

Castor

Castor eConsent Site User Guide

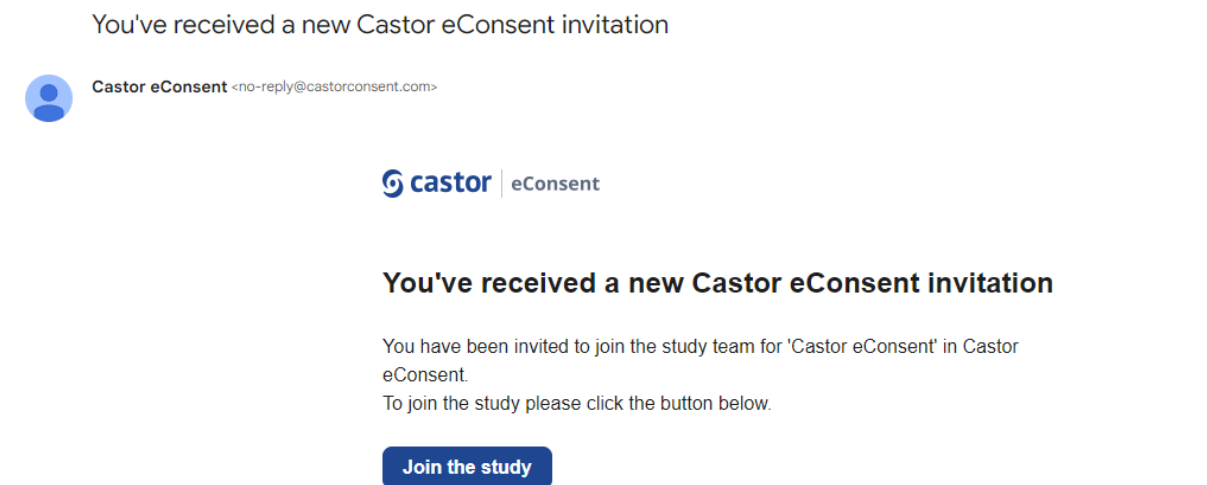
Version 2025.1

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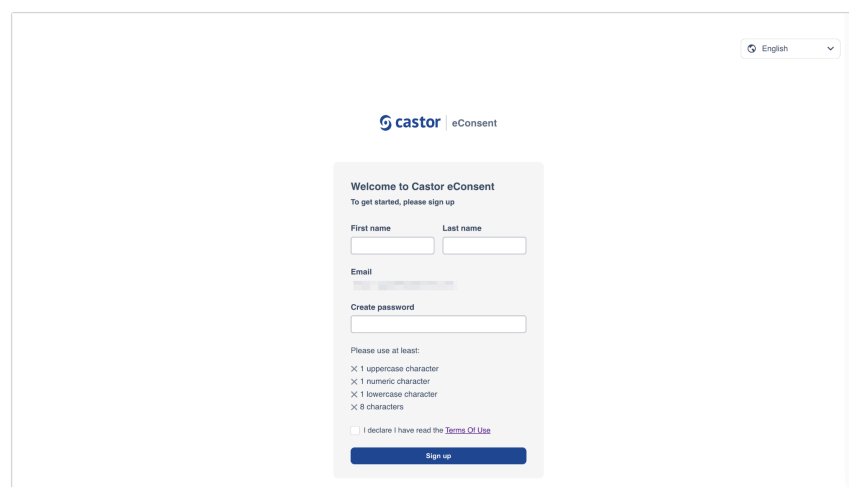
1. Register an account

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.



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". The form includes fields for "First name", "Last name", and "Email". Below these is a "Create password" field. A list of requirements is shown: "Please use at least: X 1 uppercase character, X 1 numeric character, X 1 lowercase character, X 8 characters". At the bottom, there is a checkbox for "I declare I have read the Terms Of Use" and a blue "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 URLs based 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.

castor eConsent

Europe

USA

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:

Help us improve

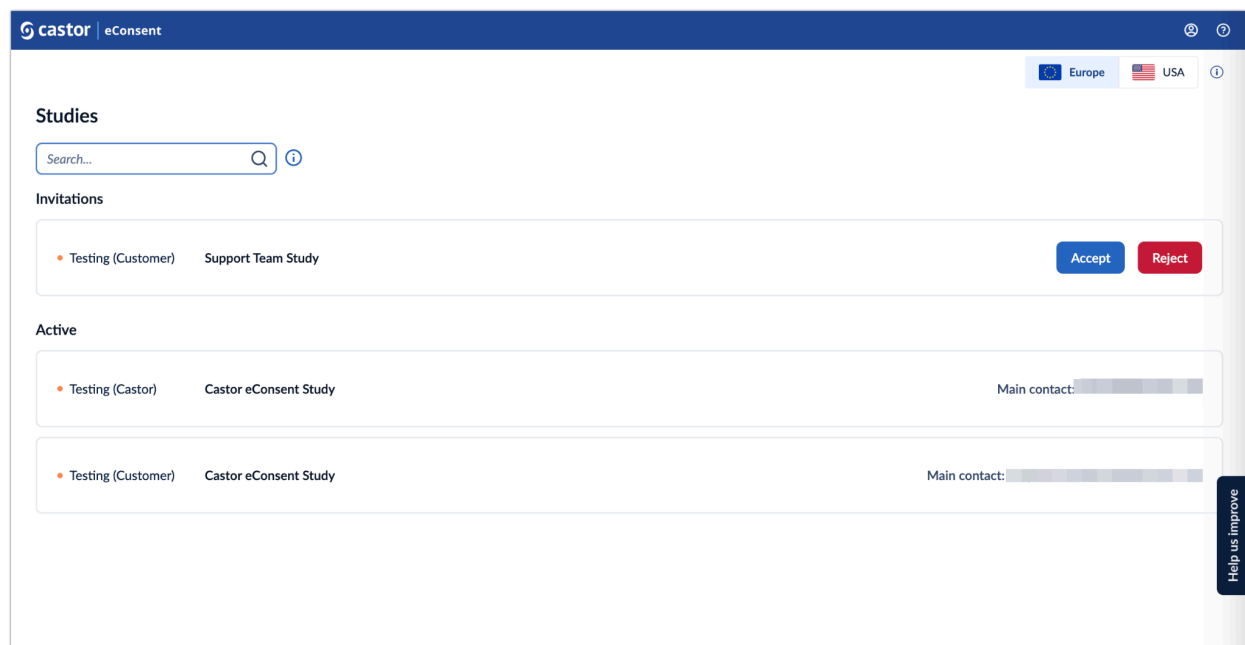
3. Open a study

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.

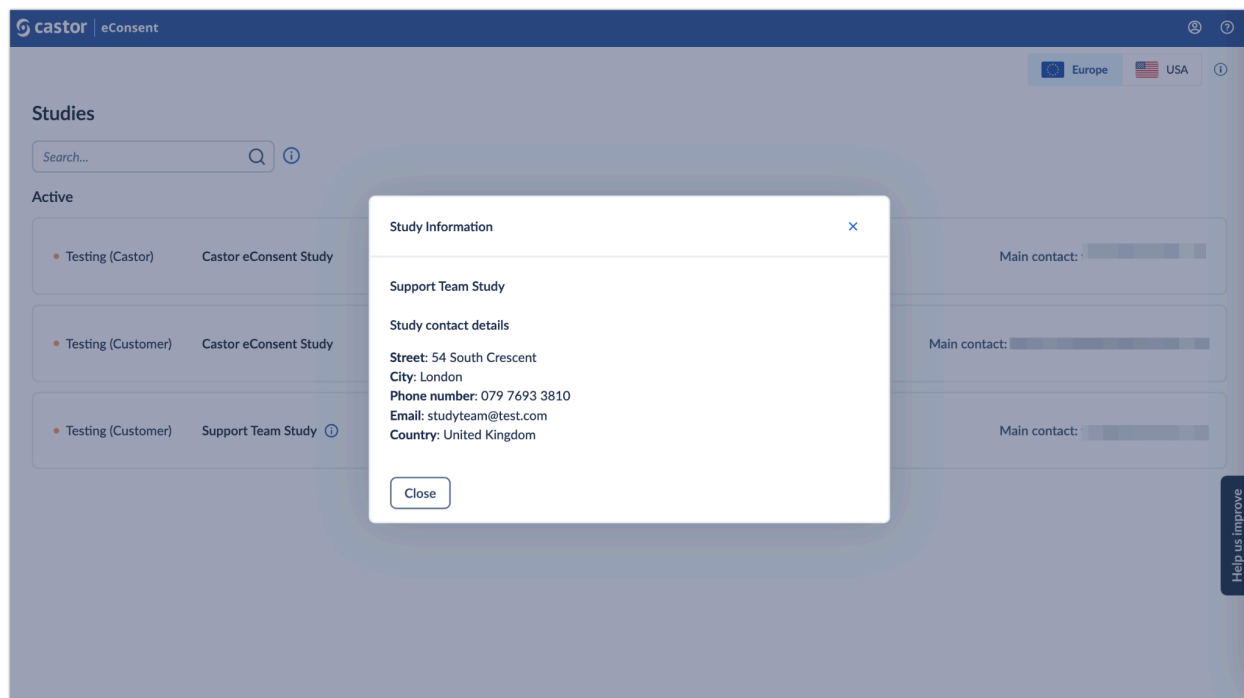
Rejecting the invitation cannot be undone and you will need to contact the study admin to request a new invite.



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: [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

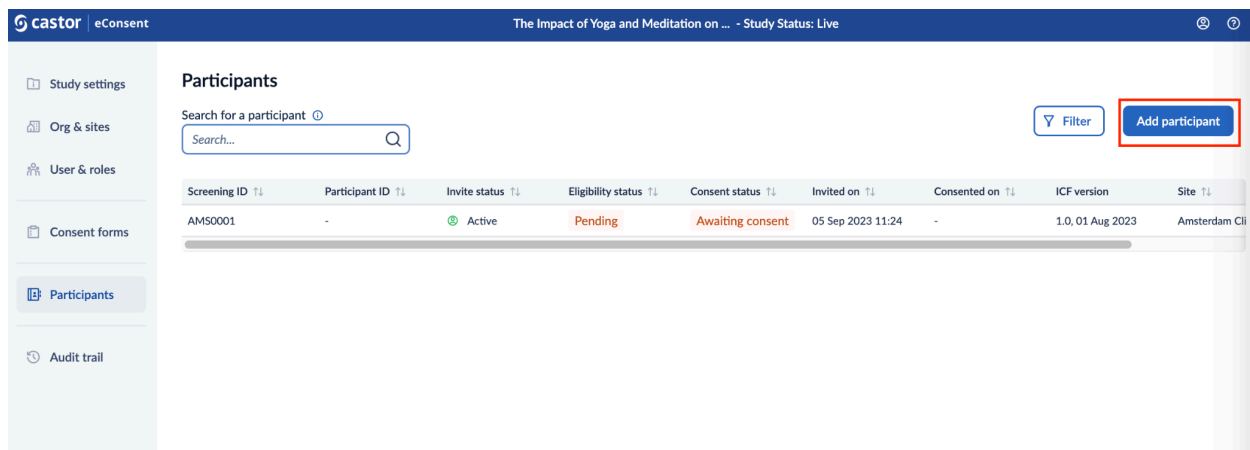


Studies for which an invitation has been accepted will appear in the 'Active' section and it is possible to access the study by clicking on the study row.

