New e-Consent Framework Guide

Introduction

Purpose

The purpose of this document is to empower you, as Principal Investigators, project managers, data managers, regulatory compliance officers, researchers, and study coordinators, with comprehensive guidance and detailed instructions for effectively using the new e-Consent Framework and PDF Snapshot features in REDCap . By understanding and utilizing these functionalities, you can enhance your research projects and feel confident in your abilities to manage and utilize these features.

By offering a thorough understanding of the features, best practices, and regulatory compliance information, this document ensures that users can streamline the consent process, improve participant engagement, ensure data integrity and security, achieve regulatory compliance, and enhance project management.

Audience

This document is intended for all REDCap users who are involved in setting up and managing consent forms and data collection in REDCap projects.

Overview of e-Consent and PDF Snapshot Features

The e-Consent Framework and PDF Snapshot features in REDCap offer robust tools for obtaining, managing, and storing electronic consent forms. These features are designed to enhance capabilities for creating, customizing, and archiving consent forms, ensuring compliance with regulatory requirements, and improving data integrity.

e-Consent Framework

The e-Consent Framework in REDCap enables researchers to create electronic consent forms that participants can complete and sign online. Key features of the e-Consent Framework include:

- **Customizable Consent Forms:** Users can design consent forms with various field types, including text, dropdowns, and signature fields, to meet specific study and regulatory requirements.
- **Version Control:** The system supports version control, allowing users to manage and present new versions of consent forms as needed while maintaining historical versions for audit purposes. This is crucial for ensuring compliance with requirements for document control.
- **Certification Page:** A certification page at the end of the survey displays an in-line PDF copy of the completed consent form for participant review and certification. The certification language is customizable to meet specific regulatory requirements.
- **Support for Multi-Form Signing:** The e-Consent Framework supports capturing signatures across multiple forms, enabling the collection of signatures from different

stakeholders. Each form independently uses the e-Consent Framework and generates its own PDF snapshot for the e-Consent portion.

- **Read-Only PDF Snapshot Trigger:** When the e-Consent Framework is enabled, it automatically produces a read-only PDF snapshot trigger that saves a PDF copy of the survey response into the project's file repository. This ensures that all e-Consent documents are archived securely and consistently.
- **Repeatable Instruments and Events:** The framework supports repeatable instruments and events, facilitating the management of longitudinal studies. This functionality is critical for maintaining consistency in multi-visit studies as per ICH E6 guidelines.
- **Multi-Language Module (MLM) Support:** The framework works seamlessly with the Multi-Language Module, allowing consent forms to be presented and completed in multiple languages, supporting regulatory requirements for non-English speaking participants.
- **Data Access Groups (DAG) Support:** The e-Consent Framework supports the use of Data Access Groups, ensuring that data access and permissions are appropriately managed, in line with regulatory requirements for data security and confidentiality.

PDF Snapshot Feature

The PDF Snapshot feature in REDCap allows for the automatic generation and storage of PDF copies of completed consent forms and other survey responses. Key features of the PDF Snapshot include:

- **Automatic Saving:** PDF copies of survey responses can be automatically saved to the project's file repository or specified fields, ensuring secure and organized storage. This aligns with FDA requirements for data integrity and traceability.
- **Custom Triggers:** Users can create custom triggers for generating PDF snapshots based on specific events or conditions, ensuring that snapshots are created at appropriate times during the study.
- **Support for Multi-Form Consents:** The PDF Snapshot feature can combine multiple forms into a single PDF snapshot, facilitating the organization and storage of multi-form consents. This supports the FDA requirement for maintaining complete and accurate records.
- **Custom Headers and Footers:** The system supports adding custom headers and footers to PDF snapshots, including text fields, smart variables, and piping. This allows for the inclusion of essential metadata, such as participant IDs and timestamps.
- **File Naming Customization:** Users can customize the file names of PDF snapshots using static text or piping, appended with the date-time of the snapshot generation. This feature supports regulatory requirements for document identification and retrieval.
- **Audit Trails:** The system maintains detailed audit trails for consent form completions and PDF snapshot generations, ensuring compliance with regulatory standards. This includes logging actions and maintaining records of who accessed or modified data and when.

- **Vault Storage Integration:** If the vault (external file storage) is enabled and e-Consent was used in any of the forms, the system can store PDF snapshots in the vault. This functionality is controlled by admin settings at both the system and project levels, ensuring that critical consent documents are securely stored and easily retrievable.

By leveraging these features, researchers can streamline the consent process, enhance data quality, and ensure that their research practices comply with legal and ethical standards, including federal and instutitional regulations.

