



# WEST VISAYAS STATE UNIVERSITY UNIFIED RESEARCH ETHICS REVIEW COMMITTEE

La Paz, Iloilo City 5000 Philippines  
Tel No. +63 (33) 330-9102

**September 11, 2023**

**TO: Principal Investigators, Researchers and Sponsors**

**CC: WVSU-URERC Members**

**RE: Process of Submissions of Proposals/Protocols to West Visayas State University-  
Unified Research Ethics Review Committee**

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This is to inform the Principal Investigators, Researchers and Sponsors that the West Visayas State University-Unified Research Ethics Review Committee (WVSU-URERC) will be gradually implementing an online submission process. In view of this, I am sending you the procedures to be followed in submitting your documents to the WVSU-URERC. This memorandum will take effect immediately. Please note that this is just the initial step in the gradual implementation towards full electronic submissions.

**For Initial Submission:**

1. The PI/Researcher shall submit the documents both hard copy and electronic copy to WVSU-URERC.
2. The required files shall be uploaded in a cloud storage/google drive. The files must be organized by each folder classifying different sections such as Cover Letter, WVSU URERC Forms, Main Protocol/Proposal, Informed Consent Forms, Patient Materials, Investigator's Brochure, CVs/GCP Certificates/PRC IDs, and other required documents. The files should be in PDF format and searchable except for Evaluation Forms for initial review that can be downloaded from WVSU-URERC website <https://urerc.wvsu.edu.ph/> (Form 2.3 Protocol Evaluation and Form 2.4 ICF/Assent Evaluation) that should be in word format to be accomplished by the reviewers.
3. The WVSU-URERC Secretariat shall screen the submission package for correctness and completeness, after which she will email the PI/Researcher regarding the receipt of documents or screening issues that need to be addressed. Once the documents are complete and accurate the WVSU-URERC Secretariat will notify the PI/Researcher to submit the hard copy documents within three (3) working days. Acknowledgement of receipt is the date of submission of hard copy documents.
4. Submit the proposal/protocol package via email with the following subject:  
For initial submission: TYPE of submission\_Last Name of the PI/Researcher  
(Example: INITIAL SUBMISSION\_Dela Cruz)
5. Electronic submissions shall be sent to the WVSU-URERC's official email address: [ubrerc\\_wvsu@yahoo.com.ph](mailto:ubrerc_wvsu@yahoo.com.ph) while for hard copy submissions, submit two (2) complete sets of printed copies of the required forms and basic documents to WVSU-URERC Office at Ground Flr., Research and Extension Building II, WVSU.



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## **For Resubmission and Other Post-Approval submissions (Amendment, Continuing Review, Final Report, Study Termination, Serious Adverse Event, Protocol Deviation, SUSAR, Notifications):**

1. For resubmission and other post-approval submissions, both hardcopy and electronic copy of the required files may be sent at the same time without the need for the electronic copy to be screened by the WVSU-URERC Secretariat.
2. The PI/Researcher shall send the files in a cloud storage/google drive. The files must be organized by each folder classifying different sections: Cover Letter, WVSU URERC Forms, Revised Protocol/Proposal, Informed Consent Forms, Patient Materials, Investigator's Brochure, and other required documents. The files should be in PDF format and searchable except for Evaluation Forms that can be downloaded from WVSU-URERC website <https://urerc.wvsu.edu.ph/> (e.g. Form 2.9 Summary of Revisions, Form 3.1 Protocol Amendment Review, Form 3.2 Progress Report, Form 3.3 Final Report, etc.) that should be in word format to be accomplished by the reviewers.
3. Submit the resubmission/other post-approval submission package via email with the following subject: TYPE of submission\_Last Name of the PI/Researcher\_URERC Protocol Number (Example: RESUBMISSION/AMENDMENT/CONTINUING REVIEW/FINAL REPORT\_Dela Cruz\_WVSU.URERC-2023.IS\_001)
4. Electronic submissions shall be sent to the WVSU-URERC's official email address: [ubrerc\\_wvsu@yahoo.com.ph](mailto:ubrerc_wvsu@yahoo.com.ph) while for hard copy submissions, submit two (2) complete sets of printed copies of the required forms and basic documents to WVSU-URERC Office at Ground Flr., Research and Extension Building II, WVSU.
5. Date of acknowledgement of receipt shall be based on the date of receipt of both the hard copy and electronic copy of the proposal/protocol package. Documents shall be submitted before 2pm shall be considered to have been received on the day it was sent. Protocols sent after 2pm, shall be considered to have been received on the next working day.

