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# **OVERVIEW OF CHANGES IN UPDATE 8/29/2024**

## New features: Enhanced e-Consent Framework and PDF Snapshot Functionality

#### Overview

* A new page named “Settings for e-Consent & PDF Snapshots” (linked from the Online Designer) serves as the new location where users can enable and set up the e-Consent Framework for a given survey and also set up triggers for storing PDF Snapshots. In previous versions, the e-Consent Framework and PDF Snapshot settings all existed on the Survey Settings page as several disparate options, but now they have been consolidated on this new page as two separate tabs. While these two exist as separate features, there is some overlap of functionality since the e-Consent Framework does ultimately store a copy of the PDF Snapshot for the e-Consent response. In addition to moving these features to the new page, both have been given enhancements, which are detailed below.
* View a 5-minute overview video of the new features: <https://redcap.link/econsent2vid>

#### Overall Benefits of the New Features

* Streamlined Consent Process: Simplify and enhance the electronic consent process for both researchers and participants.
* Improved Data Integrity: Ensure secure and organized storage of consent forms and survey responses.
* Enhanced Compliance: Meet regulatory standards such as ICH and FDA requirements with robust version control and audit trails.

#### Enhanced e-Consent Framework

* Customizable Consent Forms with Version Control: Design consent forms and manage new versions of consent forms while maintaining historical versions for audit purposes. During the setup process for consent forms, their location can be set in relation to a single Descriptive field on the survey. A consent form can exist as an inline PDF or as rich text. A consent form can be associated with a specific MLM language and/or a Data Access Group if the project users wish to have the consent form be used for a specific language (chosen by the participant) and/or DAG (to which the record has been assigned). This allows for language-specific consent forms and DAG-specific consent forms, if needed.
* File Naming Customization: Customize the file names of PDF snapshots for e-Consent responses using static text or piping, appended with date-time stamps.
* Custom Notes: An optional custom notes field can be utilized for each e-Consent survey for bookkeeping purposes. The custom notes are neither displayed on the survey nor anywhere else in the application.
* Custom Headers and Footers: Add custom headers and footers to PDF snapshots created via the e-Consent Framework, including the use of text fields, smart variables, and piping.
* Audit Trails: Improved, detailed audit trails for consent form completions and PDF snapshot generations.
* Change/improvement: When using MLM together with the e-Consent Framework, downloading an instrument PDF of a completed e-Consent survey response (or if the e-Consent survey response is included in a generated PDF that contains non-e-Consent instruments), the e-Consent survey response itself in the PDF will always be rendered in the language in which the participant originally consented.
* Change/improvement: When reviewing draft mode changes, if a consent form’s anchor Descriptive field is deleted or moved to another instrument, it now gets listed as a critical issue in the list of drafted changes.
* Change/improvement: When a user views a completed/signed e-Consent response on a data entry form, in which a consent form was used on the survey, near the top of the page will be displayed the version of the consent form that was used. Also, the consent form itself (i.e., the inline PDF or rich text) displayed on the page will always be the consent form under which the participant originally consented. For example, if a participant consented using consent form v2.0, then even though a new consent form (v3.0) has been added to the project at some point afterward, the data entry form for that participant’s response will always display consent form v2.0 so that the user will always see the survey response and its consent form exactly as the participant originally viewed it.

#### New action tag @CONSENT-VERSION

* This action tag represents the version of the consent form being used by the e-Consent Framework for the current e-Consent survey context (i.e., current record, event, survey, data access group, MLM language, etc.). NOTE: This action tag only adds a new value to the field when its field value is blank and only when the instrument is being completed in an e-Consent survey context. Also, this action tag can only be used if the e-Consent Framework has been enabled for a survey and only if one or more consent forms have been defined for that survey.

