Castor

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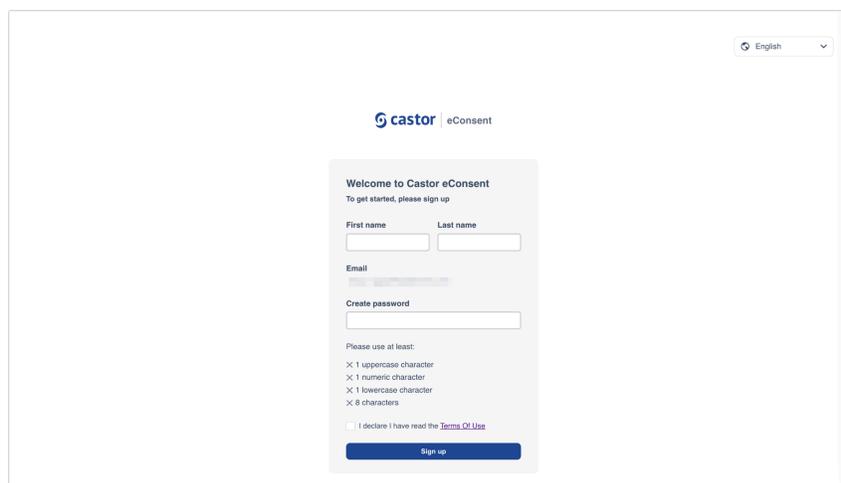
You will need to accept the Terms of Use and provide the following details when registering the account:

- 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.

3. Open a study

After logging in, the 'Studies' overview will be displayed with two sections, 'Invitations' and 'Active'.

Rejecting the invitation cannot be undone and you will need to contact the study admin or the main contact to request a new invite.
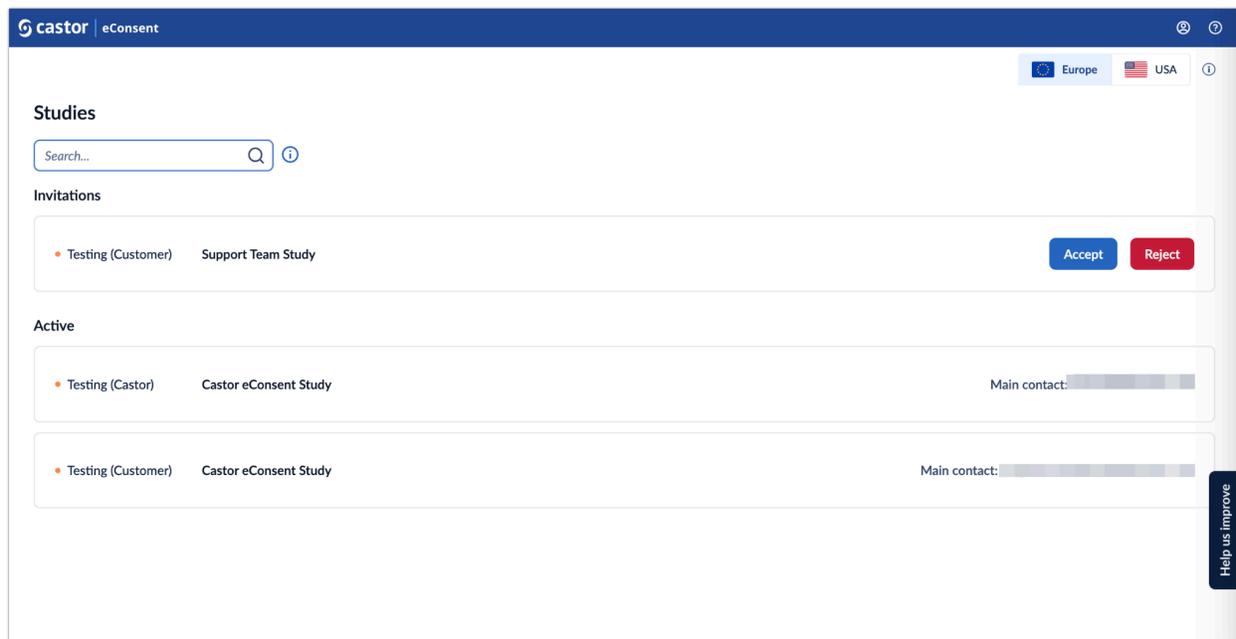
The 'Studies' overview consists of the following elements:

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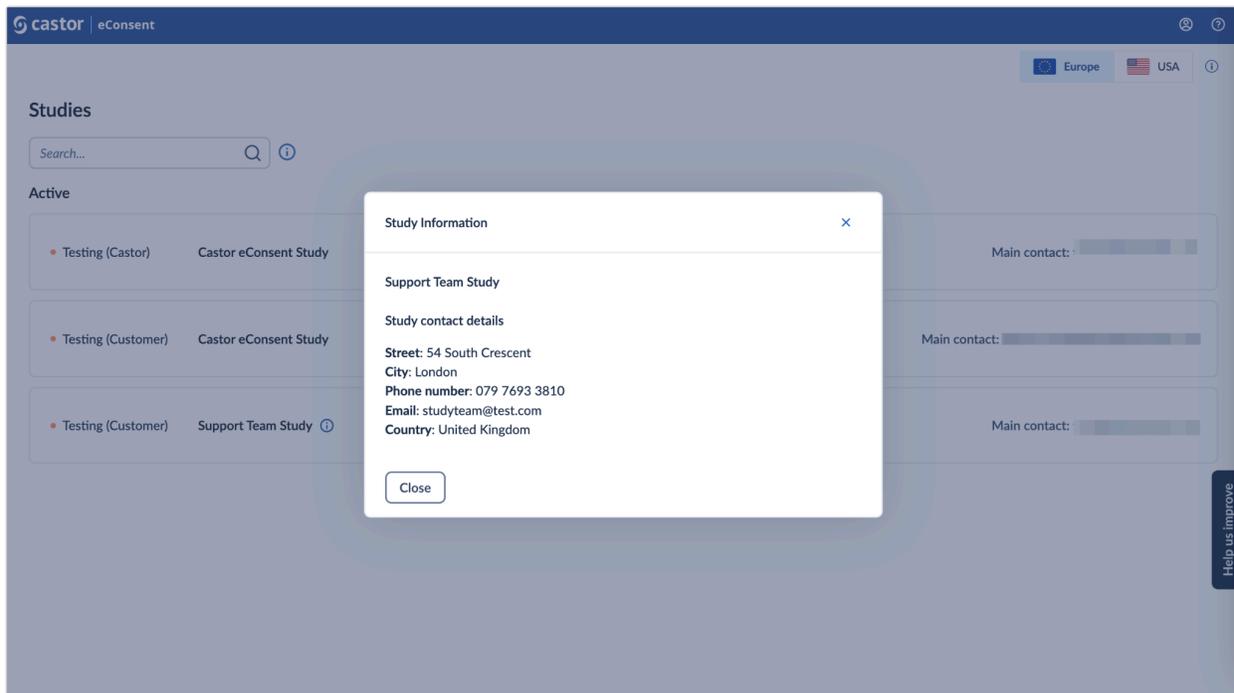
Studies for which an invitation has been accepted will appear in the 'Active' section and it is possible to access the study by clicking on the study row.

4. Study Settings

After opening the study, on the left hand side of the screen you will see the navigation panel.
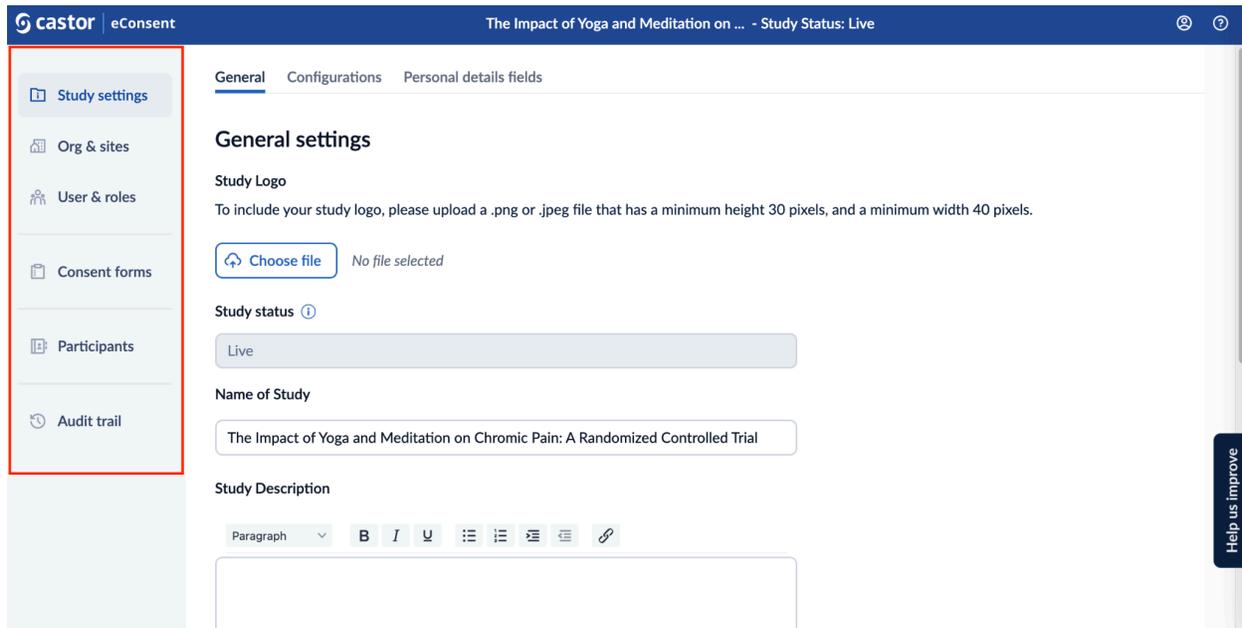
The 'Study settings' tab allows configuring the main study details. The tab contains the following sub-tabs:

