3. Monitoring Procedures

3.1 Review of Protocol Amendments
3.2 Review of Progress Report
3.3. Review of Final Report
3.4 Review of Serious Adverse Event
3.5 Review of Protocol Violation/Protocol Deviation
3.6 Responding to Participant's Request/Query
3.7 Study Site Visit
3.8 Review of Early Protocol Termination

FORM 3.1 PROTOCOL AMENDMENT REVIEW
FORM 3.2 PROGRESS REPORT
FORM 3.3 FINAL REPORT
FORM 3.4 SERIOUS ADVERSE EVENT REPORT
FORM 3.5 DEVIATION/NON-COMPLIANCE/VIOLATION REPORT
FORM 3.6 REQUEST/QUERY RECORD
FORM 3.7 SITE VISIT REPORT
FORM 3.8 STUDY TERMINATION

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3.1. Review of Protocol Amendments

3.1.1 Purpose

To describe the WVSU URERC review procedure for amendments of the protocol and related documents.

3.1.2 Scope

This SOP applies to previously approved study protocols and related documents that are being amended later and submitted for approval to the URERC. Any amendment of the study related documents may not be implemented until reviewed and approved by the URERC.

3.1.3. Responsibilities

It is the responsibility of the URERC Secretariat to manage the protocol amendment package submitted by the Principal Investigator (PI)/Researcher.

It is the responsibility of the original primary reviewers to review the amendments and recommend appropriate action.

It is the responsibility of the URERC Chair to determine whether the amendment goes to expedited or full committee review. The URERC approves the final decision for amendments submitted by the PI/Researcher to the URERC.

3.1.4. Process Flow/Steps

STEP	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Receive the protocol amendment package and check its completeness	Staff	7 days
2	Determine type of review & identify Primary Reviewers	Chair; Secretariat	
3	Forward amendment package to Primary Reviewers	Staff; Primary Reviewers	
4	Discuss major amendment or report the expedited review results to the URERC during full board meeting	URERC Members	1 day
5	Communicate decision to Principal Investigator/Researcher	Secretariat; Chair	7 days
6	File documents & update protocol file index and the protocol database	Staff	1 day

Diagram 10. Review of Protocol Amendments

3.1.5 Detailed Instructions

Step 1 Receive the protocol amendment package and check its completeness

1.1. The WVSU URERC should properly inform the Principal Investigator (PI)/Researcher to submit an application for amendment whenever there is any change regarding the composition of the study team, the study site, the protocol and related documents that it previously approved using Form 3.1 Protocol Amendment Review.

1.2. The URERC Staff checks the completeness of the protocol amendment package submitted by the PI/Researcher. Staff also verifies whether the Protocol Code Number and forms used are correct.

1.3. The PI/Researcher records the submission in the log book.

Step 2 Determine type of review & identify Primary Reviewers

2.1. The URERC Chair/Member Secretary reviews document to determine whether amendment is major or minor.

2.2. Major protocol amendments: increase risk to study participants and require full board review. These include but are not limited to the following:

A. Modification of treatment – addition or reduction of treatments
B. Any changes in inclusion/exclusion criteria
C. Change in study design
D. Change in method of dosage formulation, such as, oral to intravenous
E. Significant change in the number of subjects
F. Significant decrease or increase in dosage amount
G. Any other changes that will entail more than minimal risk.

2.3. Minor protocol amendments: those which are unlikely to compromise the integrity of the research or the welfare and rights of the participants and present no new ethical issues; and changes that are administrative in nature can be expedited.

2.4. The URERC Staff identifies the Primary Reviewers who did the initial review and verifies URERC approval of the initial protocol submission.

2.5. If Primary Reviewers are not available to do the review, URERC Chair and/or Member-Secretary do the review provided they do not have conflict of interest (COI). Otherwise the Chair designates qualified members to do the review.

Step 3 Forward amendment package to Primary Reviewers

3.1. The URERC Staff prepares the protocol amendment package; should it be deemed necessary, the staff photocopies relevant documents of previous review/s of the protocol that will provide the Primary Reviewers with background information that will facilitate the assessment of the proposed amendment/s.

3.2. Better still, the Primary Reviewers should go to the URERC office to review the pertinent documents in the protocol file and determine whether the proposed changes in the protocol will cause a change in the risk-benefit ratio of the approved protocol.

3.3. The URERC Staff records the protocol amendment package in the Logbook for Outgoing Documents.

3.4. The URERC Staff sends the protocol amendment package and relevant documents of previous review/s to the Primary Reviewers.

3.5. The Primary Reviewer or his/her alternate reviews the amended documents and compares them with the previously URERC- approved documents in the protocol file folder to assess if the proposed amendment/s would alter the risk/benefit ratio and to make appropriate recommendations using Form 3.1 Protocol Amendment Review.

3.6. Major protocol amendments are reviewed by full board while minor protocol amendments are reviewed by expedited review by the Primary Reviewers/Chair/Member Secretary.

Step 4 Discuss major amendment or report the expedited review results to the URERC during full board meeting

4.1. The URERC decides whether or not there is a need for the PI/Researcher to clarify, elaborate or explain further the amendment/s. The following are possible review decisions of the Board:

A. Approval
B. Major revisions to the protocol/informed consent form
C. Minor revisions to the protocol/informed consent form
D. Disapproval

4.2. <u>For Minor Protocol Amendment</u>: The Primary Reviewer or his/her alternate submits the results of the review using Form 3.1 Protocol Amendment Review.

4.3. The review decision is reported to the URERC during the full committee meeting.

Step 5 Communicate decision to Principal Investigator/Researcher

5.1. Refer to SOP 4.4 Communicating URERC Decision to the Principal Investigator/Researcher.
5.2. The URERC Staff prepares either Form 2.7 Approval Letter/Form 2.8 Notification of URERC Decision for signature of URERC Chair.
5.3. The URERC Staff releases the communication to the PI/Researcher.