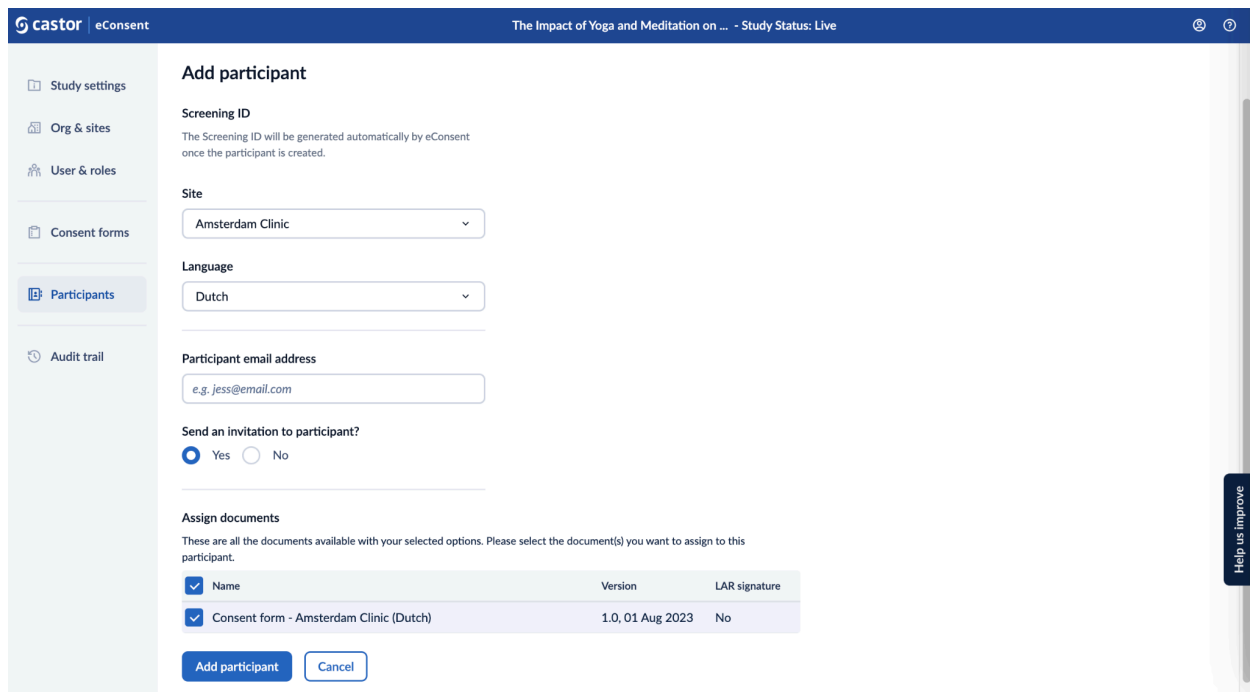
4. Adding a participant

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.



castor | eConsent | The Impact of Yoga and Meditation on ... - Study Status: Live

Add participant

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

Site
Amsterdam Clinic

Language
Dutch

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.

<input checked="" type="checkbox"/>	Name	Version	LAR signature
<input checked="" type="checkbox"/>	Consent form - Amsterdam Clinic (Dutch)	1.0, 01 Aug 2023	No

Add participant **Cancel**

Help us improve

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.

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The Impact of Yoga and Meditation on ... - Study Status: Live

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

Participants

Search for a participant

Filter Add participant

Screening ID	Participant ID	Invite status	Eligibility status	Consent status	Invited on	Consented on	ICF version	Site	Options
AMS0007	-	Not invited	Pending	-	-	-	1.0, 01 Aug 2023	Amsterdam Clinic	
AMS0006	-	Invited	Pass	Awaiting consent	17 Sep 2023 11:44	-	1.0, 01 Aug 2023	Amsterdam Clinic	
AMS0005	-	Invited	Pending	Awaiting consent	06 Sep 2023 18:04	-	1.0, 01 Aug 2023	Amsterdam Clinic	
BER0001	-	Not invited	Pass	Consented	-	01 Sep 2023	1.0, 09 Aug 2023	Berlin Clinic	
AMS0004	-	Not invited	Pending	Awaiting consent	-	-	1.0, 01 Aug 2023	Amsterdam Clinic	
AMS0003	-	Not invited	Pass	Consented	-	05 Sep 2023	1.0, 01 Aug 2023	Amsterdam Clinic	
AMS0002	-	Not invited	Pass	-	-	-	1.0, 01 Aug 2023	Amsterdam Clinic	
AMS0001	-	Active	Pass	Awaiting consent	05 Sep 2023 11:24	-	1.0, 01 Aug 2023	Amsterdam Clinic	Archive

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':

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The Impact of Yoga and Meditation on ... - Study Status: Live

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

AMS0003	-	Not invited	Pass	Consented	-	05 Sep 2023
AMS0002	-	Not invited	Pass	-	-	-

End

Eligibility status
All x x

Consent status
All x x

Consented between
Start
End

Countries
All x x

Site
All x x

☒ Include archived

Apply filters

Clear all

Help us improve

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

Participants

Search for a participant 🔍

Filter Add participant

Eligibility status	Consent status	Invited on	Consented on	ICF version	Site	Options
Pending	Consented	17 Sep 2023 14:12	04 Oct 2023 10:39	1.0, 01 Aug 2023	Amsterdam Clinic	⋮
Pending	Consented	-	10 Oct 2023 17:19	1.0, 01 Aug 2023	Amsterdam Clinic	⋮
Pending	Awaiting consent	17 Sep 2023 11:44	-	1.0, 01 Aug 2023	Amsterdam Clinic	⋮
Pending	Awaiting consent	06 Sep 2023 18:04	-	1.0, 01 Aug 2023	Amsterdam Clinic	⋮
Pending	Consented	-	01 Sep 2023	1.0, 09 Aug 2023	Berlin Clinic	⋮
Pending	Awaiting consent	-	-	1.0, 01 Aug 2023	Amsterdam Clinic	⋮
Pending	Consented	-	05 Sep 2023	1.0, 01 Aug 2023	Amsterdam Clinic	⋮
Pending	-	-	-	1.0, 01 Aug 2023	Amsterdam Clinic	⋮
Pending	Awaiting consent	05 Sep 2023 11:24	-	1.0, 01 Aug 2023	Amsterdam Clinic	⋮

Unarchive

Filter X

Invite status
All x v

Invited between
Start End

Eligibility status
All x v

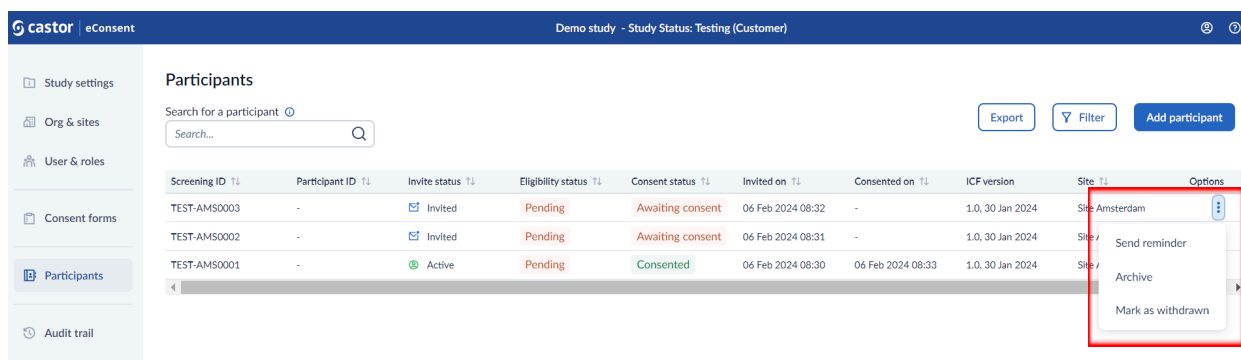
Consent status
All x v

Consented between
Start End

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.



The screenshot shows the 'Participants' page in the Castor eConsent system. The page has a sidebar with navigation links: Study settings, Org & sites, User & roles, Consent forms, Participants (selected), and Audit trail. The main content area is titled 'Participants' and includes a search bar and buttons for Export, Filter, and Add participant. A table lists participants with the following columns: Screening ID, Participant ID, Invite status, Eligibility status, Consent status, Invited on, Consented on, ICF version, Site, and Options. The table contains three rows of data. The 'Options' column for the first row (TEST-AMS0003) is open, showing a dropdown menu with three options: 'Send reminder', 'Archive', and 'Mark as withdrawn'. The 'Mark as withdrawn' option is highlighted with a red box.

Screening ID	Participant ID	Invite status	Eligibility status	Consent status	Invited on	Consented on	ICF version	Site	Options
TEST-AMS0003	-	Invited	Pending	Awaiting consent	06 Feb 2024 08:32	-	1.0, 30 Jan 2024	Site Amsterdam	Send reminder Archive Mark as withdrawn
TEST-AMS0002	-	Invited	Pending	Awaiting consent	06 Feb 2024 08:31	-	1.0, 30 Jan 2024	Site /	
TEST-AMS0001	-	Active	Pending	Consented	06 Feb 2024 08:30	06 Feb 2024 08:33	1.0, 30 Jan 2024	Site /	

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 allow 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.

Mark as withdrawn

Withdrawal date

19.02.2024

Reason for withdrawal

☒ Adverse event or side effects
 ☐ Disease progression
 ☐ Lack of efficacy
 ☐ Inconvenience
 ☐ Other

Send email notification to participant?

☒ Yes
 ☐ No

Cancel

Mark as withdrawn

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.

