5. Writing and Revising SOPs

5.1   Writing SOPs
5.2   Revising SOPs

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5.1 Writing SOPs

5.1.1 Purpose
To describe the procedures for writing Standard Operating Procedures (SOP) used by the WVSU-URERC.

5.1.2 Scope
This SOP provides instructions on how the new WVSU-URERC Standard Operation Procedures are prepared, approved and distributed.

5.1.3 Responsibility
It is the responsibility of the Chair of the WVSU-URERC to organize an SOP Team to formulate the SOPs of the URERC.

The SOP Team is an ad hoc committee composed of designated URERC Members and invited resource persons. The team is responsible for drafting new SOPs and revising existing SOPs when necessary. The team must follow existing institutional procedures when drafting SOPs in consultation with the Chair and URERC staff. The team submits the draft SOPs to the Chair.

The Chair convenes a full board URERC meeting to review and finalize draft SOPs and submit the final draft to the WVSU President for final approval.

The URERC staff is responsible for keeping all versions of SOPS and ensures that all URERC members have access to current versions of SOPs to guide them in the performance of their functions.

5.1.4 Process Flow/Steps

STEP	ACTIVITY	PERSON/S RESPONSIBLE
1	Organize an SOP Team	URERC Chair
2	Identify reference templates with corresponding layout	SOP Team
3	Draft new SOPs	SOP Team
4	Review and finalize new SOP in an URERC meeting and submit to the WVSU President	URERC Chair and Members
5	Distribute approved SOPs and keep copies in the URERC files	URERC Staff

Diagram 25. Writing SOPs

5.1.5 Detailed Instructions

Step 1 Organize an SOP Team

    1.1.   The Chair assigns members to be part of the SOP Team, and invites resource persons as needed.

    1.2.   The SOP Team receives an orientation from the URERC Chair regarding its duties and responsibilities.

    1.3.   The URERC Chair may organize SOP Team workshops to facilitate the drafting of SOPs.

Step 2 Identify reference templates with corresponding layout

    2.1.   Identify reference templates with corresponding layout from SOPs of other RECs to guide the SOP team in drafting new SOPs.

    2.2.   A URERC SOP has the following format:

        A. SOP Number

        B. Title

        C. Purpose of the SOP

        D. Scope which defines the extent of coverage of the SOP and its limitations

        E. Responsibility identifies the persons assigned to perform specific tasks during SOP implementation

        F. Process Flow/Steps

        G. Detailed instructions which elaborate the steps outlined in the process flow

        H. Standard forms and checklists to be used

        I. Glossary

        J. References

        K. List of Acronyms

    2.3.   Each SOP should be given a number and a title that is self-explanatory and is easily understood.

    2.4.   The SOP Document History describes the different versions of the document by version no., version date and description of main charges.

    2.5.   The typical SOP uses a header with the following elements:

        A. Institutional seal or logo

        B. Name of institution

        C. SOP identifier

        D. SOP title

        E. Effective date

Step 3 Draft new SOPs

    3.1.   The URERC SOPs should contain details under the following main topics:

        A. Introduction – contains a statement of ethical principles that will guide the URERC.

        B. Structure and Composition of the URERC – describes the composition of URERC membership with specific review functions.

        C. Initial Review Procedures – describe types of review and initial review procedures.

        D. Monitoring Procedures – describe how the URERC monitor implementation of approved protocols.

        E. Management of Meetings, Documentation and Archiving – describe administrative procedures that support the review functions.

        F. Writing and Revising SOPs – describes how to draft and revise SOPs.

    3.2. The SOP Team submits the completed SOP draft to the Chair.

Step 4 Review and finalize new SOP in an URERC meeting and submit to the WVSU President

    4.1.   The URERC Chair presents the draft SOPs during an URERC meeting for the members to discuss and finalize the draft.

    4.2.   The URERC Chair submits the approved draft to the WVSU President for approval.

Step 5 Distribute approved SOPs and keep copies in the URERC files

    5.1.   The approved SOPs will be implemented after approval by the WVSU President.

    5.2.   The URERC Staff distributes the new SOPs to all URERC Members and files the original copy in the URERC storage cabinet.

