



ECTU Central Office SOP ECTU_REDCap_03: Build Process – Individual Instrument

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Signature	Date
Signature on file Author: Tony Wackett, Trial Support Officer	25 th May 2016
Signature on file Reviewed By: Allan Walker, IT Systems Manager	25 th May 2016
Signature on file Approved By: Allan Walker, IT Systems Manager	25 th May 2016

1. PURPOSE

This SOP covers the build process for an individual instrument within a REDCap application by ECTU personnel.

2. SCOPE

This SOP applies to all databases produced using the REDCap application by ECTU personnel.

It covers the creation of an instrument, producing the training document and producing the validation document.

3. PROCEDURE

3.1. Produce the Instrument as per the initial specification

3.2. Produce a training document for the instrument.

3.2.1. The training document must be written in enough detail so the end-users can follow it step-by-step. Including:

- How to access the instrument for a particular study participant.
- Describes the behaviour of the instrument with regards to branching logic and fields that must be completed.
- Describes how to save and flag the data as complete.

3.3. Produce the Validation Plan

3.3.1. The validation plan is a document that specifies which features of the instrument should be tested. These features include but are not limited to:

- Ranges for values – numbers, dates and times if these are in the initial specification
 - Provide a range of edge and middle cases for each field and state the expected result on save e.g for a range of 0 to 1

Value	Expected Result	Actual result
-0.01	Bad	
0	Good	
0.1	Good	
0.4	Good	
0.6	Good	
0.9	Good	
1	Good	
1.01	Bad	

- Branching logic.

- Confirmation that the fields and data types match the CRF/initial specification.
 - Data Access Groups are in place (if specified).
- 3.3.2.** The validation plan is a versioned document. The ECTU REDCap Validation plan template must be used when producing a validation plan.
- 3.3.3.** The Validation plan should be signed and dated by the author of the plan.
- 3.3.4.** Once a plan is finalised a validation document is produced from the plan. The validation document is a versioned document. The ECTU REDCap validation document template must be used when producing a validation document.
- 3.3.5.** The creator of the instrument and validation plan must not be the person who performs the validation process for the instrument.
- 3.3.6.** The validation document should be signed and dated by the validator irrespective of whether the instrument passes or fails validation.
- 3.3.7.** All completed validation plans and documents will be retained by ECTU.

4. RELEVANT DOCUMENTS

REDCapExampleTrainingDocument.docx.
 REDCapExampleValidationPlan.docx.
 REDCapExampleValidationDocument.docx.
 ECTU Central Office SOP ECTU_SOP_RedCap_02 Initial Specification v2.0.doc

5. DOCUMENT HISTORY

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