REDCap Project Validation – Guidance Document

Clinical Research Unit |Cumming School of Medicine | University of Calgary

Project Name: _____

Principal Investigator Name: _____

Purpose

On April 20, 2023, the CRU successfully upgraded REDCap to v. 13.1.26 to resolve a critical security vulnerability communicated by the REDCap vendor. We thank you for your understanding and patience, given the urgent and priority nature of this emergency upgrade.

This document can be used by study teams for the purpose of project level validation following this emergency upgrade. Project validation by the study team will include and ensure that all functional requirements listed in the table below have been tested, or deemed not applicable, and are functioning as expected according to project and study requirements.

NOTE – The CRU does NOT require a completed copy of this document to be returned, it is intended for guidance purposes only.

REDCap Project Component	Details	Complete and Accurate?
CRFs/Data Collection Forms	**Instruments –** All data collection forms are included in the project.	_____ YES _____ NO
	Fields - Data collection forms contain all the required fields/questions and accurately reflect the CRF documentation.	_____ YES _____ NO
	Field Validation – Any required field validations have been implemented and function as required. Definition: Individual REDCap fields can be set to require specific kinds of data to be entered. For example, ranges for data entry, dates, signatures, numbers, file uploads, etc.	_____ YES _____ NO

	Branching Logic - Branching logic has been implemented where needed and is working as required according to project specifications. *NOTE: the best way to test branching logic is to create a test record and enter test data within the relevant form/fields.* Definition: Fields that are only shown on data entry forms when specific conditions are met.	_____ YES _____ NO _____ N/A
	Calculated Fields – Calculated fields have been implemented where required and are generating accurate and correct outputs. *NOTE: the best way to test calculations is to create a test record and enter test data within the relevant form/fields.* Definition: Fields that automatically perform specified calculations based on previously entered data (e.g., scoring fields).	_____ YES _____ NO _____ N/A
	E-signatures/E-consent frameworks have been implemented according to project specifications and are working as expected.	_____ YES _____ NO _____ N/A
	Piping – All required instances of piping are present in the project and working as required according to project specifications. *NOTE: the best way to test piping is to create a test record and enter test data within the relevant form/fields.* Definition: Allows data entered in a different field/form/event to be pre-filled in a different location in the project.	_____ YES _____ NO _____ N/A
Project Set-Up	**Arms** – All required arms have been created and set-up according to project requirements. Definition: Allows for the creation of distinct study groups within a single project with unique events/timepoints.	_____ YES _____ NO _____ N/A

	Events – All required events have been created and set-up according to project requirements. Definition: Allows for the grouping of individual instruments into distinct timepoints or study activities. Events can be unique to individual arms.	_____ YES _____ NO _____ N/A
	User Roles & User Rights – The appropriate users have been given access to the study with the correct user rights (e.g., Project Design and Setup, Logging, User Rights, Data Exports, etc.). User roles have been created as required with the appropriate permissions. Definition: User roles and user rights are used to grant users access to and editing privileges for different project features. User roles can be created and assigned to multiple users, giving them all the same permissions. Or, user rights can be customized and assigned specifically and uniquely to each project user.	_____ YES _____ NO
	Data Access Groups – All DAGs have been created and set-up according to project requirements. Definition: DAGs can be created to group records together according to specific criteria (e.g., study site). Specific access to these DAGs can then be granted to individual project users.	_____ YES _____ NO _____ N/A
	Randomization – The randomization schema has been created and implemented according to study requirements. Definition: The process that assigns participants/subjects by chance (rather than by choice) into specific study groups.	_____ YES _____ NO _____ N/A
	Logging (Audit Trail) - The appropriate individuals have been granted user rights to access the logging feature in the project. Definition: Grants user access to view a log of all occurrences of data exports, design changes, record creation, updating & deletion, user creation, record locking, and page views.	_____ YES _____ NO

Survey Set-Up	**Surveys Enabled & Sending –** The appropriate instruments in the project have been enabled as surveys and are able to be sent either manually or automatically (see below) based on project requirements. Definition: When an instrument is enabled as a survey, it can be sent to participants to complete via a link sent to their email address. Participants do not need to login to the REDCap platform to complete the survey. These survey links and invitations can be configured in a variety of ways based on study requirements.	_____ YES _____ NO _____ N/A
	Public Survey Links – Public surveys links have been created for the appropriate surveys and are functioning properly according to study requirements. Definition: A single survey link that can be published to a website or sent to participants via email. Allows for anonymous data collection, unless a participant identifier is collected in the survey.	_____ YES _____ NO _____ N/A
	Automated Survey Invitations – Automated survey invitations have been set up according to study requirements and are functioning as expected. Definition: Surveys can be configured to be sent to participants automatically under specific conditions and at specific timepoints.	_____ YES _____ NO _____ N/A
	Survey Queue/Auto-Continue – According to project requirements, surveys assigned to specific timepoints or study activities are sent together using a single survey link. Definition: The Survey Queue and Auto-Continue are two ways to group surveys together according to study timepoint or activity. In this way, a participant can complete all required surveys at that timepoint using a single survey link.	_____ YES _____ NO _____ N/A

