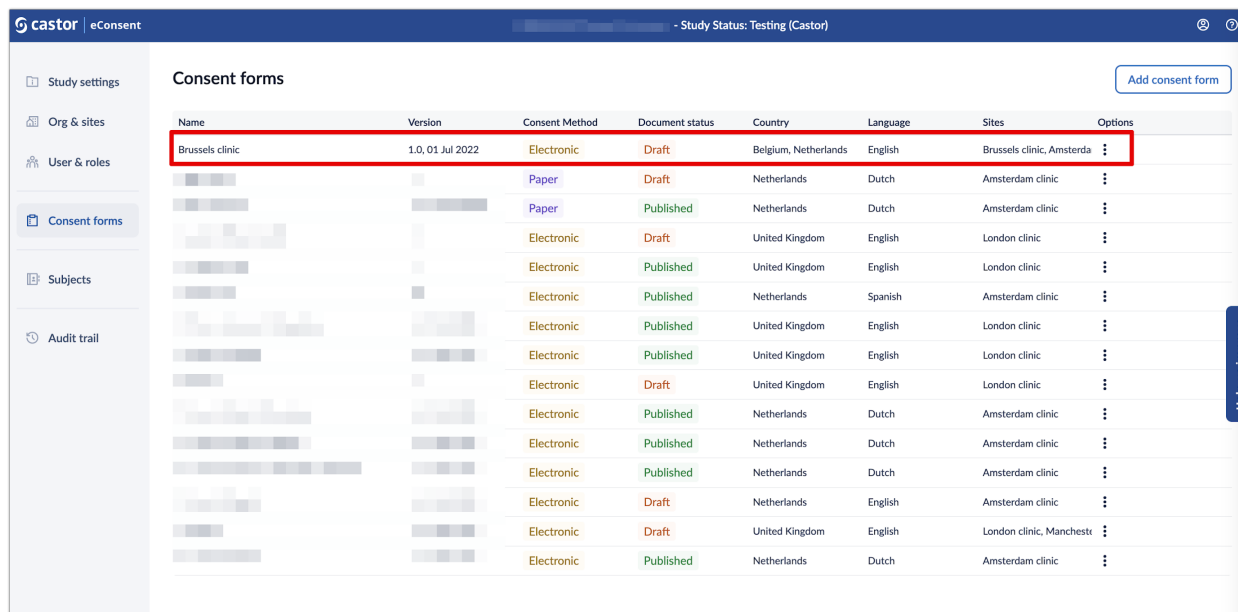
Consent method
☒ Electronic (created with the eConsent ICF Builder)
☐ Paper (used to upload a form signed on paper)

Create Cancel

- **Document name:** title of a consent form
- **Country:** country(ies) to which a form can be linked
- **Sites:** site(s) where a consent form is available
- **Language:** language of a form
- **Version number:** current version of the form
- **Version date:** date of the form version
- **Approval date IRB-EC:** date when the form was approved by IRB-EC
- **Consent method:** Electronic (created with the eConsent ICF Builder) or Paper (used to upload a form signed on paper)

Navigating back to the 'Consent Forms' overview will cancel any applied changes.

3. Click on the 'Create' button to create a form. Once the form is created, the status of the form will be changed to 'Draft' and it will be displayed in the [Consent Forms](#) overview.



Name	Version	Consent Method	Document status	Country	Language	Sites	Options
Brussels clinic	1.0, 01 Jul 2022	Electronic	Draft	Belgium, Netherlands	English	Brussels clinic, Amsterdam clinic	⋮
		Paper	Draft	Netherlands	Dutch	Amsterdam clinic	⋮
		Paper	Published	Netherlands	Dutch	Amsterdam clinic	⋮
		Electronic	Draft	United Kingdom	English	London clinic	⋮
		Electronic	Published	United Kingdom	English	London clinic	⋮
		Electronic	Published	Netherlands	Spanish	Amsterdam clinic	⋮
		Electronic	Published	United Kingdom	English	London clinic	⋮
		Electronic	Draft	United Kingdom	English	London clinic	⋮
		Electronic	Published	Netherlands	Dutch	Amsterdam clinic	⋮
		Electronic	Published	Netherlands	Dutch	Amsterdam clinic	⋮
		Electronic	Published	Netherlands	Dutch	Amsterdam clinic	⋮
		Electronic	Draft	Netherlands	English	Amsterdam clinic	⋮
		Electronic	Draft	United Kingdom	English	London clinic, Manchest	⋮
		Electronic	Published	Netherlands	Dutch	Amsterdam clinic	⋮

4. To access additional options (Duplicate, Preview, Download, Archive) for each form press the three dots menu on the row related to a consent form.

5. After the form is created, you will need to add the form text and set the relevant form properties. Click on the form row to start adding content to your form.

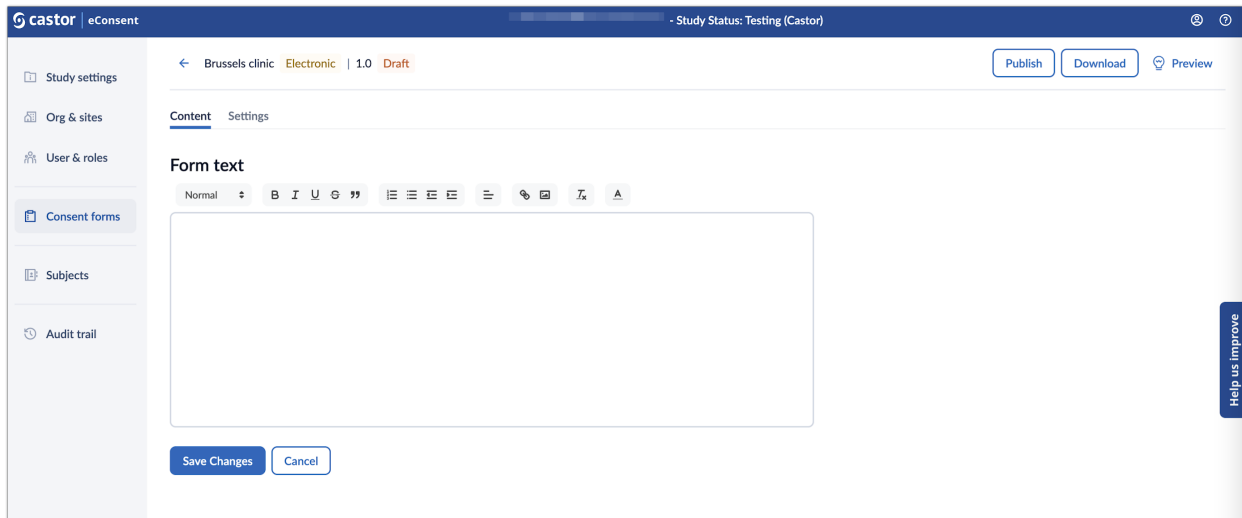
The 'Content' and 'Settings' tabs allow you to define your form fields and other properties.

7.2 Paper Consent Form

When creating a paper consent form, you will be redirected to the 'Paper form settings' page where you can specify the paper form properties: Document name, country, sites, language, version number, version date, approval date IRB-EC.

7.3 Electronic Consent Form Content

For electronic consent forms, In the 'Content' tab, you are able to define the form text, add checkboxes and signature statements, and publish, download or preview your consent form.

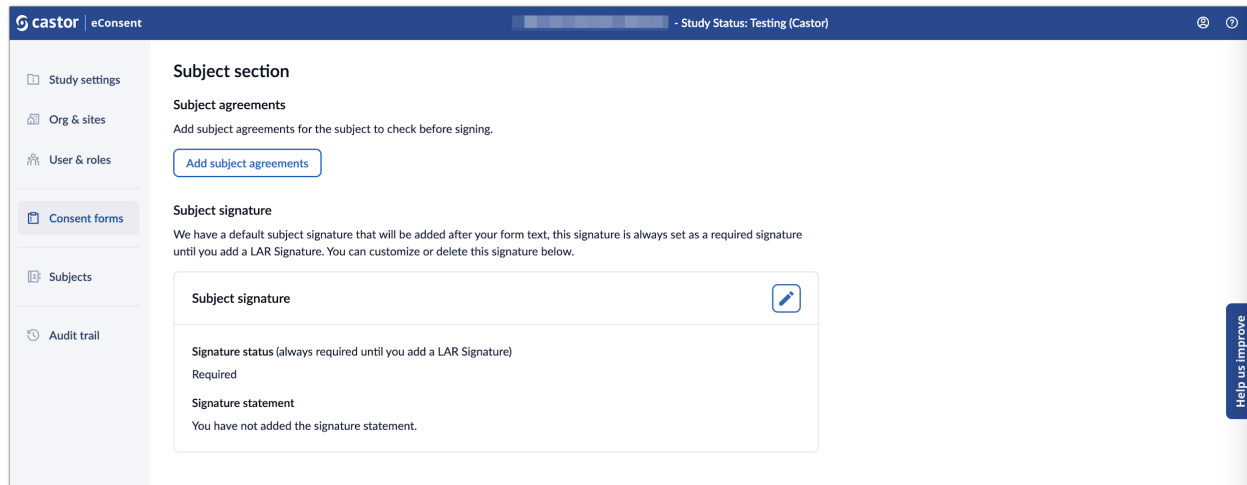


Form text: here you can include the form text and format the text. Make sure to click on the 'Save changes' button, as the text will not be saved automatically.

In the following sections you can define signature statements for subjects, legally authorized representatives and study team members. The needed signatures on the consent forms can be configured for each form.

7.3.1 Subject Section

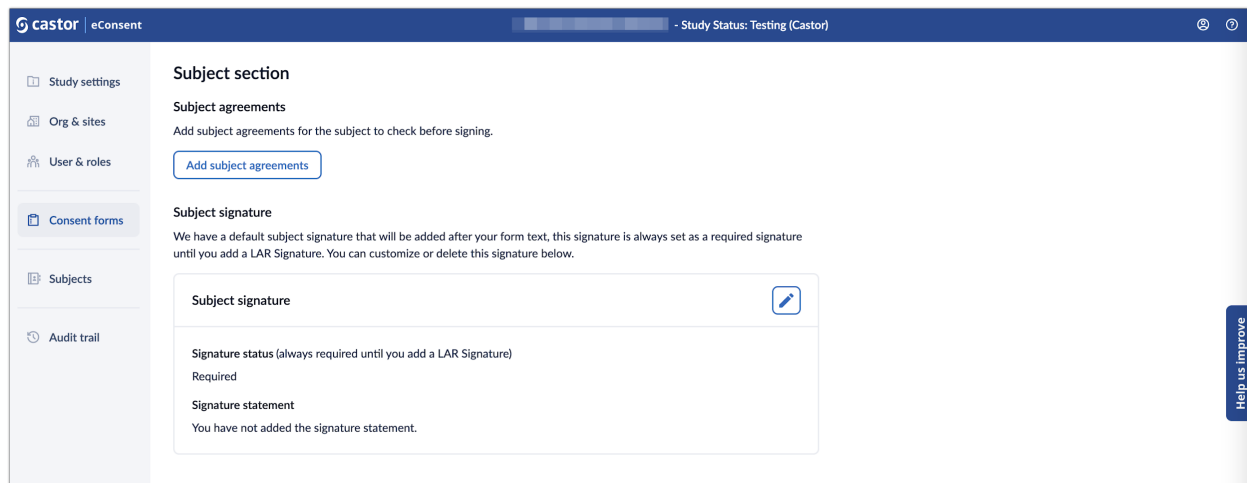
In the subject section you can define subject agreements and signature statements.



Subject agreements

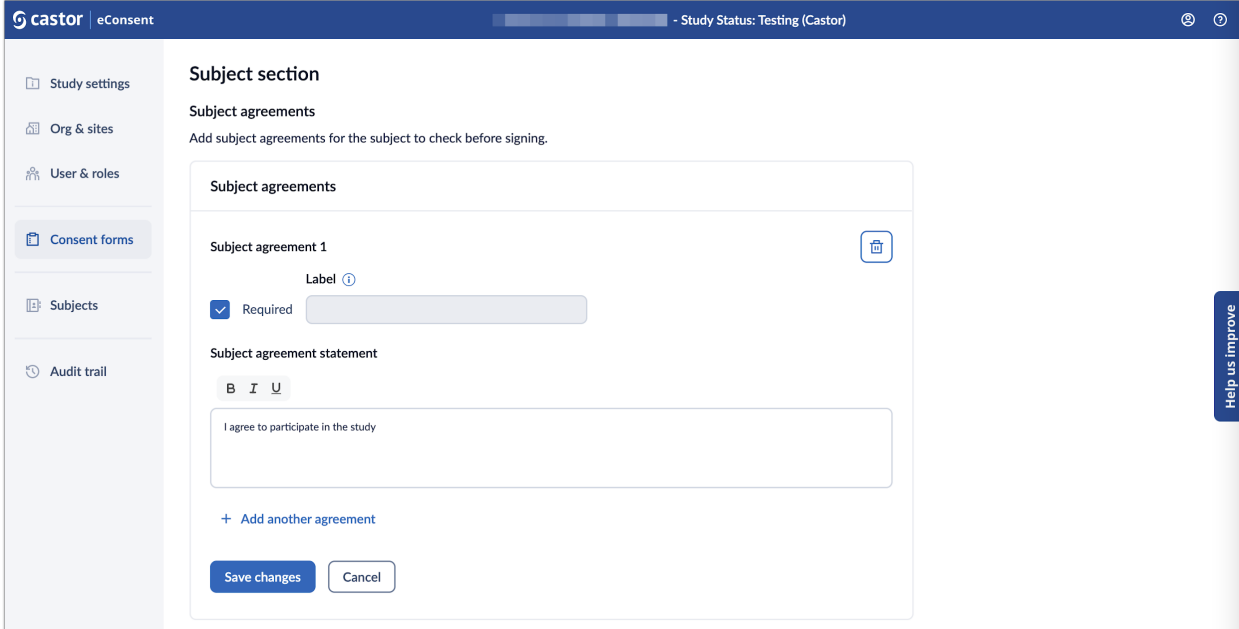
It is possible to add subject agreements for the subject to check before signing. Follow the steps below to add/edit or remove a subject agreement:

