

	WEST VISAYAS STATE UNIVERSITY UNIFIED RESEARCH ETHICS REVIEW COMMITTEE	SOP No: 4
	4. MEETING CONDUCT, DOCUMENTATION AND ARCHIVING	Version No: 03
		Approval Date: 04/14/21
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4. Meeting Conduct, Documentation and Archiving

- 4.1 Preparation of the Agenda of the Meeting
- 4.2 Conduct of a Full Board Meeting
- 4.3 Preparation of the Minutes of the Meeting
- 4.4 Communicating URERC Decision to the Principal Investigator/Researcher
- 4.5 Management of Active Study Files
- 4.6 Archiving of Inactive Study Files
- 4.7 Maintenance of Confidentiality of Study Files and URERC Documents

FORM 4.1 NOTICE OF MEETING

FORM 4.2 AGENDA OF THE MEETING

FORM 4.3 MINUTES OF THE MEETING

FORM 4.4 CONFIDENTIALITY AGREEMENT FORM FOR NON-MEMBERS

Supersedes:	January 12, 2017 SOP of the URERC
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4.1. Preparation of the Agenda of the Meeting

4.1.1 Purpose

To describe the procedures involved in agenda preparation before the conduct of the full board meeting of the WVSU-URERC.

4.1.2 Scope

This SOP provides instructions related the preparation of the agenda of the meeting before a full board meeting.

4.1.3 Responsibility

It is the responsibility of URERC Secretariat, composed of the URERC Staff under the supervision of the Member Secretary to prepare the meeting agenda before an URERC full board meeting.

4.1.4 Process Flow/Steps

STEP	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Prepare and finalize the Agenda of the Meeting	Member Secretary, Staff	7 days
2	Make arrangements for the meeting	Staff	
3	Distribute Notice of Meeting	Staff	
4	File a copy of the agenda after the meeting	Staff	1 day

Diagram 18. Steps in Preparing the Meeting Agenda

4.1.5 Detailed Instructions

Step 1 Prepare and finalize the Agenda of the Meeting

- 1.1. One week before the scheduled meeting date, the URERC Staff checks the submissions since the last full board meeting and prepares a list of items for review during the next full board meeting.
- 1.2. The URERC Staff uses the Form 4.2 Agenda of the Meeting to classify the items for review.

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- 1.3. The URERC Staff forwards the draft agenda of the meeting to the URERC Member Secretary to review and finalize.
- 1.4. The URERC Member Secretary reviews the draft agenda of the meeting and makes changes, if needed, then it will be presented to the URERC Chair for approval and comments and it becomes the provisional agenda of the meeting. The provisional agenda of the meeting is presented at beginning of the full board meeting and URERC members are given the chance to suggest additional items to finalize the meeting agenda.

Step 2 Make arrangements for the meeting

- 2.1. URERC Staff contacts URERC members to check who will be available to attend the meeting to ensure quorum.
- 2.2. The URERC Staff makes the necessary arrangements:
 - A. Reservation of meeting room on the scheduled meeting date and time, when necessary;
 - B. Snacks of meeting attendees.
- 2.3. Prepares relevant documents to be distributed to URERC Members who confirmed to attend the meeting.

Step 3 Distribute Notice of Meeting

- 3.1. URERC Staff distributes Form 4.1 Notice of Meeting together with the relevant documents for review to REC Members 7 days prior to the meeting date.

Step 4 File a copy of the agenda after the meeting

- 4.1. URERC Secretariat takes note of changes in the provisional agenda of the meeting after this is presented for approval to the URERC. If there are no changes, the provisional agenda becomes the final agenda of the meeting.
- 4.2. URERC Staff files a copy of the final agenda of the meeting in the appropriate file folder of the URERC.

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4.2 Conduct of a Full Board Meeting

4.2.1 Purpose

To describe the procedures of WVSU-URERC when it conducts a full board meeting to review protocol submissions.

4.2.2 Scope

This SOP describes the various steps the URERC follows to review various types of protocol submissions, the types of decision and action taken as well as necessary documentation to record its proceedings.

4.2.3 Responsibility

It is the responsibility of the URERC Chair to preside over the meeting and exercise leadership to enable the URERC Members and URERC Staff to fulfil their designated roles in the review of protocol related documents submitted to the URERC in an efficient and effective manner. It is the responsibility of the Member Secretary to ensure that quorum will be met, that the required documents needed are available, to supervise the staff taking real time minutes of the proceedings and to report the results of expedited review.

