

Standard Operating Procedure

Title:	PREPARATION, REVIEW, APPROVAL AND ISSUE OF STANDARD OPERATING PROCEDURES
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REF: SOP 001	Version: 04	Issue No: 1
Template Source: Merseyside & Cheshire Cancer Research Network		Date: 18/02/05
Reviewed by: Professor Rod Owen		Date: 05/11/2009
Approved by: Dr M J Maxwell		Date: 21/05/07
Due for Revision		Date: 05/11/2012
This SOP is effective from:		Replaces: Version 03 (21/05/07)

1. BACKGROUND

A Standard Operating Procedure (SOP) sets out the way matters must (i.e. mandatory) or should (i.e. advisory) be performed. SOPs are written instructions and records of procedures agreed and adopted by Wirral University Teaching Hospital NHS Foundation Trust following consultation and discussion where appropriate.

SOPs should be clear, concise, of common style, format and content, available where and when needed and be subject of a system of document control.

It is necessary to review the procedure and amend the SOP accordingly. Similarly, SOPs can become outdated and as such need to be reviewed on a regular basis. Annual review is the accepted guideline.

2. PURPOSE

To describe the procedure for raising, approving and issuing SOPs, including revision and updating of these SOPs.

3. OTHER RELATED PROCEDURES

All Wirral Hospital Research & Development SOPs

4. WHEN?

An SOP should be written as soon as the need for a standard written procedure for an activity is identified.

Deficiencies requiring SOP amendments should be dealt with at the earliest opportunity and no later than the next scheduled SOP review. SOPs should be reviewed every two years.

5. WHO

SOPs should be written by a person competent and experienced to do so. It is accepted that the best person to write the SOP is the person who performs the procedure regularly. The Research & Development Operational Committee will decide this.

The Research & Development Manager or equivalent person will number and issue all SOPs to staff; and will also be responsible for organising the annual review of SOPs.

All staff are responsible for identifying any deficiencies in the SOPs to the Research & Development Manager.

All staff must adhere to SOPs

6. HOW?

- All SOPs should be prepared according to the format defined below:

Header:	None								
Footer:	Page X of Y (e.g. Page 1 of 3) Arial 12 font, black, centred								
Main Body Text:	Arial 12 font, black, not indented								
Header 1:	Arial, 14 font, bold, black, numbered (e.g. 1., 2., 3. etc)								
Header 2:	Arial, 12 font, bold, black, outline numbered (e.g. 1.1, 1.2 etc)								
Line Spacing:	Single line spacing								
Margins:	<table> <tr> <td>Top Margin</td> <td>2 cm</td> </tr> <tr> <td>Bottom Margin</td> <td>2 cm</td> </tr> <tr> <td>Left Margin</td> <td>2.5 cm</td> </tr> <tr> <td>Right Margin</td> <td>2.5 cm</td> </tr> </table>	Top Margin	2 cm	Bottom Margin	2 cm	Left Margin	2.5 cm	Right Margin	2.5 cm
Top Margin	2 cm								
Bottom Margin	2 cm								
Left Margin	2.5 cm								
Right Margin	2.5 cm								
Gutter:	0 cm								
From edge header:	1 cm								
From edge footer:	0.5 cm								
Justification:	On								
Bullet point 1:	Normal bullet points •(not arrows or boxes) Indented at 0cm, text position indented at 0.63cm								
Bullet point 2:	Dash bullet point - Indented at 0.5cm, text position indented at 1.2cm								
Paper size:	A4								

PREPARATION, REVIEW, APPROVAL AND ISSUE OF STANDARD OPERATING PROCEDURES	
REF: SOP 001	VERSION: 03

Front Page only:

Ist line: Wirral University Teaching Hospital Foundation Trust logo
Arial 16 font, bold, blue

Standard Operating Procedure

Title: <i>Insert title. Arial 14 font, bold, normal, black, left aligned</i>

REF: SOP <i>insert 3 digit no.</i>	Version: <i>insert 2 digit no.</i>	Issue No: <i>insert 2 digit</i>
Template Source:		Date:
Modified by:		Date:
Approved by:		Date: 21/05/07
Due for Revision		Date: 21/05/09
This SOP is effective from:		Replaces:

Every page:

<i>Insert title SOP here, Arial 10 font, normal, black, centred</i>	
REF: SOP <i>insert 3 digit SOP number</i>	VERSION: <i>insert 2 digit version number</i>

- The SOP should be contain the following sections:
 - **Background**
Briefly discuss the background to the procedure, making reference to legal requirements and national or international guidance. Consider the driving forces or why the procedure is necessary.
 - **Purpose**
Describe the procedure to be followed and the setting in which the SOP applies.
 - **Other Related Procedures:**
List of other SOPs referenced in the document, or related to the procedure
 - **When?**
Describe at what stage of clinical trial activity the SOP applies
 - **Who?**
Describe the responsibilities of staff following the procedure
 - **How?**
Describe the procedure in a clear, step-wise manner
- Each SOP should be reviewed at draft stage by staff that will use it to identify the issues addressed.

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- The Research & Development Manager should review each SOP.
- An electronic copy of the satisfactory draft SOP should be provided to the Research & Development Manager or equivalent person. All other paper and electronic copies of the draft should be destroyed.
- The Research & Development Manager or equivalent person will assign the next lowest available sequential 3-digit number to the SOP, and enter this number in the table on each page. The names of the author and the approver will be entered in the table on page 1. A master copy will be printed.
- The author will sign and date the table on page 1 to show date of preparation
- The person or committee who approves the SOP will sign and date the table on page 1 to show date of approval
- The Research & Development Manager or equivalent person will write the date it is effective from, and indicate whether it replaces an existing SOP and if so, which.
- All SOPs should be reviewed annually by the Research & Development Manager or equivalent person.
- Deficiencies in SOPs should be recorded and notified to the Research & Development Manager, who will arrange for appropriate SOP'S prepared or existing ones modified to address these deficiencies.
- Copies of superseded SOPs will be destroyed, and the master copy retained.