Step 6 File documents & update protocol file index and the protocol database

6.1. The URERC Staff ensures that the version number and date marked on the amended documents are correct.
6.2. The URERC Staff keeps a copy of all protocol amendment related documents in the protocol file folder, updates the protocol file index and the protocol database.

3.2 Review of Progress Reports

3.2.1 Purpose

To describe the WVSU URERC review procedures for progress report for renewal of WVSU URERC approval.

3.2.2 Scope

This SOP provides instructions for the review of progress reports that are required by the URERC to be submitted by the Principal Investigator to monitor the safety of participants enrolled in a study.

The annual report becomes the basis for continuing review of protocols the approval of which needs to be renewed every year.

This SOP applies to the conduct of any continuing review of study protocols involving human subjects at intervals appropriate to the degree of risk but not less than once a year. Depending upon the degree of risk to the participants, the nature of the studies, and the vulnerability of the study participants and duration of the study, the URERC may require more frequent submission of progress report.

All progress reports of clinical trials are reported to Full Board unless the site has stopped recruitment or is already in the patient safety follow up period.

3.2.3 Responsibility

It is the responsibility of the URERC Secretariat to remind investigators/researchers to submit the progress reports one month before the due date, to forward the reports to the primary reviewers for review, and to communicate the URERC decision to the Principal Investigator (PI)/Researcher.

It is the responsibility of the Primary Reviewers to review the reports to check completeness of the information, as well as changes in the risk/benefit ratio and ensure that it is in accordance with the protocol and related documents approved by the URERC.

3.2.4 Process Flow/Steps

STEP	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Receive the progress report package and check its completeness	Staff	7 days
2	Determine type of review & identify Primary Reviewers	Chair/ Member Secretary	
3	Forward progress report to Primary Reviewers for review	Staff; Primary Reviewers	
4	Discuss the progress report or report the expedited review result to the URERC during full board meeting	URERC Members; Chair/Member Secretary	1 day
5	Communicate the URERC decision to Principal Investigator/Researcher	Secretariat; Chair	7 days
6	File documents & update protocol file index and protocol database	Staff	1 day

Diagram 11. Review of Progress Reports

3.2.5 Detailed Instructions

Step 1 Receive the progress report package and check its completeness

1.1. The URERC Staff periodically checks the protocol database to track due dates of progress reports of study protocols approved by the URERC.
1.2. The URERC Staff prepares and sends a reminder letter addressed to the PI/Researcher one month before the due date of the report.
1.3. For studies of long term duration (more than 3 years), the PI and the rest of the study team are required to submit evidence of updated Good Clinical Practice (GCP) Training.
1.4. The URERC Staff checks the completeness of submitted application for review package and whether forms used are correct.
1.5. The PI/Researcher records the submission in the log book.

Step 2 Determine type of review & identify Primary Reviewers

2.1. The continuing review of protocol initially reviewed at full board is again reviewed at full board.
2.2. The URERC Staff identifies the Primary Reviewers who did the initial review.

2.3. If Primary Reviewers are not available to do the review, the URERC Chair and/or Member Secretary may do the review provided they do not have COI. Otherwise the Chair designates qualified members to do the review.

Step 3 Forward progress report to Primary Reviewers for review

3.1. Should it be deemed necessary, the URERC Staff photocopies relevant documents of previous review/s of the protocol such as current versions of the protocol, informed consent forms (ICF), protocol amendments, protocol deviations and on-site SAEs/SUSARs since the last continuing review. They will provide the Primary Reviewer/s with background information to facilitate the assessment of risk-benefit ratio. Better still, the Primary Reviewers can go to the URERC office to review pertinent documents in the protocol file folder and determine whether there is a change in the risk-benefit ratio.

3.2. The URERC Staff sends the progress report package to the Primary Reviewers at least 7 days before full-board meeting.

3.3. Primary Reviewers conduct continuing review of progress/annual report if they are in accordance with the protocol and related documents approved by the URERC.

3.4. Primary Reviewers refer to documents in the protocol file folder to check compliance with the latest URERC approved protocol and ICF.

3.5. In the review of the progress/annual report, the following are the key evaluation points:

A. Risk Assessment
   1. The risks to the subjects are minimized
   2. The risks to the subjects are reasonable in relation to anticipated benefits, if any, and the importance of the knowledge that may be expected to be gained from the study.

B. Adequacy of Informed Consent
   1. Informed consent/Assent forms current (most recent)
   2. Appropriate, new significant findings since the last continuing review that may be related to the subjects' willingness to continue participation provided to enrolled subjects (e.g., important toxicity or adverse event information)

C. Local Issues
   1. Changes in the investigator's situation or qualifications (e.g., suspension of hospital privileges, medical license; involvement in numerous clinical trials)

2. Evaluation, investigation and resolution of complaints related to the research, if any.
3. Changes in the acceptability of the proposed research in terms of institutional commitments (e.g., personnel and financial resources, adequacy of facilities) and regulations, applicable national law, or standards of professional conduct of practice.)
4. Report from third party observation of the research (including the informed consent process) carried out
5. Investigator concerns about trial conduct at the local site (e.g., study coordinator ineffectiveness, inability of subjects to understand sections of the informed consent document required by institutional policies), if any.

D. Trial Progress
1. Start date of the study and expected duration
2. Total subject enrollment
   2.1. Expected enrollment
   2.2. Actual enrollment
   2.3. Enrollment issues
3. Subject withdrawal
   3.1. Number of subjects who withdrew
   3.2. Lost to follow-up
   3.3. Summary of reasons for withdrawal at local site

3.6. The URERC may also request the Principal Investigator/Researcher to provide additional information, when necessary.

Step 4 Discuss the progress report or report the expedited review result to the URERC during full board meeting

For full board review of progress report:

4.1. The URERC Secretariat includes the application for renewal of URERC approval in the agenda.

4.2. The protocol file folder for continuing review, including relevant URERC meeting minutes, should be made available during the meeting.