- 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.
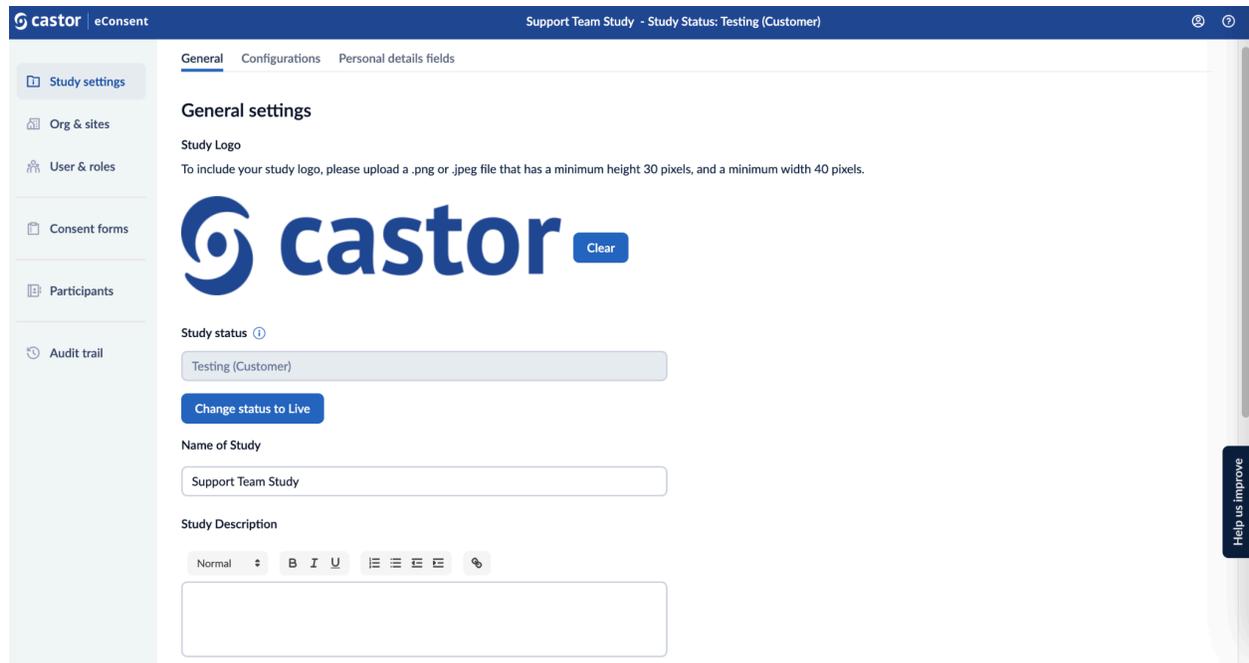
- **Study logo:** To include your study logo, please upload a .png or .jpeg file that has a height between 30 and a minimum width 40 pixels. To remove the logo, click on the 'Clear' button.
- **Study status:** This field displays the study status information. A study goes through the following statuses: Testing (Castor), Testing (Customer), Live.**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 Study status

Only users with the 'Organization admin' and 'Study admin' role can set the study to 'Live'.

Use the Study settings tab, General settings subtab to change the status of your study.

The **Study status** field displays the study status information. Each study progresses through the following statuses:

- **Testing (Castor)**: The study is being tested by Organization admin. Audit trail events during this study status are marked with the status 'Testing (Castor)'.
- **Testing (Customer)**: The study has passed the quality checks by Organization admin and is handed over to the Study Admin to perform User Acceptance Testing (UAT). Audit trail events during this study status are marked with the status 'Testing (Customer)'.
- **Live**: The study has passed the quality checks by Organization admin and UAT by the Study Admin. All the participant records that were created during both 'Testing' study statuses are automatically archived. Audit trail events during this study status are marked with the status 'Live'.

Once the study status has been changed, it is not possible to revert to the previous status.

4.1.2 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.

- **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.
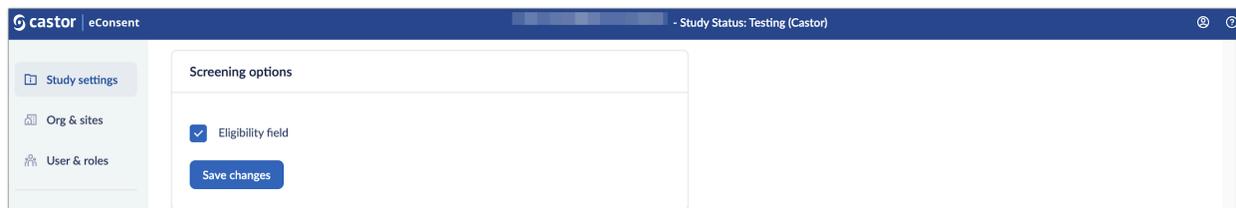
4.2 Configurations

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

4.2.1 Screening options

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

- A study setting '**Eligibility field'** allows the collection of your participant 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 participant.
- It is not possible to make changes to the screening options once the study is set to live.

4.2.2 Screening and Participant ID's

It is possible to configure screening ID and participant ID for your study.
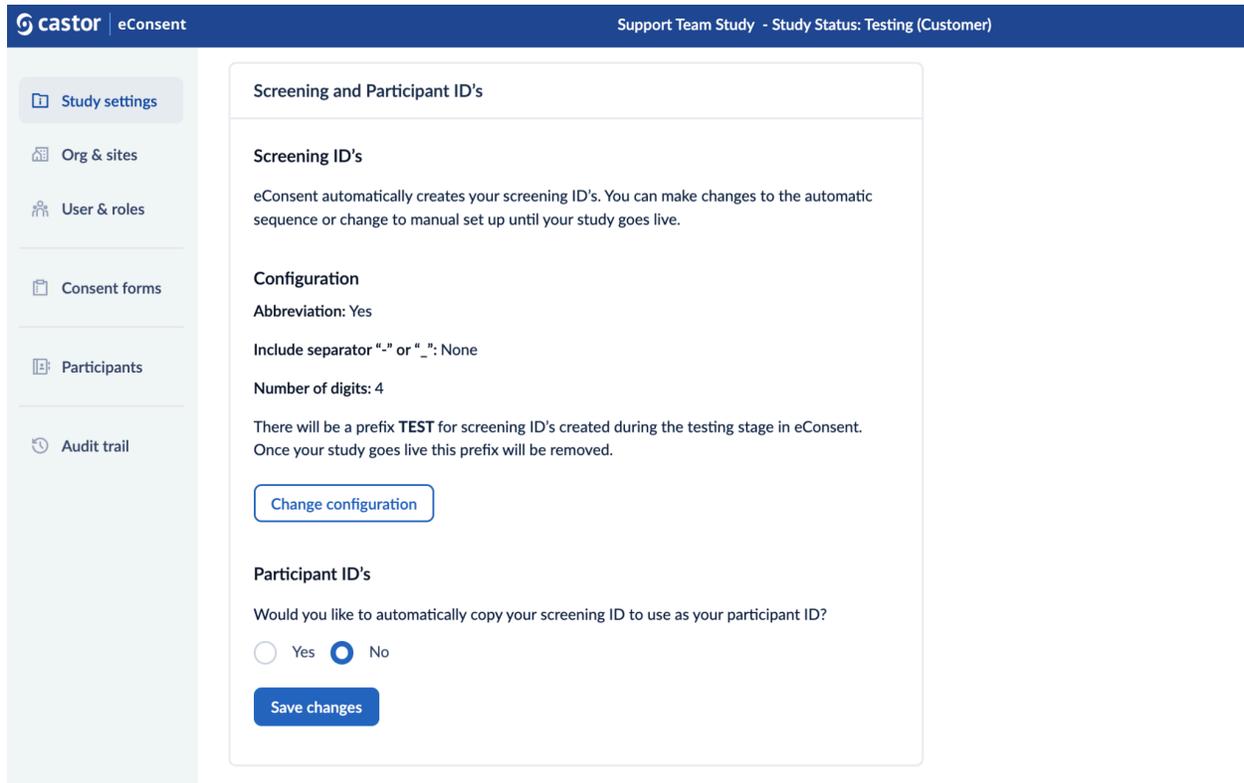
- **Screening ID's:**
  - eConsent automatically creates your screening ID's. You can make changes to the automatic sequence or change to manual set up until your study goes live.
  - To configure the Screening ID's, click on the 'Change configuration' button, set the field 'Set up automatic eConsent 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.
  - You cannot make changes to the screening ID's once the study is set to live.

- **Participant ID's:**
    - A study setting to let eConsent automatically generate screening ID's. 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 participant 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 participant ID?' to 'Yes'.
    - You cannot make changes to the participant ID's once the study is set to live.

4.2.3 Consent options

The 'Consent options' section allows to enable the following features:
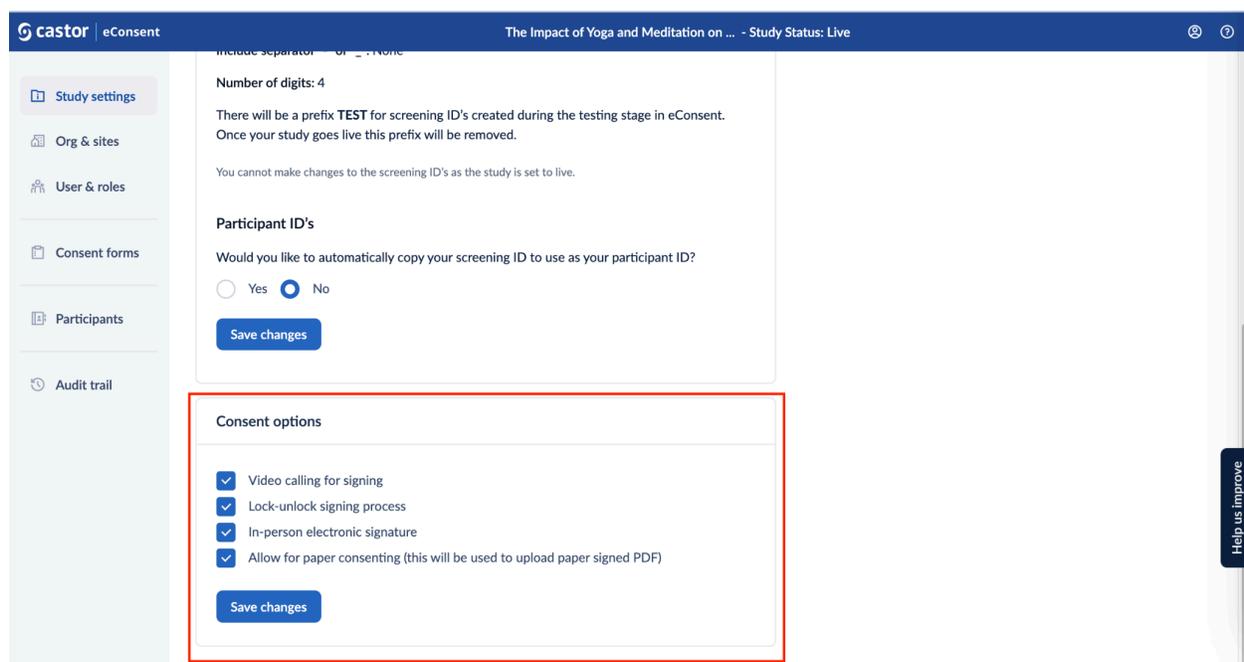
- **Video calling for signing**: This will activate the possibility to perform a video call.
- **Lock-unlock signing process**: When the ICF is locked by default, it will first have to be unlocked by a study team member to allow for the participant to sign. To enable or disable these features, check 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 participant.
  - The study team member that is conducting the consent procedure first has to confirm the participant'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 participant, the participant 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.

