

# Development, review and approval of Standard Operating Procedures (SOPs)

SOP ID: SOP\_1.0.0-DvtSOP-120831

## SOP development and approval

SOP developed by	Date	Associated document(s)
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Supersedes documents: N/A

## SOP Revisions

Approved by:	Date	Signature (only required for PoCoG hard copy)	Description of change(s)

Date Administered: 17/02/2012

Recommended date for review: 17/2/2014

## Foreword

The Psycho-oncology Co-operative Research Group (PoCoG) has developed a program of quality assurance for Psycho-Oncology Research. PoCoG's Quality System requires documentation of both management and procedural activities. This guidance document *Development, review and approval of Standard Operating Procedures (SOPs)*, provides a standard working tool to guide routine quality system management and technical activities.

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Psycho-oncology Co-operative Research Group 2011



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## Overview

A Standard Operating Procedure (SOP) is a set of written instructions that document a routine or repetitive activity which is followed by a research group, institution or facility acting under the auspices of PoCoG, to conduct either an endorsed or administered study or as a PoCoG member. The development and use of SOPs are an integral part of a successful quality system. It provides information to perform a task or process appropriately and consistently to ensure pre-determined specification and a quality end-result. SOPs describe both technical and operational elements of conducting research studies that would be managed under a Quality Assurance (QA) and Management Plan compliant with governmental and international regulations.

## Purpose

This SOP documents the processes for developing SOPs for trial processes such as the entry, maintenance and analyses of data, to facilitate consistent conformance to technical and quality system requirements and to support data quality.

## Scope

This SOP applies to the preparation and maintenance of PoCoG SOPs for research studies.

## Guiding Principles

Research studies should be conducted in accordance with applicable legislation and regulatory standards. Thus, this document has been guided by the following resources:

- [International Conference on Harmonisation of Technical Requirements \(ICH\)](#),
- [National Health and Medical Research Council National Statement on Ethical Conduct in Human Research](#) (henceforth referred to as the 'national statement'),
- The [Australian Code for the Responsible Conduct of Research](#),
- Note for [Guidance on the Good Clinical Practice, Annotated with Therapeutic Goods and Administration's](#) comments and the TGA's Australian Clinical Trial Handbook,
- [Declaration of Helsinki](#).
- [Other guidelines as applicable](#)

## Definitions and Abbreviations

Administrator	PoCoG staff member assigned to maintain the original SOPs and to distribute new/revised SOPs for review and approval.
Approver(s)	Person(s) authorised to approve the SOPs. For PoCoG SOPs this will be the Scientific Advisory Committee and PoCoG Chairs or their delegated authorities.
Author(s)	Responsible for developing the SOP according to the standards set out in this SOP. The author(s) of the SOP is anyone delegated responsibility for the preparation of the SOP by PoCoG.
Chief Investigator	An investigator sits on the <i>Trial/Study Management Committee</i> and is listed

	on the grant. The chief investigator will have had a role in the development of the research proposal and protocol
Clinical Trial/ Study	Any investigation in humans intended to discover or verify the effects and/or to identify any adverse reactions an investigational product(s) with the objective of ascertaining its safety and/or efficacy.
Principal Investigator	The investigator assigned the responsibility for the coordination of investigators at different centres participating in a multicentre trial. Often the principal investigator will lead the <i>Management Committee</i> and is also CIA. Also: Coordinating Investigator.
Quality Assurance (QA)	Assurance of quality is a set of preventive activities, which are focused on processes. In other words, all those planned and systematic actions that are established to ensure that the study is performed and the data are generated, documented (recorded), and reported in compliance with <i>Good Clinical Practice (GCP)</i> and the applicable regulatory requirement(s).
Quality Control (QC)	Quality control is a detection activity, which is focused on detecting the problems. The operational techniques and activities undertaken within the <i>quality assurance</i> system to verify that the requirements for quality of the study-related activities have been fulfilled.
Reviewer	Knowledgeable person who reviews the new/revised SOP.
Scientific Advisory Committee (SAC)	A group of individuals who have been assembled to offer advice on the scientific quality of studies.
Site Investigator	The person responsible for the conduct of the clinical trial at a trial site. They are also responsible for the clinical care of the patient. If a trial is conducted by a team of individuals at a trial site, the site investigator is the leader of the team. <i>NOTE: in the psycho-oncology non-intervention studies the clinical care of the patient remains with the treatment team while the conduct of the study at the site is the responsibility of the PI and the coordinating centre.</i>
Standard Operating Procedures (SOPs)	Detailed written instructions designed to achieve uniformity of the performance of a specific function.

## Qualifications and Responsibilities

The personnel developing the SOPs should have some expertise in the procedure and process being described or with the development of SOPs. They will be responsible for developing the SOPs and associated documents in accordance with national and international guidelines and regulations, as appropriate.

### 1. Procedure

#### 1.1. SOP Preparation

SOPs should be written by a team of individuals knowledgeable about the activity and PoCoG's internal structure. Involvement of a number of individuals will increase the quality of the SOP and will also promote "buy-in" from potential users of the SOP.

The SOP should be written with sufficient detail so that someone with limited experience with or knowledge of the process can successfully reproduce the process. The experience requirement for performing an activity should be noted in the section on personnel qualifications including whether a basic course or additional training is required.

Where possible and appropriate, the SOP should be flexible for use across study designs.