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Demo study - Study Status: Testing (Customer)

Study settings

Org & sites

User & roles

Consent forms

Participants

Audit trail

Participants

Search for a participant

Export

Filter

Add participant

Screening ID	Participant ID	Invite status	Eligibility status	Consent status	Invited on	Consented on	ICF version	Site	Options
TEST-AH-00002	-	Invited	Pending	Awaiting consent	06 Feb 2024 09:31	-	1.0, 30 Jan 2024	Site Amsterdam	
TEST-AH-00001	-	Active	Pending	Consented	06 Feb 2024 08:30	06 Feb 2024 08:33	1.0, 30 Jan 2024	Site Amsterdam	

Filter

Invite status

All

Invited between

Start

End

Eligibility status

All

Consent status

All

Consented between

Start

End

Countries

Netherlands

Site

Site Amsterdam

☐ Include archived
 ☒ Include withdrawn

Apply filters

Clear all

☐ Include archived

☒ Include withdrawn

Apply filters

Clear all

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:

castor | eConsent

Demo study - Study Status: Testing (Customer)

Study settings

Org & sites

User & roles

Consent forms

Participants

Audit trail

Participants

Search for a participant

Export Filter Add participant

Screening ID	Participant ID	Invite status	Eligibility status	Consent status	Invited on	Consented on	ICF version	Site	Options
TEST-AMS0003	-	Invited	Pending	Withdrawn	06 Feb 2024 08:32	-	1.0, 30 Jan 2024	Site Amsterdam	<div> <div></div> <div>Unmark as withdrawn</div> </div>
TEST-AMS0002	-	Invited	Pending	Awaiting consent	06 Feb 2024 08:31	-	1.0, 30 Jan 2024	Site Amsterdam	
TEST-AMS0001	-	Active	Pending	Consented	06 Feb 2024 08:30	06 Feb 2024 08:33	1.0, 30 Jan 2024	Site Amsterdam	

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

Unmark as withdrawn

Are you sure you wish to unmark as withdrawn?

Cancel

Unmark as withdrawn

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 the After 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

eConsent

The Impact of Yoga and Meditation on ... - Study Status: Live

Study settings

Org & sites

User & roles

Consent forms

Participants

Audit trail

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

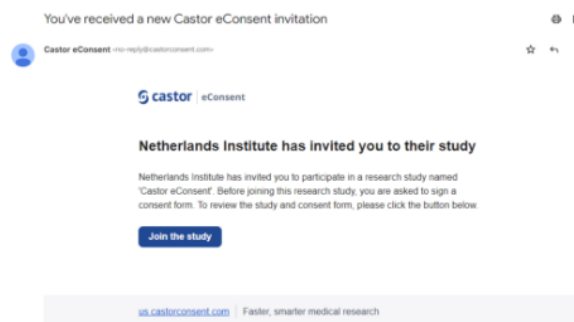
Assign documents
These are all the documents available with your selected options. Please select the document(s) you want to assign to this participant.

<input checked="" type="checkbox"/>	Name	Version	LAR signature
<input checked="" type="checkbox"/>	Consent form - Amsterdam Clinic (Dutch)	1.0, 01 Aug 2023	No

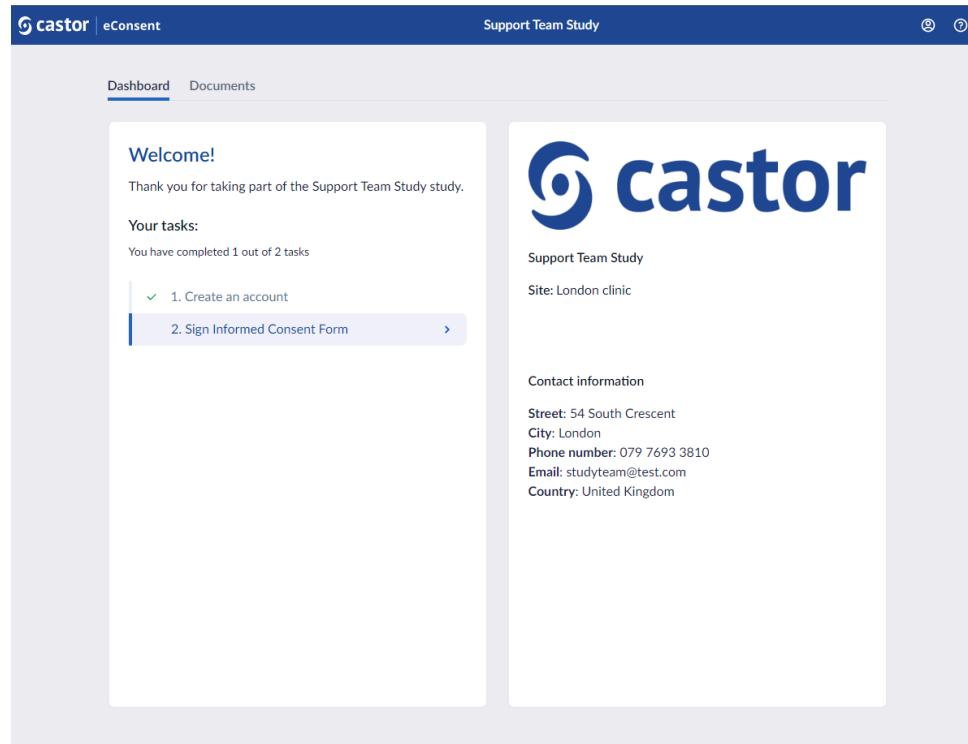
- You will then be redirected to the 'Participants' listing.
- From the 'Participants' listing, double click on the participant row
- You will be presented with the participant details
- If eligibility is checked in the study, the 'Eligibility status' will be automatically set to 'Pending'. Click on 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.
- 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 the "unlocked" in the pop-up window. The form will now become available for the participant for signature.
- Depending on the consent form settings, electronic signatures can allow for either handwritten or typed-in signatures. If both are allowed, participants can choose their preferred method during signing.

13. 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.



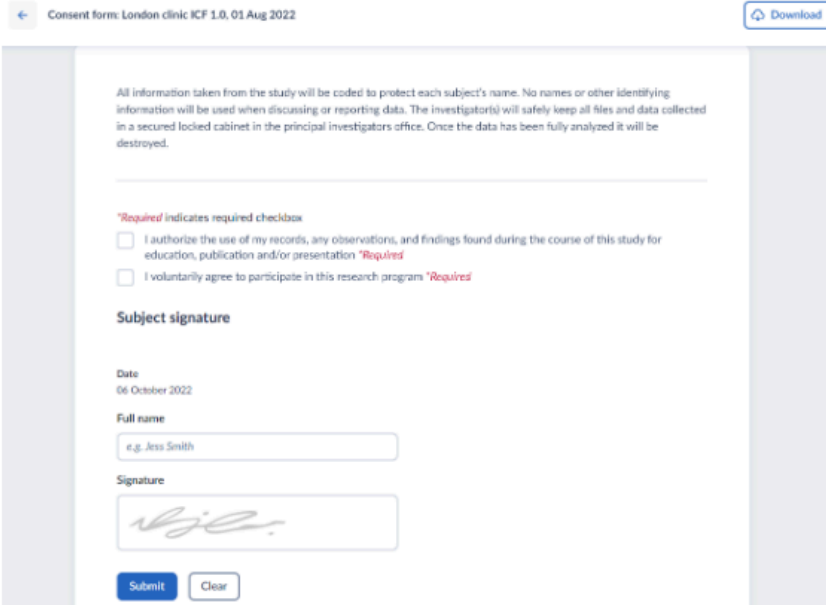
After setting up their account and logging in, a dashboard will be presented.



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.



← 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
e.g. Jess Smith

Signature


[Submit](#) [Clear](#)

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:

Study settings

Org & sites

User & roles

Consent forms

Participants

Audit trail

Profile

Consent Forms

Audit trail

Participant profile

Screening ID	Participant ID	Created by
AMS0001	-	Tonya Support
Site	Language	Invite status
Amsterdam Clinic	Dutch	Active

Personal details

Date of birth

Gender

Contact information

Consent information (most recent)

Send reminder

Consent status	Consent form sent on	Consent form signed on
Awaiting consent	05 Sep 2023 11:24	-
Consent form	Version	Consent method
Consent form - Amsterdam Clinic (Dutch)	1.0, 01 Aug 2023	Electronic

