2. Initial Review Procedures

2.1 Management of Protocol Submissions
2.2 Use of Study Assessment Forms
2.3 Exempt from Review
2.4 Expedited Review
2.5 Full Board Review
2.6 Review of Resubmission

FORM 2.1 APPLICATION FOR REVIEW
FORM 2.2 PROTOCOL SUMMARY SHEET
FORM 2.3 PROTOCOL EVALUATION
FORM 2.4 INFORMED CONSENT/ASSENT EVALUATION
FORM 2.5 CERTIFICATE OF EXEMPTION FROM ETHICS REVIEW
FORM 2.6 ASSIGNMENT OF PRIMARY REVIEWERS
FORM 2.7 APPROVAL LETTER
FORM 2.8 NOTIFICATION OF URERC DECISION
FORM 2.9 SUMMARY OF REVISIONS

Supersedes:	January 12, 2017 SOP of the URERC
Authored by:	WVSU-URERC SOP Team
	Victor A. Amantillo Jr., M.D.
	Fred P. Guillergan, M.D.
	Edna A. Medez, M.D.
	Tomasito R. Sy, M.D.
	Roberto P. Villanueva, M.D., J.D.
Effective Date:	September 20, 2021
Endorsed for approval by:	Roberto P. Villanueva, M.D., J.D. *Chair of the Committee*
Approved by:	Joselito F. Villaruz, M.D., Ph.D., FPPS *WVSU President*
Approval Date:	April 14, 2021

2.1 Management of Protocol Submission

2.1.1 Purpose

To describe the WVSU-URERC procedures for managing the submission of the initial proposal/protocol package for review - from the time of receipt to filing of the initial protocol package in the active file storage cabinet.

2.1.2 Scope

This procedure applies to all proposals/protocols submitted to the URERC for ethical review.

The URERC accepts the following proposals/protocols for review:

1. WVSU Faculty, students and staff from main and external campuses
2. Researches done by residents, students, consultants and hospital employees in WVSU Medical Center;
3. Researches referred from the PNHRS, PCHRD, DOST, PHIC, PHREB, DOH, FDA, CHED, industry organizations, etc. on the condition that the host hospital/institution where the proposal will be done accepts the review of URERC and agrees to abide by the rules and regulations that the URERC follows.
4. Approved researches by other REC's done in sites outside the WVSU for continuing review in case study has not been completed and the original REC ceases to function or becomes irrelevant for whatever reason.

The other research sites also agree to provide the necessary environment to ensure the safe and ethical conduct of the research, including oversight and stewardship functions as necessary as they agree to monitor procedures that the committee may deem necessary. These conditions should be written in a document and signed by other hospitals/ institutions that accept URERC review.

2.1.3 Responsibility

The URERC Secretariat manages all proposal/protocol submissions to the URERC. It covers the actions to be done from the time of submission to the filing of the initial protocol package in the Active File cabinet.

2.1.4 Process Flow/Steps

STEP	ACTIVITY	PERSON(S) RESPONSIBLE	TIMELINE
1	Receive the initial proposal/protocol package for review and check the completeness of the submission	Staff	To be done in 7 days
2	Assign a permanent code to the protocol package	Staff	
3	Determine the type of review and the Primary Reviewers	Chair/Member Secretary	
4	Prepare the proposal/protocol review package for distribution to the Primary Reviewers	Staff	
5	Encode the proposal/protocol package in the protocol database	Staff	
6	File the initial proposal/protocol package in a properly labelled protocol file folder and place it in the active file cabinet	Staff	

Diagram 4. Proposal/Protocol Submission Process

2.1.5 Detailed Instructions

Step 1 Receive the initial proposal/protocol package for review and check the completeness of the submission

1.1. The URERC Staff ensures that the Form 2.1 Application for Review and the Form 2.2 Protocol Summary Sheet are completely filled out, signed and dated by the researcher/investigator. For all research proposals of students (including thesis/dissertations of master and doctorate students), faculty, resident physicians (on training), and fellows, require submission of the endorsement from the department and the technical review committee.

1.2. All WVSU funded proposals need technical review. The Technical Review Committee should have addressed the technical issues in the study proposal prior to ethics review. The technical review panel should sign the technical review approval for submission to the URERC.

1.3. For non- WVSU funded proposals/protocols, a document stating that the research proposal/protocol has undergone and passed technical review should be attached to the study proposal/protocol submitted for ethical review.

1.4. Upon submission of the initial proposal/protocol for URERC review, the principal investigator (PI)/researcher or his/her representative should ensure that the proposal/protocol follows the standard proposal/protocol format and contains a summary sheet.

1.5. The PI/Researcher logs the submission of the proposal/protocol in the Logbook for Incoming Documents.

Step 2 Assign a permanent code to the protocol package

2.1. For efficient file management, the staff uses a unique identifier to refer to this file, the Protocol Code Number. This code number is given as follows:

WVSU.URERC-YYYY.Category_000; where:

WVSU : West Visayas State University
URERC : Unified Research Ethics Review Committee
YYYY : Year of Submission
Category:
- COMS College of Medicine Students
- CONS College of Nursing Students
- IS International Study/Clinical Trial
- RP-I Resident Physician of WVSU Medical Center
- RP-O Resident Physician Outside of WVSU Medical Center
- UGS-I Undergraduate Student of WVSU
- UGS-O Undergraduate Student of Non-WVSU
- GS-I Graduate Student of WVSU
- GS-O Graduate Student of Non-WVSU
- OI Outside Institution
- PR Professional Researches

000 : Chronological number per category based on order of receipt

For example, if the proposal/protocol entitled "Clinical Drug Trial of XYZ on Pediatric Patients" is the first International Study/Clinical Trial protocol received in 2017, the code that should be used is, WVSU.URERC-2017.IS_001. The code will be communicated to the Principal Investigator/Researcher in all communications regarding the proposal/protocol.

2.2. Instruct the person submitting the package to inform the researcher/PI to use the Protocol Code Number to identify the proposal/protocol in all submissions and in all his/her communications to the URERC.