4.3. During the meeting, the Primary Reviewers present a summary of the progress of the research, any significant issues and their recommendation to full-board.

4.4. The URERC members determine the need for the investigator to elaborate, explain or clarify any aspect of the progress/annual report as deemed necessary.

4.5. The following are the possible URERC decisions for continuing review:

A. Renew approval

B. Request additional information
C. Recommend modification
D. Suspend:
    1. Enrollment of new subjects
    2. Research procedures in currently enrolled subjects - entire study
E. Disapprove renewal

4.6. Approval of progress report reviewed by the Primary Reviewers by expedited procedure is reported to the board meeting by the Chair/Member Secretary.

Step 5 Communicate the URERC decision to Principal Investigator/Researcher

5.1. The URERC Secretariat takes note of the decision and/or discussion during the board meeting in the meeting minutes and communicates with the PI/Researcher if further action is required.
5.2. URERC Staff prepares Form 2.7 Approval Letter or Form 2.8 Notification of URERC Decision for signature of URERC Chair.
5.3. The URERC Staff releases the notification or approval to the PI/Researcher.

Step 6 File documents & update protocol file index and protocol database

6.1. URERC Staff keeps the continuing review application package together with the review comments of the Primary Reviewer/s in the protocol file folder and updates the protocol file index.
6.2. URERC Staff updates the protocol database.

3.3 Review of Final Reports

3.3.1 Purpose

To describe the WVSU-URERC review procedures for Final Reports.

3.3.2 Scope

This SOP provides instructions for the review of final reports that are required by the WVSU-URERC to be submitted by the Principal Investigator/Researcher when the approved study is completed or when the study site is closed. The final report when approved by the URERC becomes the basis for initiation of the archiving procedure. This SOP applies to the review of final/closure report of a study protocol approved by the URERC.

3.3.3 Responsibility

It is the responsibility of the URERC Staff to identify study protocols whose final reports are due.

It is the responsibility of the Primary Reviewers to review the reports to check completeness of information and to ensure that the data are in accordance with the protocol and other related documents approved by the URERC.

3.3.4 Process Flow/Steps

STEP	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Receive the Final Report package and check its completeness	Staff	7 days
2	Identify Primary Reviewers	Chair; Secretariat	
3	Forward Final Report to Primary Reviewers for review	Staff; Primary Reviewers	
4	Approve the Final Report during URERC full board meeting	URERC Members; Chair/Member Secretary	1 day
5	Communicate URERC decision to Principal Investigator/Researcher	Secretariat; Chair	7 days
6	File documents & update protocol file index and protocol database	Staff	1 day

Diagram 12. Review of Final Reports

3.3.5 Detailed Instructions

Step 1 Receive the Final Report package and check its completeness

1.1. The submission shall include the accomplished Form 3.3 Final Report. An abstract is included for researcher-initiated protocols.

1.2. The URERC Staff verifies the completeness of the submission and whether the Protocol Code Number and the forms used are correct.

Step 2 Identify Primary Reviewers

2.1. The URERC Staff identifies the Primary Reviewers of the protocol from the protocol database.

2.2. If the Primary Reviewer is not available, the review is done either by the URERC Chair/Member Secretary, or qualified Member/s designated by the Chair/Member Secretary.

Step 3 Forward Final Report to Primary Reviewers for review

3.1. The URERC Staff records the Final Report package in the Log of Outgoing Documents.

3.2. The Final Report package is forwarded to the Primary Reviewer/s at least 7 days before the full board meeting.

3.3. The Primary Reviewer/s accomplish the review by commenting and recommending appropriate action on the Final Report form.

3.4. Primary Reviewer signs and dates the form and returns the Final Report package to the URERC Staff.

Step 4 Approve the Final Report during URERC full board meeting

4.1. The Primary Reviewer presents the results of the review.

4.2. The URERC decision can be any of the following:

A. Acknowledged/Accepted
B. Request for further information
C. Recommend further action

4.3. The Secretariat takes note of the decision and/or discussion during the board meeting in the meeting minutes.

Step 5 Communicate URERC decision to Principal Investigator/Researcher

5.1. If further action is required, the URERC Staff prepares Form 2.8 Notification of URERC Decision for signature of the URERC Chair.

5.2. The URERC Staff releases the notification to the PI/Researcher.

Step 6 File documents & update protocol file index and protocol database

6.1. The URERC Staff files the accomplished, signed and dated Final Report and other related documents in the protocol file folder and updates the protocol file index.

6.2. Upon approval of the Final Report, the study protocol is classified as inactive, the Protocol Code Number is updated and the protocol file folder re-labeled and transferred to storage cabinet for inactive files.

6.3. URERC Staff updates the protocol database.

3.4 Review of Serious Adverse Events

3.4.1 Purpose

To describe the WVSU URERC review procedures for Serious Adverse Events (SAE).

3.4.2 Scope

This SOP applies to the review of Serious Adverse Events (SAE) and Suspected Unexpected Serious Adverse Reaction (SUSAR) reports submitted by investigators and sponsors to the URERC to comply with ICH GCP. The URERC reviews such reports to determine appropriate action to protect the safety of participants in an approved study.

ICH-GCP E6 defines a Serious Adverse Event (SAE) or a Serious Adverse Drug Reaction (ADR) as any untoward medical occurrence that at any dose:

A. Results in death;
B. Is life threatening;
C. Requires hospitalization or prolongation of existing hospitalization;
D. Results in persistent or significant disability or incapacity, or;
E. Results in a congenital anomaly or birth defect.

