REDCap e-Consent Setup Guide

Step 0: Before You Build an e-Consent Survey

- Confirm with the IRB that e-Consent is acceptable for the study.
- Use the IRB-approved consent language and stamped consent form, if applicable.
- Determine who needs to sign: participant, parent/guardian, legally authorized representative, study staff, investigator, or others.
- Decide whether the consent will be completed remotely, in person, or both.
- Plan how the completed consent PDF will be reviewed, accessed, and retained.

Once you have conduct and met the requirements of the pre-build descried above, proceed to buildl your e-Consent by following the steps below.

Step 1: Enable Surveys in the Project

The e-Consent Framework can only be used with REDCap survey instruments.

1. Navigate to **Project Setup**.
2. Under **Main Project Settings**, enable:
    - **Use surveys in this project?**

Tip: If the project was originally built only for data entry, enabling surveys converts instruments into participant-facing forms.

Step 2: Build the Consent Instrument

1. Go to the **Online Designer**.
2. Create a new instrument or modify an existing one.
3. Add all required consent content and fields.

Recommended Fields

- Participant first name
- Participant last name
- Date of birth (optional, depending on workflow)
- Signature field
- Date signed
- Required acknowledgements/check boxes

Important: Signature fields used for e-Consent should be marked as **Required Fields**.
REDCap supports two primary approaches to presenting the e-Consent:

- **Inline PDF Consent (Recommended):**
  Upload the IRB-approved consent PDF so participants view the exact approved document.
- **Rich Text Consent:**
  Build the consent language directly inside REDCap using descriptive text fields and formatting.

Best Practice: Use the Inline PDF option whenever possible for regulated or formally approved research studies.

Step 3: Enable the Instrument as a Survey

1. Return to the **Online Designer**.
2. Locate the consent instrument.
3. Select **Enable** under the survey column.
4. Configure any desired survey settings.

Common Survey Settings

- Survey title
- Instructions
- Save & Return Later
- Survey Queue
- Automated Survey Invitations (ASIs)
- Survey Notifications

Step 4: Open the e-Consent Framework

1. From the **Online Designer**, select: **e-Consent and PDF Snapshots**
2. Select: **Enable the e-Consent Framework for a survey**
3. Choose the survey instrument you want to use for consent.

Step 5: Configure e-Consent Settings

REDCap will prompt you to configure the e-Consent settings. Required configuration elements icnlude:

- First Name field
- Last Name field
- Signature field
- Date

Optional elements include:

- Date of birth field
- Custom PDF header
- Custom PDF footer
- File naming format
- Additional PDF storage location

Note: REDCap automatically saves completed e-Consent PDFs to the File Repository. This automatic archive cannot be disabled.

Step 6: Add the Consent Form Version

1. Select **Add consent form**.
2. Enter the consent version number.
3. Select the descriptive field where the consent should display.
4. Upload the approved consent PDF or add consent text.
5. Save the consent version.

Versioning Considerations:

- Each REDCap consent version must be unique.
- Version numbers cannot be reused once activated.
- Maintain consistency between IRB approval versions and REDCap versions.

Important: Once saved, the new consent version becomes active immediately.

Step 7: Configure PDF Snapshot Settings (Optional Advanced Setup)
Additional PDF Snapshot triggers can be configured to generate custom PDFs or combine multiple forms into a single document.

1. Navigate to:
   - **e-Consent and PDF Snapshots**
   - **PDF Snapshots of Records**
2. Select **Add new trigger**.

Example Trigger Logic: [consent_complete] = “2”

Additional Options:

- Select which instruments to include
- Save a single survey or combine multiple surveys
- Store translated versions (MLM)
- Save to File Repository or File Upload fields
- Customize PDF file names using piping

Step 8: Multi-Signature or Multi-Form Workflows

Some studies require multiple signatures, such as:

- Participant + research staff
- Parent/guardian + child assent
- Legally authorized representative workflows

In these situations:

- Create separate instruments for each signing role when appropriate.
- Enable e-Consent independently for each survey.
- Use PDF Snapshot triggers to combine completed forms into a single PDF if desired.

Example Multi-Signature Logic: [participant_sign_complete]=”2” AND [staff_sign_complete]=”2”

Step 9: Multi-Language Management (MLM)

REDCap’s Multi-Language Management module can be used with e-Consent workflows.
Recommended MLM Workflow

- Enable MLM in Project Setup
- Create translated consent content
- Add separate consent versions for each language
- Test all translated PDFs carefully

Step 10: Data Access Groups (DAGs)

DAGs can be used to support site-specific or role-specific consent workflows.

- Create DAGs on the User Rights page
- Assign users appropriately
- Configure DAG-specific consent versions if needed
- Verify that access restrictions work correctly

Step 11: Test the Entire Workflow
Thorough testing is critical before moving an e-Consent project to Production.

Recommended Testing Checklist:

- Test on desktop and mobile devices
- Verify required fields and signatures
- Confirm survey certification works correctly
- Verify PDF generation and storage
- Review the generated PDF carefully
- Test Survey Queue and ASI behavior
- Test MLM and DAG workflows if used

- Verify all branching logic and calculations