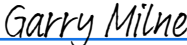
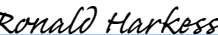






ECTU Central Office SOP ECTU_IT_01: Initial Set-up Procedure

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Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	14 Mar 2012	Initial creation
2.0	10 Jun 2016	Record updated processes after discussion with the sponsor.
3.0	01 Jul 2024	Moved to new template. Substantive changes throughout to reflect current processes. Minor formatting changes.

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1.0 PURPOSE

The purpose of this SOP is to describe the initial setup process for a project.

2.0 SCOPE

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

3.0 RESPONSIBILITIES

The ECTU Software developers are responsible for implementing the tasks set out in this SOP.

The Trial Manager or designee is responsible for providing the dataset (developed by all key stakeholders) necessary for creating the initial specification.

The Trial Statistician (or designee) is responsible for creating the Randomisation System Description and Confirmation document, if a treatment allocation algorithm is implemented for the project.

4.0 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.

4.1. Initial Specification

4.1.1. An initial specification should be in place before creating a bespoke database, and is made up of the documents that identify the key elements of the project. The key elements are:

- The dataset, that has been developed by all key stakeholders, provided by the Trial Manager or designee
- Protocol or equivalent document that describes the visit schedule
- Protocol or equivalent document that describes the treatment allocation mechanism.
- Protocol or equivalent document that describes any other relevant requirements

4.2. Release Specification

4.2.1. A Release specification should 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:

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- 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, 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_SOP_IT_02 Feature Development for details.

4.3. Risk Assessment

A risk assessment is carried out by the Software Developer using the version-controlled Risk Assessment Template prior to initial release, and saved within Section 9 of the Trial Master File (TMF).

4.4. System Level Security Policy

A system level security policy is to be in place, using the IT006 System Level Security Template. This is to be a version-controlled document and saved within Section 9 of the Trial Master File

4.5. Treatment Allocation

If a treatment allocation algorithm is implemented for the project, the Randomisation System Description and Confirmation document is created by the Trial Statistician (or designee), with input from the Software Developer where required. It should describe the algorithm used and contains the confirmation that the algorithm operates as expected. The document will be saved within Section 9 of the TMF.

4.6. Additional Requirements Document

A template for additional requirements document (see section 5) should be created and saved in the TMF, Section 9. At this stage it is not expected any additional requirements will as yet be identified.

4.7. System Release Document

A template system release document (see section 5) should be created and saved in the TMF, Section 9. At this stage this will record no system releases. This will be updated for every subsequent version of the database that is released, and signed off by the Software Developer.

5.0 RELEVANT DOCUMENTS AND REFERENCES

[ECTU Website:](#)

- ECTU Central Office SOP ECTU_IT_02: Feature Development

[On ECTU Shared Drive:](#)

- IT003 System Release Document Template
- IT004 Additional Requirements Template
- IT005 Risk Assessment Template

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- IT006 System Level Security Template

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Final Audit Report

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