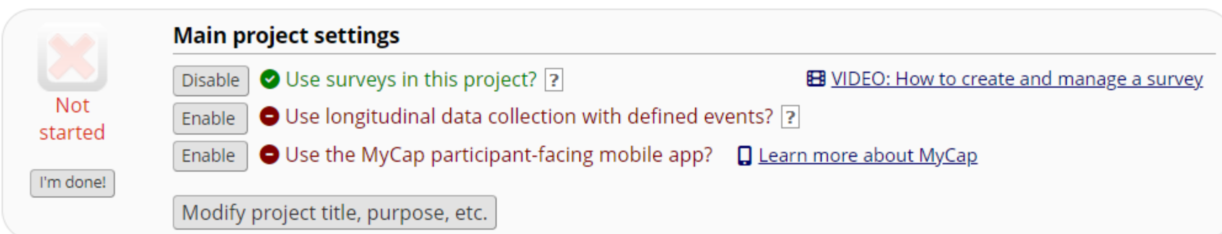
Setting Up e-Consent and PDF Snapshots

This section will guide you through the steps necessary to set up and configure the e-Consent Framework and PDF Snapshots in your REDCap project. Proper setup ensures that your electronic consent process is compliant, secure, and efficient.

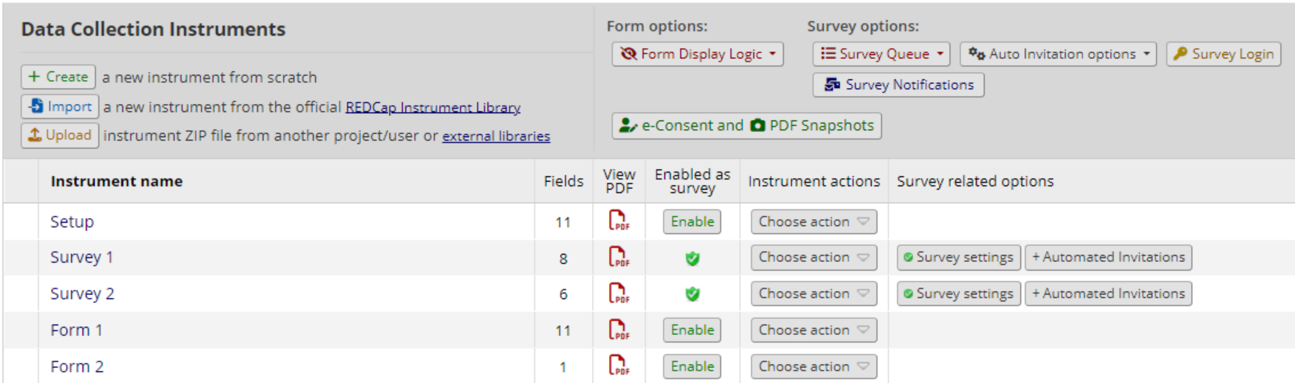
Enabling e-Consent Framework

Step-by-Step Instructions:

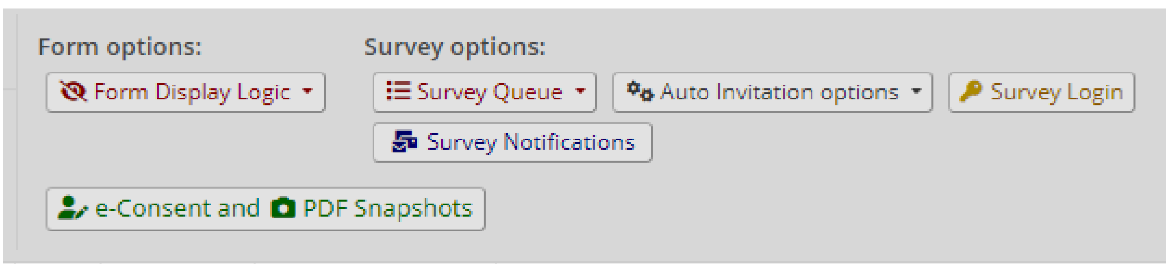
1. **Enable Survey Mode for the Instrument:**
    - Navigate to the Project Setup page in your REDCap project.
    - In the Main project settings section, enable survey functionality by checking the Enable checkbox next to Use surveys in this project.