A Suspected Unexpected Serious Adverse Reaction (SUSAR) is a serious event the nature and severity of which is not consistent with the applicable product information. In the case of an unapproved investigational product, the event is not consistent with the Investigator's Brochure (IB). In the case of a licensed product, the event is not consistent with the approved package insert or summary of product characteristics.

3.4.3 Responsibilities

A. The primary responsibility of the URERC is to conduct an appropriate review of SAE and SUSAR reports to ensure oversight over the safety of participants enrolled in the study.
B. The URERC should also make sure that researchers are made aware of its policies and procedures concerning SAE reporting.
    1. PI/Researcher must submit on-site SAE/SUSAR reports within 7 days from it occurrence.
    2. PI/Researcher must submit SAE/SUSAR reports occurring from other site as soon as they receive the reports from the sponsor.
C. The URERC sets up the necessary mechanisms to receive SAE and SUSAR reports from investigators and sponsors of researches that it has approved.

D. The URERC also receives SAE and SUSAR reports from other sites within and outside the country. It is the responsibility of the URERC to be updated about safety issues related to studies that it has approved.

3.4.4 Process Flow/Steps

STEP	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Receive SAE/SUSAR Report	Staff	14 days
2	Determine type of review and forward SAE Reports to designated reviewer	Member Secretary	
3	Review on-site and offsite SAEs	Primary Reviewers; Designated URERC Members	
4	Discuss on-site SAE reports at full board to ensure patient safety	URERC Members; Chair/Member Secretary	
5	Communicate decision to Principal Investigator/Researcher	Secretariat; Chair	
6	File documents in protocol file folder and update SAE database	Staff	

Diagram 13. Review Process for Serious Adverse Events

3.4.5 Detailed Instructions

Step 1 Receive SAE/SUSAR Report

1.1. The URERC Staff checks submitted documents for completeness and whether Protocol Code Number and form used are correct.

Step 2 Determine type of review and forward SAE Reports to designated reviewer

2.1. On-site SAEs and SUSARs are reviewed by a suitable member designated by the Chair.

2.2. The designated member classifies the on-site report whether expected or unexpected.

2.3. Off-site SAEs are reviewed through expedited process by a URERC designated member to note the trends in SAE occurrence. They are classified whether off-site within the country or off-site outside the country.

2.4. The designated member recommends appropriate action to be done by the URERC.

Step 3 Review on-site and offsite SAEs

3.1. The URERC should adopt appropriate response depending on the site where the SAE/SUSAR happened.

3.2. For SAEs that occur onsite, the URERC should analyze the investigator/sponsor's assessment (related, unexpected):

A. Assessment of the SAE is unlikely or unrelated to the study drug or article: The report is reviewed at the convened meeting by full committee.

B. Assessment of the SAE is definitely, possibly, or probably related to the study drug or article: The report is added to the agenda for review at a convened meeting by full committee.

C. Assessment of the SAE is unexpected/unanticipated and definitely, possibly, or probably related to the study drug or article: The report is added to the agenda for review at a convened meeting by full committee.

3.3. For multicenter, international studies, note the trend of occurrence of SAE/ SUSAR in study sites in foreign counties and other local sites. For multicenter, national studies, note the nature (related or expected) of the SAE/ SUSAR.

Step 4 Discuss on-site SAE reports at full board to ensure patient safety

4.1. Primary Reviewers or designated member/s present the results of review to full-board.

4.2. Full-board discusses on-site SAEs and its impact to patient safety.

4.3. After deliberation the URERC decides on appropriate action as follows:

A. Request PI/Researcher to follow up subjects and update URERC of the outcome of the SAE;

B. Request an amendment to the protocol or consent form;

C. Request further information;

D. Suspension of:

1. Enrollment of new research participants until further review by the URERC;
2. All trial-related procedures (except those intended for the safety and well-being of the participants) until further review by the URERC;

E. Termination of the study;

F. Take note and continue monitoring;

G. Conduct Study Site Visit.

4.4. Designated member reports trends in off-site SAEs for full board information. This will be reported on a quarterly basis to full board.

Step 5 Communicate decision to Principal Investigator/Researcher

5.1. If necessary, URERC Staff prepares Form 2.8 Notification of URERC Decision about SAE Report for URERC Chair's signature.

5.2. Forward the notice to the PI/Researcher.

Step 6 File documents in protocol file folder and update SAE database

6.1. URERC Staff files the documents in the protocol file folder and updates the protocol file index.

6.2. URERC Staff encodes the SAE or updates the SAE Database.

3.5 Review of Protocol Violation/Protocol Deviation

3.5.1 Purpose

To describe the WVSU-URERC review procedures for Protocol Violation/Deviation.

3.5.2 Scope

This SOP provides instructions for taking action and maintaining records of various types of protocol deviation or violations:

A. It includes Investigators/Researchers who fail to comply with the procedures in the approved protocol or to comply with national/ international guidelines for the conduct of human research, including those who fail to respond to the URERC's requests.
B. It also covers action taken by the URERC related to Protocol Violation/Deviation Reports submitted by the Principal Investigator/Researcher related to any event at the site that is not in compliance with the protocol documents previously approved by the URERC.

3.5.3 Responsibility

It is the responsibility of the URERC Staff to receive protocol violation/ deviation reports submitted to the URERC. It is the responsibility of the URERC Chair or Member Secretary or Primary Reviewer to take action related to protocol violation/ deviation.

3.5.4 Process Flow/Steps

STEP	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Receive Protocol Violation/Deviation Report	Staff	14 days
2	Forward Protocol Violation/Deviation Report to designated reviewer	Staff	
3	Discuss/report during full board meeting for decision/information	URERC Members; Chair/Member Secretary	
4	Communicate decision to Principal Investigator/Researcher	Secretariat; Chair	
5	File documents in protocol file folder and update protocol database	Staff	

Diagram 14. Review Process for Protocol Violation/Deviation

3.5.5 Detailed Instructions

Step 1 Receive Protocol Violation/Deviation Report

1.1. Reports of protocol deviation/violation may come directly from the PI/Researcher, or as result of study site monitoring by the Clinical Monitor/Sponsor or the URERC Site Visit Team, or from related documents received by the URERC.

