STANDARD OPERATING PROCEDURE:
Preparation, Approval, Review and Implementation of Research Standard Operating Procedures

SOP REFERENCE NUMBER	CLPG19 SOP 14
VERSION NUMBER	Version 1
REPLACES SEPT DOCUMENT	SOP 20 - Preparation, Approval, Review and Implementation of Research SOPs (V1.0; 4 August 2014)
REPLACES NEP DOCUMENT	STANDARD OPERATING PROCEDURE: Preparation, Approval, Review and Implementation of Research Standard Operating Procedures v2
KEY CHANGES FROM PREVIOUS VERSION	
AUTHOR	Research & Development Manager
CONSULTATION GROUPS	
IMPLEMENTATION DATE	
AMENDMENT DATE(S)	
LAST REVIEW DATE	
NEXT REVIEW DATE	
APPROVAL BY	
RATIFICATION BY	
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SOP SUMMARY

The procedure for preparing, approving, and reviewing Research Standard Operating Procedures.

The Trust monitors the implementation of and compliance with this policy in the following ways:

Monitoring of implementation and compliance with this procedure will be undertaken by the Executive Medical Director, Research manager, Research lead, R&D department staff and R&D group.

Services	Applicable	Comments
Trustwide	✓	
Essex MH&LD		
CHS		

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1. BACKGROUND

Standard Operating Procedures within clinical trials are detailed written instructions to achieve uniformity and set out the way practice and procedures must (i.e. mandatory) or should (i.e. advisory) be performed. SOPs are written instructions and records of procedures agreed and adopted by the Researchers following consultation and discussion as 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.

2. PURPOSE

To describe the procedure for preparing, approving, and reviewing Research Standard Operating Procedures.

3. PROCEDURE

Identified appropriate staff members should review each SOP at draft stage, and deficiencies addressed.

The R&D Manager is responsible for ensuring that SOPs are reviewed, revised, approved and issued according to this SOP.

All clinical research staff are responsible for identifying any deficiencies in the SOPs and notifying the R&D Manager accordingly.

A 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 rectified at the earliest opportunity but no later than the next SOP review.

SOPs can become outdated as a result of changes in clinical practice and the regulatory environment. All SOPs need to be reviewed every two years as an integrated part of clinical research practice.

A brief discussion of the background to the SOP should be provided, making reference to legal requirements and national or international guidance. All clinical trials SOPs must be prepared according to a standard format defined by this SOP. Draft SOPs must be submitted for R&D and Trust approval according to the appropriate local processes.

Each SOP should be version controlled and dated.

The R&D Manager will be responsible for and manage a system of dissemination of SOPs and retrieval of superseded SOPs, and maintain robust records.

The R&D Manager will be responsible for the training of clinical research staff in the implementation and application of SOPs.

The R&D Manager should review all SOPs in accordance with Trust policy.

Each SOP should have an individual version number and ratified date. The previous version number should be noted on the front sheet.

Copies of superseded SOPs will be destroyed, and only the master copy retained and archived in order for regulatory bodies to review (as required).

3.1 Process for Implementation of SOPs

1. Research SOPs will be produced as described in the Preparation, Approval, Review and Implementation of Standard Operating Procedures that apply to Clinical Trials SOP.

2. The R&D Manager will ensure that up-to-date copies of ratified SOPs are on the R&D website and available in the R&D Office.

3. The R&D Manager will provide SOP training sessions as required.

4. Files will be made available containing all ratified SOPs and signature logs.

4. SUPPORTING DOCUMENTS

CP1 – Policy for Development, Review and Control of Trust Approved Documents
CPG1 – Procedure for Development, Review and Control of Trust Approved Documents