1. In the 'Subject agreements' section, click on the 'Add subject agreements' button to add an agreement.

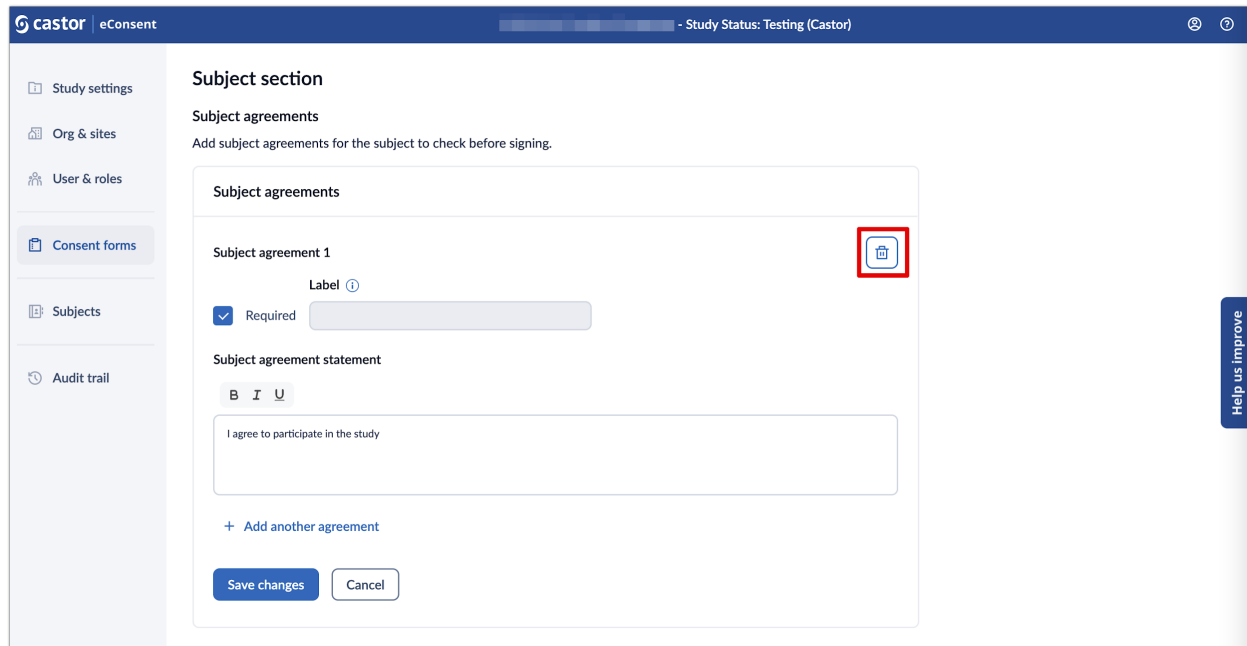


2. A 'Subject agreement' dialog window will appear which allows to define the following properties of a subject agreement:

- **Required:** this option will make the subject agreement mandatory;
- **Label:** title for the agreement. You can only add a label to optional agreements;
- **Subject agreement statement:** the text of the agreement.

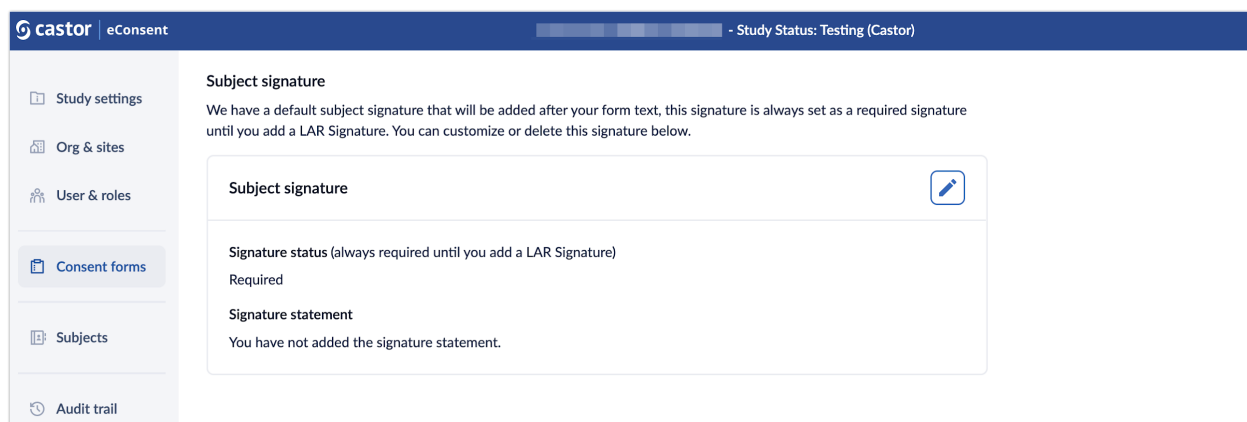


3. Press the 'Add another agreement' button to add additional agreements.
4. Press on the 'Save changes' button to add the agreement(s) to your consent form. Pressing 'Cancel' will reverse the changes.
5. To delete a subject agreement, click on the trash bin icon.



Subject signature

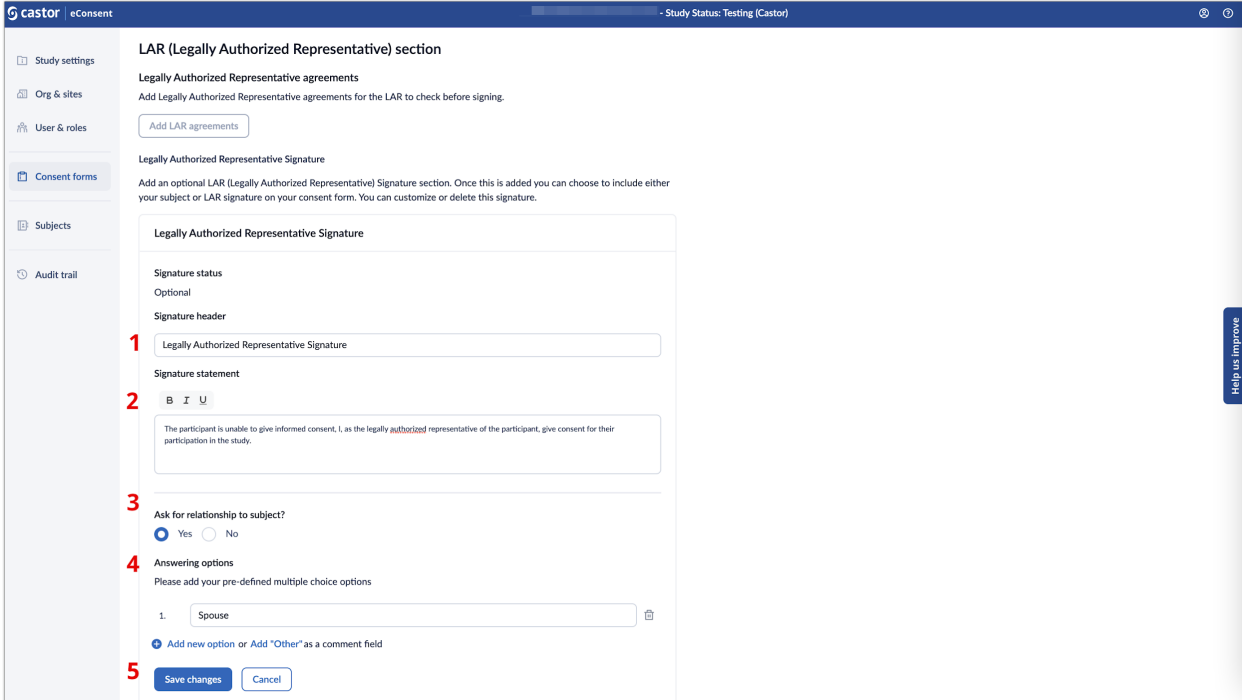
A default subject signature will be added after your form text, this signature is always set as a required signature until you add a LAR Signature. Clicking on the 'pencil' icon allows you to edit signature statements.

7.3.2 LAR (Legally Authorized Representative) section

In this section you can add an optional LAR (Legally Authorized Representative) Signature.

Once this is added you can choose to include either your subject or LAR signature on your consent form.



The screenshot shows the 'LAR (Legally Authorized Representative) section' configuration page in the Castor eConsent system. The page has a sidebar on the left with navigation links: Study settings, Org & sites, User & roles, Consent forms (selected), Subjects, and Audit trail. The main content area is titled 'LAR (Legally Authorized Representative) section' and contains the following elements:

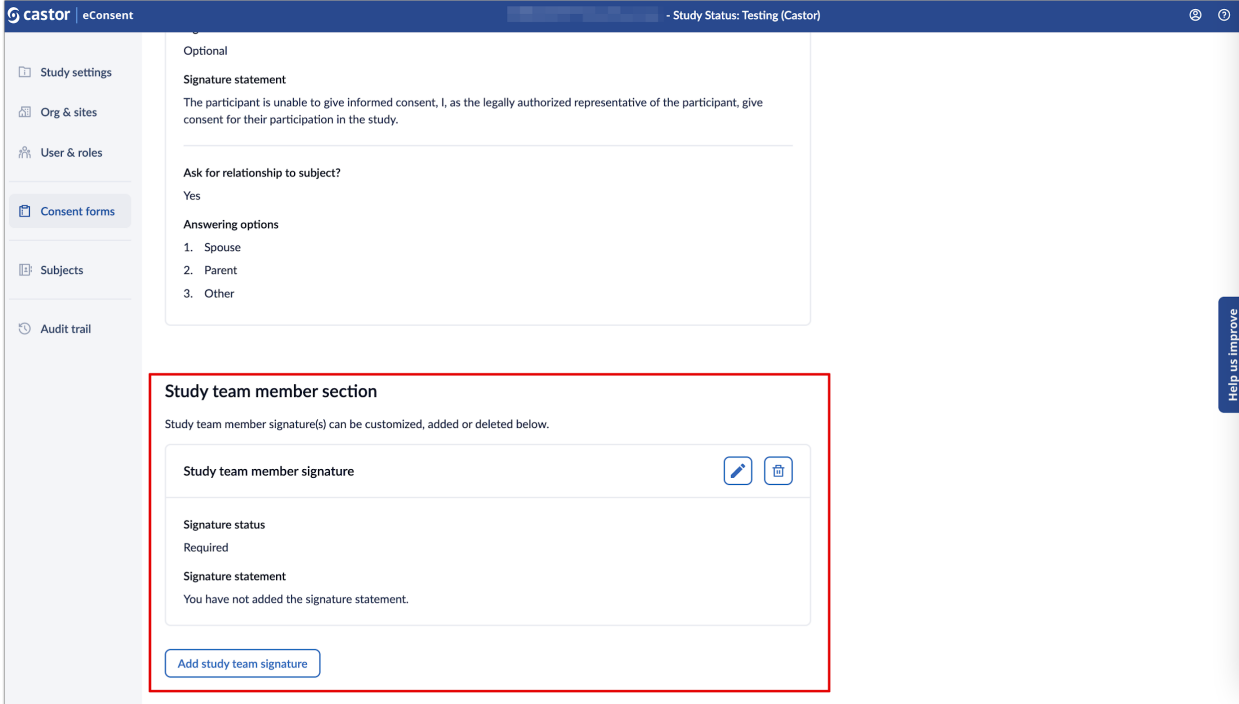
- Legally Authorized Representative agreements:** A section with a button 'Add LAR agreements' and a description: 'Add Legally Authorized Representative agreements for the LAR to check before signing.'
- Legally Authorized Representative Signature:** A section with a description: 'Add an optional LAR (Legally Authorized Representative) Signature section. Once this is added you can choose to include either your subject or LAR signature on your consent form. You can customize or delete this signature.'
- Legally Authorized Representative Signature configuration:** A form with the following fields:
 - Signature status:** A dropdown menu with 'Optional' selected.
 - Signature header:** A text input field with the value 'Legally Authorized Representative Signature' (labeled with a red '1').
 - Signature statement:** A rich text editor with the value 'The participant is unable to give informed consent, I, as the legally authorized representative of the participant, give consent for their participation in the study.' (labeled with a red '2').
 - Ask for relationship to subject?:** A radio button group with 'Yes' selected (labeled with a red '3').
 - Answering options:** A section with the text 'Please add your pre-defined multiple choice options'. It contains a list with one item: '1. Spouse' (labeled with a red '4'). Below the list are buttons for 'Add new option' and 'Add "Other" as a comment field'.
 - Save/Cancel buttons:** At the bottom of the form are 'Save changes' (labeled with a red '5') and 'Cancel' buttons.

1. **Signature header:** allows you to define your customized signature title (maximum 60 characters).
2. **Signature statements:** here you can define the signature statement for the user that will sign the consent form.
3. **Ask for relationship to subject?:** selecting 'Yes' will allow you to add a list of options (multiple choice) for users to specify their relationship to subject using the 'Add new option' button.
4. **Answering options:** Here you can add your pre-defined multiple choice options. Additionally, you can choose the 'Add Other' as a comment where the users can provide their own answer in the text field. If the relationship to the subject is not required, selecting the 'No' option disables the question in the LAR signature section.

5. Click on the '**Save changes**' button to add the LAR signature. If you would like to reverse the changes, click on the 'Cancel' button.

