<Title – this should clearly identify the procedure>

<**Instructions:** Throughout the template document you will note sections of bracketed text “< >” which represents either instructions or examples where text is to be placed.>

SOP ID: SOP-<type>-<yymmdd>

SOP development and approval

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **SOP developed by** | **Date** | | **Associated document(s)** | |
| <Name>  <Position> | <Date> | | **<File name>** | |
| Review panel: <Names> | | | | |
|  | |  | |  |
| **Approved by** | | **Date** | | **Signature** |
| <Name>  PoCoG Chair | | <Date> | |  |
| <Name>  PoCoG Scientific Advisory Committee Chair | | <Date> | |  |

**Supersedes documents:** <document>

SOP Revisions

|  |  |  |  |
| --- | --- | --- | --- |
| **Approved by:** | **Date** | **Signature** (only required for PoCoG hard copy) | **Description of change(s)** |
| <Name>  PoCoG Chair | <Date> |  |  |
| <Name>  PoCoC Scientific Advisory Committee Chair | <Date> |  |
| <Name>  PoCoG Chair | <Date> |  |  |
| <Name>  PoCoC Scientific Advisory Committee Chair | <Date> |  |

**Date Administered:** <Date>

**Recommended date for review:** <Date>

# Foreword

**<** Include here an explanation of what the document is, and contact details for queries.>

The Psycho-Oncology Cooperative Research Group (PoGoG) 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 <title>, provides a standard working tool for <explanation>.

Questions regarding this document should be directed to:

Research Program Manager

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Please refer to [www.pocog.org.au](http://www.pocog.org.au) for the latest version of this and associated documents.

# Table of Contents

< Include a list of the contents of the document with page references>

# Overview

<Provide a brief overview about the SOP>

# Purpose

<Describe the purpose of the work or process.>

# Scope

<Outline the scope and limits of the SOP.>

# Guiding Principles

<Reference any sources and legislation that are relevant to the procedure. In particular referencing the relevant International Conference on Harmonisation documentation on Good Clinical Practice and the National Health and Medical Research Council National Statement on Ethical Conduct in Human Research is recommended. An example is provided below: >

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 documentation on Good Clinical Practice (ICH-GCP, <http://www.ich.org/home.html>) and the Therapeutic Goods Administration (TGA) annotated version (<http://www.tga.gov.au/industry/clinical-trials-note-ich13595.htm>).
* the National Health and Medical Research Council National Statement on Ethical Conduct in Human Research (henceforth referred to as the ‘national statement’, <http://www.nhmrc.gov.au/publications/synopses/e35syn.htm>),
* The Australian Code for the Responsible Conduct of Research (<http://www.nhmrc.gov.au/publications/synopses/r39syn.htm>),
* Therapeutic Goods Administration’s Australian Clinical Trial Handbook (<http://www.tga.gov.au/industry/clinical-trials-handbook.htm>), and
* Declaration of Helsinki (<http://www.wma.net/en/30publications/10policies/b3/index.html>).

# Definitions and Abbreviations

<Define any specialized or unusual terms either in a separate definition section or in the appropriate discussion section. Define any acronyms or abbreviations (which should be limited unless an acronym is commonly used).>

# Qualifications and Responsibilities

<Identify any special qualifications users should have, such as certification or training experience, to complete the task satisfactorily. Denote any individual or positions having responsibility for the activity being described (accountability and responsibility must be included with every SOP).>

# Procedure(s)

<Denote what sequential procedures should be followed, divided into significant sections. Use figures and cartoons where helpful. It is often helpful to include a process flow chart.>

# Safety procedures

<Include here health and safety warnings for procedures that could result in personal injury or loss of life, emphasising the importance of adhering to the SOP, where relevant. Also address any precautions in relation to equipment damage or actions that may compromise results. List/ specify any equipment or materials required or calibration/standardisation that should be done. Where appropriate provide some trouble shooting advice.>

# Records management

<Denote which, if any, forms or software are to be used and locations of files, and indicate reports required and frequency. Also provide information about data and record storage and clarify any calculations that need to be performed (where appropriate list mathematical steps).>

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

<Generally, assurance of quality is a set of preventative activities which are focused on processes. Quality Control (QC) activities are those that detect defects in quality. Therefore, under the QA you outline the Quality Control (QC) activities (checks and tests) that are designed to allow self-verification of the quality and consistency of the work. These QC mechanisms are then used as part of the QA process to determine whether any corrective or preventative actions are required. Please describe the preparation of appropriate QC procedures (self-checks, such as re-counting or reidentification) and QC material (e.g. evaluation forms) that are required to demonstrate successful research practice. Specific criteria for each should be included. Describe the frequency of checks and discuss the rationale for decisions. Describe the limits/criteria for QC data/results and actions required when QC data exceed these limits/ criteria.>

## Checklists

<Include/ describe relevant checklists. Checklists included as part of a process are to be referenced at the points in the SOP where they are to be used. Remember that the checklist is not the SOP, but a part of the SOP >

## Forms

< Include/ describe relevant forms. Forms included as part of a process are to be referenced at the points in the SOP where they are to be used. >

## Templates

<Include/describe the relevant templates. Templates included as part of a process are to be referenced at the points in the SOP where they are to be used. For example:

The template for developing an SOP can be found at: <insert filepath/link> >

# References

<Cite all references noted in the body of the SOP. Documents or procedures that interface with the SOP should be fully referenced (including version), such as related SOPs, published literature, or methods manuals. Attach any that are not readily available.>

# Useful resources

<Include, where relevant, a list of useful resources.>