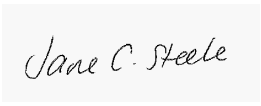
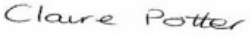
RESEARCH & INNOVATION SERVICES

UNIVERSITY OF SUSSEX

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Writing and Review of Standard Operating Procedures

SOP reference:	UOS-RIS-GOV-SOP-001
Version number:	1.0
Date:	12-Oct-2026
Effective date:	12-Oct-2026
Next review date:	11-Oct-2029

	Name	**Designation**	**Signature**	**Date**
Author:	Jane Steele	Research Ethics, Integrity and Governance Senior Manager		05-Oct-2026
Reviewer:	Caroline Gordon	Head of Research Ethics, Integrity and Governance		12-Oct-2026
Approved by:	Claire Potter	Director of Research and Innovation Services		09-Oct-2026

1. Purpose and scope

Standard Operating Procedures (SOPs) are formal documents that describe the procedures that must be followed to complete a task. They ensure that those procedures are performed consistently and accurately.

This SOP describes the procedures for writing, reviewing, approving, and implementing SOPs, which describe the processes and systems that support Research Governance at the University of Sussex. Establishing and maintaining robust SOPs for this purpose is essential to mitigate operational, regulatory, and compliance risks and for achieving the required quality and standards.

This SOP applies to all members of staff at the University of Sussex (including Brighton and Sussex Medical School) involved in writing, reviewing, approving, and implementing SOPs relating to procedures and systems in place that support Research Governance.

This SOP is expected to be used in conjunction with the relevant University of Sussex policies and the Code of Practice for Research.

2. Abbreviations

AWERB	University of Sussex Animal Welfare and Ethical Review Body
F-REC	Faculty - Research Ethics Committee
HSC SCC	University of Sussex Health and Social Care Sponsorship Sub-Committee
HTA CG	Human Tissue Authority Licence Co-ordination Group
PVCRI	Pro-Vice-Chancellor (Research and Innovation)
REIG	Research Ethics, Integrity and Governance
REIG SC	REIG Sub-Committee
RIS	Division of Research and Innovation Services
SOP	Standard Operating Procedure

3. Background

Research Governance can be defined as the framework comprising a broad range of regulations, policies, principles, and standards of good practice that ensure research is planned, conducted, monitored and reported ethically, legally, safely and to a high standard of quality. It is applicable to research studies using both human participants and animals.

In the UK, several pieces of legislation, together with key regulatory frameworks and documents describing standards of good practice, support the principles of Research Governance. These include:

☐ UK Policy Framework for Health and Social Care Research

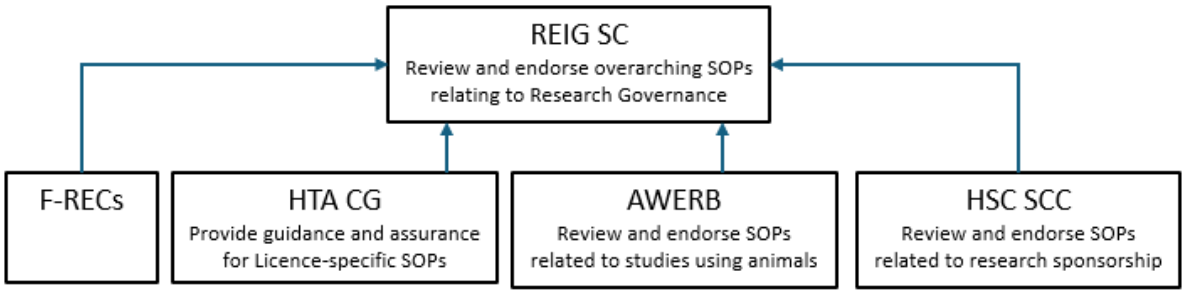
The framework requires that a research sponsor takes overall responsibility for a study being conducted in accordance with the applicable requirements.

The University of Sussex takes on the role of sponsor for a wide range of research studies being conducted within the NHS, Social Care**,** and prison settings.

☐ International Council for Harmonisation Guideline for Good Clinical Practice E6(R3)

- ☐ The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025
- ☐ The Medical Devices Regulations 2002
- ☐ Data Protection Act 2018
- ☐ UK General Data Protection Regulation (UK GDPR)
- ☐ Human Tissue Act 2004
- ☐ Mental Capacity Act 2005
- ☐ Animals (Scientific Procedures) Act 1986
- ☐ Ethical Framework for Obtaining Materials from Sentient Animals

At the University of Sussex, the Animal Welfare and Ethical Review Body (AWERB), the Health and Social Care Sponsorship Sub-Committee (HSC SSC), the Human Tissue Authority Licence Co-Ordination Group (HTA CG) and all Faculty-Research Ethics Committees (F-RECs) report to the Research Ethics, Integrity and Governance Sub-Committee (REIG SC) of Senate, see diagram below:



This SOP covers the writing of SOPs for all of these committees except the HTA CG and supports a series of SOPs describing the life cycle of a research study, from application through to study closure and archiving where appropriate.