**We will only acknowledge the online submissions coming directly from the Site Principal Investigator/Research Team.**

Attached are the following detailed instructions and list of documentary requirements on the different types of submissions to WVSU-URERC.

For your information and guidance. Thank you very much.

Very Truly Yours,

A handwritten signature in black ink, appearing to read 'Roberto P. Villanueva'.

**ROBERTO P. VILLANUEVA, M.D., J.D.**  
Chair, WVSU-URERC



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## List of Requirements and Detailed Instructions on Different Types of Submissions to WVSU-URERC

### ***I. INITIAL SUBMISSION- This is the first application for ethical approval.***

1. Submit the initial submission protocol/proposal package with the following subject: TYPE of submission\_Last Name of the PI/Researcher. (Ex.: INITIAL SUBMISSION\_Dela Cruz).
2. Email and send via google drive link/cloud storage to WVSU-URERC email address the following requirements:

#### List of Requirements for Initial Submission

- Application for Review (letter of request addressed to the ERC Chair)  
Signatories Complete (Principal Investigator, Adviser, Research Coordinator, Dean)
- Form 2.1 Application for Review
- Form 2.2 Protocol Summary Sheet
- Form 2.3 Protocol Evaluation (in word form)
- Form 2.4 Informed Consent/Assent Evaluation (in word form)  
*(Note: applicable if your research proposal involves human participants)*
- Technical Review Approval Form
- 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)  
*(Note: provide certificate of validation of study tools once modified or self-made)*
- 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)
- Certificate of GCP Training (in cases of a Clinical Drug Trial)
- PRC ID of Principal Investigators/Researcher and Co-Investigators/Research Team
- Information regarding Funding, Sponsors, Institutional Affiliations, other potential Conflicts of Interest



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- Contracts and Approval of relevant offices (Memorandum of Agreement (MOA) if study is collaborative in nature: Executed Materials Transfer Agreement (MTA), Intellectual Property Approval, Investigational Device Exemption (IDE), when relevant
  - GANTT Chart
  - Study Proposal Budget
  - Footers to indicate document version and date
  - (Note: footers must be continuous from proposal to appendices)
  - Page number (Continuous Paging)
3. The files shall be organized by each folder classifying different sections such as Cover Letter, WVSU URERC Forms, Main Protocol/Proposal, Informed Consent Forms, Patient Materials, Investigator's Brochure, CVs/GCP Certificates/PRC IDs, and other required documents.

### **II. RESUBMISSION-This is the response to initial review or recommendations from the WVSU-URERC reviewers communicated through an official Notification Letter (Form 2.8).**

1. Submit the resubmission package via email with the following subject: Type of submission\_Last Name\_URERC Protocol Number. (Ex. RESUBMISSION\_Dela Cruz\_WVSU.URERC-2023.IS\_001)
2. Integrate the recommended revisions in the study proposal/protocol.
3. Make a cover letter addressed to the Chair of the Committee indicating the submission of revisions for review (signed by the PI/Researcher, Research Adviser, Research Coordinator, Dean)
4. Submit the accomplished Form 2.1 Application for Review and tick the box resubmission
5. Accomplish Form 2.9 Summary of Revisions completely and accurately (in a word version, to be accomplished by the reviewers) 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.
6. Attach a paper marker on the pages where changes are made. Modified parts should be bold-faced and highlighted.
7. Place page-footers indicating the date of revision and the version number of the revised proposal/protocol, informed consent forms and other documents.

### **III. STUDY PROTOCOL AMENDMENT**

1. Submit the amendment package via email with the following subject: Type of submission\_Last name\_URERC Protocol Code. (Ex: AMENDMENT\_DELA CRUZ\_WVSU.URERC-2023.IS\_001).
2. Make a cover letter addressed to the Chair of the Committee indicating the amendments for review and justification of revisions (signed by the PI/Researcher, Research Adviser, Research Coordinator, Dean).
3. Submit the signed Form 2.1 Application for Review and tick the box Protocol Amendment.
4. Accomplish Form 3.1 Amendment Review completely and accurately, and in version in word form (to be accomplished by the reviewers).
5. In Form 3.1, specify the items to be amended (previous versions), amended versions and reasons for amendment. State the pages/sections where the changes are made. Highlight and bold-faced the amended versions.
6. If there are changes in the approved protocol and documents, ensure to update version number and date.



