# United Lincolnshire Hospitals NHS

NHS Trust

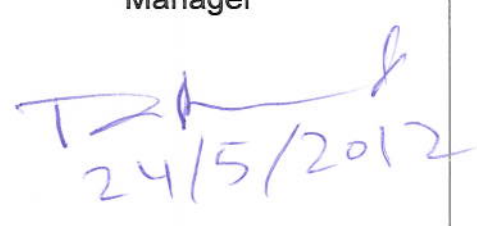## How to write a
## Standard Operating Procedure

| SOP Title | How to write an SOP – Procedure for the preparation for approval, process, distribution and uptake of ULHT SOPs |
|---|---|
| SOP No. | SOP 1 |
| Author | Julia Farmery |
| Consulted Departments | Lincolnshire Clinical Research Facility, Research and Development, trust consultants and research staff. |
| Lead Manager | Dr. Tanweer Ahmed Director of LCRF and Research and Development Manager |
| Sign and Print Name | *[signature]* 24/5/2012 |
| Original date of publication | 10/03/2010 |
| Date current version published | 24/05/2012 |
| Review date of SOP | 24/05/2014 |
| Version 2 (Changes detailed on Index of SOP) | Version 1 Superseded on 24/05/2012 |

This is a controlled document, when printed this document is no longer controlled

1

## Tracked Changes to SOP 2 – Adverse Events/Serious Adverse Events and Suspected Unexpected Adverse Events

| Paragraph | Changes |
|---|---|
| 1. Purpose | • Added purpose of SOP<br>• Added details of EU Clinical Trial Directive.<br>• Removed: details on Medicines for Human Use (Clinical Trials) regulations 2004, summary of who the SOP applies to and what is covered in the SOP, summary of EU Clinical Trial Directive<br>• Added details of Research Governance Framework for Health and Social Care (2nd Edition) 2005 |
| 2. Applies to | • Amended to read 'All staff involved in research/clinical trials and all SOPs written from ULHT. |
| 4. Definitions | • Removed 'GMP'<br>• Added LCRF |
| 5. Policy | • Noted that where relevant, hosted studies must also follow R&D SOPs<br>• Added guidelines for SOP training and custodianship of SOP training records.<br>• Added Research Governance Framework for Health and Social Care (2nd Edition) 2005<br>• Added EU Clinical Trial Directive (2001/20/EC) |
| 6. Procedure | • Amended 3<sup>rd</sup> Paragraph changing 'UK Trial Regulations' to UK Statutory Regulations'.<br>• Removed 'ICH' from 'ICH GCP' and amended sentence to 'non-CTIMP' only.<br>• Removed paragraph 5 on where use of SOPs is expected to be seen.<br>• Added location of hard and soft copies of SOPs |
| 7. Responsibilities | • Added when SOPs will be updated.<br>• Removed point that SOPs will be updated every two years as stated at end of SOP.<br>• Specified responsibilities for SOP authorship and creation. |
| 8. References | • Added Research Governance Framework for Health and Social Care (2<sup>nd</sup> Edition) 2005. |

## 1. Purpose:

The purpose of this SOP is to describe the procedure for the preparation, approval, process, distribution and uptake of ULHT SOPs.

Standard Operating Procedures (SOPs) ensure that United Lincolnshire Hospitals Trust is adhering to the best practice transposed into UK Law : The Medicines for Human Use (Clinical Trials) regulations (2004), as amended and the EU Clinical Trial Directive (2001/20/EC)

Scope

This SOP will be the core document for the development of future SOPs, thus acting as a guideline for the development of future SOPs, thus acting as a guideline for the development & framework underpinning their purpose.

All SOPs should be in line and consistent with this document. All SOPs must be reviewed and approved before use. Training must be given on all SOPs to ensure coherent and consistent methodological practice.

The legislation highlights the laws and regulations for us to adhere and follow within our work and practice, thereby SOPs are formulated to relay the provisions of the above regulation and to ensure the high standards of practice are maintained, ensuring research is ethical, credible, scientific and in line with the principles of statutory regulation and the Research Governance Framework for Health and Social Care (2nd Edition) 2005.

