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| **FORM 2.1** **APPLICATION FOR REVIEW** |

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| URERC Protocol Number |  |

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| --- | --- | --- | --- |
| Sponsor Protocol Number |  | Date of Submission |  |

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| Type of Submission | | | |
|  | | | |
|  | Initial Review |  | Continuing Review |
|  |  | | |
|  | Resubmission |  | Protocol Termination |
|  |  | | |
|  | Protocol Amendment |  | Final Report |

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| --- | --- |
| Title |  |

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| Principal Investigator/Researcher Information | | | |
| *Name* |  | | |
|  | | | |
| *Contact Number* |  | *E-mail Address* |  |
|  |  |  |  |
| *Address* |  | | |
|  | | | |
| *Institution* |  | | |

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| --- | --- |
| Sponsor |  |

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

If you have answered yes to any of the above questions, please include a brief explanation.

For any other types of Conflict of Interest, please indicate: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator/Researcher’s Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*For WVSU-URERC Secretariat*

Documents Received:

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|  | Application for Review (letter of request addressed to the ERC Chair) with complete signatories *(Principal Investigator, Adviser, Research Coordinator or Dean)* |
|  | 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 2.10 Summary of Recommendations |
|  | Form 3.1 Protocol Amendment Review |
|  | Form 3.2 Progress Report |
|  | Form 3.3 Final Report |
|  | Form 3.8 Study Termination |
|  | 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 |
|  | 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) for all members of the Research Team |
|  | 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 |
|  | Page number (Continuous Paging) |

Received by:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_