**REVIEW CHECKLIST**

**STUDY PROTOCOL INFORMATION**

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| --- | --- |
| PWUERC Code:1 |  |
| Study Protocol Title: |  |
| Principal Investigator: |  |
| Study Protocol Submission Date |  |
| Verified Complete by: |  |

1. **Basic Documents (must submit)**

* Review Checklist
* Registration and Application Form
* Protocol Assessment Form
* Study Protocol
* Data collection forms (including CRFs)
* CV of PI and study team members
* Proof of payment of ethics review fee (as applicable)

1. **Study-specific Documents (submit as needed)**

* Informed Consent Assessment Form (for studies with human participants)
* Informed consent form in English (for studies with human participants)
* Informed consent form in local language (for studies with human participants)
* Assent form in English (for studies involving minors and relevant populations deemed incompetent to sign an informed consent form)
* Assent form in local language (for studies involving minors and relevant populations deemed incompetent to sign an informed consent form)
* Good Clinical Practice (GCP) Training Certificate of PI, Co-I and the rest of the study team (for clinical trials)
* Recruitment advertisements (as needed by the study protocol)
* Other information or documents for participants (such as diaries, etc.)
* Material Transfer Agreement (for any research involving transfer of biological specimens)
* Memorandum of Agreement (for collaborative studies)
* Previous ethical review approvals/clearances (for students/personnel of foreign universities researching in the Philippines or those with prior ethical review)
* National Commission for Indigenous People (NCIP) Clearance (for studies with indigenous populations; can be processed while PWUERC review is ongoing)
* Clearance or permit from respective regulatory authorities (such as FDA approval for clinical trials and DENR local transport permit, applicable)

**REGISTRATION AND APPLICATION FORM**

**FOR INITIAL REVIEW AND RESUBMISSION**

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| **APPLICATION INFORMATION**  **Instructions: Fill up the necessary information and highlight specific choice (e.g. Initial Review)** | |
| **1. Study Protocol Code:** | PWUERC CODE:1 |
| **2. Study Title:** |  |
| **3. Type of Submission:** | * Initial Review (Version 1) * Resubmission, Version Number: |
| **4. Date of Submission:** |  |
| **5. Study Category:** | * Research involving human participants * Research involving non-human living vertebrates * Other (indicate): |
| **6. Type of Study:**  If the study is of a mixed type, please check and specify all fields that apply | * Humanities   Specify Field:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   * Social Sciences   Specify Field:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   * Science and Technology   Specify Field:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   * Basic Sciences   Specify Field:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   * Clinical   Specify Field:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   * Others, please indicate:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **7. Category of Primary Investigator:** | * PWU Faculty, Specify School or Program:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ * PWU Undergraduate Student, Specify degree program:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ * PWU Graduate Student, Specify degree program:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ * Non-PWU:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   (NOTE: This category requires completion of PART III: AUTHORIZATION AND ACKNOWLEDGEMENT OF REVIEW below)   * Others, please specify:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **8. Purpose of study:** | * Academic requirement (Thesis, Dissertation, Training Requirement) * Independent research work * Multi-institutional collaboration (within the Philippines only) * Multi-country collaboration * Others, please specify:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **9. Ethical Considerations Section:**  Please include a section in your proposal addressing these ethical considerations, as they apply to your study | a. Protection of privacy and confidentiality of research information including data protection plan  b. vulnerability of research participants  c. Risks of the study (including social risks)  d. Benefits of the study  e. Patient-related compensations/reimbursements/entitlements  f. Informed consent process and recruitment procedures  g. Terms of reference of collaborative study (as applicable, such as intellectual property agreements and similar concerns)  h. Terms of available study-related insurance |
| **10. Study Duration:** |  |
| **11. Use of special: population or vulnerable groups:** Please mark all that apply | * Children (under 18) * Indigenous People * Elderly * People on welfare/social assistance * Poor and unemployed * Patients in emergency care * Homeless persons * Refugees or displaced persons * Patients with incurable diseases * Prisoners * Others (indicate) * Not applicable |
| **12. Endorsing School/ Unit/ Institution:** | * School of Arts and Science * Conrado Benitez Institute of Business Education * School of Education * School of Fine Arts and Design * School of Food Technology * School of Environmental Science * Helena Z. Benitez – International Relations and Diplomacy * School of Hospitality Management * School of Medical Technology * School of Music * School of Nursing * School of Nutrition * School of Pharmacy * School of Social Work * School of Tourism * Non-PWU (local):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ * Non-PWU (foreign institution):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **13. Study Site Oversight:**  If different from the PWU endorsing institution | * PWU unit, Specify: * Non-PWU with local IRB/ERB/ERC * Non-PWU without local IRB/ERB/ERC |
| **14. Funding agency:** | **TYPE OF FUNDING AGENCY**   * 14.1 PWU or PWU unit, Specify:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ * 14.2 Investigator * 14.3 National Government agency/ office/ entity   Specify:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   * 14.4 Multilateral Agency (UN agencies and other intergovernmental agencies)   Specify:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   * 14.5 Private company or Non-governmental organization (NGO),   Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   * 14.6 Others (indicate):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **15. Study Budget:**  Please indicate total amount and attach budget sheet with line item amounts |  |

