PERFORM Centre

Standard Operating Procedure

Guidelines for preparing Standard Operating Procedures

PC-SOP-GA-001-v05

Revision History

Version	Reason for Revision	Date
05	Removed guidelines for preparing PERFORM Operating Documents and simplified SOP. Changed Review period from 2 to 3 years.	January/21/2019

1. Overview

1.1 Purpose

The PERFORM Centre is a shared facility with many different core areas with vastly different research capabilities and modes of operation. The intent is to have a simple PERFORM-wide documentation system that ensures all users can easily implement a culture of quality at the PERFORM Centre.

The content of this standard operating procedure (SOP) provides guidelines for: preparing, reviewing and approving SOPs.

1.2 Scope

- SOP preparation and approval process
- Description of maintenance procedures for SOPs
- Procedure for numbering SOPs
- Guidelines for writing SOPs

This SOP will cover the overall practice and definitions for guidance documentation at the PERFORM Centre which includes the authorship, reviewing and approval process. Any other type of document is out of scope for this SOP.

1.3 Responsibility

- PERFORM Staff that is involved in composing an SOP needs to be trained on this SOP.

PERFORM Centre

- Scientific director ensures that this SOP is adhered to in all PERFORM SOPS.

2. Definition of Terms and Abbreviations

Area Manager	Person responsible for all activities in a given area of PERFORM such as the athletic therapy clinic, clinical analysis laboratories, conditioning floor, etc.
Custodian	Person responsible for assigning unique code to both SOPs and PODs as well as for proper administration, distribution, filing and archiving of official copies.
Project Lead	Person responsible for all aspects of a given project at PERFORM.
Standard Operating Procedure (SOP)	SOP's at PERFORM are any operating document that require a full review process and approval by the SD.
User	Person using space or equipment at the PERFORM Centre that has received adequate technical and safety training.

3. SOP Preparation and Approval Process

Some basic conditions for working in all areas of PERFORM are governed by PERFORM-wide SOPs (such a hazardous waste disposal, security, etc.) and will be referenced in the general administration SOPs.

All activities at PERFORM operate according to the overall policies of Concordia University. As such, authors and reviewers of guidance documents (e.g. – SOPs) must take care that there are no statements that are contrary to Concordia's set of policies.

Table 1 provides an overview of the SOP preparation and approval process.

Document Type	Content	Review period	Sign off
SOP ▼ Core Area	- Area health and safety - Proper conduct/local practices - Training needs	Max 3 years or as needed	Author Reviewer SD

Table 1: SOP preparation and approval process

PERFORM Centre

3.1 SOP Responsibility and Approval Process

In order for an SOP to take effect at PERFORM, it has to have the minimum sign off from the following individuals:
- Author
- Reviewer
- Scientific Director (SD)

The author, is responsible for gathering all the pertinent information and preparing the SOP in a clear and concise manner, keeping in mind that the reader may have no prior knowledge of the practices at PERFORM. The SOP should be a guide for the reader with cross referencing to other relevant documents or materials.

The author(s) is also responsible for determining the appropriate reviewer(s) for an SOP and for for taking the SOP through the approval workflow.

The reviewers, should be selected as subject matter experts and be familiar with both Concordia University's and PERFORM's SOP practices. Their role is to ensure that the content is accurate to the best of their knowledge. Multiple reviewers can split up the task according to the author's suggestions. There should be no more than 3 reviewers.

The scientific director ensures that the SOP is in line with PERFORM's quality standards and that it is compatible with other SOPs administered by PERFORM.

Once an SOP is in effect, it is the responsibility of the appropriate PERFORM staff members as well as principle investigators / projects leads and all users to ensure adherence to the SOP.

3.2 Workflow for SOP preparation

3.2.1 Custodian

Once an SOP is written and reviewed it is passed on to the custodian for numbering. The custodian maintains a record for all SOPs written at PERFORM. For new SOPs, when the initial review is completed and the SOP is finalized, the SOP will be assigned a new SOP number by the custodian.

