	University of the Philippines Manila **RESEARCH ETHICS BOARD**	UPMREB SOP 005/02-1-2012
	V. PREPARING SOPs & GUIDELINES	Effective Date: 29 July 2019

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1. Objectives

This Standard Operating Procedure (SOP) defines the process for writing, reviewing, distributing, amending, and storing UPMREB SOPs and Guidelines.

2. Scope

This SOP applies to any UPMREB SOPs and their amended versions as published and distributed by the UPMREB.

3. Responsibilities

The UPMREB Coordinator is responsible for ascertaining the need for new SOPs/Guidelines and amendments to existing ones based on changes in international and national guidelines and policies or requests from various stakeholders including UPMREB Members. The UPMREB Chair is responsible for designating an SOP Team, chaired by the UPMREB Coordinator, which drafts new SOPs and Guidelines and amends them as needed. The team is responsible for proposing design and format as well as the substantial contents of the SOP or Guideline. UPMREB members are responsible for UPMREB consensus action on the proposed SOP or Guideline, the outcome of which is endorsed by the UPMREB Chair to the UP Manila Chancellor through the Vice-Chancellor for Research for approval. The UP Manila Chancellor is responsible for the final approval of all SOPs and Guidelines. The UPMREB Secretariat Staff is responsible for storing and distribution.

4. Preparing Standard Operating Procedures (SOPs) and Guidelines Workflow

ACTIVITIES	RESPONSIBILITY
Design SOP/Guideline format, coding, and layout ↓	SOP Team
Write new/review existing SOP/Guideline ↓	SOP Team
Present new/revised SOP/Guidelines to the UPMREB ↓	UPMREB Coordinator, UPMREB Chair
Decide on UPMREB action ↓	UPMREB Members
Approve new/revised SOP/Guideline ↓	UP Manila Chancellor
Disseminate and store new SOP/Guideline	Secretariat Staff

DETAILED INSTRUCTIONS

4.1. **Design of the format, coding (using an identifier), and layout**

4.1.1. An SOP follows the format:

- **Number and version**, which follows the SOP on coding of SOPs and Guidelines
- **Title**, which is descriptive of contents
- **Objectives**, which defines the purpose and intended outcome
- **Scope**, which defines the extent of coverage of the SOP and its limitations
- **Responsibilities**, which delineates tasking and accountabilities for SOP implementation
- **Workflow** when necessary, which provides a graphic representation of the essential steps to implement the SOP
- **Detailed instructions**, which elaborates the steps outline in workflow
- **UPMREB FORM 5(D)2012: DOCUMENT HISTORY**, which tabulates the different versions (from draft to final versions) of the document by author, version, date, and description of main changes
- **Forms**, which are documents to be filled out or accomplished by different parties as required by the SOP, with **a list of forms**
- **References**, which lists the instruments use to draft the Guideline such as other SOPs, guidelines, or policies
- **Appendices** which provide elaborations or clarifications of specific sections including glossary and list of abbreviations

4.1.2. Each SOP is alphanumerically coded: **UPMREB SOP XXX/YY-W-ZZZZ**, where **XXX** is a three-digit number corresponding to the chapter, **YY** is a two-digit number identifying the version of the SOP, and **W** is a one-digit number identifying the version of SOP with minor changes in the SOP, and **ZZZZ** refers to the year the SOP was first drafted. **YY** (version) starts from 01 and **W** starts with 0. Thus, the SOP on writing of SOPs is identified with the code **UPMREB SOP 005/01-0-2012**, 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).

4.1.3. Minor changes refer to editorial, grammatical, or administrative changes that have no substantial effect on procedures. Major changes, on the other hand,

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are those that have a substantial effect on procedures, definitions, requirements, and similar considerations.