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| **16. Previous ethics approval or clearance Issued by other sites:** | * Name of Institutional Review Board or Ethics Review Board: * Date of ethics approval * Date of expiration of ethics approval * Not applicable |
| **17. Primary Investigator’s Name (PI):** |  |
| **18. Birthday:** |  |
| **19. PI Address:** |  |
| **20. PI phone/fax/mobile:** |  |
| **21. PI Email:** |  |
| **22. Other Ongoing studies of PI:**  Please add more rows if needed | Title:  PWUERB Code (if applicable): |
| **23. Declaration of Conflict of Interest of PI :** | * I have no conflict of interest in any form (financial, proprietary, professional) with the sponsor/s, the study, my Co-Investigators, or the site. * I have personal/family financial interest in the results of the study   Describe nature of conflict:   * I have proprietary interest in the research (patent, trademark, copyright, licensing)   Describe nature of conflict: |
| **24. Other investigators with corresponding task description** (add additional rows as applicable) | Co-Investigator:  Task description:  Co-Investigator:  Task description: |
| **25. Submitted by:** |  |
| **26. PI signature:** |  |

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If the protocol has been reviewed by an IRB where PWUERC has existing MOU, review can be waved.

**PROTOCOL ASSESSMENT FORM**

**STUDY PROTOCOL INFORMATION**

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| --- | --- |
| PWUERC Code:1 |  |
| Study Protocol Title: |  |
| Principal Investigator: |  |
| Study Protocol Submission Date |  |

**INSTRUCTIONS:**

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| **To the Principal Investigator:** | Please indicate in the space provided below whether or not the specified assessment point is addressed by your study protocol. To facilitate the evaluation of the assessment point, indicate the page and paragraph where this information can be found. |
| **To the Primary Reviewer:** | Please evaluate how the assessment points outlined below have been appropriately addressed by the study protocol, as applicable, by conforming the submitted information and putting your comments in the space provided under ‘’REVIEWER COMMENTS.’’ Finalize your review by indicating your conclusions under ‘’RECOMMENDED ACTION’’ and signing in space provided for the primary reviewer. |

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|  | To be filled out by the PI |  |  |
| **ASSESSMENT POINTS** | Indicate if the study protocol contains the specified assessment point | Page and paragraph where it can be found | **REVIEWER COMMENTS** |
| **1. SCIENTIFIC DESIGN** | **YES** | **N/A** |  |
| **1.1. Objectives**  Review of viability of expected output |  |  |  |
| **1.2. Literature Review**  Review of results of previous animal/human studies showing known risks and benefits of intervention, including known adverse drug effects, in case of drug trials. |  |  |  |
| **1.3. Research design**  Review of appropriateness of design in view of objectives |  |  |  |
| **1.4. Sampling design**  Review of appropriateness of sampling methods and techniques |  |  |  |
| **1.5. Sample size**  Review of computation of sample size |  |  |  |
| **1.6. Statistical analysis plan (SAP)**  Review of appropriateness of statistical methods to be used and how participant data will be summarized |  |  |  |
| **1.7. Data analysis plan**  Review of appropriateness of statistical and non-statistical methods of data analysis |  |  |  |