Consent call

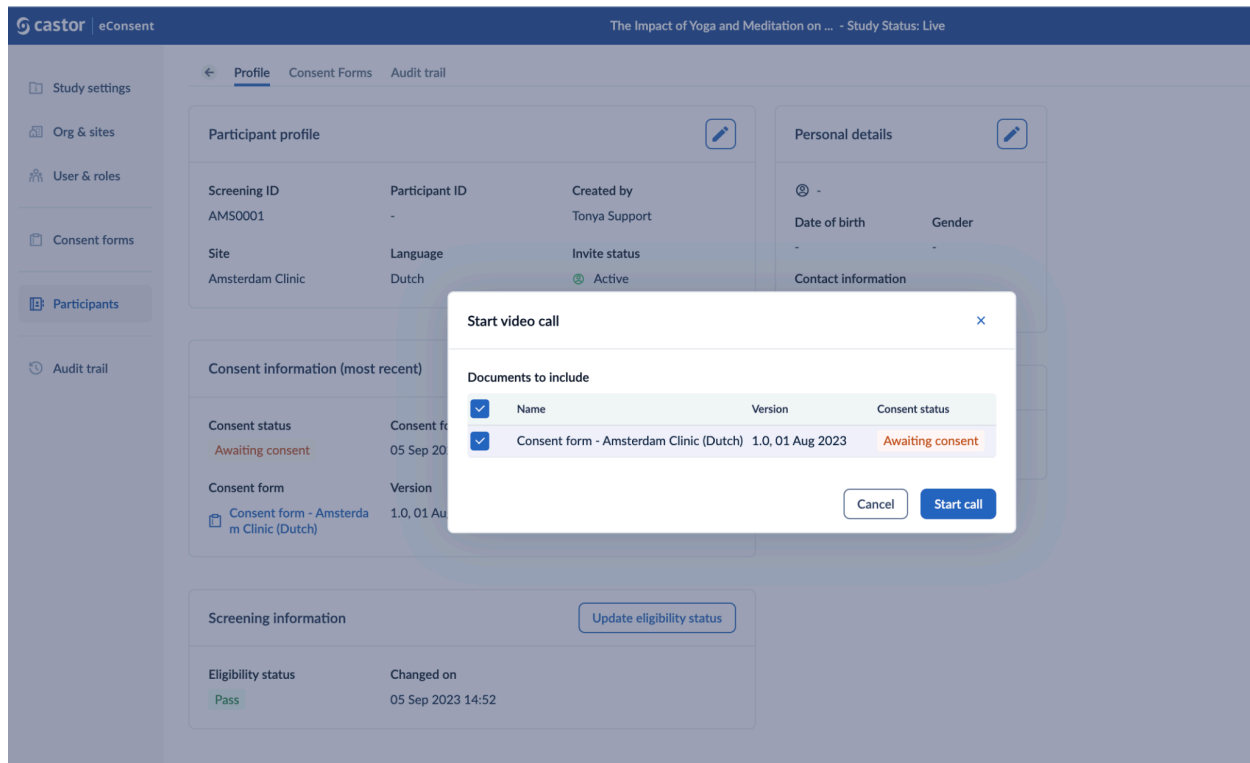
Start call

Screening information

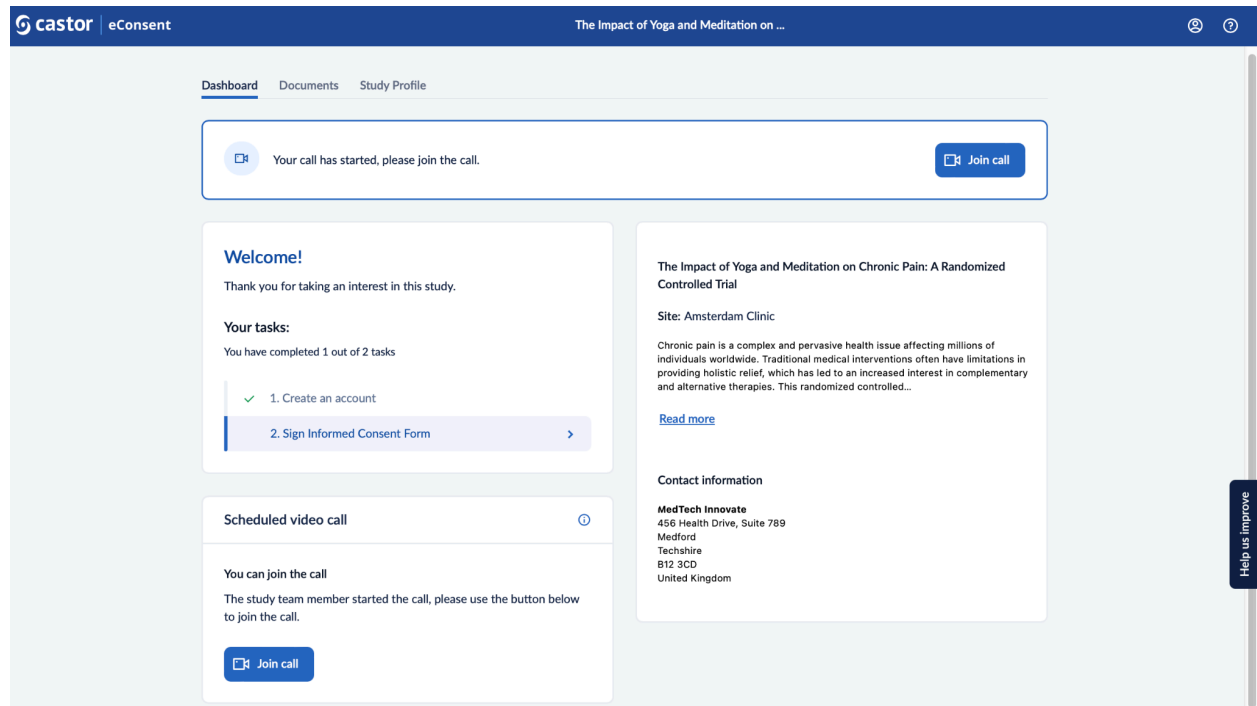
Update eligibility status

Eligibility status	Changed on
Pass	05 Sep 2023 14:52

- 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



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'.

 eConsent
 The Impact of Yoga and Meditation on ... - Study Status: Live

Study settings

Org & sites

User & roles

Consent forms

Participants

Audit trail

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

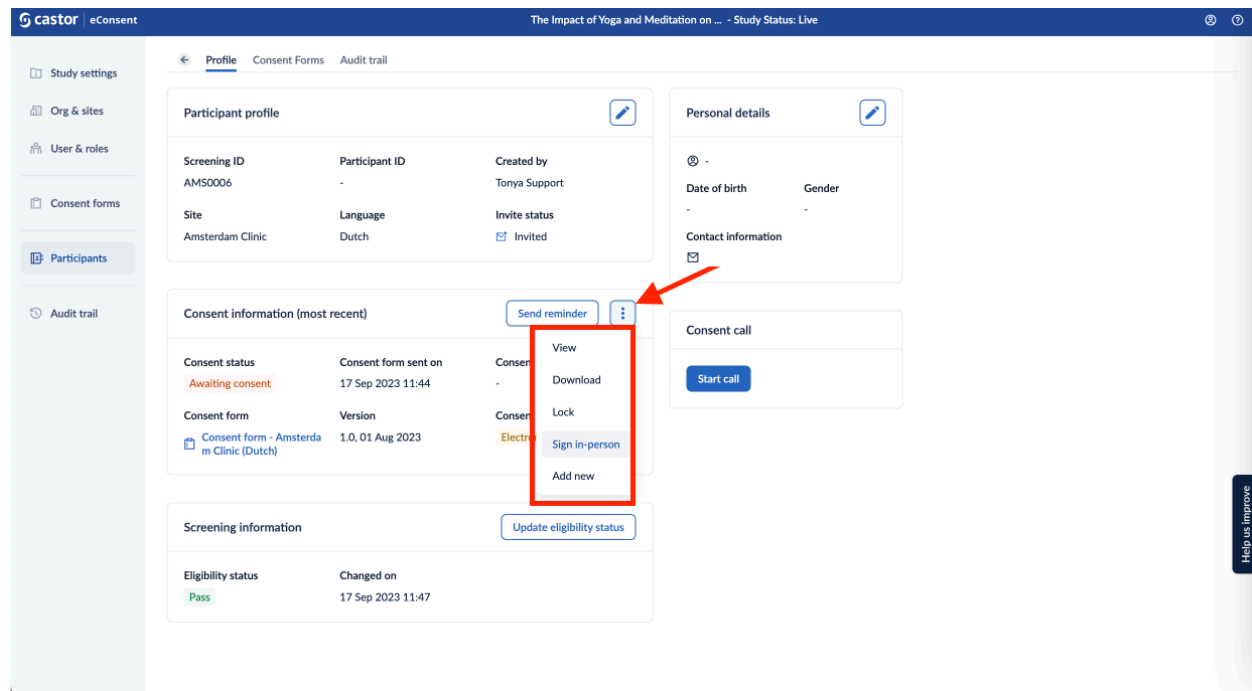
Send an invitation to participant?
☐ Yes ☒ No

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

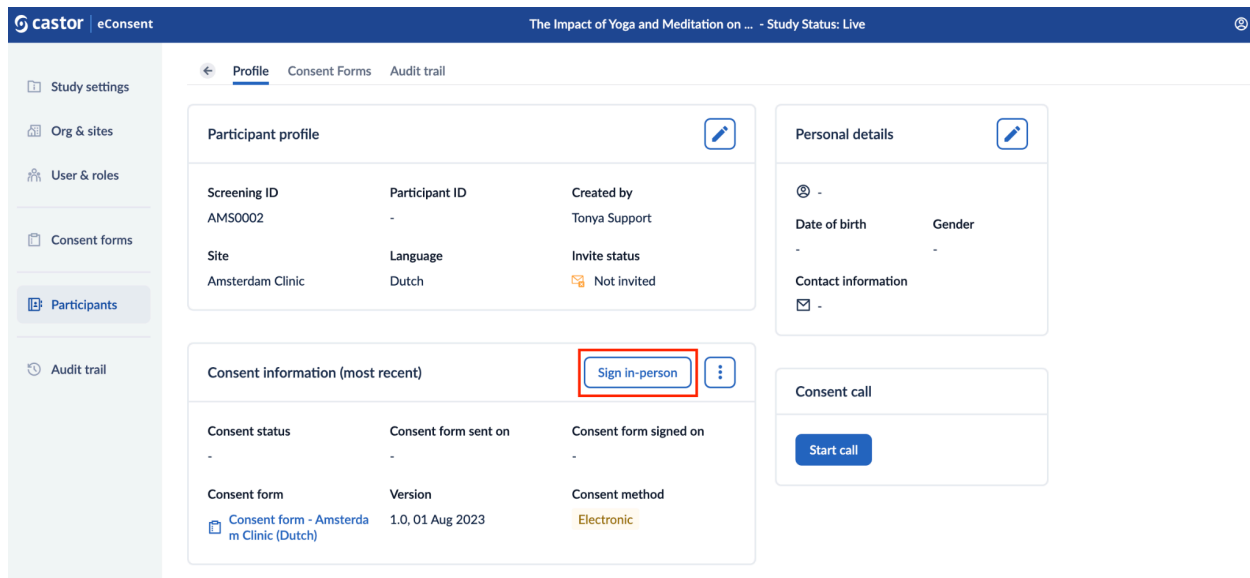
<input checked="" type="checkbox"/>	Name	Version	LAR signature
<input checked="" type="checkbox"/>	Consent form - Amsterdam Clinic (Dutch)	1.0, 01 Aug 2023	No

Add participant
Cancel

- 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):

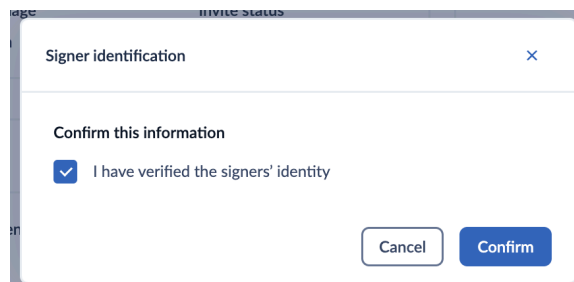


- In case where no invite to a participant is sent and when there is already an ICF added which hasn't been signed by the participant yet (status of the ICF is "Awaiting consent" if the invite is already sent, or "undefined" if there is no invite sent), in the 'Consent information (most recent)' section, click on the "Sign in-person" option:



The screenshot shows the Castor eConsent interface for a study titled "The Impact of Yoga and Meditation on ...". The study status is "Live". The left sidebar contains navigation options: Study settings, Org & sites, User & roles, Consent forms, Participants (selected), and Audit trail. The main content area is divided into three sections: Participant profile, Personal details, and Consent information (most recent). The Participant profile section shows Screening ID (AMS0002), Participant ID (-), Created by (Tonya Support), Site (Amsterdam Clinic), Language (Dutch), and Invite status (Not invited). The Personal details section shows Date of birth (-), Gender (-), and Contact information (-). The Consent information (most recent) section shows Consent status (-), Consent form sent on (-), Consent form signed on (-), Consent form (Consent form - Amsterdam Clinic (Dutch)), Version (1.0, 01 Aug 2023), and Consent method (Electronic). A red box highlights the "Sign in-person" button in the Consent information section.