Step 3 Determine the type of review and the primary reviewers

4.1. There are three (3) types of review:
   A. Exempt from Review – for negligible risk protocols
   B. Expedited Review – for low-risk protocols
   C. Full Board Review – for medium to high-risk protocols.

4.2. The following are some types of documents/researches that may be **exempt** from review:
   A. Research about public behavior (voting trends, opinion surveys, etc.)
   B. Evaluation of public programs by the agency itself
   C. Quality control studies by the agency itself
   D. Standard educational tests and curriculum development
   E. Surveillance functions of DOH
   F. Historical and cultural events
   G. Research involving large statistical data without identifiers
   H. Research not involving humans or human data
   I. Research involving anonymized human tissues

4.3. **Expedited Review** - Minimal/low risk health research that requires personal information:
   A. About a topic that should not result in causing social stigma
   B. Does not involve vulnerable populations
   C. Retrospective studies using anonymized data from medical WVSU URERC records
   D. Studies using simple questionnaires without identifiers
   E. Laboratory research that uses anonymized human tissue/specimen

4.4. **Full Board Review** may be about the following:
   A. Human health research involving medium to high risks to human participants
   B. Intervention studies involving experimental treatments like clinical trials
   C. May involve vulnerable populations who should be protected
   D. Involves private information that may cause stigma
   E. <u>The Chair/Member Secretary designates at least two URERC Members to be the primary reviewers of the proposal/protocol regardless of whether the type of review is expedited or full review.</u>
   F. Primary reviewers are selected on the basis of expertise related to the proposal/protocol.
   G. The medical/scientific reviewer analyzes the scientific and ethical aspects of the protocol while the non-medical member focuses on the informed consent form (ICF) and ICF procedure.

H. If the URERC membership does not have the needed expertise, the Chair/Member Secretary chooses from the roster of independent consultants. If none of the existing independent consultants are available, a consultant with the needed expertise is recruited as per SOP on Appointment of Independent Consultants (SOP No. 1.2).

Step 4 Prepare the protocol review package for distribution to the primary reviewers

4.1. The timeline from receipt of complete package to distribution to primary reviewers is within 7 calendar days.

4.2. The initial protocol review package consists of all the documents in the initial protocol package plus blank copies of the evaluation forms**.**

Step 5 Encode the protocol package in the protocol database

5.1. After ensuring the completeness of the initial protocol package the URERC Staff encodes the pertinent data in the electronic protocol database.

5.2. As soon as subsequent data is available, the staff completes the required protocol details in the protocol database.

Step 6 File the initial protocol package in a properly labelled protocol file folder and place it in the active file cabinet

6.1. Write the WVSU-URERC Protocol Code Number of the protocol on the side of the file binder. Label should also include the following details:

A. Full title of the research (if possible)
B. Name of the Principal Investigator/Researcher
C. Sponsor Protocol Code Number (if applicable)
D. Name of the Sponsor (if applicable)

6.2. For international studies or clinical trials, attach a protocol file index that should serve as a Table of Contents for each protocol file folder.

6.3. File the properly labelled protocol file folder in the appropriate shelf of the storage cabinet for active study files taking note of the sequence of protocol code numbers on the file folders.

2.2 Use of Study Assessment Forms

2.2.1 Purpose

To describe the WVSU-URERC procedures related to the use of study assessment forms in ethics review.

2.2.2 Scope

This SOP applies to the use of the study assessment forms in the review and assessment of protocols and related documents submitted to URERC for initial review and approval. The URERC uses two study assessment forms that are accomplished by individual primary reviewers. All comments, evaluations, recommendations and the initial decision of each reviewer regarding a proposal/protocol are all noted in these two forms.

The study assessment forms are designed to standardize the review process and to facilitate reporting of recommendations and comments given to each individual proposal/protocol and related documents.

There are two (2) URERC assessment forms for proposal/protocol review:

1. Form 2.3 Protocol Evaluation
2. Form 2.4 Informed Consent/Assent Evaluation

2.2.3 Responsibility

It is the responsibility of the URERC reviewers to individually fill out the assessment forms after reviewing each study proposal/protocol. The URERC staff is responsible for reminding the primary reviewers to submit the accomplished assessment forms.

2.2.4 Process Flow/Steps

STEP	ACTIVITY	PERSON(S) RESPONSIBLE	TIMELINE
1	Fill out the study assessment forms when reviewing the proposal/protocol and related documents	Primary Reviewers	5-10 days
2	Submit accomplished study assessment forms	Primary Reviewers	
3	Collate and review accomplished assessment forms for appropriate action	Staff; Chair/Member Secretary	1 day
4	File copies of accomplished assessment forms and other review documents in the protocol folder	Staff	1 day

Diagram 5. Steps in the Use of Assessment Forms

2.2.5 Detailed Instructions

Step 1 Fill out the study assessment forms when reviewing the proposal/protocol and related documents

1.1. The Primary Reviewers read the proposal/protocol and related documents, and complete the assessment forms.

1.2. Primary Reviewers should also do literature review to ensure updated knowledge about the protocol.

1.3. The URERC primary medical reviewer accomplishes Form 2.3 Protocol Evaluation and Form 2.4 Informed Consent/Assent Evaluation while the primary non-medical reviewer focuses on the informed consent/assent form only.

1.4. The Protocol Evaluation form allows review of the technical and ethical issues as follows:

A. Rationale and Significance of the Study
B. Objectives of the Study
C. Review of Literature
D. Sample Size
E. Methodology and Data Management
F. Inclusion/Exclusion Criteria
G. Control arms (placebo, if any)
H. Withdrawal or Discontinuation Criteria
I. Vulnerability Determination
J. Risk/ Benefit Assessment

1.5. The Informed Consent/Assent Evaluation form enables review of the following:

A. Full disclosure of information, including risks and benefits that may be derived from the study
B. Use of understandable language, with appropriate translation
C. Voluntary participation
D. Confidentiality
E. Appropriate person to sign the consent form

1.6. If an Assent Form is required, it should be reviewed to ensure that the proper form is available and the appropriate signature is required.

