Standard Operating Procedure

Guidelines for preparing Standard Operating Procedures (SOPs)

PC-SOP-GA-001-v06

Revision History

Version	Reason for Revision	Date
06	To reflect the change from the PERFORM Centre to the School of Health.	July/4/2023

1. Overview

1.1 Purpose

The intent is to have a simple documentation system that ensures a safe and effective working environment for the School of Health, housed in the PC building, This is a shared facility with vastly different research areas, capabilities and modes of operation.

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 School of Health which includes the authorship, reviewing and approval process.

1.3 Responsibility

- Staff: Will be composing SOPs, based on the training they receive and the guidance of this document
- The Director, School of Health: Ensures that this SOP is adhered to in all SOPS.

2. Definition of Terms and Abbreviations

Area Manager	Person responsible for all activities in each area of The School of Health such as the athletic therapy clinic, clinical analysis laboratories, conditioning floor, etc.
BookR	Term referring to the booking system for the School of Health.
Custodian	Person responsible for assigning unique code to all operating documents 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 The School of Health.
Standard Operating Procedure (SOP)	An operating document that clearly documents a process to be followed in the PC building.
User	Person using space or equipment in the PC building that has received adequate technical and safety training.

3. SOP Preparation and Approval Process

Some basic conditions for working in all areas of the PC building are governed by a center-wide SOPs (such a environmental health and safety trainings, security, etc.) and will be referenced in the general administration SOPs.

All activities related to the School of Health 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 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 Director, School of health

Table 1: SOP preparation and approval process

3.1 SOP Responsibility and Approval Process

In order for an SOP to take effect, it must meet approval from the following individuals:
- Author
- Reviewer
- Director, School of Health

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 Concordia. The SOP should be a guide for the reader and cross reference other relevant documents or materials.

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

The reviewers, should be selected as subject matter experts and be familiar with Concordia University 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 Director, School of Health ensures that the SOP is in line with the University's quality standards and that it is compatible with other SOPs administered by the School of Health.

Once an SOP is in effect, it is the responsibility of the appropriate School of Health staff as well as principle investigators / project leads and all users to review and adhere 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 for the School of Health. 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 building location
- 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
CA: Clinical Analysis Suite	**CF**: Conditioning Floor
FA: Functional Assessment	**IM**: Imaging Suite
NS: Nutrition Suite	**PS**: Physiological Suite
SL: Sleep Laboratories	

The fourth subunit will be allocated by the custodian.

3.2.3 Archiving and dissemination of SOPs

The signed SOPs will be maintained by the SOP custodian who will store them accordingly. The SOP will be made available to users online as a controlled PDF document. This version will not include the authorization page.

It is the responsibility of all School of Health staff to ensure that existing SOPs, either general or those specific or related to their lab or area, are read and followed, and that new lab or 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:
- 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 current Concordia University template.
- All titles, subtitles, and text will be written in black. The only exception will be the Concordia University 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: Concordia University logo
- 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.
- **Responsibility**; describe in detail the responsibility of Principle Investigators/Researchers/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 outlined 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.