



CHAPTER 5: Writing and Revising SOP

1. Writing and Revising Standard Operating Procedures (SOPs)
2. Writing SOPs
3. Revising SOPs
4. Version History

Authored by: DLSMHSI-IEC Secretariat

Approval/Effective
Date: November 2019

Approved by: (original signed)

Charles Y. Yu, MD, MSc, FPCP, FPCCP
Vice Chancellor for Research



1. Writing and Revising Standard Operating Procedures (SOPs)

1.1 Purpose

To define the process for writing and revising Standard Operating Procedures (SOPs) used by the De La Salle Medical and Health Sciences Institute-Independent Ethics Committee (DLSMHSI-IEC).

1.2 Scope

This SOP provides instructions on how the DLSMHSI-IEC SOPs are prepared, approved and distributed.

1.3 Responsibility

1.3.1 It is the responsibility of the Chair of DLSMHSI-IEC to appoint an SOP Team to formulate or revise the SOPs of the DLSMHSI-IEC. The Chair designates the members of the team, initiates approval processing of final version of SOPs, and submits the SOP to the Vice Chancellor for Research (VCR) for final approval.

1.3.2 The SOP Team is an ad hoc committee composed of appointed DLSMHSI-IEC members composed of at least three (3) members together with the IEC Secretariat, and with invited resource persons. The team is responsible for proposing and formulating new SOPs, and reviewing and revising existing SOPs when necessary. The team must follow existing procedures, format, and coding system of the hospital when drafting or editing any SOP's of the hospital, and consult the Secretariat and Chair about the need for new or revised versions of SOPs. The team submits SOP drafts to the Chair for approval processing. The Secretariat is responsible for coordinating the writing and revising of SOPs, maintaining current SOPs with a complete SOP list, ensuring that all DLSMHSI-IEC members have access to the SOPs and are working according to the current version of the SOPs.

1.3.3 DLSMHSI-IEC members are responsible for reviewing and approving the drafts of new or revised SOPs in a full board meeting every two years thereafter keeping a copy of complete SOPs, and performing their functions according to current SOPs. The SOP will be reviewed and updated should there be any new national ethical guidelines which shall be issued and should be incorporated in the IEC operating procedures when necessary.

1.3.4 The Vice Chancellor for Research (VCR) is responsible for the final approval of all SOPs.



2. Writing SOPs

2.1 Process Flow for New SOP

	ACTIVITY	RESPONSIBILITY
Step 1	Designate an SOP Team	Chair
Step 2	Design the format, layout, identifier of SOP	SOP Team
Step 3	Write a new SOP and submit it to the Chair	SOP Team
Step 4	Review and approve new SOP draft in a full board meeting and submit to the Vice Chancellor for Research (VCR).	Chair/IEC Members
Step 5	File and distribute approved SOPs	Secretariat

2.2 Description of Detailed Procedures

2.2.1. The Chair designates an SOP Team.

- The Chair assigns members and non-members, as needed, to be part of the SOP Team
- The SOP Team receives an orientation from the Chair regarding duties and responsibilities
- The Chair can organize SOP Team workshop to facilitate and drafting of SOPs.

2.2.2. The SOP Team designs the format, layout, identifier of the SOP.

- The Design and the format and the layout of an SOP is based on the following guidelines:
 - An SOP is written according to the following format:
 - Version of the chapter and number of revisions for the year
 - Title
 - Objectives of the SOP
 - Scope which includes description and purpose of the SOP
 - A flowchart when necessary
 - Detailed instructions
 - Assign an identifier to the SOP
Each SOP chapter is given a code and a title that is self-explanatory and is easily understood. For the De La Salle Health Sciences



Institute-Independent Ethics Committee (DLSMHSI-IEC) SOPs, the following format is used: DLSMHSI-IEC-SOP XX/YY-W-ZZZZ where XX is a two-digit number corresponding to the chapter, YY is a two-digit number identifying the version of the SOP (version starts from 01), W is a one-digit number identifying the version of SOP with minor changes in the SOP (it starts with 0), and ZZZZ is a four-digit number identifying the year of SOP was drafted or revised.

Thus, the SOP on writing of SOPs is identified with the code DLSMHSI-IEC SOP 05/01-0-2012 signifying that this SOP can be seen in Chapter 5, it is the first version (005/01), and has no minor changes, (05/01-0) as of 2012 (when it was first drafted).

- The layout of a typical SOP uses a header with the following elements:
 - Institutional seal or logo
 - Name of institution
 - SOP identifier
 - SOP section
 - SOP title
 - Effective date
 - Page number
- SOP is introduced by a cover laid out as a typical SOP page with the following additional items included:
 - Summary content after the title
 - Institutional contact details (address, telephone numbers, facsimile number, email address)
 - Date of the previous version; if not applicable, the date of previous issue is indicated by “N/A” (not applicable)
 - Name of the authors/editors
 - Approval information such as approving authorities and offices.

