UNIVERSITY OF SUSSEX

Standard Operating Procedures on SOPs (CTIMPs)

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Date:	26 March 2021
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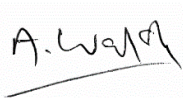
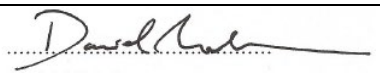
Author: Antony Walsh **Designation:** Research Governance Officer	**Signature** 	**Date** 26 March 2021
Authorised By: Dr Daniel Michelson **Designation**: SSC Chair		29.3.21

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1.0	15 April 2021	

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[1] http://www.sussex.ac.uk/staff/research/governance

Acknowledgement BSUHT

1. Purpose & Scope

1.1 This Standard Operating Procedure (SOP) describes the process for writing, approving, implementing and reviewing University of Sussex (US) SOPs relating to Clinical Trials of Medicinal Products (CTIMPs) – i.e. all trials which come under the Regulations, where US is the sponsor. The requirements of this SOP should be applied as a minimum to such trials and in conjunction with all applicable University policies.

1.2 The scope of the document is for all schools at the University of Sussex, all members of staff with substantive employment and students registered at the University (including Brighton and Sussex Medical School).

2. Introduction

2.1 In order to be compliant with the European Directive on Good Clinical Practice in Clinical Trials (2001/20/EC) and The Medicines for Human Use (Clinical Trials) Regulations (2004 and subsequent amendments) organisations conducting Clinical Trials of Investigational Medicinal Products must have clearly documented Standard Operating Procedures covering all aspects of conducting Clinical Trials. The SOPs also apply to all other projects that fall under the UK Policy Framework for Health and Social Care Research (2017).

2.2 A Standard Operating Procedure (SOP) is defined by ICH Harmonised Tripartite Guideline for Good Clinical Practice as "Detailed, written instructions to achieve uniformity of the performance of a specific function". These SOPs are written instructions and records of procedures agreed and adopted by the University of Sussex (US).

3. Responsibilities

- The ***Chair of the Sponsorship Sub-Committee*** has overall responsibility for reviewing and approving SOPs for CTIMPs
- ***All researchers*** are responsible for ensuring research is conducted in accordance with the clinical trials regulations and University of Sussex SOPs, policies, regulations and the 'Code of Practice for Research'[2]

4. Procedure

[2] https://www.sussex.ac.uk/webteam/gateway/file.php?name=code-of-practice-for-research-june-2018.pdf&site=377

Writing SOPs

4.1 A SOP should be written as soon as the need for a standard written procedure for an activity is required. It must be written by a suitable member (by experience and competency) of the University Research Governance Office or delegated university employee. The name of the author will be displayed at the top of the document in Table 1 (see Template for the production of University of Sussex SOPs, Appendix I the SOP Template, Appendix).

4.2 All amendments, advancements and new legislation must be incorporated into existing SOPs at the two year review point or sooner if required.

Front Page

4.3 The following information shall feature on the front page of all SOPs using the standard template:

a. Title of SOP

b. Unique SOP number for reference purposes.
This will be located in the table on the front page and in the footer of the document.
c. Date of document
d. Date on which the document becomes effective

Contents and layout

4.4 The SOPs must be produced in the standard template outlined in Appendix 1. It should incorporate the following bold titles:

1. **Purpose & Scope** – this section should outline the reason for creating the SOP and how it applies within the University of Sussex and its collaborating partners.

2. **Introduction** – this section should outline the aim of the SOP and identify any background legislation and important context.

3. **Responsibilities** – this section should list the individuals with roles and provide details of their specific responsibilities in relation to the SOP concerned.

4. **Procedure** – this section should detail how the aims will be achieved. This will clearly indicate a step-by-step description of the procedure to be followed.

5. **Training –** the standard training statement about the status of the document

6. **Abbreviations –** include any abbreviations or acronyms used in the SOP, its appendices and any associated forms or documents.

7. **Cross-Referenced SOPs**– an ordered list of all cross-referenced SOPs must be provided in this section.

8. **References**– this section should list all external relevant reference points (legislation, guidance etc.)

9. **Appendices** – all appendices referenced in the SOP must be listed accordingly and copies of the appendices provided at the end of the SOP.

Approval and authorisation

4.5 All SOPs will require final approval and authorisation. They will be reviewed by the Chair of the Sponsorship Sub Committee. The signature on a SOP will authorise the associated forms which should show an identical issue date to the SOP.

Review and Amendment of SOPs

4.6 SOPs will be reviewed as necessary when there are changes in current processes, guidelines and regulations. A SOP can be suspended following evidence from an individual of a significant change in practice. If this is necessary, an email will be circulated to all relevant individuals and the SOP will be reviewed by the Sponsorship Sub-Committee(SSC) or the SSC Chair exercising Chair's Action. The SOP will be amended and authorised in accordance with due process.

Distribution and storage

4.7 All SOPs will be added to the Research Ethics, Integrity and Governance team website once authorised. It is the responsibility of all researchers to check the website regularly to determine whether SOPs have been added or amended.

4.8 A master file containing all versions of SOPs will be kept by the Research Governance team.

Consultation, Approval and Ratification Process

4.9 All University-wide Clinical Trials documents are written by a member of staff with relevant expertise and experience. Additional advice is sought from members of the research community within the University or external advisors, as necessary.

Document Approval Process

4.10 Standard Operating Procedures are approved by the Chair of the Sponsorship Sub-Committee.

4.11 Policies are ratified by the University Research Governance and Quality Assurance Sponsorship Sub-Committee. Researchers should maintain a record of having read and understood SOPs in their personal development/ CPD files.

5. Training

5.1 This is a 'read and understand' SOP. Please note that the Research Governance Office discourages the retention of hard copies of SOPs and can only guarantee that the most up-to-date version is on the University website.

6. Abbreviations

CTIMP	Clinical Trial of an Investigational or Medicinal Product
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
SOP	Standard Operating Procedure
SSC	Sponsorship Sub-Committee
US	University of Sussex

7. Cross Referenced SOPs

None

8. References

Clinical Trials Regulations 2004 (SI 2004/1031)
http://www.legislation.gov.uk/uksi/2004/1031/pdfs/uksi_20041031_en.pdf

Appendix 1 – SOP Template

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Standard Operating Procedures on {PROCESS}

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SOP Reference:	
Version Number:	
Date:	
Effective Date:	

Author: **Designation:**	**Signature**	**Date**
Authorised By: **Designation:**		

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1.0 Purpose & Scope

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[3] http://www.sussex.ac.uk/staff/research/governance

2.0 Introduction

<text>

3.0 Responsibilities

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4.0 Procedure

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5.0 Training

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6.0 Abbreviations

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7.0 Cross-Referenced SOPs

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8.0 References

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9.0 Appendices

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