4.1.4. SOP Forms are alphanumerically coded: **UPMREB FORM X(A)VVVV: <NAME OF DOCUMENT>,** where **X** is a one-digit number corresponding to the chapter, **A** is a unique letter that serves as an identifier of the form, and **VVVV** refers to the year the version of the form. **A** (letter identifier) follows the letter of the alphabet and starts with **A**, and **VVVV** (version year) starts with the year the SOP was first drafted. Thus, the document which tabulates the different versions (from draft to final versions) of the SOP is identified as **UPMREB FORM 5(D)2012: DOCUMENT HISTORY,** indicating that the form is a part of **SOP 5: Preparing SOPs and Guidelines,** it is the fourth form, this version was drafted in 2012, and it is named as the Document History. Major revisions including changes in the form content and how the form is used would merit a change in **VVVV**.

4.1.5. A Guideline follows the format:

- **Number and version,** which follows the SOP on coding SOPs and Guidelines
- **Title,** which is descriptive of contents
- **Table of contents,** which lists all major headers and subheadings of the Guideline including the appendices and page numbers on which these appear
- **Introduction,** which includes a summary and explanation of the purpose of the Guideline, a short note on how the Guideline was prepared, and a short note on how to use it
- **Detailed description,** which represents the final text that is short and clear
- **UPMREB FORM 5(D)2012: DOCUMENT HISTORY**, which tabulates the different versions (from draft to final versions) of the document by author, version, date, and description of main changes
- **References,** which lists the instruments use to draft the Guideline such as other guidelines or policies
- **Appendices,** which provide elaborations of specific guideline sections including glossary and list of abbreviations

4.1.6. A Guideline is alphanumerically coded in sequence: **UPMREB GL XX**, where **XX** is a two-number that indicates sequence, for example **01** means it is the

first guideline issued by the UPMREB. The code is followed by a version number which indicates whether a specific guideline document is a *draft version, final version, final version with minor revisions or final version with major revisions*.

- Draft version is indicated as "Version N.0" followed by the word "draft"; for example *GL 01 Version 1.0 draft* means draft first version
- Final version is indicated removing the word "draft"
- Final version with minor revisions is indicated by "Version N.n" followed by the word "final"; for example *Version 1.1 final* means the final version had undergone one round of minor revisions
- Final version with major revisions is indicated by "Version (N+1).0" followed by the word "final"; for example *Version 2.0 final* means the final version had undergone one round of major revisions.

- 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.

4.1.7. The layout of a typical SOP or Guideline page **[UPMREB FORM 5(A)2012: SOP OR GUIDELINE TEMPLATE]** uses a **header** with the following elements:

- Institutional seal or logo
- Name of institution
- SOP/Guideline code
- SOP/Guideline title
- Effective date
- Page number
- SOP/Guideline content and a **footer** indicating file name, directory and path included, of the corresponding electronic document, if the file can be accessed through a website or Uniform Resource Locator (URL), or a server

4.1.8. The SOP/Guideline is introduced by a cover page **[UPMREB FORM 5(B)2012: SOP OR GUIDELINE COVER PAGE]** laid out as a typical SOP or Guideline 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

5. Writing and review of new SOP/Guideline

5.1. SOPs and Guidelines are issued by the UPMREB in order to facilitate transparent, clear, and systematic implementation of its functions.

5.2. New SOPs and Guidelines may be issued in not less than three-year intervals; unless regulations on which these documents are based have significantly changed in the interim.

5.3. Existing SOPs and Guidelines are reviewed every three (3) years; unless regulations on which these documents are based have significantly changed in the interim.

5.4. Any amendment or revision must be written and submitted to the UPMREB Coordinator for compilation and processing by respective parties, such as UPMREB Members or UPM authorities, in preparation for the next round of SOP or Guideline review.