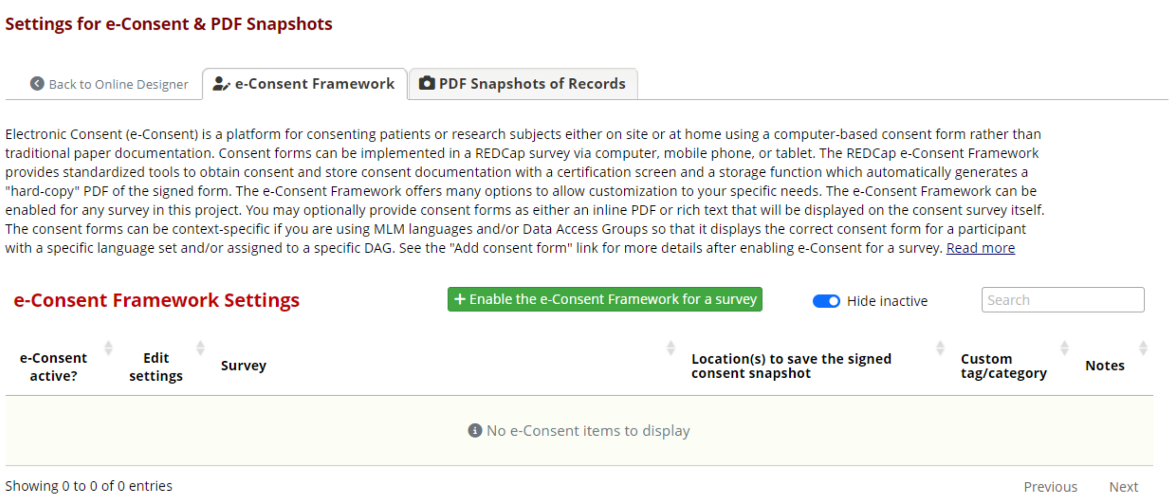
2. **Develop the e-Consent Instrument:**
    - Go to the Online Designer.
    - Select the instrument you want to use for e-Consent.
    - Design your consent form, ensuring it includes all necessary fields such as participant name, date of birth, and signature fields.
    - Consider adding a descriptive field as a placeholder for the PDF version of the consent form or for a rich text editor version of the consent. This setup helps manage version control.
3. **Enable Survey for the Instrument:**
    - Still within the Online Designer, enable survey functionality for the instrument by clicking the “Enable” button next to the instrument name.
    - Configure survey settings as needed.



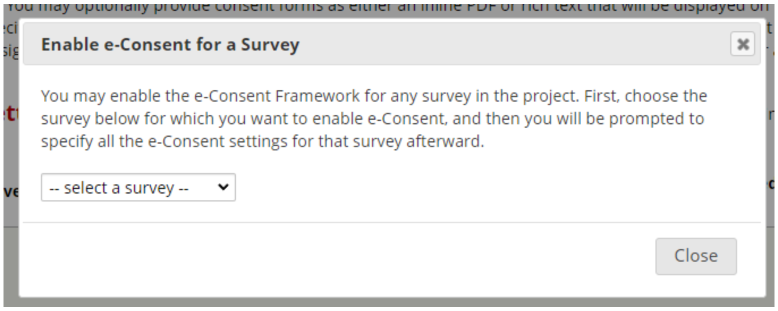
4. **Enable the e-Consent Framework:**
    - In the Online Designer, click on the “e-Consent and PDF Snapshots” button.



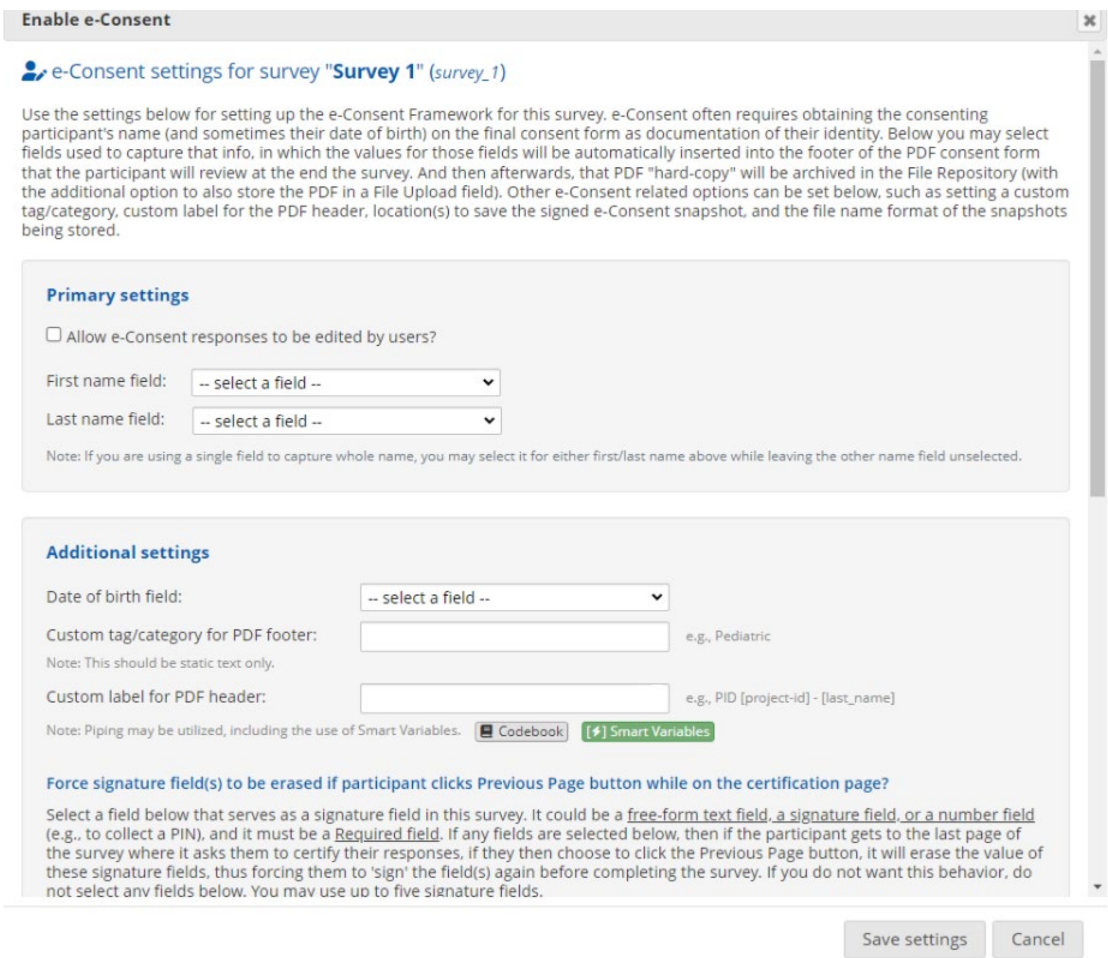
    - Click on the “Enable the e-Consent Framework for a survey” button.