It is the responsibility of URERC Members to prepare and participate in URERC full board meetings to enable the URERC to conduct good review and take appropriate action related to documents submitted to the URERC.

It is the responsibility of the URERC Staff to prepare and make available all documents needed during the meeting and to take down minutes of the proceedings.

4.2.4 Process Flow/Steps

STEP	ACTIVITY	PERSON/S RESPONSIBLE
1	Call the meeting to order	Chair
2	Determine Quorum	Member Secretary
3	Declare Conflict of Interest (COI)	URERC Members
4	Approve the minutes of the previous Full Board Meeting and discuss business arising from the minutes	URERC Members
5	Approve or modify the Agenda of the Meeting	URERC Members

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STEP	ACTIVITY	PERSON/S RESPONSIBLE
6	Discuss and decide on protocols for initial review	Primary Reviewers; URERC Members
7	Decide on protocol document resubmission	Primary Reviewers; URERC Members
8	Discuss and decide on Protocol Amendments	Primary Reviewers; URERC Members
9	Discuss and decide on Progress Reports for full board review	Primary Reviewers; URERC Members
10	Discuss and decide on Final Reports	Primary Reviewers; URERC Members
11	Report Serious Adverse Events (SAEs) and Suspected Unexpected Serious Adverse Reaction (SUSAR) Reports for appropriate action	Designated URERC Member; URERC Members
12	Discuss Protocol Deviation/ Violation Reports for appropriate action	Primary Reviewers; URERC Members
13	Report Expedited Review results	Staff; URERC Members
14	Report/Discuss other matters for Full Board action/information	Chair/ Member Secretary; URERC Members
15	Formally close the Full Board Meeting	Chair

Diagram 19. Steps in the Conduct of a Full Board Meeting

4.2.5 Detailed Instructions

Step 1 Call the meeting to order

- 1.1. The Chair declares the formal opening of the meeting at the appointed time and place once majority of the members are present.

Step 2 Determine Quorum

- 2.1. The Member Secretary checks and reports if the quorum requirements are met to enable the meeting to start. URERC quorum requirements should comply with national and international requirements and as defined in these SOPs. Quorum should be maintained throughout the duration of the meeting when

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members are required to vote to arrive at a decision. The following should be met to constitute quorum in a full board meeting of URERC:

- A. 50% + one or eight URERC members;
- B. Medical/scientific person;
- C. A non-affiliated/non scientific person
- D. Good gender representation

Step 3 Declare Conflict of Interest (COI)

- 3.1. The Chair asks the URERC Members to declare their conflict of interest (COI) related to any protocols/proposals to be discussed.
- 3.2. The URERC Members checks the agenda and declares their COI related to any protocol/proposal to be reviewed. They should be asked to leave the room during the discussion of such protocols/proposals, unless they are asked to reply to questions for clarification. Quorum should be maintained when conflicted members leave the room. They return to the room after discussion of their protocol/proposal.

Step 4 Approve the minutes of the previous Full Board Meeting and discuss business arising from the minutes

- 4.1. The minutes of the previous meeting should have been sent to all members before the meeting for comments. The Chair asks the members to approve the minutes of the previous meeting and ask the members to voice out their comments, if any.
- 4.2. The Chair also asks the members to comment about issues arising from the minutes and the discussions are recorded in the current minutes by the Secretariat.

Step 5 Approve or modify the Agenda of the Meeting

- 5.1. The Chair asks the Members to examine and approve the items in the Agenda of the Meeting.
- 5.2. URERC Members may suggest additional items for discussion and the meeting agenda may be modified to include additional items for discussion.

Step 6 Discuss and decide on protocols for initial review

- 6.1. The list of protocols/proposals for initial review are discussed according to the following procedures:
 - A. The primary medical reviewer summarizes the protocol/proposal to enable the members to understand it.

