Navigation Sheet – E-consent Framework

Compliance & Data Office

Research Support Office

Karolinska Institutet

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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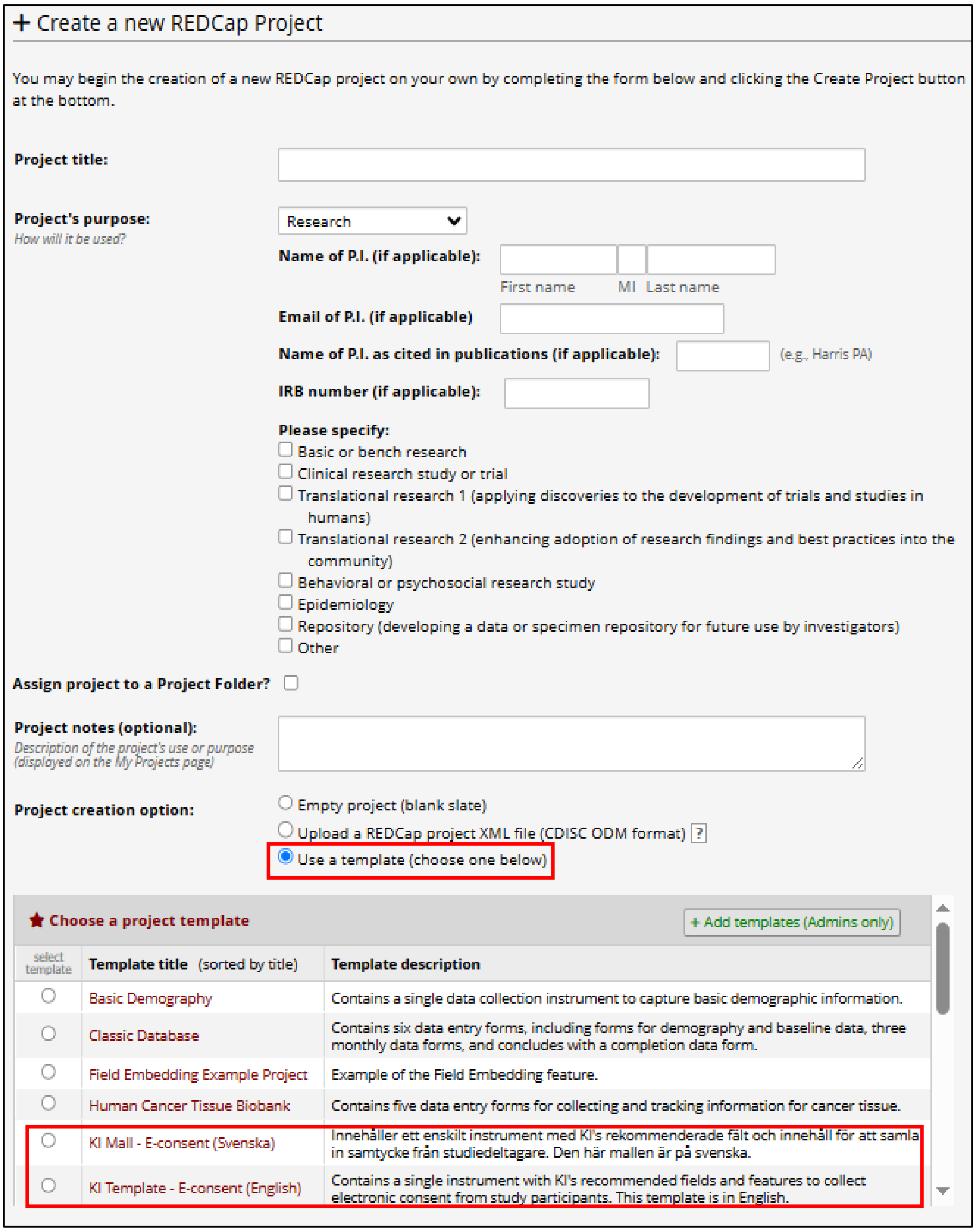
Set up your Consent Instrument

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: Research
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**
	Basic Demography	Contains a single data collection instrument to capture basic demographic information.
	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.
	Field Embedding Example Project	Example of the Field Embedding feature.
	Human Cancer Tissue Biobank	Contains five data entry forms for collecting and tracking information for cancer tissue.
	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.
	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.