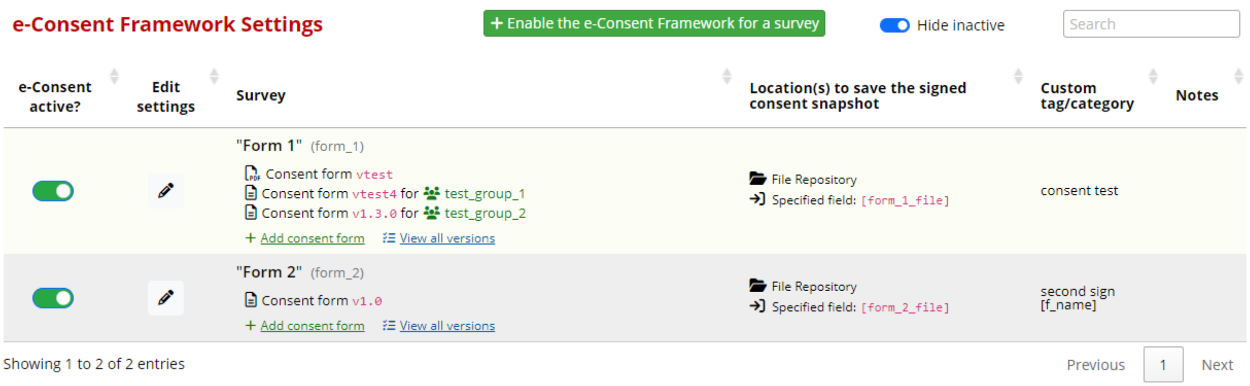
- Select the survey you want to enable for the e-Consent Framework.



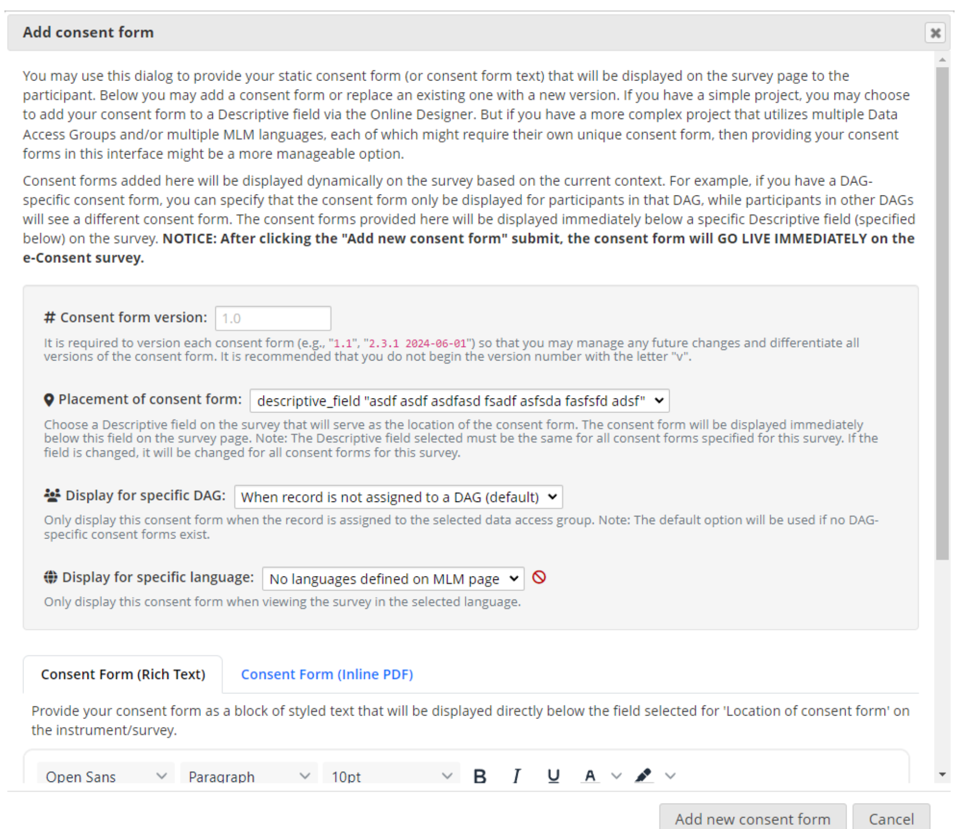
- Complete the e-Consent settings, ensuring all required fields are configured correctly. Including:
  - Specify Field for PDF Storage: Optionally, choose a specified field where the PDF will be saved in addition to the file repository.
  - Customize Snapshot File Name: Customize the snapshot's file name template as needed.



