<date of issuance>

**<name of the PI/LR>**

Principal Investigator/Lead Researcher

<affiliation>

<address>

**Re: Approval Decision on <Initial Review/Resubmission No.\_> of <protocol code>**

**Title: <protocol title>**

Dear <name of PI/LR>,

The **Palawan State University Research Ethics Review Committee (PSURERC)** reviewed your study titled “<title>” and all its related documents. After the primary review, the committee decided to approve your protocol.

The attached ethical clearance is dated <date> and is valid for one year.

Please be reminded that the following submissions should be submitted for monitoring purposes and as applicable:

1. Progress Report – which should be submitted on <date> using *PSURERC Form 3.1A Progress Report Form*
2. Early Study Termination Application – if there is a plan for early termination of the study, this should be submitted a week before the planned termination using *PSURERC Form 3.2 Early Study Termination Application/Report Form*
3. Early Study Termination Report – if the study has been terminated early, this should be submitted within a week after the early termination of the study
4. Amendment Request –which should be submitted if there are intended changes in the approved protocol using *PSURERC Form 3.3 Amendment Request Form*
5. Protocol Deviations Report – which should be submitted within 5 calendar days from the detection of the protocol deviation using *PSURERC Form 3.4 Protocol Deviations Report*
6. Reportable Negative Event Report – if there are occurrences in the study site that indicate risks or actual harms to participants and members of the research team and the integrity of data, this should be reported within 72 hours after the event has come to the researcher's attention; note that urgent and high-risk events should be reported immediately, within 24 hours of the event. Use *PSURERC Form 3.5A Reportable Negative Event Report*
7. SAE and SUSAR Report - this should be reported within 72 hours after the event has come to the researcher's attention; note that urgent and high-risk events should be reported immediately, within 24 hours of the event; use *PSURERC Form 3.5B SAE and SUSAR Report Form*
8. Continuing Review Application – if there is a need to extend the approval and clearance validity, this application should be submitted at least four weeks before the ethical clearance of a protocol expires; use *PSURERC Form 3.6A Continuing Review Application Form*
9. Final Report – should be submitted within a month after the completion of the study using *PSURERC Form 3.7 Final Report Form*

Depending on status of the study and if the PSURERC deems it necessary, the study site might be visited by a Site Visit Team of the Committee.

Noncompliance with the required submissions may result in sanctions that will be imposed by the PSURERC depending on the severity and frequency of violations and noncompliance.

Please note that the PSURERC retains the right to:

* Withdraw or amend the signed Ethics Clearance Certificate if any unethical principles or practices are revealed or suspected, the relevant information has been withheld or misrepresented, there are required regulatory changes of whatsoever nature, or the conditions provided have not been adhered to.
* Request access to any information or data at any time during the course or after the completion of the study.

Very truly yours,

**<NAME OF CHAIR>**

**Chair, PSURERC**