	Survey Reminders – Survey reminders to be sent to participants have been configured as needed according to study requirements. Definition: Reminders can be sent to participants who have not completed a required survey(s) at customizable frequencies and timepoints.	_____ YES _____ NO _____ N/A
	Survey Completion Notifications – Survey completion notifications have been configured according to project requirements and are functioning as expected. Definition: Study team members can be notified by email when participants complete one or more surveys in the study.	_____ YES _____ NO _____ N/A
Additional REDCap Features	**Alerts & Notifications** – All required Alerts & Notifications have been created and are functioning according to study requirements. *NOTE: delayed notifications will not be able to be tested.* Definition: Feature that allows users to create and send customized email notifications to study staff, participants, or other collaborators.	_____ YES _____ NO _____ N/A
	Calendar & Scheduling Module – The Calendar and Scheduling Module have been set up and configured according to project requirements. Definition: Allows users to track study progress and to update calendar events, such as mark milestones or enter ad hoc meetings. The calendar and scheduling module together can be used to add, view and update project records which are due for manipulation.	_____ YES _____ NO _____ N/A

	Double Data Entry – Double Data Entry has been enabled and set-up according to project requirements. Definition: Enabling double data entry allows users to designate any two project users or roles as "Data Entry Person 1" and "Data Entry Person 2". Once each designated data entry person has created an instance of the same record, both instances can then be compared side by side on the Data Comparison Tool page and merged into a third instance.	_____ YES _____ NO _____ N/A
	Project Bookmarks - All required project bookmarks have been set-up and function according to project requirements. Definition: The bookmark module allows users to set up custom links that point to webpages that exist either inside or outside REDCap.	_____ YES _____ NO _____ N/A
	Data Reports – All required data reports have been created and deliver the expected result when tested. Definition: From within the Data Exports, Reports & Stats page, custom reports can be set up pro-actively to pull specific datasets and can then be generated throughout the course of the study by the study team, if needed.	_____ YES _____ NO _____ N/A
	Medical Coding (e.g., MedDRA) – The appropriate medical coding has been configured and is functioning according to project requirements. Definition: Standardized medical dictionaries used to code CRFs like Adverse Events, Serious Adverse Events, Medical History, etc…	_____ YES _____ NO _____ N/A
	Field Comments - If the Data Resolution Workflow is not required, field comments are enabled (by default) and the appropriate individuals have the user rights needed to create and view comments. Definition: When the Data Resolution Workflow is not enabled, the field comments, indicated by the balloon icon next to a field, are enabled by default. Any user with data entry rights can create comments. These comments are recorded in the Field Comment Log.	_____ YES _____ NO

	Data Resolution Workflow - The data resolution workflow has been implemented and functions according to project requirements. Definition: Sometimes called a data query, this workflow is a process for managing and documenting resolution of data entry issues.	_____ YES _____ NO _____ N/A
REDCap Project Add-Ons	**Twilio** – If required, Twilio has been enabled in your project and is working according to project requirements. Definition: Twilio is a third-party web service allowing users to send survey invitations to participants as SMS text messages or voice calls.	_____ YES _____ NO _____ N/A
	RC Mobile - If required for offline data collection, the REDCap Mobile app has been downloaded and the project is working as expected on this platform. Definition: The REDCap mobile app can be downloaded to any mobile device (e.g., smart phones, tablets) and used for offline data collection.	_____ YES _____ NO _____ N/A
	External Modules – If applicable, all external modules have been enabled and are working as expected. Definition: REDCap platform add-on that extends functionality within an individual project.	_____ YES _____ NO _____ N/A
CRU Custom Integrations and Builds	**Token & API (Application Programming Interface)** - All required API connections have been created and function according to project requirements. Study users and third-party service teams have been instructed and are knowledgeable on how to use the API connections. Definition: An interface that allows external applications to connect to REDCap remotely and is used for programmatically retrieving or modifying data or settings within REDCap.	_____ YES _____ NO _____ N/A

	One-Pagers – All required one-pagers have been built and function as expected and as required. All study team members know how to access the required one-pagers. Definition: Custom scripts written to pull specific data elements from the REDCap database and combine them into a document for use by the study team.	_____ YES _____ NO _____ N/A