Standard Operating Procedure

Guidelines for preparing Standard Operating Procedures and PERFORM Operating Documents

Revision History

<table>
<thead>
<tr>
<th>Version</th>
<th>Reason for Revision</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>02</td>
<td>Update to current template</td>
<td>Sep/11/2014</td>
</tr>
<tr>
<td></td>
<td>Reflect current practices</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Reflect leadership change from CAO to SD</td>
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<tr>
<td></td>
<td>• Updated list of definitions</td>
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<td></td>
<td>• Updated archiving and dissemination procedures</td>
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</tr>
<tr>
<td>03</td>
<td>Name change: teaching laboratory and group training room will all be named “multi-function laboratories”.</td>
<td>Nov/14/2014</td>
</tr>
<tr>
<td>04</td>
<td>Correction to revision history</td>
<td>Mar/20/2015</td>
</tr>
<tr>
<td></td>
<td>• Removed “change platform name from “Specialized Lab” to “Flexible Lab” ”</td>
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Summary

The content of this standard operating procedure (SOP) provides guidelines for: preparing, reviewing and approving SOPs as well as PERFORM operating documents (PODs). General guidelines regarding protocols are also given. Definition of terms will be covered and working templates are provided.
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1. Definition of Terms

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<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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</thead>
<tbody>
<tr>
<td>Area Manager</td>
<td>Person responsible for all activities in a given area of PERFORM such as the athletic therapy clinic, clinical analysis laboratories, conditioning floor, etc.</td>
</tr>
<tr>
<td>Custodian</td>
<td>Person responsible for assigning unique code to both SOPs and PODs as well as for proper administration, distribution, filing and archiving of official copies.</td>
</tr>
<tr>
<td>PERFORM</td>
<td>The PERFORM Centre at Concordia University.</td>
</tr>
<tr>
<td>PERFORM Employee</td>
<td>Concordia employee that has been assigned to PERFORM.</td>
</tr>
<tr>
<td>PERFORM operating document (POD)</td>
<td>Operating documents that are specific to an instrument or technique that require approval by area managers.</td>
</tr>
<tr>
<td>Scientific Director (SD)</td>
<td>Senior executive of PERFORM responsible for all research and administrative aspects of the centre.</td>
</tr>
<tr>
<td>Standard Operating Procedure (SOP)</td>
<td>SOP’s at PERFORM are any operating document that require a full review process and approval by the SD.</td>
</tr>
<tr>
<td>Users</td>
<td>Person using space or equipment at the PERFORM Centre that has received adequate technical and safety training.</td>
</tr>
</tbody>
</table>

2. Introduction

2.1 Background

The objective of this SOP is to provide the overall rationale and guidance on preparing SOPs and PODs that are implemented at the PERFORM Centre. 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.

2.2 Purpose

- Define documentation framework for guidance documents at PERFORM
- SOP and POD preparation and approval process
- Description of maintenance procedures for SOPs and PODs
- Procedure for numbering SOPs and PODs
- Guidelines for writing SOPs and PODs
- General guidelines for writing protocols
2.3 Scope

The scope of 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.

2.4 Responsibility

- PERFORM Staff that is involved in composing an SOP or POD needs to be trained on this SOP.
- Area Managers ensure that this SOP is adhered to regarding PODs.
- Scientific director ensures that this SOP is adhered to regarding SOPs.

2.5 Relevant Documents

Not applicable

3. Guidance Documentation Framework for PERFORM

The workflow of activities at PERFORM is covered by the following framework:

\[
\text{SOP} \leftarrow \text{multiple PODs} \quad \text{POD} \leftarrow \text{multiple protocols}
\]

SOP: Operating within a given physical and/or functional (="core") area of PERFORM, such as Clinical Analysis, is detailed by few SOPs.

POD: Within that functional/core area, there may be specific tasks, or equipment. The operation of each apparatus is governed by a single POD.

Protocol: On any given machine, a wide variety of possible protocols can be developed.

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 core area SOP.

Figure 1 provides an overview of the guidance documentation framework at PERFORM. All activities at PERFORM operate according to the overall policies of Concordia University. As such, authors and reviewers of guidance documents must take care that there are no statements that are contrary to Concordia’s set of policies.
3.1 Standard Operating Procedure (Overview)

As summarized in Figure 1, SOPs are area specific and are meant to cover general health and safety as well as proper conduct and local practices. The SOP should have common elements for all areas as well as address area specific regulations or protocols. The structure of the SOPs should be similar in that they start with PERFORM-wide policies and procedures followed by area specific description for proper conduct. The review period for SOP is up to 2 years.

3.2 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 complete reference for
the reader with cross referencing to other relevant documents or materials. For
instance, if the SOP is providing guidance on proper health and safety, the source
document from Concordia University should be referenced or even provided for the
reader’s convenience.

The author(s) is also responsible for determining the appropriate reviewer(s) for an
SOP. For instance, if there are health and safety, biosafety, and radiation issues covered
in the SOP, then representatives from each of these operation units should be included
as a reviewer on the SOP. Authors should also consider including potential users of the
facilities if this is feasible.