3.2.2 SOP Numbering

SOP numbering will comply with the following format of 5 sub-units:

PC-SOP-GA-001-v01

- The first sub-unit (PC) identifies the PERFORM Centre ownership

PERFORM Centre

- The second sub-unit (SOP) identifies type of document as being a Standard Operating Procedure
- The third sub-unit (GA) refers to the abbreviated department name
- The fourth sub-unit (001) refers to the chronological order of the SOP starting with 001 and advancing chronologically with each new SOP issued
- The last sub-unit (v01) is the version control number
- Each sub-unit is separated by a dash line

The abbreviated names for each department are as follows:

GA: General Administration	**AT**: Athletic Therapy
MF: Multi-Function Areas	**CF**: Conditioning Floor
CP: Cardio-Pulmonary	**IM**: Imaging Suite
FA: Functional Assessment	**CA**: Clinical Analysis Suite
SL: Sleep Laboratories	**NS**: Nutrition Suite

The fourth subunit will be allocated by the custodian.

3.2.3 Archiving and dissemination of SOPs

The signed original of new or revised SOPs will be given to the SOP custodian who will file it in a safe place. The SOP will then be made available to users online as a controlled PDF document. This version will not include the authorization page. Once each user has read and understood the new and revised SOP, that user shall provide an electronic consent by clicking on the appropriate boxes.

It is the responsibility of all area managers and area supervisors to ensure that existing SOPs, either general or those specific or related to their departments, are read and followed, and that new departmental or core area SOPs are prepared as required.

All SOPs will be reviewed at least once every three (3) years to ensure that SOPs are updated.

If an SOP is no longer valid it will be taken offline and archived. The SOP number will not be used again.

3.3 Writing format for new or revised SOPs

All SOPs will be written according to the following guidelines:

PERFORM Centre

- Use Concordia standard font Gill Sans MT size 12 font.
- Where applicable, all SOPs will be written in the imperative or conditional present. This means that sentences will be constructed as commands (imperative) or will be declarative conditional phrases using "will", or "shall".
- Letter sizes for titles, subtitles and text will comply with the official PERFORM Centre template.
- All titles, subtitles, and text will be written in black. The only exception will be the PERFORM Centre header, and the footer, on the original authorized SOP.

3.4 Sections for SOPs

3.4.1 Header

Contained in the header are:
- On the left side: The current PERFORM Centre/Concordia University wordmark
- On the right side: The SOP reference number

3.4.2   Footer

Contained in the footer are:
- On the left side: the SOP reference number (same as in the header)
- The following statement in the center: "Printed copies are not controlled"
- On the right side: page number with both current and total page numbering (do not include the sign off page)

3.4.3   First page

The first page must include the following information at the top of the page:
- **Document type** (ie: SOP)
- **SOP title**
- **SOP number**
- **Revision history**: This should be presented as a table containing the latest version number, reasons for revision with a brief description of the changes made, and the date that the SOP was signed off and put into effect.

3.4.4   Overview

Sections included in the overview may include:
- **Purpose**; Provide a short paragraph for the reader to be able to quickly assess the content of the SOP. Specify the objectives of the SOP.
- **Scope**; where the applicability and what the SOP controls is described. Also included is what the SOP does not control where there is a possibility of confusion.

PERFORM Centre

- **Responsibility**; describe in detail the responsibility of Principle Investigators/Researchers/PERFORM staff for following the SOP.

3.4.5. Definitions of terms and abbreviations

The terms used in the SOP are clearly defined, especially when using words that can be open to interpretation. Avoid repeating definitions oulined in other relevant SOP.

3.4.6   Training

Training requirements can be described as well as the supervisory structure and responsibilities.

3.4.7   SOP Content

The organization and material that is contained in the SOP content section is left to the author's best judgment. However, some items should be discussed, such as:

- Cascading numbering system should be used (e.g. 1.1.2)

- Forms pertaining to the procedure (referred to in the text of the SOP) should be referenced.

Note: Templates for SOPs are made available in word format on the BookR.