

REDCap

Consentement électronique Framework



Introduction :

L'outil E-consent framework, mis à disposition dans REDCap permet la mise en place de consentement électronique signé pour les études distantes non interventionnelles.

Comment fonctionne le cadre de l'e-Consentement :

L'option d'enquête "Auto-Archiver + e-Consent Framework" ajoute deux choses au processus d'enquête habituel.

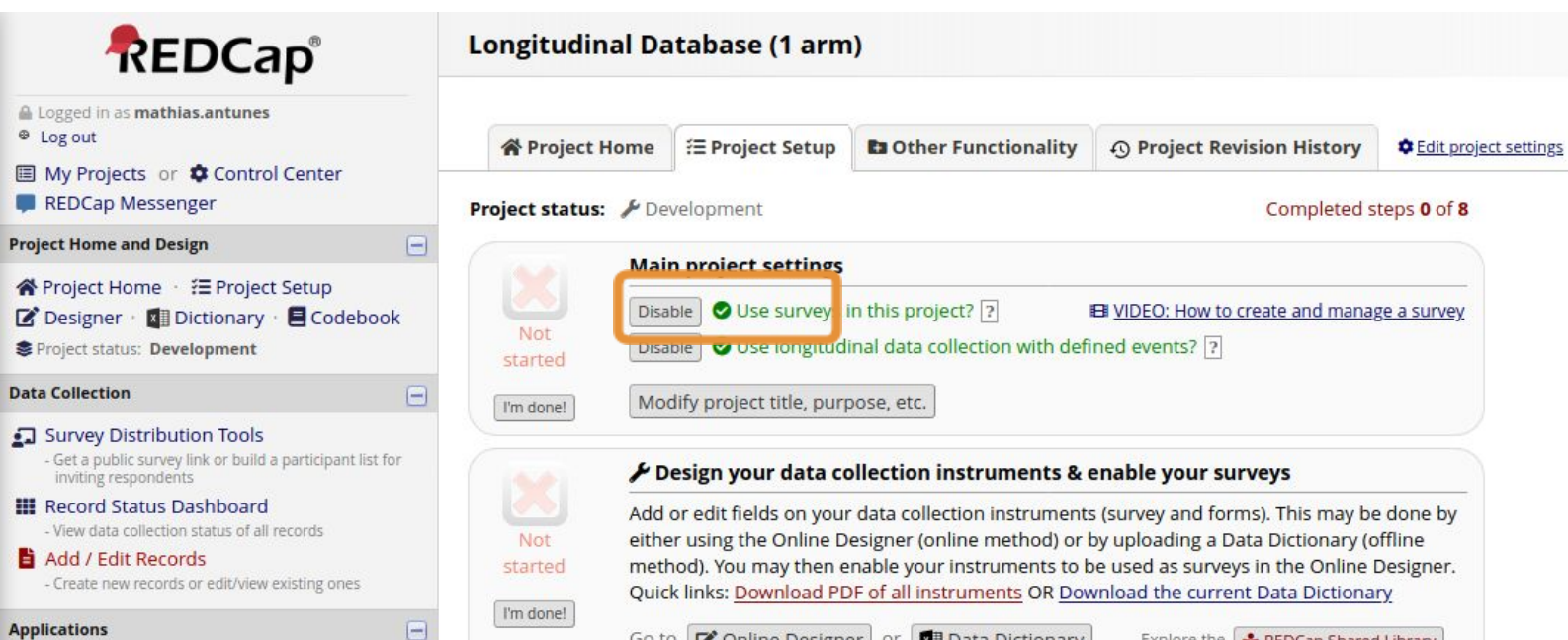
- 1) Avant qu'un participant ne remplisse l'enquête, une page de certification supplémentaire est ajoutée à la fin de l'enquête qui affiche une copie PDF de ses réponses à l'enquête dans laquelle il lui sera demandé de confirmer que toutes les informations contenues dans le document sont correctes. Une fois qu'il aura confirmé que tout est correct, l'enquête sera alors marquée comme étant terminée. L'enquête ne sera pas considérée comme terminée tant qu'ils n'auront pas franchi l'étape de certification.
- 2) Une fois l'enquête terminée, une copie statique de leurs réponses sous la forme d'un PDF spécifique au consentement sera stockée dans le dépôt de fichiers du projet. Les valeurs des options du cadre du consentement électronique seront insérées dans le PDF spécifique au consentement au bas de chaque page du PDF. Ces valeurs (c'est-à-dire le nom, la date de naissance, etc.) sont ajoutées au PDF comme documentation supplémentaire de l'identité de la personne qui donne son consentement.

Pourquoi appelle-t-on cela un "framework" ?

