How to setup eConsent Study Tracker Push/Pull from REDCap Feature

Benefit from the convenience of pulling your fully signed eConsent pdf directly from REDCap into Study Tracker. This feature offers the assurance that the correct pdf is uploaded into Study Tracker for FSM Policy Compliance while reducing the steps involved in completing this task. This handout is designed to provide the setup requirements in both REDCap and Study Tracker. All setup requirements must be completed in order for this feature to activate. **Please note:** Only one REDCap project can be set up per NU IRB study in Study Tracker.

Study Tracker Setup Requirements

Study Tracker will automatically import any study from the IRB that receives an "Approved" or "External IRB" study status. Any study with an active IRB status in Study Tracker is eligible for setup of this feature.

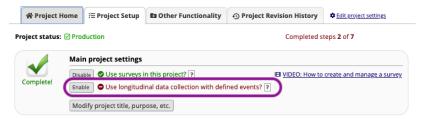| Compliance	IRB Number	Name	Status	Accrual	Favorite
			Show all		Show all
✓	STUXXXXXXXX	Demo/Test Study	Approved	47	★

REDCap Setup Requirements

The IRB must approve your usage of eCosent in REDCap for every study that will be utilizing eConsent. Approval of specific usage of the Study Tracker Push/Pull feature is not needed in order to use this feature. Once the eConsent instrument is setup in REDCap, ensure the following setup requirements are met for your REDCap project:

1. The eConsent project exists on Northwestern's instance of REDCap. eConsent instruments housed on affiliate instances of REDCap will not work.
2. Only one REDCap project at a time can be linked to an STU in Study Tracker (one REDCap API per study).

3. The project does <u>not</u> have longitudinal feature enabled.

4. "Record_id" is the first field on the <u>first</u> instrument.

5. An instrument named "econsent" exists in the project.*

If you are renaming an instrument that previously existed ensure that the new name of "econsent" replaced the existing name by checking the Codebook.
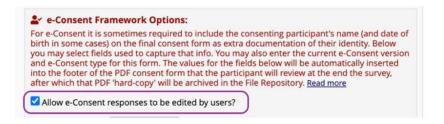
6. The field"consent_date" exists in the project and "consent_date" has field validation in the format yyyy-mm-dd.

7. The field "case_number" exists in the project; and must be unique for each record.

8. The eConsent Framework feature, under Survey Settings, is only a requirement of utilizing eConsent for FDA studies. However, it is HIGHLY recommended that all studies enable this feature for the signature validation and file repository benefits. When the eConsent Framework feature is enabled in REDCap, you must also enable the option "Allow e-Consent responses to be edited by users?". This will allow a study team member to go back in and append the required case number to the completed eConsent form which allows the participant matching in Study Tracker to take place.

9. Add the user "study_tracker_webservice" to your project with API import/export rights and "Full Data Set" privileges under "Data Export" rights.

10. Send an email request to studytracker@northwestern.edu to link your study in Study Tracker to your REDCap project. Please include REDCap project name, PID (project identifier number) AND study NU IRB number. Once Study Tracker Support can confirm that the requirements have been met correctly, they will set up the API token for this study/project and send a confirmation email to the requestor.

How to use the eConsent push/pull feature in REDCap & Study Tracker

After setup is completed, the feature may be used. This feature only works when the key fields that complete the communication between systems are recorded correctly.
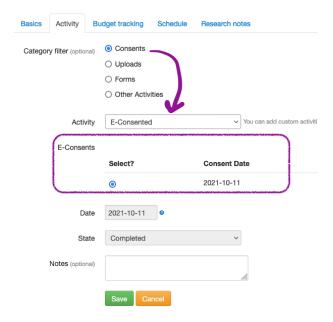
In REDCap:

After a participant completes the eConsent form, a study team member must edit the form to append a case number to the participant completed consent form and save the form with case number.
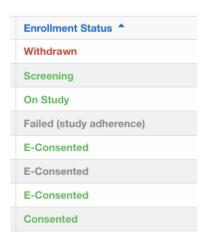
In Study Tracker:

Create a participant profile for the newly consented participant and be sure to add the **same case number** for the participant as entered into the eConsent in REDCap and save the profile.

After the participant's profile has been created you will then log the Consented activity by selecting the "Consents" option under the participant's Activity tab. From the drop down option select "E-Consented" and the consented date as recorded it REDCap will populate along with the pdf form that matches and click "SAVE".

Participants who have signed an eConsent form that has pulled form REDCap into Study Tracker will show as "E-Consented" in Study Tracker.

For further questions on this feature please contact the Study Tracker Support Team at studytracker@northwestern.edu. For information on how to get started with REDCap, consult the REDCap NUCATS page or email the REDCap Support Team at redcap@northwestern.edu.