Finally, the author is responsible for taking the SOP through the approval workflow as
described on Figure 2.

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.

The scientific director ensures that the SOP is in line with PERFORM’s mission of quality
and that it is compatible with other SOPs and PODs administered by PERFORM. The
SD also ensures the dissemination and implementation of a new or revised SOP. Once
signed, the SOP will become effective after 10 working days to allow distribution and
reading of the final version by those affected by the SOP.

Once an SOP is in effect, it is the responsibility of all PERFORM staff members as well as
principle investigators and their research team to ensure that the SOP is adhered to.

3.3 PERFORM Operating Document (Overview)

The PODs provide general guidance on using a particular instrument or piece of
equipment. PERFORM is a shared facility, as such all users need to understand the
procedures for keeping equipment in proper working order. This is not just as a
courtesy to others but it is an imperative that the data generated at PERFORM meets
minimum quality standards.

Any information that a user would need to know before using a particular instrument at
PERFORM should be included. Topics that would be covered in a POD include (but are
not limited to):

- Health and Safety concerns regarding a particular instrument
- Preventative maintenance requirements
- Operational qualifications
3.4 POD Responsibility and Approval Process

Authors, like with the SOP, are responsible for gathering all the relevant information for a particular instrument (or group of similar instruments), and preparing a clear, concise but complete POD. The POD should be understandable by a lay person who is untrained with this particular equipment. Note: This does not mean the instrument’s manual needs to be re-written, but it should be referenced and made available to the potential user during their training.

Authors, with the help of their line manager, should also identify appropriate reviewers for the POD they are preparing.

Reviewers should be selected as subject matter experts and should be particularly concerned with the content of the POD. Thus, like the SOP, if there are particular health and safety issues that need be addressed, then reviewers should include the relevant members of Concordia’s Environmental Health & Safety department.

Area managers provide the final sign off of a POD. They are responsible for ensuring that the POD is in line with PERFORM’s overall quality objectives, that it's compatible with the activities conducted in their area of responsibility and that the POD follows the general guidelines provided in this SOP. They are also responsible for archiving, disseminating and implementing a new POD. Note: Area managers can also be authors on a POD.
4. Preparation of an SOP

4.1 Workflow for SOP preparation

The SOP preparation workflow should follow the process as described in Figure 2.

Figure 2: SOP workflow. Authors prepare initial draft which gets reviewed. Once draft is finalized the custodian will assign a unique number and the SD will provide the final approval. The author is responsible for the document until the SOP receives final sign off, at which point it is filed by the SOP custodian.
4.2 Custodian

Once an SOP is written and reviewed it is passed on to the custodian for numbering. The custodian retains a spreadsheet for all SOPs written at PERFORM, and is the only person allowed to give an SOP a number. For new SOPs, when the initial review is completed and the SOP is finalized, the SOP will be assigned a new SOP number from the custodian. The custodian will register this number into the SOP spreadsheet, so it cannot be duplicated.

4.3 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
- 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:

<table>
<thead>
<tr>
<th>GA: General Administration</th>
<th>AT: Athletic Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>MF: Multi-Function Laboratories</td>
<td>CF: Conditioning Floor</td>
</tr>
<tr>
<td>CP: Cardio-Pulmonary</td>
<td>IM: Imaging Suite</td>
</tr>
<tr>
<td>FA: Functional Assessment</td>
<td>CA: Clinical Analysis Suite</td>
</tr>
<tr>
<td>SL: Specialized Laboratories</td>
<td>NS: Nutrition Suite</td>
</tr>
</tbody>
</table>

The fourth subunit will be allocated by the custodian.

4.4 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. For users that do not have access to the PERFORM web site to review SOPs, a copy will be emailed to the user. That user will
then sign and date the SOP reading record form (see Appendix I) with the relevant SOP number. The SOP reading record form shall be used to track acknowledgement and compliance of all authorized SOPs at the PERFORM Centre. The custodian is responsible for the maintenance and storage of each SOP reading record form. It is the responsibility of all managers and area coordinators 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 two years to ensure that SOPs are updated.

4.4 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 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.

4.5 Mandatory Sections for SOPs

4.5.1 Cover page

The cover page must include the following information

- **Document type** (ie: SOP)
- **Title**
- **Document Code**
- **Revision history**: This should be presented as a table containing the 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.
- **Summary**: Provide a short paragraph for the reader to be able to quickly assess the content of the SOP.

4.5.2 Table of Contents

4.5.3 Header

Contained in the header are:

- On the left side: The current PERFORM Centre/Concordia University wordmark
PERFORM Centre

- On the right side: The SOP reference number

4.5.4 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)

4.5.5 Introduction
Sections included in the introduction are:
- **Background**: where information is given to the reader as to the reasons for creating the SOP.
- **Purpose**: where the objectives of the SOP are described.
- **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/PERFORM staff for following the SOP.
- **Relevant documents**: a list of policies or other associated SOPs that are reference material for the current SOP.

4.5.6 Definitions
The terms used in the SOP are clearly defined, especially when using words that can be open to interpretation.

