Title: Standard Operating Procedure (SOP): REDCap Project Change Control

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Author: Luke Stevens, Research Data Systems Manager, CEBU

Author Signature:　　　　　　　　　　**Date:** 06-May-2022

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Signed by: 96637f12-a7c0-419e-b794-686a7fcb7ff8

The author is signing to confirm the technical content of this document

Reviewed and Approved by:

Professor Katherine Lee, Co-Group Leader Clinical Epidemiology & Biostatistics (CEBU)

Signature:　　　　　　　　　　**Date:** 06-May-2022

Recoverable Signature

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Signed by: 3954ba31-81b4-4c75-9c2c-67c09b00b993

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Document History

Revision	Modified by	Change No.	Description of Change
1.0	Luke Stevens	N/A	New Issue

Contents

1.   PURPOSE

To document procedures for managing changes to the configuration of a REDCap project and its data capture forms.

This version of the standard operating procedure (SOP) is intended for use in projects not subject to the full rigors of compliance with Good Clinical Practice (GCP) requirements. For projects subject to GCP use the counterpart SOP specific for trials.

2.   RESPONSIBILITY AND SCOPE

Managing changes to projects in MCRI's REDCap is the responsibility of the research project team. A user with access to a project that includes the "Project Design and Setup" permission has the ability to make changes to the project's data capture forms and also to other project configuration settings.

2.1.   Types of Change

Some types of change to data capture forms or other project configurations may have an adverse impact on existing project data, and therefore it is important that the change process be controlled. One step in the process is to review the proposed changes to determine whether comprehensive testing by the user is required before implementing the changes in the Production project.

Examples of changes that MAY be deemed not to require explicit user acceptance testing (UAT) prior to release are:

- Minor, simple alterations or corrections to the text of alerts or automated survey invitations.
- Minor, simple alterations or corrections to the configuration of a small number of data capture fields.
- Minor, simple alterations or corrections to calculated field expressions, branching logic, or automated survey invitation/alert trigger logic.
- Deletion of a data capture form.
- Addition of existing forms to events in a longitudinal project design.
- Removal of forms from events (because this task may only be performed by REDCap administrators).
- Minor, simple alterations to the configuration of external modules utilised by the project.
- Enabling or disabling features under "Additional customizations" e.g. custom record label, missing value codes.

Changes such as the following should ALWAYS be subject to appropriate UAT prior to release:

- Non-trivial alterations to automated survey invitations or alerts.
- Non-trivial alterations to calculated field expressions or branching logic.
- Non-trivial alterations to existing data capture forms.
- Addition of new data capture forms.

2.2. Testing

Thorough testing involves more than just creating a record and having a quick look that everything looks basically OK. Review each change you have made You should go through each form in detail making checks like these:

- All fields expected are present.
- All categorical fields have the correct options specified.
- Text box fields have the correct validation type, for example:
  - Date[time] fields have a date[time] validation (look for the date picker).
  - Integer fields accept only whole numbers.
  - Email address fields accept only a valid email address.
  - An ordinary single-line text box is used where a short response is expected.
  - A notes box is used where longer, multi-line text entry is expected.
- That additional functionality is operating as you require:
  - Piping
  - Calculations
  - Branching logic
  - Action tags
- Fields that should be mandatory are marked as "required" (and vice versa).
- Range checks are correctly specified.
- Look for typographical errors in field and value labels and headers.
- Evaluate the clarity of the layout. Would some additional section headers improve the flow? Do certain items of text require additional emphasis?
- Consistency in wording and labelling.

3. APPLICABILITY

This SOP applies to all users of MCRI's REDCap application that have the "Project Design and Setup" permission in a REDCap project that is in Production status either by virtue of having created the project themselves or having been granted this level of permission by another project user.