- 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:

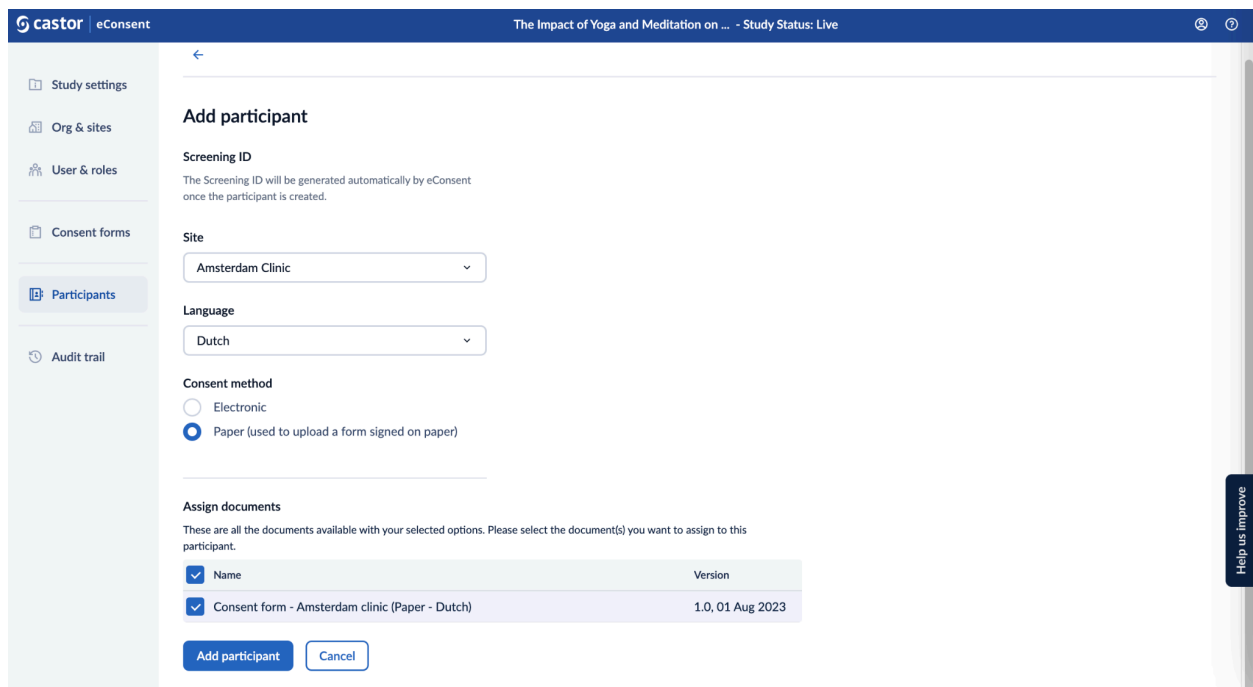


The screenshot shows a "Signer identification" dialog box. It contains a section titled "Confirm this information" with a checked checkbox and the text "I have verified the signers' identity". At the bottom right, there are two buttons: "Cancel" and "Confirm".

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.



Castor eConsent The Impact of Yoga and Meditation on ... - Study Status: Live

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)

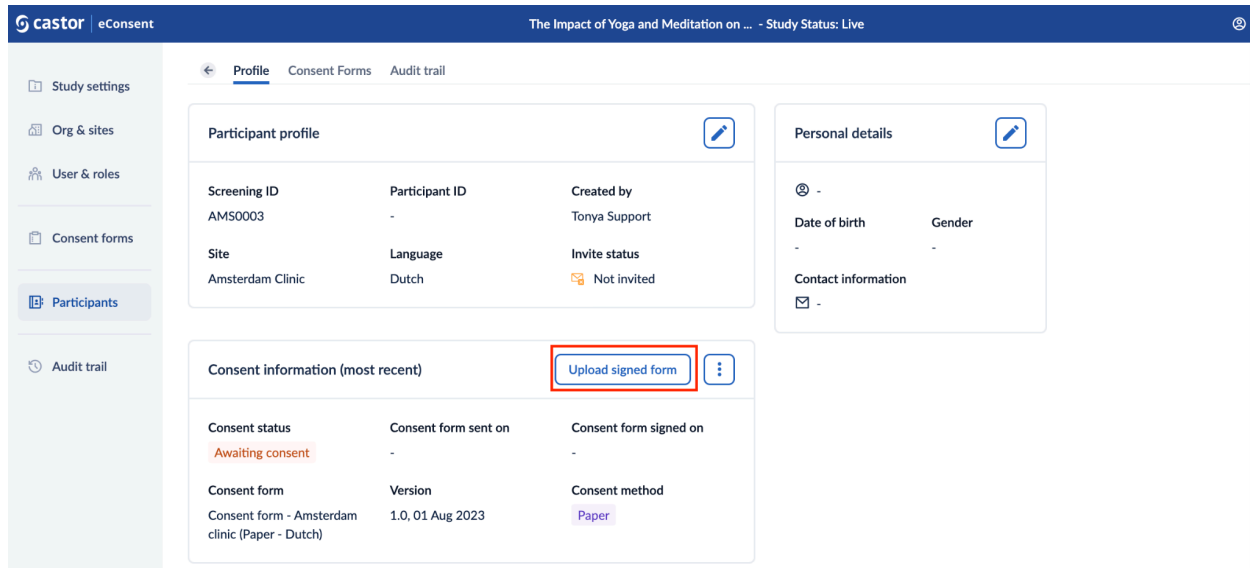
Assign documents
These are all the documents available with your selected options. Please select the document(s) you want to assign to this participant.

✓ Name	Version
✓ Consent form - Amsterdam clinic (Paper - Dutch)	1.0, 01 Aug 2023

Add participant **Cancel**

Help us improve

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.

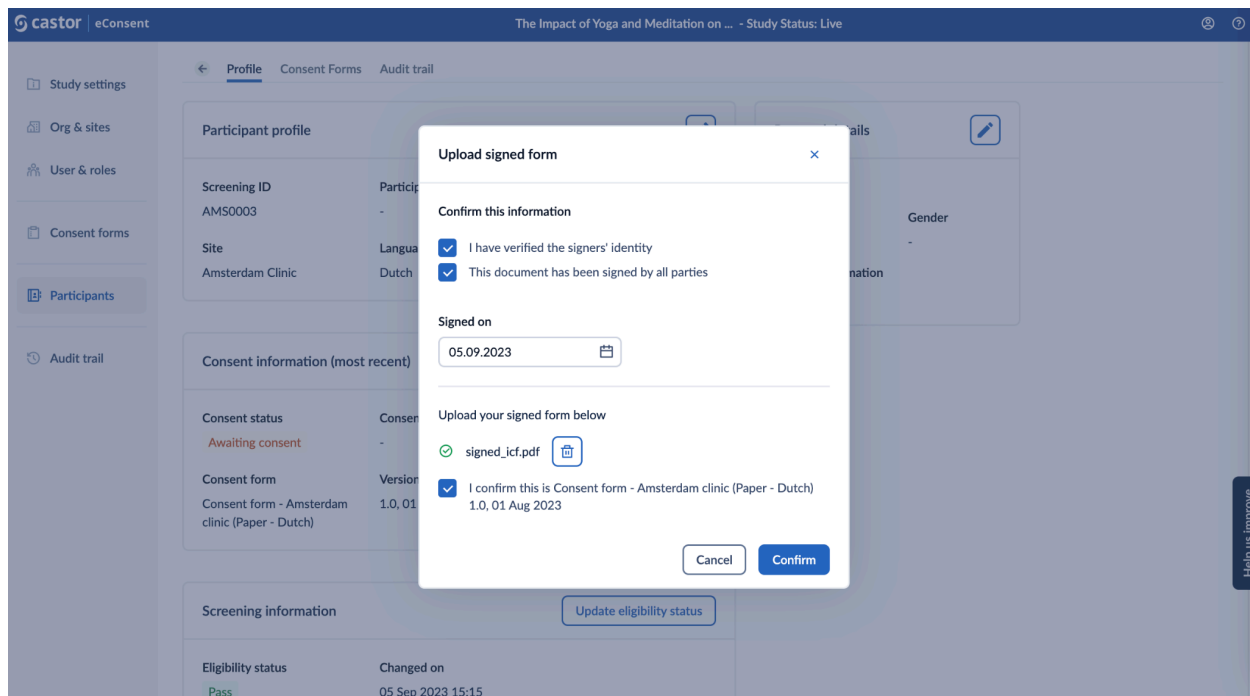


The screenshot shows the 'Profile' tab in the Castor eConsent system. The 'Consent information (most recent)' section is highlighted with a red box around the 'Upload signed form' button. The participant's profile details are as follows:

Participant profile		
Screening ID AMS0003	Participant ID -	Created by Tonya Support
Site Amsterdam Clinic	Language Dutch	Invite status Not invited

Consent information (most recent)		
Consent status Awaiting consent	Consent form sent on -	Consent form signed on -
Consent form Consent form - Amsterdam clinic (Paper - Dutch)	Version 1.0, 01 Aug 2023	Consent method Paper

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.