HTA-licensed activities are excluded from this SOP because they fall under four individually held Human Tissue Authority Licences, each of which is the responsibility of its own Designated Individual, who is accountable for maintaining the relevant SOPs and seeking advice and guidance from the HTA CG where appropriate.

A consistent format is used for the development of SOPs. Appendix A to this document provides the template.

4. Responsibilities

- ☐ The Director of Research and Innovation Services or the Pro-Vice-Chancellor (Research and Innovation) (PVCRI) are responsible for the approval of new and updated SOPs relating to Research Governance.
- ☐ As the senior committee, the REIG SC is responsible for reviewing, and recommending the approval of, new and updated overarching SOPs relating to Research Governance that apply to the F-RECs and/or across the remit of multiple committees.
- ☐ The HSC SCC is responsible for reviewing, and recommending the approval of, new and updated SOPs relating to University of Sussex research sponsorship within its remit.

- ☐ The AWERB is responsible for reviewing, and recommending the approval of, new and updated SOPs relating to Research Governance that describe procedures specific to research involving animals or material derived from sentient animals.
- ☐ The HTA CG is responsible for providing guidance and assurance for HTA licence-specific SOPs.
- ☐ The Head of REIG is responsible for:
    - Co-ordinating the development, implementation, review and update of SOPs relating to Research Governance.
    - Developing SOPs where appropriate and ensuring that all SOPs relating to Research Governance are written, reviewed and approved by personnel with the appropriate experience and competency.
    - Reviewing draft SOPs relating to Research Governance (new documents, or updates to existing SOPs).
    - Ensuring that SOPs relating to Research Governance are reviewed and updated as necessary.
- ☐ All members of staff at the University of Sussex involved in writing, authorising, implementing, and/or reviewing SOPs relating to Research Governance must follow this SOP.
- ☐ Researchers with leadership or management roles are responsible for ensuring that researchers are aware of SOPs relating to Research Governance, where they can be accessed, and that they check the REIG web pages regularly to see if SOPs have been added or amended.
- ☐ Users of SOPs relating to Research Governance are responsible for reporting any issues or inadequacies to the REIG team.

5. Procedure

5.1. Development of new SOPs relating to Research Governance

5.1.1. The Head of REIG will assign all new SOPs with a reference of the format 'UOS-RIS-XXX-SOP-YYY'.

XXX will be:

GOV (for SOPs reviewed by the REIG SC), or

SSC (for SOPs reviewed by the HSC SCC), or

AWERB (for SOPs reviewed by the AWERB), and

YYY will be a sequential number 001, 002, 003 etc.).

5.1.2. The assigned author will produce the first draft using the template provided in Appendix A to this document.

5.1.3. On completion of the first draft, the document will be reviewed by the Head of REIG or an appropriate senior manager/delegated reviewer to ensure that the SOP:

- ☐ Contains all relevant sections.
- ☐ Is clear and easy to understand.

- ☐ Has appropriate cross referencing in place.
- ☐ Is in line with current standards, policies, and regulations.
- ☐ Reflects current/best practices.

5.1.4. The reviewer may seek input from persons with relevant expertise where necessary.

5.1.5. The final draft will be reviewed by the REIG SC, the HSC SSC or the AWERB as appropriate. They may recommend approval of the document as is or provide additional comments.

5.1.6. The assigned author will incorporate any changes requested by the REIG SC, the HSC SCC or the AWERB.

5.1.7. The finalised SOP will be approved by the PVCRI or the Director of Research and Innovation Services.

5.1.8. The assigned author will collect signatures for the cover page and complete the version history at the end of the document.

5.1.9. The finalised SOP will be uploaded onto the REIG web pages.

5.2. Review and update of SOPs relating to Research Governance

5.2.1. SOPs will be reviewed at least every three (3) years. They may undergo review sooner if there are changes to processes, guidelines, and/or regulations, or if a user identifies and reports issues or inadequacies to the REIG team. Depending on the extent or magnitude of the changes that may be required, the Head of REIG will decide whether an SOP requires immediate review, or whether it may wait until the next 3-year review date.