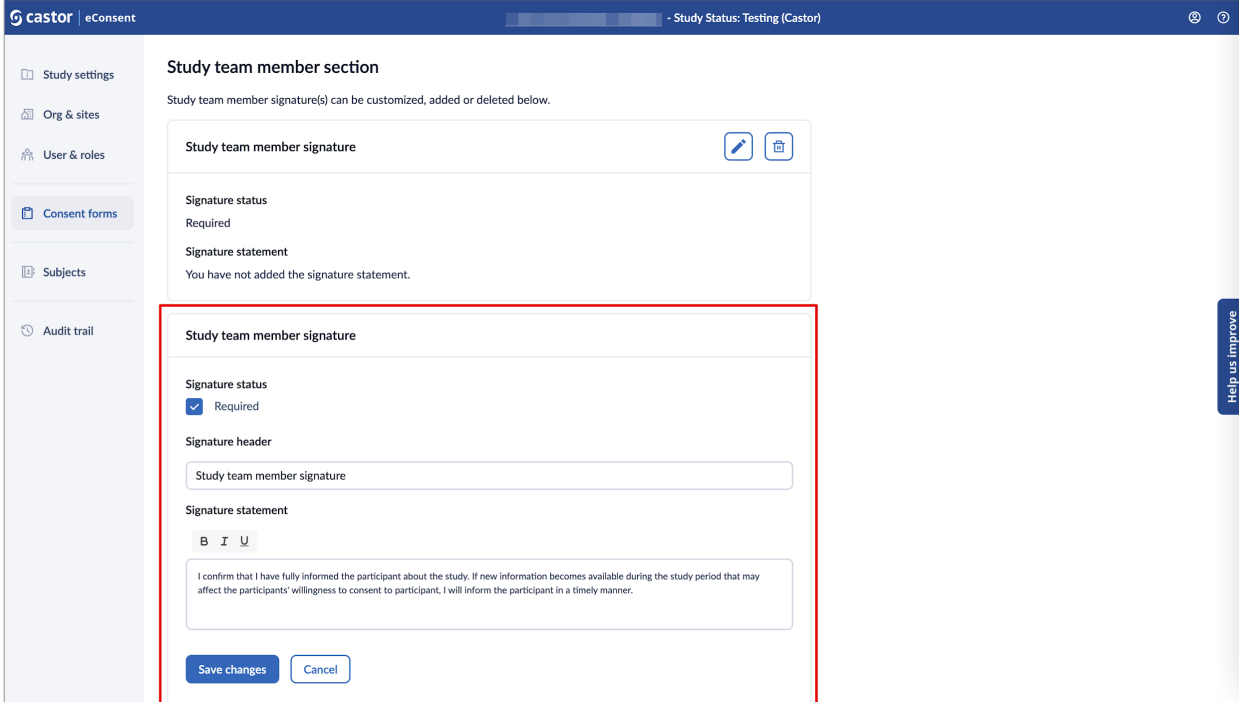
7.3.3 Study team member section

In this section you can add, customize or delete study team member signatures.



The screenshot shows the Castor eConsent interface. The left sidebar contains navigation links: Study settings, Org & sites, User & roles, Consent forms (highlighted), Subjects, and Audit trail. The main content area is titled 'Study Status: Testing (Castor)'. It contains several sections: 'Optional', 'Signature statement' (with a text area), 'Ask for relationship to subject?' (with a 'Yes' option), and 'Answering options' (a list: 1. Spouse, 2. Parent, 3. Other). Below these is the 'Study team member section', which is highlighted with a red box. This section includes the text 'Study team member signature(s) can be customized, added or deleted below.' and a table with one row for 'Study team member signature'. The table has columns for 'Signature status' (set to 'Required') and 'Signature statement' (with the text 'You have not added the signature statement.'). To the right of the table are edit and delete icons. Below the table is a button labeled 'Add study team signature'. A 'Help us improve' button is visible on the right side of the interface.

It is possible to have none or maximum two study team signatures. When only one signature is added, it will be set to 'Required' by default. The headers of the study team member signatures are configurable per ICF template.



To add or edit a study team member signature, follow the steps below:

1. By default, one study team member signature is present on a form. Click on the pencil icon to edit the signature or on the trash bin icon to remove the signature.
2. When editing the study team member signature, you can define the 'Signature header' and the 'Signature statement'.
3. Click on the 'Save changes' button to add the signature.
4. To add the second study team signature, click on the 'Add study team' signature'.

A second study team member signature can be added to the ICF template by clicking on the 'Add study team signature' button.

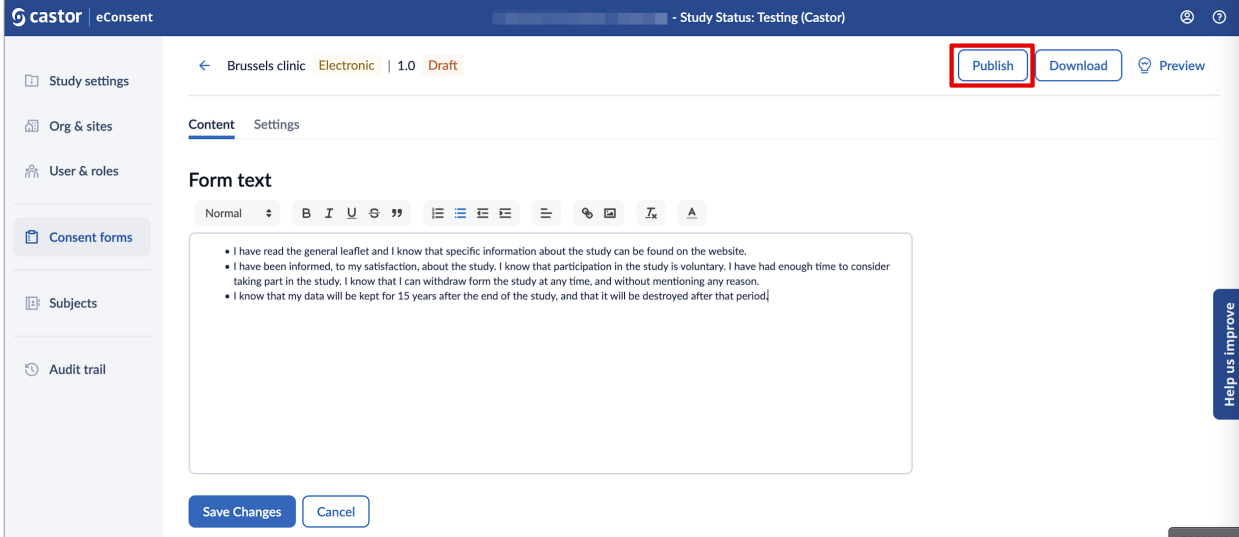
- This second signature can be setup as:
 - **Required** - The second study team member signature component always needs to be signed before the ICF is set to completely signed (status 'Consented');
 - **Optional** - If it is unknown upfront whether a second study team member signature is needed for a specific form or subject, the second signature can

be marked as optional. In that case, the second study team member signature component needs to be (de)activated by the first study team member that signs the ICF. If the signature component is deactivated, it can no longer be signed. If the signature component is activated, it has to be signed before the ICF is set to completely signed ('Consented').

- The section 'Additional signature(s) details' in the 'Consent form (most recent)' card on the profile page of the subject displays the consent status of the additional signature, the header name of the additional signature, and whether a notification has been sent.
- When there is a required second signature component, or an activated optional second signature component, a signature can be requested by sending an email notification.
- Should a second signature component be activated by mistake, this component can be deactivated again via the action by clicking on the three dot menu of the ICF. This also works the other way around; a deactivated signature component can be activated again.
- The second study team member signature component can be signed by users with sign rights. The second signatory cannot be the same as the one who is required to sign on the first signature component.
- Activating or deactivating the signature components is logged on the audit trail.

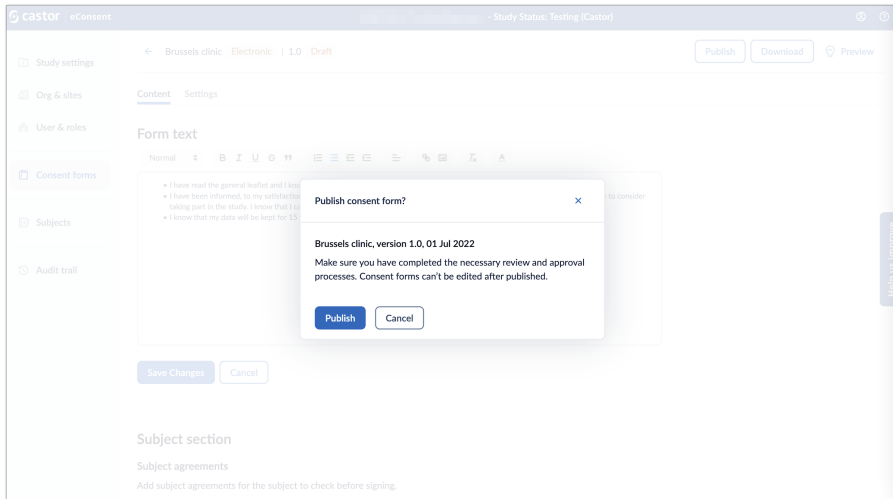
7.4 Publishing the form

When you have finished editing the form, you can publish the form by clicking the 'Publish' button at the top of the 'Content' tab.



The screenshot shows the Castor eConsent interface for a study named 'Brussels clinic'. The 'Content' tab is active, and the 'Form text' section is visible. The 'Publish' button is highlighted with a red box. The interface includes a sidebar with navigation options: Study settings, Org & sites, User & roles, Consent forms, Subjects, and Audit trail. The top right corner shows the study status as 'Testing (Castor)' and buttons for 'Publish', 'Download', and 'Preview'. The 'Form text' area contains a list of bullet points regarding the study's general leaflet and data retention policy.

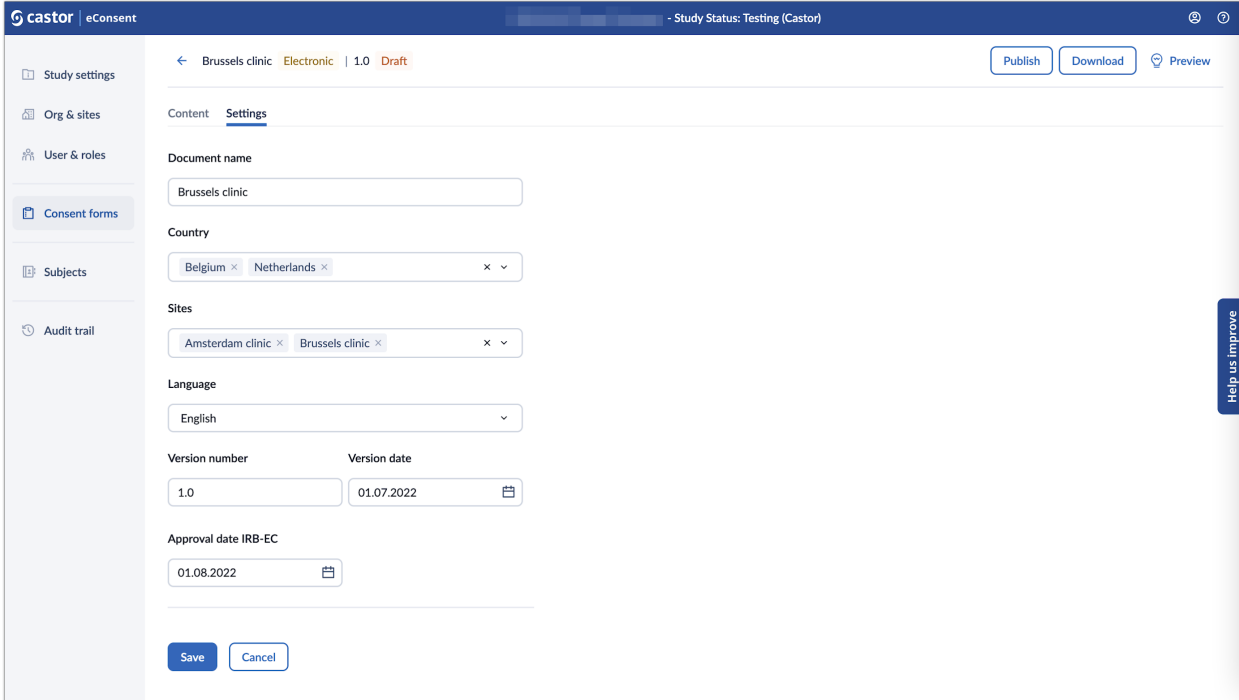
Once the form is published, it will no longer be possible to edit the content of the form. Please ensure you have completed the necessary review and approval processes prior to publishing. Click 'Publish' to publish the form.



The screenshot shows the Castor eConsent interface with a 'Publish consent form?' dialog box open. The dialog box contains the following text: 'Brussels clinic, version 1.0, 01 Jul 2022. Make sure you have completed the necessary review and approval processes. Consent forms can't be edited after published.' The dialog box has 'Publish' and 'Cancel' buttons. The background interface shows the 'Form text' section and the 'Subject section' with 'Subject agreements'.

7.5 Settings

In the 'Settings' page, you can change the form settings such as Form name, Country and Site(s) to which the form will be available, Language, Version number and Version date.



The screenshot shows the 'Settings' page in the Castor eConsent interface. The top navigation bar includes the Castor logo, 'eConsent', and a breadcrumb trail: 'Brussels clinic' > 'Electronic' > '1.0' > 'Draft'. On the right of the top bar are buttons for 'Publish', 'Download', and 'Preview'. A vertical sidebar on the left contains navigation links: 'Study settings', 'Org & sites', 'User & roles', 'Consent forms' (highlighted), 'Subjects', and 'Audit trail'. The main content area is titled 'Settings' and contains the following fields:

- Document name:** A text input field containing 'Brussels clinic'.
- Country:** A multi-select dropdown menu showing 'Belgium' and 'Netherlands'.
- Sites:** A multi-select dropdown menu showing 'Amsterdam clinic' and 'Brussels clinic'.
- Language:** A dropdown menu showing 'English'.
- Version number:** A text input field containing '1.0'.
- Version date:** A date input field containing '01.07.2022' with a calendar icon.
- Approval date IRB-EC:** A date input field containing '01.08.2022' with a calendar icon.

At the bottom of the settings area are 'Save' and 'Cancel' buttons. A vertical button labeled 'Help us improve' is located on the right edge of the main content area.