1.7. Review the qualifications of the PI and the research team to include the following:

A. Education and specialty
B. GCP training <u>(if necessary)</u>

1.8. Review the sites where the study will be conducted.

Step 2 Submit accomplished study assessment forms

2.1. The primary reviewer signs, dates and submits accomplished study assessment forms to the URERC Staff within 10 working days for full review and 5 working days for expedited review after receipt of the documents.

Step 3 Collate and review accomplished assessment forms for appropriate action

3.1. The URERC Staff checks whether the forms are complete and collates the completed assessment forms.

3.2. If the proposal/protocol is for expedited review, the Chair/Member Secretary determines if there are no conflicting recommendations and if there is an agreement in the review/decision. If there are conflicting recommendations and/or disagreements in the review decision, the Chair/Member Secretary forwards the proposal/protocol for Full Review.

Step 4 File copies of accomplished assessment forms and other review documents in the protocol folder

4.1. The URERC Staff files the accomplished assessment forms in the protocol file folder and updates the protocol file index and protocol database with the date of submission.

2.3 Exempt from Review

2.3.1 Purpose

To describe the WVSU-URERC procedures for the review of protocols that qualify for exemption from review.

2.3.2 Scope

This SOP applies to the review of a study protocol submitted to the WVSU-URERC that qualifies for exemption from review.

2.3.3 Responsibility

The Chair or an URERC Member designated by the Chair is responsible for the assessment whether the submitted proposal qualifies for exemption from review.

2.3.4 Process Flow/Steps

STEP	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Review a proposal applying for exemption from review	Chair/ Designated Member	To be done within 7 days
2	Issue Certificate of Exemption or recommend for expedited or full review	Chair	
3	Prepare a report of proposals that are exempt from review to full review	Staff	
4	Communicate the URERC decision to the Principal Investigator/Researcher	Chair; Staff	
5	File copy of the documents and update protocol database for exemption from review	Staff	

Diagram 6. Exempt from Review Process

2.3.5 Detailed Instructions

Step 1 Review a proposal applying for exemption from review

1.1. The Chair or a designated URERC Member who does not have any conflict of interest reviews the research proposal applying for exemption from review.

1.2. The Chair or a designated URERC Member then evaluates the research proposal using the Exemption Criteria (SOP 2.1 Management of Protocol Submissions).

Step 2 Issue Certificate of Exemption or recommend for expedited or full review

2.1. If the proposal qualifies for exemption from review, the reviewer submits the results of the assessment to the Secretariat for the URERC Staff to prepare a certificate of exemption from review (Form 2.5 Certificate of Exemption from Ethics Review).

2.2. If the proposal does not meet the Exemption Criteria, the Chair reclassifies the proposal for expedited or full review.

Step 3 Prepare a report of proposals that are exempt from review to full review

3.1. The URERC Staff prepares a report to the next full review meeting to include details of all proposals exempted from review.

Step 4 Communicate the URERC decision to the Principal Investigator/Researcher

4.1. The URERC Staff prepares Form 2.5 Certificate of Exemption from Ethics Review and forwards to the Chair for signature.

4.2. The URERC Staff issues the Certificate of Exemption to the Principal Investigator or Researcher.

Step 5 File copy of the documents and update protocol database for exemption from review

5.1. The URERC Staff files the proposal in the appropriate shelf of the storage cabinet.

5.2. Update protocol database for exemption from review.

2.4 Expedited Review of Submitted Protocols

2.4.1 Purpose

To describe the WVSU-URERC procedures for the review of proposal/protocols that qualify for Expedited Review.

2.4.2 Scope

This SOP applies to the initial and continuing review and approval of study proposal/protocols with minimal risk to study participants. In general, Expedited Review is done:

1. In minimal/low risk health research that requires personal information (ex. review of medical records)
2. About a topic that should not result in causing social stigma
3. In retrospective studies using anonymized data
4. In health studies using simple questionnaires without identifiers
5. In laboratory research that uses anonymized human tissue/specimen

2.4.3 Responsibility

Expedited Review is the responsibility of assigned primary reviewers appointed to assess a proposal/protocol that qualifies for the expedited process. The same assessment forms used for Full Board Review should be used to evaluate the scientific and ethical merits of the proposal/protocol.

2.4.4 Process Flow/Steps

STEP	ACTIVITY	PERSON(S) RESPONSIBLE	TIMELINE
1	Determine that the submission qualifies for Expedited Review	Chair /Member Secretary	3 days
2	Assign Primary Reviewers (medical/scientific and a non-medical/non-scientific members)	Chair /Member Secretary	
3	Send the protocol package to the Primary Reviewers	Staff	
4	Review the documents with the use of the assessment forms	Primary Reviewers	5 days
5	Return the accomplished assessment forms to the Secretariat	Primary Reviewers	
6	Collate and review the assessment forms to take appropriate action	Chair /Member Secretary	5 days
7	Communicate the URERC decision to the Principal Investigator/Researcher	Staff	
8	Report to Full Board Review Expedited Review results	Secretariat	1 day
9	File copies of the documents in the protocol file folder and update the protocol database	Staff	

Diagram 7. Expedited Review Process

2.4.5 Detailed Instructions

Step 1 Determine that the submission qualifies for Expedited Review

1.1. The Chair or Member Secretary determines that the submission qualifies for Expedited Review.

1.2. For initial review: The Chair/ Member Secretary checks if the submitted proposal/protocol qualifies for expedited review. The following are types of proposals/protocols that can be subjected to expedited review after initial submission:

A. Proposals/Protocols of a non-confidential nature (not of a private character, e.g. relate to sexual preference etc., or not about a sensitive issue that may cause social stigma), not likely to harm the status or interests of the study participants and not likely to offend the sensibilities or cause psychological stress to the people involved.

B. Proposals/Protocols **not** involving vulnerable subjects (individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation of benefits associated with participation or of a retaliatory response in case of refusal to retaliate, patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors and those incapable of giving consent).
C. Proposals/Protocols that involve collection of anonymized biological specimens for research purposes by non-invasive means (e.g. collection of small amounts of blood, body fluids or excreta non-invasively, collection of hair or nail clippings in a non-disfiguring or non-threatening manner).
D. Research involving data, documents or specimens that have been previously collected.
E. Proposed continuing review of previously expedited protocols, minor protocol amendments and end of study reports.