The screenshot shows the 'Upload signed form' pop-up window. The window prompts the user to confirm information and upload the signed form. The details are as follows:

Confirm this information

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

Signed on
05.09.2023

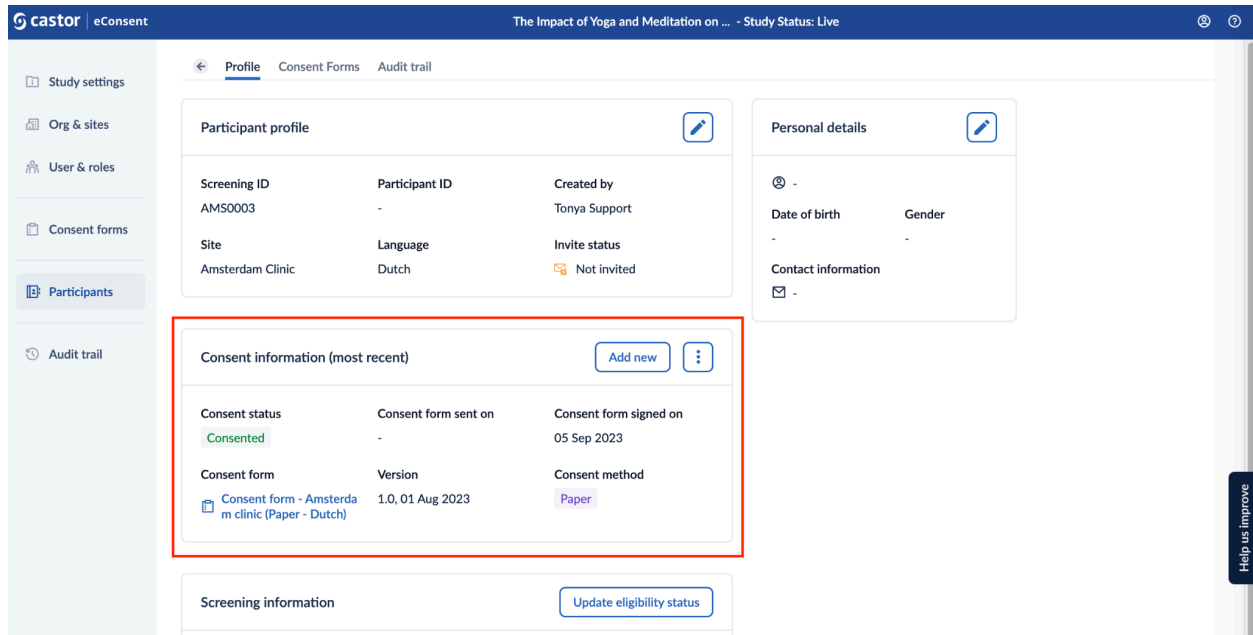
Upload your signed form below

- ☒ signed_lcf.pdf
- ☒ I confirm this is Consent form - Amsterdam clinic (Paper - Dutch) 1.0, 01 Aug 2023

Buttons: Cancel, Confirm

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

- 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.

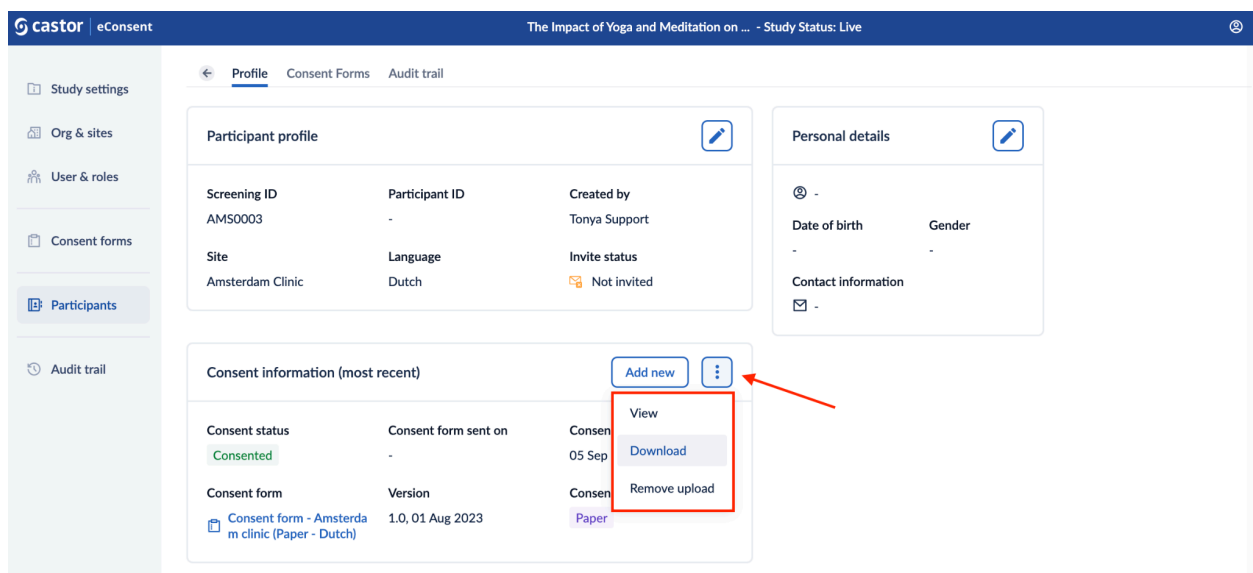


The screenshot shows the Castor eConsent interface for a study titled 'The Impact of Yoga and Meditation on ...'. The 'Participants' section is active in the left sidebar. The main content area displays the 'Consent information (most recent)' section, which is highlighted with a red box. This section contains the following information:

Consent status	Consent form sent on	Consent form signed on
Consented	-	05 Sep 2023
Consent form	Version	Consent method
Consent form - Amsterdam clinic (Paper - Dutch)	1.0, 01 Aug 2023	Paper

Below the consent information, there is a 'Screening information' section with an 'Update eligibility status' button. The 'Personal details' section on the right shows fields for Date of birth, Gender, and Contact information, all of which are currently empty.

- 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:



This screenshot shows the same Castor eConsent interface as the previous one, but with the 'Consent information (most recent)' section expanded to show the options menu. A red box highlights the 'View', 'Download', and 'Remove upload' options, and a red arrow points to the three-dot menu icon that triggers this list.

Consent status	Consent form sent on	Consent form signed on
Consented	-	05 Sep
Consent form	Version	Consent method
Consent form - Amsterdam clinic (Paper - Dutch)	1.0, 01 Aug 2023	Paper

The options menu is displayed as follows:

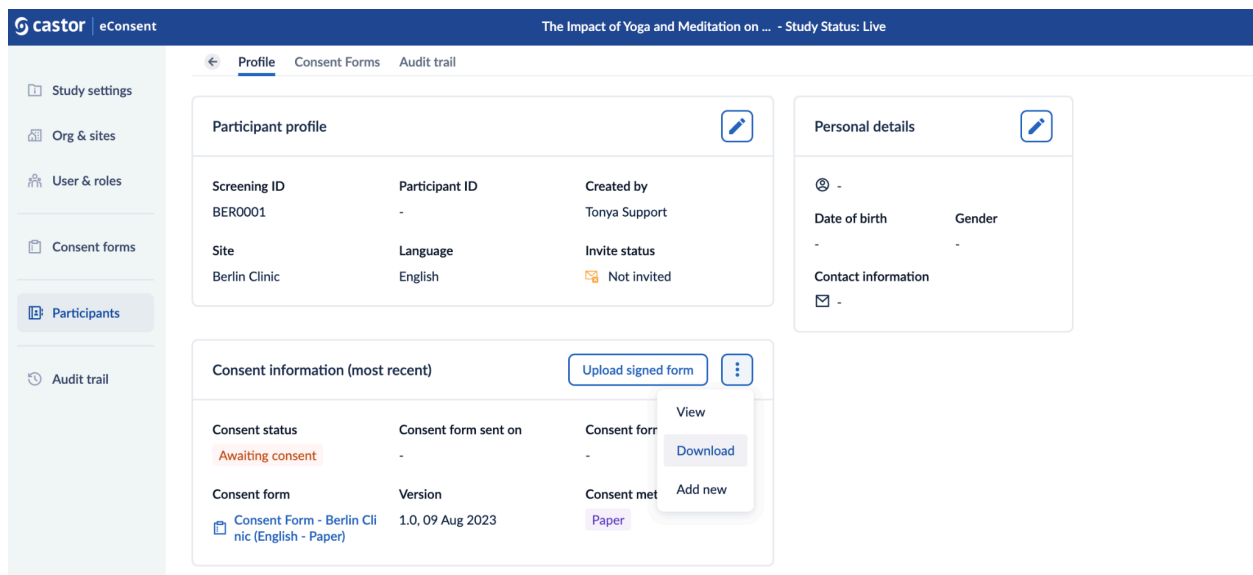
- View
- Download
- Remove upload

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.



castor eConsent The Impact of Yoga and Meditation on ... - Study Status: Live

Profile Consent Forms Audit trail

Participant profile

Screening ID BER0001	Participant ID -	Created by Tonya Support
Site Berlin Clinic	Language English	Invite status Not invited

Personal details

@ -

Date of birth - Gender -

Contact information
✉ -

Consent information (most recent)

Upload signed form

Consent status Awaiting consent	Consent form sent on -	Consent form -
Consent form Consent Form - Berlin Clinic (English - Paper)	Version 1.0, 09 Aug 2023	Consent method Paper

View
Download
Add new

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

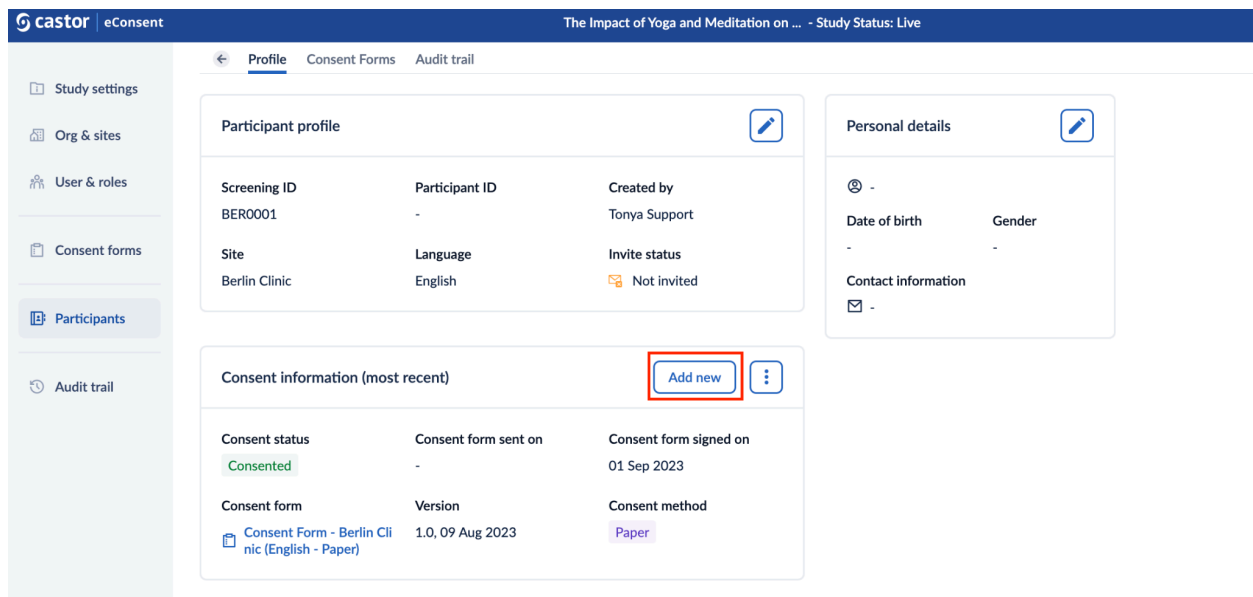
3. In the dialog box confirm the required information and upload the file by selecting “choose file” or drag and drop the file into the box and confirm.

