



ECTU Central Office SOP ECTU_REDCap_05: Project Release

SOP number:	ECTU_REDCap_05
Version number:	3.0
Effective date:	21 st November 2016

Signature	Date
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1. PURPOSE

The purpose of this SOP is to ensure that all relevant processes are complete prior to the Project being released.

2. SCOPE

This SOP applies to all databases produced using the REDCap application within the auspices of ECTU.

3. PROCEDURE

3.1 Pre-release documentation

3.1.1 Project validator confirms that all appropriate validation has occurred and the system is in a fit state to go live. For the initial release this will cover all features in the initial specification – ECTU Central Office SOP ECTU_REDCap_02, Initial Specification. For subsequent releases this will cover all features specified in the Additional Requirements document. This is confirmed by the project validator signing and dating the ‘Validation Complete Confirmation’ document.

3.1.2 Paper CRF update. If this is not the initial release but a subsequent release then there must be updated paper CRFs to reflect the feature modifications along with an incremented instrument version number.

3.1.3 Client confirmation. The identified client for the project should confirm they’ve seen all the relevant validation documents and system modifications by signing the ‘Validation Complete Client Confirmation’ document.

3.1.4 User email addresses and roles. The client provides the email addresses and roles for each user and if necessary, the Data Access Groups.

3.2 Make System or System Modifications ‘Live’

The process for Initial Release and any subsequent releases differ slightly.

3.2.1 Initial Release

1. Copy the project to the ‘production’ site, excluding any test data.
2. Add the users to the appropriate roles.
3. Notify the client in writing that the database is now active.
4. Update the System Release History Document

3.2.2 Subsequent Release

1. If necessary, update the paper version of the CRF to show the modifications. The version number of each instrument modified is also incremented on the paper CRF.
2. Ensure the Additional Requirements Log contains all the modifications for this release.
3. Freeze the production database.
4. Download the complete dataset for each instrument that was modified in preparation for this release. This will be retained internally by ECTU with appropriate limits on access.

5. Duplicate the changes made to each instrument on the frozen production database.
6. Confirm the changes are the same in both the development and production databases by following these steps:
 - a. Download the REDCap “data dictionary” from both the development and production databases. These are downloaded as csv files.
 - b. Save both the files into the project folder named “DataDictionary<<VersionX>>ConfirmModifications”.
 - c. Compare both files using a file “Diff” tool.
 - d. If an event name was changed as a result of the additional requirement ensure that this change has occurred on both the development database and production database.
 - e. If both development and production data dictionaries match and event names on the development and production database match then the production system can be unfrozen.
 - f. Update the System Release History document.
 - g. Update the Additional Requirements log.
 - h. Notify the client in writing that the system has been updated and released.

4. GLOSSARY

4.1 Definition of an event

As referred to in section 3.2.2, an event in REDCap terminology is the term given to columns in Longitudinal projects. The event allows instruments to be repeated at different points in the database allowing instruments to represent temporally separated real life events. The event name is the alphanumeric tag used to distinguish between events.

5. RELEVANT DOCUMENTS

REDCAP Validation Complete Confirmation template v2.0
 REDCAP Validation Complete Client Confirmation template v1.0
 REDCAP System Release History template v1.0
 REDCAP Additional Requirements template v1.0
ECT Unit/SOPs/Finalised SOP and WPD/IT and REDCap/REDCap Documents

ECTU Central Office SOP ECTU_REDCap_02 Initial Specification v2.0
ECT Unit/SOPs/Finalised SOP and WPD/IT and REDCap/SOP/Current pdf for use

6. DOCUMENT HISTORY

Version Number:	Effective Date:	Reason(s) for change(s):
1.0	25 th November 2015	New document
2.0	26 th May 2016	Change to name as REDCap allocated separate naming convention to IT. SOP name in relevant documents changed

3.0	21 st November 2016	Additional instructions added to section 3.2.2 (subsections d and e) regarding events. Section 4 added for definition of an event Formatting and numbering altered and simplified for ease of use Location of relevant documents added in section 5
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