After the form is published, you will be able to modify the 'Country' and 'Sites' to which the form is linked in the 'Settings' tab and other fields will be grayed out.

eConsent

Study Status: Testing (Castor)

Download
Preview

Study settings
Org & sites
User & roles
Consent forms
Subjects
Audit trail

Brussels clinic
Electronic
1.0
Published

Preview
Settings

Document name

Brussels clinic

Country

Belgium
Netherlands

Sites

Amsterdam clinic
Brussels clinic

Language

English

Version number
Version date

1.0
01.07.2022

Approval date IRB-EC

01.08.2022

Save
Cancel

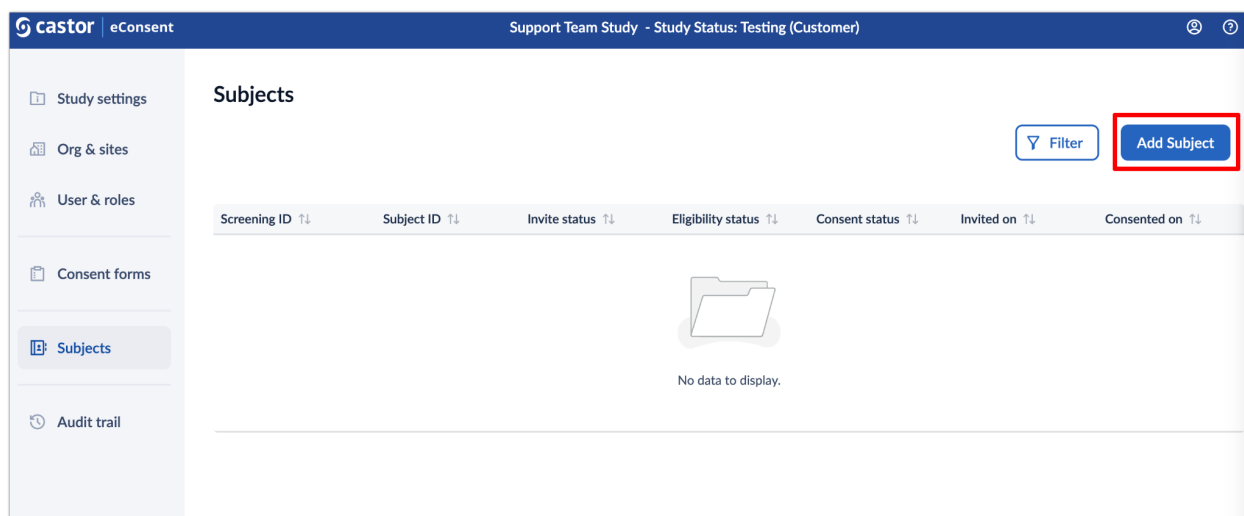
Help us improve

8. Adding a subject

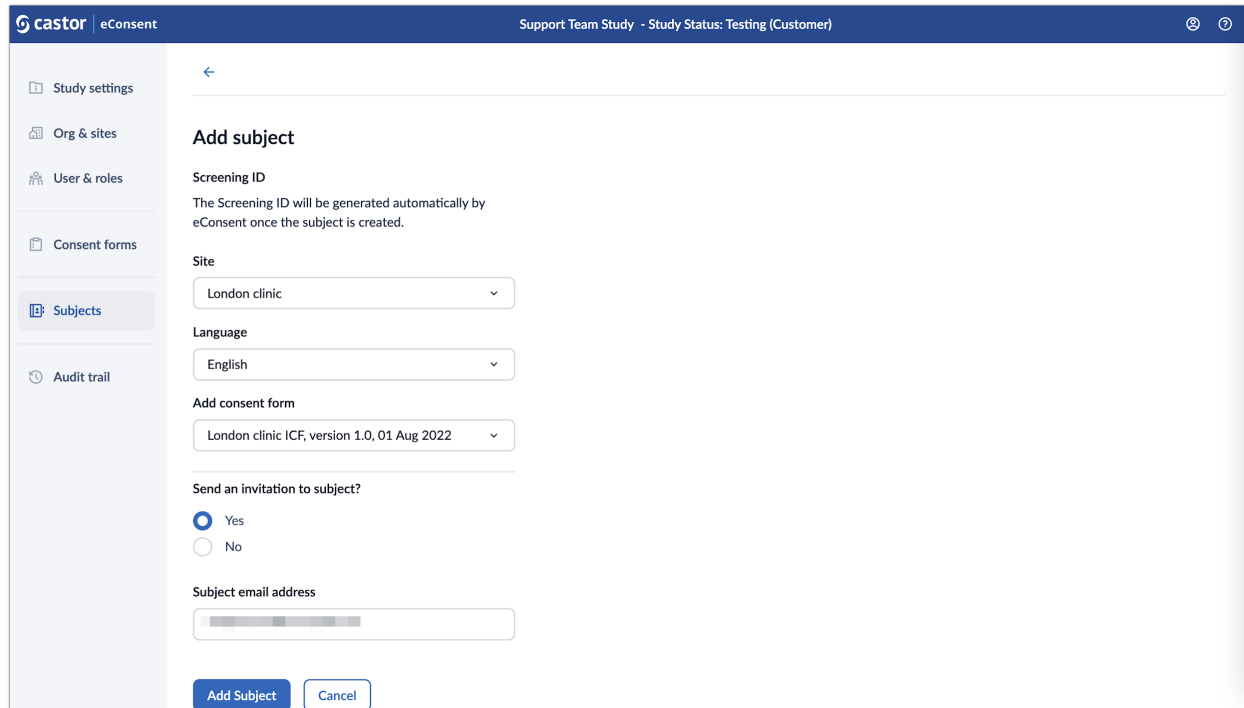
Only users with the 'Site Admin' rights can create subjects.

To create a new subject in your study, follow the steps below:

1. Navigate to the '[Subjects](#)' overview
2. Press the 'Add Subject' button



3. On the 'Add subject' screen, fill out the details:
 - **Site:** choose a site where a subject should be created.
 - **Language:** specify the language
 - **Add consent form:** choose the applicable consent form
 - **Send an invitation to subject?:** set this option to 'Yes' if you wish to send an email invitation to the subject and to 'No' if no notification emails should be sent.
 - **Subject email address:** if you wish to send an invitation to a subject, make sure to add the subject's email address. If no notification should be sent, please skip this field.



If you only have rights for one site or one consent form, the applicable fields will be automatically populated.

4. Once you are ready, click on the 'Add Subject' button to add the subject. Clicking on 'Cancel' will discard all the information. You will be redirected to the 'Subjects' overview screen.
5. When a subject is created, a screening ID will be generated automatically to the 'Subjects' overview.

9. Signing a eConsent form

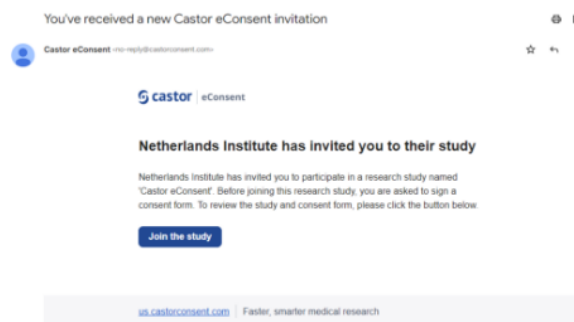
Castor eConsent platform supports two consent methods: Electronic (created with the eConsent ICF Builder) or Paper (used to upload a form signed on paper). Consenting can be done electronically with a subject account or without a subject account (in-person signing). In cases where a paper consent method is used, signed consent forms can be uploaded into the eConsent platform.

9.1 Electronic signing

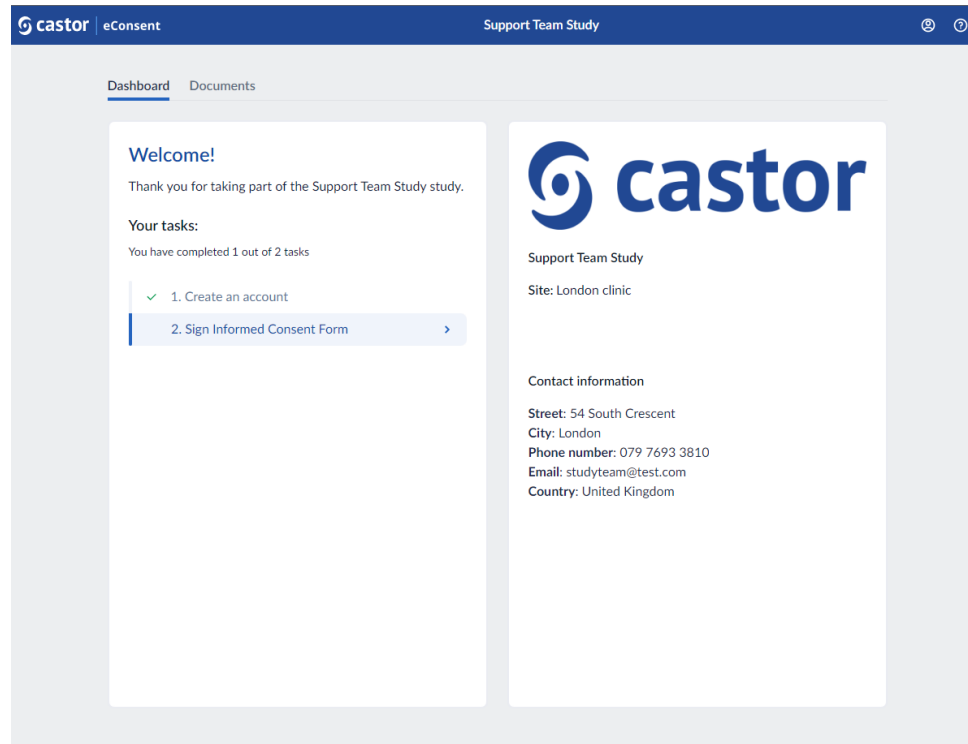
When choosing an electronic consent method, participants can consent online with an account or in-person without creating an account.

9.1.1 Electronic signing with an account (remotely)

A participant can electronically sign a consent form by creating an account from the invitation email. When a participant clicks on the 'Join the study' button, they need to [create an account](#) if they don't have one yet. Participants with an account, can login using their credentials.




After setting up their account and logging in, a dashboard will be presented.




The participant will need to Press the 'Sign Informed Consent Form' where they can download the consent form or view and sign.



Upon selecting 'View & Sign', the participant will then select the required fields, type their full name, add their electronic signature, then press the 'Submit' button to submit their signature.


Consent form: London clinic ICF 1.0, 01 Aug 2022


Download

All information taken from the study will be coded to protect each subject's name. No names or other identifying information will be used when discussing or reporting data. The investigator(s) will safely keep all files and data collected in a secured locked cabinet in the principal investigators office. Once the data has been fully analyzed it will be destroyed.

***Required** indicates required checkbox

☐ I authorize the use of my records, any observations, and findings found during the course of this study for education, publication and/or presentation ***Required**