1.3. For resubmitted documents: URERC decision for minor revisions qualifies for expedited review by the Primary Reviewers or Chair/ Member Secretary.
1.4. Submissions after initial approval may qualify for expedited review as follows:
A. Administrative revisions, such as correction of typing errors.
B. Addition or deletion of non-procedural items, such as the addition/change in study personnel or changes in their address or contact number, change in laboratories, and the like.
C. The research activity includes only minor changes from previously approved protocol.
D. Minor protocol amendments that do not change the risk/ benefit assessment.
E. Progress/Final reports that were initially reviewed by expedited review and that do not deviate from approval given by the URERC.
F. Serious Adverse Events (SAEs) that are off-site provided these are not Suspected Unexpected Serious Adverse Reactions (SUSARs).

Step 2 Assign Primary Reviewers (medical/scientific and a non-medical/non-scientific members)

2.1. Using Form 2.6 Assignment of Primary Reviewers, the Chair or the Member Secretary assigns Primary Reviewers (medical/scientific and a non-medical/non-scientific members) to review the submitted documents.
2.2. The Chair/Member Secretary assigns a Medical/ Scientific Reviewer (URERC Member or Independent Consultant) to review the scientific and ethical merits of the proposal/protocol related documents.

2.3. The Chair/Member Secretary assigns a non-medical/ non-scientific member to review the informed consent forms.

Step 3 Send the protocol package to the Primary Reviewers

3.1. The URERC Staff contacts the designated Primary Reviewers to determine if they can review the protocol documents within the 5 day deadline. If not, other Primary Reviewers are identified.

3.2. The URERC Staff prepares the protocol package and the corresponding assessment forms and forwards them to the designated reviewers.

3.3. The URERC Staff logs the proposal/protocol documents in the logbook for Outgoing Documents.

Step 4 Review the documents with the use of the assessment forms

4.1. The Primary Reviewer reads the proposal/protocol and related documents, and completes the assessment forms. The URERC primary medical reviewer accomplishes both the protocol (Form 2.3 Protocol Evaluation) and ICF assessment forms (Form 2.4 Informed Consent/Assent Evaluation) while the primary non-medical reviewer evaluates informed consent documents.

4.2. The Primary Reviewer decides whether the protocol can be approved, revised or disapproved.

4.3. When revision is required, the researchers are informed to revise and resubmit to the URERC for approval.

4.4. Disapproved protocols are automatically forwarded to full review for discussion and decision. Disapproval cannot be done at the expedited level.

Step 5 Return the accomplished assessment forms to the Secretariat

5.1. The Primary Reviewer signs, dates the assessment form/s and returns them to the Secretariat within 5 days from receipt of the protocol review package.

5.2. The Secretariat checks completeness of the assessment forms and forwards them to the Chair/Member Secretary to recommend appropriate URERC follow up action.

Step 6 Collate and review the assessment forms to take appropriate action

6.1. The Member Secretary or the Chair reviews the completed assessment forms to determine if there is agreement in the review/ decision. The comments and decision are consolidated and communicated to the PI/Researcher.

6.2. If there are conflicting recommendations and/ or disagreements in the review decision, the Chair evaluates the disagreement to determine whether the proposal/protocol will be elevated for Full Board Review. When the

proposal/protocol is disapproved, the Member Secretary includes the proposal/protocol in the next full review meeting for discussion and decision of full board.

Step 7 Communicate the URERC decision to the Principal Investigator/Researcher

7.1. The URERC Staff communicates approval to the PI/Researcher and uses Form 2.7 Approval Letter.

7.2. In case revision is required, the comments are sent to the PI/Researcher using Form 2.8 Notification of URERC Decision, for the PI/Researcher to comply with the required revisions. The PI/Researcher resubmits the documents to the URERC using Form 2.9 Summary of Revisions.

Step 8 Report to Full Board Review Expedited Review results

8.1. The URERC Secretariat includes the list of protocols approved through expedited review in the agenda of the meeting.

8.2. The report and discussion are included in the minutes of the meeting.

Step 9 File copies of the documents in the protocol file folder and update the protocol database

9.1. The URERC Staff files a copy of the approved documents in the protocol file folder and updates the protocol database.

2.5 Full Review of Submitted Protocols

2.5.1 Purpose

To describe the WVSU-URERC procedures when proposal/protocol submissions are classified for Full Board Review.

2.5.2 Scope

This SOP applies to the WVSU-URERC Full Board Review and approval of study proposals/protocols during initial and continuing review.

2.5.3 Responsibility

Full Board Review is the joint responsibility of all WVSU URERC Members who review and make decisions on the proposal/protocol related documents during a convened full board meeting.

In general, Full Board Review is done for proposals/protocols that involve medium to high risk interventions to human like experimental treatments in clinical trials that may involve vulnerable human subjects.

2.5.4 Process Flow/Steps

STEP	ACTIVITY	PERSON(S) RESPONSIBLE	TIMELINE
1	Determine if the submission should undergo Full Board Review	Chair/ Member Secretary	3 days
2	Assign Primary Reviewers (medical/scientific and a non-medical/non-scientific members)	Chair/ Member Secretary	
3	Send the protocol package to the Primary Reviewers	Staff	
4	Review the documents with the use of the assessment forms.	Primary Reviewers	10 days
5	Return the accomplished assessment forms to the Secretariat	Primary Reviewers	
6	Discuss and decide on the proposal/protocol and related documents during a convened full board meeting	Members	1 day
7	Communicate the URERC decision to the Principal Investigator/Researcher	Chair; Staff	7 days

STEP	ACTIVITY	PERSON(S) RESPONSIBLE	TIMELINE
8	File copies of the documents in the protocol file folder and update the protocol database	Staff	1 day

Diagram 8. Full Board Review Process

2.5.5 Detailed Instructions

Step 1 Determine if the submission should undergo Full Board Review

1.1. The URERC Chair or the Member Secretary determines if the submitted proposal/protocol documents should undergo Full Board Review.

1.2. The Chair/ Member Secretary screens the proposal/protocol to identify those that should be discussed at full board.

1.3. For initial review: The Chair/ Member Secretary goes over the submitted proposal/protocol and decides if it should undergo Full Board Review based on assessment of risks.