- Save the settings.



5. **Add a New Consent Version:**
   - Click the "Add consent form" button within the e-Consent Framework settings.
   - Complete the add version settings form, including specifying the version number and details of the consent form.
   - Note: The version number in REDCap is a control measure for version control. Once used, it cannot be reused. It is recommended to maintain separate REDCap version numbers and document version numbers to avoid confusion.



6. **Verify Setup:**
    - Test the e-Consent setup to ensure everything is configured correctly.
    - Navigate through the survey as a participant would, ensuring that the e-Consent form is presented correctly, and the PDF snapshot functionality works as expected.

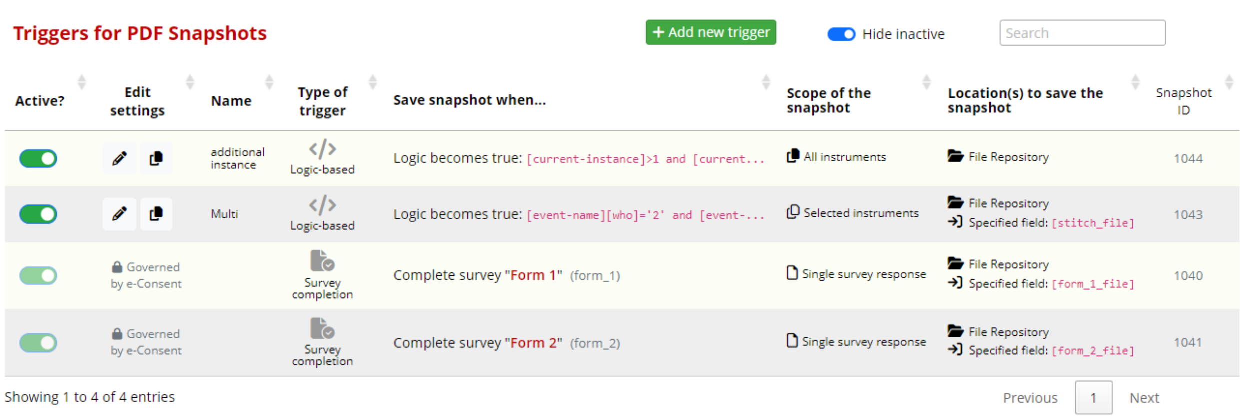
Considerations:

- **Automatic PDF Snapshot:** When the e-Consent Framework is enabled for a survey, a PDF snapshot trigger is automatically created. This trigger is located in the PDF Snapshots tab and is a read-only trigger that pairs with the e-Consent Framework, ensuring that a PDF snapshot of the e-Consent form is always saved.
- **Version Control:** Once a version number is used, it cannot be reused. Ensure that your REDCap version numbers and document version numbers are separate to prevent confusion.
- **One-to-One Setup:** The e-Consent Framework configuration is one-to-one, meaning each setup is specific to one instrument/survey. Consider this when designing branching logic-based forms or multi-version active forms, as the setup will vary depending on your specific requirements.

Setting Up PDF Snapshots

Step-by-Step Instructions:

1. **Access e-Consent Framework and PDF Snapshots:**
    - Click on the "e-Consent and PDF Snapshots" button from the online designer.
    - Click on the "PDF Snapshots of Records" tab.



