ECTU Central Office SOP ECTU_IT_01: Initial Setup Procedure

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1. **PURPOSE**

To describe the initial setup process for a project

2. **SCOPE**

This SOP applies to all the research support systems developed in-house by Edinburgh Clinical Trials Unit.

3. **PROCEDURE**

This procedure describes the steps to be taken and the documentation that is to be in place prior to a system undergoing its initial release.

3.1. Initial Specification

3.1.1. An initial specification is to be in place.
The initial specification is made up of the documents that identify the key elements of the project. The key elements are:
- The dataset. Represented usually by the Case Report Form.
- Protocol or equivalent document that describes the visit schedule
- Protocol or equivalent document that describes the treatment allocation mechanism.

3.2. Release Specification

3.2.1. A Release specification is to be in place.
The release specification is the final specification for the system prior to it undergoing initial release. The release specification is made up of:
- A feature list made up of each of the features that make up the initial release of the system. This list must be confirmed complete and signed and dated by the person carrying out the role of validator for the system.
- The set of completed validation documentation for each feature. See ECTU_IT_02 Feature Development for details.

3.3. Risk Assessment

3.3.1. A risk assessment is to be carried out and documented in a version-controlled document prior to initial release.

3.4. System Level Security Policy

3.4.1. A system level security policy is to be in place. This is to be a version-controlled document.

3.5. Treatment Allocation

If a treatment allocation algorithm is implemented for the project then the following documents are to be in place.

3.5.1. Treatment Allocation description. This document should describe the algorithm used.
3.5.2. As part of the release specification, documentation to show the treatment allocation algorithm operates as expected.

3.6. Additional Requirements template

3.6.1. A template additional requirements document is to be in place. At this stage it is not expected any additional requirements will as yet be identified.

3.7. System Release template

3.7.1. A template system release document is to be in place. At this stage this will record no system releases.

4. RELEVANT DOCUMENTS

ECTU Central Office SOP ECTU_IT_02: Feature Development v2.0

5. DOCUMENT HISTORY

Version Number:	Effective Date:	Reason(s) for change(s):
1	14-Mar-2012	New document
2	10th June 2016	Record updated processes after discussion with the sponsor.

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