    5.3.   The URERC SOP Manual with downloadable forms are uploaded on the URERC website for the use of and guidance of researchers.

5.2 Revising SOPs

5.2.1 Purpose

To describe the procedures for revising SOPs used by the WVSU-URERC.

5.2.2 Scope

This SOP provides instructions on how to revise existing SOPs.

5.2.3 Responsibility

It is the responsibility of the URERC Members to suggest revisions in existing SOPs.

The URERC Chair appoints an SOP Team, an ad hoc committee composed of designated URERC Members and invited resource persons. The team is responsible for revising relevant parts of the existing SOPs. The team must follow existing institutional procedures when drafting or editing SOPs and consults the Secretariat and Chair about revisions. The team submits the revised sections of the SOPs to the Chair.

The Chair convenes a full board URERC meeting to review and finalize revised SOPs and submit the final draft to the WVSU President for final approval.

The Secretariat is responsible for keeping all versions of SOPs and ensures that all URERC Members have access to current versions of SOPs to guide them in the performance of their functions.

5.2.4 Process Flow/Steps

STEP	ACTIVITY	PERSON/S RESPONSIBLE
1	Propose to revise an SOP	URERC Members
2	Review existing SOPs	SOP Team
3	Review and discuss SOP revision in full board URERC meeting	URERC Members
4	Submit to the WVSU President for approval	URERC Chair
5	File and distribute revised SOP	URERC Staff
6	Retrieve and archive copies of superseded SOP	URERC Staff

Diagram 26. Revising SOPs

5.2.5 Detailed Instructions

Step 1 Propose to revise an SOP

1.1. SOPs are reviewed at least every three years and may be revised, as necessary by the URERC Members.

1.2. A revision should be substantial enough to warrant major changes like substantial effect on procedures, definitions, requirements and similar considerations. Minor changes refer to editorial, grammatical or administrative changes that have no substantial effect on procedures.

1.3. When an SOP section does not cover what it should, or does not follow new regulations, a revision may become necessary.

1.4. Any member of the URERC may propose for the revision of the SOPs.

Step 2 Review existing SOPs

2.1. The URERC Chair appoints the SOP team or an URERC Member designated by the Chair to draft the revision.

2.2. The SOP team prepares the draft of revisions.

2.3. The URERC Chair presents the revised SOPs to the URERC for deliberation during a full board URERC meeting.

Step 3 Review and discuss SOP revision in full board URERC meeting

3.1. The URERC Chair convenes a full board meeting to discuss the revisions and finalize the draft.

Step 4 Submit to the WVSU President for approval

4.1. The URERC Chair submits the final version of the revised SOP to the WVSU President for final approval.

4.2. The approved version of revised SOPs will be implemented from the date of approval by the WVSU President.

Step 5 File and distribute revised SOP

5.1. Upon approval, the URERC Staff distributes the printed copy of the revised SOPs to the URERC Members and files and retrieves the copies of superseded SOPs for disposal.

5.2. URERC Staff changes the electronic copy of the SOP published in the URERC website with the newly revised version.

5.3. URERC Staff maintains an updated URERC SOP Manual in the office.

5.4. URERC Staff retains the original signed copy of the revised SOP in the SOP Masterfile.

5.5. The original copy of the superseded copy is transferred to the archive after the updating of the SOP Document History.

Step 6 Retrieve and archive copies of superseded SOP

6.1. The URERC Staff archives the superseded version of the SOP as part of the historical file maintained by the URERC.

6.2. The word "SUPERSEDED" is stamped on the cover page of the superseded SOPs with the date of archiving.

6.3. All printed copies of the superseded SOP in circulation are retrieved and disposed by shredding.

History of WVSU URERC SOP Chapter 5

Version No.	Date	Authors	Main Change
01	2014 October 15	Henrietta C. Española, M.D.	First Draft
02	2017 January 12	Fred P. Guillergan, M.D. Victor A. Amantillo, Jr., M.D.	Second Draft
03	2021 April 14	Fred P. Guillergan, M.D.	Version revised according to the Department of Health Standard Operating Procedure