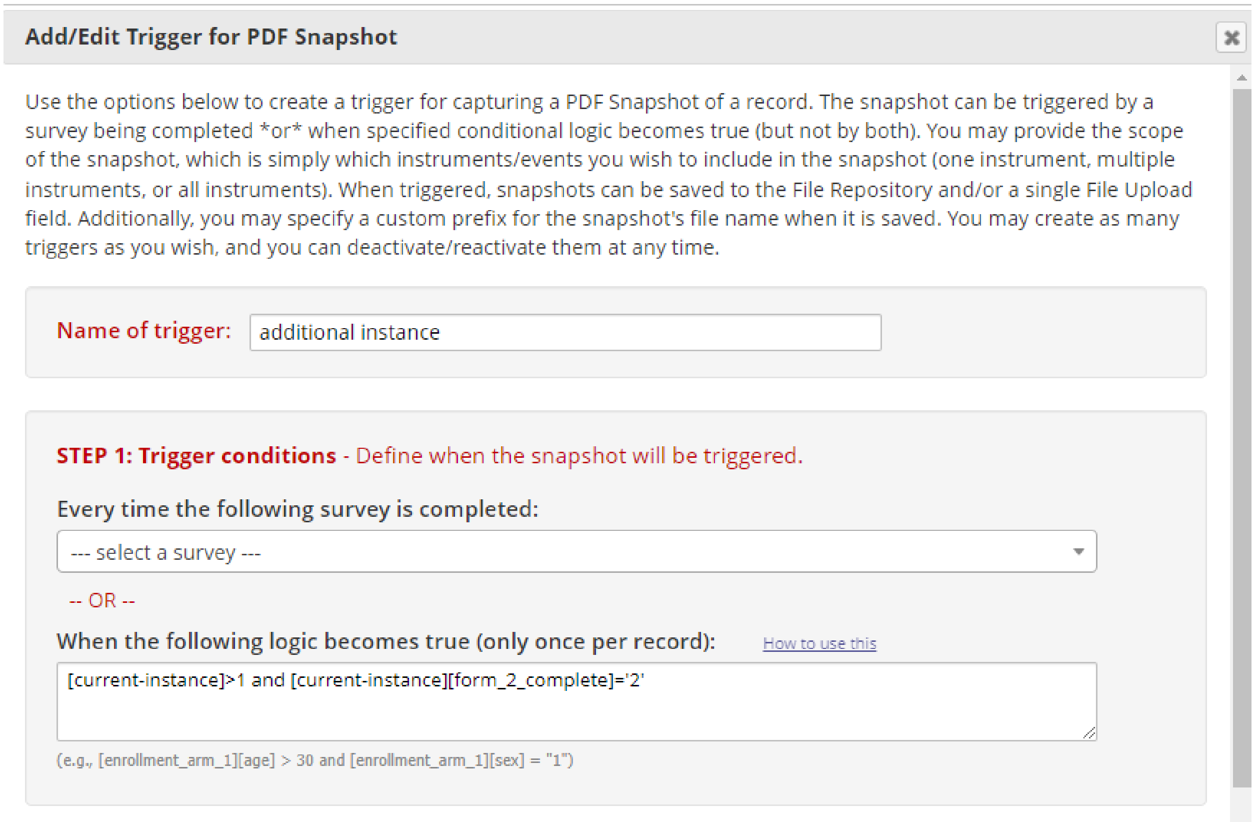
Triggers for PDF Snapshots

+ Add new trigger   Hide inactive   Search

Active?	Edit settings	Name	Type of trigger	Save snapshot when...	Scope of the snapshot	Location(s) to save the snapshot	Snapshot ID
		additional instance	Logic-based	Logic becomes true: [current-instance]>1 and [current...	All instruments	File Repository	1044
		Multi	Logic-based	Logic becomes true: [event-name][who]='2' and [event-...	Selected instruments	File Repository Specified field: [stitch_file]	1043
	Governed by e-Consent		Survey completion	Complete survey "Form 1" (form_1)	Single survey response	File Repository Specified field: [form_1_file]	1040
	Governed by e-Consent		Survey completion	Complete survey "Form 2" (form_2)	Single survey response	File Repository Specified field: [form_2_file]	1041

Showing 1 to 4 of 4 entries   Previous 1 Next

2. **Add New Trigger:**



Add/Edit Trigger for PDF Snapshot

Use the options below to create a trigger for capturing a PDF Snapshot of a record. The snapshot can be triggered by a survey being completed *or* when specified conditional logic becomes true (but not by both). You may provide the scope of the snapshot, which is simply which instruments/events you wish to include in the snapshot (one instrument, multiple instruments, or all instruments). When triggered, snapshots can be saved to the File Repository and/or a single File Upload field. Additionally, you may specify a custom prefix for the snapshot's file name when it is saved. You may create as many triggers as you wish, and you can deactivate/reactivate them at any time.

Name of trigger: additional instance

STEP 1: Trigger conditions - Define when the snapshot will be triggered.

Every time the following survey is completed:

--- select a survey ---

-- OR --

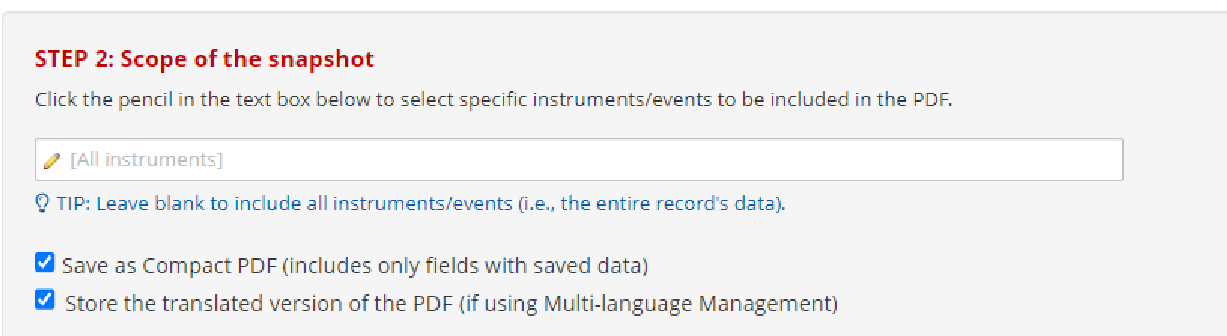
When the following logic becomes true (only once per record): How to use this