## 4.2.4 Participant withdrawal settings

It is possible to withdraw a participant from the participant detail page. Within the study settings, a study administrator can toggle the 'Reason for withdrawal' setting. When turning this setting on, a reason must be provided when withdrawing the participant. Next to that, the administrator can configure the reasons an investigator can choose when withdrawing.

- To **edit** a default reason for withdrawal, simply place the cursor in the field and start editing the provided text.
- To **remove** the reason for withdrawal click on the trash bin icon.
- To **add** a reason for withdrawal click on the '+Add new option'.
- To **save** or **cancel** changes use the relevant buttons - 'Save changes' or 'Cancel' - at the bottom.

When withdrawing a participant, the study team member is able to select a pre-configured reason for withdrawal.
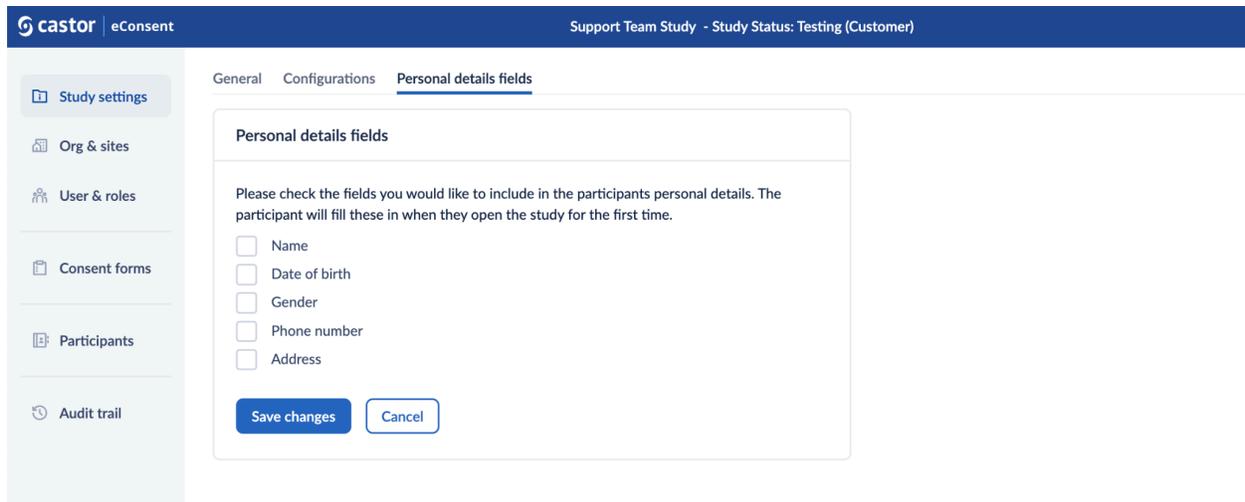
When withdrawing a participant, a study team member can choose **'Other'** as a reason for withdrawal. This allows them to **fill in a custom reason** in a text field.

After confirmation, the reason for withdrawal is added to the **audit trail event**.
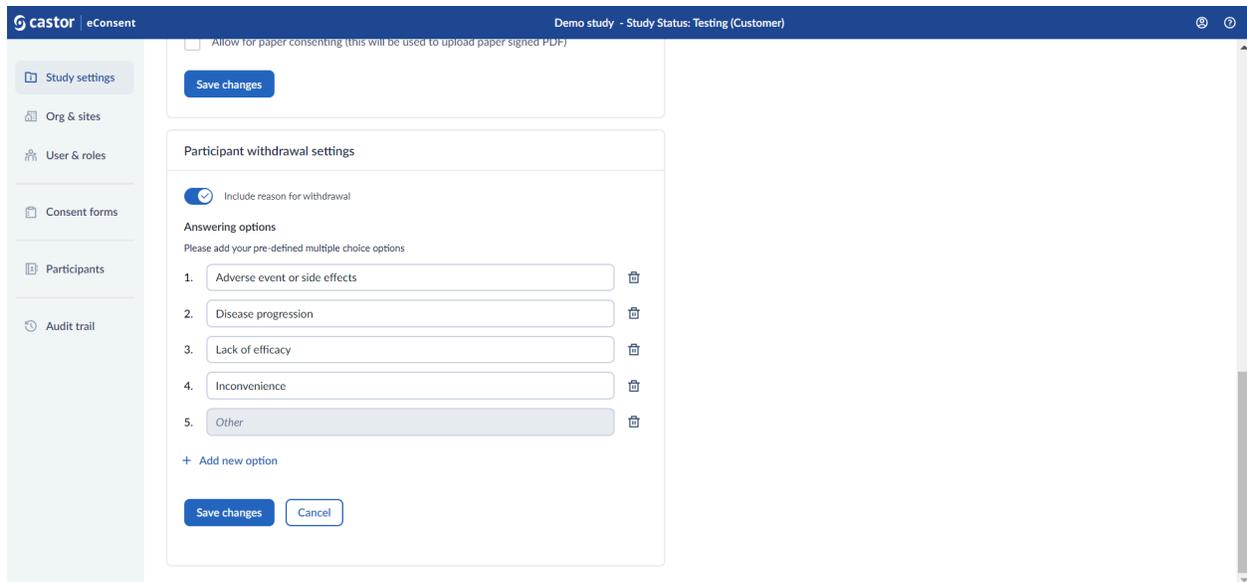
4.3 Personal details fields

Additional personal details of the participants 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 participants will be prompted to fill in the data. You can also add and edit this information.

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

5. Managing overseeing organization and sites

The 'Overseeing Organization & Sites' overview allows adding new study sites and managing existing ones.

5.1 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:

2. Enter the site details such as Site name, Abbreviation, and Country

3. Click 'Add site' to save the changes:

To edit the site details or to delete a site:

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

2. A pop-up window will appear where you can adjust the site details accordingly.
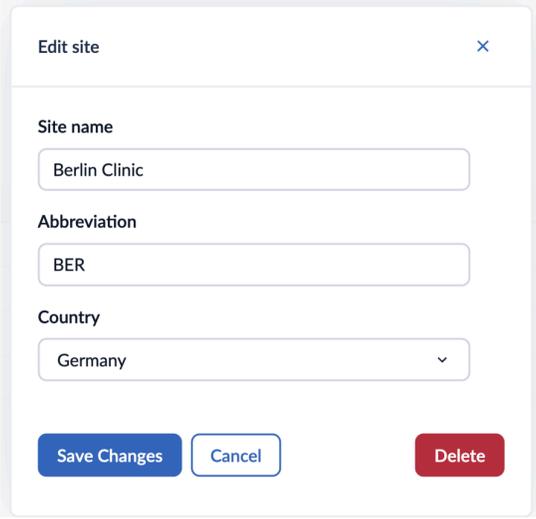
3. After editing the site information, click on 'Save changes' to apply the changes.
4. If you would like to delete the site, click on the 'Delete' button. A confirmation message will appear. Keep in mind that it is not possible to delete a site, if it is associated with a participant, an informed consent form or a user.

6. User and roles

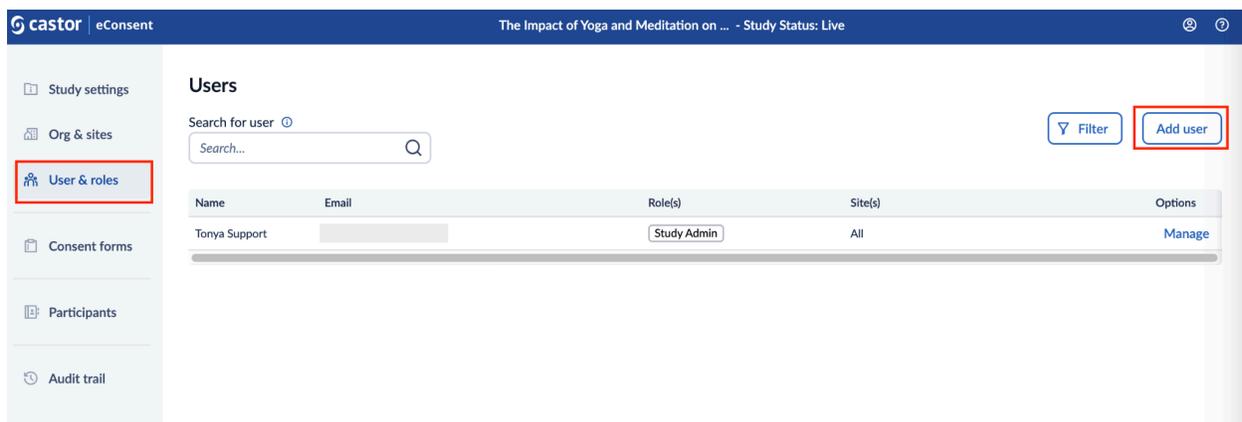The User & Roles page displays the names, emails, roles, and sites for everyone with access to your study. From this page, it is possible to revoke access, view pending study invitations, and re-send or cancel invitations.

6.1 Adding a user

1. Navigate to the 'Users' tab.

2. Click on 'Add user' to add someone to the study.

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.
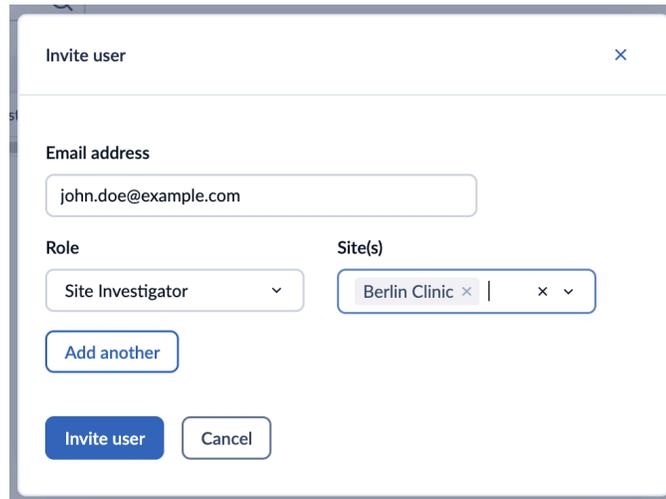
4. Press 'Invite user'. The added users will be shown in the Users list.