☐ I voluntarily agree to participate in this research program ***Required**

Subject signature

Date
06 October 2022

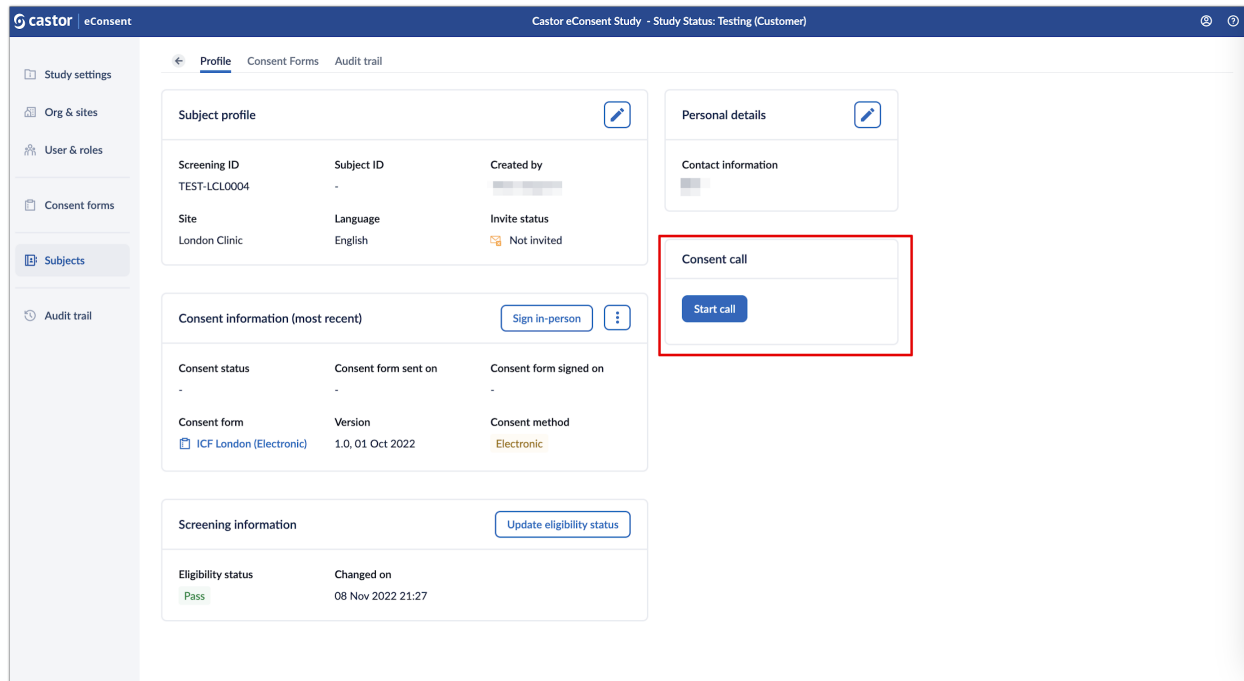
Full name

Signature

9.1.2 Electronic signing via a Video-call (remotely)

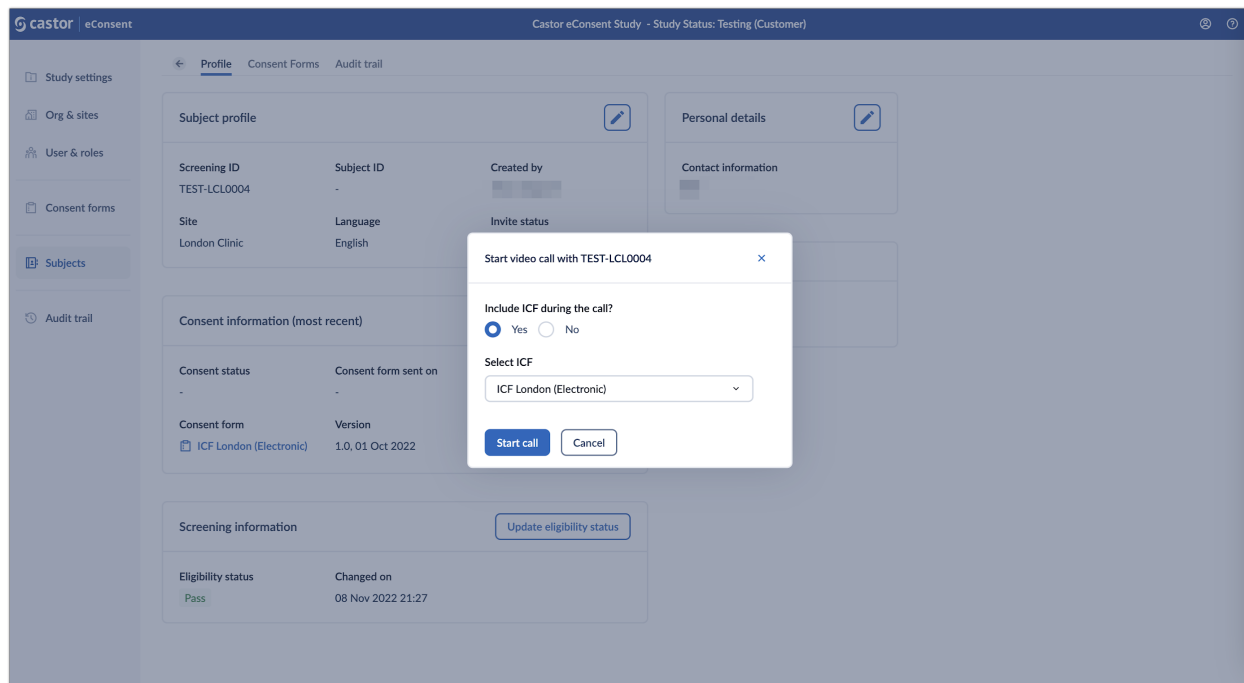
When the option 'Video calling for signing' is enabled in the study settings tab, it is possible to obtain informed consent remotely via a video call.

1. Once the configuration is enabled, when opening an individual subject, a 'Consent call' card will appear:



The screenshot shows the Castor eConsent interface for a specific subject. The 'Consent call' card is highlighted with a red box. The interface includes a sidebar with navigation options like 'Study settings', 'Org & sites', 'User & roles', 'Consent forms', 'Subjects', and 'Audit trail'. The main content area displays the subject's profile, consent information, and screening information. The 'Consent call' card is located on the right side of the main content area, below the 'Contact information' card. It contains a 'Start call' button.

2. Click on the 'Start call' button to initiate the video call. A pop-up window will appear which allows to specify whether an ICF form should be included in the call. Specify which ICF should be included in the 'Select ICF' dropdown field and click 'Start call' button to proceed to the call:



3. You will be redirected to the call screen. During the call, the following options are presented:
 - Unlock to enable signing/Lock to disable signing which allows to enable the ICF for signing and lock it after the form has been signed
 - Start video/Stop video which allows to turn on/off the investigator's camera
 - Mute/Unmute to turn on/off the investigator's microphone
 - End call button to finish the call
 - Arrow to return back to the subject overview

ICF London (Electronic)
Unlock to enable signing
Start video
Mute

- I have read the general leaflet and I know that specific information about the study can be found on the website.
- I have been informed, to my satisfaction, about the study. I know that participation in the study is voluntary. I have had enough time to consider taking part in the study. I know that I can withdraw from the study at any time, and without mentioning any reason.
- I know that my data will be kept for 15 years after the end of the study, and that it will be destroyed after that period.

**Required indicates required checkbox*

☐ I agree to participate in the study. **Required*

☐ I grant permission for residual material (for example my blood) and collected medical information to be saved and used for 15 years after the study.

Subject signature

Date

Full name

Signature

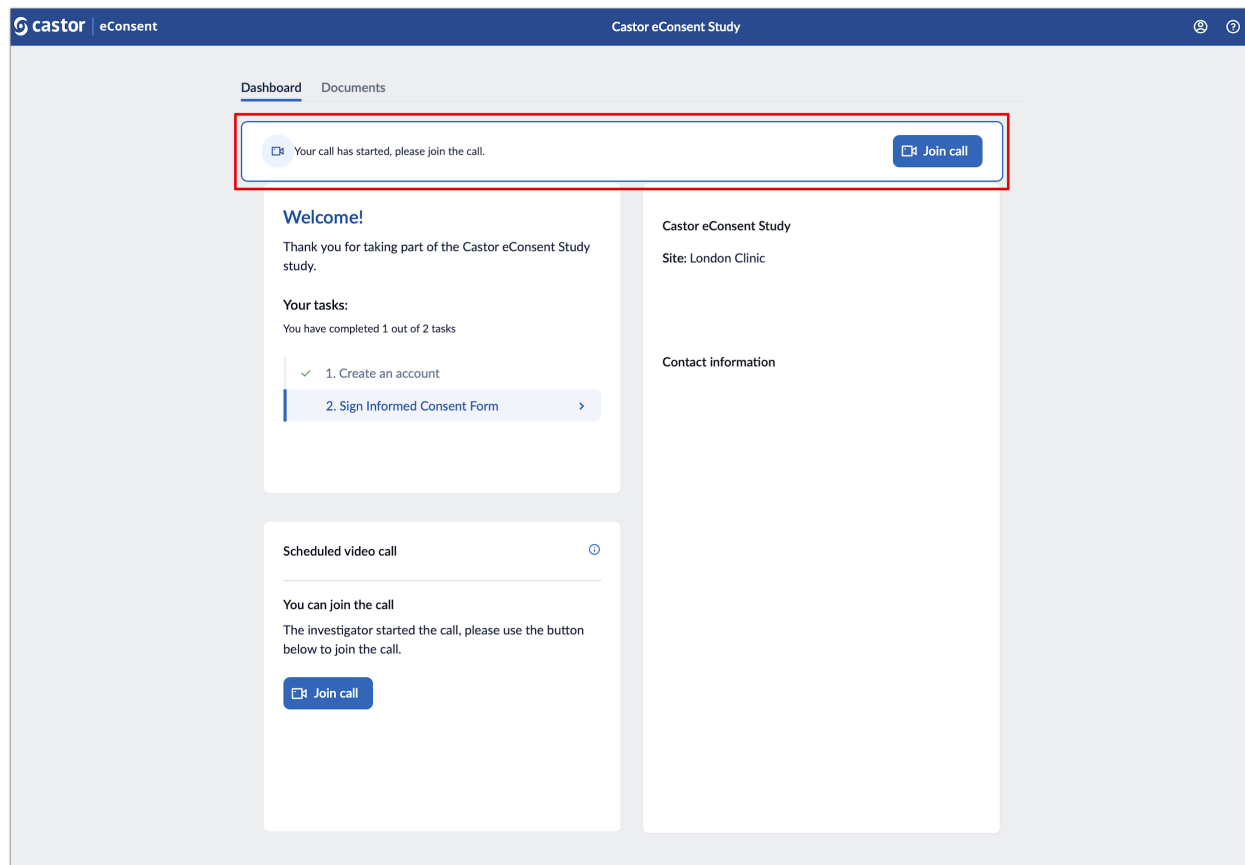
Submit Clear

Your video is turned off

Waiting for the subject to join the call

Please ensure you've joined your consent call at the agreed time and date.

4. Once the investigator starts the call, the subject will see an invitation to 'Join call' within the 'Dashboard' tab.



5. To finish a call, click on the End call button



Please refer to the article [Troubleshooting Video/Audio](#) on how to resolve potential video/audio issues.

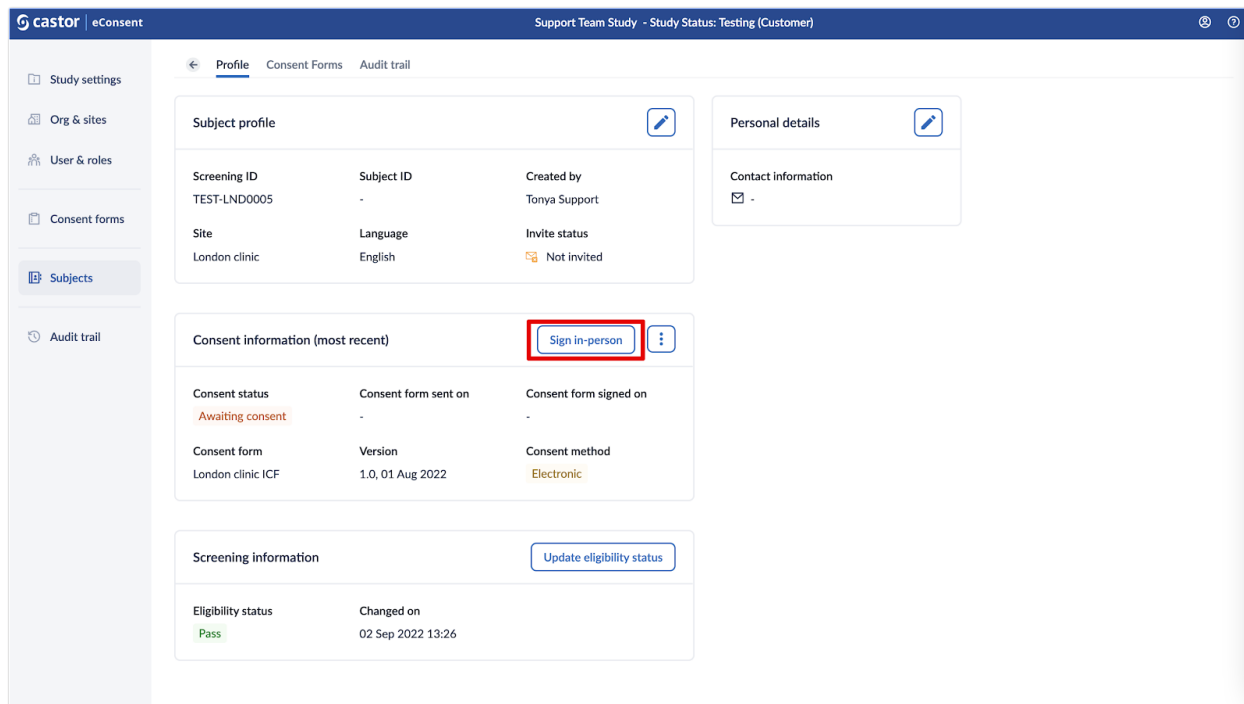
9.1.3 Electronic signing in-person

If a participant is invited to sign the consent form online but instead wishes to sign in-person, if the study allows, follow the steps below.

In-person signing, with or without an account

If the study allows in-person signing, the study team members with the 'Site Admin', 'Study Investigator', 'Site Investigator' roles can start the in-person signing flow:

1. Navigate to the 'Subjects' overview and click on the subject row.
2. When there is already an ICF added which hasn't been signed by the subject yet (status of the ICF is "Awaiting consent" if the invite is already sent, or "undefined" if there is no invite sent), in the 'Consent information (most recent)' section, click on the "Sign in-person" option:

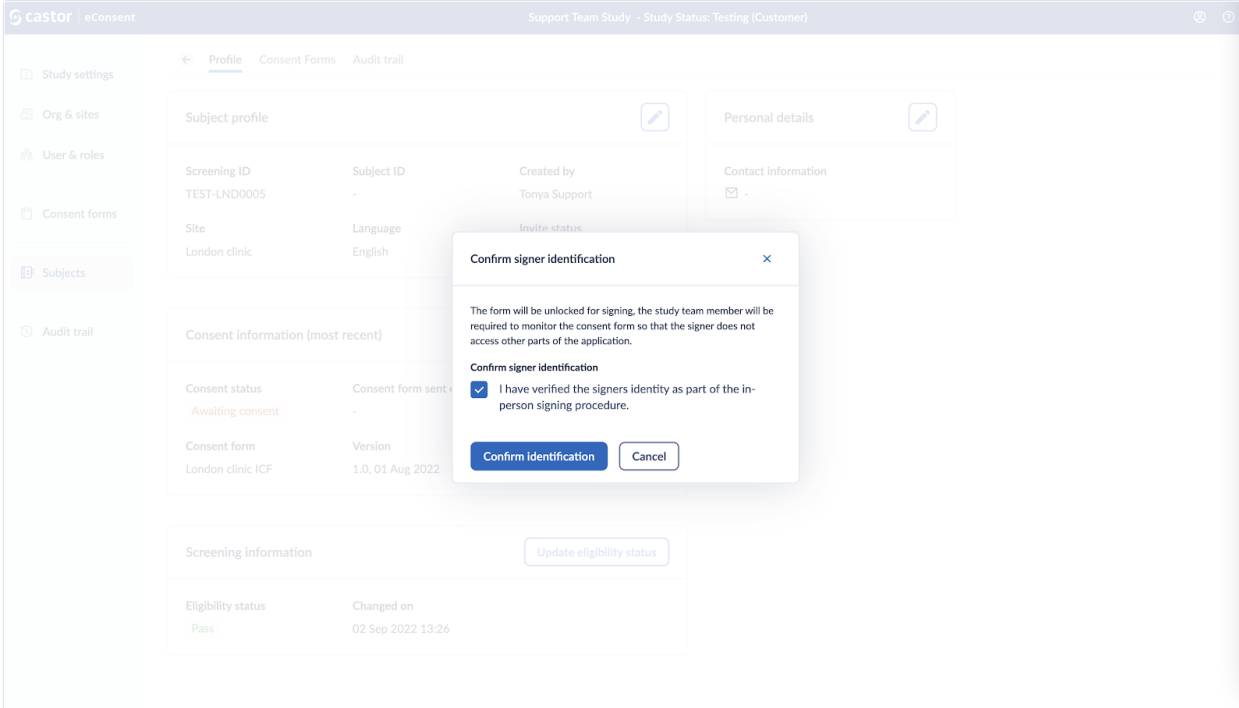


The screenshot shows the Castor eConsent interface for a study named 'Support Team Study - Study Status: Testing (Customer)'. The left sidebar contains navigation options: Study settings, Org & sites, User & roles, Consent forms, Subjects (selected), and Audit trail. The main content area is divided into three tabs: Profile, Consent Forms, and Audit trail. The 'Profile' tab is active, showing the 'Subject profile' section with details: Screening ID (TEST-LND0005), Subject ID (-), Created by (Tonya Support), Site (London clinic), Language (English), and Invite status (Not invited). To the right is the 'Personal details' section with 'Contact information' (email icon, -). Below the subject profile is the 'Consent information (most recent)' section, which contains a table with consent details. The 'Sign in-person' button is highlighted with a red box. At the bottom is the 'Screening information' section with 'Eligibility status' (Pass) and 'Changed on' (02 Sep 2022 13:26).

