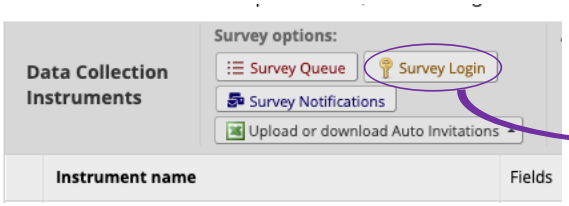
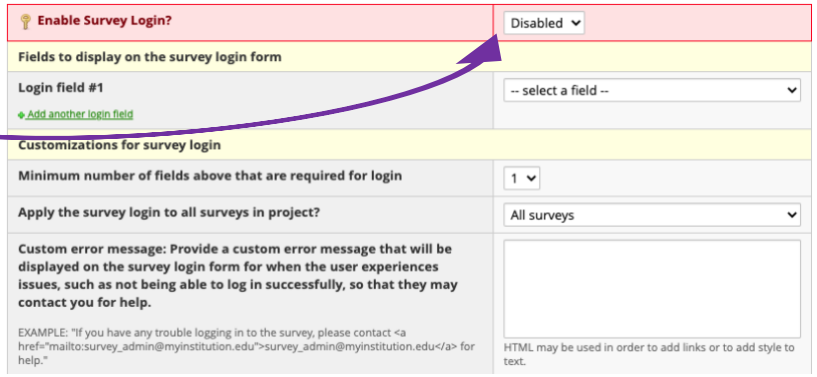
eConsent: 21 CFR Part 11 Compliance Framework for FDA Studies

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)

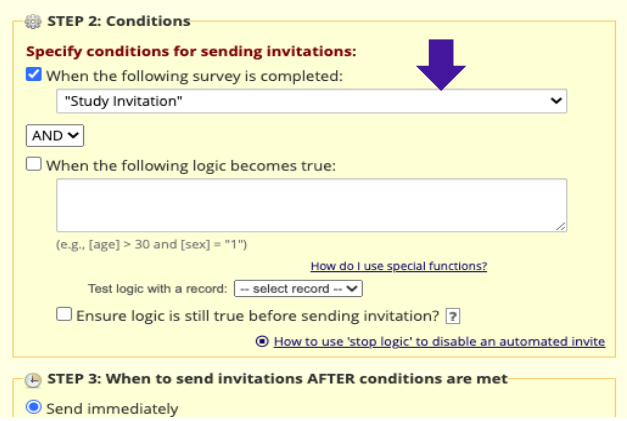
The Survey Login feature ensures the criteria of **validation** is met for compliance. Be sure to change the "Disabled" setting to "Enabled." Map the Login field #1 with the "Shared Secret for e-signature surveys" field (from Consent Routing) so that the same prompted login question/shared secret appears 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.





Ensure <u>all</u> 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.



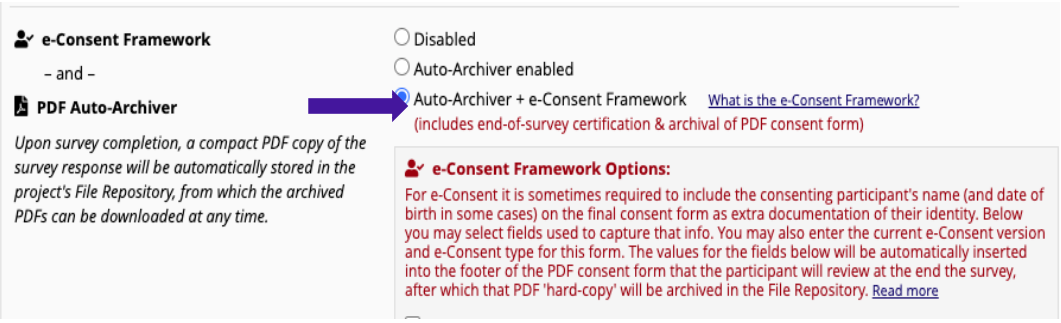
Automated Invitations (under Online Designer)

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.



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.