

STANDARD OPERATING PROCEDURE

Document version control

<i>SOP History</i>	<i>None</i>
<i>SOP Number</i>	<i>C101</i>
<i>Created</i>	<i>STH Research Department (AL)</i>
<i>Reviewed</i>	<i>STH Research Department (DP)</i>
<i>Superseded</i>	<i>1.1</i>
<i>Version</i>	<i>1.2</i>
<i>Date</i>	<i>12 August 2009</i>
<i>Related SOPs</i>	<i>None</i>
<i>Approved by</i>	<i>Research Manager</i>

Standard Operating Procedure: Research Department

Document version control

This SOP has been produced in accordance with Research Governance Framework 2005 and ICH GCP. This SOP will outline the procedure for a unified approach to version control of all documents that are created, used by or submitted to the Research Department.

Background

- It is essential that all users of a document use the most up to date version in order to ensure that accurate procedures are being followed at all times.
- It is essential that an audit trail of version controlled documents is made available once a document is approved for use and subsequently reviewed and/or changed.

Definition

It is STH Research Department policy that all documents developed, used or submitted must be designated a unique numerical version and date of creation.

Procedure

Prior to approval (Draft)

1. The author of the document numbers the original version 'Draft v (Version) 1.0' and the date of creation.
2. The author re-numbers the version when making administrative changes (grammar, spelling, syntax) to the document, using a decimal place – 'Draft v1.1', 'Draft v1.2' etc. and dates the documents.
3. The author re-numbers the version when making substantial changes (changes in content, procedure or additions of information) to the document and also dates the documents.
 - 3.1 The version number increases incrementally with each new substantial change- 'Draft v2.0', 'Draft v3.0'.
 - 3.2 The numbering continues with the administrative changes rule with each version- 'Draft v2.1', 'Draft v2.2' etc.
4. The author files the previous electronic version of the document in the designated archive section of their departmental network drive^a.
5. The relevant qualified person reviews and approves the document.
6. The author files the latest electronic draft version in the designated archive section of their departmental network drive^a and deletes all previous draft versions.

After approval

1. The author re-numbers the final version of the document 'version 1.0' and adds the date of approval.
2. The author re-numbers the version when making administrative changes (grammar, spelling, syntax) to the document, using a decimal place – 'v1.1', 'v1.2' etc. and dates the documents.
3. The author re-numbers the version when making substantial changes (changes in content, procedure or additions of information) to the document and also dates the documents.
 - 3.1 The version number increases incrementally with each new substantial change- 'v2.0', 'v3.0'.
 - 3.2 The numbering continues with the administrative changes rule with each version- 'v2.1', 'v2.2' etc.
4. The author files the previous electronic version of the document in the designated archive section of their departmental network drive^a.
5. The relevant qualified person reviews and approves the document.
6. The author files the latest electronic draft version in the designated archive section of their departmental network drive^a and keeps all previous approved versions.

Footnote

^aIndividuals should save their work on the Trust network rather than on their computer hard drive. For those working in the STH Research Department, save to the archive section of the department shared drive (S:\General).