

In order to utilize REDCap for eConsent for FDA studies, you must adhere to the following 21 CFR Part 11 compliance requirements:

1. The Project Owner (requestor of the project) must have completed the [required training specific to 21 CFR Part 11 Compliance](#) in addition to the REDCap New Project Owner Training (if they are new to REDCap).
2. The Project Owner must have signed the attestation form. This form is part of the training and is required in order to be able to request projects for this purpose.
3. You must follow the workflow described in the training and incorporate the requirements into the approved compliant workflow template found in this [eConsent: 21 CFR Part 11 Compliance Framework for FDA Studies document](#).

Once Steps 1 & 2 are completed, the Project Owner will be able to request a new project with the approved template. REDCap Support will create the project for you with the template already uploaded for you to begin updating to reflect your study's NU IRB approved language.