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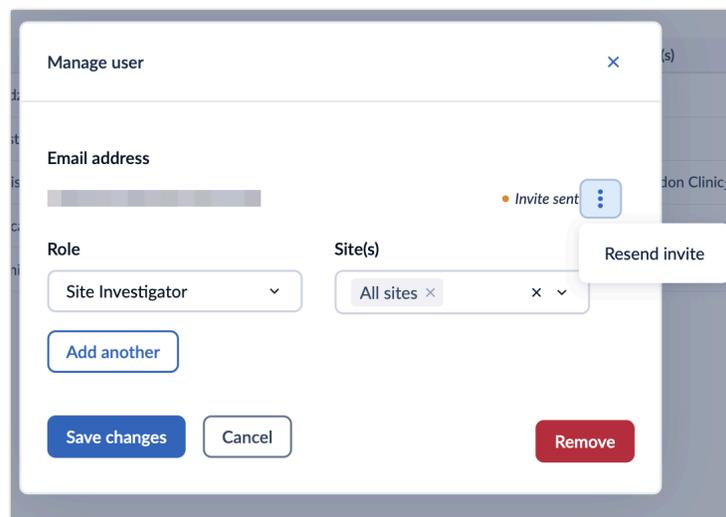
6. If you would like to remove the user, click on the 'Remove' button.

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, 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, 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. The Study investigator can export signature information.
- **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. The Study monitor can export signature information.
- **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.
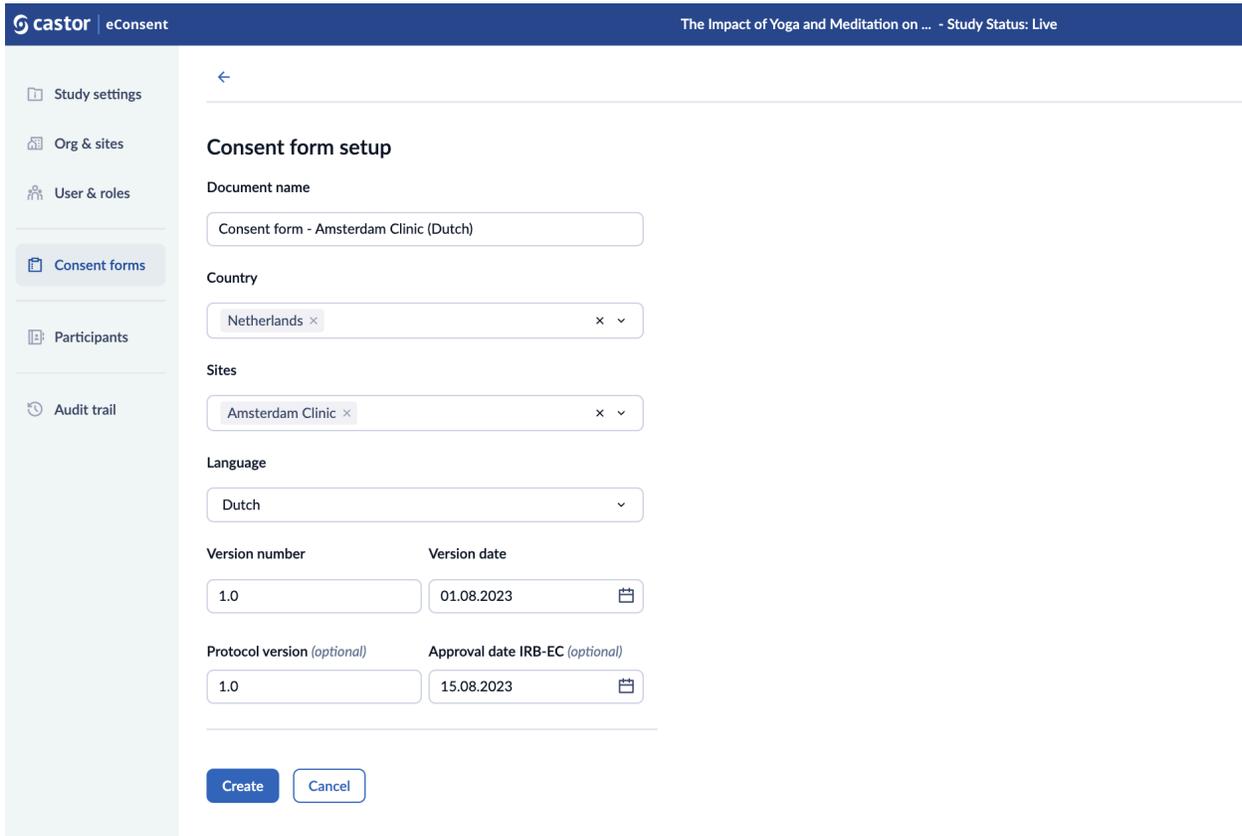
7. Consent forms

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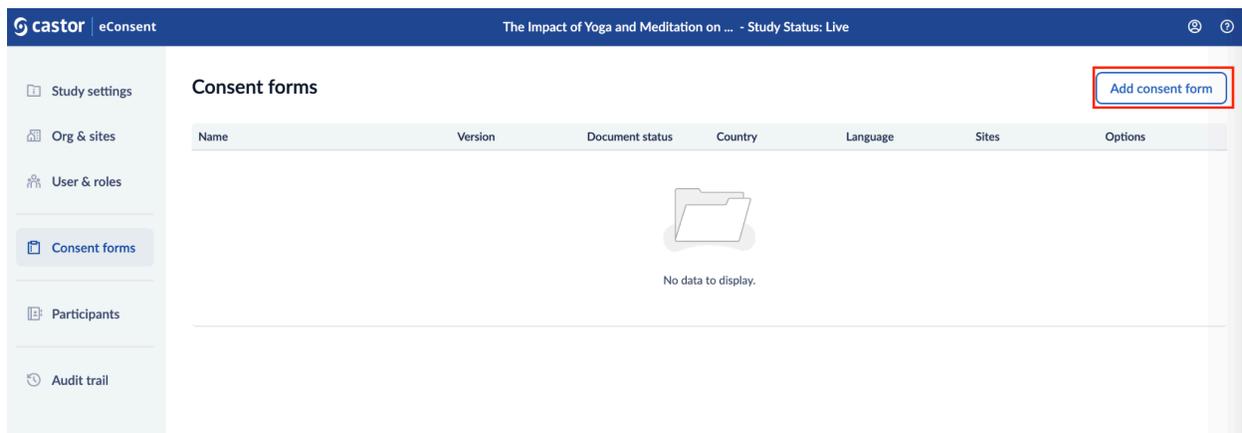
2. You will be taken to the 'Consent form setup' page to specify the details of the new consent form:

- **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.

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.
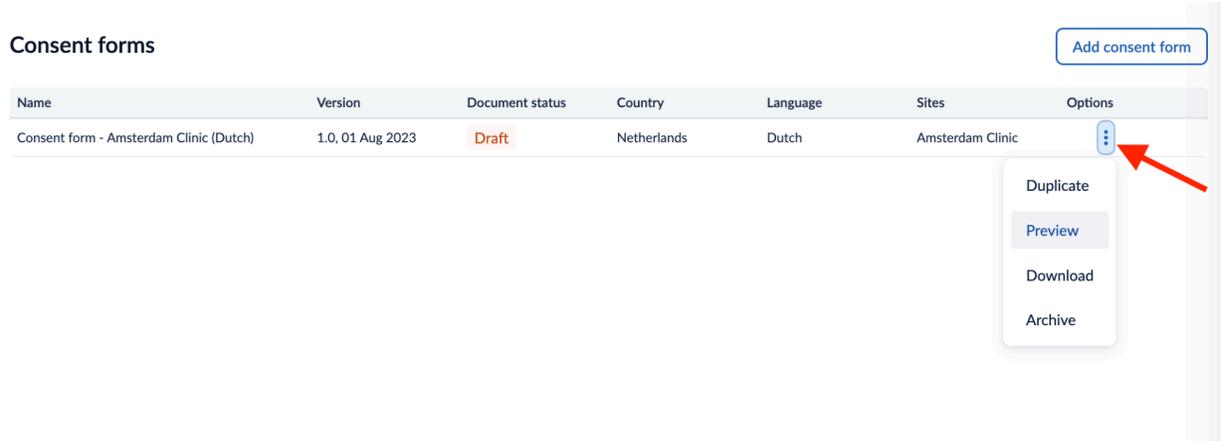

5. After the form is created, you will need to add the form text and set the relevant form properties. Click on the form row to start adding content to your form.

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.
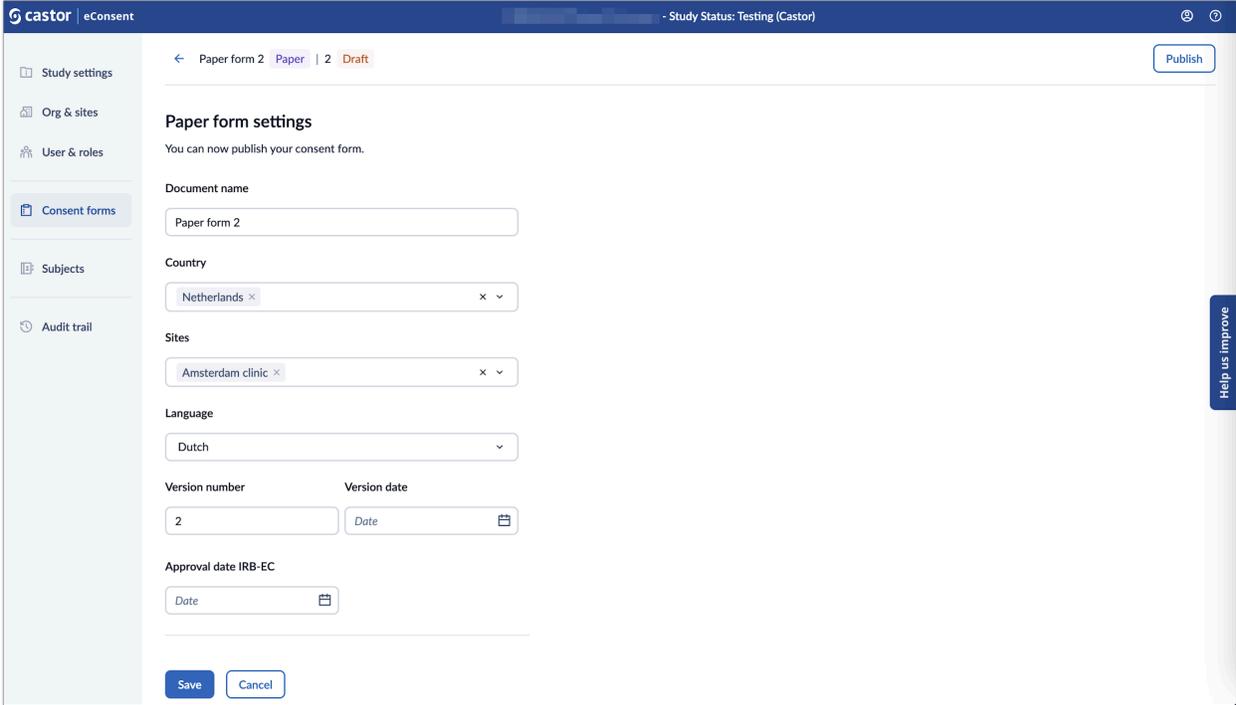
Press 'Save' to save the draft of your form.

