Castor

Castor eConsent Site User Guide

Version 2024.1

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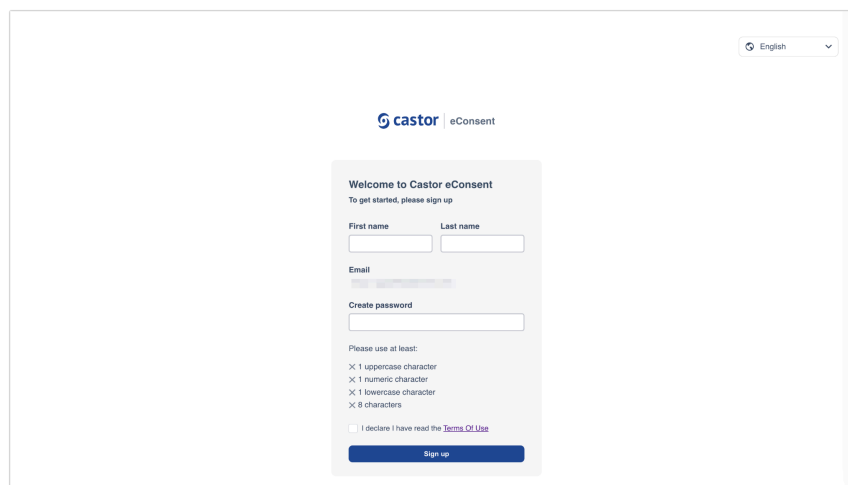
By clicking the 'Join the Study' link provided in the email, you will be directed to the registration page:

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.

Studies

Search... 🔍 ⓘ

Active

| ● Live	The Impact of Yoga and Meditation on Chronic Pain: A Randomize... ⓘ	Main contact:
● Testing (Castor)	**Castor eConsent Study (Testing)**	Main contact:
● Testing (Customer)	**Castor eConsent Study**	
● Testing (Customer)	**Support Team Study** ⓘ	Main contact:

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 to join a study 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.
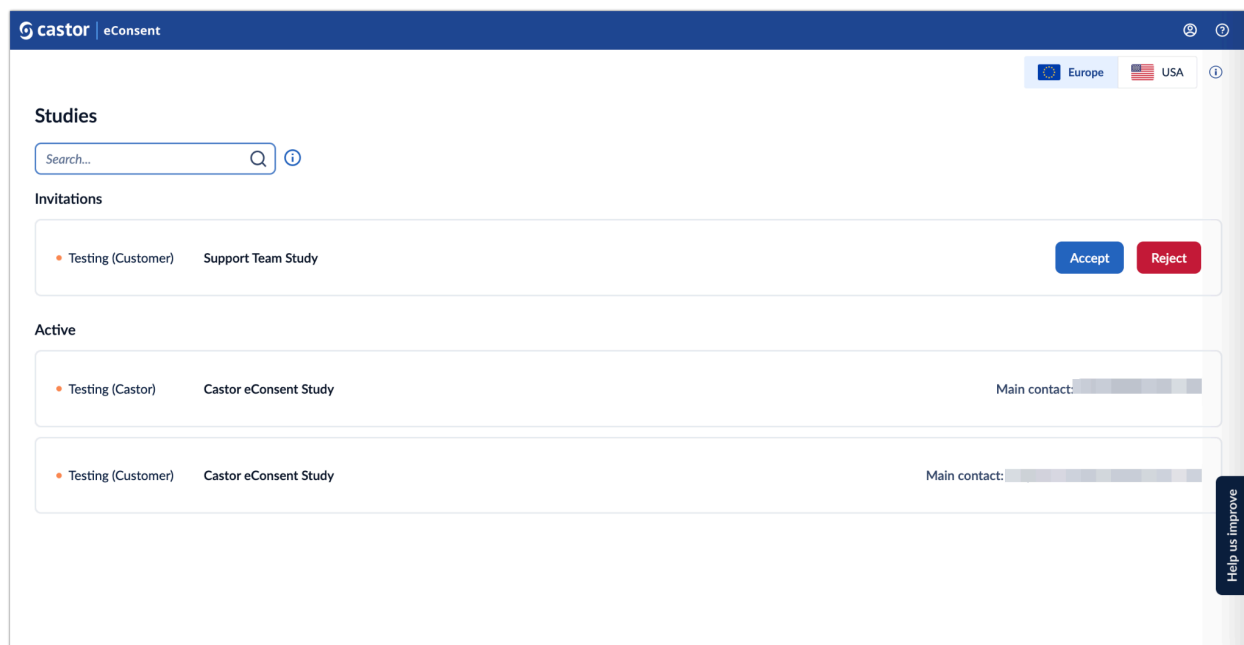
The 'Studies' overview consists of the following elements:

- **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: <u>Study status in eConsent</u>
  - **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
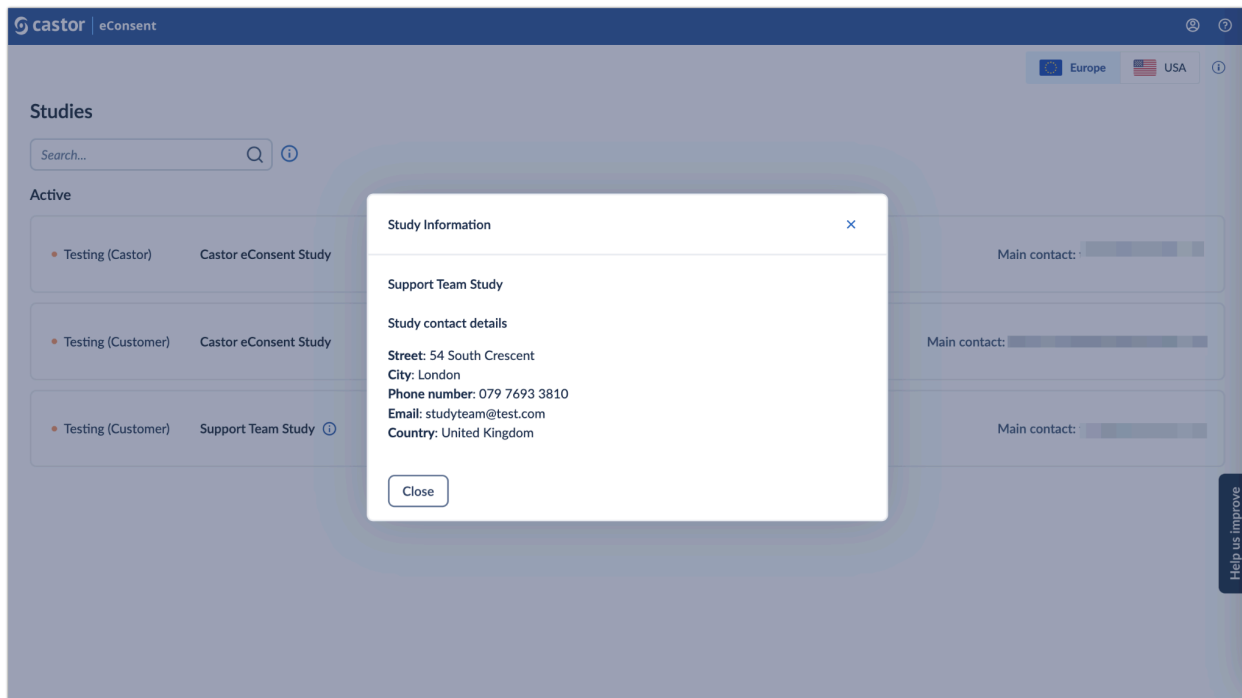
Studies for which an invitation has been accepted will appear in the 'Active' section and it is possible to access the study by clicking on the study row.

