

Navigation Sheet – E-consent Framework

Compliance & Data Office

Research Support Office



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Introduction

This guide provides an overview of REDCap's e-consent (electronic consent) framework as well as recommendations as to how to set up REDCap's e-consent at KI. E-consent may replace traditional paper consent if certain guidelines are followed and if e-consent falls within your study's ethics approval.

Activating REDCap's e-consent framework adds several functions to a survey instrument, such as a verification page, the ability to upload consent forms in different languages, and the automatic creation of PDFs of completed consent forms that can be exported easily.

KI has created an e-consent template, which can be selected when creating a new project or imported into your existing project by uploading an instrument ZIP-file. This template can be used as is or may be adjusted if necessary.

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Set up your Consent Instrument

First you need to create an Instrument containing all fields related to the informed consent form. KI has made an example with suggested fields and phrases that aims to guarantee a secure way of identifying the study participant.

The example instrument can be added to your project in different ways.

- When creating a new project, you can choose the project template “KI Template – E-consent (English)” / “KI Mall – E-consent (Svenska)”. The consent instrument will then already be available in your project.

+ Create a new REDCap Project

You may begin the creation of a new REDCap project on your own by completing the form below and clicking the Create Project button at the bottom.

Project title:

Project's purpose: How will it be used?

Name of P.I. (if applicable): First name MI Last name

Email of P.I. (if applicable)

Name of P.I. as cited in publications (if applicable): (e.g., Harris PA)

IRB number (if applicable):

Please specify:

Basic or bench research

Clinical research study or trial

Translational research 1 (applying discoveries to the development of trials and studies in humans)

Translational research 2 (enhancing adoption of research findings and best practices into the community)

Behavioral or psychosocial research study

Epidemiology

Repository (developing a data or specimen repository for future use by investigators)

Other

Assign project to a Project Folder?

Project notes (optional): Description of the project's use or purpose (displayed on the My Projects page)

Project creation option:

Empty project (blank slate)

Upload a REDCap project XML file (CDISC ODM format) [?](#)

Use a template (choose one below)

★ Choose a project template [+ Add templates \(Admins only\)](#)

select template	Template title (sorted by title)	Template description
<input type="radio"/>	Basic Demography	Contains a single data collection instrument to capture basic demographic information.
<input type="radio"/>	Classic Database	Contains six data entry forms, including forms for demography and baseline data, three monthly data forms, and concludes with a completion data form.
<input type="radio"/>	Field Embedding Example Project	Example of the Field Embedding feature.
<input type="radio"/>	Human Cancer Tissue Biobank	Contains five data entry forms for collecting and tracking information for cancer tissue.
<input type="radio"/>	KI Mall - E-consent (Svenska)	Innehåller ett enskilt instrument med KI's rekommenderade fält och innehåll för att samla in samtycke från studiedeltagare. Den här mallen är på svenska.
<input type="radio"/>	KI Template - E-consent (English)	Contains a single instrument with KI's recommended fields and features to collect electronic consent from study participants. This template is in English.

- Alternatively, you can upload the instrument as a ZIP-file to an already existing project. The ZIP-file is available to download here: [E-consent template files](#). Choose the preferred language (English or Swedish) and download the entire folder. Next, open your REDCap project and Online Designer, click the yellow Upload button and choose the ZIP file inside the folder you just downloaded.

If you prefer to create your own instrument, we recommend to at least include fields for name, date of birth and a descriptive field to where you can upload the participant information sheet.

Please make sure you have a defined process for handling cases where participants withdraw their consent.

Enable e-consent in your REDCap project

You enable the e-consent framework in *Online Designer*. The e-consent framework can only be activated for instruments that have been enabled as surveys.