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.
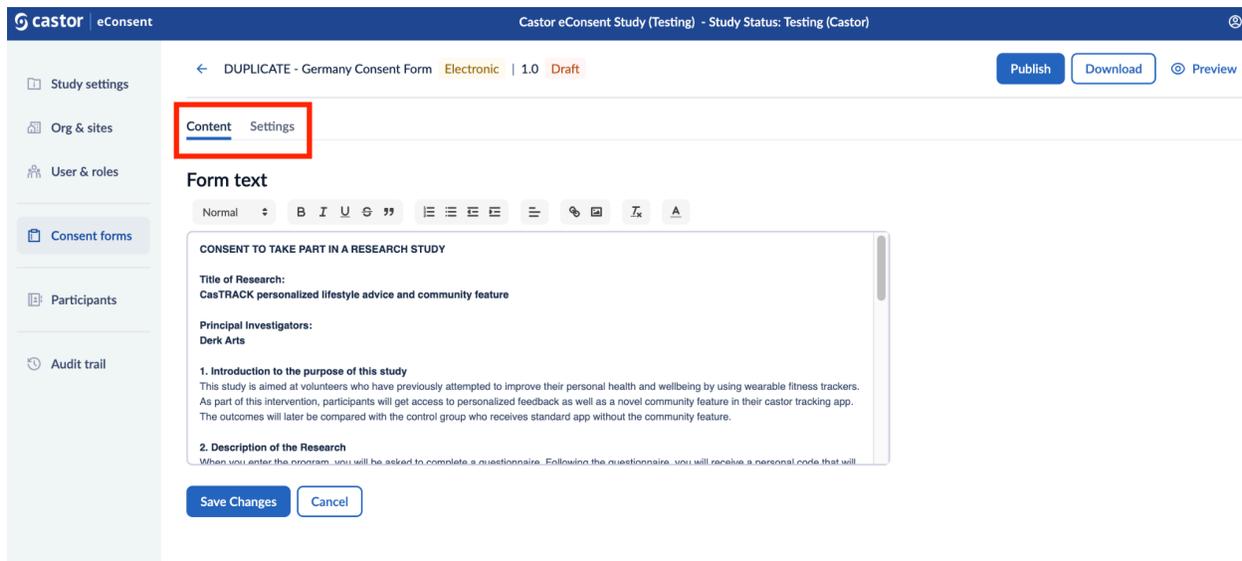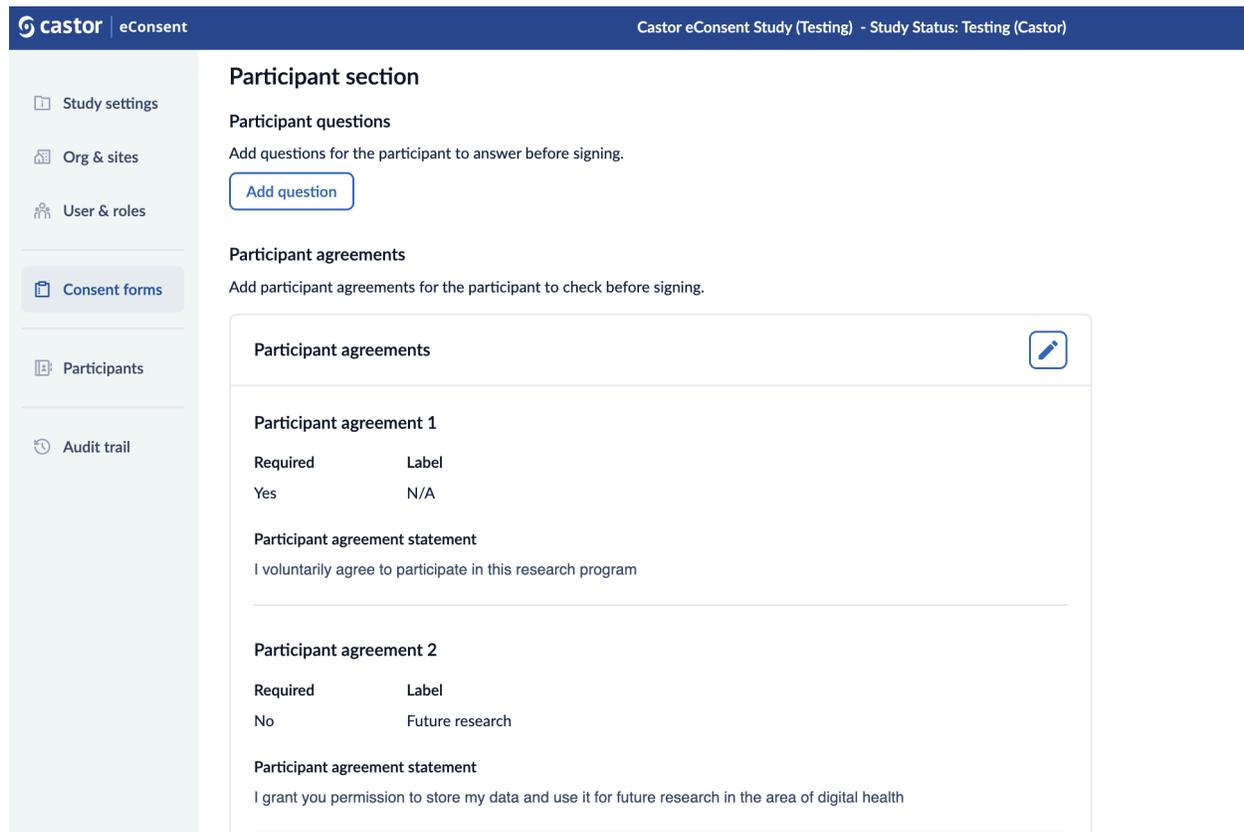

Form text: here you can include the form text and format the text. Make sure to click on the 'Save changes' button, as the text will not be saved automatically.

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

7.3.1 Participant Section

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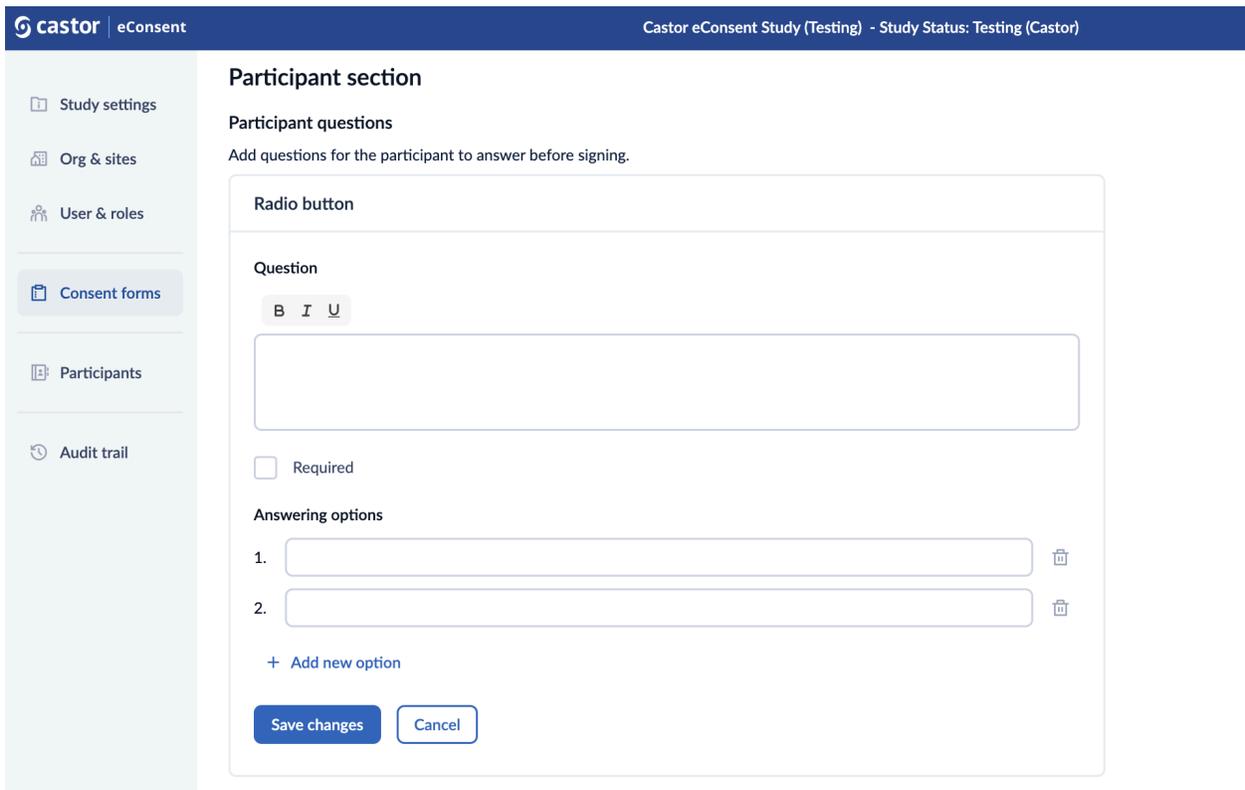

7.3.1.1 Participant questions

The "Participant questions" feature allows incorporating radio button questions into the Informed Consent Forms. This enables participants to easily select responses from radio button options while signing the form.