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| **1.8. Inclusion criteria**  Review of precision of criteria both for scientific merit and safety concerns; and of equitable selection. |  |  |  |
| **1.9. Exclusion criteria**  Review of criteria precision both for scientific merit and safety concerns; and of justified exclusion. |  |  |  |
| **1.10. Withdrawal criteria**  Review of criteria precision both for scientific merit and safety concerns |  |  |  |
| **2. CONDUCT OF STUDY** |  | | |
| **2.1. Specimen handling**  Review of specimen storage, access, disposal, and terms of use. |  |  |  |
| **2.2. PI qualifications**  Review of CV and relevant certifications to ascertain capability to manage study related risks |  |  |  |
| **2.3. Suitability of site**  Review of adequacy of qualified staff and infrastructures. |  |  |  |
| **2.4. Duration**  Review of length/extent of human participant involvement in the study |  |  |  |
| **3. ETHICAL CONSIDERATIONS** |  | | |
| **3.1. Conflict of interest**  Review of management of conflict arising from financial, familial, or proprietary considerations of the PI, sponsor of the study site. |  |  |  |
| **3.2. Privacy and confidentiality**  Review of measures or guarantees to protect privacy and confidentiality of participant information as indicated by data collection methods including data protection plans |  |  |  |
| **3.3 Informed consent Process**  Review of application of the principle of respect for persons, who may solicit consent, how and when it will be done; who may give consent especially in case of special populations like minors and those who are not legally competent to give consent or indigenous people which require additional clearances |  |  |  |
| **3.4. Vulnerability**  Review of involvement of vulnerable study populations and impact on informed consent (see 3.3). Vulnerable groups include children, the elderly, ethnic and racial minority groups, the homeless, prisoners, people with incurable disease, people who are politically powerless, or junior members of a hierarchical group. |  |  |  |
| **3.5. Recruitment**  Review of manner of recruitment including appropriateness of identified recruiting parties. |  |  |  |
| **3.6. Assent**  Review of feasibility of obtaining assent vis a vis incompetence to consent; Review of applicability of the assent age brackets in children:  0-under 7: No assent  7-under 12: Verbal assent  12-under15: Simplified Assent Form  15-under18: Co-sign informed consent form with parents. |  |  |  |
| **3.7. Risks**  Review of level of risk and measures to mitigate these risks (including physical,psychological,social,economic), including plans for adverse event management; Review of justification for allowable use of placebo as detailed in the Declaration of Heisinki (as applicable) |  |  |  |
| **3.8. Benefits**  Review of potential direct benefit to participants; the potential to yield generalizable knowledge about the participants’ condition/problem; non-material compensation to participant (health education or other creative benefits), where no clear, direct benefit from the project will be received by the participant. |  |  |  |
| **3.9. Incentives or compensation**  Review of amount and method of compensations, financial incentives, or reimbursement of study-related expenses |  |  |  |
| **3.10. Community Considerations**  Review of impact of the research on the community where the research occurs and/or to whom findings can be linked; including issues like stigma or draining of local capacity; sensitivity to cultural traditions, and involvement of the community in decisions about the conduct of study |  |  |  |
| **3.11. Collaborative study terms of reference**  Review of terms of collaborative study especially in case of multi-country/multi-institutional studies, including intellectual property rights, publication rights, information and responsibility sharing, transparency, capacity building. |  |  |  |

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| **RECOMMENDED ACTION:**   * Approved conditionally, subject to amendments * Approved conditionally, subject to clarification * Approved conditionally, subject to submission of further documentation * Decision deferred * Not approved | | |
| **JUSTIFICATION FOR RECOMMENDATION:** | | |
| Name/Sig: | Name/Sig: | Name/Sig: |
| **PRIMARY REVIEWER**  Date: | **PWU ERC SECRETARY**  Date: | **PWU ERC CHAIR**  Date: |

**INFORMED CONSENT ASSESSMENT FORM**

**STUDY PROTOCOL INFORMATION**

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| --- | --- |
| PWUERC Code:1 |  |
| Study Protocol Title: |  |
| Principal Investigator: |  |
| Study Protocol Submission Date |  |

**INSTRUCTIONS:**

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| --- | --- |
| **To the Principal Investigator:** | Please indicate in the space provided below whether or not the specified element is addressed by the informed consent form (ICF).  To facilitate the evaluation of the assessment point, indicate the page and paragraph where this information can be found. |
| **To the Primary Reviewer:** | Please evaluate how the elements outlined below have been appropriately addressed by the informed consent form (ICF), as applicable, and by confirming the submitted information and putting your comments in the space provided under “REVIEWER COMMENTS.” Finalize your review by indicating your conclusions under ‘’RECOMMENDED ACTION’’ and signing in space provided for the primary reviewer. |