Le "framework du consentement électronique" est appelé "framework" parce que le fait d'activer cette option ne constitue pas à lui seul un processus de consentement électronique, mais fournit simplement le cadre ou le mécanisme général qui vous permettra de fournir un consentement électronique aux patients/sujets. En tant qu'administrateur d'enquête, vous devez toujours créer votre enquête e-Consent et toutes les questions qu'elle contient, y compris le nom, la date de naissance et la manière dont vous souhaitez saisir la signature. Ce framework vous permet de mettre en œuvre votre processus de consentement électronique en fournissant des outils standardisés (écran de certification + stockage automatique du formulaire de consentement sous forme de PDF "papier") tout en vous offrant la possibilité de personnaliser votre enquête comme vous le souhaitez.

ETAPES :

1. Activer le mode Enquête "Survey" (Résultat en image après activation)



Longitudinal Database (1 arm)

Project status: Development Completed steps 0 of 8

Main project settings

Disable ☒ Use survey in this project? [VIDEO: How to create and manage a survey](#)

Disable ☒ Use longitudinal data collection with defined events? [?](#)



Design your data collection instruments & enable your surveys

Add or edit fields on your data collection instruments (survey and forms). This may be done by either using the Online Designer (online method) or by uploading a Data Dictionary (offline method). You may then enable your instruments to be used as surveys in the Online Designer. Quick links: [Download PDF of all instruments](#) OR [Download the current Data Dictionary](#)


2. Ouvrir les paramètres de Survey du questionnaire dans lequel vous souhaitez intégrer le consentement.(un instrument dédié est conseillé !)

Data Collection Instruments		Survey options:		Add new instrument:		
		Survey Queue	Survey Login	Create	a new instrument from scratch	
		Survey Notifications		Import	a new instrument from the official REDCap Shared Library ?	
		Upload or download Auto Invitations		Upload	instrument ZIP file from another project/user or external libraries ?	
Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey-related options	
Demographics	25	PDF	Enable	Choose action v		
Baseline Data	8	PDF	Enable	Choose action v		
Visit Lab Data	5	PDF	Enable	Choose action v		
Patient Morale Questionnaire	4	PDF	Enable	Choose action v	Survey settings + Automated Invitations	
Visit Blood Workup	9	PDF	Enable	Choose action v		
Visit Observed Behavior	14	PDF	Enable	Choose action v		
Completion Data	12	PDF	Enable	Choose action v		
Completion Project Questionnaire	13	PDF	Enable	Choose action v		

3. Aller en bas de la page et activer le e-consent framework, puis paramétrer les champs pour le nom prénom et date de naissance :

 **e-Consent Framework**
 – and –
 **PDF Auto-Archiver**
Upon survey completion, a compact PDF copy of the survey response will be automatically stored in the project's File Repository, from which the archived PDFs can be downloaded at any time.

☐ Disabled
☐ Auto-Archiver enabled
☒ Auto-Archiver + e-Consent Framework [What is the e-Consent Framework?](#)
 (includes end-of-survey certification & archival of PDF consent form)

 **e-Consent Framework Options:**

For e-Consent it is sometimes required to include the consenting participant's name (and date of birth in some cases) on the final consent form as extra documentation of their identity. Below you may select fields used to capture that info. You may also enter the current e-Consent version and e-Consent type for this form. The values for the fields below will be automatically inserted into the footer of the PDF consent form that the participant will review at the end the survey, after which that PDF 'hard-copy' will be archived in the File Repository. [Read more](#)

☐ Allow e-Consent responses to be edited by users?

e-Consent version: e.g., 4

First name field: -- select a field --

Last name field: -- select a field --

Note: If you are using a single field to capture whole name, you may select it for either first/last name above while leaving the other name field unselected.

Optional fields (these are not always necessary for e-Consent):

e-Consent type: e.g., Pediatric

Date of birth field: -- select a field --

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 a field --

Signature field #2: -- select a field --

[+ Select another signature field](#)

4. Lire la documentation présente dans le bouton "What is e-consent Framework?":

What is the e-Consent Framework?
✕

What is e-Consent?

Electronic-Consent (e-Consent) is a platform for consenting patients or research subjects either on site or at home using a computer-based consent form rather than traditional paper documentation. Consent forms can be implemented in a REDCap survey via computer, mobile phone, or tablet. **Most importantly, it is highly recommended that you have a discussion with your local Institutional Review Board (IRB) if you wish to do e-Consent in REDCap.**

How the e-Consent Framework works

The 'Auto-Archiver + e-Consent Framework' survey option adds two things to the typical survey-taking process. 1) Before a participant completes the survey, an extra certification page is added to end of the survey that displays an in-line PDF copy of their survey responses in which they will be asked to confirm that all information in the document is correct. Once they confirm all is correct, the survey will then be marked as complete. The survey will not be considered complete until they fulfill the certification step. 2) Upon completion of the survey, a static copy of their responses in the form of a consent-specific PDF will be stored in the project's File Repository. The consent-specific PDF will have the values of the e-Consent Framework Options inserted at the bottom of each page in the PDF. These values (i.e., name, date of birth, etc.) are added to the PDF as extra documentation of the identity of the person who is consenting.

