

eConsent: 21 CFR Part 11 Compliance Framework for FDA Studies

Now that your new eConsent project has been created with the 21 CFR Part 11 Compliant workflow template, you can begin customizing the project to reflect your IRB approved consent form and apply the roles and instruments applicable to your study using this template. Please note that the instruments labeled “Consent Routing” and “Consent Verification” should not be removed from your project as they are critical to the key requirements of Validation and Audit Trail for compliance. The following modules are not automatically transferred as part of project creation. Your project setup design must include the following in order to finalize the 21 CFR Part 11 Compliance workflow.

Survey Login (under Online Designer)

The Survey Login feature ensures the criteria of **validation** is met for compliance. Be sure to change the “Disabled” setting to “Enabled.” Map the Login field #1 with the “Shared Secret for e-signature surveys” field (from Consent Routing) so that the same prompted login question/shared secret appears to emailed recipients for survey access. Since the secret phrase was issued outside of the eConsent project, this validation will confirm the emailed recipient is the individual listed in the Consent Routing instrument for the specific role.

The screenshot shows the configuration interface for Survey Login. On the left, under 'Survey options', the 'Survey Login' button is circled in purple. A purple arrow points from this circle to the 'Enable Survey Login?' dropdown menu in the main configuration panel, which is currently set to 'Disabled'. The main configuration panel includes sections for 'Fields to display on the survey login form', 'Customizations for survey login', and a 'Custom error message' field.

Ensure all of the following requirements are set

up:

- 1.) Enable Survey Login is changed to **“Enabled”**
- 2.) Map the Login field #1 to the **route_secret “Shared secret for e-signature surveys”** field
- 3.) Apply the survey login feature to **“All surveys”**
- 4.) Enter a **“Custom Error Message”** so that the recipient knows what to do in the event they enter the incorrect shared secret. For example, this can include a message with an email or telephone number of a study contact.

STEP 2: Conditions

Specify conditions for sending invitations:

When the following survey is completed:
 "Study Invitation" (indicated by a blue arrow)

When the following logic becomes true:
 (e.g., [age] > 30 and [sex] = "1")

Ensure logic is still true before sending invitation?

STEP 3: When to send invitations AFTER conditions are met

Send immediately

Automated Invitations (under Online Designer)

The current emailed invitation automation set in the template begins when the “Study Invitation” instrument has a completed status recorded. The “Study Consent”* instrument is sent automatically once the “Study Invitation” is completed. All other surveys, to the LAR(s), Translator(s), Witness(es), will automatically be sent once the “Study

Consent” is completed. These settings should be changed to reflect your study’s needs. For example, if you are not going to utilize the “Study Invitation” instrument, you should change the automation to begin once the “Study Consent” instrument is completed.

**If using the Study Tracker Push/Pull feature, you will need to rename the instrument “Study Consent” to “eConsent” for the feature to work.*

Survey Settings (under Online Designer)

A critical component of 21 CFR Part 11 Compliance is **record retention**. You must enable “Auto-Archiver + e-Consent Framework” for each survey (self-reporting instrument). Mapping the field names to the instrument will assist with quickly identifying the instrument in the File Repository. Remember, if this is not enabled, then the files are not being archived and the workflow is not compliant.

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 of the survey, after which that PDF 'hard-copy' will be archived in the File Repository. [Read more](#)

While under Survey Settings, you should consider updating the sections that include messaging to the recipient, “Survey Instructions” and

“Survey Completion Text”. This can include details as to how to correctly complete the instrument and what to expect after completion. Optional features like sending a confirmation email with a copy of the completed pdf or the ability to download a copy of the completed pdf are found in this section. Please refer to your IRB approval to ensure these features are being used appropriately.

For further questions on REDCap, please contact the REDCap Support Team at redcap@northwestern.edu. Additional resources and information regarding the [NUCATS REDCap page](#).