5.2.2. An appropriate author will be assigned to conduct an in-depth review of the SOP.

5.2.3. If the SOP does not require updating it will pass straight to committee for review (see Step 5.1.5 above).

5.2.4. If the SOP requires updating:

- ☐ The author will develop a draft version of the updated document using the template provided in Appendix A.
- ☐ On completion of the revised draft, the document will be reviewed by the Head of REIG or an appropriate senior manager/delegated reviewer (see Step 5.1.3 above).
- ☐ The final draft updated SOP will be reviewed by the REIG SC, the HSC SSC or the AWERB as appropriate. They may recommend approval of the document as is or have additional comments.

5.2.5. The assigned author will incorporate any changes requested by the relevant committee.

5.2.6. The finalised SOP will be approved by the PVCRI or the Director of Research and Innovation Services.

5.2.7. The assigned author will collect signatures for the cover page and update the version history at the end of the document.

5.2.8. The superseded SOP will be removed from the REIG web pages and replaced with the updated version.

5.3. Version control

5.3.1. An SOP will be called “draft” until it has been approved.

5.3.2. The first ever draft version will have version number 0.1 and any following drafts will be version number 0.2, 0.3 etc. Typically, the number changes following an update after further review of the draft.

5.3.3. The first approved version will have version number 1.0. Any draft updates following on from the first version will have version number 1.1, 1.2 etc. Any further approved versions will have version number 2.0, 3.0 etc.

5.3.4. The SOP version history on the document front cover will be amended with each change to the SOP.

5.4. Distribution and storage

5.4.1. The current version of all SOPs will be added to the REIG web pages once effective.

5.4.2. An electronic archive of all signed and approved versions of all SOPs will be kept by the REIG team in alignment with the timeframes specified in the University’s Master Records Retention Schedule, to ensure a clear audit trail.

5.5. Withdrawal

5.5.1. An SOP will be withdrawn from current use if it describes a process that is obsolete.

5.5.2. SOPs withdrawn from current use will be retained in the electronic archive maintained by the REIG team as per the University’s Master Records Retention Schedule.

6. Related documents

N/A

7. References

University of Sussex Research Ethics Policy

Code of Practice for Research

UK Policy Framework for Health and Social Care Research

International Council for Harmonisation Guideline for Good Clinical Practice E6(R3)

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

The Medical Devices Regulations 2002

Data Protection Act 2018

UK General Data Protection Regulation (UK GDPR)

Human Tissue Act 2004

Mental Capacity Act 2005

Animals (Scientific Procedures) Act 1986

University of Sussex Master Records Retention Schedule

Ethical Framework for Obtaining Materials from Sentient Animals

8. Appendices

APPENDIX A. Template for the development of SOPs related to Research Governance procedures.

APPENDIX B. Example of a procedural flow diagram.

VERSION HISTORY

Version number	Effective date	Reason for update
1.0	12-Oct-2026	Original version

APPENDIX A. Template for the development of SOPs related to Research Governance.

- ☐ Use pages 9 - 11 of this document as the template for writing SOPs.
- ☐ Ensure that you include the document title in the header and the document code and version number in the footer.

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□

Title of SOP

SOP reference:	UOS-RIS-XXX-SOP-YYY
Version number:	X.X
Date:	dd-mmm-yyyy
Effective date:	dd-mmm-yyyy
Next review date:	dd-mmm-yyyy

	Name	**Designation**	**Signature**	**Date**
Author:				dd-mmm-yyyy
Reviewer:				dd-mmm-yyyy
Approved by:				dd-mmm-yyyy

1. Purpose and scope

In a succinct way explain why this SOP is required. Describe what and who this SOP applies to.

2. Abbreviations

List all abbreviations used in the document (add/delete rows as required).

Typical example included below:

SOP	Standard Operating Procedure

3. Background

Describe the setting of the document, e.g., regulatory background, organisational requirement.

4. Responsibilities

This section describes who will do what. General terminology should be used, and some examples are given below.

☐ The Chief Investigator is responsible for approving and signing the Study Protocol.

☐ The sponsor is responsible for approving any modifications to the study.

5. Procedure

This section can be produced in a variety of formats.

As a numbered list:

5.1. As a numbered list

5.1.1. As a numbered list

As a bulleted list:

Useful if there is no specific order to be followed.

☐ As a bulleted list

- As a bulleted list

As a flow diagram:

If steps are taken in parallel or repeated, this may be easier and clearer to work with. An example is given in Appendix B of this document.

6. Related documents

List any related policies, procedures and/or tools. This section may not be relevant, in which case write N/A.

7. References

List any references used in the document. This section may not be relevant, in which case write N/A.

8. Appendices

List any appendices attached to the document. This section may not be relevant, in which case write N/A.

VERSION HISTORY

Version number	Effective date	Reason for update

APPENDIX B. Example of procedural flow diagram