Consent information (most recent)		
Consent status	Consent form sent on	Consent form signed on
Awaiting consent	-	-
Consent form	Version	Consent method
London clinic ICF	1.0, 01 Aug 2022	Electronic

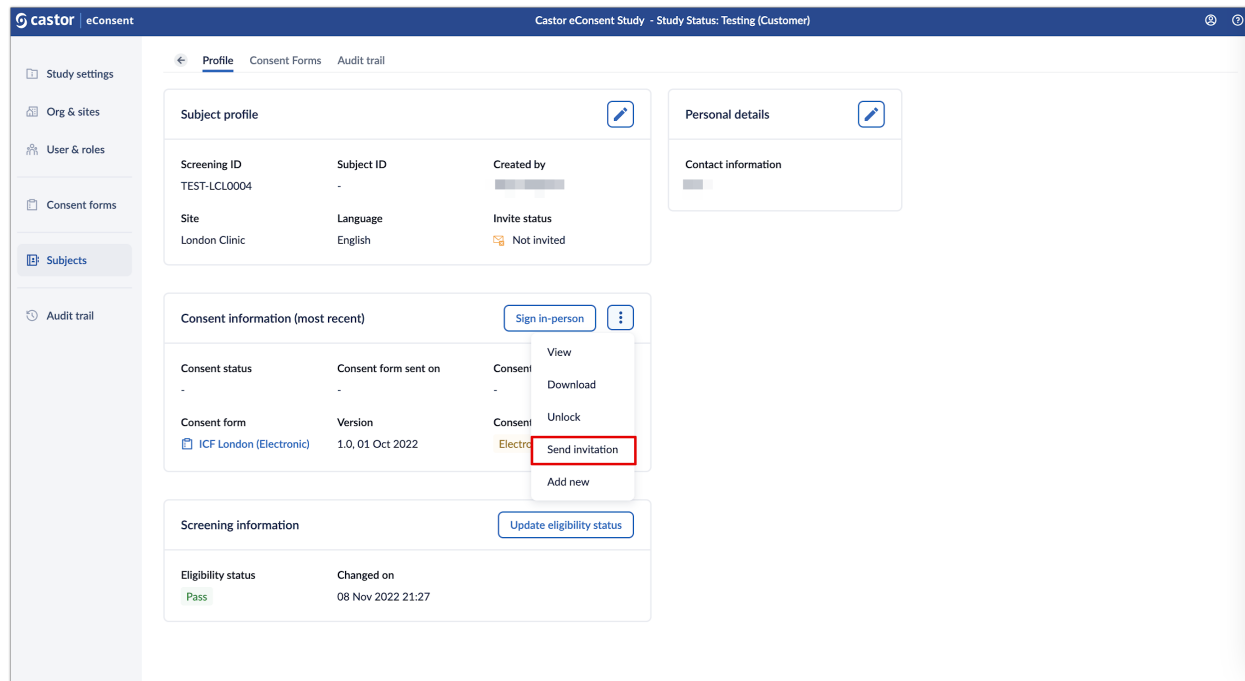
3. After clicking on the "Sign in-person" options, a confirmation dialog will be shown with the following message: "The form will be unlocked for signing, the study team member will be required to monitor the consent form so that the signer does not

access other parts of the application.” Select the checkmark for the confirmation statement “I have verified the signer's identity as part of the in-person signing procedure.” and click on the ‘Confirm identification’ button to proceed further:



The screenshot shows the Castor eConsent interface for a study named 'Support Team Study' with a status of 'Testing (Customer)'. The left sidebar contains navigation options: Study settings, Org & sites, User & roles, Consent forms, Subjects, and Audit trail. The main content area is divided into three tabs: Profile, Consent Forms, and Audit trail. The 'Profile' tab is active, displaying a 'Subject profile' section with fields for Screening ID (TEST-LND0005), Subject ID (-), Created by (Tonya Support), Site (London clinic), Language (English), and Invite status. A 'Personal details' section is also visible. A 'Consent Information (most recent)' section shows the Consent status as 'Awaiting consent', Consent form as 'London clinic ICF', and Version as '1.0, 01 Aug 2022'. A 'Screening Information' section shows the Eligibility status as 'Pass' and Changed on '02 Sep 2022 13:26'. A modal dialog titled 'Confirm signer identification' is open in the center, containing the text: 'The form will be unlocked for signing, the study team member will be required to monitor the consent form so that the signer does not access other parts of the application.' Below this text is a section titled 'Confirm signer identification' with a checked checkbox and the statement 'I have verified the signers identity as part of the in-person signing procedure.' At the bottom of the modal are two buttons: 'Confirm identification' and 'Cancel'.

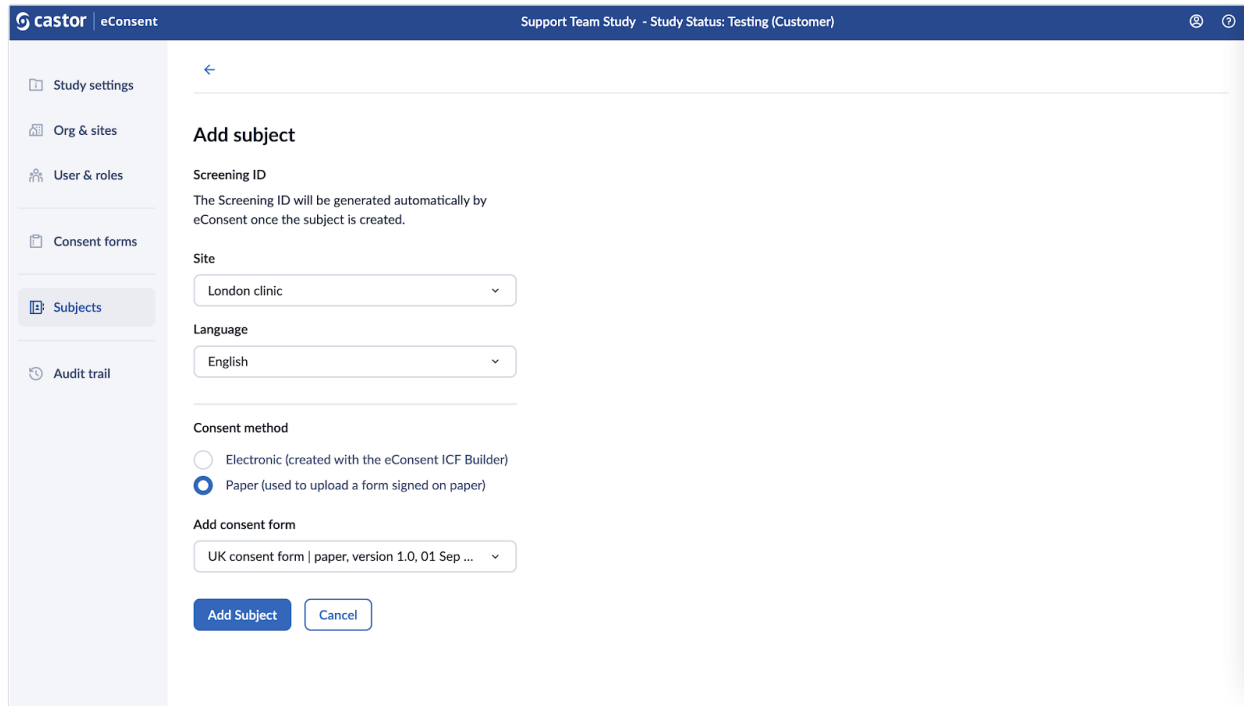
For electronic ICFs, it is also possible to invite a participant to sign an ICF by clicking on the three dots menu and choosing the option to ‘Send invitation’.



9.2 Consenting on paper

If the ICF template uses a paper consent method and this method is enabled in the study Settings tab, a scan/copy of the paper signed ICF can be uploaded against the template.

1. When adding a subject, choose the 'Paper (used to upload a form signed on paper)' and select the applicable paper consent form.



castor | eConsent Support Team Study - Study Status: Testing (Customer)

Study settings

Org & sites

User & roles

Consent forms

Subjects

Audit trail

Add subject

Screening ID
The Screening ID will be generated automatically by eConsent once the subject is created.

Site
London clinic

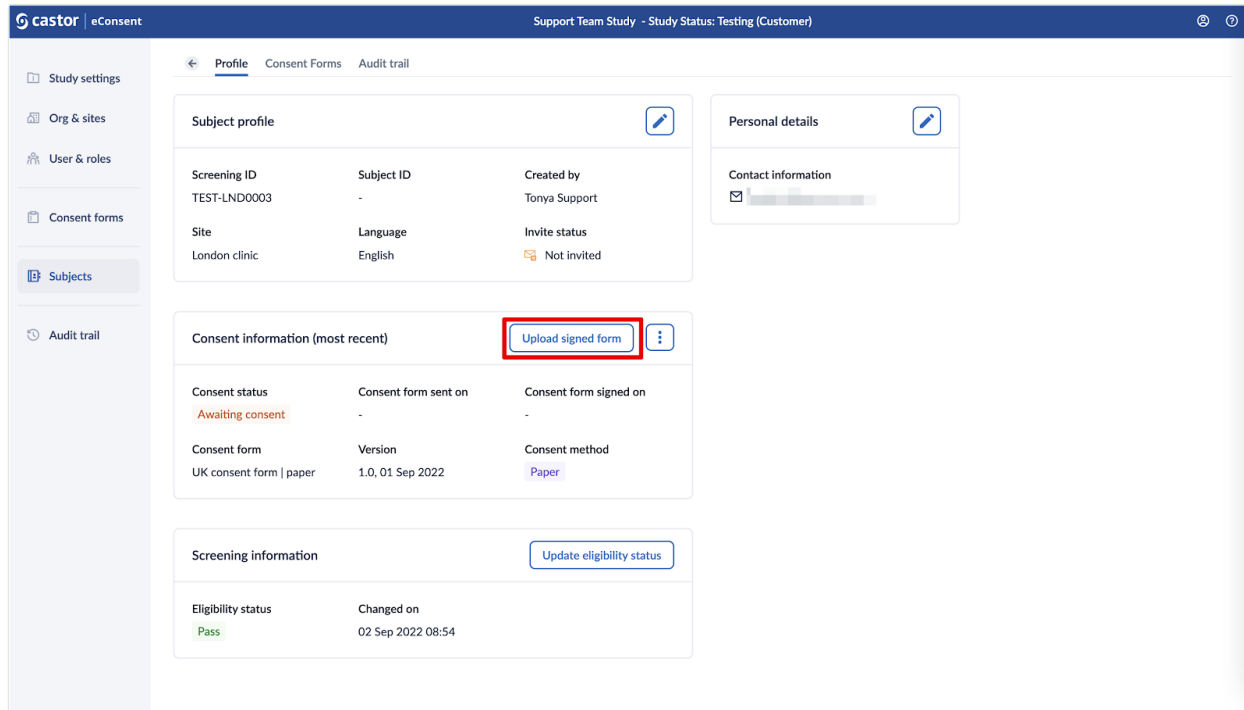
Language
English

Consent method
☐ Electronic (created with the eConsent ICF Builder)
☒ Paper (used to upload a form signed on paper)

Add consent form
UK consent form | paper, version 1.0, 01 Sep ...

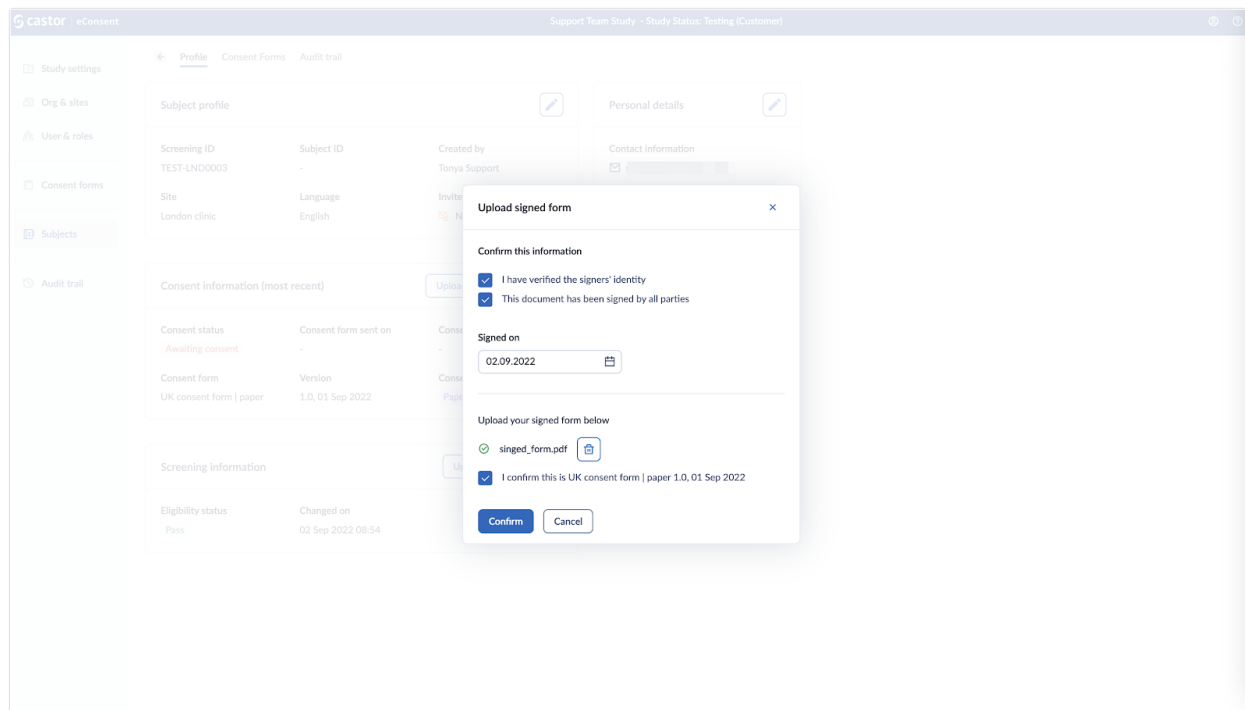
Add Subject Cancel

2. After the subject is added, in the Subjects overview, click on the subject row.
3. In the 'Consent information (most recent)' section, click on the 'Upload signed form' button.