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- B. He/she uses the assessment form to comment on the technical and ethical issues in the protocol/proposal and makes recommendations about clarification, revision or approval. He/she also comments on the qualifications of the researchers and the sites.
- C. When applicable, the Independent Consultant attends the meeting to clarify issues related to the study protocol/proposal to assist in the review of proposals/protocols that require his/her expertise in addition to those available within the URERC. They will not be counted during determination of quorum and will not be able to vote for full board decisions.
- D. The Chair opens the protocol/proposal for discussion of URERC Members taking note of additional and contradictory comments.
- E. The Principal Investigator (PI)/Researcher may be called to enter the room to answer questions and clarify certain protocol/proposal related matters, after which, he/she is asked to leave the room.
- F. The Chair summarizes the points raised and notes different views among members that should be resolved. The Chair asks the members to decide by consensus based on the decision points in the SOPs:
 - 1. Approval (no further revision of the documents is required)
 - 2. Minor Revision
 - 3. Major Revision
 - 4. Disapproval

In case of disagreement, the decision is reached by voting. A majority vote of all the members present in the meeting is needed in order to reach a decision. In case no decision point gets a majority vote, another vote shall be made between the two choices with the most votes.
- G. The Non-Medical/ Non Scientific Reviewer presents his/her assessment of the Patient Information Sheet and Informed Consent Form making use of Form 2.4 Informed Consent/Assent Evaluation. The comments should note the discrepancies between the protocol/proposal and the information sheet, the correct consent or assent is enclosed, and provisions for proper signatures in the form.
- H. The Member Secretary takes note of the results, records them and includes them in the minutes of the meeting.
- I. Once the protocol/proposal documents are approved, the URERC should agree on the frequency of continuing review.

Step 7 Decide on protocol document resubmission

- 7.1. Resubmission of protocols/proposals required for major revision are discussed at full board.

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7.2. The Primary Reviewers check if the researchers complied with the URERC requirements and recommends appropriate decision. The URERC Members vote to approve the resubmission.

Step 8 Discuss and decide on Protocol Amendments

- 8.1. The Chair screens amendments to determine protocol amendments that require full board review and to ensure inclusion in the meeting agenda.
- 8.2. The Primary Reviewers review the amendment and presents their assessment to full board.
- 8.3. The URERC members decide by consensus to approve/disapprove the amendment.

Step 9 Discuss and decide on Progress Reports for full board review

- 9.1. The URERC Staff/Member Secretary screens progress reports that require full board review to ensure inclusion in the meeting agenda.
- 9.2. The Primary Reviewers review progress reports and present their assessment to full board.
- 9.3. The URERC members vote to either note and accept or approve the progress reports.

Step 10 Discuss and decide on Final Reports

- 10.1. All Final Reports are discussed at full board.
- 10.2. The Primary Reviewers review final reports and present their assessment to full board.
- 10.3. The URERC Members decide by consensus whether to accept/approve final reports or request for further information as needed.

Step 11 Report Serious Adverse Events (SAEs) and Suspected Unexpected Serious Adverse Reaction (SUSAR) Reports for appropriate action

- 11.1. The URERC Staff prepares a list of SAEs and SUSARs and submits them to full board for appropriate action.
- 11.2. The Designated URERC SAE/ SUSAR Reviewer reviews the SAE/SUSAR Reports and present their assessment and recommendation for appropriate action to full board.
- 11.3. The URERC Members decide by consensus to take corresponding action on the SAE/ SUSAR Reports.

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Step 12 Discuss Protocol Deviation/ Violation Reports for appropriate action

- 12.1. The URERC Staff includes all Protocol Deviation/Violation Reports in the Agenda of the Meeting.
- 12.2. The Designated Protocol Deviation Reviewers review the reports and present their assessment and recommendation for appropriate action to full board.
- 12.3. The URERC Members decide by consensus to take corresponding action on the Protocol Deviation/ Violation Reports.

Step 13 Report Expedited Review results

- 13.1. The URERC Staff includes a list of all expedited review results approved by the Primary Reviewers in the Agenda of the Meeting.
- 13.2. URERC Members may comment on the report.

Step 14 Report/Discuss other matters for Full Board action/information

- 14.1. The Chair/Member Secretary or any URERC Member may suggest items or other matters for the information or discussion by full board.
- 14.2. The Chair/Member Secretary or any URERC Member may report queries and complaints that may need board discussion for appropriate action.

Step 15 Formally close the Full Board Meeting

- 15.1. The URERC Chair formally closes the full board meeting after determination that all the items on the meeting agenda have been discussed.