Study teams can customize the answer options for each radio button question, tailoring the choices to match the specific study requirements. Additionally, study teams can set radio button questions as required, promoting thorough data collection by preventing document saving until all required questions are answered. This can be useful for adding comprehension questions.
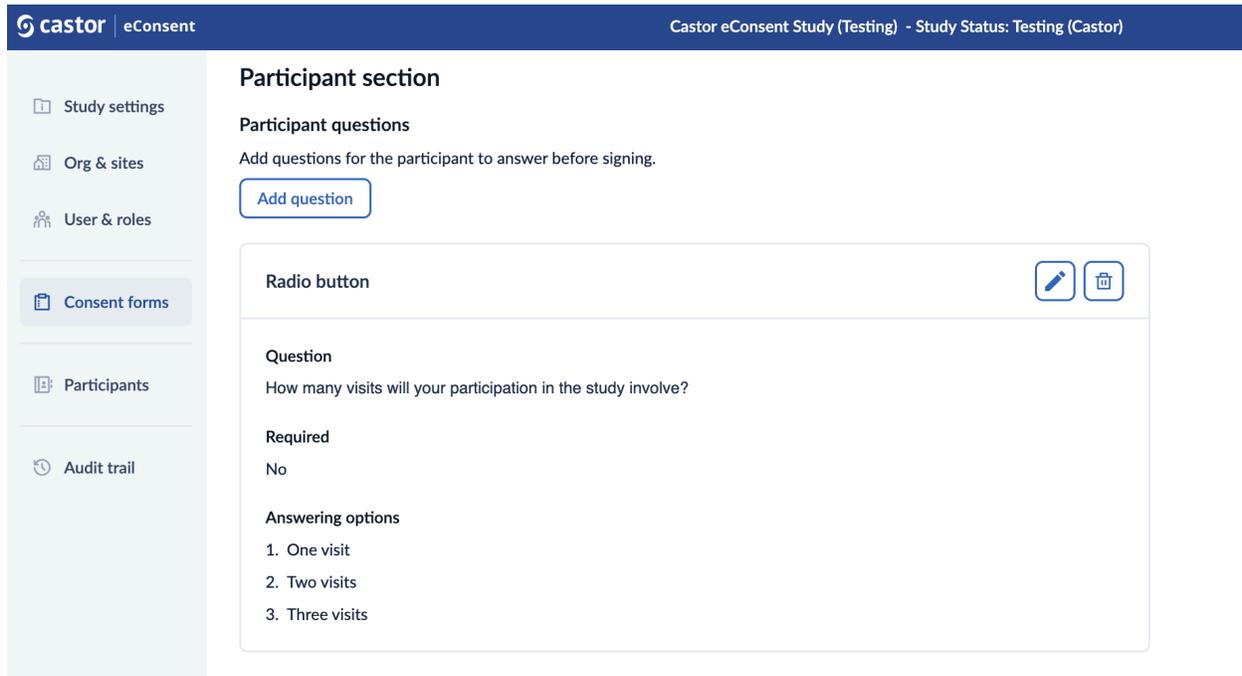
To add a question:

1. Click on the "Add question" button
2. Fill out the question text field
3. Select the "Required" checkbox field to make the question mandatory
4. In the "Answering options" section, add possible answers. To add a new answer option, click on the "+Add new option" button. To delete an answer option, click on the trash bin icon next to an option.

5. Click the "Save changes" button to save the question. Once the question is saved, it will appear in the "Participant questions" section.

6. Click on the pencil icon to edit the question (possible while the form is not published) or on the trash bin icon to delete the question. When clicking on the delete button, a pop-up window will appear asking to confirm the deletion of the question.

Participant section

Participant questions

Add questions for the participant to answer before signing.

Study settings

Org & sites

User & roles

Consent forms

Participants

Audit trail

[Add question]

Radio button

Question
How many visits will your participation in the study involve?

Required
No

Answering options
1. One visit
2. Two visits
3. Three visits

Radio button questions and their corresponding answers are prominently displayed in both the PDF version of unsigned and signed ICFs, ensuring accurate data representation.

 Furthermore, these participant questions and answers are seamlessly integrated into ICF information exports, streamlining data sharing and management. Changes to radio button questions are tracked in the audit trail, enhancing transparency and accountability throughout the research process.

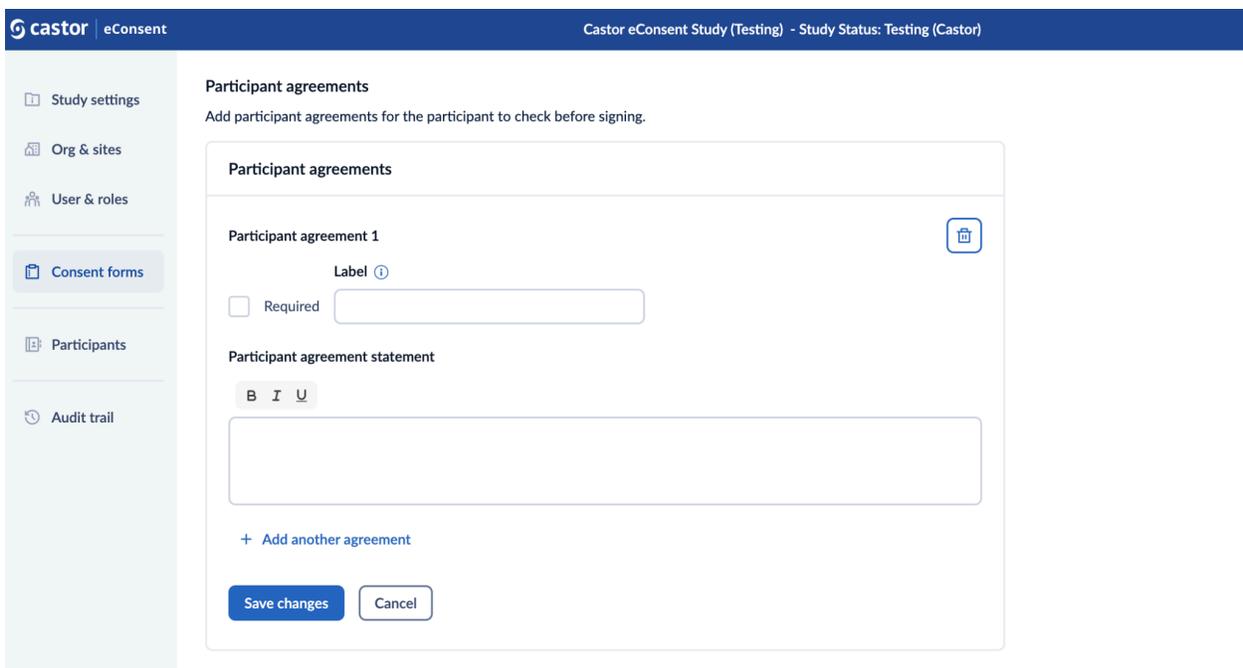### 7.3.1.2 Participant agreements

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

1. In the 'Participant agreements' section, click on the 'Add participant agreements' button to add an agreement.
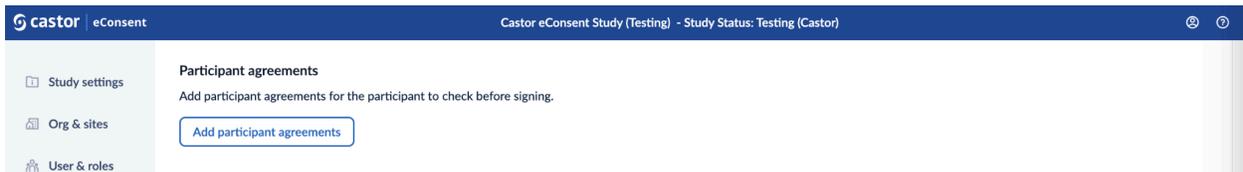
2. A 'participant agreement' dialog window will appear which allows to define the following properties of a participant agreement:

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

3. Press the 'Add another agreement' button to add additional agreements.

4. To delete a participant agreement, click on the trash bin icon.

5. Press on the 'Save changes' button to add the agreement(s) to your consent form. Pressing 'Cancel' will reverse the changes.

7.3.1.3 Participant signature

A default participant signature will be added after your form text, this signature is always set as a required signature until you add a LAR Signature.
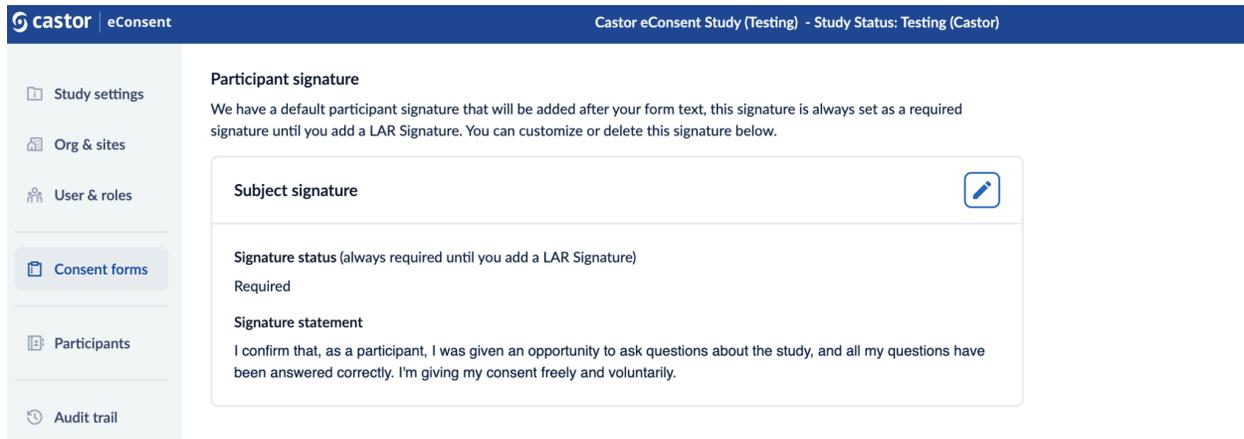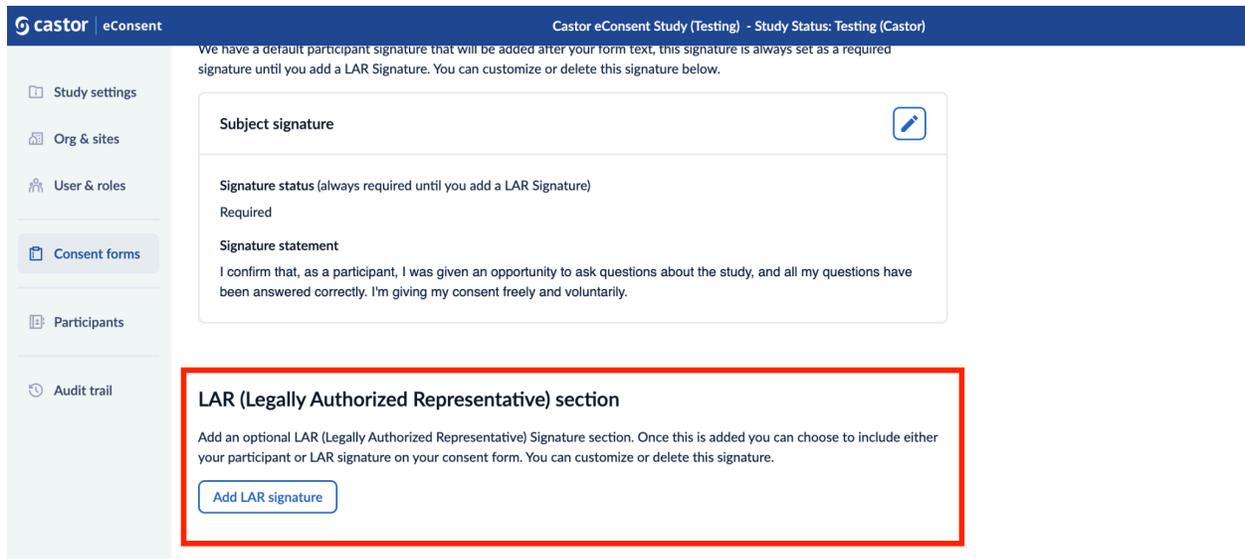

