# SOP Writing and Review

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| SOP Reference: RGIT_SOP_011 | |
| Version Number: 10.0 | |
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| Author: Wong, Cheuk Fung, Research Governance and Quality Assurance Manager | |
| Approved by: Keith Boland, Senior Clinical Trial Manager | Date: Keith Boland Digitally signed by Keith Boland Date: 2024.02.06 11:27:24 Z |

| 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<br>Template removed and administrative changes to SOP.<br>JRCO name change to RGIT |
| Version 9.0 | 01 Feb 2022 | Update made on who can authorise and sign off SOP changes. |
| Version 10.0 | 06 Feb 2024 | Scheduled review |

## 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.

The Imperial College London RGIT SOPs will be written to outline (and achieve performance uniformity 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 the SOPs produced by the Research Governance and Integrity Team (RGIT) must be used in conjunction with the 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 in line with unambiguous SOPs. The whole process from the setup of research studies to the archiving of completed studies should be described by a continuous series of SOPs.

The 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 as detailed in this procedure.

## 3. RESPONSIBILITIES

This SOP must be followed by the RGIT and chief investigators (CIs) and clinical trial teams of all proposed Imperial College sponsored studies. The 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 the RGIT to ensure that this SOP is updated by the review date or as necessary.

The 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. The Imperial College adopted font is the 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. Also, 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 the 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 the final review to include relevant SOP details including the allocation of a SOP number.

The authorisation is the final stage of quality control, before that an RGIT SOP can be implemented. If the approver does not feel that the SOP is fit for purpose, they should make their comments and return it to the author who will address the comments made.

Documents can only be authorised by the head of RGIT. If there happens to be a time that the head of RGIT is unable to sign off the SOPs (e.g., due to long absence), then the other members of the senior management team (SMT) (that is, the research governance managers, RGM, and clinical trials manager, CTM) are delegated the task of signing off and approving urgent SOPs. The SMT member will 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 will sign off the SOP. Also, the SOPs will have to be signed electronically as per the RGIT_SOP 043 and filed in the shared drive SOP folder.

If for any reason an electronic signature cannot be obtained, then the head of RGIT would sign the SOP with a wet-ink signature and file it in the shared drive SOP folder.

The PDF files of all authorised SOPs are available on the RGIT website. However, if an RGIT staff member requires the word version of a SOP (e.g., to update it), this can be requested to the QA team.

### 4.3. SOP referencing

Each RGIT SOP and template produced by the RGIT will be issued with a unique SOP number. This number identifies that the origin of the document is the IC AHSC RGIT and whether it is a SOP, WPD (Working Practice Document), an Imperial College Policy (IC) or a SOP associated template with a given number (00X). Please see some examples:

- 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 that are associated with an SOP will be given a reference number and will only be updated when changes are necessarily required, that is, when certain inaccuracies may affect the process and compliance of trials or research conducted.

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

### 4.4. Version Control

The SOP version history in the table on the document front cover should be amended with each change to the SOP. A SOP will be called “draft” until it has been authorised. Once finalised, the document will be called “final” version X.0 or the next whole version number. Any updates to the SOP will result in an increase in version number. The final ‘master’ copies of these documents will be saved within the RGIT shared drive and only the online versions will be listed as their active controlled document. Any print-off of SOPs will be classed as uncontrolled documents, and the readers will be referred to the RGIT website for any up-to-date versions of it.

### 4.5. SOP review

All SOPs will have an effective date (which is the date of implementation following authorisation by the head of RGIT) and a review date issued. By default, the review date will be set to 3 years from the effective date, unless otherwise stated. The RGIT SOPs will also be reviewed on an ad hoc basis, that is, as a result of any amendments to legislation, or process and/or organisational change. However, where there are changes that does not require immediate/urgent update e.g. typographical corrections etc these can be logged in the SOP Correction record tracker within the shared drive so that it can be implemented at the next review.

During the 3 yearly reviews, an appropriate RGIT staff member will be assigned as an author to a SOP, and it will be their responsibility to conduct an in-depth review of the SOP. The checks by the author must include but will not be limited to:

- Abbreviations and definitions
- Appendices
- Contacts
- Current Legislation
- Document/ web links: that is, 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/logos.
  - 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 changes/updates by the author. The reviewer should follow the process outlined in section 4.1 of this SOP.

### 4.6. Distribution of SOPs

All RGIT SOPs will be added to the SOP, Associated Documents & Templates page within the RGIT website once authorised. It is the responsibility of all staff at Imperial to check the website regularly and look for those SOPs that have been added or amended. Indeed, the RGIT QA team distributes the authorised SOPs/templates to the RGIT staff, and the QA Teams of the Imperial CTU (ICTU) and Imperial Clinical Research Facility only.

#### 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.

All RGIT staff members will be required to sign the RGIT_TEMP_001 (SOP read and acknowledge signature log – see appendix 1) for every new SOP that is released within 1 month (or immediately before they need to work by the relevant SOP).

Following the completion of a 3 yearly SOP review (where all SOPs are reviewed and approved together) or a new starter joining the team, the QA team will send the same template RGIT_TEMP_001 but detailing the latest SOPs and versions to the RGIT staff so they can read, acknowledge and sign off within 2 months.

Once all the signatures are completed QA team would check and validate all the signatures on log.

#### 4.6.2 SOP deviations

Whilst deviations from SOPs and processes are generally not expected, it is important to document these. For SOP deviations that are related to a specific study, the staff involved will document this within a file note and store it in the trial master file and sponsor file. For SOP deviations which are generic and not related to a particular study, the staff involved will document this within a file note in the shared drive. The RGIT QA team will keep track of all SOP deviations which are generic and not study related.

### 4.7. Clinical Trial Unit (CTU)/groups SOPs

Clinical trials may be managed/coordinated by delegated clinical trial groups e.g., CTUs. These CTUs/groups may choose to use the RGIT SOPs to run their studies or use their existing set of SOPs and quality management system (QMS) to

run/coordinate the study. If an alternative QMS is agreed for use, the RGIT will require to maintain oversight of this and assess this and the study as described in section 4.7. Please note that the CTU is responsible for the review, management and control of their own SOPs/QMS.

### 4.7.1. Internal Imperial CTU

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

After that this has been completed, the cycle continues: that is, the CTU representative will complete the **statement of compliance to RGIT SOPs (appendix 4)** to only include the discrepancies covering the period since the last form was reviewed and the whole process will repeat. Once the new discrepancies (if any) are agreed these will be added to the **RGIT log of approved waivers (appendix 5),** which will now include both old and newly agreed discrepancies.

### 4.7.2. External CTU

For studies where external CTUs are used (for limited studies), the assessment of the procedure to be used will be defined on a case by cases basis. This includes (but is not limited to) the RGIT QA team obtaining satisfactory confirmation that the CTU SOPs/QMS complies with the relevant GCP. For CTIMP studies, the CTU will write their own trial specific SOPs, and the RGIT CTIMP team will review these as part of their oversight of the study.

## 5. REFERENCES

**ICH Guideline for Good Clinical Practice E6 R2**

**RGIT_SOP_043 Electronic Signature**

SOP, Associated Documents & Templates page (RGIT website) (cited on 05/04/2023)

## 6. APPENDICES

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