4. Adding a participant

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

1. Navigate to the 'Participants' overview
2. Press the 'Add participant' button
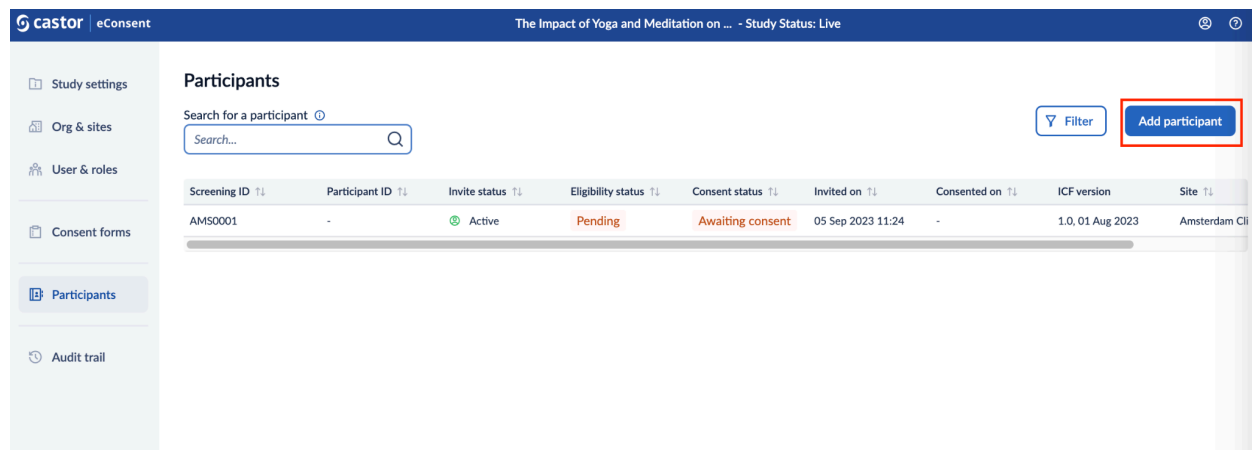
3. On the 'Add participant' screen, fill out the details:
   ○ **Site**: choose a site where a participant should be created.
   ○ **Language**: specify the language
   ○ **Add consent form**: choose the applicable consent form
   ○ **Send an invitation to participant?**: set this option to 'Yes' if you wish to send an email invitation to the participant and to 'No' if no notification emails should be sent.
   ○ **Participant email address**: if you wish to send an invitation to a participant, make sure to add the participant's email address. If no notification should be sent, please skip this field.
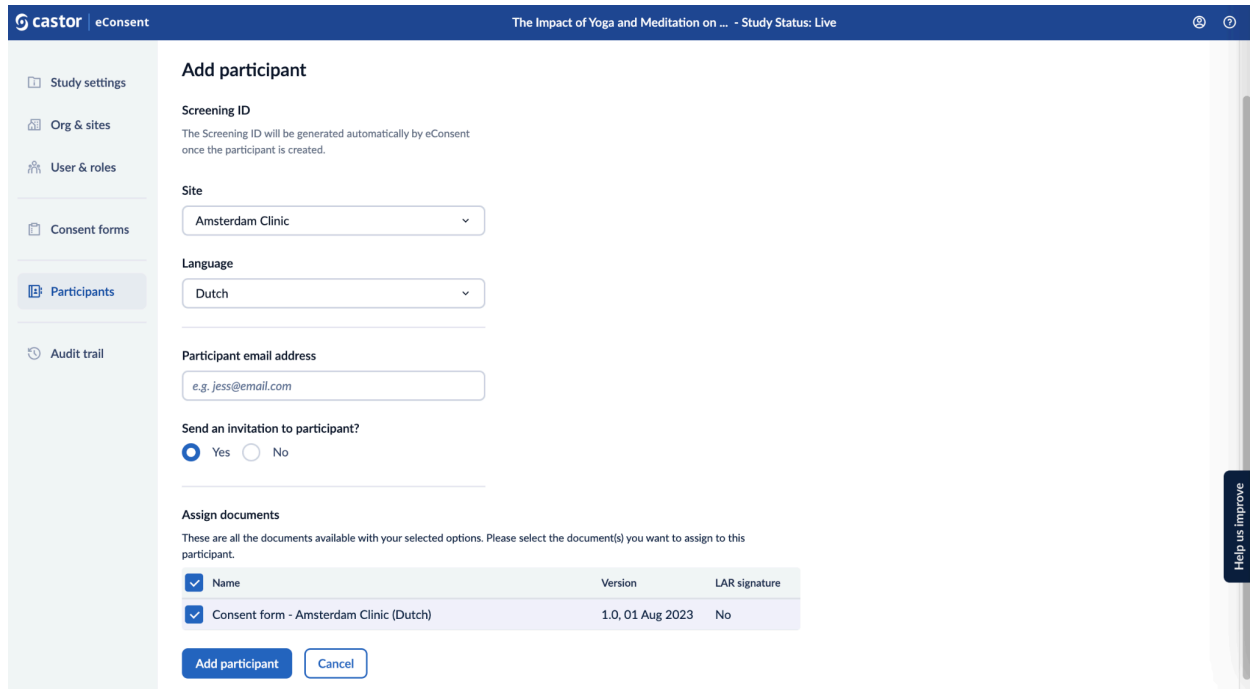
If you only have rights for one site or one consent form, the applicable fields will be automatically populated.

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

4.1 (Un)Archiving a participant

1. To archive a participant, start by navigating to the 'Participants' listing.

2. Locate the participant you wish to archive, then click on the three-dot context menu in the Options column.

3. From the dropdown menu, select the 'Archive Participant' option. This will securely archive the participant, and please note that after archiving, the participant ID cannot be reused.

4. Once the participant ID is archived, it will no longer be displayed in the 'Participants' page. To locate the archived participant ID, click on the 'Filter' button and choose 'Include archived' option, afterwards click 'Apply filters':

5. Locate the archive participant, click on the context menu (three dots) and choose 'Unarchive' option:

4.1 (Un)Marking a participant as withdrawn

A study team member with PII rights can withdraw a participant from the participant list.

1. To mark a participant as withdrawn, start by navigating to the 'Participants' listing.
2. Locate the participant you wish to mark as withdrawn, then click on the three-dot context menu in the Options column.
3. From the dropdown menu, select the 'Mark as withdrawn' option. This will securely mark the participant as withdrawn.

4. In a new pop-up window select a date of withdrawal. This date is then also included in the Audit Trail Event that is logged.
5. Select the reason for withdrawal. If you select 'Other' it will allows you to provide a custom reason in a text field.
6. Decide to send an automatic confirmation email to the participant after the withdrawal is processed.
7. To save or cancel changes use the relevant buttons - 'Mark as withdrawn' or 'Cancel' - at the bottom.

7. Withdrawn participants are hidden from the participant overview by default. They can be shown by turning on the Include withdrawn' in the filter menu.