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4.3 Preparation of the Minutes of the Meeting

4.3.1 Purpose

To describe procedures for the preparation and approval of the minutes of the WVSU-URERC full board meeting.

4.3.2 Scope

This SOP provides instructions related to the preparation of the URERC full board meeting minutes and its approval by the URERC Members.

4.3.3 Responsibility

It is the responsibility of the Secretariat, composed of the URERC Staff under the supervision of the Member Secretary, to document the conduct of the full board meeting, including the issues discussed, the decisions and recommendations made in accordance with the items in the URERC meeting agenda.

4.3.4 Process Flow/Steps

STEP	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Prepare template of Minutes of Meeting	Secretariat	7 days
2	Preparation/Correction/ Finalization of Minutes of the Meeting	Secretariat	
3	Approve Minutes of the Meeting	URERC Members	1 day
4	File Minutes of the Meeting	Staff	1 day

Diagram 20. Steps in the Preparation of the Meeting Minutes

4.3.5 Detailed Instructions

Step 1 Prepare template of Minutes of Meeting

- 1.1. The URERC Staff fills out the basic information about each protocol submission for review using Form 4.3 Minutes of the Meeting template with identifying information (Protocol number, Title, PI, Sponsor, etc.).

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- 1.2. The URERC Secretariat uses this prepared template to document the proceedings during the full board meeting.

Step 2 Preparation/Correction/ Finalization of Minutes of the Meeting

- 2.1. As the URERC meeting proceeds, the URERC Secretariat takes minutes of the meeting in real time according to the prescribed format and projects this on the multimedia screen to enable the URERC Members to closely follow the proceedings, and to facilitate the recapitulation of discussion points by the URERC Chair/ Presiding Officer.
- 2.2. The URERC decisions and recommendations are collective in nature. No attribution to specific URERC Member is stated in the minutes.
- 2.3. The Minutes of the Meeting should include the following items:
 - A. Date and venue of the meeting
 - B. Member attendance
 - C. Attendance of PI/Researchers, Independent Consultant and guest or observer, if any
 - D. Presiding Officer
 - E. Time when the meeting was called to order
 - F. Status of quorum at the start of the meeting
 - G. Members who declared COI and the protocol/proposal concerned
 - H. Discussion of items based on the order in agenda of the meeting
 - I. Summary of technical and ethical discussion points and recommendations
 - J. URERC decision and voting results, if any, according to decision categories, abstention and votes for disapproval with reasons given.
 1. If the review decision (for initial and continuing reviews) is “approved”, the frequency of submission of progress report are determined.
 2. If the review decision is disapproved, the reasons for the disapproval are stated.
 3. If the review decision (for initial and continuing reviews) is “for revision”, the items to be revised are identified and the type of review for the resubmission is defined.
 - K. List of protocols approved through expedited review for the information of URERC Members.
 - L. Name and signature of the person who prepared the minutes.
 - M. Name and signature of the Chair to indicate the contents have been verified and corrected.

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- 2.4. The URERC Staff prepares the draft of the Minutes of the Meeting and submits it to the Member Secretary for correction and finalization within 5 days from the date of the meeting.
- 2.5. The URERC Secretariat finalizes minutes of the meeting incorporating corrections from the Member Secretary.
- 2.6. The URERC Staff distributes the final version of the minutes of the meeting together with the Notice of Meeting for the next URERC meeting.

Step 3 Approve Minutes of the Meeting

- 3.1. During the next full board meeting, the URERC Chair asks the members to approve the Minutes.
- 3.2. The URERC Members may suggest further corrections.
- 3.3. The URERC Members approve the Minutes.
- 3.4. The URERC Chair signs approval after the meeting.

Step 4 File Minutes of the Meeting

- 4.1. The URERC Staff files approved Form 4.3 Minutes of the Meeting in the appropriate file folder of the URERC.
- 4.2. Excerpts of meeting minutes may be extracted and filed in specific protocol file folder, and the protocol file index is updated.

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4.4 Communicating URERC Decision to the Principal Investigator/Researcher

4.4.1 Purpose

To describe the procedure for communicating the WVSU-URERC decision to the Principal Investigator/Researcher.

4.4.2 Scope

This SOP provides instructions related to the preparation of URERC communication to the Principal Investigator (PI)/Researcher and the management of such documents.

