Imperial College London

Research Governance and Integrity Team

Imperial College Healthcare NHS Trust

This is a controlled document.
The master document is posted on the RGIT website and any print-off of this document will be classed as uncontrolled.

Researchers and their teams may print off this document for training and reference purposes but are responsible for regularly checking the RGIT website for more recent versions

SOP Writing and Review

SOP Reference: RGIT_SOP_011	
Version Number: 9.0	
Effective Date: 01 Feb 2022	Review by: 19 Oct 2023
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Approved by: Ruth Nicholson, Head of Research Governance and Integrity	Date:

Version	Date	Reason for Change
Version 1.0	10 May 2007	1st Edition
Version 2.0	19 Jun 2008	Annual review
Version 3.0	08 Feb 2010	Formation of Joint Research Office
Version 4.0	14 Jul 2011	Annual Review
Version 5.0	30 Nov 2012	Annual Review
Version 6.0	18 Feb 2015	Scheduled Review
Version 7.0	11 Jul 2017	Scheduled Review
Version 8.0	19 Oct 2020	Scheduled Review Template removed and administrative changes to SOP. JRCO name change to RGIT
Version 9.0	01 Feb 2022	Update made on who can authorise and sign off SOP changes.

Table of Contents

1. PURPOSE

This Standard Operating Procedure (SOP) describes the process for writing, reviewing and implementing Imperial College Academic Health Science Centre (AHSC) SOPs. SOPs are written to enable the Sponsor to implement systems that assure the quality of every aspect of the clinical study.

At the highest level, SOP review ensures that at any time point, each of these SOPs will be fit for purpose and that they can be referenced unambiguously.

Imperial College London RGIT SOPs will be written to outline to achieve uniformity of performance of specific processes and procedures when approving, managing and conducting research at Imperial College.

2. INTRODUCTION

A SOP is a formal document that describes the procedures that must be followed to complete a task. All SOPs produced by the Research Governance and Integrity Team (RGIT) must be used in conjunction with our associated NHS Trusts and other Imperial College London and Imperial College Healthcare NHS Trust policies and procedures.

An important aspect of a quality system is to work according to unambiguous SOPs. The whole process from set up of research studies to archiving of completed studies should be described by a continuous series of SOPs.

Good Clinical Practice (GCP) clearly rules out the use of SOPs which represent vague statements of intent. It states that SOPs should be detailed and set out in writing. The RGIT has implemented GCP by means of SOPs that are written to an agreed format detailed in this SOP.

3. RESPONSIBILITIES

This SOP must be followed by the RGIT and the Chief Investigators (CI) and clinical trial teams of all proposed Imperial College sponsored studies. RGIT staff members involved in writing, reviewing or conducting a scheduled review must comply with this SOP.

It is the responsibility of the Head of Research Governance and Integrity to ensure that this SOP is updated by the review date or as necessary.

Imperial College AHSC SOPs are designed to be used as a template for individual departments and will require local tailoring by researchers and study teams to meet the requirements of individual projects.

4. PROCEDURE

4.1. Writing SOPs

Draft SOPs should be written on the RGIT SOP template, Appendix 1. Imperial College's adopted font is Arial therefore all SOPs must be written in this font. The Title

of the SOP must be size 26, headers must be size 12 and all other text must be size 11. Each SOP must contain the following headers:

1. Purpose
2. Introduction
3. Responsibilities
4. Procedure
5. References
6. Appendices

On completion of a draft RGIT SOP the document will be circulated to the reviewer(s) for comments. The reviewer(s) should provide comments in the manner directed. The author should consider all reviewers' comments and following any relevant discussion, incorporate as necessary. The author may choose to reject comments if they are not felt to be appropriate. This review will include but not be limited to readability, conciseness and accuracy of information.

4.2. Authorising SOPs

Once the final review has been completed by the author, the SOP is then sent to the QA team for final review and an allocation of the SOP number is added to the SOP.

Authorisation is the final stage of quality control before a RGIT SOP can be implemented. If the approver does not feel the SOP is fit for purpose they should make their comments and return the SOP to the Author to address the comments made.

Documents can only be authorised by the Head of Research Governance and Integrity Team (RGIT) who will sign the final hardcopy of the SOP before distribution. If there happens to be a time that the Head of RGIT is unable to sign off the SOPs, then the other members of the Senior Management Team (SMT): the Research Governance Managers (RGM) and the Clinical Trials Manager (CTM) are delegated the task of signing off and approving the SOPs. The SMT are able to sign off the SOPs relevant to their role and area of expertise i.e. if the SOP is in relation to CTIMP, then the CTM is able to sign off the SOP. The signed hardcopy will then be scanned and filed in the SOP folder in the following location: Q:\SOPs\All SOPS\Current\FINAL VERSION SOPS\signed SOPs.

If for any reason a hardcopy signature cannot be obtained, then the Head of RGIT would apply an electronic signature (RGIT_SOP_043) and the SOP is then filed in Q:\SOPs\All SOPS\Electronically Signed SOPs.

4.3. SOP referencing

Each RGIT and SOP template produced by the RGIT will be issued with a unique SOP number. This number identifies that the origin of the document is the Imperial College AHSC Research Governance and Integrity Team (RGIT) and whether it is an SOP or WPD (Working Practice Document) or is Imperial College Policy (IC) or a Template with the SOP number (001).

e.g. the reference number for this SOP is RGIT_SOP_011.
e.g. the reference number for a Template is RGIT_TEMP_0XX.