[current-instance]>1 and [current-instance][form_2_complete]='2'

(e.g., [enrollment_arm_1][age] > 30 and [enrollment_arm_1][sex] = "1")

- Click the "Add new trigger" button to create a new PDF snapshot trigger.
- Define the conditions that will activate the trigger.

  For example: `[form_complete]="2"`
- Specify the forms and/or surveys that will be included in the snapshot.



STEP 2: Scope of the snapshot

Click the pencil in the text box below to select specific instruments/events to be included in the PDF.

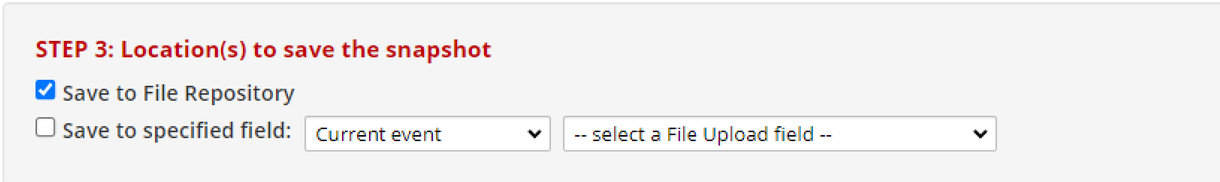
[All instruments]

TIP: Leave blank to include all instruments/events (i.e., the entire record's data).

☑ Save as Compact PDF (includes only fields with saved data)

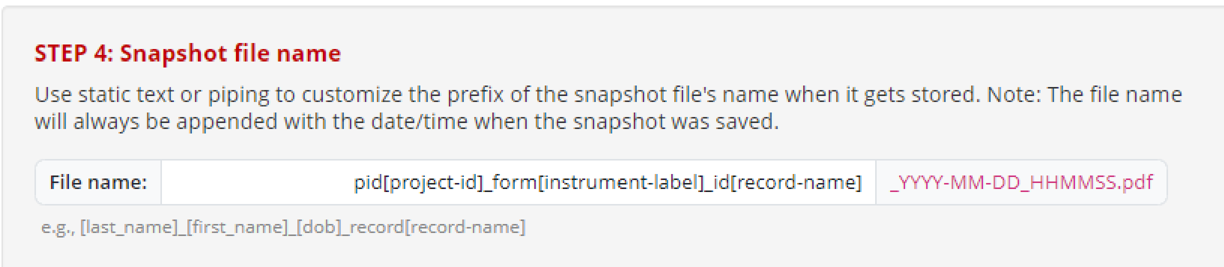
☑ Store the translated version of the PDF (if using Multi-language Management)

- Specify Storage Location: Options include:
  1. The file repository
  2. A specified field within the project



3. The external file storage (vault), if enabled and allowed by the admin

- Customize File Name Template**:** Define the file name template for the snapshot. This can include static text, piping, and date-time stamps.



- Save the newly configured PDF snapshot trigger.

3. **Verify Setup:**
    - Test the PDF Snapshot setup to ensure everything is configured correctly.
    - Navigate through the form/survey, ensuring that the PDF snapshot functionality works as expected.

Considerations:

- Triggers can be active or inactive.
- Settings can be modified as needed.

Instructions for Multi-Form Signing

Design Multi-Form Consents:

1. **Identify Stakeholders:** Determine all the stakeholders who need to sign the consent forms (e.g., participant, guardian, investigator).
2. **Create Separate Forms:** Develop separate instruments for each stakeholder, ensuring each form meets the specific requirements for their role.
    - Note: The best practice for individuals assigned a consenting role on the Delegation of Authority Log is for that individual to log into REDCap, ensuring that the audit trail captures their information. However, double-check your institutional policies and local regulations for the most current best practice and required method.