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.



The screenshot shows the Castor eConsent interface for a study titled "The Impact of Yoga and Meditation on ...". The study status is "Live". The interface is divided into a left sidebar with navigation options (Study settings, Org & sites, User & roles, Consent forms, Participants, Audit trail) and a main content area. The main content area has tabs for Profile, Consent Forms, and Audit trail. The Profile tab is active, showing a participant's profile and consent information.

Participant profile

Screening ID BER0001	Participant ID -	Created by Tonya Support
Site Berlin Clinic	Language English	Invite status Not invited

Personal details

Date of birth -	Gender -
Contact information -	

Consent information (most recent)

Consent status Consented	Consent form sent on -	Consent form signed on 01 Sep 2023
Consent form Consent Form - Berlin Clinic (English - Paper)	Version 1.0, 09 Aug 2023	Consent method Paper

The "Add new" button in the "Consent information" section is highlighted with a red box.

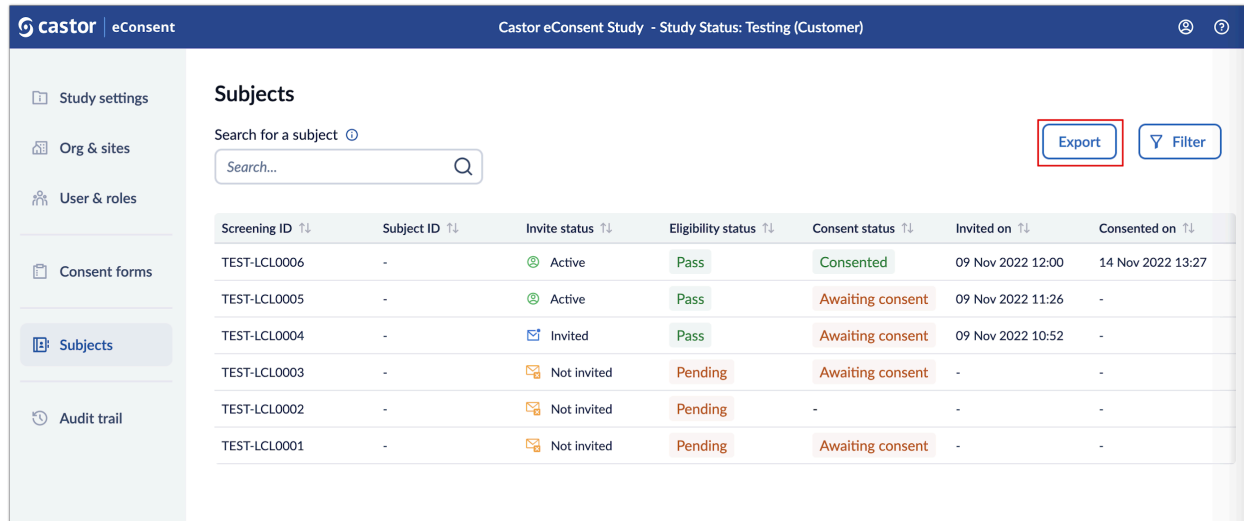
3. In a new pop-up screen, you can repeat the process for on-site, remote or paper consent by selecting the relevant consent method and consent form.
4. Once required settings are set and the consent form is selected, press ‘Add’ to continue.
5. The consent status will be updated to ‘Awaiting consent’.

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:

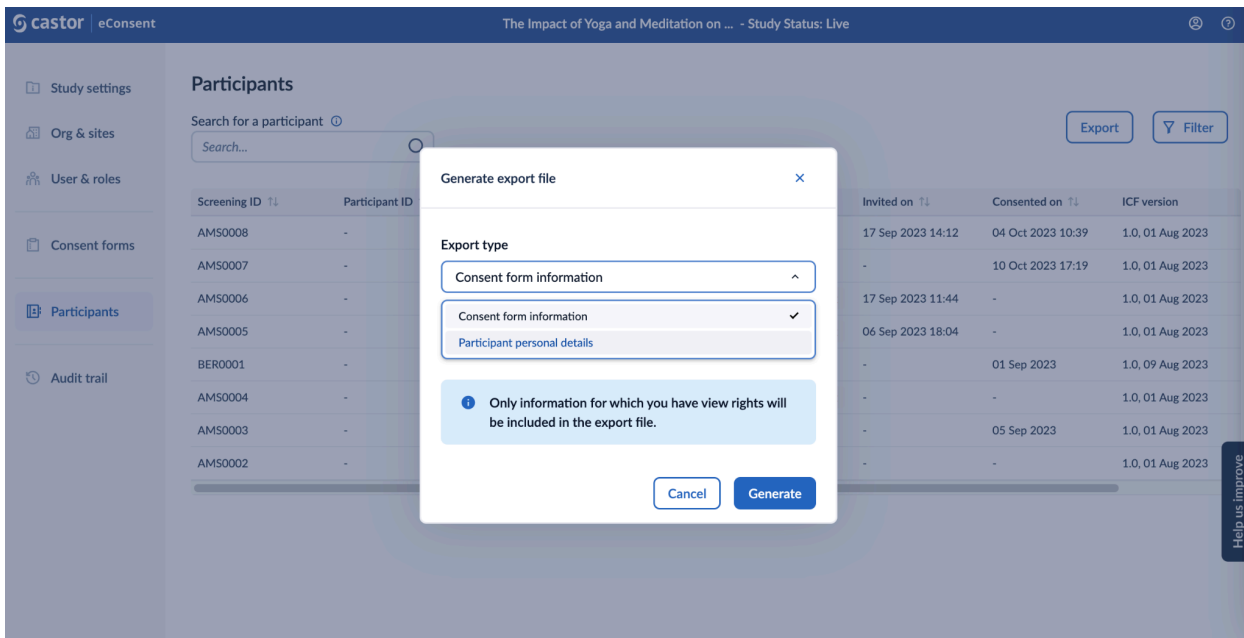
1. In the 'participants Overview', click on the 'Export' button:



The screenshot shows the 'Subjects' page in the Castor eConsent interface. The page title is 'Castor eConsent Study - Study Status: Testing (Customer)'. On the left sidebar, 'Subjects' is selected. The main area has a search bar and an 'Export' button (highlighted with a red box) and a 'Filter' button. Below is a table of subjects.

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	-	-

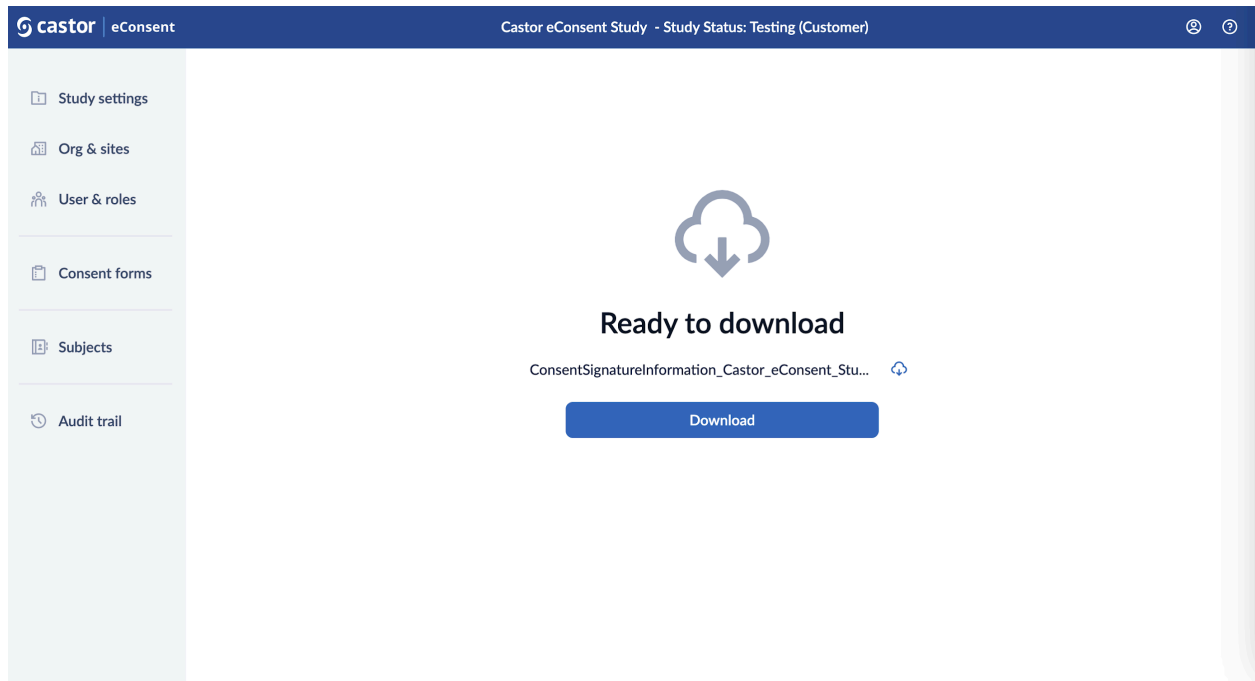
2. In the 'Generate export file' pop-up window, in the 'Export type', select 'Consent form information' or 'Participant personal details' option. Click on the 'Generate' button to proceed with the export. Only signature information for which you have view rights will be included in the export file.



The screenshot shows the 'Participants' page in the Castor eConsent interface. The page title is 'The Impact of Yoga and Meditation on ... - Study Status: Live'. On the left sidebar, 'Participants' is selected. The main area has a search bar and 'Export' and 'Filter' buttons. A 'Generate export file' pop-up window is open in the center, showing the 'Export type' dropdown menu with 'Consent form information' selected. Below the dropdown is a note: 'Only information for which you have view rights will be included in the export file.' The 'Generate' button is highlighted.