4.5.7 Training
Training requirements for an SOP should be described as well as the supervisory structure and responsibilities.

4.5.8 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 placed as an Appendix to the SOP and clearly identified as “Recommended Sample or Form.”
5. Preparation of a POD

5.1 Workflow for preparing a POD

Figure 3: POD workflow. Authors prepare the initial draft and may ask appropriate reviewers to also sign off on the document. Manager provides the final sign off for PODs. Note that in cases where the manager and the author are the same person then it is strongly recommended to obtain at least one reviewer.

5.2 Assigning a POD number

The custodian will assign a new POD number which complies with the following format of 5 sub-units:

PC-POD-GA-001-v01

- Where the first sub-unit (PC) identifies the PERFORM Centre ownership.
- The second sub-unit (POD) identifies type of document as being a PERFORM Operating Document.
- The third sub-unit (GA) refers to the same abbreviated names for the area in which the POD will be in effect as described in section 4.3 (SOP Numbering).
- The fourth sub-unit (001) refers to the chronological order of the POD starting with 001 and advancing chronologically with each new POD issued.
- The last sub-unit (v01) is the version control number.
- Each sub-unit is separated by a dash line.

5.3 Archiving and Disseminating PODs

The custodian responsible for storage and dissemination of PODs. They will ensure that PODs are made available online, and that the signed copy is stored in a safe
location. Managers need to ensure that PODs are being followed within their area and that appropriate training is administered to users.

5.4 Writing format for new or revised PODs

All PODs will be written according to the following guidelines:
- Use Concordia standard font Gill Sans MT size 12 font.
- Where applicable, all PODs 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 POD

5.5 Mandatory Sections for PODs

1. Cover page

The cover page must include the following information
- Document type (ie: POD)
- Title
- Document Code
- Summary: Provide a short paragraph for the reader to be able to quickly assess the content of the POD

2. Table of Contents

3. Header

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

4. Footer

Contained in the footer are:
- On the left side: the POD 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)
5. Main body of the POD

This is left to the author’s best judgment with the only guideline being that PODs should be prepared so that they can be understood by a lay person. Topics covered should be:

- Specific health and safety considerations and needs for the equipment that the POD refers to
- Training requirements
- Local practice regarding a certain equipment as a shared facility

Note: Templates for SOPs and PODs are made available in word format.

6. General Guidelines for Protocol Preparation

Each study conducted at the PERFORM Centre will generate specific protocols for either data collection or analysis. Some of these protocols will be owned and managed by PERFORM, but most will be owned and managed by the principle investigator associated to a study. Typically a protocol is defined as the culmination of method development and validation for use of equipment or analytical instrumentation. As such, it is the principle investigator’s responsibility that the protocol developed is compatible with PERFORM’s SOPs and PODs. In special circumstances a protocol may be promoted to either a POD or SOP depending on the investigator’s regulatory needs for a specific study.

The format and content of written protocols is at the investigator’s discretion. However, PERFORM does provide a suggested template for protocols. Protocols should be written in a clear concise manner with clear definitions for technical terms and acronyms and that all reference materials are easily attainable by the reader.

Note that it is the principle investigator’s responsibility to ensure that any protocol run at PERFORM conforms to Concordia policy matters such as ethics and health and safety. For example, protocols that involve human subjects or specimen samples or even data analysis on humans, have to be reviewed and approved by the Concordia University’s human research ethics committee.
APPENDIX I

SOP Training Record Form
SOP Training Record

SOP Title

SOP Code

<table>
<thead>
<tr>
<th>Ownership</th>
<th>Document type</th>
<th>Area</th>
<th>SOP Number</th>
<th>Version</th>
</tr>
</thead>
<tbody>
<tr>
<td>PC</td>
<td>SOP</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Training Record

<table>
<thead>
<tr>
<th>Full Name</th>
<th>Institution</th>
<th>Contact (email or phone number)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Signature

Sign here and return to SOP custodian

Date
APPENDIX II

POD Training Record Form
POD Title

POD Code

<table>
<thead>
<tr>
<th>Ownership</th>
<th>Document type</th>
<th>Area</th>
<th>SOP Number</th>
<th>Version</th>
</tr>
</thead>
<tbody>
<tr>
<td>PC</td>
<td>POD</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Training Record

<table>
<thead>
<tr>
<th>Full Name</th>
<th>Institution</th>
<th>Contact (email or phone number)</th>
</tr>
</thead>
</table>

Signature

_________________________    __________________________
Sign here                     Date
PERFORM Centre

**SOP Title**

*Guidelines for preparing Standard Operating Procedures and PERFORM Operating Documents*

**SOP Code**

<table>
<thead>
<tr>
<th>Ownership</th>
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<tbody>
<tr>
<td>PC</td>
<td>SOP</td>
<td>GA</td>
<td>001</td>
<td>04</td>
</tr>
</tbody>
</table>

**Training Record**

<table>
<thead>
<tr>
<th>Full Name</th>
<th>Institution</th>
<th>Contact (email or phone number)</th>
</tr>
</thead>
</table>

**Signature**

Sign here and return to SOP custodian

Date