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|  | To be filled out by the PI |  |  |
| **ASSESSMENT POINTS** | Indicate if the study ICF contains the specified assessment point | Page and paragraph where it can be found | **REVIEWER COMMENTS** |
|  | **YES** | **N/A** |  |
| 1.Statement that the study involves research |  |  |  |
| 2. Statement describing the purpose of the study |  |  |  |
| 3. Study-related treatments and probability for random assignment |  |  |  |
| 4. Study procedures including all invasive procedures |  |  |  |
| 5. Responsibilities of the participant |  |  |  |
| 6. Expected duration of participation in the study |  |  |  |
| 7. Approximate number of participants in the study |  |  |  |
| 8. Study aspects that are experimental |  |  |  |
| 9. Foreseeable risks to participant/embryo/fetus/nursing infant; including pain, discomfort, or inconvenience associated with participation including risks to spouse or partner; |  |  |  |

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| 10. Risks from allowable use of placebo (as applicable) |  |  |  |
| 11. Reasonably expected benefits or absence of direct benefit to participants, as applicable |  |  |  |
| 12. Expected benefits to the community or to society, or contributions to scientific knowledge |  |  |  |
| 13. Description of post-study access to the study product or intervention that have been proven safe and effective |  |  |  |
| 14. Alternative procedures or treatment available to participant |  |  |  |
| 15. Compensation or insurance or treatment entitlements of the participant in case of study-related injury. |  |  |  |
| 16. Anticipated payment, if any, to the participant in the course of the study; whether money or other forms of material goods, and if so, the kind and amount |  |  |  |
| 17. Compensation (or no plans of compensation) for the participant or the participant’s family or dependents in case of disability or death resulting from study-related injuries. |  |  |  |
| 18. Anticipated expenses, if any, to the participant in the course of the study |  |  |  |
| 19. Statement that participation is voluntary, and that participant may withdraw anytime without penalty or loss of benefit to which the participant is entitled. |  |  |  |
| 20. Statement that the study monitor(s), auditor(s), the PWUERB Ethics Review Panel, and regulatory authorities will be granted direct access to participant’s medical records for purposes ONLY of verification of clinical trial procedures and data. |  |  |  |
| 21. Statement that the records identifying the participants will be kept confidential and will not be made publicly available, to the extent permitted by law; and that the identity of the participant will remain confidential in the event the study results are published; including limitations to the investigator’s ability to guarantee confidentiality. |  |  |  |
| 22. Description of policy regarding the use of genetic tests and familial genetic information, and the precautions in place to prevent disclosure of results to immediate family relative or to others without consent of the participant |  |  |  |
| 23. Possible direct or secondary use of participant’s medical records and biological specimens taken in the course of clinical care or in the course of this study |  |  |  |

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| 24. Plans to destroy collected biological specimen at the end of the study; if not, details about storage (duration, type of storage facility, location, access information) and possible future use; affirming participant’s right to refuse future use, refuse storage, or have the materials destroyed |  |  |  |
| 25. Plants to develop commercial products from biological specimens and whether the participant will receive monetary or other benefit from such development |  |  |  |
| 26. Statement that the participant or participant’s legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to willingness of the participant to continue to participation |  |  |  |
| 27. Statement describing access of participant to the result of the study |  |  |  |
| 28. Statement describing extent of participant’s right to access his/her records (or lack thereof vis a vis pending request for approval of non or partial disclosure) |  |  |  |
| 29. Foreseeable circumstances and reasons under which participation in the study may be terminated |  |  |  |
| 30. Sponsor, institutional affiliation of the investigators, and nature and sources of funds |  |  |  |
| 31. Statement whether the investigator is serving only as an investigator or as both investigator and the participant’s healthcare provider |  |  |  |
| 32. Person(s) to contact in the study team for further information regarding the study and whom to contact in the event of study-related injury |  |  |  |
| 33. Statement that the PWU Ethics Review Board has approved the study, and may be reached through the following contact for information regarding rights of study participants, including grievances and complaints: |  |  |  |

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| **RECOMMENDED ACTION:**   * Approved conditionally, subject to amendments * Approved conditionally, subject to clarification * Approved conditionally, subject to submission of further documentation * Decision deferred * Not approved | | |
| **JUSTIFICATION FOR RECOMMENDATION:** | | |
| Name/Sig: | Name/Sig: | Name/Sig: |
| **PRIMARY REVIEWER**  Date: | **PWU ERC SECRETARY**  Date: | **PWU ERC CHAIR**  Date: |