4.4.3 Responsibility

It is the responsibility of the URERC Secretariat to prepare the Approval or Notification Letter for the PI/Researcher to be signed by the URERC Chair.

4.4.4 Process Flow/Steps

STEP	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Prepare Notification/ Approval Letter to PI/Researcher	Staff, Chair	7 days
2	Send Notification/ Approval Letter to PI/Researcher	Staff	1 day
3	File Notification/ Approval Letter to PI/Researcher	Staff	1 day
4	Update protocol database	Staff	

Diagram 21. Communicating URERC Decision to the Principal Investigator/Researcher

4.3.5 Detailed Instructions

Step 1 Prepare Notification/ Approval Letter to PI/Researcher

- 1.1. Based on the final version of the Minutes of the Meeting, the URERC Staff prepares the URERC communication to the PI/Researcher in duplicate copies using the standard SOP template (Form 2.7 Approval Letter; Form 2.8 Notification of URERC Decision).

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- 1.2. For the Notification Letter, the URERC Staff copies the list of recommendations from the meeting minutes to communicate them to the PI/Researcher.
- 1.3. The URERC Chair signs and dates the Notification/Approval Letter.
- 1.4. All Notifications/Approval Letters should be ready within 7 calendar days after the meeting date for full board or 7 calendar days after receipt of expedited review results.

Step 2 Send Notification/Approval Letter to PI/Researcher

- 2.1. The URERC Staff informs the PI/Researcher that the original copy of the Notification or Approval Letter is ready for pick-up.
- 2.2. URERC Staff releases one copy of the Notification/Approval Letter to the PI/Researcher. The PI/Researcher then signs and dates the duplicate copy of the Notification/Approval Letter and logs in the Logbook for Outgoing Documents to indicate receipt of the original copy.

Step 3 File Notification/Approval Letter to PI/Researcher

- 3.1. The URERC Staff files the duplicate copy of the Notification/Approval Letter in the protocol file folder and updates the protocol file index.

Step 4 Update protocol database

- 4.1. The URERC Staff updates the protocol data base.

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4.5 Management of Active Study Files

4.5.1 Purpose

To describe the WVSU-URERC procedures related to the management of active study files, documents and records.

4.5.2 Scope

This SOP provides instructions related to the management of active study files that include protocol submissions, all documents that reflect all actions taken by the URERC before completion of the study. It also provides instructions for the maintenance and storage of other URERC documents that include SOPs, URERC Membership Files, Agenda and Minutes of the Meeting, relevant international and national regulations and guidelines, etc.

4.5.3 Responsibility

It is the responsibility of URERC Staff to manage all protocol submissions and documents that reflect all URERC actions and organize them in an orderly manner. The URERC Staff also manages the maintenance and storage of all URERC documents and records.

4.5.4 Process Flow/Steps

STEP	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	File protocol and other protocol related documents in an organized manner	Staff	7 days
2	Update protocol file folder regularly as documents come or are produced	Staff	
3	Store properly labelled protocol file folder in the appropriately labelled file storage cabinet	Staff	
4	Create an electronic protocol database and update it regularly with PI/Researcher submissions and URERC decisions/ actions	Staff	
5	Keep other URERC files in storage cabinets	Staff	

Diagram 22. Management of Active Study Files

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4.4.5 Detailed Instructions

Step 1 File protocol and other protocol related documents in an organized manner

- 1.1. Protocol files are considered active from the moment the protocols are received for initial review until such time they are inactivated either by its completion or termination or its withdrawal from the review process. Active protocol files are either those undergoing URERC review process or URERC-approved ongoing studies. It is necessary to use a unique identifier or code to refer to protocol file for efficient file management and retrieval.
- 1.2. Study Protocols are identified using a unique identification number known as Protocol Code Number given by the URERC as described in SOP 2.1 on Management of Protocol Submission.
- 1.3. The protocol file folder contains the following documents arranged chronologically in an organized manner according to the protocol file index per type of submission (e.g. initial submission, protocol amendment, progress report, SAE Reports, Protocol Violation/Deviation, etc.):
 - A. All versions of study protocol;
 - B. Related documents that come with the study protocol;
 - C. Principal Investigator/Researcher and Co-investigators' CVs and other similar documents;
 - D. Reviewers' assessment forms;
 - E. Amendment Reports;
 - F. Continuing review applications;
 - G. Serious Adverse Event Reports or Safety Notifications;
 - H. Non-compliance (Deviation or Violation) Reports;
 - I. Participant Queries;
 - J. Site Visit Reports;
 - K. Approval Letters;
 - L. Notifications of URERC Decision;
 - M. Miscellaneous communication;
 - N. Related minutes of meetings;
 - O. Final Report.
- 1.4. The URERC Staff files all protocol related documents in a durable binder and in chronological sequence with the most recent file/document at the top. The URERC Staff updates the protocol file index whenever a new document is filed.
- 1.5. The URERC Staff labels the protocol binder (Protocol Code Number, Name of PI/Researcher and Sponsor on the file binder).