8. The consent status of the participant changes to 'Withdrawn' when they are withdrawn from the study.

9. A study team member with PII rights can **undo the withdrawal of a participant**. To undo participant withdrawal, locate the withdrawn participant, click on the context menu (three dots) and choose 'Unmark as withdrawn' option:

10. Then confirm by selecting the 'Unmark as withdrawn' button.

11. An Audit Trail Event will be logged to document this change.

12. The study status will change back to the original status of the participant and the restricted access is removed from theAfter being withdrawn, participants have the same

type of access as archived participants. They can view the study, their documents and their participant details. However, they can not change anything or sign any documents.

13. An active participant can either be withdrawn or archived. After withdrawing, a participant can not be archived anymore and vice versa.

14.When withdrawing a participant record with a LAR attached to it, the study team member will be asked if the LAR should be notified instead of the participant.

5. 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 participant account or without a participant account (in-person signing). In cases where a paper consent method is used, signed consent forms can be uploaded into the eConsent platform.

If your desired consent form is not visible or your desired consent method (paper or electronic) is not present, please reach out to the study admin and request the study admin to add the consent method or consent form to your site.

5.1 Electronic signing

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

5.1.1 Electronic signing with an account (remotely)
To initiate the electronic signing, follow these steps:

1. Add a participant from the 'Participants' tab
2. When adding a new participant, choose 'Electronic' consent method
3. In the 'Participant email address' add the participant's email
4. If the signing procedure happens remotely, select 'Yes' in the 'Send an invitation to participant?' field
5. Choose the relevant documents in the 'Assign documents' section
6. Click on the 'Add participant' button create a participant and send an invite

Add participant

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

Site
Amsterdam Clinic ⌄

Language
Dutch ⌄

Consent method
⦿ Electronic
○ Paper (used to upload a form signed on paper)

Participant email address
e.g. jess@email.com

Send an invitation to participant?
⦿ Yes ○ No

Assign documents
These are all the documents available with your selected options. Please select the document(s) you want to assign to this participant.

☑ Name	Version	LAR signature
☑ Consent form - Amsterdam Clinic (Dutch)	1.0, 01 Aug 2023	No

[Add participant] [Cancel]

7. You will then be redirected to the 'Participants' listing.
8. From the 'Participants' listing, double click on the participant row
9. You will be presented with the participant details
10. If eligibility is checked in the study, the 'Eligibility status' will be automatically set to 'Pending'. Click on the 'Update eligibility status' button to change the eligibility status. Choose from the following options: Pass, Pending, Fail. If an integration is set up with a Castor CDMS study, the eligibility field might be updated automatically, check with the study admin if this is applicable for your study.
11. To allow a participant to sign the form, in the 'Consent information (most recent)' section, click on the 'Unlock' button. Please confirm you would like to update the form status to unlocked in the pop-up window. The form will now become available for the participant for signature.
12. In order to prompt your invitee once more, simply click on the 'Send Reminder' button to resend the invitation.

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.
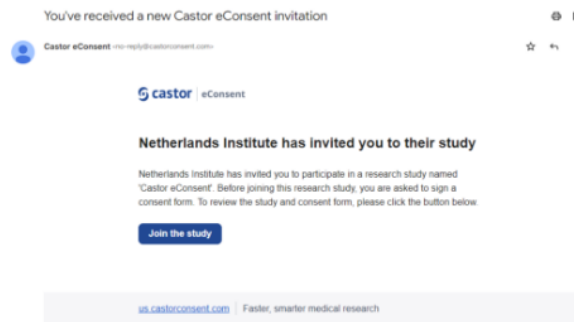
After setting up their account and logging in, a dashboard will be presented.
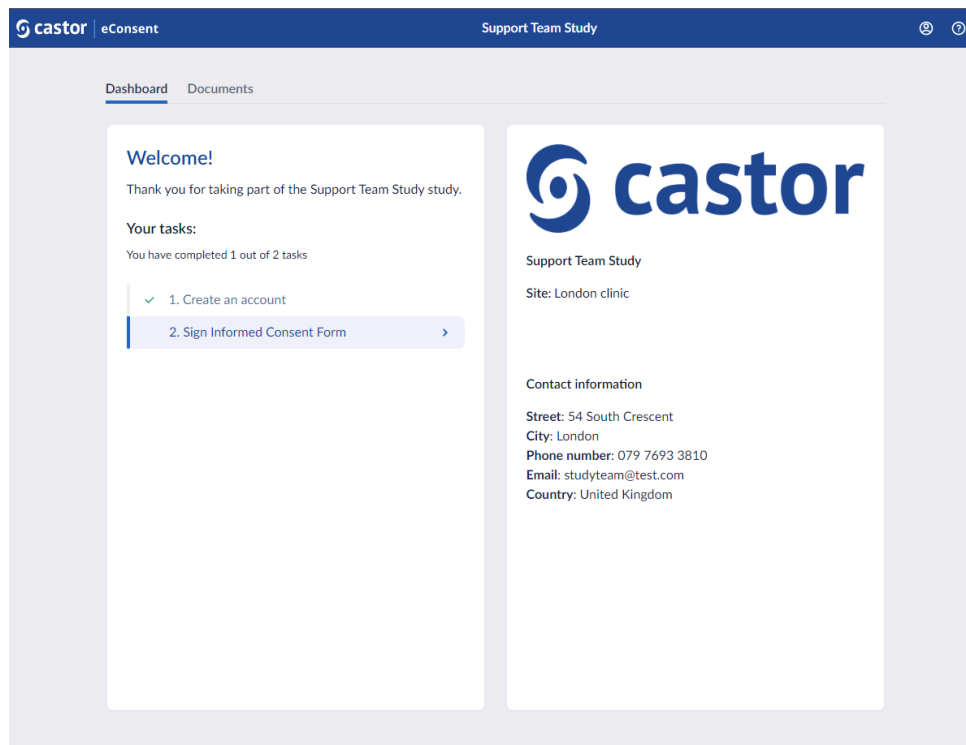
The participant will need to Press the 'Sign Informed Consent Form' where they can download the consent form or view and sign.
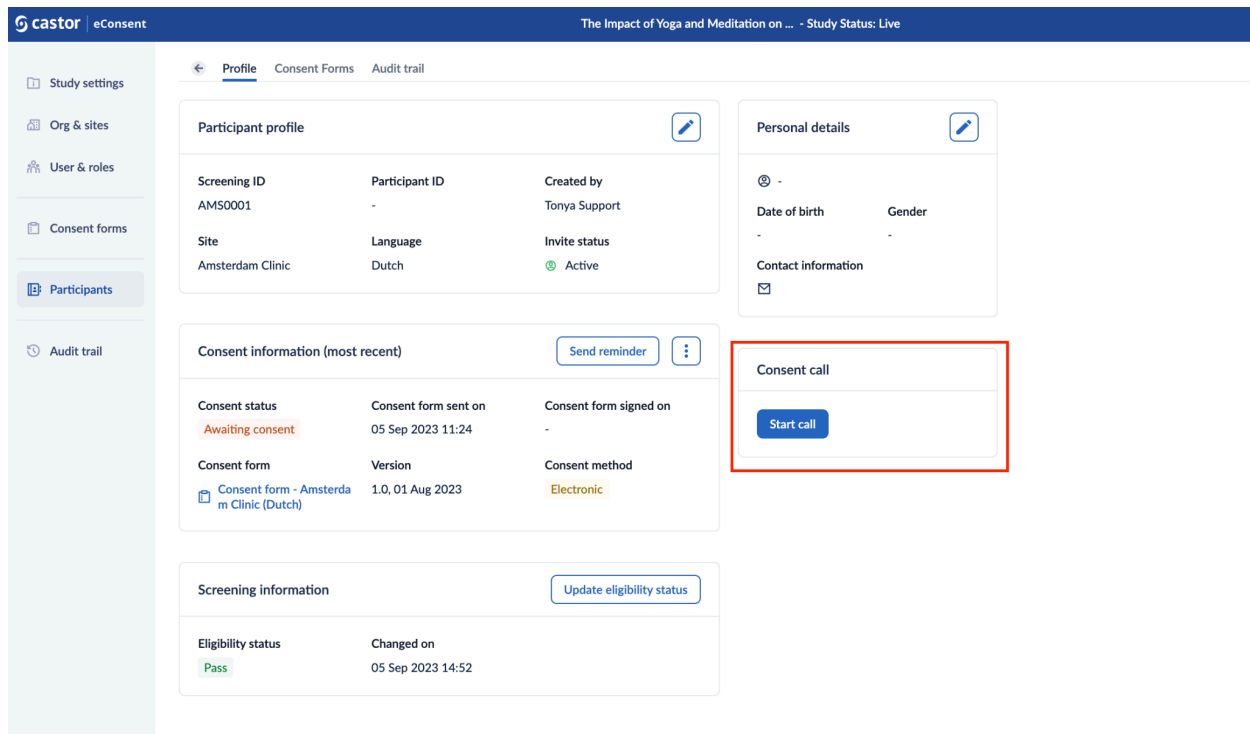
Upon selecting 'View & Sign', the participant will then select the required fields, type their full name, add their electronic signature, then press the 'Submit' button to submit their signature.
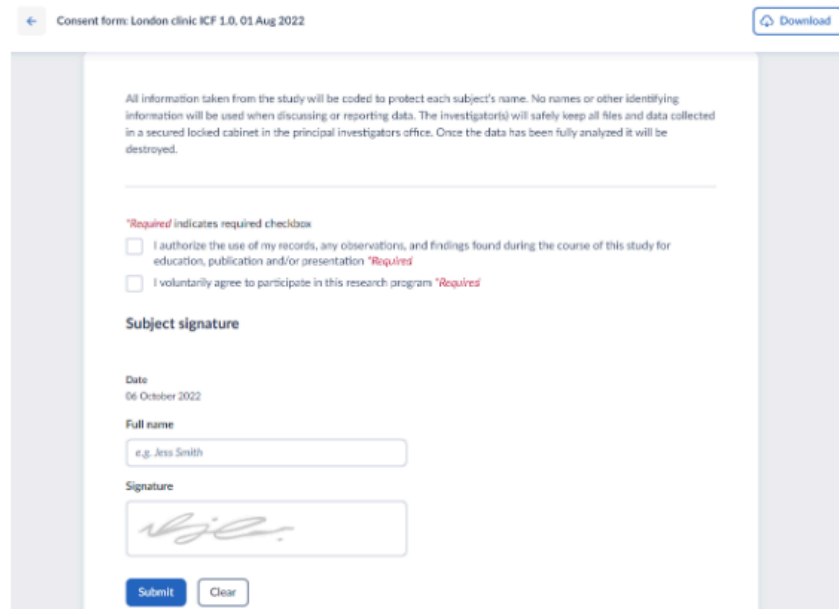
5.1.2 Electronic signing via a Video-call (remotely)