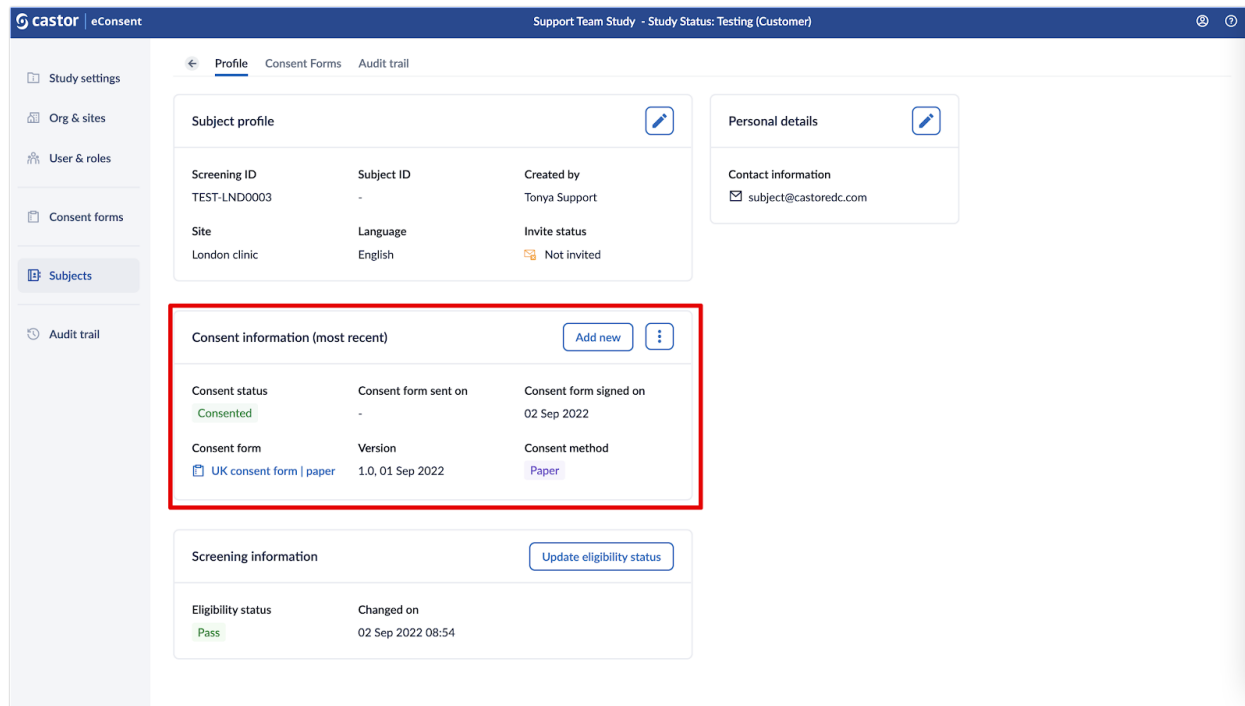
The screenshot shows the 'Profile' tab in the Castor eConsent interface. The left sidebar contains navigation links: Study settings, Org & sites, User & roles, Consent forms, Subjects (highlighted), and Audit trail. The main content area is titled 'Support Team Study - Study Status: Testing (Customer)' and has tabs for Profile, Consent Forms, and Audit trail. The 'Profile' tab is active, showing a 'Subject profile' section with fields for Screening ID (TEST-LND0003), Subject ID (-), Created by (Tonya Support), Site (London clinic), Language (English), and Invite status (Not invited). To the right is a 'Personal details' section with a 'Contact information' field. Below the subject profile is a 'Consent information (most recent)' section with a red box highlighting the 'Upload signed form' button. This section also displays 'Consent status' (Awaiting consent), 'Consent form sent on' (-), 'Consent form signed on' (-), 'Consent form' (UK consent form | paper), 'Version' (1.0, 01 Sep 2022), and 'Consent method' (Paper). At the bottom is a 'Screening information' section with 'Eligibility status' (Pass) and 'Changed on' (02 Sep 2022 08:54).

4. In the 'Upload signed form' pop-up window, confirm the requested details and upload the signed form. To save the form, click on the 'Confirm' button.



Accepted files: .pdf, .jpeg, .jpg, .png and the maximum file size is 15 Mb.

5. After the file is uploaded, the 'Consent status' will be automatically changed to 'Consented' in the 'Consent information (most recent)' section.



Subject profile

Screening ID	Subject ID	Created by
TEST-LND0003	-	Tonya Support
Site	Language	Invite status
London clinic	English	Not invited

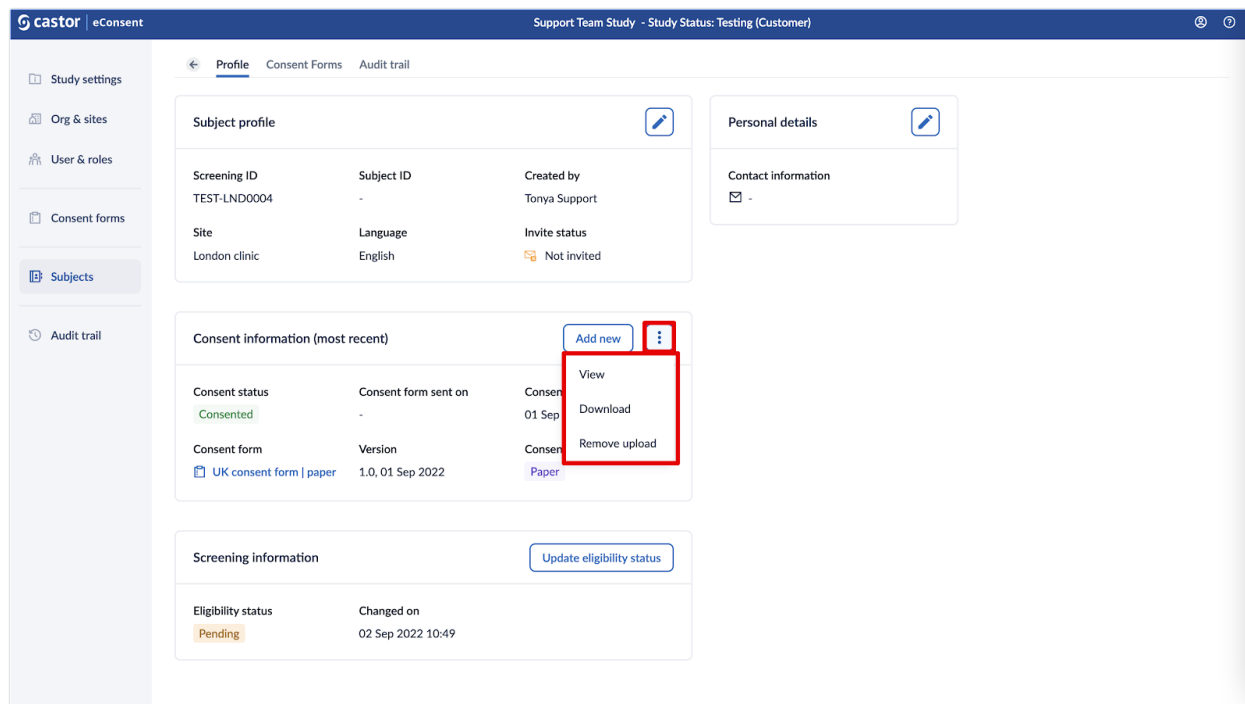
Consent information (most recent)

Consent status	Consent form sent on	Consent form signed on
Consented	-	02 Sep 2022
Consent form	Version	Consent method
UK consent form paper	1.0, 01 Sep 2022	Paper

Screening information

Eligibility status	Changed on
Pass	02 Sep 2022 08:54

6. If you would like to view, download or remove the uploaded file, click on the options menu (three dots) in the 'Consent information (most recent)' section:



Subject profile

Screening ID	Subject ID	Created by
TEST-LND0004	-	Tonya Support
Site	Language	Invite status
London clinic	English	Not invited

Consent information (most recent)

Consent status	Consent form sent on	Consent form signed on
Consented	-	01 Sep
Consent form	Version	Consent method
UK consent form paper	1.0, 01 Sep 2022	Paper

Screening information

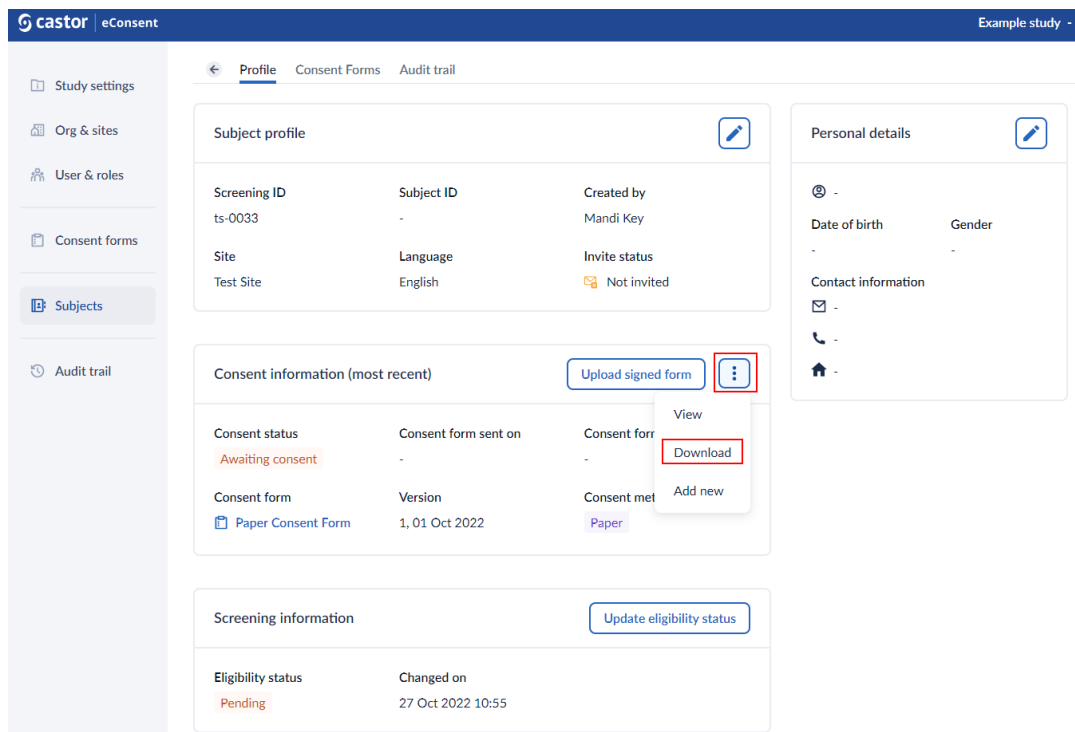
Eligibility status	Changed on
Pending	02 Sep 2022 10:49

If a subject/LAR has been invited to the study, they will also be able to view the uploaded paper form.

9.3 Print-to-sign

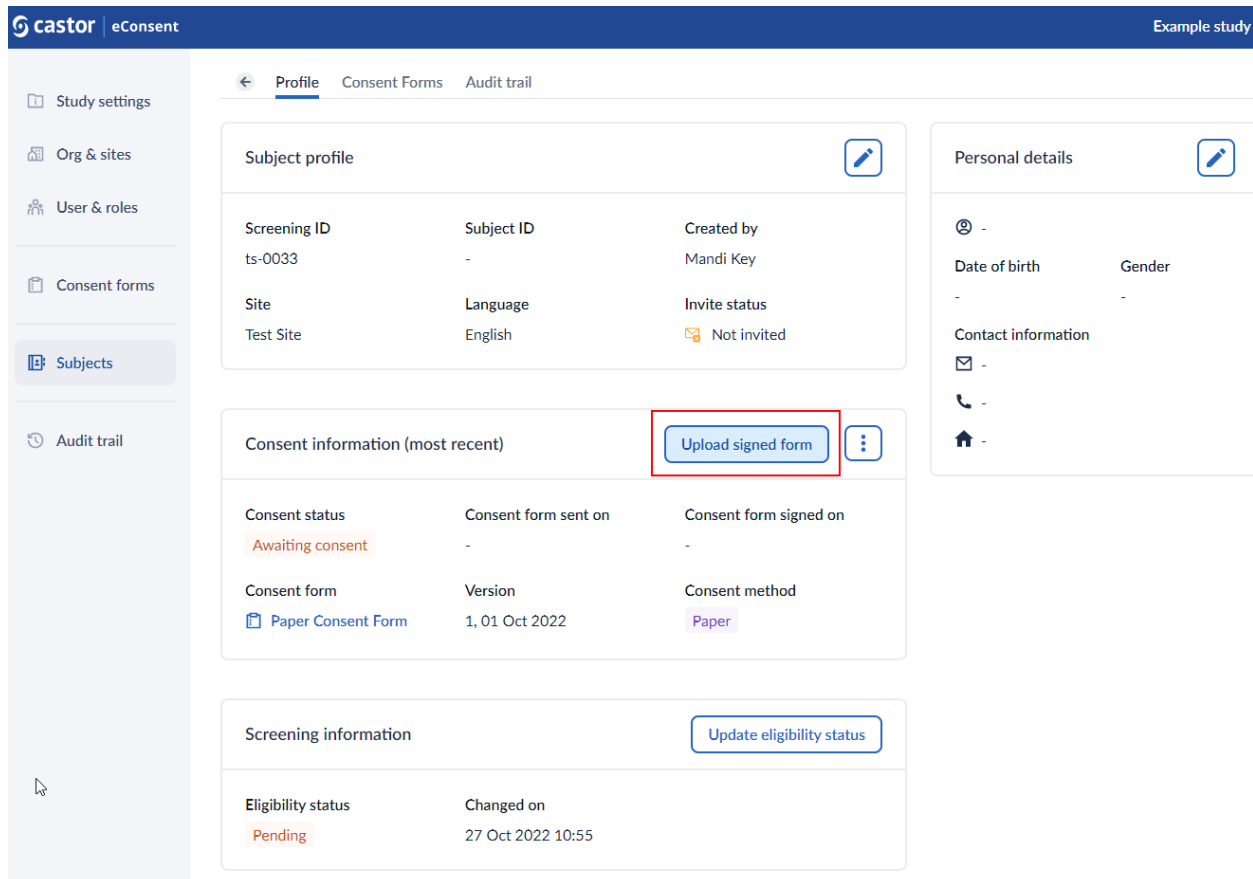
The ICF builder for ICF templates that use a paper consent method allows pdf file uploads. This means that the finalized “paper” ICF file can be uploaded against the eConsent paper ICF template. By doing so, the actual content of the ICF becomes available for site members. The site member can download and print the ICF template directly from the eConsent subject record, in order to make sure the right ICF version is getting signed.

