Technology, Infrastructure and Environment Directorate Clinical Research Governance Team

Standard Operating Procedure

Production and Control of Standard Operating Procedures

SOP001

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1. Introduction

Standard Operating Procedures (SOP) are written instructions aimed at achieving uniformity in the performance of specific functions. This document sets out the requirements for production and control of Standard Operating Procedures (SOPs) and controlled documents that form part of the Quality Management System (QMS) for Clinical Research including Clinical Trials of Investigational Medicinal Products (CTIMPs) and Clinical Investigations of Medical Devices sponsored by the University of Liverpool (UoL). The role of Sponsor is facilitated by the Clinical Research Governance Team (CRGT), part of the Technology, Infrastructure and Environment Directorate within the Faculty of Health and Life Sciences.

The CRGT Sponsor SOPs CRGT are designed to ensure that clinical research and its supporting activities are conducted to the principles of ICH GCP and in compliance with The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 (the Regulations) and any other relevant regulations and frameworks. This includes, but is not limited to, The Medical Devices Regulations 2002, the Principles of Good Clinical Practice, the Data Protection Act 2018, UK General Data Protection Regulation (UK GDPR), the Mental Capacity Act 2005, the Human Tissue Act 2004, the Concordat to Support Research Integrity (25 October 2019), and Good Clinical Practice (GCP) guidelines.

Controlled documents are SOPs, forms, templates, and work instructions included in the CRGT Sponsor Quality Management System. SOPs are procedures which have been agreed and adopted by the CRGT following appropriate discussion and ratification and will be used as a training and development tool for members of the University.

All controlled documents are under strict version control which enables users to determine one version of a document from another. This ensures that the current version is used which describes the current approved procedures.

Ideagen Quality Management is the electronic document management system that facilitates document control for CRGT controlled documents.

2. Scope of Procedure

The purpose of this document is to describe the procedure to be followed to ensure that SOPs are produced in a consistent format and are adequately controlled. This will ensure that University staff work to the same closely controlled standards.

This SOP covers the preparation, review, approval and distribution of new procedures, storage, review and update of controlled documents. This SOP also describes the procedure to be followed when controlled documents are to be suspended or withdrawn from use.

This document also applies to the controlled documents that fall under the remit of the Human Material Governance Team within CRGT.

3. Who

This procedure applies to all staff working within clinical research sponsored by the University and those creating, reviewing and distributing SOP's and Controlled Documents within the CRGT. An appropriate level of Ideagen Quality Management training will be provided to all members of staff who will be creating, reviewing and approving documents using the system. Where staff are working within a separate Quality Management System (i.e. within a Clinical Trials Unit) it is expected that the local QMS takes precedence, unless there is significant disparity in the expectations. In such situations it is expected that the Sponsor SOP takes precedence but may be subject to a case-by-case review.

4. When

This SOP should be referred to whenever an SOP or controlled document is created, approved, issued, amended or withdrawn.

5. Management of controlled documents

The Document Controller is the Senior Clinical Research Governance Manager who will maintain and administer Ideagen Quality Management.

The Human Material Governance Manager will maintain oversight of controlled documents that fall under the remit of the Human Material Governance Team.

Ideagen Quality Management provides a full history of each SOP and controlled document so signed master copies will not be retained.

6. Creation, approval and issuing of a new SOP

Once the need for a SOP has been identified a title for the new SOP should be proposed to the Document Controller. All SOPs must be in a standard format using TEM001 SOP Template.

The Document Controller will add the proposed SOP title to Ideagen Quality Management, issue a draft SOP number and identify the author. TEM001 will be provided to the author via Ideagen Quality Management.

The SOP author will write a draft of the SOP using the current version of TEM001 providing as much detail as possible regarding the subject of the SOP.

The drafting and editing of the document should be completed using the 'Check Out' function in Ideagen Quality Management to ensure there is only one draft version of the document.

The author should conduct a final review of the SOP once completed. The SOP will then be provided to appropriately qualified persons for review before ratification at the appropriate committee where applicable. The review will be facilitated via Ideagen Quality Management. The reviewers will depend on the type of SOP but will usually be a member of the Senior Management team of the CRGT and

the Chair of the ratifying committee. The Senior Clinical Research Governance Manager or Human Material Governance Manager will identify if any further reviewers are required.

Once initial review has been undertaken and comments have been incorporated the SOP should go to the relevant review committee for approval. For Sponsorship related SOPs this will usually be the Clinical Research Regulatory Oversight Committee (CRROC), with input from the Liverpool Health Partners (LHP) JRO (Joint Research Office) Sponsorship Committee where beneficial for the content of the SOP. For Human Material related SOPs this will usually be the Human Material Oversight Committee. Upon satisfactory review and ratification by the appropriate committee, the Chair of the ratifying committee will provide approval for the document via Ideagen Quality Management or via email. The author is also required to approve the document in this way.