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 participant, a 'Consent call' card will appear:

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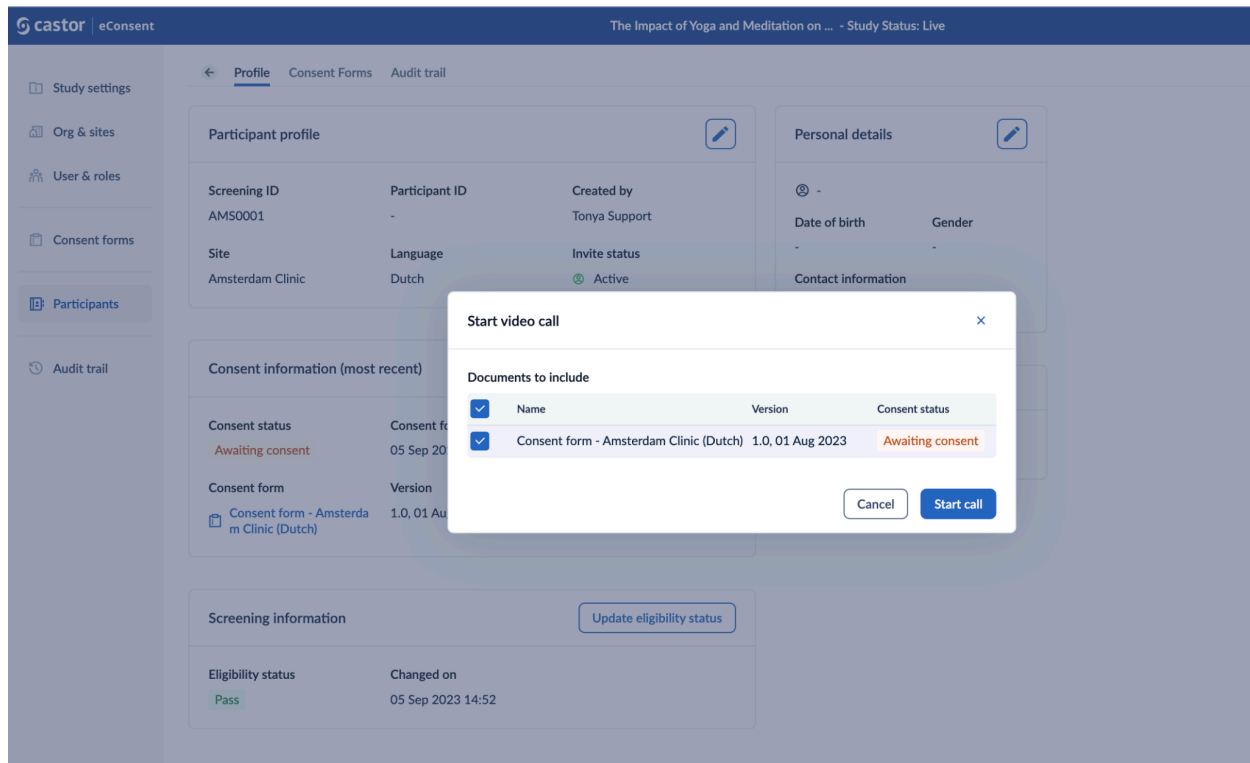
3. You will be redirected to the call screen. During the call, the following options are presented:
   - Unlock to enable signing/Lock to disable signing which allows to enable the ICF for signing and lock it after the form has been signed
   - Start video/Stop video which allows to turn on/off the investigator's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