1.2. The URERC Members performing monitoring of the research study at the trial site may detect protocol violation/deviation if the implementation of the research is not conducted as per approved protocol or institutional, national or international standards.

1.3. It is the responsibility of the Principal Investigator/Researcher to determine whether a protocol violation/deviation is major or minor, and ensure proper reporting to URERC. If the PI/Researcher is unsure whether the variance is a violation or deviation s/he should seek advice from the sponsor to ensure appropriate action is taken.

1.4. The URERC Staff checks submitted documents for completeness and whether Protocol Code Number and form used are correct.

1.5. The PI/Researcher records the submission in the Log of Incoming Documents.

Step 2 Forward Protocol Violation/Deviation Report to designated reviewer

2.1. Major protocol violation/deviation is a persistent protocol noncompliance with potentially serious consequences that could put patients' safety at risk or critically affect data analysis.

2.2. Minor protocol deviation is a non-systematic protocol noncompliance with minor consequences, in terms of its effect on the participant's/subject's rights, safety or welfare, or the integrity of study data; includes deviations that are administrative in nature.

2.3. Protocol violation in a research study should be discussed at Full Board meeting.

2.4. The URERC Secretariat includes the Protocol Violation/Deviation Report in the meeting agenda for the month.

2.5. The URERC Chair refers the Protocol Violation/Deviation Report to the designated member at initial review.

2.6. The URERC Staff records the report and forwards the package to the designated reviewer at least 7 days before the full committee meeting.

2.7. The designated reviewer assesses if the protocol violation/deviation impacts on patient safety or the integrity of the data.

2.8. The designated reviewer completes the review and recommends corrective actions, if any, within 7 days after receipt.

2.9. Forward their assessment to the Secretariat.

2.10. The result of the review decision is reported to full board for discussion.

Step 3 Discuss/report during full board meeting for decision/information

3.1. The designated reviewer presents the result of his/her assessment to full board that deliberates on effects of the protocol violation/ deviation on the rights and safety or research participants or integrity of data.

3.2. Possible decisions are as follows:

A. Acknowledged – no further information or action required

B. Additional information required – additional information is needed in order to properly evaluate the violation

C. Correction and/or corrective actions are required. The URERC must specify the corrective measures to prevent harm to current and future research participants.

Step 4 Communicate decision to Principal Investigator/Researcher

4.1. If the PI/Researcher or sponsor requires a written notification, the URERC Staff prepares the Notification Letter for signature of the URERC Chair and is released to the PI/Researcher.

4.2. If correction and/or corrective action are required from the PI/Researcher, the PI/Researcher is requested to provide the information within 10 days.

4.3. A site visit may also be required by the URERC.

Step 5 File documents in protocol file folder and update protocol database

5.1. URERC Staff checks if Protocol Violation/Deviation Report is completely accomplished, signed and dated by Primary Reviewers and files the document in the protocol file folder, and updates the protocol file index.

5.2. Filed documents should also include the Study Site Monitoring Visit Report, if a post-review study site visit was conducted.

5.3. The URERC Staff records the protocol violation/deviation in the protocol violation/deviation database to facilitate tracking of repetitive violations/deviations of the same nature.

3.6 Responding to Participant Requests/Queries

3.6.1 Purpose

To describe the WVSU URERC procedures related to participant requests and/or queries.

3.6.2 Scope

This SOP applies to all queries and requests related to the rights and well-being of the research participants in studies approved by the URERC.

3.6.3 Responsibility

A designated member of the Secretariat is responsible for receiving participant queries and requests related to their participation, refers relevant issues to the URERC Chair to take appropriate action. The Secretariat keeps records of all actions taken by the URERC.

3.6.4 Process Flow/Steps

STEP	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Receive the complaint or injury	Staff	7 days
2	Review the complaint/inquiry	Chair/Member Secretary	
3	Discuss in convened meeting or report the decision/action taken to full board	URERC Members; Chair/Member Secretary	
4	Communicate URERC's response	Secretariat; Chair	
5	File pertinent documents	Staff	

Diagram 15. Steps in Responding to Requests/Queries

3.6.5 Detailed Instructions

Step 1 Receive the complaint or injury

1.1. Study protocol-related complaints and inquiries may come from research participants, or other parties.
1.2. The URERC Staff receives the complaint.
1.3. The URERC Staff may assist to put the complaint in writing especially if the complainant or inquiring party is a research participant.

1.4. The URERC Staff responds to inquiry, if it is within its authority to do so or refers the complaint or inquiry to the Chair/Member-Secretary for appropriate action.
1.5. The URERC Staff records the submitted document in the Log of Incoming Documents.

Step 2 Review the complaint/inquiry

2.1. The URERC Chair or Member Secretary reviews the complaint.
2.2. The PI/Researcher may be contacted to provide clarification or further information.

Step 3 Discuss in convened meeting or report the decision/action taken to full board

3.1. The Chair presents a serious complaint to full board for discussion.
3.2. The URERC Members discuss to take appropriate actions.

Step 4 Communicate URERC's response

4.1. The URERC Secretariat prepares response to inquiry complaint within 7 days from the time of review.

Step 5 File pertinent documents

5.1. The URERC Staff files the accomplished Form 3.6 Request/Query Record together with the letter of inquiry/complaint and excerpts of the meeting minutes when this was deliberated or reported in the protocol file folder.
5.2. The URERC Staff updates the protocol file index.

3.7 Site Visits

3.7.1 Purpose

To describe the WVSU-URERC procedures related to the conduct of site visits.

