



## ECTU Central Office SOP ECTU\_REDCap\_06: Project Modifications

<b>SOP number:</b>	ECTU_REDCap_06
<b>Version number:</b>	2
<b>Effective date:</b>	26 <sup>th</sup> May 2016

<b>Signature</b>	<b>Date</b>
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## 1. PURPOSE

The purpose of this SOP is to ensure that all validation and release processes are carried out each time a project that is already getting used is modified.

## 2. SCOPE

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

## 3. PROCEDURE

### 3.1. When a change is requested

- 3.1.1. Add a new item to the Additional Requirements log for the project. The template for this log is called Additional Requirements template and can be found in the 'SOP\_REDCap\_05 Release' folder.
- 3.1.2. The Additional Requirements sections to be completed are:
  - 3.1.2.1. Ensure the next number is used for the new additional request. (i.e. If this is the first additional request then the number is 1. If this is the second, then the number is 2. Etc.)
  - 3.1.2.2. Add a Name for the Additional Requirement.
  - 3.1.2.3. The date of the request and the name and role of the person requesting the modification.
  - 3.1.2.4. A short description of the required modification.
  - 3.1.2.5. Whether or not the change is accepted for implementation. If not accepted then a reason why not should be recorded.
  - 3.1.2.6. The name and role of the ECTU staff member accepting or rejecting the request.
- 3.1.3. If the change is not accepted for implementation no further actions are carried out.
- 3.1.4. If the change is accepted for modification the following actions are taken for each Instrument or project-level feature that is to be modified.
  - 3.1.4.1. Changes are implemented within the development system (not the live production system).
  - 3.1.4.2. The previous versions of the Training Document, the Validation Plan and the Validation document are copied to the Superseded Versions folder. If necessary create a sub folder with the name of the instrument and inside this folder a further sub-folder named as today's date in the form 'yyyy-mm-dd'.
  - 3.1.4.3. The previous version of the Training document is updated by:
    - 3.1.4.3.1. Incrementing the Version number.
    - 3.1.4.3.2. Add a row to the Document History table at the top of the training document giving the date of the change, who made the change (including role) and what the changes were.
    - 3.1.4.3.3. The document is now updated to reflect the latest modifications.
  - 3.1.4.4. The previous versions of the Validation Plan and Validation Document are updated in the same manner as the Training Document.
  - 3.1.4.5. If ECTU is managing the production of the paper CRF, then this is updated, ensuring it matches the modified instrument in content and version number.
- 3.1.5. Once the Training Document, Validation Plan and Validation Document are updated the validator (not the staff member responsible for making the changes) uses the Training Document and Validation Document to validate the instrument.
- 3.1.6. Once the validation tests have passed for all modified instruments and project-level features the modifications can be introduced to the production system by following the procedure in SOP\_REDCap\_05 section 3.2.2 Subsequent Release.

## 4. RELEVANT DOCUMENTS

REDCap Additional Requirements Template.docx  
ECTU Central Office SOP ECTU\_REDCap\_05 Project Release  
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**5. DOCUMENT HISTORY**

Version Number:	Effective Date:	Reason(s) for change(s):
1	25 <sup>th</sup> November 2015	New document
2	26 <sup>th</sup> May 2016	Change to name as REDCap allocated a separate naming convention to IT