Once the document has gained the appropriate approvals the document owner is required to issue the document in Ideagen Quality Management. Upon issuing of the document Ideagen Quality Management will convert the document to PDF and automatically update the document to include the following information (where document tags have been included. If not included the author must ensure this is updated manually);

- Issue date
- Version number
- Reference number
- Title

The Document Controller will ensure an electronic copy (PDF) is uploaded on the CRGT webpages so that it is available for all staff to view. A note will be added to the SOP to note that any printed versions of the document are uncontrolled and only the version on the CRGT webpages will be maintained.

7. Creation, approval and issuing of a new controlled document

Once the need for a new controlled document (other than an SOP) has been identified the draft document should be provided to the Document Controller who will add the document to Ideagen Quality Management and add the author to the document attributes.

The drafting and editing of the document should be completed using the 'Check Out' function in Ideagen Quality Management to ensure there is only one draft version of the document.

The document will be provided to appropriately qualified persons for review before ratification at the appropriate committee if required. The reviewers will depend on the type of Document but will usually be a member of the Senior Management team of the CRGT and the Chair of the ratifying committee. The Senior Clinical Research Governance Manager or Human Material Governance Manager will identify if any further reviewers are required.

Version controlled documents that are created solely for use within the CRGT will not require committee ratification, however if the document is to be used by individuals outside of the department, then it should be subject to formal Committee ratification.

If ratification is not required, then the author will be required to provide approval following appropriate review. If ratification is required, the Chair of the ratifying committee will provide approval for the document via Ideagen Quality Management or via email once satisfactory ratification is completed. The author is also required to approve the document in this way.

Once the document has gained the appropriate approvals the document owner is required to issue the document in Ideagen Quality Management. Upon issuing of the document Ideagen Quality Management will automatically update the document to include the following information (where document tags have been included. If not included the author must ensure this is updated manually);

- Issue date
- Version number
- Reference number
- Title

If appropriate the Document Controller will ensure a copy is uploaded to the CRGT internal web pages so that it is available to University staff to use.

8. Review and update of issued SOPs

SOPs will be reviewed every two years unless changes are required before this time has elapsed.

For SOPs that have reached their natural review date:

Ideagen Quality Management maintains a calendar of review dates and will provide a reminder to the author and/or document owner 6 months before the review date is reached.

The person responsible for review (usually the document owner) will receive a Request for Review from which they can begin the review of the document. The person responsible for review can be assigned or changed at this point if it is not the document owner.

Once the person responsible has conducted the review of the document the following actions can be taken depending on the outcome;

- If no amendments are required to the document, then the review can be closed and completed. A reason must be provided for the closure of the review. The document will be revised to state a new review date, but the issue and effective date will remain the same. The document should be re-distributed to copyholders.
- If amendments are required then the review, approval and issue process should be followed as per section 6

For SOPs that need to be changed prior to the natural review date:

A Change Request must be completed for the appropriate SOP in Ideagen Quality Management. This can be completed by the document owner and/or author on identification of a required change, or by a member of the CRGT with appropriate rights to do this.

Ideagen Quality Management will alert the document owner to the Change Request who may then accept or reject the request. If the request is rejected a reason must be provided.

The review, approval and issuing of the document will then occur as per the usual review process.

9. Review and update of existing controlled documents (other than SOPs)

Controlled documents do not have a standard review period. If applicable a Change Request must be completed for the appropriate document in Ideagen Quality Management.

Ideagen Quality Management will alert the document owner to the Change Request who may then accept or reject the request. If the request is rejected a reason must be provided.

The author will draft the required changes to the document and the review, approval and issue process should be followed as per section 7.

10. Withdrawal of an SOP or controlled document

When an SOP or controlled document is no longer required the document owner or author must be notified via a Change Request in Ideagen Quality Management.

If the reason for withdrawing the document is accepted by the document owner or author, the document should be archived within Ideagen Quality Management. The document will remain part of Ideagen Quality Management and can still be viewed but will be removed from document lists and circulation.

Ideagen Quality Management will inform all copyholders that the document has been withdrawn.

The document author should then ensure the document is removed from the CRGT Webpage.

An SOP may only be withdrawn once the procedure is no longer followed. If a SOP is to be superseded the previous one must not be withdrawn until the replacement version is issued.

11. Distribution of SOPs and controlled documents

SOPs and controlled documents will be distributed as outlined below;

Clinical Research Governance Sponsorship Team

SOPs - Members of the team will be added to the Ideagen Quality Management Document Record as Copyholders. Team members will be required to read and acknowledge the latest version of the SOP by the Active Date or within 7 working days whichever is sooner.

Controlled documents - Members of the team will be added to the Ideagen Quality Management Document Record as Notified Only. There is no requirement for the team members to formal acknowledge the latest version within Ideagen Quality Management.

Liverpool Clinical Trials Centre (LCTC) Quality Assurance (QA) Team

SOPs – A member of the LCTC QA Team will be added to the Ideagen Quality Management Document Record as a Copyholder, to ensure that LCTC are aware of changes to Sponsor SOPs that may impact LCTC operations. LCTC are responsible for ensuring that their SOPs are updated as required. LCTC QA will be requested to read and acknowledge the latest version of the SOP by the Active Date or within 7 working days whichever is sooner.