5.5. A request for amendment or revision is accomplished by filling out **UPMREB FORM 5(C)2012: REQUEST FOR AMENDMENT OF AN SOP OR GUIDELINE.** The UPMREB Coordinator is responsible for initial review of the request, procurement of relevant information, recommendation of further action as follows:

- Confirm need for amendment or revision, forward to SOP Team
- Request further information (state)
- Forward to content expert for opinion

5.6. When the need for a new SOP or Guideline has been identified and agreed on, the UPMREB Coordinator will organize the writing process whereby a draft will be written by the SOP Team designated by the Chair. The draft is regarded as a consensus issuance by the SOP Team, and may be a result of consultation with other stakeholders prior to completion.

6. Presentation of new/revised SOP/Guideline to the UPMREB

6.1. The draft version is submitted by the SOP Team to the UPMREB Coordinator.

6.2. The UPMREB Coordinator organizes a UPMREB Executive Committee Meeting, which is expected to be attended by majority of the UPMREB Panel Chairs and Panel Secretaries.

6.3. The UPMREB Chair, or his designee, presents the new/revised SOP or Guideline to the UPMREB during this Executive Committee Meeting and presides over the deliberation.

7. Decision of UPMREB action on new/revised SOP/Guideline

7.1. During the Executive Committee Meeting, UPMREB members will deliberate on the proposed draft and arrive at a consensus action. *Favorable action by consensus* requires representation of majority of the UPMREB panels through the Panel Chairs or their respective representatives.

7.2. During the general assembly, changes to the SOP will be disseminated and training may be considered depending on the extent and nature of the SOP changes.

7.3. If a consensus cannot be achieved, the matter is put to a vote. *Favorable action by voting* requires representation of majority of the UPMREB panels, by way of the presence of all Panel Chairs, with a vote of **two-thirds plus one** of the members present in the meeting.

7.4. Action can be deferred if recommendations for further amendments or revisions are lodged during the forum, in which case, the UPMREB Coordinator will supervise the documentation of requested amendments or revisions and call for a subsequent meeting, no more than thirty (30) days from the date of this forum.

7.5. Decisions are documented by the secretariat through minutes of the executive committee meeting [UPMREB FORM 4(T)2019]. Agenda and minutes of executive committee and general assembly meetings are considered administrative records and managed in accordance with SOP IV-6.

8. Approval of new/revised SOP/Guideline for implementation

8.1. The effective date of the document is reckoned as the date of UPMREB approval indicated by favorable action of UPMREB as detailed in section 7.0 above. This date

is reflected in document history (**UPMREB FORM 5(D)2012: DOCUMENT HISTORY).**

8.2. Upon functional approval by UPMREB, the approved SOP is endorsed by the UPMREB Chair to the UP Manila Chancellor through the Vice-Chancellor for Research for processing of final approval.

8.3. Final approval is indicated by the dated signature of the UP Manila Chancellor on the cover page of the document.

8.4. In case of unfavorable consideration or disapproval at the level of the Vice-Chancellor for Research or the Chancellor, a letter describing the reasons for disapproval will be secured by the Secretariat from these respective offices and forwarded to the SOP Team for action. The revised document will be processed in accordance with Section 4.0 above.

8.5. Both the UPMREB approval date and the final approval date are indicated in the cover page of the document (UPMREB FORM 5(B)2012: SOP OR GUIDELINE COVER PAGE).

9. Dissemination and storage of new/revised SOP/Guideline

9.1. The printed copy of the approved SOPs and Guidelines will be made available upon request to UPMREB Members and UP Manila authorities within **thirty (30)** days of approval by the UP Manila Chancellor.

9.2. An electronic copy of an approved SOP or Guideline will be published as soon as possible in the UPMREB website to make it immediately available.

9.3. One (1) complete originally signed set of current SOPs is maintained by the UPMREB Secretariat Staff, which can be reproduced as needed.

9.4. In case of amended or revised SOP or Guideline documents, the old version will undergo archiving procedures by the Secretariat Staff. The word "SUPERSEDED" is stamped on all pages of one complete set of the old version, after which it is stored separately from the current version.

9.5. Superseded versions are indicated in the **UPMREB FORM 5(D)2012: DOCUMENT HISTORY** of the new version by Secretariat Staff prior to storage.