Enable e-Consent Framework Independently:

- Go to the Online Designer.
- Select each instrument designed for the different stakeholders.
- Enable the e-Consent Framework for each instrument independently.
- Configure each form's settings, including PDF storage and file name customization, as described in the previous sections.
- Note: Automatic PDF Snapshots only work on instruments enabled as surveys. For individuals signing in data form mode, add a certification statement with their signature and a purpose for signing statement or box

Combine PDF Snapshots:

1. **Access e-Consent Framework and PDF Snapshots:**
    - Click on the "e-Consent and PDF Snapshots" button from the Online Designer.
    - Click on the "PDF Snapshots of Records" tab.
2. **Add New Trigger:**
    - Click the "Add new trigger" button to create a new PDF snapshot trigger.
    - Define the conditions that will activate the trigger.
        - Multiple unique signatures examples:
            - Participant and Research Staff signature scenario:

              ```
              [participant_sign_complete]="2" AND
              [staff_sign_complete]="2"
              ```

            - Parent, Child, and Research Staff signature scenario:

              ```
              [parent_sign_complete]="2" AND
              [child_sign_complete]="2" AND
              [staff_sign_complete]="2"
              ```

    - Specify the forms and/or surveys that will be included in the snapshot.
    - Specify Storage Location: Options include:
        1. The file repository
        2. A specified field within the project
        3. The external file storage (vault), if enabled and allowed by the admin
    - Customize File Name Template: Define the file name template for the snapshot. This can include static text, piping, and date-time stamps.
    - Save the newly configured PDF snapshot trigger.
3. **Verify Setup:**
    - Test the PDF Snapshot setup to ensure everything is configured correctly.

- Navigate through the form/survey, ensuring that the PDF snapshot functionality works as expected.

Instructions for Multi-Language Module (MLM)

Enable Multi-Language Module (MLM):

1. **Configure MLM:**
   - Go to the Project Setup page.
   - Enable the Multi-Language Module.
   - Configure the module settings to support the languages needed for your study.
2. **Translate Consent Forms:**
   - Translate each consent form into the required languages.
   - Ensure translations are accurate and include all necessary regulatory information.
3. **Create Consent Versions:**
   - In the e-Consent Framework, create a new consent version for each language. When adding a new version, specify that it belongs to the corresponding language. This ensures that participants see the consent form in their preferred language.
4. **Verify Translations:**
   - Test the translated consent forms to ensure they display correctly in the survey and e-Consent Framework settings.

Instructions for Data Access Groups (DAG):

Enable Data Access Groups (DAG):

1. **Set Up DAGs:**
   - Navigate to the User Rights page.
   - Create Data Access Groups based on the roles and responsibilities of different user groups.
2. **Assign Users to DAGs:**
   - Assign users to appropriate DAGs to control access to specific data and consent forms.
   - Ensure that DAG settings comply with regulatory requirements for data security and confidentiality.
3. **Verify DAG Settings:**
   - Test the DAG configuration to ensure that users only have access to the data they are authorized to see.

4. **Configure e-Consent for DAGs:**
    - Enable e-Consent Framework for Instruments. Go to the Online Designer and enable the e-Consent Framework for each instrument as needed.
    - Set Up DAG-Specific Consent Versions. When adding new consent versions, ensure that they are correctly configured to be visible to the appropriate DAGs. This can be done by setting conditions or using custom triggers that specify DAGs.
5. **Verify DAG Configuration:**
    - Test Access Controls: Test the configuration to ensure that users in different DAGs can only access the data and consent forms they are authorized to see.
    - Check Audit Trails: Verify that the audit trails correctly log actions by users in different DAGs, ensuring compliance with regulatory standards.

DAG Considerations:

- Regularly review and update DAG configurations to maintain compliance with changing project needs and regulatory requirements.
- Ensure that all users understand their access permissions and responsibilities within their DAG.

Ensuring Compliance and Security

Data Encryption:

- REDCap data, including data related to e-Consent and PDF Snapshots, is **ONLY** encrypted during transmission - it is NOT encrypted during storage.
- Verify your study's and institutional encryption requirements to ensure this meets compliance.

Note for End-Users: If you have concerns or questions about data encryption, please contact your REDCap administrator for more information.

Access Controls:

1. Implement Access Controls:
    - Restrict access to e-Consent and PDF Snapshot data to authorized personnel only.
    - Use REDCap's User Rights settings to configure access controls.
2. Review User Permissions:
    - Regularly review user permissions to ensure they align with current project needs and regulatory requirements.

- Adjust permissions as necessary to maintain compliance with confidentiality standards.

Audit Trails:

1. Automatic Logging:
    - REDCap automatically logs all actions related to e-Consent and PDF Snapshots.
2. Review Audit Logs:
    - Review audit logs regularly to monitor for unauthorized access or modifications.
    - Ensure that audit trails provide a complete record of who accessed or modified data and when, in compliance with regulatory standards.
    - Use the audit logs to verify that all e-Consent and PDF Snapshot activities are correctly tracked and compliant with internal and external regulatory requirements.

Conclusion

The e-Consent Framework and PDF Snapshot features in REDCap provide robust and flexible tools for managing electronic consent in research projects. By leveraging these features, you can enhance your consent processes' efficiency, compliance, and security, ensuring that your research adheres to regulatory standards.

For more information: Watch the tutorial to understand the updated e-Consent and PDF Snapshot functionalities: **Video Tutorial**