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Step 2 Update protocol file folder regularly as documents come or are produced

- 2.1. The URERC Staff ensures that every protocol-related document received is logged. This log should contain at least the following items:
 - A. Date/Time received
 - B. Protocol Code Number
 - C. Study Title
 - D. Principal Investigator(s)/Researcher
 - E. Initial of Person who received the document
 - F. Type of Submission (e.g. Protocol for Initial Review, Resubmitted Protocol Application for Protocol Amendment, Protocol Violation/Deviation Report, SAE Report, etc.)
 - G. URERC Action Required
- 2.2. The URERC Staff also logs protocol and protocol-related documents when they are forwarded to URERC Members for review. This log should contain the following items:
 - A. Date Sent
 - B. Sending Person
 - C. Receiving Person/Primary Reviewer
 - D. Content of Document
 - E. Remarks
- 2.3. Protocol-related paper files/documents are added to the protocol file folder after review or have been accomplished (assessment forms, URERC decision letters, etc.).
- 2.4. URERC Staff files the binders in locked cabinets.

Step 3 Store properly labelled protocol file folder in the appropriately labelled file storage cabinet

- 3.1. URERC Staff places the protocol file binders in the shelf and sequentially arranged according to their Protocol Code Number.
- 3.2. The storage cabinets are labelled with the year when the protocols were submitted.
- 3.3. All active study files are kept in a secure filing cabinet, with access limited only to URERC Chair and Secretariat. The URERC Staff keeps the keys of the file storage cabinets.
- 3.4. Actives files can be accessed outside of regular protocol review in accordance with the SOP 4.7 Maintenance of Confidentiality of Study Files and URERC Documents.

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Step 4 Create an electronic protocol database and update it regularly with PI/Researcher submissions and URERC decisions/ actions

- 4.1. The URERC Staff creates and maintains an electronic database to contain a list of all protocols received by the URERC with sufficient columns to contain all protocol related information, PI/Researcher submissions and action taken by the URERC from initial review to final report approval.
- 4.2. The secure protocol database should facilitate protocol monitoring including due dates of reports and determining active protocol status. The database should use an electronic format and be password protected. It should have at least the following fields:
 - A. Protocol Code
 - B. Protocol Title
 - C. Department
 - D. PI/Researcher and details
 - E. Submission date
 - F. Full board or Expedited Review Date
 - G. Primary Reviewers
 - H. Review decision
 - I. Full Committee Review Meeting Date
 - J. Approval Date and Expiration Date
 - K. Due Date for Progress Report
 - L. Date of Approval
 - M. Date of Final Report
- 4.3. The URERC Staff maintains a back-up copy of the protocol database in an external drive that is updated every 1st day of the month, or the following day if the day falls on a non-working day.

Step 5 Keep other URERC files in storage cabinets

- 5.1. The URERC Staff keeps other URERC files that include the SOPs, Membership Files, international and national guidelines and regulations, etc. in the office cabinets and regularly update them for reference of the URERC Members.

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4.6 Archiving of Inactive Study Files

4.6.1 Purpose

To describe WVSU-URERC procedures related to archiving of terminated, inactive and completed studies.

4.6.2 Scope

This SOP provides instructions to the Secretariat related to requirements for archiving completed study protocols after the Final Report or other relevant documents have been received.

4.6.3 Responsibility

It is the responsibility of the URERC Staff, under the supervision of the Member Secretary, to archive in an orderly manner all protocol files that have been terminated, completed or are no longer active. They are kept together in a designated place in the university where confidentiality and security of the documents can be maintained.