## 2. Applies to:

All staff involved in research/clinical trials.

All SOPs written for United Lincolnshire Hospitals.

## 3. Relevant SOP Documentation

**(Other relevant SOPs should be listed here)**

SOP Template SOP 2

- Links to other SOPs should be cross referenced

## 4. Definitions:

**(Definitions of Abbreviations in the SOP document should be located in this section)**

SOP – Standard Operating Practice

ULHT – United Lincolnshire Hospital Trust

LCRF – Lincolnshire Clinical Research Facility

## 5. Policy:

**(All relevant policies should be documented in this section)**

- All SOPs developed for United Lincolnshire Hospitals NHS Trust (ULHT) must be followed for any studies we sponsor and where applicable, studies we host. All individuals using these SOPs will have to complete a recording relating to proof of reading and acceptance. These should be kept in all individuals training records and original forms kept in the SOP master file. Signed SOPs should be returned within a month of the individuals receiving the SOPs.

- SOP documents will be kept by the Research Governance Manager for the Trust, this individual will maintain this file and its contents.

- Research Governance Framework for Health and Social Care (2nd Edition) 2005 accessed on 15/03/2012 available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/Publication sPolicyAndGuidance/ DH_ 4108962

- The UK Clinical Trial Regulations No. 1031, No. 2754, No. 2759, No. 1928, No. 2984, No. 941, No. 1164.

- EU Clinical Trial Directive (2001/20/EC) accessed on 15/03/2012, available at: http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:121:003 4:0044:en:PDF

## 6. Procedure:

**(Details of how, what, where and when should be stated)**

- Standard Operating Procedures (SOPs) are detailed, written instructions in an aim to achieve uniformity on the performance of a specific function.

- They are the core of the products and services we offer. SOPs are written instructions that clearly define the "who", "what", "where", "why" and exactly how things are done and by whom. The SOPs formulated, aim is to adhere to the UK statutory regulations which are all relevant to our areas of practice.

- A key component of GCP is to have properly drafted SOPs which cover all trials we partake in, whether we are a host or a sponsor.

- SOPs developed in the future should comply with the template guide SOP 2, in line with the current version.

- SOPs are available on the website and via the shared drive. SOPs should be additionally stored in the SOP Trial Master File located in the Clinical Research Facility.

- All members of the research team employed/contracted to ULHT are required to comply, as relevant, with the SOPs and be aware of their responsibilities.

- Any changes made to the SOPs should be only with approval from the Author and Lead manager.

## 7. Responsibilities

**Responsibilities are two fold within this SOP:**

### 1. Responsibilities of SOP Creation

SOPs should be developed when a need arises for their production and generation

United Lincolnshire Hospital and all staff working with clinical trials have an ethical responsibility under the Statutory Instrument of the Research Governance Framework for Health and Social Care (2nd Edition) 2005 to adhere to Good Clinical Practice. The SOPs will be reviewed if a subsequent

change happened within policy or legislation. All staff have a responsibility to inform their line-managers if they have any concerns or issues regarding SOPs.

## 2. Responsibilities of SOP Author

An appropriate person should be assigned to the task

They should be appropriately qualified for duties and the job they are doing

They should have an understanding of the relevant policies and literature to fulfil their role.

## 8. References:

**(This section should give reference to all of the documents discussed, where information is contained, within an SOP)**

Hutchinson, D. (2009) The UK Clinical Trial Regulations – Indexed and Consolidated. Canary Ltd: Surrey.

ICH Harmonised Tripartite Guideline (1996) ICH Guideline for Good Clinical Practice. CPMP/ICH/135/95/Step 5, Explanatory Note and Comments to the above, issued as CPMP/768/97.

Research Governance Framework for Health and Social Care (2nd Edition) 2005. Department of Health

**This SOP will be reviewed every two years, a more updated revision of the SOP will be implemented if new local, national or international regulations change. This would therefore replace the existing document. All SOPs can be located on the Research and Development's shared file and a hard copy of all SOPs are kept in the SOP Trial Master File**