4. The participant will need to login to the participant portal and choose the relevant study in the 'Studies' overview.

5. Once the investigator starts the call, the participant 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.
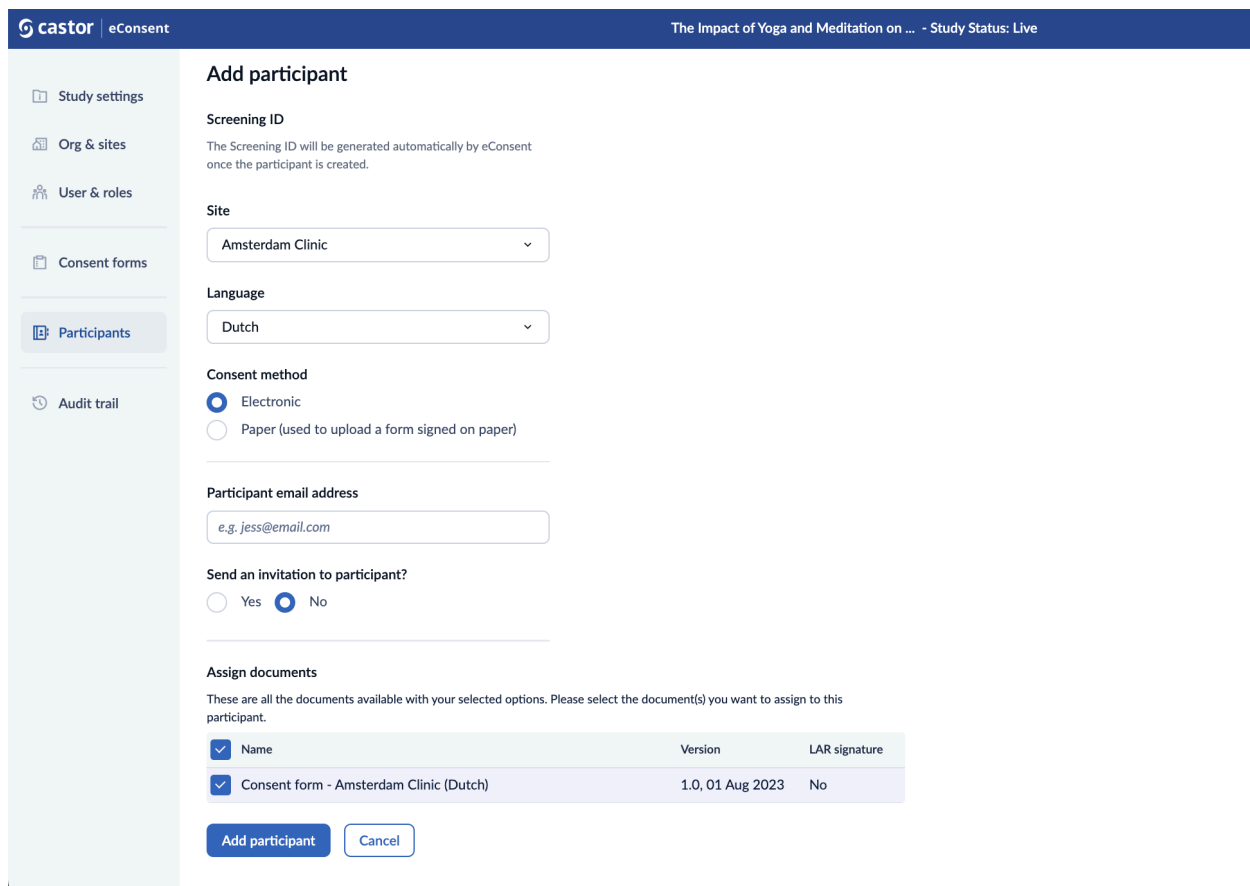
5.1.3 Electronic signing in-person

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 'Participants' overview and click on the 'Add participant' button or choose an existing participant.
2. When creating a new participant, you may want to set the field 'Send an invitation to participant' to 'No'. In this case, an email invite will not be sent and the invite status in the Participants listing will be set to 'Not invited'.

3. Participants who received an invite per email can also use the in-person signing flow. In this case, the option to sign in-person will appear in the 'Consent information (most recent)' section in the context menu (three dots menu):

4. In case where no invite to a participant is sent and when there is already an ICF added which hasn't been signed by the participant 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:
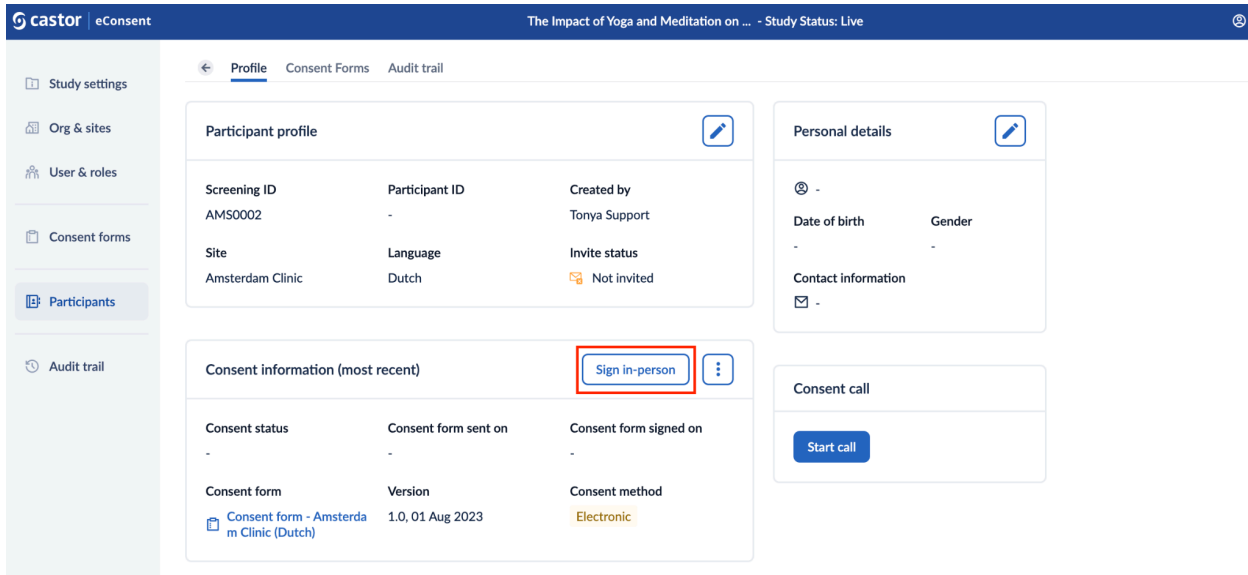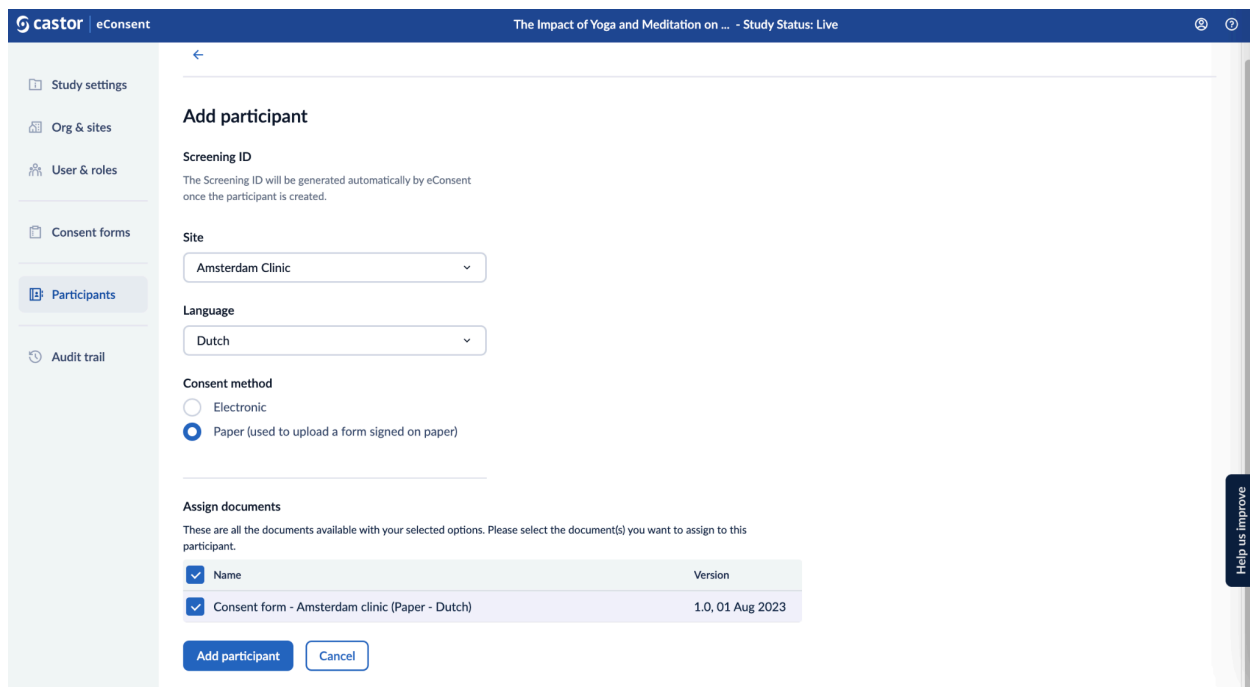
5. After clicking on the "Sign in-person" options, a confirmation dialog will be shown with the following message: "The form will be unlocked for signing, the study team member will be required to monitor the consent form so that the signer does not access other parts of the application." Select the 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:
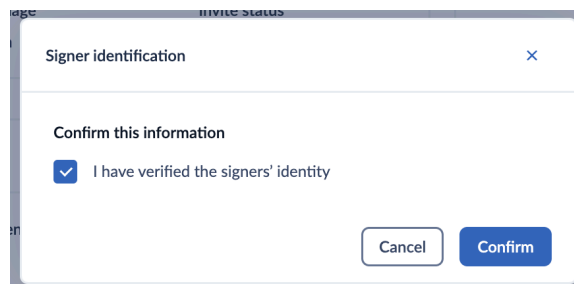
5.2 Consenting on paper