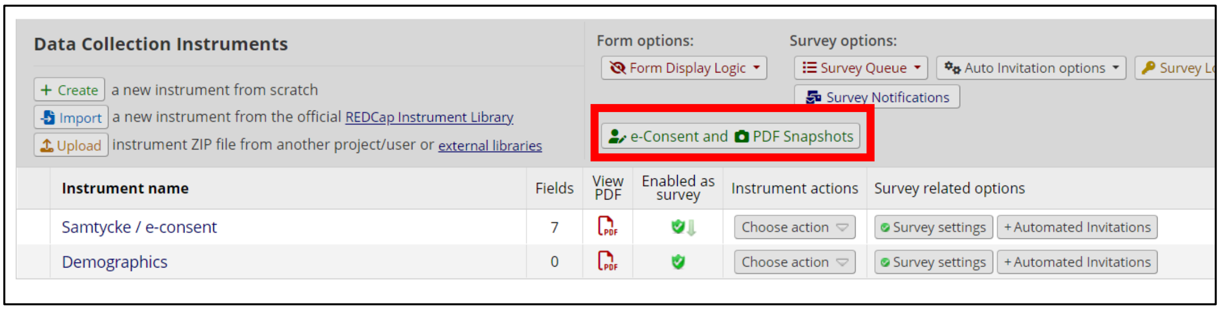
- Alternatively, you can upload the instrument as a ZIP-file to an already existing project. The ZIP-file is available to download here: E-consent template files. Choose the preferred language (English or Swedish) and download the entire folder. Next, open your REDCap project and Online Designer, click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

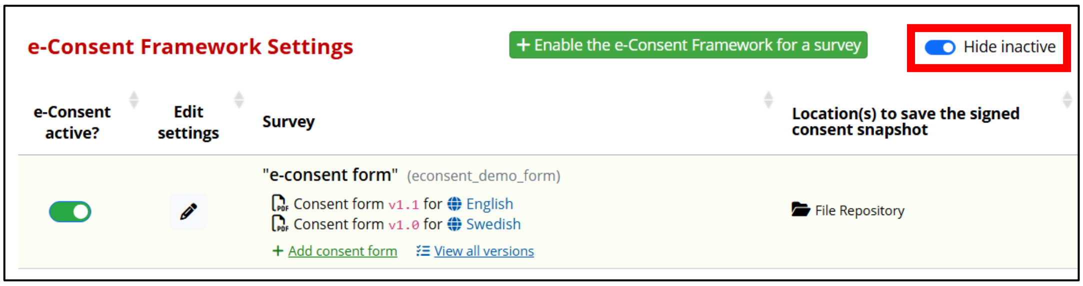


It is possible to activate more than one survey for e-consent, meaning several e-consent forms containing different fields/variables can be used within the same project. This can be useful if you have different groups of study participants e.g. age groups, needing age-specific consent forms.

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



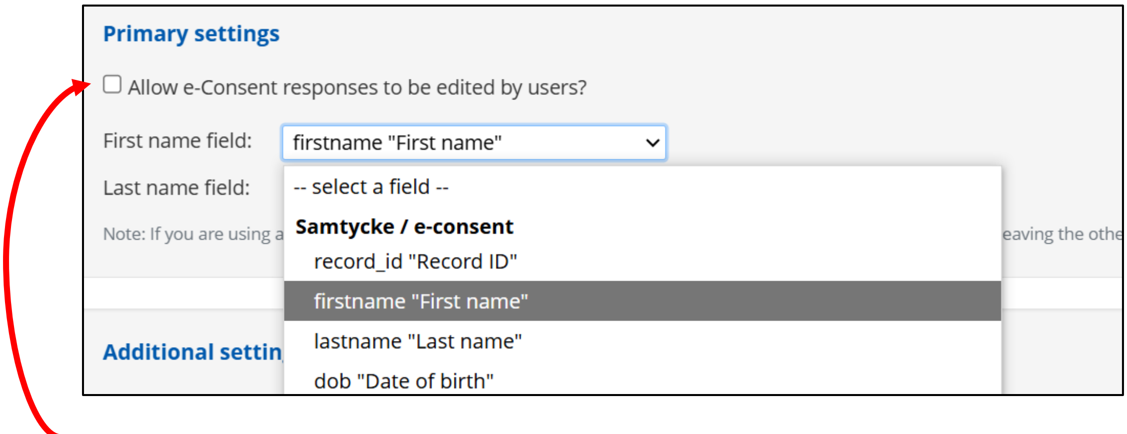
Here, you can deactivate the e-consent framework for specific surveys after which they will be hidden from this page.