2.2.3. The SOP Team writes a new SOP and submits it to the Chair.

- The SOP Team makes a draft of the SOP based on the design and format detailed above.
- The SOP Team submits completed draft to the Chair.

2.2.4. The IEC Chair and members Review and approve new SOP draft in a full board meeting and submits to the Vice Chancellor for Research (VCR).

- The IEC Chair submits the draft to full board review where IEC members deliberate on the draft.



- Upon full board approval, the Chair submits the approved draft to the Vice Chancellor for Research (VCR) for final approval.
- Vice Chancellor for Research (VCR) approves the SOP by signing in the appropriate section in the cover page.
- The approved SOPs will be implemented from the date of approval by the Vice Chancellor for Research (VCR).

2.2.5 The IEC Secretariat file and distribute approved SOPs.

- Upon approval of Angelo King Medical Research Center (AKMRC) Vice Chancellor for Research (VCR), the Secretariat distributes SOP to DLSMHSI-IEC members, and publishes the SOP through the Hospital website (www.dlshsi.edu.ph).
- The Secretariat distributes the printed copy of the approved SOPs to the DLSMHSI-IEC members and staff; with an electronic copy published through the Hospital website.
- The Secretariat retains one copy of the complete originally signed SOP.



3. Revising SOPs

3.1. Process Flow

	ACTIVITY	RESPONSIBILITY
Step 1	Propose to revise the SOP	IEC Member/s
Step 2	Review, discuss and approve the SOP draft revision in a full board meeting.	IEC Members
Step 3	Approve and sign the SOP revision	Chair/VCR
Step 4	File and distribute the revised SOP	Secretariat
Step 5	Archive the superseded SOP	Secretariat

3.2 Detailed Instructions

3.2.1. IEC Member/s proposes to revise the SOP.

- As the IEC sees fit, an existing SOP may be revised. A revision should be substantial (correction of grammatical is not considered as substantial; a change in the identifier of an SOP is considered substantial. Minor changes refer to editorial, grammatical, or administrative changes that have no substantial effect on procedures. Major changes, on the other hand, are those that have a substantial effect on procedures, definitions, requirements, and similar considerations.
- When an SOP is difficult to understand or does not cover what it should, a revision may become necessary. The SOP may be reviewed regularly by the SOP Team every two years.
- The SOP Team or any member of the board may propose for the revision of the SOPs and submit a written proposal to the SOP Team.
- Any proposal for revision must be written and submitted by the SOP Team to the board for review, approval, coding, and inclusion into the document.

3.2.2. IEC Members review, discuss and approve the SOP draft revision in a full board meeting.

- When the need for a revision of SOP has been identified and agreed on, a draft will be written by a designated member of the DLSMHSI-IEC. A draft of the revised SOPs will be discussed by the IEC members. The draft version will be reviewed by the Chair who will submit it to the Vice Chancellor for Research for approval.



- The SOP Team drafts the revision, noting that the SOP identifier reflects the chronological number and date of the revision. If an SOP supersedes a previous version, indicate the previous SOP version and the main changes in the historical form.
- The Chair submits the drafts to the full board review where the IEC members deliberate on the draft.

3.2.3. The IEC Chair and the VCR shall approve and sign the SOP revision.

- The Chair submits the approved draft to the Vice Chancellor for Research (VCR) for final approval.
- The Angelo King Medical Research Center (AKMRC) Vice Chancellor for Research (VCR) approves the revised SOP by signing on the appropriate section of the cover page.
- The approved revised SOP will be implemented from the date of approval by the AKMRC Vice Chancellor for Research (VCR).

3.2.4. The IEC Secretariat files and distributes the revised SOP.

- Upon approval of AKMRC Vice Chancellor for Research, the Secretariat distributes the printed revised SOP to DLSMHSI-IEC members, updates the electronic SOP manual, and publishes the SOP through the Hospital website.
- The IEC Secretariat maintains the originally signed updated SOP manual in the DLSMHSI-IEC office and retains one copy of the originally signed outdated versions.
- The IEC Secretariat collects the old SOP manuals in exchange of the revised manual.
- The IEC Secretariat includes the revised SOP in the SOPs manual that is currently used.

3.2.5. The IEC Secretariat archives the superseded SOP.

- The Secretariat archives the superseded version of the SOP in the historical file maintained by the De La Salle Medical and Health Sciences Institute-Independent Ethics Committee (DLSMHSI-IEC).
- Superseded SOPs are clearly marked "superseded" with the year of archiving stamped in the cover page.
- Outdated SOPs are considered a permanent file.



4. Version History

Version No.	Authors	Reviewer/s	Approved Date	Approved By	Effectivity Date
1	Dr. Frias	NA	22 Oct 2012	IEC Committee	22 Oct 2012
2	Dr. Frias & Ms. Bayas	PHREB	15 Jun 2016	PHREB	15 Jun 2016
3	Dr. Frias & Ms. Panaligan	PHREB			