4.6.4 Process Flow/Steps

STEP	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Identify inactive protocol files	Staff	7 days
2	Affix appropriate label to files for archiving	Staff	
3	Transfer files to the archiving storage area/room	Staff	
4	Update protocol database	Staff	

Diagram 23. Archiving of Inactive Study Files

4.6.5 Detailed Instructions

Step 1 Identify inactive protocol files

- 1.1. Studies are considered to be completed and inactive when the closure/final report of the study has been reviewed and approved by the URERC.
- 1.2. Studies are also classified as inactive when no further communication has been received by the URERC after two years.

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- 1.3. Studies that underwent early termination are subsequently categorized as inactive upon receipt of relevant information about termination.
- 1.4. The URERC Staff removes the protocol file folders from the storage file cabinet for active studies, checks its contents and updates the protocol file index.
- 1.5. URERC Staff shreds extra copies that are not needed.

Step 2 Affix appropriate label to files for archiving

- 2.1. The URERC Staff labels protocol file as inactive by assigning an archive number to the protocol by adding the (year of archiving) as a suffix to the original protocol code. For example if the Final Report of protocol WVSU.URERC-IS.2010_001 is archived in 2018, the archiving code is WVSU.URERC-IS.2010-001/2018.

Step 3 Transfer files to the archiving storage area/room

- 3.1. The URERC Staff transfers the protocol file to the designated secure archive area/room.
- 3.2. As in active study files, protocol files in the secure storage cabinet for inactive studies are arranged sequentially. The storage cabinet is properly labeled with the year in the original protocol code.
- 3.3. Protocols are archived for 3 years. Archived protocols can be accessed in accordance with the SOP 4.7 Maintenance of Confidentiality of Study Files and URERC Documents.
- 3.4. After 3 years in the archive, the protocol files may be transferred to the university archive or shredded.

Step 4 Update protocol database

- 4.1. The archiving data should be entered accordingly in the protocol database.
- 4.2. URERC Staff reviews entries in the protocol data base for the protocol for archiving, to check if all fields are completely filled.

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4.7 Maintenance of Confidentiality of Study Files and URERC Documents

4.7.1 Purpose

To describe WVSU-URERC procedures related to maintaining the confidentiality of the study files and other URERC documents.

4.7.2 Scope

This SOP provides instructions to the URERC Secretariat related to maintaining the confidentiality of all study files and documents.

4.7.3 Responsibility

It is the responsibility of URERC Secretariat, under the supervision of the Member Secretary, to ensure that confidentiality is maintained in the management of all study files and records and to follow the confidentiality procedures when requests to access the files are granted.

4.7.4 Process Flow/Steps

STEP	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Properly manage all active and inactive URERC files	Staff; Member Secretary	1 day
2	Receive request to access confidential files	Staff	1 day
3	Approve and log in requests for access and retrieval of documents	Secretariat	1 day
4	Supervise the use of retrieved confidential document	Staff	1 day
5	Return document to the protocol file folder	Staff	1 day

Diagram 24. Maintaining Confidentiality of Files and Documents

4.7.5 Detailed Instructions

Step 1 Properly manage all active and inactive URERC files

- 1.1. The URERC Staff properly handles original documents and copies of these documents during the day-to-day operation of the URERC to protect the confidentiality of study files and related documents. Proper handling also involves proper control and care in the distribution and storage of confidential documents of the URERC.

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- 1.2. Study files submitted to the URERC and related documents are considered confidential, such as:
 - A. Study protocols and related documents (case report forms, informed consent documents, diary forms, scientific documents, expert opinions or reviews)
 - B. URERC documents (Minutes of the Meeting, advice, and decisions)
 - C. Correspondence (with experts, auditors, study participants, etc.)

Step 2 Receive request to access confidential files

- 2.1. Access to URERC confidential documents is subject to the following limitations:
 - A. URERC Members and Staff with a signed Confidentiality Agreement and Conflict of Interest Disclosure can access confidential documents outside of regular protocol review access, upon request.
 - B. Non-members can access specific documents by submitting a formal request. The Secretariat will require Form 4.4 Confidentiality Agreement Form for Non-Members to be signed by the person making the request, and approved by the URERC Chair or Vice-Chair or designated URERC Member in the absence of the URERC Chair.
 - C. Regulatory authorities can have full access to URERC documents provided it is within their mandate (e.g. FDA), and within a reasonable notice to make the files available.
- 2.2. The URERC Staff records all transactions whenever any document of the URERC is accessed as described above.