Clicking on the 'pencil' icon allows you to edit signature statements.

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 participant or LAR signature on your consent form.

Click on the 'Add LAR signature' button to configure the signature:

- **Signature statu**s: displays whether the LAR signature is required or optional
- **Signature header**: allows you to define your customized signature title (maximum 60 characters).
- **Signature statemen**t: here you can define the signature statement for the participant who will sign the consent form.
- **Ask for relationship to participant?**: selecting 'Yes' will allow you to add a list of options (multiple choice) for users to specify their relationship to the participant using the 'Add new option' button.
- **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 participant is not required, selecting the 'No' option disables the question in the LAR signature section.
- Click on the Save changes button to add the LAR signature. If you would like to reverse the changes, click on the 'Cancel' button.

- Once the signature is published, it will be visible in the "Legally Authorized Representative Signature" section. Press on the pencil icon to edit the signature or on the trash bin icon to delete it:

castoredc.com | 37

7.3.3 Study team member section

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

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 'Saved 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');
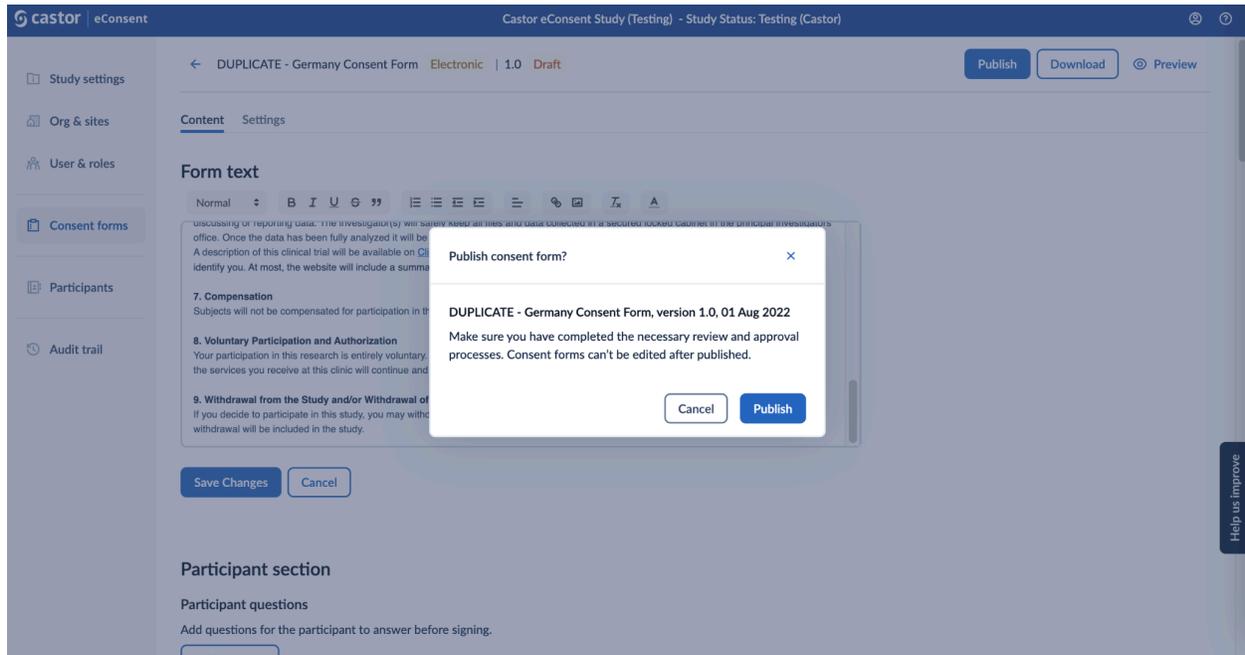
- **Optional** - If it is unknown upfront whether a second study team member signature is needed for a specific form or participant, the second signature can be marked as optional. In that case, the second study team member signature component needs to be (de)activated by the first study team member 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 participant 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.
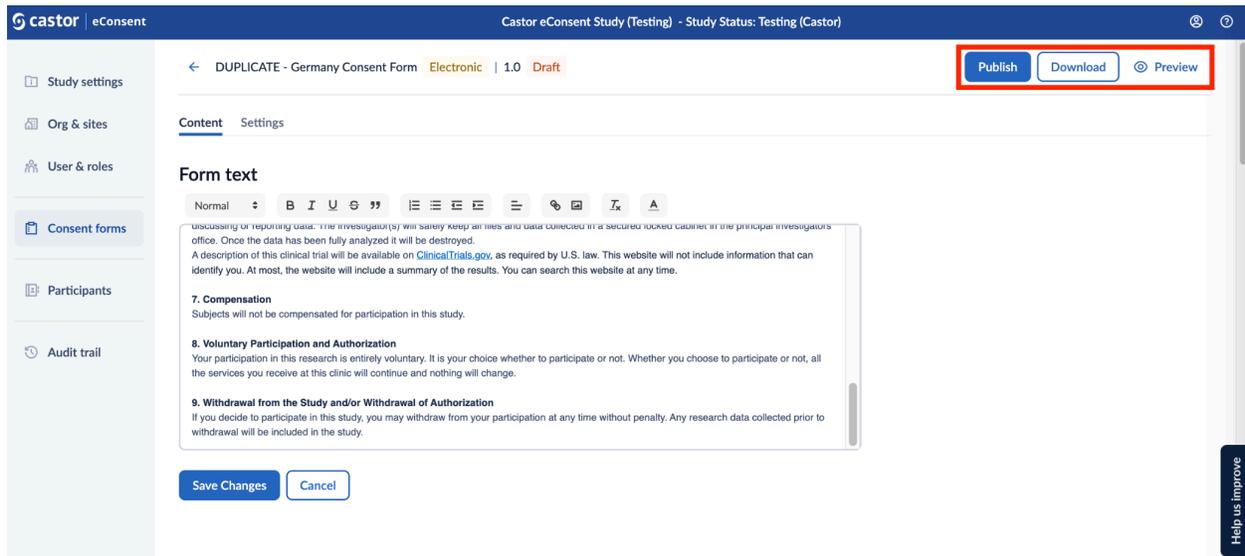
Once the form is published, it will no longer be possible to edit the content of the form. Please ensure you have completed the necessary review and approval processes prior to publishing. Click 'Publish' to publish the form.

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.

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.

8. Audit trail

The audit trail is a log of study related events:

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

To view audit trail for in the participant view, click on the 'Audit trail' tab:
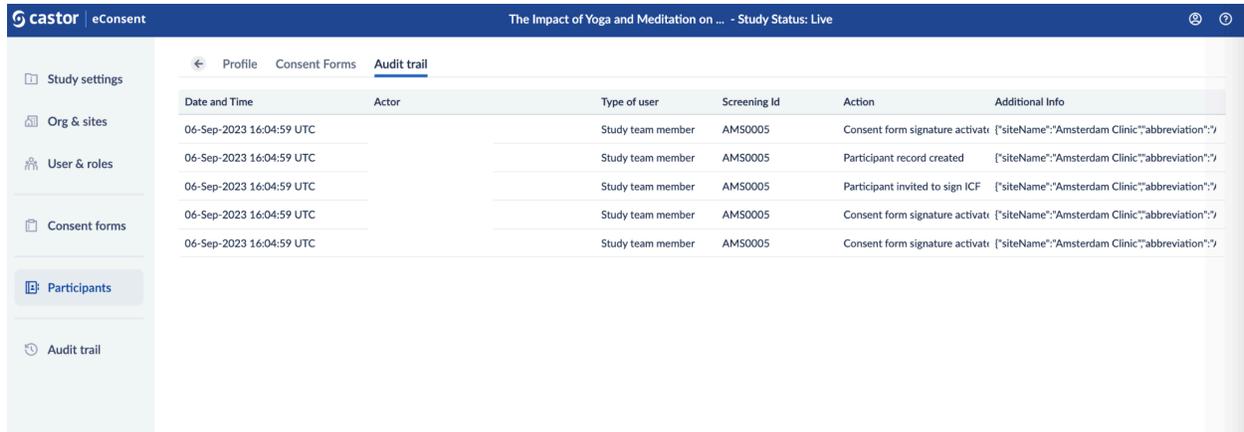
8.1 Audit trail export