Language used should be concise and easy-to-read. The information presented should be unambiguous, step-by-step, and not overly complicated. The active voice and present verb tense should be used. The term "you" should not be used, but implied. Process flow diagrams may be used. Abbreviations should be limited unless an acronym is commonly used. Acronyms are to be defined when first mentioned in a procedure.

The length and format of the SOP should be determined by the decisions required and the steps involved in the procedure being described. For example, a simple procedure SOP may be a list of sequential steps, whereas a procedure with multiple decisions may require a combination of flowcharts and step-by-step instructions.

The flow chart (Figure 1) and PoCoG SOP template (see section 9.3) is to be used when developing SOPs.

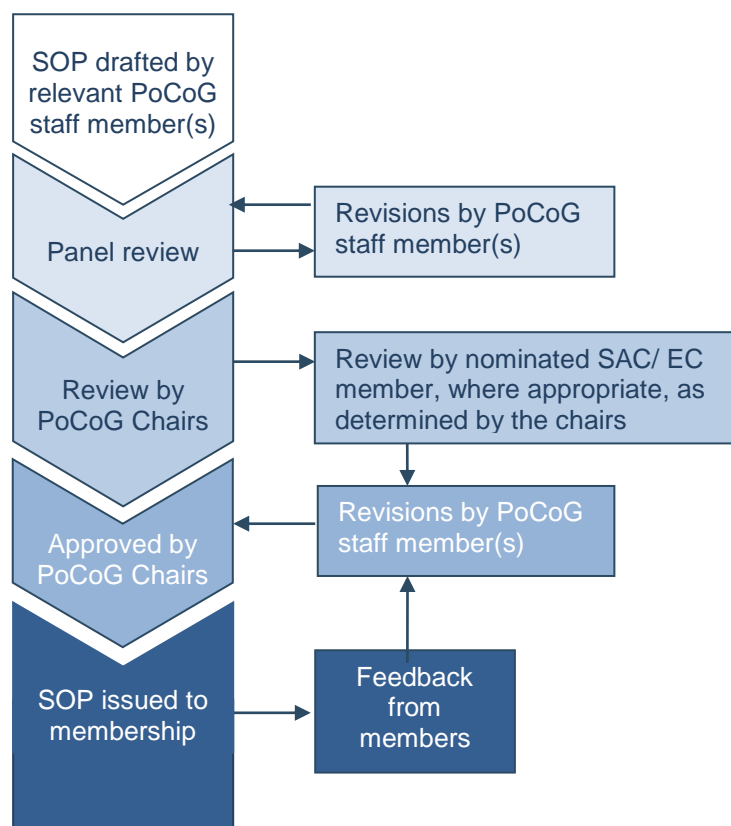


Figure 1: Flowchart for review and approval of SOPs

## 1.2. SOP content

Please refer to the SOP template for details on SOP content (see below).

## 1.3. Review Process

As shown in Figure 1 above, SOPs should be reviewed by one or more individuals with appropriate training and experience with the process (panel review). These individuals will include a review panel of 4-8 members, specifically formed for each SOP by the PoCoG Executive Office, and the PoCoG Chair and the Scientific Advisory Committee (SAC) chair. If the Chairs feel further input is needed they can nominate a member of the SAC to review the SOP. Appropriate revisions will be made based on these responses to the draft SOP. The draft SOP will then be posted on the PoCoG website with an email sent

to all PoCoG members requesting feedback within a 2 week time frame. The final draft will be approved by the PoCoG Chairs, who will sign and date it. This version will be released for use and dynamic evaluation (i.e. feedback from members will be continuously considered and appropriate revisions made to the documents). Hard copies and original signatures will be kept on file at PoCoG.

### 1.4. Dynamic Evaluation and Revision

It is especially helpful if draft SOPs are evaluated by individuals involved in research on an ongoing basis. Thus the SOPs will be released to the PoCoG membership for use. Members will have the opportunity, and will be encouraged, to give feedback to PoCoG and any difficulties or improvements that can be made. Feedback will be reviewed on an annual basis, and revisions will be made to the document by the author, with the same review processes as the original document.

## 2. Records management

Each page of an SOP, and associated documents, should have the following control documentation notation in the footer for easy reference:

<Abbreviated title of SOP> SOP-<type>-yymmdd	Last Reviewed: <Day Month Year> Page X of Y
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The PoCoG Executive Office will maintain a master list of all SOPs, which will contain details of SOP ID numbers, dated-versions (with activity logs), date of issuance, title, author, status, and any historical information regarding past versions. The current version of any SOP will be made available to PoCoG members on the PoCoG website. Outdated versions will be archived on the PoCoG server and limited to a read only format.

## 3. Quality Assurance (QA) - templates, forms and checklists

SOPs will be systematically reviewed a minimum of every two years by the PoCoG Executive Office, to ensure that the policies and procedures remain current, appropriate and relevant. The review date should be added to each SOP that has been reviewed. If an SOP describes a process that is no longer followed, it should be withdrawn from the current file and archived.

Suggested revisions to the SOPs should be emailed to [pocog.office@sydney.edu.au](mailto:pocog.office@sydney.edu.au).

### 3.1. SOP Template

A template is available for the development of an SOP (SOP\_1.3.1).

## 4. Appendix

### 4.1. Licensing

Based on conversations with Sydney University Copyright and Intellectual Property Services, PoCoG SOPs will be licensed under a [Creative Commons Attribution-NonCommercial 3.0 Unported License](#). This license lets others use and edit the documents non-commercially with acknowledgement.