Configure your e-consent settings

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

Primary settings

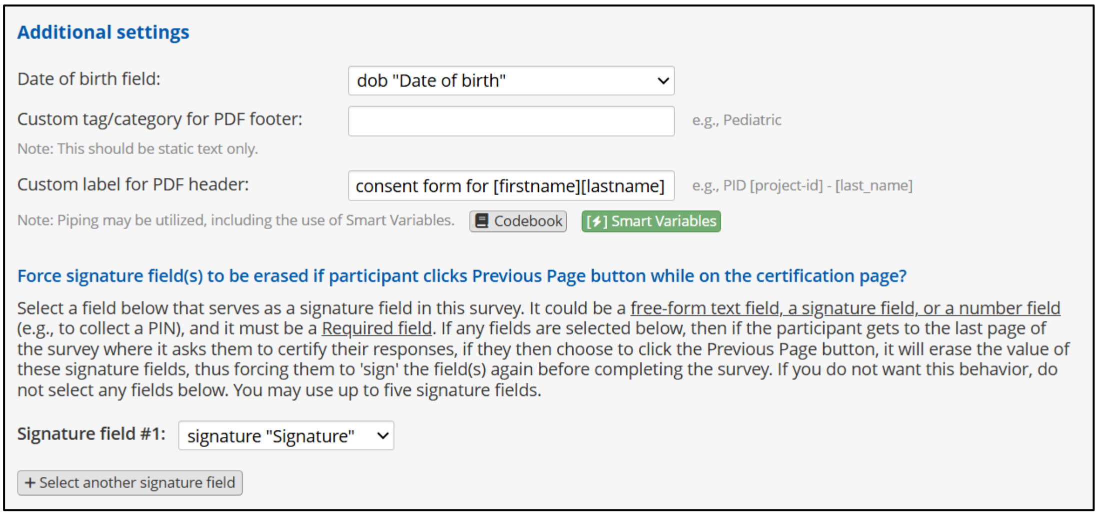
Under *Primary settings*, select the survey fields where participants write their name in your e-consent form.



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").