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7. Ensure that the study has a valid ethical approval prior to submission of any subsequent amendment applications.

## **IV. CONTINUING REVIEW APPLICATION**

1. Submit the continuing review application package via email with the following subject: Type of submission\_Last name\_URERC Protocol Number (Ex: CONTINUING REVIEW\_Dela Cruz\_WVSU.URERC-2023.IS\_001).
2. Make a cover letter addressed to the Chair of the Committee stating your intent to submit the continuing review application (signed by the PI/Researcher, Research Adviser, Research Coordinator, Dean).
3. Submit the signed Form 2.1 Application for Review and tick the box Continuing Review.
4. Accomplish Form 3.2 Progress Report completely and accurately, and a version in word form (to be accomplished by the reviewers).
5. List only reports (e.g. amendments, summary of protocol participants) that were processed and approved prior to submission of the continuing review application.
6. We advise to submit the continuing review application at least 30 days prior to expiry date of the ethical approval date.

## **V. FINAL REPORT**

1. Submit the final report package via email with the following subject: Type of submission\_Last name\_URERC Protocol Number (Ex: FINAL REPORT\_Dela Cruz\_WVSU.URERC-2023.IS\_001).
2. Make a cover letter addressed to the Chair of the Committee stating that you will submit the final report (signed by the PI/Researcher, Research Adviser, Research Coordinator, Dean).
3. Submit the signed Form 2.1 Application for Review and tick the box Final Report.
4. Accomplish Form 3.3 Final Report completely and accurately, and a version in word form (to be accomplished by the reviewers).
5. Attach the abstract of the final paper.

## **VI. STUDY TERMINATION**

1. Submit the early termination report package via email with the following subject: Type of submission\_Last name\_URERC Protocol Number (Ex: STUDY TERMINATION\_Dela Cruz\_WVSU.URERC-2023.IS\_001).
2. Make a cover letter addressed to the Chair of the Committee stating that you will submit study termination and the reasons why the study has been terminated.
3. Submit the signed Form 2.1 Application for Review and tick the box Protocol Termination.
4. Accomplish Form 3.8 Study Termination completely and accurately, and a version in word form (to be accomplished by the reviewers).
5. Attach the documents pertinent for the submission.

## **VII. SERIOUS ADVERSE EVENT**

1. Submit the Serious Adverse Event package via email with the following subject: Type of submission\_Last name\_URERC Protocol Number (Ex: SAE\_Dela Cruz\_WVSU.URERC-2023.IS\_001).
2. Make a cover letter addressed to the Chair of the Committee stating that you will submit SAE and state whether the AE is expected/unexpected and related/unrelated.



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3. Accomplish the Form 3.4 Serious Adverse Event Report completely and accurately, and a version in word form (to be accomplished by the reviewers).
4. Attach the documents pertinent for the submission.
5. SAE Reports shall be submitted to WVSU-URERC within 7 days.

### **VIII. PROTOCOL DEVIATION**

1. Submit the Protocol Deviation package via email with the following subject: Type of submission\_Last name\_URERC Protocol Number (Ex: PD\_Dela Cruz\_WVSU.URERC-2023.IS\_001).
2. Make a cover letter addressed to the Chair of the Committee stating that protocol deviations occurred at study site.
3. Accomplish the Form 3.5 Deviation /Non-Compliance/Violation Report Form completely and accurately, and a version in word form (to be accomplished by the reviewers).
4. Attach the documents pertinent for the submission.

### **IX. SUSARS**

1. Submit the SUSARs package via email with the following subject: Type of submission\_Last name\_URERC Protocol Number Code (Ex: SUSAR\_Dela Cruz\_WVSU.URERC-2023.IS\_001)
2. Make a cover letter addressed to the Chair of the Committee stating that you will submit SUSAR Reports.
3. Attach the documents pertinent for the submission.
4. SUSAR Reports shall be submitted to WVSU-URERC within 7 days.

### **X. NOTIFICATIONS**

1. Submit the Notifications package via email with the following subject: Type of submission\_Last name\_URERC Protocol Number Code (Ex: NOTIFICATIONS\_Dela Cruz\_WVSU.URERC-2023.IS\_001)
2. Make a cover letter addressed to the Chair of the Committee stating the Notifications you will submit.
3. Attach the documents pertinent for the submission.