Why is this called a 'framework'?

The 'e-Consent Framework' is referred to as a 'framework' because enabling this option alone does not provide an e-Consent process but merely provides the general framework or mechanism to allow you to provide e-Consent to patients/subjects. As a survey administrator, you must still create your e-Consent survey and all the questions in it, including name, date of birth, and how you wish to capture the signature. This framework allows you to implement your e-Consent process by providing standardized tools (certification screen + automatic storage of consent form as a 'hard-copy' PDF) while still providing the ability to customize your survey how you wish.

How can the 'signature' process be handled for e-Consent?

Patients/subjects can 'sign' their consents by typing in their name or by utilizing REDCap's 'Signature' field type (i.e., 'wet signature') on the survey. One might also assign PIN numbers to prospective participants to aid in the signature process. Please note that the signature process will NOT be implemented by REDCap automatically, so it is your responsibility as a survey administrator to construct your survey using one of the methods above in order for the signature to get captured appropriately.



What is e-Consent version and type?

e-Consent version and type are both free-form text fields whose value will be inserted at the footer of each page in the PDF. Versioning of a form is a concept whereby you may give it a number or alpha-numeric designation to represent the current version or state of the form. So if the form is modified AFTER data collection begins, then it is recommended that a new version be applied. For example, the first version might simply be '1', and after collecting the consent of a few participants, a question is modified or added, which represents a new version of the form, so you might increment the version to '2' (and so forth). The e-Consent 'type' is optional and is another free-form text field that is just a text label that you might want to display in the PDF footer to signify the type of e-Consent that this survey represents (e.g., pediatric). The type is often used to distinguish between multiple e-Consent forms within a project.

Close

5. Le questionnaire peut ensuite être rempli avec toutes les informations de consentement :

E-Consent


Resize font:  

Please complete the survey below.

Thank you!

1) **firstname**

2) **lastname**

3) **dob**  Today D-M-Y

Nihil est enim virtute amabilius, nihil quod magis adliciat ad diligendum, quippe cum propter virtutem et probitatem etiam eos, quos numquam vidimus, quodam modo diligamus. Quis est qui C. Fabrici, M'. Curi non cum caritate aliqua benevola memoriam usurpet, quos numquam viderit? quis autem est, qui Tarquinius Superbum, qui Sp. Cassium, Sp. Maelium non oderit? Cum duobus ducibus de imperio in Italia est decertatum, Pyrrho et Hannibale; ab altero propter probitatem eius non nimis alienos animos habemus, alterum propter crudelitatem semper haec civitas oderit.

Nam sole orto magnitudine angusti gurgitis sed profundi a transitu arcebantur et dum piscatorios quaerunt lenunculos vel innare temere contextis cratibus parant, effusae legiones, quae hiemabant tunc apud Siden, isdem impetu occurrere veloci. et signis prope ripam locatis ad manus comminus conserendas denseta scutorum conpage semet scientissime praestuebant, ausos quoque aliquos fiducia nandi vel cavatis arborum truncis amnem permeare latenter facillime trucidarunt.

Cumque pertinacius ut legum gnarus accusatorem flagitaret atque sollemnia, doctus id Caesar libertatemque superbiam ratus tamquam obrectatorem audacem excarnificari praecepit, qui ita evisceratus ut cruciatibus membra deessent, inplorans caelo iustitiam, torvum renidens fundato pectore mansit immobilis nec se incusare nec quemquam alium passus et tandem nec confessus nec confutatus cum abiecto consorte poenali est morte multatus. et ducebatur intrepidus temporum iniquitati insultans, imitatus Zenonem illum veterem Stoicum qui ut mentiretur quaedam laceratus diutius, avulsam sedibus linguam suam cum cruento sputamine in oculos interrogantis Cyprii regis inpegit.

4) **signature** [Add signature](#)

* must provide value

Next Page >>

6. A la fin du Survey une page affichant le PDF du consentement précédemment lu et signé, avec une case à cocher notifiant qu'il s'agit d'un consentement, s'affichera :

E-Consent

Displayed below is a read-only copy of your survey responses. Please review it and the options at the bottom.

1 sur 1

Zoom automatique

E-Consent

Page 1

Please complete the survey below.

Thank you!

1) firstname	Mathias
2) lastname	Antunes
3) dob	01-01-1996

Nihil est enim virtute amabilius, nihil quod magis adliciat ad diligendum, quippe cum propter virtutem et probitatem etiam eos, quos numquam vidimus, quodam modo diligamus. Quis est qui C. Fabrici, M'. Curi non cum caritate aliqua benevola memoriam usurpet, quos numquam viderit? quis autem est, qui Tarquinius Superbum, qui Sp. Cassium,

☐ I certify that all the 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.

<< Previous Page

Submit

Powered by REDCap