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. Make sure that a paper consent form is created in the 'Consent forms' tab first, otherwise it will not be possible to upload a paper ICF.

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

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

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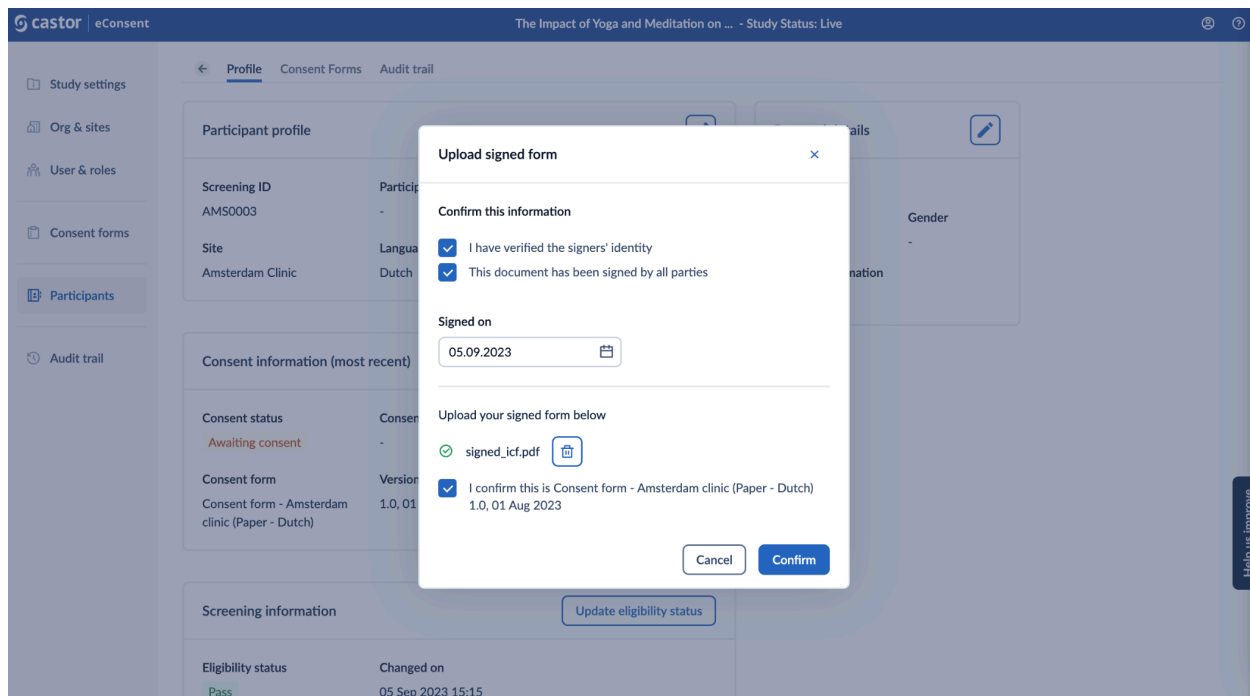
Accepted files: .pdf, .jpeg, .jpg, .png and the maximum file size is 15 Mb.

5. After the file is uploaded, the 'Consent status' will be automatically changed to 'Consented' in the 'Consent information (most recent)' section in case there are no other pending documents for signature.

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:

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

5.3 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 participant record, in order to make sure the right ICF version is getting signed.