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.
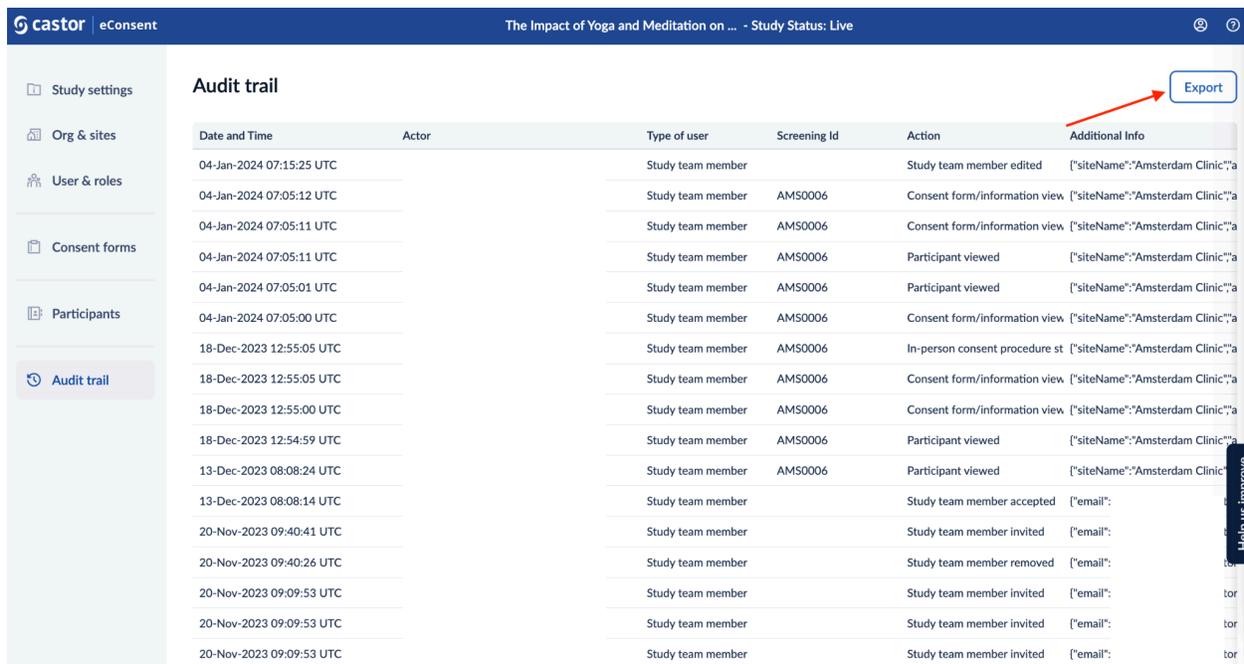
A pop-up window will appear, click 'Generate' to run the export:
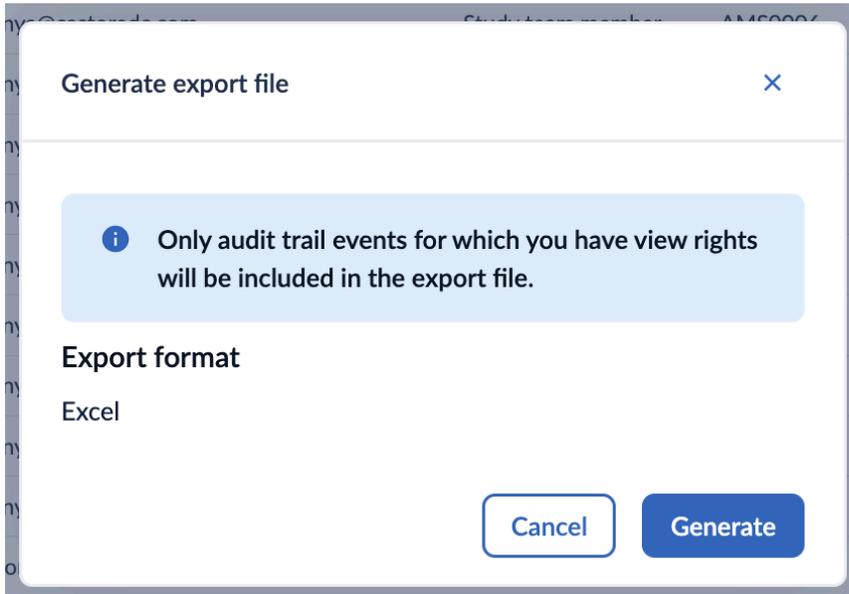
Only audit trail events for which you have view rights will be included in the export file. You will receive an email notification when the file is ready to download.

9. Castor eConsent and CDMS implementation process

For study admins who are building their own eConsent and CDMS studies and would like to request an integration between those studies, the following steps are required to set up your eConsent and CDMS studies integration:

Step 1: Request for an Organization/Admin account
Step 2: Build eC and CDMS studies
Step 3: Submit a request for integration

Step 1: Obtain Access and Sign the Service Agreement

Once you have signed the service agreement, you will be required to complete an account creation form. This form collects important information needed to set up your admin account in Castor eConsent. Here are the details you need to provide:

- **Organization Name**: Provide the name of your organization or institution. This ensures that your study is properly associated with your entity.
- **Email Address for the Admin Account**: Specify the email address that will be associated with the admin account in Castor eConsent. Ensure that this email address is accessible and will be actively monitored by the person responsible for managing the eConsent process.
- **Country**: Indicate the country where your organization is located. This information is essential for regulatory compliance purposes.
- **Region for Information Storage**: Choose the region where you would like your eConsent data to be stored. Castor offers options for data storage in the European Union (EU) or the United States (US). Consider any data protection or residency requirements when making this selection.
- **Integration with Landing Page or Enrollment Portal**: Inform Castor if you plan to integrate eConsent with a landing page or enrollment portal. This allows for a seamless participant experience and streamlines the enrollment process.

Step 2: Build eC and CDMS

Once you are logged in, you can create a study by clicking on the "Create new study" button and then begin configuring it.

Cator CDMS and eConsent workflows

Consider one of the following workflows which is applicable for your eC and CDMS studies.

Castor offers four standard workflow options depending on study requirements:

- **Consent Standalone**: Participants provide their informed consent electronically using this workflow.
- **Screening (ePRO) --> eConsen**t: Participants complete a screening process with electronic patient-reported outcome (ePRO) before moving on to the eConsent process.
- **eConsent --> Data Capture**: Participants go through the eConsent process first and then data capture activities occur, such as filling out surveys or other data collection forms.
- **Screening (ePRO) --> eConsent --> Data Capture**: In this workflow, a participant first completes screening with ePRO, followed by the eConsent process in case they are eligible, and concludes with data capture activities.

If Castor is creating a landing page for participant recruitment, collaborate with your Project Manager to ensure a seamless integration between the landing page and eConsent process for a better participant experience.

Before requesting integration between Castor CMDS and eConsent products, make sure you have built both your CMDS and eConsent studies. Additionally, a signed service agreement is required for the integration process.

If none of the standard workflows suit your study requirements, custom development may be needed. Contact your account manager to discuss your specific needs and obtain a custom development quote.

Step 3: Submitting a request for integration

If you are integrating eConsent with any other Castor products, please ensure that the integration is complete and tested before setting your study live.

Option 1: eConsent Standalone

If you have eConsent Standalone (Option1) please follow the below instructions:

- After your study has passed your quality checks and UAT, you can set your study 'Live'. All the participant records that were created during 'Testing' are automatically archived. Audit trail events during this study status are marked with the status 'Live'.
- Only an Organization admin or a Study admin can set a study live.
- Once the study status has been changed, it is not possible to revert to the previous status.

Option 2: Screening Survey (ePRO) + eConsent

If you wish to (pre)screen participants before they consent and allow participant creation in CDMS automatically, you can only do so by using a browser based participant survey sent via ePRO. Integration functionality is not possible using Castor Connect.

- In eConsent, select 'Eligibility field' as a Screening Option in your study's settings.
- In CDMS, please also include an eligibility calculation in your survey. The outcome of this calculation will toggle the 'Eligibility field' in eConsent for the creation and sending of an informed consent form automatically from eConsent.

After you have built your Informed Consent Form in eConsent and your Pre-screening survey in CDMS, please send the following details to ec-requests@castoredc.com :

- eConsent URL - Visible when you are logged in eConsent and on the Study Settings tab
- CDMS - server region of your study
- CDMS - Study ID

- CDMS - Name of the Survey Package that contains pre-screening survey
- CDMS - Field variable name and value from pre-screening survey that indicates eligibility
- Sites (name and abbreviation) to integrate in eConsent and CDMS (requires that the sites are created in both products and identical)
- Your email address
- Your name

The Castor Technical Implementation team will access your CDMS study to create a user account, define the API user rights, enable API access, and verify/gather UIDs and variable names. Your eConsent study will be accessed to integrate the sites in both products and set the trigger for participant creation.

Option 3: eConsent + Data Capture (CDMS)

If you only want a participant record to be created in CDMS after the informed consent process, before they consent and allow participant creation in CDMS automatically, we can do so by triggering participant creation in CDMS with 1 of the 2 following triggers: 1) Participant signs ICF or 2) ICF is countersigned by study staff. All forms assigned to the participant must be signed in order for the participant record in CDMS to be created.

After you have built your Informed Consent Form in eConsent and your study for data capture in CDMS, please provide the following information:

- eConsent URL - Visible when you are logged in eConsent and on the Study Settings tab
- Trigger - Participant signs or Countersigned
- CDMS - server region
- CDMS - Study ID
- Sites (name and abbreviation) to integrate in eConsent and CDMS (requires that the sites are created in both products and identical)

The Castor Technical Implementation team will access your CDMS study to create a user account, define the API user rights, enable API access, and verify/gather UIDs and variable names. Your eConsent study will be accessed to integrate the sites in both products and set the trigger for participant creation.

Option 4: Screening Survey (ePRO) + eConsent + Data Capture

You can prevent participant ID generation and Data Capture until a participant is first pre-screened AND then consented. This combines the functionality presented in Options 2 and 3. For this, you will have to build one eConsent study, two CDMS studies, one with a pre-screening survey, and another for Data Capture. Screening and Data Capture must be created in separate CDMS studies. The details for both CDMS studies are required.

Please provide the following information:

- eConsent URL - Visible when you are logged in eConsent and on the Study Settings tab
- Trigger - Participant signs or Countersigned
- Screening CDMS - server region of your study
- Screening CDMS - Study ID
- Screening CDMS - Name of the Survey Package that contains pre-screening survey
- Screening CDMS - Field variable name and value from pre-screening survey that indicates eligibility
- Data Capture CDMS - Study ID
- Sites (name and abbreviation) to integrate in eConsent and both studies CDMS (requires that the sites are created in both products and identical)

The Castor Technical Implementation team will access your CDMS studies to create user accounts, define the API user rights, enable API access, and verify/gather UIDs and variable names. Your eConsent study will be accessed to integrate the sites in both products and set the trigger for participant creation.

10. 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 eConsent online knowledge base](#). If you have any questions or concerns, please contact us at support@castoredc.com