1.4. The following are types of proposals/protocols that should be reviewed at a convened Full Board Meeting:

A. Clinical trials about investigational new drugs, biologics or device in various phases (Phase 1, 2, 3);
B. Phase 4 intervention research involving drugs, biologics or devices;
C. Proposals/Protocols including questionnaires and social interventions that are confidential in nature (about private behavior, e.g. related to sexual preferences etc.; or about sensitive issues that may cause social stigma, psychological, legal, economic and other forms of social harm;
D. Intervention proposals/protocols involving vulnerable subjects (patients with incurable diseases, persons in nursing homes, patients in emergency situations, ethnic minority groups, homeless persons, refugees, minors and those incapable of giving consent) that require additional protection from the URERC during review;
E. Proposals/Protocols that involve collection of identifiable biological specimens from vulnerable groups, etc.

1.5. For resubmitted documents: URERC decision for major revision of documents (proposal/protocol, ICF, etc.) requires full board review of revisions.

1.6. The following continuing review submissions should undergo Full Board Review as follows:

A. Amendments that involve major changes from previously approved protocol or consent form (major changes in the inclusion/ exclusion criteria, safety issues, etc.);
B. Major amendments that change the risk/ benefit ratio;
C. Major protocol violations;
D. Progress reports of ongoing studies that involve medium to high risks to human subjects/ participants
E. Onsite SAEs or SUSARs that involve safety issues.

Step 2 Assign Primary Reviewers (medical/scientific and a non-medical/non-scientific members)

2.1. The Chair/ Member Secretary assigns a Medical/ Scientific Reviewer (URERC Member or Independent Consultant) to review the scientific and ethical merits of the proposal/protocol related documents.
2.2. The Chair/ Member Secretary assigns a non-medical/ non-scientific member to review the informed consent forms.

Step 3 Send the protocol package to the Primary Reviewers

3.1. The URERC Staff contacts the designated Primary Reviewers to determine if they can review the protocol documents within the 10 day deadline. If not, other primary reviewers are identified.
3.2. The URERC Staff prepares the protocol package and the corresponding assessment forms and forwards them to the designated reviewers.
3.3. The URERC Staff logs the proposal/protocol documents in the Logbook for Outgoing Documents.

Step 4 Review the documents with the use of the assessment forms

4.1. The Primary Reviewer reads the proposal/protocol and related documents, and completes the assessment forms. The URERC primary medical reviewer accomplishes both the protocol (Form 2.3 Protocol Evaluation) and ICF assessment forms (Form 2.4 Informed Consent/Assent Evaluation) while the primary non-medical reviewer evaluates informed consent documents.
4.2. The Primary Reviewer recommends the type of decision for initial review of proposal/protocol related documents:
A. Approved
B. Minor Revisions required
C. Major Revisions required
D. Disapproved

4.3. The Primary Reviewer also checks the Curriculum Vitae (CV) or information about the investigators/researchers (including GCP training for clinical trials), the study sites and other proposal/protocol related documents, including advertisements:
   A. Consider whether study and training background of the Principal Investigator/Researcher are related to the study.
   B. Look for disclosure or declaration of potential conflict of interest.

4.4. The Primary Reviewer determines if the facilities and infrastructure at study site are suitable for the study.

Step 5 Return the accomplished assessment forms to the Secretariat

5.1. The Primary Reviewer signs, dates the assessment form/s and returns them to the Secretariat within 10 days from receipt of the protocol review package.

5.2. The Secretariat checks completeness of the assessment forms.

Step 6 Discuss and decide on the proposal/protocol and related documents during a convened full board meeting

6.1 The URERC members discuss and decide on the proposal/protocol and related documents during a convened full board meeting.

6.2 The URERC conducts a full board meeting to discuss and make a decision about the protocol and related documents. (Refer to SOP 4.2 Conduct of a Full Board Meeting)

6.3 The members of the URERC attending the full board meeting have to approve the following:
   A. Principal and Co Investigators/Researchers and members of the research team
   B. Proposal/Protocol
   C. Informed Consent/Assent Forms
   D. Advertisements or recruitment materials
   E. Study sites covered by the application

6.4 The URERC members vote on specific items to arrive at a decision as follows:
   A. Approval (when no further revision is required)
   B. Minor Revision (requires minor changes in the documents such as typographical errors, administrative issues, additional explanations, etc.)
   C. Major Revision (requires revision of study design, major sections of the proposal/protocol or ICF that affect patient safety or credibility of data)

D. Disapproval (due to ethical or legal concerns). Reasons for vote of disapproval should be noted in the minutes and communicated to the PI/Researcher.

6.5 If the study is approved, the URERC determines the frequency of continuing review.

6.6 All meeting deliberations and decision regarding a proposal/protocol are noted in the meeting minutes. (Refer to SOP 4.3 Preparation of the Minutes of the Meeting)

Step 7 Communicate the URERC decision to the Principal Investigator/Researcher

7.1 The URERC Staff communicates the URERC decision to the PI/Researcher.

7.2 All URERC decisions are communicated to the PI/Researcher.

A. Approval: The URERC Staff prepares the Approval Letter to be signed by the Chair.

B. Minor Revision: The URERC Staff prepares the Notification of URERC Decision to inform the PI/Researcher of the required revisions in the proposal/protocol, ICF or any related document. The resubmitted documents undergo Expedited Review before approval is granted. The Chair/Member Secretary reviews and checks compliance to URERC recommendations of the resubmitted documents, before granting approval.

C. Major Revision: The URERC Staff prepares the Notification of URERC Decision to inform the PI/Researcher of the required revisions in the proposal/protocol, the ICF or related document. The resubmitted documents are referred to Primary Reviewers and discussed at Full Board Review, once more before approval is granted.

D. Disapproval: The URERC Staff prepares the Notification of URERC Decision to inform the PI/Researcher of the decision. The reasons should be clearly stated in the notice. (Refer to SOP 4.4 Communicating URERC Decisions to the Principal Investigator/Researcher).

Step 8 File copies of the documents in the protocol file folder and update the protocol database

8.1 The URERC Staff files a copy of the approved documents in the protocol file folder and updates the protocol database.