1. To download, open the participant record and in the "Consent Information (most recent) dialogue box select the options menu (three dots) to the right and select download.
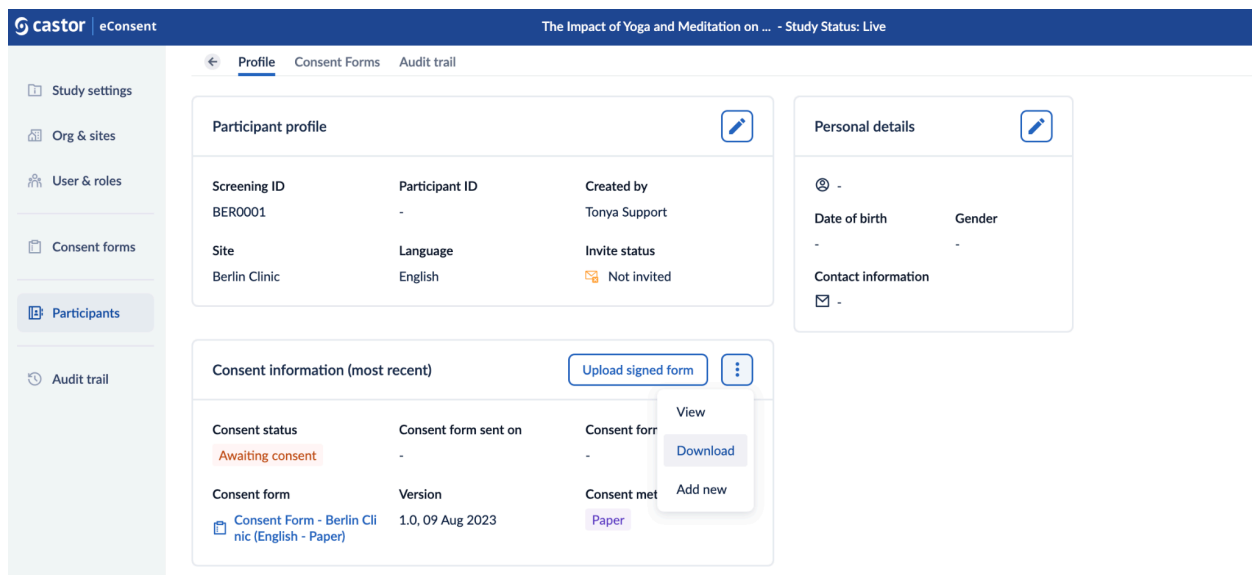
2. Once the printed version is signed by all parties, a scan can be uploaded into the system by selecting "Upload signed form".
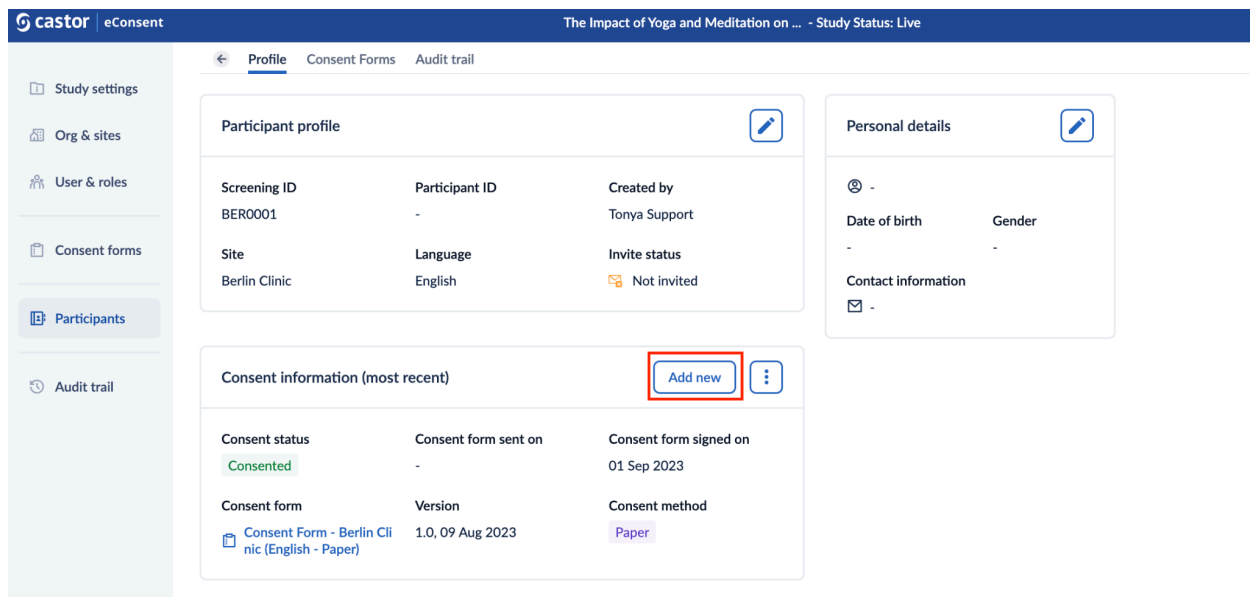
3. In the dialog box confirm the required information and upload the file by selecting "choose file" or drag and drop the file into the box and confirm.

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

5.4 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'.

6. Exporting consent form and participant information

Users with the 'Study Investigator' or 'Study Monitor' role are able to generate the export that contains consent form signature or participant personal details information.

To export the consent form or personal details information, follow the steps below:

1. In the 'participants Overview', click on the 'Export' button:
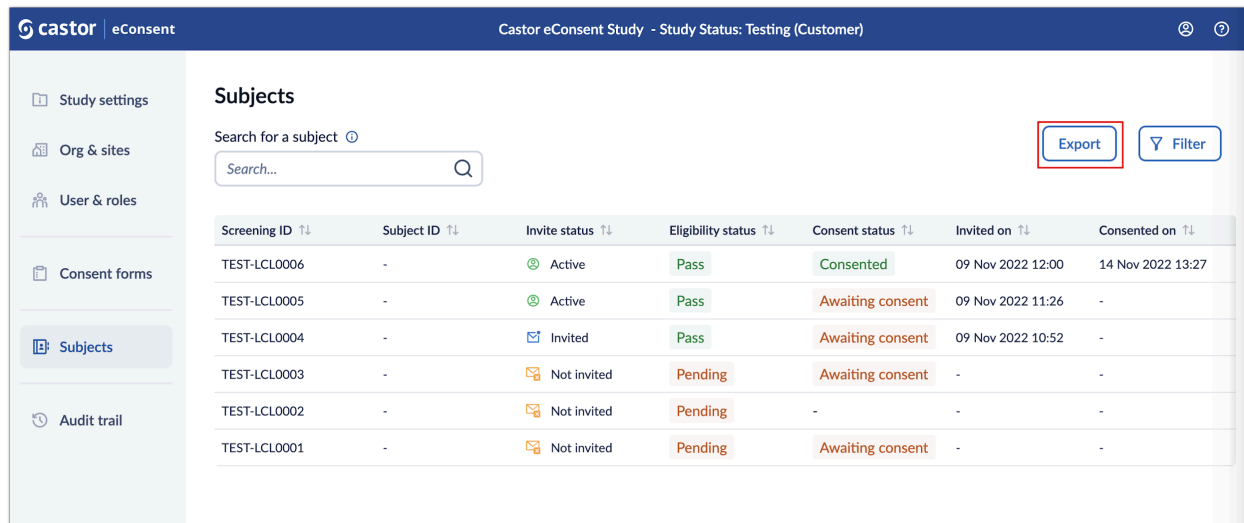
2. In the 'Generate export file' pop-up window, in the 'Export type', select 'Consent form information' or 'Participant personal details' option. Click on the 'Generate' button to proceed with the export. Only signature information for which you have view rights will be included in the export file.
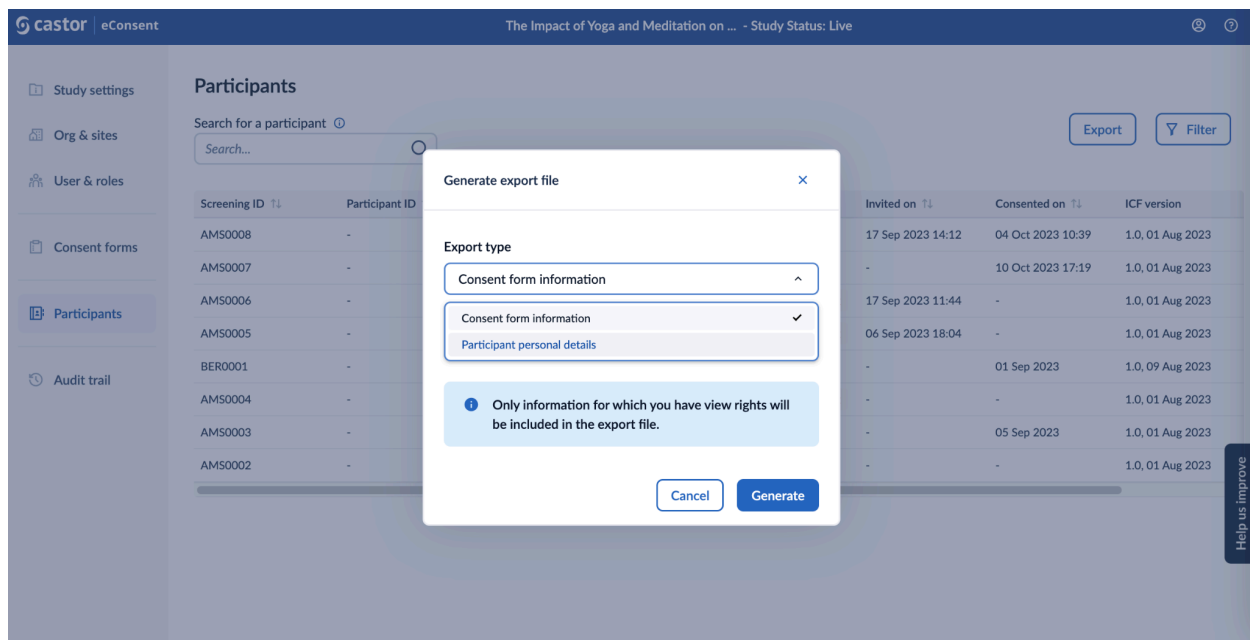
3. Once the export is generated, the requester is notified by an email that includes a personal download link. The generated export can then be downloaded from within eConsent by clicking on the 'Download' button.
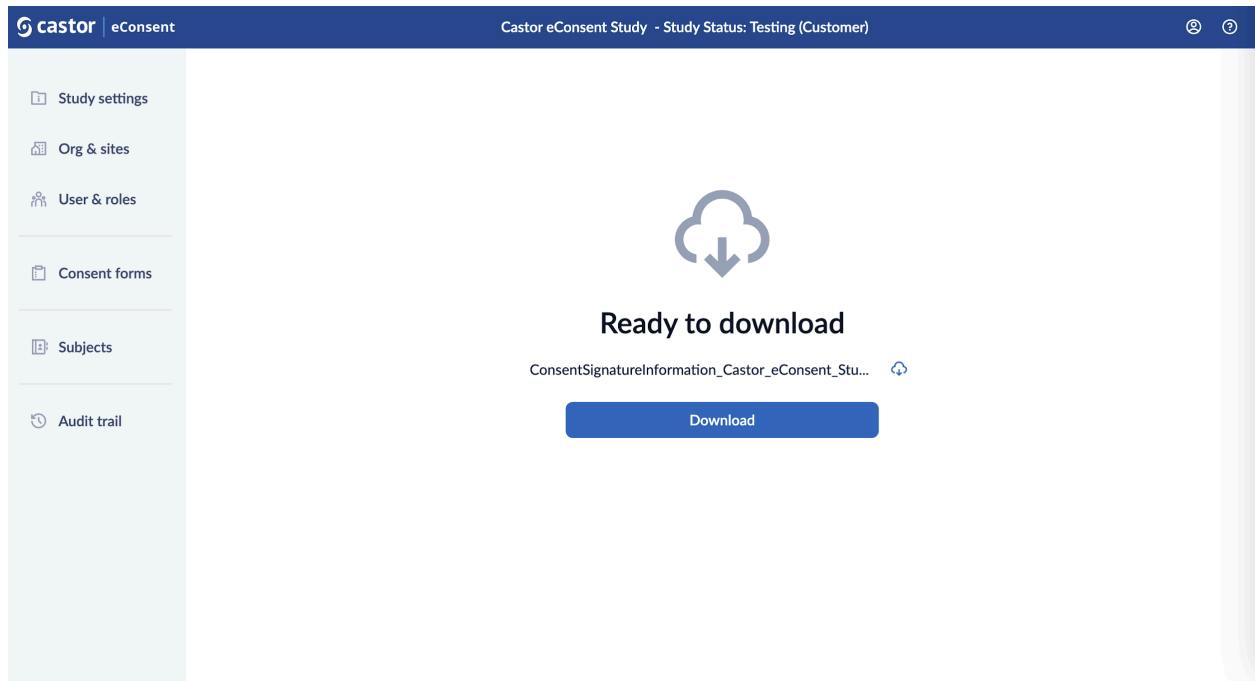
7. Audit trail