The screenshot shows the 'Data Collection Instruments' section in REDCap. It includes buttons for 'Create', 'Import', and 'Upload'. A red box highlights the 'e-Consent and PDF Snapshots' button. Below this is a table of instruments:

Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey related options
Samtycke / e-consent	7			Choose action	Survey settings + Automated Invitations
Demographics	0			Choose action	Survey settings + Automated Invitations



The screenshot shows the 'e-Consent Framework Settings' page. A red box highlights the '+ Enable the e-Consent Framework for a survey' button. Below this is a table of e-consent forms:

e-Consent active?	Edit settings	Survey	Location(s) to save the signed consent snapshot
<input checked="" type="checkbox"/>		"Samtycke / e-consent" (samtycke_econsent) Consent form v1.1 + Add consent form View all versions	File Repository

Showing 1 to 1 of 1 entries

It is possible to activate more than one survey for e-consent, meaning several e-consent forms containing different fields/variables can be used within the same project. This can be useful if you have different groups of study participants e.g. age groups, needing age-specific consent forms.

Setting up the e-consent framework

Once e-consent has been enabled for a specific survey, several features and settings become available:

Activate/deactivate e-consent for enabled surveys



Here, you can deactivate the e-consent framework for specific surveys after which they will be hidden from this page.

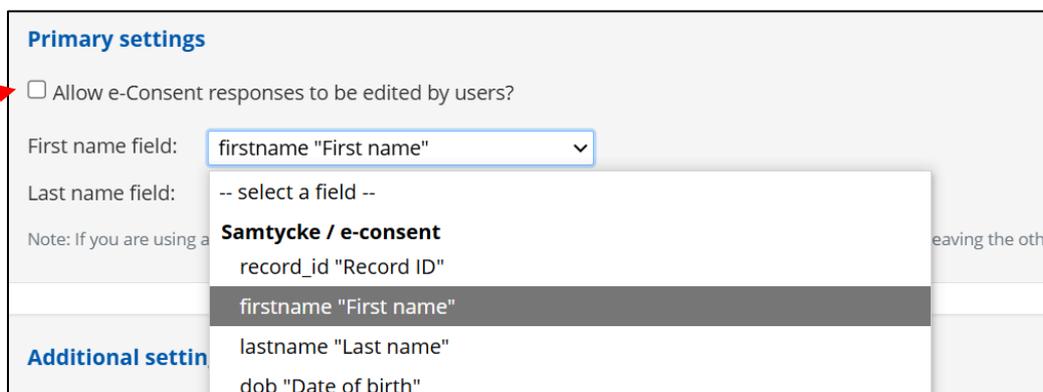
Configure your e-consent settings

These settings determine what information will be included on the PDF saved in your *File Repository*.



Primary settings

Under *Primary settings*, select the survey fields where participants write their name in your e-consent form.



Note: KI does *not* recommend to "allow e-Consent responses to be edited by users". Leave this box unchecked.

Additional settings

Under *Additional settings*, you select which field collects date of birth (if applicable), whether you want a custom tag in the footer of the PDF, and what custom label you want in the header of the PDF (e.g. “consent form for XY”).

Additional settings

Date of birth field:

Custom tag/category for PDF footer: e.g., Pediatric
Note: This should be static text only.

Custom label for PDF header: e.g., PID [project-id] - [last_name]
Note: Piping may be utilized, including the use of Smart Variables. [Codebook](#) [Smart Variables](#)

Force signature field(s) to be erased if participant clicks Previous Page button while on the certification page?

Select a field below that serves as a signature field in this survey. It could be a [free-form text field](#), a [signature field](#), or a [number field](#) (e.g., to collect a PIN), and it must be a [Required field](#). If any fields are selected below, then if the participant gets to the last page of the survey where it asks them to certify their responses, if they then choose to click the Previous Page button, it will erase the value of these signature fields, thus forcing them to 'sign' the field(s) again before completing the survey. If you do not want this behavior, do not select any fields below. You may use up to five signature fields.

Signature field #1:

[+ Select another signature field](#)

Additionally, you choose the signature field (or fields if collecting more than one signature).

All this information is added to the PDF snapshot which is then automatically saved in your project's *File Repository*.

Other settings

Finally, you may also establish what rules the file name of each PDF follows as well as add optional notes.

Location(s) to save the signed consent snapshot

Save to File Repository
 Save to specified field:
 Store the translated version of the PDF (if using Multi-language Management)

Snapshot file name

Use static text or piping to customize the prefix of the snapshot file's name when it gets stored. Note: The file name will always be appended with the date/time when the snapshot was saved.