To download, open the subject record and in the “Consent Information (most recent)” dialogue box select the options menu (three dots) to the right and select download.



The screenshot shows the Castor eConsent interface for a subject record. The left sidebar contains navigation links: Study settings, Org & sites, User & roles, Consent forms, Subjects (highlighted), and Audit trail. The main content area is titled 'Profile' and includes tabs for Profile, Consent Forms, and Audit trail. The 'Subject profile' section displays fields for Screening ID (ts-0033), Subject ID (-), Created by (Mandi Key), Site (Test Site), Language (English), and Invite status (Not invited). The 'Consent information (most recent)' section shows a table with columns for Consent status (Awaiting consent), Consent form sent on (-), Consent form (-), Consent form version (1, 01 Oct 2022), and Consent method (Paper). A dropdown menu is open next to the 'Consent form' field, showing options: View, Download (highlighted), and Add new. The 'Screening information' section shows the Eligibility status (Pending) and Changed on (27 Oct 2022 10:55).

Once the printed version is signed by all parties, a scan can be uploaded into the system by selecting “Upload signed form”.



The screenshot shows the Castor eConsent interface for an 'Example study'. The left sidebar contains navigation links: Study settings, Org & sites, User & roles, Consent forms, Subjects (selected), and Audit trail. The main content area has tabs for Profile, Consent Forms, and Audit trail. The 'Profile' tab is active, displaying three sections: Subject profile, Consent information (most recent), and Screening information. The 'Subject profile' section shows details like Screening ID (ts-0033), Subject ID (-), Created by (Mandi Key), Site (Test Site), Language (English), and Invite status (Not invited). The 'Consent information (most recent)' section shows Consent status (Awaiting consent), Consent form sent on (-), Consent form signed on (-), Consent form (Paper Consent Form), Version (1, 01 Oct 2022), and Consent method (Paper). The 'Screening information' section shows Eligibility status (Pending) and Changed on (27 Oct 2022 10:55). The 'Upload signed form' button in the 'Consent information' section is highlighted with a red box.


In the dialog box confirm the required information and upload the file by selecting “choose file” or drag and drop the file into the box and confirm.

Upload signed form


Confirm this information

☐ I have verified the signers' identity
 ☐ This document has been signed by all parties

Signed on



Upload your signed form below



Drag and drop file here

or

Choose file

Accepted files: pdf, jpeg, jpg, png

Max file size: 15MB

☐ I confirm this is Paper Consent Form 1, 01 Oct 2022

Confirm

Cancel

Accepted file formats: .pdf, .jpeg, .jpg, .png and the maximum file size is 15 Mb.

9.4 Reconsenting

If a participant needs to be reconsented during the study, follow the steps below:

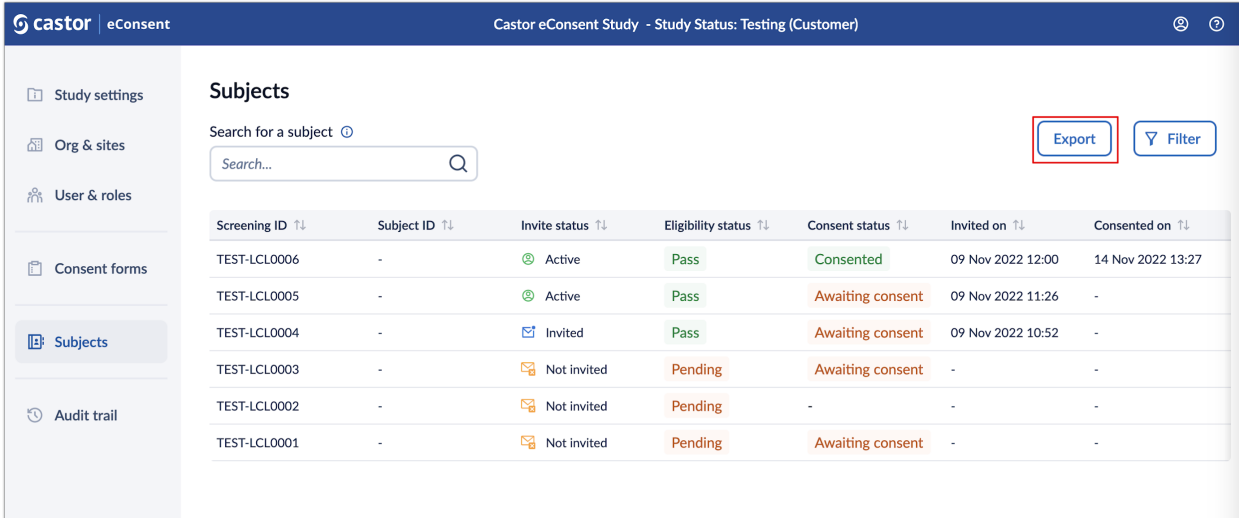
1. Select the participant row to access the participant's profile.
2. Press the 'Add New' button to assign the new consent form.
3. In a new pop-up screen, you can repeat the process for on-site, remote or paper consent by selecting the relevant consent method and consent form.
4. Once required settings are set and the consent form is selected, press 'Add' to continue.
5. The consent status will be updated to 'Awaiting consent'.

10. Exporting signature information

Users with the 'Study Investigator' or 'Study Monitor' role are able to generate the export that contains signature information.

To export the signature information, follow the steps below:

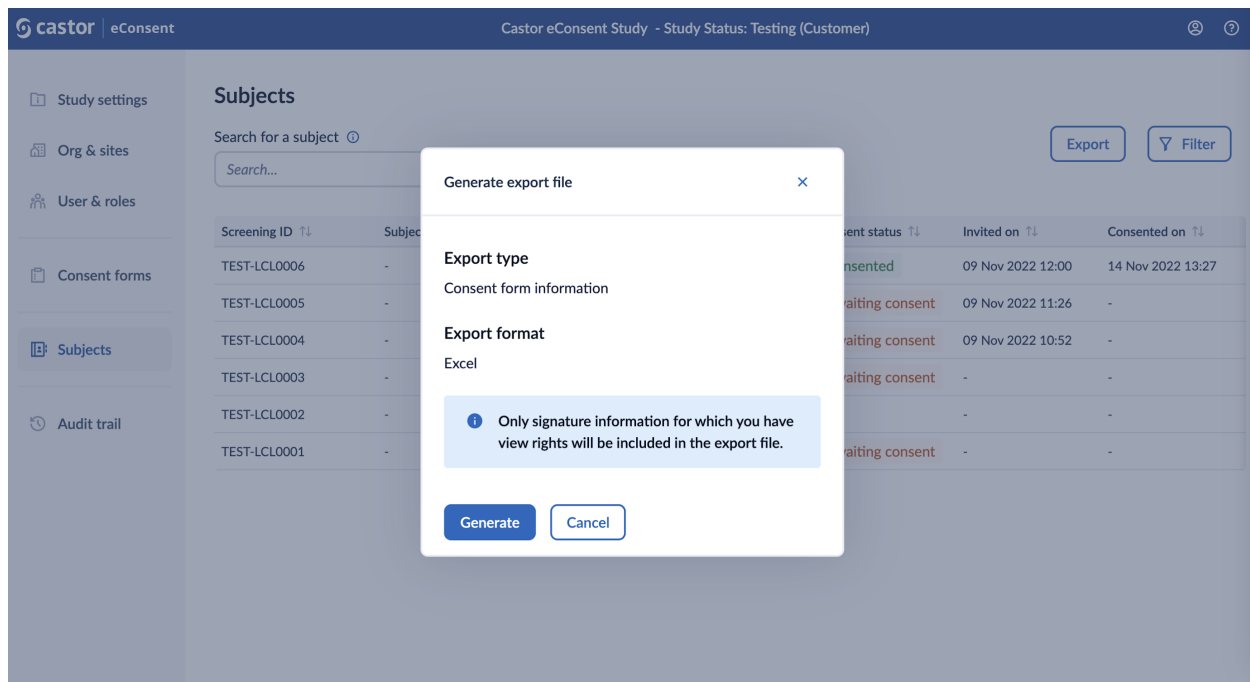
1. In the 'Subjects Overview', click on the 'Export' button:



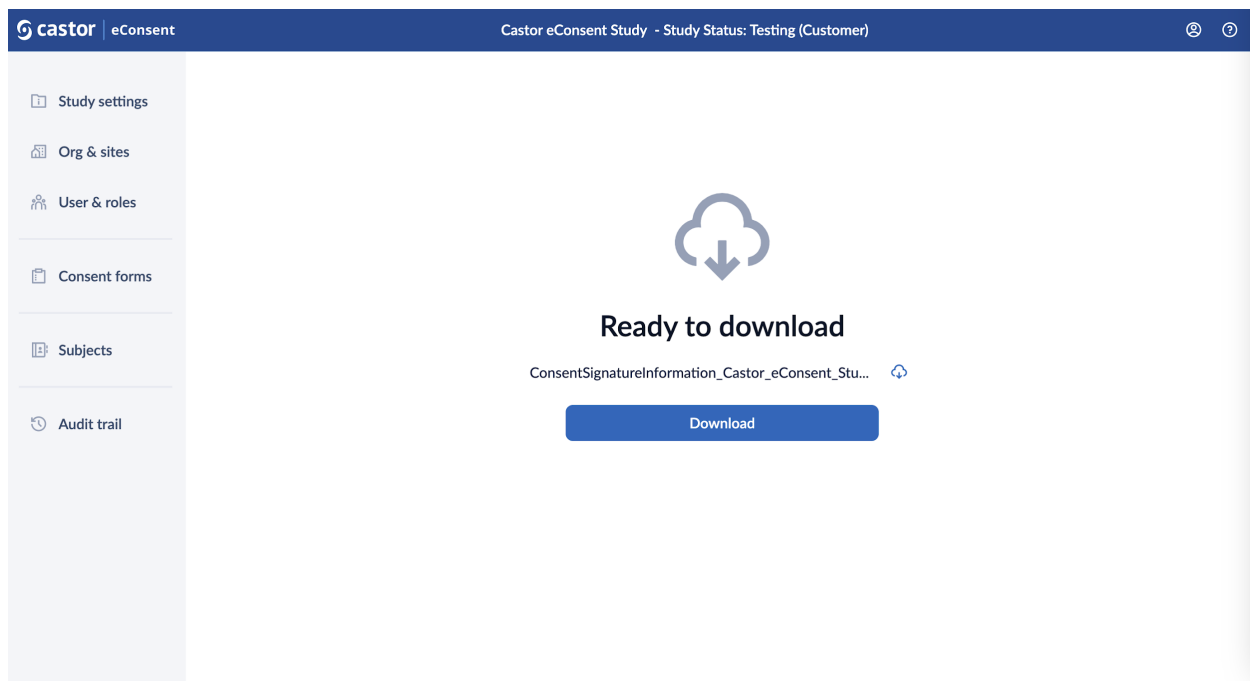
The screenshot shows the 'Subjects' page in the Castor eConsent interface. The page title is 'Subjects'. There is a search bar with the placeholder text 'Search for a subject' and a search icon. To the right of the search bar are two buttons: 'Export' (highlighted with a red box) and 'Filter'. Below the search bar is a table with the following columns: Screening ID, Subject ID, Invite status, Eligibility status, Consent status, Invited on, and Consented on. The table contains six rows of data.

Screening ID	Subject ID	Invite status	Eligibility status	Consent status	Invited on	Consented on
TEST-LCL0006	-	Active	Pass	Consented	09 Nov 2022 12:00	14 Nov 2022 13:27
TEST-LCL0005	-	Active	Pass	Awaiting consent	09 Nov 2022 11:26	-
TEST-LCL0004	-	Invited	Pass	Awaiting consent	09 Nov 2022 10:52	-
TEST-LCL0003	-	Not invited	Pending	Awaiting consent	-	-
TEST-LCL0002	-	Not invited	Pending	-	-	-
TEST-LCL0001	-	Not invited	Pending	Awaiting consent	-	-

2. In the pop-up window, click on the 'Generate' button to proceed with the export. Only signature information for which you have view rights will be included in the export file.



- Once the export is generated, the requester is notified by an email that includes a personal download link. The generated export can then be downloaded from within eConsent by clicking on the 'Download' button.



12. Further Information

If you would like to view our Castor eConsent video tutorials, you can do so [here](#).

For more information regarding creating and managing study as a study admin, please check Castor EDC's knowledge base:

https://helpdesk.castoredc.com/en_US/castor-econsent-manual. If you have any questions or concerns, please contact us at support@castoredc.com