



ECTU Central Office SOP ECTU_IT_02: Feature Development

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Signature	Date
Signature on file Author: Allan Walker, IT and Systems Manager	6 th June 2016
Signature on file Reviewed By: Garry Milne, Senior IT Programmer	6 th June 2016
Signature on file Reviewed By: Ronnie Harkess, Senior IT Programmer	6 th June 2016
Signature on file Reviewed By: David Buchanan, Senior IT Programmer	6 th June 2016
Signature on file Approved By: Allan Walker, IT and Systems Manager	6 th June 2016

1. PURPOSE

To describe the process for producing and validating a system feature.

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 process of validating a system feature and the documentation to be in place before the feature can be included in the live system.

3.1. Feature documentation to be produced

If the feature is part of the user interface then the following documentation is to be produced

3.1.2 Training and Description document

This document describes how to use the feature and contains a complete set of screenshots of the feature and step-by-step instructions of how to use the feature. This document will be produced by the member(s) of staff responsible for implementing the feature. This is a version-controlled document.

3.1.3 Validation Plan document

This document contains a list of the items of the feature that require validation. This will include the behaviour of the feature and confirmation of the dataset. This document will be produced by the member(s) of staff responsible for implementing the feature. This is a version-controlled document.

3.1.4 Validation document

This document contains the same items as the validation plan but is designed to be completed by the person fulfilling the validator role. This is a version-controlled document.

3.1.5 If the feature is not part of the user interface then the Training and Description document will not be produced. The validation plan and validation documents will be produced. Any supporting documentation as evidence of automated testing will be referred to within the validation plan and validation document.

3.2 Version Control

Each of the three documents must share the same feature version.

The feature version is composed of an integer representing the major component and an integer representing the minor component, separated by an underscore.

If this is the initial version of the feature then the major component and minor component are both set to 1 (i.e. 1_1).

If this is an update to a feature in production then the major component is incremented by 1 and remains at that value until the feature version is released to production. The minor component is incremented each time a set of Training validation plan and validation documents are produced.

3.3 Validating the feature using the documentation.

The documentation mentioned above will be used to validate the feature by following these steps.

- 3.3.1 The member of the system development team responsible for the feature signs and dates the validation plan. This plan is filed in the project's documentation folder.
- 3.3.2 The Training and description document and the validation document will be delivered to the person performing the validator role for the feature.
- 3.3.3 The validator returns the signed and dated Training and Description document to the responsible member of the system development team. This document is filed along with the validation plan.
- 3.3.4 The validator returns the completed validation document to the responsible member of the system development team. The document is filed along with the validation plan.
- 3.3.5 This process repeats until the validator approves the feature for release.

Each time the validator returns a validation document that fails to approve the feature for release the responsible member of the system development team will:

- Adjust the feature as necessary.
- Produce updated versions of the Training and Documentation, Validation Plan and Validation documents. The minor component of the version number should be incremented by 1 from the previous versions of the document. The major component should remain unchanged.

4. RELEVANT DOCUMENTS

5. DOCUMENT HISTORY

Version Number:	Effective Date:	Reason(s) for change(s):
1	14-Mar-2012	New document
2		Reflect process changes. Change title from System Component Development