2.6 Review of Resubmission

2.6.1 Purpose

To describe the procedures of WVSU-URERC when the proposal/protocol resubmissions are received.

2.6.2 Scope

This SOP applies to the WVSU-URERC review and approval of study proposals/protocols recommended for minor or major revisions during initial and continuing review

2.6.3 Responsibility

It is the responsibility of the WVSU-URERC Chair/Secretariat to classify resubmitted protocols for expedited or full board review.

It is the responsibility of Primary Reviewers to review the resubmitted documents to determine if they have complied with the required modifications before granting approval during Expedited Review or to recommend approval of proposals/protocols with major revisions to Full Board.

It is the responsibility of WVSU-URERC Members to approve resubmitted proposals/protocols with major revisions after discussion.

2.6.4 Process Flow/Steps

STEP	ACTIVITY	PERSON(S) RESPONSIBLE	TIMELINE
1	Receive the resubmitted proposal/protocol package from the Principal Investigator/Researcher	Staff	1 day
2	Send the protocol package to the Primary Reviewers	Staff	1 day
3	Review if the resubmission complied with the required revisions	Primary Reviewers	5-10 days
4	Return the documents with a decision after Expedited Review or recommend a decision to Full Board	Primary Reviewers	
5	Discuss and decide on major revisions received during a Full Board Meeting	URERC Members	1 day
6	Accomplish the Approval Letter and communicate the decision to the Principal Investigator/Researcher	Chair; Staff	1 day

STEP	ACTIVITY	PERSON(S) RESPONSIBLE	TIMELINE
7	File copies of the documents in the protocol file folder and update the protocol database	Staff	1 day

Diagram 9. Review of Resubmission

2.6.5 Detailed Instructions

Step 1 Receive the resubmitted proposal/protocol package from the Principal Investigator/Researcher

1.1. The URERC Staff receives the resubmitted proposal/protocol documents from the Principal Investigator/Researcher.

Step 2 Send the protocol package to the Primary Reviewers

2.1. The URERC Staff sends the package to the Primary Reviewers during initial review.

2.2. The URERC Staff logs the proposal/protocol documents in the Logbook for Outgoing Documents.

Step 3 Review if the resubmission complied with the required revisions

3.1. The Chair/Member Secretary or designated Primary Reviewer may review minor proposal/protocol revisions.

3.2. The Primary Reviewer reviews the resubmitted documents and compares it with the requirements for revisions.

Step 4 Return the documents with a decision after Expedited Review or recommend a decision to Full Board

4.1. The Primary Reviewer returns the resubmission package indicating their decision.

4.2. In Expedited Review, the Primary Reviewer approves the resubmitted documents if the PI/Researcher has substantially complied with the required revisions.

4.3. Minor revisions recommended by Full Board should also go to Expedited Review.

4.4. For Major Revisions for full board discussion, the Primary Reviewer recommends approval.

Step 5 Discuss and decide on major revisions received during a Full Board Meeting

5.1. The Primary Reviewer resends their assessment of Major Revisions during full board discussion and makes a recommendation for approval.

5.2. URERC Members decide by consensus to endorse or not to endorse the recommendation for approval.

Step 6 Accomplish the Approval Letter and communicate the decision to the PI/Researcher

6.1. For approved resubmitted proposals/protocols, the URERC Staff prepares Form 2.7 Approval Letter that the Chair should sign.

6.2. The URERC decision is communicated to the PI/Researcher.

Step 7 File copies of the documents in the protocol file folder and update the protocol database

7.1. The URERC Staff files a copy of the approved documents in the protocol file folder and updates the protocol database.

FORM 2.1 APPLICATION FOR REVIEW

URERC Protocol Number			
Sponsor Protocol Number		Date of Submission	

Type of Submission

- ☐ Initial Review
- ☐ Continuing Review
- ☐ Resubmission
- ☐ Protocol Termination
- ☐ Protocol Amendment
- ☐ Final Report

Title	

Principal Investigator/Researcher Information			
Name			
Mobile Number		*Telephone Number*	
E-mail Address			
Institution			
Sponsor			

Conflict of Interest Declaration *(Relationship with the Sponsor)*			
	Are you a regular employee of the Sponsor?	☐ Yes	☐ No
	Did you do consultancy or part time work for the Sponsor?	☐ Yes	☐ No
	In the past year, did you receive P250,000 or more from the Sponsor?	☐ Yes	☐ No
	Other benefits from the Sponsor (e.g. travel)	_____	
	Other ties with the Sponsor	_____	

Principal Investigator/Researcher's Signature: _____ Date: _____

For WVSU-URERC Secretariat

Documents Received:

	Application for Review (letter of request addressed to the ERC Chair)
	_Signatories Complete (Principal Investigator, Adviser, Research Coordinator, Dean)
	Technical Review Approval Form
	Form 2.1 APPLICATION FOR REVIEW
	Form 2.2 PROTOCOL SUMMARY SHEET
	Form 2.3 PROTOCOL EVALUATION
	Form 2.4 INFORMED CONSENT/ASSENT EVALUATION
	Ethics Review Approval Form from other ERCs (if applicable)
	Research Proposal that includes but not limited to the ff:
	Title
	Rationale and Significance of the Study
	Objectives of the Study
	Review of Related Literature
	Description of the Study Population
	Inclusion/Exclusion Criteria
	Methodology and Procedures
	Ethical Considerations
	Data Analysis
	References
	Informed Consent/Assent Documents
	English ICF (with version and date)
	Hiligaynon or Local language ICF (if applicable, with version and date)
	Assent (with version and date)
	LAR (with version and date)
	Others:
	Study Tools (Questionnaires, Case Report Form, Posters/Advertisements for Recruitment, etc.) with version and date)
	Study Drug/Medical Device Information like Investigator Brochures/Published Literature/Medical Device Manufacture's Design, if relevant
	CV of Principal Investigators/Researcher and Co-Investigators/Research Team (signed and dated)
	Certficate of GCP Training (in cases of a Clinical Drug Trial)
	Information regarding Funding, Sponsors, Institutional Affiliations, other potential Conflicts of Interest
	Contracts and Approval of relevant offices (Memorandum of Agreement (MOA) if study is collaborative in nature: Materials Transfer Agreement (MTA), Intelllectual Property Approval, Investigational Device Exemption (IDE), when relevant
	GANTT Chart
	Study Proposal Budget
	Footers to indicate document version and date of last amendment
	Page number (Continuous Paging)

