ECTU Central Office SOP ECTU_REDCap_02: Initial Specification

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Authorship and Approval			
Name and Designation	Author/Reviewer/ Approval	Date	Signature
Michelle Steven, Data Manager	v3.0 Author	15th February 2019	Signature on file
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Michelle Steven, Data Manager	v3.0 Approval	16th February 2019	Signature on file

Document Revision History		
Version No	Date	Summary of Revisions
1.0	25th November 2015	New document
2.0	26th May 2016	Change to name as REDCap allocated separate naming convention to IT
3.0	1st March 2019	Updated at scheduled review. Document moved to new template. Extensive changes to document due to procedural changes. REDCap Initial Specification Template implemented and reference added to SOP

1. PURPOSE

This Standard Operating Procedure (SOP) defines the documentation that must be included as part of the initial specification for a REDCap database developed by ECTU

2. SCOPE

This SOP applies to all University of Edinburgh Staff employed within ECTU who are responsible for managing studies using a REDCap database. For studies where ECTU is responsible for providing the REDCap database without an assigned ECTU Trial Manager, the REDCap Developer is responsible for informing external trial staff of the documentation required for the initial specification

3. PROCEDURE

The initial specification for a REDCap electronic system consists of:

- REDCap Initial Specification template which must be signed off by the Chief Investigator, Trial Manager or project designee.
- Supporting documentation as described in Section 3.2

3.1 REDCap Initial Specification Template

The REDCap Initial Specification template provides a description of the REDCap functionality to be included for each project. At a minimum, the following details must be recorded in the Initial Specification document:

- Description of REDCap Event and Arm structure or the reason this is not applicable
- Data roles required for initial release
- Subject identifiers to be used in the project (two methods of adding subjects are available):
    - o Sequential numbering allocated by REDCap
    - o Custom identifier manually entered by the user
- Description of the project randomisation, where applicable

If extra functionality is required for a project (e.g. Scheduling, Data Resolution Workflow), this must be described in the REDCap Initial Specification template.

3.2. Supporting Documentation

The following supporting documentation must be provided as part of the REDCap Initial Specification document before it is approved and signed:

- Finalised protocol
- Finalised pCRF (if applicable)
- REDCap codebook/data dictionary providing:
    - o List of all fields and pages on the database
    - o Behaviour of each field
    - o Description of project events, arms, and instrument mapping

3.3 Initial Specification Approval

The REDCap Initial Specification document must be signed and dated by the Chief Investigator, Trial Manager, or project designee and a member of the ECTU Data Management team or designee. The completed document must be retained and filed electronically on the shared drive with the hard copy filed in a project specific folder.

Once the REDCap Initial Specification document is signed, the project validation process can begin. Project validation must not begin before the REDCap Initial Specification document is signed.

4. RELEVANT DOCUMENTS AND REFERENCES

REDCap Initial Specification Template (on shared drive)
ECT Unit/Data Management/Templates/REDCap Initial Specification Template