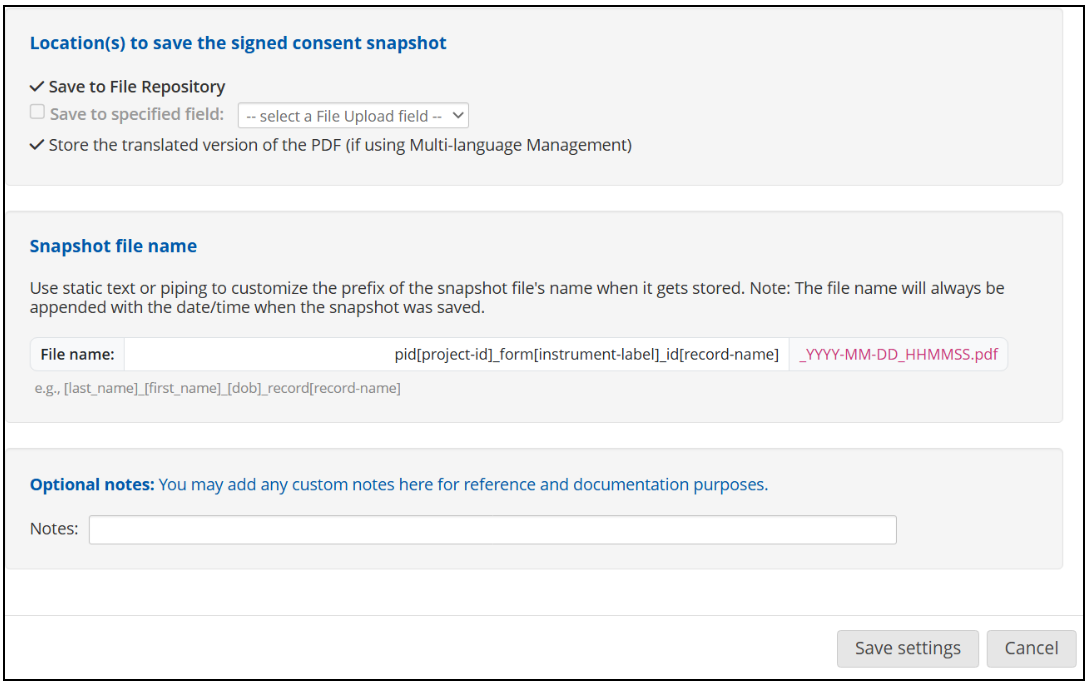


Additionally, you choose the signature field (or fields if collecting more than one signature).

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

Other settings

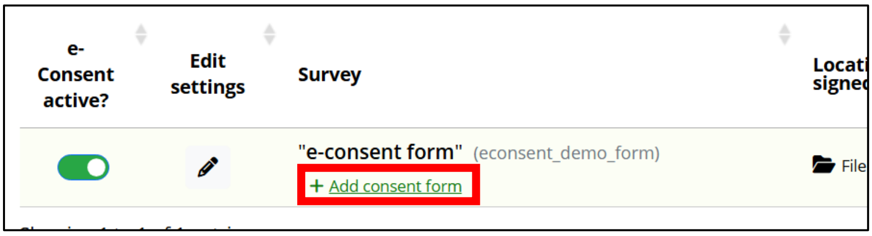
Finally, you may also establish what rules the file name of each PDF follows as well as add optional notes.



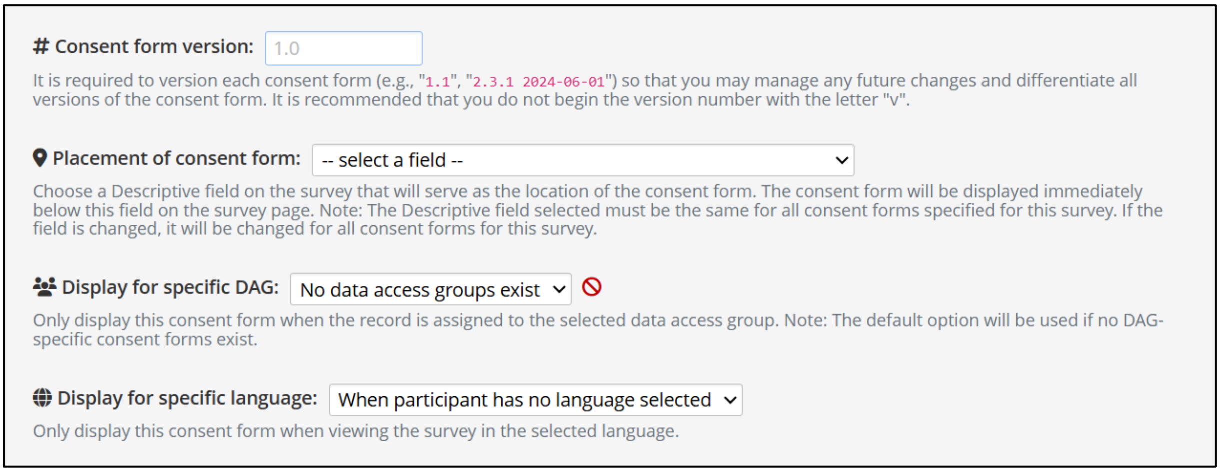
Once ready, click on "Save settings".