Remarks:

_____

Received:

_____ Date: _____

FORM 2.2 PROTOCOL SUMMARY SHEET

URERC Protocol Number		Sponsor Protocol Number	

Title	
Principal Investigator/ Researcher	
Sponsor	
Rationale	
Objectives	
Design/Methodology	
Inclusion Criteria	
Exclusion Criteria	
Data Analysis Plan	
Study Outcomes	

FORM 2.3 PROTOCOL EVALUATION

URERC Protocol Number			
Sponsor Protocol Number		Date of Submission	
Title			
Principal Investigator/ Researcher			
Institution/Department		Contact Number	
Total Number of Participants		Number of Study Sites	
Sponsor		Contact Number	
Duration of the Study			

Type of Study

☐ Intervention ☐ Epidemiology ☐ Observational study
☐ Document review ☐ Individual based ☐ Genetic
☐ Social Survey ☐ Others *(specify)* _____

Description of the Study in brief: (*Mark whatever applies to the study)*

☐ Randomized	☐ Drug	☐ Use of Genetic Materials
☐ Double blind	☐ Medical Device	☐ Multicenter study
☐ Single blind	☐ Vaccine	☐ Global protocol
☐ Open label	☐ Diagnostics	☐ Sponsor Initiated
☐ Observational	☐ Questionnaire	☐ Investigator Initiated

The following sections are for URERC use only:

Type of Review	☐ Full Board	☐ Expedited	☐ Exempt
Primary Reviewers			

A. PROTOCOL DOCUMENT REVIEW

1.	Objectives of the Study ☐ Clear ☐ Unclear	Comments/What should be improved:
2.	Need for Human Participants ☐ Yes ☐ No	Comments:
3.	Background Information ☐ Sufficient ☐ Insufficient	Comments:
4.	Methodology ☐ Clear ☐ Not Clear	Comments
5.	Sufficient number of participants? ☐ Yes ☐ No	Comment:
6.	Control Arms (placebo, if any) ☐ Yes ☐ No	Comment:
7.	Data Analysis Plan ☐ Appropriate ☐ Not Appropriate	Comment:
8.	Study Outcomes ☐ Defined ☐ Incomplete ☐ Not Defined	Comment:
9.	Level of Risk ☐ Negligible ☐ Low-Medium ☐ High	Comment:
10.	Risk Assessment ☐ Acceptable ☐ Unacceptable	Comment:
11.	Benefits Assessment ☐ Acceptable ☐ Unacceptable	Comment:
12.	Inclusion Criteria ☐ Appropriate ☐ Inappropriate	Comment:

13.	Exclusion Criteria ☐ Appropriate ☐ Inappropriate		Comment:
14.	Withdrawal Criteria ☐ Appropriate ☐ Inappropriate		Comment:
15.	Involvement of Vulnerable Participants ☐ Yes ☐ No		Comment:
16.	Protection of Vulnerable Participants ☐ Appropriate ☐ Inappropriate		Comment:
17.	Voluntary, Non-Coercive Recruitment of Participants ☐ Yes ☐ No		Comment:
18.	Are the qualifications and experience of the participating investigators, research team appropriate? ☐ Yes ☐ No		Comment:
19.	Disclosure of Potential Conflicts of Interest ☐ Yes ☐ No		Comment:
20.	Facilities and infrastructure of participating sites ☐ Appropriate ☐ Inappropriate		Comment:
21.	Community Consultation ☐ Yes ☐ No ☐ N/A		Comment:
22.	Involvement of local researchers and communities in the protocol preparation and implementation ☐ Yes ☐ No		Comment:
23.	Contribution to local capacity building ☐ Yes ☐ No ☐ N/A		Comment:

24. Benefit to local communities
☐ Yes ☐ No ☐ N/A
Comment:

25. Sharing of study results
☐ Yes ☐ No ☐ N/A
Comment:

26. Are blood/tissue samples sent abroad?
☐ Yes ☐ No ☐ N/A
Comment:

B. RECOMMENDATION

DECISION	☐ Approval	☐ Minor Revision/ Resubmission
	☐ Major Revision/ Resubmission	☐ Disapproval

Comments (Identify Items for Revision)	

Reviewer's Name and Signature		Date	

FORM 2.4 INFORMED CONSENT / ASSENT EVALUATION

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

Pls. check:

☐ CONSENT ☐ ASSENT

The following are for URERC use only.

A. INFORMED CONSENT / ASSENT

1.	Does the Informed Consent / Assent document state that the procedures are primarily intended for research? ☐ Yes ☐ No	Comment:
2.	Are procedures for obtaining Informed Consent / Assent appropriate? ☐ Yes ☐ No	Comment:
3.	Do the Informed Consent / Assent document contain comprehensive and relevant information? ☐ Complete ☐ Incomplete	Comment:
4.	Is the information provided in the protocol consistent with those in the consent form? ☐ Consistent ☐ Inconsistent	Comment:
5.	Are study related risks mentioned in the consent / assent form? ☐ Complete ☐ Incomplete	Comment:
6.	Is the language in the Informed Consent /Assent document understandable? ☐ Clear ☐ Unclear	Comment:
7.	Is the translation of Informed Consent / Assent in Hiligaynon clear, well-stated, non-threatening, conversational and uses correct words in the local language/dialect? ☐ Yes ☐ No	Comment:
8.	Is there adequate protection of vulnerable participants? ☐ Yes ☐ No	Comment:

9.	Are the different forms (consent, assent, patient representative) appropriate for the types of study participants? ☐ Complete ☐ Incomplete	Comment:
10.	Are names and contact numbers from the research team and the URERC in the Informed Consent? ☐ Yes ☐ No	Comment:
11.	Does the Informed Consent / Assent mention privacy & confidentiality protection? ☐ Yes ☐ No	Comment:
12.	Is there any inducement for participation? ☐ Unlikely ☐ Likely	Comment:
13.	Is there provision for medical / psychosocial support? ☐ Appropriate ☐ Inappropriate	Comment:
14.	Is there provision for treatment of study-related injuries ☐ Appropriate ☐ Inappropriate	Comment:
15.	Is there provision for compensation? ☐ Appropriate ☐ Inappropriate	Comment:

B. RECOMMENDATION

DECISION	☐ Approval	☐ Minor Revision/ Resubmission
	☐ Major Revision/ Resubmission	☐ Disapproval
Comments *(Identify items for revision)*		
Reviewer's Name and Signature		Date

FORM 2.5 CERTIFICATE OF EXEMPTION FROM ETHICS REVIEW

Date

URERC Protocol Number		Sponsor Protocol Number	
Principal Investigator/ Researcher		Sponsor	
Title			
Version Number		Version Date	
Informed Consent Form Version Number		Version Date	
Other Documents			

The proposal was submitted to the West Visayas State University-Unified Research Ethics Review Committee (WVSU-URERC) for initial evaluation to determine if the study is exempt from ethical review. Based on the criteria for exempt stated in the National Ethical Guidelines for Health and Health-Related Research 2017, the study can proceed without further ethical review. Hence, approval is given to conduct the study. However, the researcher will still be required to submit to the WVSU-URERC the requisite reports such as but not limited to protocol amendment, protocol deviation, annual progress report, serious adverse events, suspected unexpected serious adverse reactions and final report as the need arises.

_____ _____

Chair, WVSU-URERC Date

Received:

_____ _____

(Signature over Printed Name) Date

FORM 2.6 ASSIGNMENT OF PRIMARY REVIEWERS

URERC Protocol Number	
Sponsor Protocol Number	
Date of Submission	
Principal Investigator/ Researcher	
Sponsor	
Primary Reviewers	1.
	2.
	3.
	4.
	5.
Independent Consultant	
Assigned by:	_____ CHAIR/MEMBER SECRETARY, URERC
Date	
Type of Review	☐ Full Review ☐ Expedited
Date Due	

FORM 2.7 APPROVAL LETTER

Date

This is to certify that the following protocol and related documents have been granted approval by the West Visayas State University Unified Research Ethics Review Committee for implementation.

URERC Protocol Number		Sponsor Protocol Number	
Principal Investigator/Researcher		Sponsor	
Title			
Version Number		Version Date	
Informed Consent Form Version Number		Version Date	
Other Documents			

Type of Review	☐ Expedited ☐ Full Board Review	Duration of Approval

Review Date _____

Primary Reviewers:

Name	Position on EC	Qualification/ Position
_____	_____	_____
_____	_____	_____
_____	_____	_____

The West Visayas State University Unified Research Ethics Review Committee was organized and operates according to the laws, policies, rules and regulations of the ICH-GCP.

_____ _____

Chair, WVSU-URERC Date

Investigator/Researcher Responsibilities after Approval:

- Submit document amendments for URERC approval before implementing them
- Submit SAE and SUSAR reports to the URERC within 7 days
- Submit Annual Progress Report
- Submit Final Report after completion of protocol procedures at the study site
- Report Protocol Deviation/ Violation
- Comply with all relevant international and national guidelines and regulations
- Abide by the principles of good clinical practice and ethical research

Received:

_____ _____

(Signature over Printed Name) Date

FORM 2.8 NOTIFICATION OF URERC DECISION

Date

To _____

Contact Number _____

This is to inform you of the URERC decision related to your application for review of the following documents:

URERC Protocol Number		Sponsor Protocol Number	

Type of Submission

- ☐ Initial Review
- ☐ Resubmission
- ☐ Amendment
- ☐ Others

Principal Investigator/ Researcher		Sponsor	
Title			
Version Number		Version Date	
Informed Consent Form Version Number		Version Date	
Other Documents			

Type of Review	URERC Decision
☐ Expedited	☐ Approved
☐ Full Board Review	☐ Minor Revisions required
Review Date:	☐ Major Revisions required
_____	☐ More information required
	☐ Others:
	_____

Details of Action Required from the Principal Investigator/Researcher

Instructions:

a. Integrate the recommended revisions in the study proposal/protocol.
b. Make a cover letter addressed to the Chair of the Committee indicating the submission of revisions for review.
c. Submit the accomplished Form 2.1 Application for Review and 2.9 Summary of Revisions together with the revised study proposal/protocol. The cut-off date of submission is 60 days after receiving this letter. Failure to respond within the given timeframe will inactivate the application and the study proposal/protocol will be archived. Resubmission of the same proposal will begin with the first step of the application process.
d. Attach a paper marker on the pages were changes are made. Modified parts should be bold-faced and highlighted.
e. Place page-footers indicating the date of revision and the version number of the revised proposal/protocol, informed consent forms and other documents.

_____ _____

Chair, WVSU-URERC Date

Received:

_____ _____

(Signature over Printed Name) Date

WEST VISAYAS STATE UNIVERSITY
UNIFIED RESEARCH ETHICS REVIEW COMMITTEE
La Paz, Iloilo City 5000 Philippines
Tel No. +63 (033) 330 91 02

FORM 2.9 SUMMARY OF REVISIONS

For the URERC Secretariat

URERC Protocol Number		**Date of Initial Submission**	
Review Number	___ 1st ___ 2nd ___ 3rd ___ 4th	**Initial Review Date**	

For the Principal Investigator/Researcher

Title			
Principal Investigator/ Researcher		**Contact Number**	

Reviewer	Recommended Revisions	Indicate Yes, if revised; No if not	If No, State Reason(s)	If Yes, Indicate Section & Page
	1. 2.			
	1. 2.			
	1. 2.			

For the Reviewer

Recommendation (Please check)	Justification for Recommendation
_____ Approved	
_____ For Minor Revision	
_____ For Major Revision	
_____ Disapproved	
_____ Pending; requires clarifications before arriving at a decision	

Reviewer's Signature over Printed Name: _____ Date: _____

Page 1 of 1

Form 2.9 Rev.:000

History of WVSU URERC SOP Chapter 2

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