Screening ID	Participant ID	Invited on	Consented on	ICF version
AMS0008	-	17 Sep 2023 14:12	04 Oct 2023 10:39	1.0, 01 Aug 2023
AMS0007	-	-	10 Oct 2023 17:19	1.0, 01 Aug 2023
AMS0006	-	17 Sep 2023 11:44	-	1.0, 01 Aug 2023
AMS0005	-	06 Sep 2023 18:04	-	1.0, 01 Aug 2023
BER0001	-	-	01 Sep 2023	1.0, 09 Aug 2023
AMS0004	-	-	-	1.0, 01 Aug 2023
AMS0003	-	-	05 Sep 2023	1.0, 01 Aug 2023
AMS0002	-	-	-	1.0, 01 Aug 2023

- 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:

castor

eConsent

Support Team Study - Study Status: Testing (Customer)

2

Study settings

Org & sites

User & roles

Consent forms

Subjects

Audit trail

Audit trail

Date and Time	Actor	Type of user	Screening Id	Action	Additional Info
04-Oct-2022 09:47:38 UTC		Study team member	TEST-LND0001	Subject viewed	{siteName:"London clinic",abbreviation:"LND",countryCode:"GBR"}
04-Oct-2022 09:47:38 UTC		Study team member	TEST-LND0001	Consent form/information view	{siteName:"London clinic",abbreviation:"LND",countryCode:"GBR"}
04-Oct-2022 09:03:10 UTC		Study team member	TEST-LND0001	Paper signed ICF uploaded	{siteName:"London clinic",abbreviation:"LND",countryCode:"GBR"}
04-Oct-2022 09:03:10 UTC		Study team member	TEST-LND0001	Consent form/information view	{siteName:"London clinic",abbreviation:"LND",countryCode:"GBR"}
04-Oct-2022 09:01:25 UTC		Study team member	TEST-LND0001	Consent form/information view	{siteName:"London clinic",abbreviation:"LND",countryCode:"GBR"}
04-Oct-2022 09:01:24 UTC		Study team member	TEST-LND0001	Subject edited	{siteName:"London clinic",abbreviation:"LND",countryCode:"GBR"}
04-Oct-2022 09:01:24 UTC		Study team member	TEST-LND0001	Subject invited to sign ICF	{siteName:"London clinic",abbreviation:"LND",countryCode:"GBR"}
04-Oct-2022 09:01:24 UTC		Study team member	TEST-LND0001	Subject viewed	{siteName:"London clinic",abbreviation:"LND",countryCode:"GBR"}
04-Oct-2022 08:52:18 UTC		Study team member	TEST-LND0001	Consent form/information view	{siteName:"London clinic",abbreviation:"LND",countryCode:"GBR"}
04-Oct-2022 08:52:17 UTC		Study team member	TEST-LND0001	Subject viewed	{siteName:"London clinic",abbreviation:"LND",countryCode:"GBR"}
04-Oct-2022 08:52:05 UTC		Study team member	TEST-LND0002	Consent form/information view	{siteName:"London clinic",abbreviation:"LND",countryCode:"GBR"}
04-Oct-2022 08:52:04 UTC		Study team member	TEST-LND0002	Subject viewed	{siteName:"London clinic",abbreviation:"LND",countryCode:"GBR"}
28-Sep-2022 11:58:09 UTC		Subject	TEST-LND0007	Consent form/information view	{siteName:"London clinic",abbreviation:"LND",countryCode:"GBR"}
28-Sep-2022 11:57:15 UTC		Subject	TEST-LND0007	Subject accepted invitation	{siteName:"London clinic",abbreviation:"LND",countryCode:"GBR"}
28-Sep-2022 11:54:15 UTC		Study team member	TEST-LND0007	Subject record created	{siteName:"London clinic",abbreviation:"LND",countryCode:"GBR"}
28-Sep-2022 11:54:15 UTC		Study team member	TEST-LND0007	Subject invited to sign ICF	{siteName:"London clinic",abbreviation:"LND",countryCode:"GBR"}
28-Sep-2022 10:49:23 UTC		Study team member		Study updated	[]
28-Sep-2022 10:44:13 UTC		Study team member	TEST-LND0001	Subject edited	{siteName:"London clinic",abbreviation:"LND",countryCode:"GBR"}
28-Sep-2022 10:44:13 UTC		Study team member	TEST-LND0001	Subject viewed	{siteName:"London clinic",abbreviation:"LND",countryCode:"GBR"}
28-Sep-2022 10:44:13 UTC		Study team member	TEST-LND0001	Consent form/information view	{siteName:"London clinic",abbreviation:"LND",countryCode:"GBR"}
28-Sep-2022 10:44:03 UTC		Study team member	TEST-LND0001	Consent form/information view	{siteName:"London clinic",abbreviation:"LND",countryCode:"GBR"}
28-Sep-2022 10:44:02 UTC		Study team member	TEST-LND0001	Subject viewed	{siteName:"London clinic",abbreviation:"LND",countryCode:"GBR"}

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

castor | eConsent

Support Team Study - Study Status: Testing (Customer)

Study settings

Org & sites

User & roles

Consent forms

Subjects

Audit trail

Audit trail

Date and Time

Actor

04-Oct-2022 09:47:38 UTC

04-Oct-2022 09:47:38 UTC

04-Oct-2022 09:03:10 UTC

04-Oct-2022 09:03:10 UTC

04-Oct-2022 09:01:25 UTC

04-Oct-2022 09:01:24 UTC

04-Oct-2022 09:01:24 UTC

04-Oct-2022 09:01:24 UTC

04-Oct-2022 08:52:18 UTC

04-Oct-2022 08:52:17 UTC

04-Oct-2022 08:52:05 UTC

04-Oct-2022 08:52:04 UTC

28-Sep-2022 11:58:09 UTC

28-Sep-2022 11:57:15 UTC

28-Sep-2022 11:54:15 UTC

28-Sep-2022 11:54:15 UTC

28-Sep-2022 10:49:23 UTC

28-Sep-2022 10:44:13 UTC

28-Sep-2022 10:44:13 UTC

28-Sep-2022 10:44:13 UTC

28-Sep-2022 10:44:03 UTC

28-Sep-2022 10:44:02 UTC

Study team member

Study team member

TEST-LND0001

TEST-LND0001

Consent form/information view

Subject viewed

Subject viewed on 04-Oct-2022 09:47:38 UTC

Details

Study Status

User email

User name

Type of user

Event

Date

Role

siteName

abbreviation

countryCode

screeningId

uuid

subjectLanguage

subjectEmail

Value change

Field

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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.

castor | eConsent The Impact of Yoga and Meditation on ... - Study Status: Live

Audit trail

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

Export

Date and Time	Actor	Type of user	Screening id	Action	Additional Info
04-Jan-2024 07:15:25 UTC		Study team member		Study team member edited	["siteName":"Amsterdam Clinic","a
04-Jan-2024 07:05:12 UTC		Study team member	AMS0006	Consent form/information view	["siteName":"Amsterdam Clinic","a
04-Jan-2024 07:05:11 UTC		Study team member	AMS0006	Consent form/information view	["siteName":"Amsterdam Clinic","a
04-Jan-2024 07:05:01 UTC		Study team member	AMS0006	Participant viewed	["siteName":"Amsterdam Clinic","a
04-Jan-2024 07:05:00 UTC		Study team member	AMS0006	Participant viewed	["siteName":"Amsterdam Clinic","a
18-Dec-2023 12:55:05 UTC		Study team member	AMS0006	Consent form/information view	["siteName":"Amsterdam Clinic","a
18-Dec-2023 12:55:05 UTC		Study team member	AMS0006	In-person consent procedure st	["siteName":"Amsterdam Clinic","a
18-Dec-2023 12:55:00 UTC		Study team member	AMS0006	Consent form/information view	["siteName":"Amsterdam Clinic","a
18-Dec-2023 12:55:00 UTC		Study team member	AMS0006	Consent form/information view	["siteName":"Amsterdam Clinic","a
18-Dec-2023 12:54:59 UTC		Study team member	AMS0006	Participant viewed	["siteName":"Amsterdam Clinic","a
13-Dec-2023 08:08:24 UTC		Study team member	AMS0006	Participant viewed	["siteName":"Amsterdam Clinic","a
13-Dec-2023 08:08:14 UTC		Study team member		Study team member accepted	["email":
20-Nov-2023 09:40:41 UTC		Study team member		Study team member invited	["email":
20-Nov-2023 09:40:26 UTC		Study team member		Study team member removed	["email":
20-Nov-2023 09:09:53 UTC		Study team member		Study team member invited	["email":
20-Nov-2023 09:09:53 UTC		Study team member		Study team member invited	["email":
20-Nov-2023 09:09:53 UTC		Study team member		Study team member invited	["email":

Help us improve

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

Generate export file

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

Export format

Excel

Cancel Generate

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.



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.

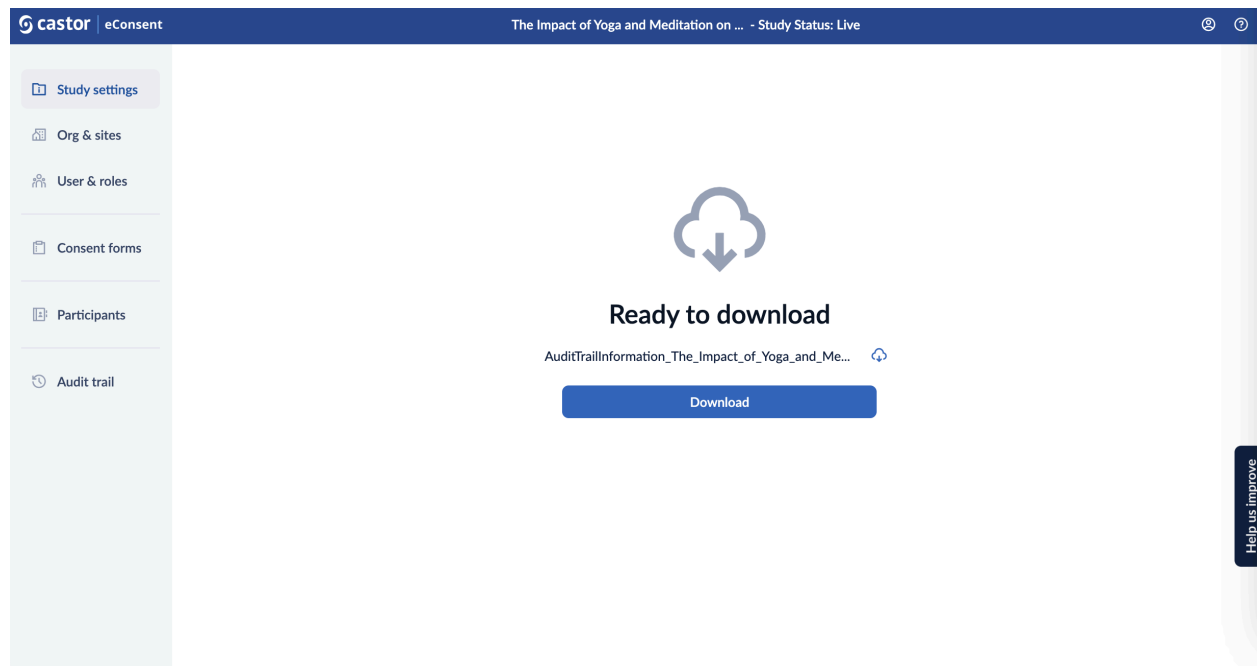
Click the following link <https://eu.castorconsent.com/studies>

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