The audit trail is a log of study related events:

To view additional details for each event, click on the row:

7.1 Audit trail export

Study roles with PII access (i.e. study investigators/monitors) will see an 'Export' button on the global audit trail page they can use to run the export.

A pop-up window will appear, click 'Generate' to run the export:

Only audit trail events for which you have view rights will be included in the export file.

You will receive an email notification when the file is ready to download. Click the link in

the email or 'Download' button to download the audit trail export. The Export is provided in the Excel format.

castor | eConsent

Your export is ready for download

Hello

Your requested export file of AuditTrailInformation_The_ Impact_of_Yoga_and_Meditation_on_Chronic_Pain:_A_Randomized_ Controlled_Trial_04-01-24_07-19-34.xlsx is now available.
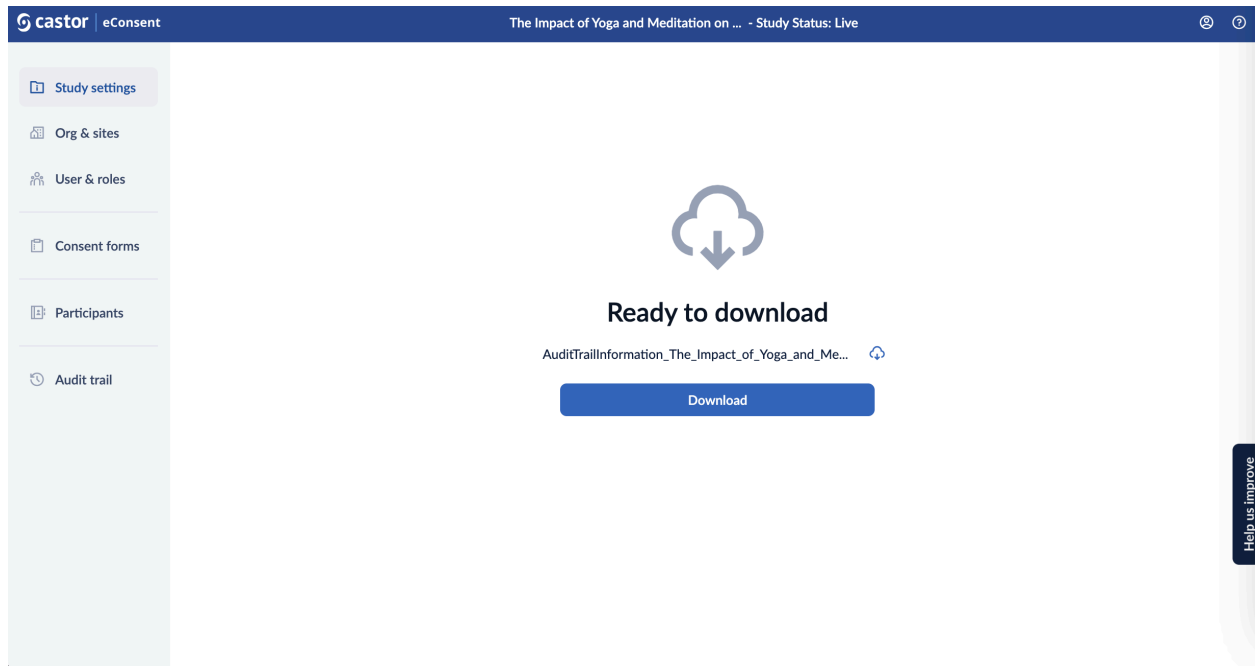
Click the following link https://eu.castorconsent.com/studies

or use the button below to download.

Download

You will then be redirected to the download page, click the 'Download' button

8. 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