

## Using REDCap for Participant eConsent – Instructional Use Brief – Ver 3.0

A new template has been created for REDCap users to leverage eConsent functionality for their REDCap project. eConsent use and operation is strictly standardized and controlled in both how it is implemented in REDCap and how it should be conducted by researchers when using the REDCap eConsent template. A majority of the functionality that is universal for eConsenting participants in a study is already built into the REDCap eConsent template. However, a portion of any eConsent setup is unique to each study and therefore all users who want to eConsent participants in REDCap need to follow the below guidelines in order to properly setup their project and prepare it for compliant eConsenting of study participants. This instructional use brief (along with a paired instructional setup brief) provides you with a checklist for assuring your project will be compliant.

Note: as properly configured, your REDCap project will be *designed* in an FDA Part11-compliant manner. However, how you use the project determines if the project remains compliant throughout your study. Understanding the steps below will help to ensure you proceed within compliance.

### Steps for Users to use an eConsent Compliant Project

- **Before moving to Production mode, familiarize yourself with the eConsent process for your project by entering at least 3 fake records to test the process start to finish. The steps below apply when a project is setup correctly.**
- The eConsent portion of your project (first 3 instruments) will operate accordingly. Please familiarize yourself with each step in this process before enrolling participants:
  1. For all new participants, complete the first instrument, **Pre-Consent Information**.
  2. Once Step 1 is completed and the instrument is saved, a unique link to the **eConsent** instrument will be mailed immediately to the participant's email address (which you entered on the **Pre-Consent Information** instrument) in the form of a REDCap survey.
  3. Once the participant completes the **eConsent** form, you will receive an email notification from REDCap that the form was completed and needs your signature. Follow the link in the email to bring up the **Consent Confirmation** form as a survey. Review the fields piped from the consent form, sign it, and Submit.
  4. The participant will then receive an email notification with the completed consent form and your consent confirmation attached as PDFs, for their records. The PDF documents are linked by the participant's Record ID (marked in the document).
  5. Now that the participant has eConsented to participating in your study, you may continue with the rest of your data collection instruments and study procedures.