File name:
e.g., [last_name]_[first_name]_[dob]_record[record-name]

Optional notes: You may add any custom notes here for reference and documentation purposes.

Notes:

[Save settings](#) [Cancel](#)

Once ready, click on “Save settings”.

Upload your Participant Information Sheet

Now, you can upload your information sheet (consent form).



In the menu that opens up, you select the version number of your consent form, where the consent form will be displayed on the survey page (it always has to be tied to a descriptive field), and whether the consent form is for a specific Data Access Group (DAG) or language setting.

Consent form version:

It is required to version each consent form (e.g., "1.1", "2.3.1 2024-06-01") so that you may manage any future changes and differentiate all versions of the consent form. It is recommended that you do not begin the version number with the letter "v".

📍 Placement of consent form:

Choose a Descriptive field on the survey that will serve as the location of the consent form. The consent form will be displayed immediately below this field on the survey page. Note: The Descriptive field selected must be the same for all consent forms specified for this survey. If the field is changed, it will be changed for all consent forms for this survey.

👤 Display for specific DAG:

Only display this consent form when the record is assigned to the selected data access group. Note: The default option will be used if no DAG-specific consent forms exist.

🌐 Display for specific language:

Only display this consent form when viewing the survey in the selected language.

Note: To be able to add consent forms in different languages, you have to add all relevant languages via *Multi Language Management* (MLM). Likewise, you have to first create DAGs to be able to assign consent forms to specific DAGs. See KI's guides on MLM and DAGs on the [staff portal](#) for more information about these settings.

Example

We want to upload two consent forms, one in English and one in Swedish.

Consent form version:

It is required to version each consent form (e.g., "1.1", "2.3.1 2024-06-01") so that you may manage any future changes and differentiate all versions of the consent form. It is recommended that you do not begin the version number with the letter "v".

📍 Placement of consent form:

Choose a Descriptive field on the survey that will serve as the location of the consent form. The consent form will be displayed immediately below this field on the survey page. Note: The Descriptive field selected must be the same for all consent forms specified for this survey. If the field is changed, it will be changed for all consent forms for this survey.

👤 Display for specific DAG:

Only display this consent form when the record is assigned to the selected data access group. Note: The default option will be used if no DAG-specific consent forms exist.

🌐 Display for specific language:

Only display this consent form when viewing the survey in the selected language.

Consent Form (Rich Text)

Provide your consent form as a block of styled text that will be displayed directly below the field selected for 'Location of consent form'.

After making the relevant selections in the menu, go to *Consent Form (Inline PDF)* and upload your first consent form, in this case the English version. Then repeat the same process to upload the Swedish version.

Both consent forms are placed under the same descriptive field. Once uploaded, all consent forms appear in your e-consent framework settings.



Test your e-consent setup

Once the e-consent framework is set up, you should test the survey.

- Go through the survey as a mock-participant; ask colleagues with different backgrounds to enter test data.
- Go through the consent form for each DAG and language setting.
- Select different answers each time to make sure that the survey behaves as expected.
- Check the PDFs in your *File Repository* and make sure they are as intended, and that all information is included.

Certification page

After completing the consent form, participants are shown a certification page where they are asked to confirm that all provided information is correct. On this page, participants can also download a PDF copy of their signed consent form.