#### Improved PDF Snapshot Functionality

* Automatic Saving: Save PDF copies of survey responses (i.e., snapshots) to the project's File Repository or to specified File Upload fields. In previous versions, this would have been set up using separate features on the Survey Settings page, but now they can be set up as specific settings of a PDF Snapshot trigger.
* Snapshot Scope: The “scope” of the snapshot must be defined when creating a new snapshot trigger. The scope refers to the data content inside the PDF, i.e., which instruments are included in the snapshot (a single instrument, multiple instruments, or all instruments/events). Note: The PDF snapshot created by completing an e-Consent survey will only ever include just that single survey response. But for non-e-Consent snapshots, users may define the scope of the snapshot.
* Custom Logic-based Triggers: Create custom triggers for generating PDF snapshots based on specific conditions using conditional logic. Whenever data is being saved for a record (on a survey, form, API, data import, etc.), if the logic of the snapshot trigger evaluates as True, then a PDF snapshot will be saved to whatever location is specified. Note: Logic-based triggers can only be triggered once per record, whereas survey-completion-based triggers (including e-Consent surveys) will store a new snapshot every time the survey is completed (because surveys may possibly be completed multiple times if certain Survey Settings are defined).
* Support for Multi-Form Consents: Combine multiple forms and/or signatures into a single PDF snapshot. Define a PDF snapshot that contains multiple instruments in order to potentially capture multiple signatures, and then store the snapshot in the File Repository or a File Upload field.
* File Naming Customization: Customize the file names of PDF snapshots using static text or piping, appended with date-time stamps.
* Audit Trails: Improved, detailed audit trails for consent form completions and PDF snapshot generations.
* Vault Storage Integration: If using the system-level feature “e-Consent Framework: PDF External Storage Settings (for all projects)”, all PDF snapshots generated via completed e-Consent surveys will automatically be stored on the external server (i.e., “The Vault”). This feature existed in previous versions and continues to function in the same way. Noted new feature: If a multi-instrument PDF snapshot is being stored in the File Repository, in which it contains at least one completed e-Consent survey response, that snapshot will automatically be stored in the Vault. However, a project-level setting named “Store non-e-Consent governed PDF Snapshots on the External Storage server if the snapshot contains a completed e-Consent response” exists on the “Edit Project Settings” page that is set to Yes/Enabled by default, in which it can be disabled if the REDCap administrator wants only e-Consent governed PDF snapshots to be stored in the Vault and thus not store multi-instrument snapshots that happen to contain an e-Consent response in the Vault.
* Snapshot Re-triggering: Perform re-triggering of PDF Snapshots while on a data entry form. If the user has “View & Edit” Data View privileges on the current instrument, they will see a “Trigger Snapshots'' link in the button box at the top-left of the page. This will allow them to trigger or re-trigger any given PDF snapshot (although “survey completion” snapshot triggers specifically require that the survey be completed first). Additionally, for logic-based triggers, the logic does not have to currently be True in order to trigger/re-trigger it.
* Note: Non-e-Consent PDF Snapshot triggers will always store the PDF in the default MLM language, but an e-Consent PDF Snapshot trigger will always store the snapshot in the participant’s chosen language.

### What About My Existing e-Consent?

#### Transition to New Features:

* **The participant experience of e-Consent will not change at all in this new version. It's just the project user's experience that is changing with multiple features (e-Consent Framework, PDF Auto-Archiver, and Save PDF to File Upload Field) being consolidated into the new e-Consent & PDF Snapshot pages.**
* New Location for e-Consent Framework: The e-Consent Framework will move from survey settings to the Online Designer page. The auto-archive feature is also moving and being renamed to PDF Snapshots. Both features will have their own control page to assist users in managing these functionalities.
* Automatic Transition: Existing e-Consents will automatically move to the new location and continue to function as set up. However, **run a test record through your consent process on go-live day to verify functionality. Document this test and its results for compliance.**

#### No Data Loss:

* Data Integrity: All existing e-Consent data will be preserved during the transition. The new system enhances functionality without compromising your existing data.

## Improvements to the Online Designer

* General user interface improvement that utilizes newer icons.
* New “Go to field” feature (invoked via Ctrl-G or Cmd-G) allows users to search for a variable by name and then navigate directly to its location in the Online Designer, even if the field is on a different instrument than the current one.
* Improved and expanded “Quick modify field(s)” popup will appear when users Ctrl-click (or Cmd-click) one or more fields or check the new checkboxes located on the far right of each field. Additions to this popup include the ability to edit the following for multiple fields: branching logic, action tags/field annotation, custom alignment, required status, identifier status, and multiple choice options (including the ability to copy choices - with new choice of location for copied fields, import choices from an existing field, convert a field to a different multiple choice field, and also append new choices using a full-blown choice editor).
  + NOTE: When updating action tags for one or more fields via the “Quick modify field(s)” popup, there is a new action tag named @DEACTIVATED-ACTION-TAGS that is *only* used in the Online Designer for the purpose of deactivating (and thus possibly reactivating) action tags. The difference between deactivating action tags and removing action tags from fields is that deactivating them leaves the action tags in a state/format so that they can be easily reactivated later, whereas removing action tags would make it very difficult to restore the action tags of many fields having many different action tags. For example, if a field has the @HIDDEN action tag and is then deactivated, its field annotation will then appear as the following: @DEACTIVATED-ACTION-TAGS @.OFF.HIDDEN, and if reactivated, it will go back to @HIDDEN again.
  + The “Quick modify field(s)” popup also includes an additional, large selector popup to allow users to select many fields on the current instrument that match certain criteria by clicking one or more icons (e.g., clicking the slider icon and then clicking the “add new selections” button will automatically select all slider fields on the page to use for the “Quick modify field(s)” popup). This makes it easy to select many fields on the page very quickly when they all match certain criteria (i.e., field type, field validation).
* Change: The drag-field feature to “drag-n-drop” a field to a new location on the instrument now operates differently - Inside of clicking and holding anywhere on a field, the user must now click and hold specifically on the Move icon for the given field in order to ready the field for being moved.

## Other Changes & Improvements

* The "Help & FAQ" page has been updated with new content.
* In a MyCap-enabled project, if users switch from classic mode (i.e., non-longitudinal) to longitudinal data collection mode or from longitudinal to classic (via the setting at the top of the Project Setup page), the MyCap task settings and Active task formats will no longer be erased in the project when changing that setting. In previous versions, all MyCap task settings and Active task formats would be completely erased in the project when moving to/from longitudinal mode.