3.7.2 Scope

This SOP applies to any visit made in any study site, on behalf of the URERC, to check compliance with URERC approved protocol and related documents and national and international standards.

3.7.3 Responsibility

It is the responsibility of the URERC to conduct study site monitoring for cause or routine.

URERC Members may recommend that a particular study site be visited.

The URERC Chair/Member Secretary selects members of the study site visit team.

3.7.4 Process Flow/Steps

STEP	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Select study site to visit	URERC Members	7 days
2	Create Study Site Visit Team	Chair/Member Secretary	
3	Prepare Study Site Visit Plan	Study Site Visit Team	
4	Notify Principal Investigator of date of site visit	Chair/Member Secretary	
5	Conduct site visit and debrief study team	Study Site Visit Team	14 days
6	Present findings during full committee meeting	Study Site Visit Team; URERC Members	
7	Communicate results of site visit and recommended actions, if any to Principal Investigator	Staff	
8	File pertinent documents	Staff	

Diagram 16. Process in Conducting Site Visits

3.7.5 Detailed Instructions

Step 1 Select study site to visit

1.1. The URERC Members may recommend to visit study sites for any of the following reasons: frequent occurrence of SAE, protocol violations, failure to submit progress reports, complaints about PI performance.

1.2. Visits may also be conducted to monitor implementation of risky protocols, PI with many ongoing studies or inexperienced PIs.

1.3. Study site visit may be conducted upon recommendation of Primary Reviewers.

Step 2 Create Study Site Visit Team

2.1. The URERC Chair/Member Secretary selects members of Study Site Visit Team and designates the Team Leader. Members should include the Primary Reviewers.

2.2. The Site Visit Team members are formally informed of their assignment.

2.3. If necessary, the URERC Staff prepares the Study Site Visit package consisting of the latest version of the approved protocol and informed consent documents, and other relevant documents, (like protocol deviation reports, on-site SAEs/SUSARs - initial and follow-up reports) and a copy of the Site Visit Report Form (Form 3.7 Site Visit Report).

Step 3 Prepare Study Site Visit Plan

3.1. The Study Site Visit Team prepares the Study Site Visit Plan that includes the following:

A. Date and time of the planned visit
B. Members of the Study Site Visit Team
C. Objectives of the Visit
D. Documents to be reviewed
E. Persons to be interviewed

3.2. The Study Site Visit Team, in consultation with the URERC Chair, is given access to documents in the protocol file folder of a study for monitoring. The Team may also photocopy some parts of the files (like advertisement materials, the informed consent form (ICF), case report form) for comparison with the documents used in the study site.

Step 4 Notify Principal Investigator of date of site visit

4.1. The URERC Staff prepares the letter informing the PI of the planned study site visit for signature by the URERC Chair. The notification is given at least 1 week before the site visit.

Step 5 Conduct site visit and debrief study team

5.1. The Study Site Visit Team conducts the site visit as per the Study Site Visit Plan. Additional guide in the conduct of the visit is the Site Visit Report Form.

5.2. At the end of the visit, the Study Site Visit Team presents the findings to the Study Team and solicits feedback.

5.3. The Study Site Visit Team completes the Site Visit Report Form. Conflicting findings should be resolved by consensus.

5.4. The report is submitted to the URERC Staff within 7 calendar days from the date of the visit.

5.5. The URERC Secretariat includes the presentation of the study site visit report in the meeting agenda.

Step 6 Present findings during full committee meeting

6.1. The Study Site Visit Team presents the report during the full committee meeting.

6.2. The URERC makes a determination whether the rights, safety and welfare of research participants are compromised and appropriate recommendations to the PI, if any.

Step 7 Communicate results of site visit and recommended actions, if any to Principal Investigator

7.1. Based on the minutes of the meeting, the URERC Staff notifies the PI of the results of the site visit. If the PI/Researcher or sponsor requires a written notification, the URERC Staff prepares the notification for the URERC Chair' signature.

7.2. The PI may be requested to provide additional information or documents or implement corrective actions.

7.3. The URERC follows up on the response or compliance of the PI/Researcher to the site visit recommendations.

Step 8 File pertinent documents

8.1. The URERC Staff files the Site Visit Report, excerpt of the minutes of the meeting when report was discussed and the notification letter (including the response from the PI, if any) in the protocol file folder and update the protocol file index.

3.8 Review of Early Protocol Termination

3.8.1 Purpose

To describe the WVSU-URERC procedures related to early termination of protocol implementation.

3.8.2 Scope

This procedure describes how the URERC proceeds and manages the premature or early termination of a protocol when subject enrollments are discontinued before the scheduled end of the study. Protocols are usually terminated at the recommendation of the Data Safety Monitoring Board (DSMB), the Scientific Director, Sponsor, Principal Investigator, by the ethics committee itself or other authorized bodies.

3.8.3 Responsibility

It is the responsibility of the URERC to act on any early protocol termination application. It is also the responsibility of the URERC to withdraw approval for any previously approved protocol when the safety or benefit of the study participants is doubtful or at risk. All applications are reviewed at Full Board for appropriate action.

The URERC Secretariat is responsible for the receipt and management of the termination documentation. The Primary Reviewers review the reasons for early termination and make a recommendation to Full Board.

3.8.4 Process Flow/Steps

STEP	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Receive application for early study termination	Staff	7 days
2	Refer notice of early termination to Primary Reviewers	Staff; Chair/Member Secretary/ Primary Reviewers	
3	Review the submission	URERC Members	
4	Deliberate decision during full board meeting	URERC Members	1 day
5	Communicate URERC decision to the Principal Investigator/Researcher	Chair; Staff	7 days
6	File pertinent documents and update protocol database	Staff	1 day

Diagram 17. Review of Early Protocol Termination Process

3.8.5 Detailed Instructions

Step 1 Receive application for early study termination

1.1. An application for early termination is submitted when a URERC approved study protocol is being recommended for termination before its scheduled completion. This is done when the rights, safety and welfare of participants are threatened or upon the request of the PI or sponsor due to operational problems.