Step 3 Approve and log in requests for access and retrieval of documents

- 3.1. A separate log is kept in the protocol folder as to record access as described above. It contains the following information:
 - A. Study file code
 - B. Date borrowed
 - C. Name of borrower
 - D. Signature of borrower upon retrieval
 - E. Signature of URERC Secretariat upon return of document to the file folder
 - F. Document copied
 - G. Number of copies made
 - H. Number of copies received
- 3.2. All requests for access are recorded by the URERC Staff in the log before copies of any documents are released.

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Step 4 Supervise the use of retrieved confidential document

- 4.1. Access to URERC documents is generally for room use only, but requests to make copies can be accommodated on a case to case basis.
- 4.2. The URERC Staff makes only the exact number of copies requested.
- 4.3. The recipient signs the URERC log upon receipt of the copies.

Step 5 Return document to the protocol file folder

- 5.1. The URERC Staff is responsible for returning the documents in the protocol file folder in the storage cabinet after making sure that all documents are complete as per protocol file index.

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FORM 4.1 NOTICE OF MEETING

Date

NOTICE OF MEETING

TO

DATE OF MEETING:
TIME OF MEETING:
VENUE OF MEETING:

Prepared By:
(Name)

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FORM 4.2 AGENDA OF THE MEETING

- I. **Prayer**
- II. **Call to Order**
- III. **Determination of Quorum**
- IV. **Presentation of Agenda**
- V. **Approval of Minutes of the Previous Meeting**
- VI. **Business arising from the Minutes of the Previous meeting**
- VII. **Protocol Review**
 - A. **Disclosure of COI among Reviewers**
 - B. **Review of New Protocol**
 - C. **Review of Resubmission**
 - D. **Review of Protocol Amendments**
 - E. **Continuing Review**
 - E.1. **Annual Progress Reports**
 - E.2. **Quarterly Progress Reports**
 - E.3. **Final Reports**
 - E.4. **Notifications**
 - F. **Report on Expedited Review**
 - G. **Report on Exempt from Ethics Review**
 - H. **Report on Serious Adverse Events (SAE)**
 - I. **Report on Protocol Deviation (PD)**
 - J. **Report on Suspected Unexpected Serious Adverse Reactions (SUSARs) and IND Safety Report**
 - K. **Report on Site Visit**
 - L. **Report on Early Termination**
 - M. **Queries or Complaints**
- VIII. **Other Matters**
- IX. **Checking of Quorum**
- X. **Adjournment**

Prepared By:

Member Secretary, URERC

Verified By:

Chair, URERC

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FORM 4.3 MINUTES OF THE MEETING

Attendance

Present Absent

- I. **Opening Prayer**
- II. **Call to Order**
- III. **Determination of Quorum**
- IV. **Presentation of Agenda**
- V. **Approval of Minutes of the Previous Meeting**
- VI. **Business arising from the Minutes of the Previous Meeting**
- VII. **Protocol Review**
 - I. **Disclosure of COI among Reviewers**
 - J. **Review of New Protocol**
 - K. **Review of Resubmission**
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 - M. **Queries or Complaints**
- VIII. **Other Matters**
- IX. **Checking of Quorum**
- X. **Adjournment**

Prepared By:
Member Secretary, URERC

Verified By:
Chair, URERC

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FORM 4.4 CONFIDENTIALITY AGREEMENT FORM FOR NON-MEMBERS

I, (Name, Surname) as a non-member of the West Visayas State University Unified Research Ethics Review Committee, understand that the documents I am given access to by the West Visayas State University-Unified Research Ethics Review Committee are confidential. I shall use the information only for the purpose indicated in this form and shall not duplicate, give or distribute these documents to any person(s) without permission from the West Visayas State University Unified Research Ethics Review Committee. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.

Requested Document	
Reason for Request	
Number of Copies Requested	

RECIPIENT

Name:

Last Name First Name MI

Signature: _____

Date: <dd/mm/yyyy>

URERC MEMBER SECRETARY

Name:

Last Name First Name MI

Signature: _____

Date: <dd/mm/yyyy>

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History of WVSU-URERC SOP Chapter 4

Version No.	Date	Authors	Main Changes
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