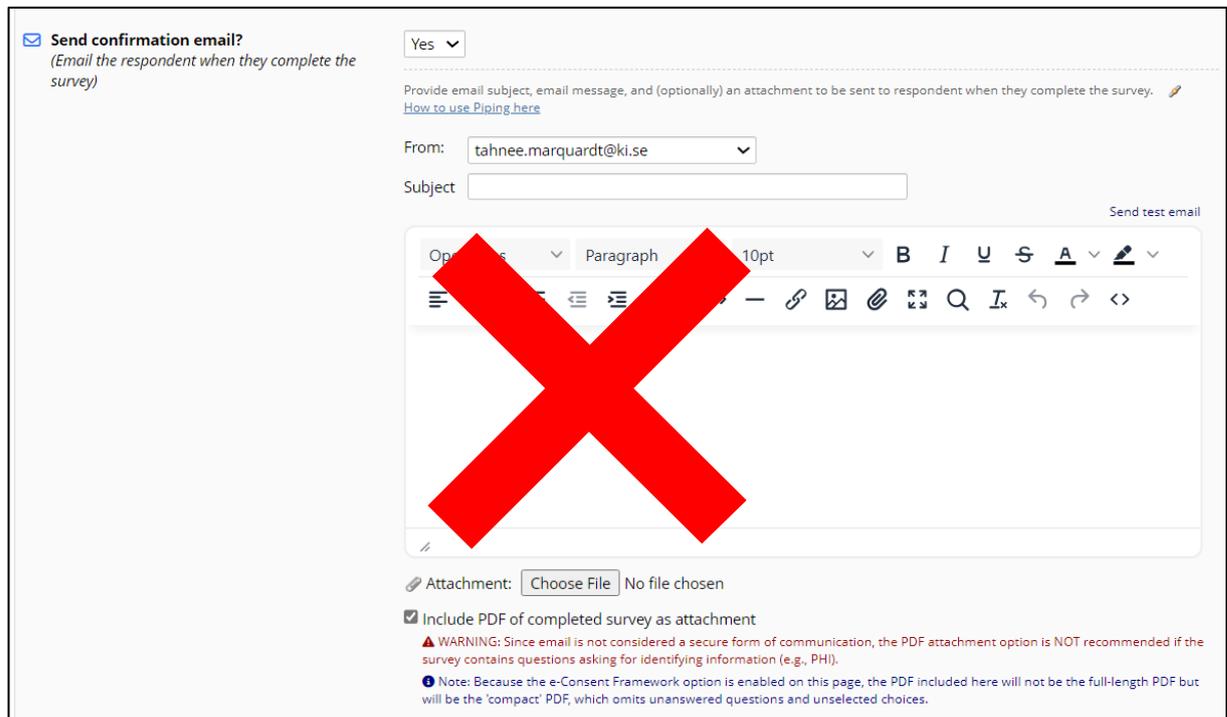
NOTE: If deleting a record or data from the e-consent survey, the PDF file in the *File Repository* will also be deleted/affected. [Make sure that only relevant REDCap users have the right to delete data or records; this is done under *User Rights* – see KI's navigation sheet on User Rights & DAGs on the [staff portal](#).

Recommended use of e-consent at KI

It is considered acceptable to collect consent electronically via REDCap. There are, however, some things to consider before doing so.

- ❖ **Since REDCap is not compatible with BankID, you would need another way to ensure that the person who is filling out the survey is actually the intended study participant.** Using the e-consent framework, according to the proposed template provided by KI, you could collect sufficient information about the participant.
- ❖ When handling sensitive personal data in REDCap it's important to **limit the access for other users in the REDCap project** so that only one, or a limited number of people, have access to this information as described in [KI's guide on REDCap User Rights & DAGs](#).
- ❖ If you choose to collect **informed consent** via REDCap, we recommend you have it **as a separate first instrument**, where you can also add a Stop function in case the participant would answer No to the consent question. The Stop function will end their participation and prevent any further surveys from being sent to them.

- ❖ There is a function in Survey Settings which allows REDCap to send a PDF copy of the completed consent form via email to the study participant. **KI does not recommend using this function** since sensitive personal data should not be sent through emails where we cannot guarantee who the recipient of the data will be.



Send confirmation email?
(Email the respondent when they complete the survey)

Yes ▾

Provide email subject, email message, and (optionally) an attachment to be sent to respondent when they complete the survey. 

[How to use Piping here](#)

From: tahnee.marquardt@ki.se ▾

Subject

Send test email

Paragraph 10pt **B** *I* U ~~S~~ **A** 

Attachment: No file chosen

Include PDF of completed survey as attachment

 **WARNING:** Since email is not considered a secure form of communication, the PDF attachment option is NOT recommended if the survey contains questions asking for identifying information (e.g., PHI).

 **Note:** Because the e-Consent Framework option is enabled on this page, the PDF included here will not be the full-length PDF but will be the 'compact' PDF, which omits unanswered questions and unselected choices.

- ❖ **Do not activate** "Allow e-Consent responses to be edited by users" in the e-consent settings.

Primary settings

Allow e-Consent responses to be edited by users?