Upload your Participant Information Sheet

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



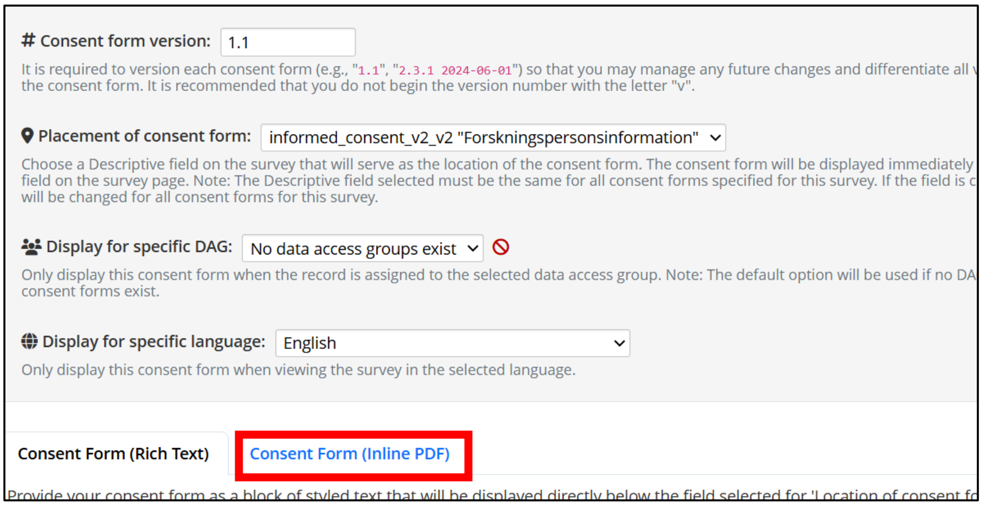
In the menu that opens up, you select the version number of your consent form, where the consent form will be displayed on the survey page (it always has to be tied to a descriptive field), and whether the consent form is for a specific Data Access Group (DAG) or language setting.



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.

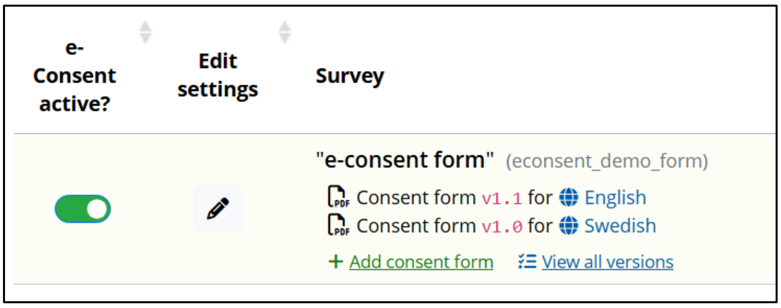
Example

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



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.



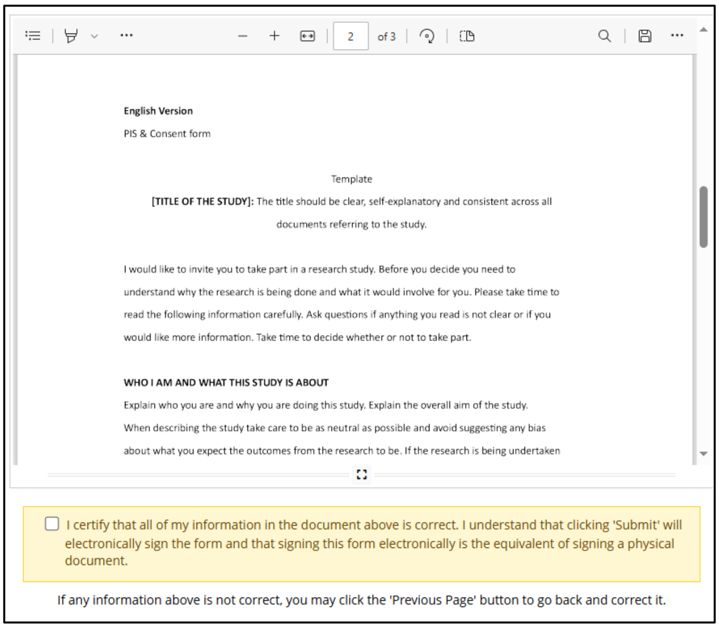
Test your e-consent setup

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.



