



Research Governance Office Sponsorship Standard Operating Procedures

Process for Creating, Reviewing, Approving and Publishing Standard Operating Procedures (SOPs)

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| SOP Reference | S-1000 |
| Version and Date | v7.0 April 2026 |
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| Job Title | Research Quality Assurance Officer |
| Reviewer/Approver | |
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| Job Title | Head of Research Governance |
| Signature |  |
| Date | 28 April 2026 |
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| Next Review Date | April 2030 |

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1.0 Introduction and Scope

Standard Operating Procedures (SOPs) are written guidelines designed to ensure tasks are carried out consistently and accurately. They outline what needs to be done, how it should be done, and who is responsible for each step.

This SOP outlines the process for the creation, approval, issue and control of SOPs used for the purposes of Research Governance or research activity that requires a Sponsor, according to the UK Policy Framework for Health and Social Care Research, within the UoL.

2.0 Definitions

Author(s)

The individual(s) responsible for drafting new SOPs or updating existing ones. Authors assess the need for an SOP or its revision, ensure that appropriate reviewers are assigned, and incorporate reviewer feedback. Authors must be suitably qualified and experienced to ensure the SOP provides a practical, accurate, and reliable description of the process.

Reviewer/Approver

A senior individual with the necessary experience and authority to review and approve an SOP. Their responsibilities include verifying the accuracy of content and compliance with all relevant regulations and guidelines, assessing the feasibility of the outlined process and ensuring consistency with the UoL's institutional standards. Approval confirms that the SOP is suitable, accurate, and ready for implementation.

Reader

The person who uses the SOP to understand and follow the required steps of a process.

Research Governance Office (RGO) SOP Catalogue

The SOP Catalogue is a controlled document maintained by the RGO. It provides a comprehensive record of all SOPs under its management. The catalogue includes key details for each SOP, such as:

- Title
- Reference number
- Superseded and current version(s) and date(s),
- Effective date(s).

Effective Date

As of 28 April 2026 the effective date of an SOP is defined as the date the document is published on the UoL Sitecore pages, making it publicly accessible to relevant users.

SOP Appendices, which may not require direct implementation by research teams, do not carry formal effective dates. However, to document their availability, the upload date to the UoL Sitecore pages will be recorded in the Effective Date column of the RGO SOP Catalogue. This approach ensures clarity on when SOPs and

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supporting documents become available, and helps maintain accurate records for governance and compliance purposes.

To allow sufficient time for user notification, training, and implementation, all RGO SOPs must be fully implemented by relevant staff within three months of their effective date.

3.0 Procedure

3.1 Identification of Need

Any UoL staff member may identify the need for a new SOP. When a request is made, it must be reviewed to determine:

- If the process is already covered by an existing SOP.
- If a new SOP is required.
- If an update to an existing SOP is required.

3.2 Assignment of Author

When a gap is identified, and a requirement for either a new SOP or an update to an existing SOP arises, a suitable individual must be assigned to draft the document.

3.3 Numbering, Naming, Version control,

3.3.1 Numbering

Each SOP must be assigned a unique reference. It should utilise the following format S-XXXX.

3.3.2 Naming

SOPs and their associated appendices documents should be named using the following structure;

S-XXXX_Short SOP name_YYYY-MM-DD_vX.X

S-XXXX_Appendix X name_YYYY-MM-DD_vX.X

3.3.3 Version Control

Each published iteration of an SOP/appendices must be clearly version and date controlled. Typically, minor revisions to an SOP result in a 0.1 increase to the version number, whereas more major revisions result in an increase of, or to the next, whole number (i.e., v1.2 = v2.0, v4.0 = v5.0).

A table detailing the changes made between subsequent revisions should be present within the 'Review Record' section of the SOP.

The SOP catalogue must be updated each time a new version of a document is published so that the history of each SOP, and its associated appendices, can be maintained.

3.4 Content Creation and Formatting

The author prepares the document(s), ensuring they reflect actual practice and regulatory requirements. SOPs should be written in a clear and concise manner

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and be as instructive as possible so that any trained individual can complete the SOP activity effectively. Any appendices should provide supplementary information that supports the SOP but is not essential to understanding the core procedure. For example, they may contain reference materials such as templates, forms, checklists, diagrams, technical data, or detailed examples that enhance usability without cluttering the main SOP.

Content should not include reference to data which may change on a regular basis (e.g., staff names and phone numbers). Where this is helpful to those undertaking a process, a webpage/working instructions document should be referenced which can be updated more easily.

Wherever reference is made to an activity covered by another SOP, the reference number of that SOP should be listed.

The format of the RGO SOPs should be standardised and therefore as of 28th April 2026 any new SOPs, or updates to previous SOPs should adhere to the formatting details contained in S-1000 Appendix 1.

3.5 Content Review and Approval

Once a document(s) has been drafted, it must be reviewed. This may involve individuals from external departments.

Any suggested changes during the review process should be carefully considered by the author and incorporated where appropriate. This step ensures the document(s) is accurate, practical, and ready for approval and implementation. Once the final version has been produced it must be approved by a reviewer/approver.

3.5.1 Review of Issued SOPs

All SOPs should be current and fit for purpose and must be reviewed at least every three years however, they may be reviewed or updated more frequently to reflect changes in practice or, following the introduction of new regulations or procedures. The 'Next Review' date for all Sponsor SOPs will be managed via the RGO SOP catalogue.

All individuals involved with an SOP (author, reviewer/approver, reader) are responsible for regularly reviewing SOPs. If any errors or deviations from current/best practice are identified in an SOP, these should be raised with the RGO.

Where an SOP is reviewed, but no changes are required, this must be documented in the SOP catalogue alongside the date the review was undertaken. The 'Next Review' date should be updated as appropriate. No changes should be made the SOP.

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3.6 Publishing

Following approval, the SOP will be published on the externally facing UoL Sitecore webpages and will be the only official version. Copies or print outs should be considered as uncontrolled versions.

4.0 Storage and Access

The SOP catalogue is the definitive list of SOPs and their supporting appendices, including all historic SOP versions. Copies of superseded versions of SOPs are available upon request.

5.0 Notification and Training

SOP users will be notified of SOP updates via the RGO bulletin. Users must familiarise themselves with the access arrangements and content of all SOPs applicable to their role. Training should be documented as per SOP S-1020.

6.0 Development Record

The table below summarises the revisions introduced in this version. Full historical change records are available within archived SOP versions.

| Date | Version number | Description of changes |
|------------|----------------|---|
| April 2026 | 7.0 | <ul style="list-style-type: none">• Changes to formatting as part of a standardisation exercise across RGO SOPs• Updates/clarification as to who can author and review/approve SOPs• Clarification as to how the SOP catalogue is maintained and how SOP effective dates are tracked.• Update of SOP process from identification of need through to publishing.• Removal of monitoring and audit criteria• Removal of office address• Removal of full historical SOP review record; only the latest approved revision is now displayed, with prior versions retained in the document archive• Other administrative changes |

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