4. PROCEDURE

The following procedures should be followed when altering the configuration of a REDCap project and its data capture forms. These steps are illustrated in the flow chart in Appendix 1.
1. Ensure no other project user with "Project Design and Setup" permissions is in the process of making changes to the REDCap project.
2. Ensure that the REDCap project has no changes in draft.
3. Determine whether or not the change requires changes to the data capture forms:
   - If not, skip the "Draft Mode" steps and proceed to step 14.
   - If so, proceed to step 4.
4. Put the REDCap project into "Draft Mode".
5. Determine whether the changes to be made require testing prior to their being implemented in the Production project (see section 2 for examples).
   - If testing is deemed not required, skip the project copy steps and proceed to step 14.
   - If testing is deemed to be required, proceed to step 6.
6. Make a copy of the Production project, considering carefully what you want to copy and what you don't. In general, copy everything but:
   - Do NOT copy project records, especially where there is identifying-data such as participant email addresses present. If participant-identifying data (name, email etc.) is copied you

MUST replace these data with non-participant data (e.g. a dummy name/your own email address) immediately after copying.
- Do NOT copy project users.

7. Develop your changes in the copy project making note of any configuration changes (i.e. changes not included within the project data dictionary – such changes must be repeated in the Production project as part of the process of making the changes live).
8. Thoroughly test your changes in the copy project (see section 2.2).
9. Perform any additional UAT and/or training required so that users are aware of upcoming changes to data capture procedures.
10. Download the data dictionary from the copy project.
11. Upload the revised data dictionary into the Production project.
12. Review the summary of drafted changes:
    - Ensure all anticipated changes are present.
    - Ensure there are no unanticipated, inadvertent changes present.
    Take note of whether administrator review of the changes will be required, and why.
13. Submit the changes to the Production project.
    - If administrator review of the changes is required, email the administrators at redcap@mcri.edu.au and demonstrate that you have conducted the required testing and that you understand the impact of the changes, and confirm that you wish to proceed.
14. Once the changes have been approved (either automatically or by an administrator) apply any additional configuration changes required (e.g. to survey settings, automated survey invitations, repeating instrument configuration, external module configuration etc.).
15. Delete the copy project. A new copy should be made for any subsequent changes. (It is acceptable to delay this step while monitoring the Production project to ensure that the changes are implemented and functioning correctly and no additional changes requiring testing are necessary.)

5.   ASSOCIATED DOCUMENTS
SOP: REDCap Project Change Control (Trials)

6.   GLOSSARY

Administrator
The REDCap Administrator(s) is a person or group responsible for administering the REDCap application within an institution. Among other tasks that administrators are required to perform is the review and approval (or rejection) of changes to Production REDCap projects that are considered by the application to have a potentially detrimental impact to the integrity of a project's existing data.

Data Dictionary
A REDCap project data dictionary is a file in CSV format containing the complete definition of all data capture fields for the project. Downloading a data dictionary from one project into another results in the data capture fields from the first being replicated in the second (and replacing any pre-existing fields in the destination project).

Development Status
A REDCap project with the status "Development" is in a state in which changes may be made freely with no regard for the integrity of existing data. This facilitates rapid and flexible development but is not appropriate where a project contains valuable data.

Production Status
A REDCap project with the status "Production" is in a state in which certain configuration and design changes are restricted in order to maintain the integrity of existing data. Projects containing valuable data, such as data captured from participants for research purposes, should be in Production status.

Project

A project within REDCap is a discrete database. The data contained within a REDCap project is completely siloed and separate from data stored within other REDCap projects. A research project may utilise multiple REDCap projects for a variety of different data capture and storage purposes.

REDCap

REDCap ("Research Electronic Data Capture") is a secure web platform for building and managing online databases and surveys. REDCap's streamlined process for rapidly creating and designing projects offers a vast array of tools that can be tailored to virtually any data collection strategy. See https://projectredcap.org for more information.

User Acceptance Testing (UAT)

User acceptance testing is a software testing process conducted in order to verify that the software is fit for the purpose it was built for

- Meets functional requirements
- Usable by end-users

During UAT of REDCap project changes, appropriate members of the project team will test the changes to ensure that the project's configuration settings and data capture forms are fit for purpose.

7.   REFERENCES

None

8.   APPENDICES

Appendix 1: Flow chart

DOCUMENT END

APPENDIX 1: FLOW CHART