English Version

PIS & Consent form

Template

[TITLE OF THE STUDY]: The title should be clear, self-explanatory and consistent across all documents referring to the study.

I would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Ask questions if anything you read is not clear or if you would like more information. Take time to decide whether or not to take part.

WHO I AM AND WHAT THIS STUDY IS ABOUT

Explain who you are and why you are doing this study. Explain the overall aim of the study. When describing the study take care to be as neutral as possible and avoid suggesting any bias about what you expect the outcomes from the research to be. If the research is being undertaken

I certify that all of my information in the document above is correct. I understand that clicking 'Submit' will electronically sign the form and that signing this form electronically is the equivalent of signing a physical document.

If any information above is not correct, you may click the 'Previous Page' button to go back and correct it.

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

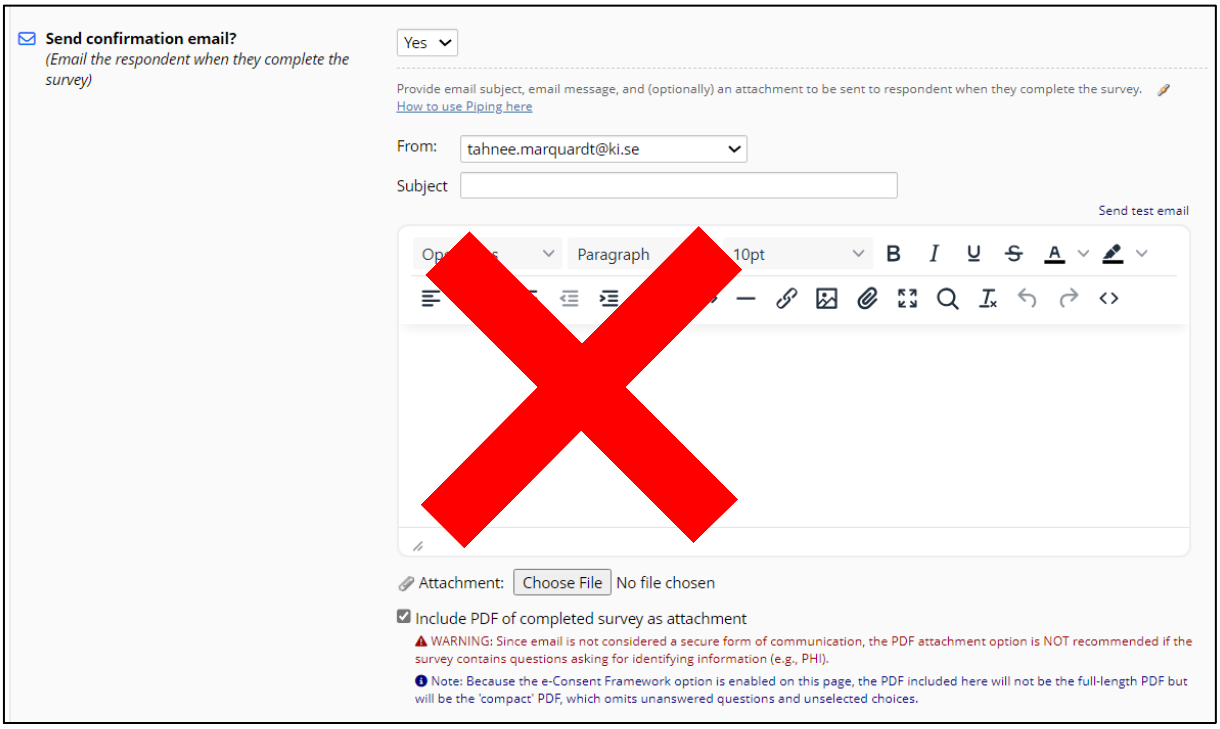
It is considered acceptable to collect consent electronically via REDCap. There are, however, some things to consider before doing so.

- **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 <u>not</u> 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.



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