All templates associated with an SOP will be given a reference number and will only be updated when necessary changes are required that affect the process and compliance of trials or research conducted.

Templates needed for the study or clinical trial, mostly consisting of forms that are utilised by the research team and the site staff will also be given a reference number to identify templates. These templates will be identified as associated documents to the SOPs and non-associated documents which may cover guidance notes or templates. Templates which are generic will be given the same generic naming convention i.e. RGIT_TEMP_0XX. Any CTIMP related templates will be updated by the CTIMPs team on a need by need basis and the updated version will be released on the website and updated in the share drive. The CTIMPs team will be responsible with ensuring all the necessary teams have been notified of the new update and ensure when conducting any monitoring visits, the correct forms are being utilised on site.

4.4. Version Control

A SOP will be called “draft” until it has been authorised. The table on the front cover documents the SOP’s version history which should be amended with each change to the SOP. Once finalised, the document will be called “final” version 1.0 or the next whole version number. Updates to the SOP will result in an increase in version number.
Final ‘master’ copies will be accessed via the Trust, College and AHSC websites as appropriate and only the online versions will be listed as the active controlled document. Any print-off of SOP’s will be classed as uncontrolled documents and readers will be referred to the online library for up-to-date versions.

4.5. SOP review

All SOPs will have an effective date issued (date of implementation following authorisation by the Head of Research Governance and Integrity Team) and a review date. The review date will be set by default as 3 years from the effective date unless otherwise stated. SOPs will also be reviewed on an ad hoc basis as a result of amendments to legislation, process or organisational change.

During the 3 year review process an appropriate RGIT staff member will be assigned as an author to an SOP. It will be their responsibility to conduct an in-depth review of the SOP. The author’s checks must include but will not be limited to:

- Abbreviations and definitions
- Appendices
- Contacts
- Current Legislation
- Document/ web links
  - Ensure that any cited links are active and include the last cited date
- Language (including spelling and grammar)
- Organisational process
- References
- Accessibility
  - Check the accessibility function in the Review tab
  - Ensure descriptions have been added for all images/logo’s

- Ensure any tables present in the SOP is in a readable order which can be checked by tabbing through

A second RGIT staff member will be selected to be the reviewer of the temporary author's changes/updates. The reviewer should follow the process outlined in section 4.1 SOP Writing.

4.6. Distribution of SOPs

All SOPs will be added to the RGIT website once authorised. It is the responsibility of all staff at Imperial College to check the website regularly to check if SOPs have been added or amended.

4.6.1. Read & Acknowledge SOPs

Every member of the RGIT team will be required to read, sign and acknowledge every version of each SOP that is released. Within the hardcopy SOP folder located in the RGIT office there will be 2 templates that will need to be signed off.
Appendix 1 is titled: "SOP Read and Acknowledge Signature Log" (RGIT_TEMP_001) this template will be attached to every new SOP and will need to be signed. Following the completion of the 3 yearly SOP review, Appendix 2 will be signed off by the team which is titled: "All SOP Read and Acknowledge Signature Log" (RGIT_TEMP_002).

4.7. Clinical Trial Unit (CTU)/groups SOPs

Clinical trials may be managed/coordinated by delegated clinical trial groups e.g. CTU. These CTU/groups may choose to use RGIT SOPs to run the studies or using their existing set of SOPs, quality management system (QMS) to run/coordinate the study. If alternative QMS is agreed for use, RGIT will require to maintain oversight of this and the study as described in the 4.7. The CTU is responsible for the review, management and control of their own SOPs/QMS.

4.7.1. Internal Imperial CTU

For internal Imperial CTU where their own SOPs/QMS is used, the relevant CTU representative should complete the **Statement of compliance to RGIT SOPs: Appendix 4** and send to RGIT for review. Once the above document is completed, RGIT will review and agree/disagree with these deviations/discrepancies, for those that was disagreed the CTU SOP should be updated to comply with the RGIT SOPs (or RGIT SOP updated if there were errors). Any agreed discrepancy/deviation (by the RGIT) can be logged into **RGIT log of approved waivers Appendix 5.**

After this is completed, the cycle continues where the CTU representative will complete the **Statement of compliance to RGIT SOPs appendix 4** to only include the discrepancies covering the time period since the last form was reviewed and the whole process repeats. Once new discrepancies (if any) are agreed this will be added to the excel (document 2) which will now include old and newly agreed discrepancies.

4.7.2. External CTU

For studies where external CTU's are used (for limited studies), oversight of the procedure will be maintained on a case by cases basis including (but not limited to) obtaining satisfactory confirmation of CTU SOPs/QMS complies with relevant GCP and/or reviewing trial specific SOPs created for each study. The CTU will write their own trial specific SOP where RGIT will review these.

5. REFERENCES

ICH Guideline for Good Clinical Practice E6 R2

6. APPENDICES

The following Appendices list the following Templates associated to this SOP which can be found on the SOP, Associated Documents & Templates page.

Appendix 1 – SOP Read and Acknowledge Signature Log – RGIT_TEMP_001
Appendix 2 – All SOP Read and Acknowledge Signature Log – RGIT_TEMP_002
Appendix 3 - SOP Template – RGIT_TEMP_023
Appendix 4 - Statement of compliance to RGIT SOPs – RGIT_TEMP_024
Appendix 5 - RGIT log of approved waivers – RGIT_TEMP_025