1.2. Recommendation for early termination may come from the Data Safety Monitoring Board (DSMB), the Scientific Director, Sponsor, Principal Investigator, URERC or other authorized bodies.

1.3. URERC Staff receives the study protocol termination package submitted by the Principal Investigator and verifies whether the Protocol Code Number and form used are correct and the completeness of Form 3.8 Study Termination.

1.4. URERC Staff checks approval given by the URERC and type of review from the protocol data base.

Step 2 Refer Notice of early termination to Primary Reviewers

2.1. The URERC Staff forwards the document package to the Primary Reviewer/s.

Step 3 Review the Submission

3.1. The Primary Reviewer assesses the termination issues and make recommendations. The Primary Reviewers review the safety data. It is important for the termination package to contain a plan to follow up the participants who are still active in the study.

3.2. For submission to full board review, the URERC Secretariat includes the review of the study for early termination in the meeting agenda.

Step 4 Deliberate decision during full board meeting

4.1. The URERC deliberates on the effects of the early study termination on the safety and welfare of study participants.

4.2. Final decision of the application are as follows:

A. Approval
B. Acknowledgment
C. Further information required

Step 5 Communicate URERC decision to the Principal Investigator/Researcher

5.1. Based on the minutes of the meeting, the URERC Staff notifies the PI/Researcher of the results of the deliberation of the early termination report. If the PI/Researcher or sponsor requires a written notification, the URERC Staff prepares the notification for the URERC Chair' signature.

5.2. The PI/Researcher may be requested to provide additional information or documents or implement actions to ensure the safety and welfare of subjects still active in the study.

Step 6 File pertinent documents and update protocol database

6.1. The URERC Staff files Form 3.8 Study Termination, excerpt of the minutes of the meeting when report was discussed and the notification letter (including the response from the PI/Researcher, if any) in the protocol file folder and update the protocol file index.

6.2. Upon approval of the early study termination application, the study protocol is classified as inactive, the Protocol Code Number is updated and the protocol file folder re-labeled and transferred to storage cabinet for inactive files.

6.3. URERC Staff updates the protocol database.

FORM 3.1 PROTOCOL AMENDMENT REVIEW

URERC Protocol Number	Sponsor Protocol Number	Date of Submission

Principal Investigator/Researcher	Sponsor	Date of Initial Approval

Protocol Title	

Items to be Amended (Previous Version)	Amended Version	Reasons for Amendment

FOR URERC USE:

Type of Amendment:	Major	☐	Minor	☐
Does the amendment increase the risk to participant?	Yes	☐	No	☐
Is there favourable benefit/risk ratio	Yes	☐	No	☐

Comments of Primary Reviewers	

Name of Primary Reviewer	Signature	Date

URERC Final Decision

Approval
Major Revisions to the protocol/informed consent form
Minor Revisions to the protocol/informed consent form
Disapproval

Name of Chair	Signature	Date

FORM 3.2 PROGRESS REPORT

URERC Protocol Number		Date of Approval	
Protocol Title			
Principal Investigator/ Researcher		Received by: Name & Signature Date Received:	
Sponsor			

ACTION REQUESTED:

For Quarterly Reports	For Annual Reports
☐ For Notification Only	☐ Renew - New Participant Accrual to Continue
☐ Terminate - Protocol Discontinued	☐ Renew - Enrolled Participant Follow Up Only
	☐ Terminate - Protocol Discontinued

1. Any amendment **to the protocol** since the last review?
   ☐ Yes ☐ No — Describe briefly:

2. Any change in participant population, recruitment or selection criteria since the last review?
   ☐ Yes ☐ No — Explain the changes

3. Any change in the Informed Consent process or documentation since the last review?
   ☐ Yes ☐ No — Explain the changes:

4. Is there any new information in recent literature or similar research that may change the risk/ benefit ratio for participants in this study?
   ☐ Yes ☐ No — Discuss and attach a narrative:

5. Any unexpected complication or side effect noted since the last review?
   ☐ Yes ☐ No — Discuss and attach a narrative:

6. Did any participant withdraw from this study since the last approval?

☐ Yes ☐ No

Reasons for withdrawal:

7. Any new investigator that has been added to or removed from the research team since the last review?

☐ Yes ☐ No

Please identify them and submit the CVs of new investigators:

8. Are there any new collaborating sites that have been added or deleted since the last review?

☐ Yes ☐ No

Please identify the sites and note the addition or deletion:

SUMMARY OF PROTOCOL PARTICIPANTS

	Since the Study Started	For the Quarter Only	For the Year
Total Screened			
Total Screened Failures			
Total Re-screened			
Total Randomized			
Total Completed			
Total Early Termination			

To be filled out by URERC Primary Reviewer

RECOMMENDATIONS:

For Quarterly Reports	For Annual Reports
☐ Noted and Accepted	☐ Approved
☐ Request further information	☐ Request an amendment to the protocol
☐ Suspend or terminate the study	☐ Request an amendment to the Consent Form
	☐ Request further information
	☐ Suspend or terminate the study

Changes to the Protocol recommended:

☐ Yes ☐ No

Comments:

Changes to the Informed Consent Form recommended:

☐ Yes ☐ No

Comments:

Primary Reviewer	Signature	Date

URERC Final Decision	

Certified by:

Name of Chair	Signature	Date

FORM 3.3 FINAL REPORT

URERC Protocol Number		Date of Approval	
Protocol Title			
Principal Investigator/ Researcher		Sponsor	
Study Site(s)			