Controlled Documents – LCTC QA are not routinely notified of new versions of controlled documents, as these documents are mainly for use by the Clinical Research Governance Sponsorship Team. Where a member of LCTC staff require use of a controlled document the latest version will provided directly to the Trial Manager upon request. If there is a specific need for LCTC to be notified of a new version a member of the LCTC QA Team will be added as Notified Only on the Ideagen Quality Management Document Record.

Chief Investigators

SOPs - Chief Investigators (CIs) are not routinely given access to Ideagen Quality Management. All SOPs are available via the Clinical Research Governance Team website, and CIs are notified via email of any new documents or new versions.

CIs are also required to sign a "Chief Investigator Sponsor Declaration" on the Sponsor Approval Letter for each of their studies. By signing the agreement, they declare that they have read and understood all applicable Sponsor SOPs and made them available to all members of their research team, including students, as well as agreeing to comply with all conditions listed in the letter. This includes ensuring the CI study team are up to date with the current Clinical Research Governance SOPs throughout the duration of the study.

Controlled Documents - CIs are not routinely notified of new versions of controlled documents, as these documents are mainly for use by the Clinical Research Governance Sponsorship Team, and where a CI requires a controlled document, the latest version will be provided directly to the CI upon request.

12. Roles and Responsibilities

Author

Any member of the University CRGT team can be the author of an SOP or controlled document, who, is best qualified by experience or competency to do so. In some cases, this may mean an SOP or Document has more than one author.

The author is responsible for ensuring that the SOP accurately and adequately describes the procedure it is being drafted for, and that appropriate expertise has been gained in the drafting.

Reviewers

Reviewers are responsible for checking that the content of the SOP or document is correct and that the procedure in the SOP or document is comprehensible and accurate.

CRGT Senior Clinical Research Governance Manager

The Senior Clinical Research Governance Manager is responsible for the effective management of Sponsorship Policies, SOPs and controlled documents, including:

- Determining the framework and structure of Policies, SOPs and controlled documents;
- Ensuring the correct sign off and approval of Policies, SOPs and controlled documents;
- Determining any additional training requirements for Policies, SOPs and controlled documents;
- Ensuring audit of SOPs where required, delegating to members of the CRGT if required.
- The maintenance of Ideagen Quality Management and functions contained within Ideagen Quality Management for review and issuing of Policies, SOPs and controlled documents;
- The coordination of the review of Policies and SOPs every two years and the re-issue, if necessary, prior to the expiry date;
- Ensuring that document copy holders complete the required actions in Ideagen Quality Management.

CRGT Human Material Governance Manager

The Human Material Governance Manager is responsible for the effective management of Human Material Governance Policies, SOPs and controlled documents, including:

- Determining the framework and structure of Policies, SOPs and controlled documents;
- Ensuring the correct sign off and approval of Policies, SOPs and controlled documents;
- Determining any additional training requirements for Policies, SOPs and controlled documents;
- Ensuring audit of SOPs where required, delegating to members of the CRGT if required.
- The maintenance of Ideagen Quality Management and functions contained within Ideagen Quality Management for review and issuing of Policies, SOPs and controlled documents;
- The coordination of the review of Policies and SOPs every two years and the re-issue, if necessary, prior to the expiry date;
- Ensuring that document copy holders complete the required actions in Ideagen Quality Management.

University staff

All staff are responsible for reporting any deficiencies in SOPs and controlled documents and notifying the Senior Clinical Research Governance Manager or Human Material Governance Manager who will then arrange for appropriate action to be taken. This may be the drafting of a new SOP or document, or the revision of current ones.

13. Abbreviations

DMS	Document Management System
CRGT	Clinical Research Governance Team
LCTC	Liverpool Clinical Trials Centre
QA	Quality Assurance
SOP	Standard Operating Procedure
University	The University of Liverpool

14. Associated Documents and References

TEM001 - SOP template

Sponsorship Policies and Standard Operating Procedures

Human Material Policies and Standard Operating Procedures

UK Policy Framework for Health and Social Care Research

The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025

The Medical Devices Regulations 2002

ICH Harmonised Guideline For Good Clinical Practice E6(R3)

Data Protection Act 2018

UK General Data Protection Regulation (UK GDPR)

Mental Capacity Act 2005

Human Tissue Act 2004

15. Training and Resources

All staff within the CRGT with the responsibility for creating, reviewing, approving and distributing SOPs and controlled documents should read and fully understand this SOP. Members of staff who are required to undertake functions within Ideagen Quality Management will be provided training

from an appropriate member of the CRGT. If any further training is required, this can be arranged with the Senior Clinical Research Governance Manager.

16. Monitoring and Audit

An internal audit of CRGT SOPs will be conducted at least 2 yearly on a risk basis.