

How to Write a Standard Operating Procedure

SOP # 001.1 Version # 1

1. Scope:

This document applies to the preparation of a Standard Operating Procedure (SOP) within the Human Metabolome Project regarding common procedures, like: laboratory compounds analysis, chemical acquisition procedures, sample identification, biosafety certification, obtaining ethics approval, sample collection, et cetera.

2. Objective:

This document describes how to write an SOP and illustrates the format design and guidelines for the preparation of all Human Metabolome Project SOPs.

3. Procedure Description:

This procedure *-How to Write a Standard Operating Procedure-* provides a rule to format and structure all future SOPs for the Human Metabolome Project, to establish a consistent approach for the SOP writing process.

All SOPs must contain the following:

3.1.Header/Footer: The standard format is a Header with the SOP's title, number, and version ID. The Footer contains the SOP's author name, page number of, creation and approval dates.

3.2.Scope: The scope is to whom and what the document applies.
Example: This document applies to SOPs writing.

3.3.Objective: The SOP aims to harmonize the procedures carried out.
Example: This SOP sets formatting standards.

3.4.Procedure: The SOP describes the steps to perform the procedure. Where necessary will refer to supplementary documentation (i.e. when there are a large number of steps).

3.5.Materials: The SOP describes the materials used.
Example: A procedure involving a chemical compound (i.e. Glucose) will indicate purity, concentration, amount, and any other pertinent information.

3.6.Equipment: The SOP describes equipment, its function and operational steps.
Example: How to measure pH with the pH meter.

3.7.Documentation: The SOP brings up all supplementary documents, and cross-references with other SOPs, as well as their location both electronically and hardcopy.

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3.8.Safety: The SOP addresses all safety issues regarding the task.

Example: The SOP describes any necessary steps to perform a safe work (i.e. wear a mask) as well as the location of the Materials Safety Data Sheets (MSDS).

3.9.Records: The SOP states where to annotate and keep records (electronic and hardcopy).

3.10.Responsibilities: The SOP assigns responsibility for the procedure. Name and dated signatures are mandatory for SOP author, reviewer, and approval.

3.11.Signatures: Authors, Reviewers, and Authorizing signatures should be attached at the end of the document, with date of approval.

4. Process:

4.1.This document gives detailed instructions to consistently perform the work, in a consistent and repeatable fashion. It may be useful for training; however, is not intended to replace it.

4.2.When the process involves numerous steps, SOPs should be written to describe sub processes (i.e. a buffer preparation, necessary for an analysis), and cross referenced by title/ID.

5. Format:

5.1.The SOP should be divided in sections (where appropriate):

- 5.1.1. Header/Footer
- 5.1.2. Scope
- 5.1.3. Objective
- 5.1.4. Materials
- 5.1.5. Equipment
- 5.1.6. Documentation
- 5.1.7. Safety
- 5.1.8. Records
- 5.1.9. Description

5.2.Document formatting:

- 5.2.1. Header/Footer
- 5.2.2. Maintain style and consistency across documents to assist in their readability.
- 5.2.3. State scope and objective at the beginning.
- 5.2.4. Give a descriptive title. Provide a tentative ID.
- 5.2.5. Illustrate the procedure by dividing it in small steps, described in one sentence.
- 5.2.6. Avoid a long list of bulleted items (<12).
- 5.2.7. Emphasize topics where mistakes are more likely to occur.

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6. Responsibility:

6.1. Author:

- 6.1.1. Follow this procedure to write SOPs.
- 6.1.2. Submit a draft for review and approval.
- 6.1.3. Cite reviewers and distribution list.

6.2. Reviewer(s):

- 6.2.1. Provide feedback and (if) necessary corrections.

6.3. Approval:

- 6.3.1. The SOP requires approval from Dr. David Wishart.

This SOP was written by: Dan Tzur _____

This SOP was formatted by: Dan Tzur _____

This SOP was reviewed by: _____

This SOP was authorized by: Dr. D Wishart _____

Date: _____