1.	Study Arms	
2.	Summary of Participants Total Screened Total Screened Failures Total Rescreened Total Randomized Total Completed Total Early Termination	
3.	Amendments to the original protocol	
4.	Summary of Onsite SAE's reported	
5.	Summary of Participant's Complaints or Grievances documented	
6.	Summary of Benefits to Participants	
7.	Summary of Indemnifications of Study Related Injury (If applicable)	
8.	Reasons for Early Terminations	
9.	Progress Reports Submitted	
10.	Duration of Study	
11.	Informed Consent Versions Used (Indicate Version and Date)	
12.	Study Objectives	
13.	Summary of Results	

PI's Name and Signature		Date	

URERC Recommendation

- ☐ Acknowledged. No further information or action required
- ☐ Additional information required
- ☐ Others: _____

Name of Reviewer	Signature	Date

FORM 3.4 SERIOUS ADVERSE EVENT REPORT

Whenever there is any Serious Adverse Event (SAE) in any research approved by the West Visayas State University Unified Research Ethics Review Committee, it has to be reported by the Principal Investigator (PI) to the URERC. Section 1 of this form should be filled out by the PI.

SECTION 1

URERC Protocol Number			
Sponsor Protocol Number		Date of Submission	
Principal Investigator/ Researcher			
Protocol Title			

Name of the Study Medicine/Device

Onset Date

☐ Initial

☐ Follow Up

Sponsor

Date of First Use

Subject's Initials / Number Code

☐ Male

Age

☐ Female

Subject's History

Laboratory Findings

Serious Adverse Event (SAE)

Seriousness

☐ Death ☐ Life Threatening

☐ Hospitalization:

☐ Initial ☐ Prolonged

☐ Disability/Incapacity

☐ Congenital Anomaly

☐ Others

Classification

☐ Drug Related ☐ Unrelated to Drug

☐ Expected ☐ Unexpected

Treatment Outcome

☐ Resolved ☐ On-going ☐ Not Applicable

Note: PI should attach standard SAE Report Form to this ERC Form.

SECTION 2 (To be filled out by URERC)

Changes to the Protocol Recommended ☐ No ☐ Yes
Comments:

Changes to the Informed Consent Form Recommended? ☐ No ☐ Yes
Comments:

URERC Final Action:

☐ Request an amendment to the protocol or the consent form.

☐ Request further information.

☐ Suspend or terminate the study.

☐ Take note and no further action needed.

☐ Others: _____

Type of Review:

☐ Expedited

☐ Full Review

Date of Full Board Meeting

_____

Name of Reviewer	Signature	Date

Documents Received By:

Name	Signature	Date

FORM 3.5 DEVIATION / NON-COMPLIANCE / VIOLATION REPORT

URERC Protocol Number	Sponsor Protocol Number	Date of Submission

Protocol Title	
Principal Investigator/ Researcher	Contact Number
Sponsor	

☐ PI Deviation from Protocol ☐ Participant Non-Compliance

☐ Major ☐ Minor

Description	
Actions Taken by PI/Researcher	

URERC Recommendation

☐ Acknowledged. No further information or action required

☐ Additional information required

☐ Corrective action required

☐ Site Visit Needed

☐ Others: _____

Type of Review:

☐ Expedited

☐ Full Review

Date of Full Board Meeting

_____

URERC Decision	

Reported By/Date	Noted By (Secretariat)/Date

FORM 3.6 REQUEST/ QUERY RECORD

Date Received		Received By	

Request From	☐ Telephone call Number	_____
	☐ Fax Number	_____
	☐ Mailed letter / Date	_____
	☐ E-mail / Date	_____
	☐ Walk-in/Date/Time	_____
	☐ Others *(specify)*	_____

Name			
Address		Contact Number	
Title of the Participating Study			
Starting Date of Participation			
Request			
Action Taken			
Outcome			

FORM 3.7 SITE VISIT REPORT

URERC Protocol Number		Date of the Visit	
Protocol Title			
Principal Investigator/s		Contact Number	
Institution/Department		Address	
Sponsor		Address	
Total Number of Expected Subjects/Participants		Total Subjects/ Participants Enrolled	

		YES	NO	COMMENTS
1.	Are site facilities appropriate?			
2.	Is confidentiality of documents maintained (e.g. cabinets with lock and keys)?			
3.	Are the test articles properly kept and maintained?			
4.	Are Informed Consent Forms complete?			
5.	Are Informed Consent Forms recent/approved versions?			
6.	Are copies of the approved versions of the protocol documents kept in the site?			
7.	Does the site keep copies of all communications with the REC in the site?			
8.	Any adverse events found?			
9.	Are Investigator functions properly delegated to qualified research personnel?			
10.	Is there appropriate documentation of qualifications of personnel?			
11.	Are all Case Record Forms up to date?			
12.	Any protocol non-compliance/violation?			
13.	How well are participants protected? (Good/Fair/Not Good)			
14.	Any outstanding tasks or results of visit?			
15.	Is there evidence of appropriate corrective action taken as recommended by the REC?			

Summary of Findings:					
Duration of Visit (Hours)		Start Time		End Time	
Name of URERC Member/Representatives					
Completed By		Date			

FORM 3.8 STUDY TERMINATION

URERC Protocol Number		Sponsor Protocol Number	
Protocol Title			
Principal Investigator/ Researcher			
Contact Number		E-Mail Address	
Institution/Department			
Sponsor			
URERC Date of Approval		Date Of Last Report	
Starting Date		Termination Date	
Number of Participants		Number Enrolled	
Reasons for Termination			
Accrual Data *(How many have completed the study? How many are still active? Plans for those who are still active in the study.)*			
Principal Investigator/Researcher Name & Signature		Date	

URERC Recommendation

- ☐ Acknowledged. No further information or action required
- ☐ Additional information required
- ☐ Others: _____

Name of Reviewer	Signature	Date

History of WVSU URERC SOP Chapter 3

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