# Registration and Application Form

**For Initial Review and Resubmission**

***Please print in A4 size paper***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **SECTION I: APPLICATION INFORMATION** | | | | |
| 1. **Study Protocol Code:** | 1.1 Reference Number:[[1]](#footnote-1) | |  | |
| 1.2 UPMREB CODE:[[2]](#footnote-2) | |  | |
| 1. **Type of Submission** | * 2.1 Initial Review * 2.2 Resubmission (responses to initial review recommendations or submission of studies with investigator-initiated changes prior to ethics approval). NOTE: version and date of version must be inserted as a document footer for all resubmissions | | | |
| 1. **Date of Submission:** | <dd/mm/yyyy> | | | |
| 1. **Study Category** | * 4.1 Research involving human participants * 4.2 Research involving non-human living vertebrates * 4.3 Others (indicate): | | | |
| 1. **Type of study:** | * 5.1 Pre-clinical Research * 5.2 **Non-clinical trial**, specifically (choose one): * 5.2.1 Diagnostics * 5.2.2 In vitro study * 5.2.3 Genetic or genomic research * 5.2.4Stem Cell Research * 5.2.5 Herbal Research * 5.2.6 Complementary and Alternative Medicine Research * 5.2.7 Research on Assisted Reproductive Technology * 5.2.8 Research on Indigenous Materials * 5.2.9 Review of medical records * 5.2.10 Epidemiological study * 5.2.11 Sociobehavioral Research * 5.2.13 Health informatics * 5.2.14 Operations/process research * 5.3 **Clinical Trial** **Type 1** (*drug or pharmaceutical trials, diagnostic trials, trials on devices, and other therapy trials)* intended for marketing registration * 5.4 **Clinical Trial Type 2** (*drug or pharmaceutical trials, diagnostic trials, trials on devices, and other therapy trials)* **NOT** intended for marketing registration * 5.5 **Post Marketing Surveillance** * 5.6 Others, please indicate: | | | |
| 1. **Category of Investigator** | * 6.1 UPM Faculty/REPS * 6.2 UPM Undergraduate Student * 6.3 UPM Graduate Student (MS, PhD, Medical Student) * 6.4 UPM-NIH Institute/Study Group Researcher, Faculty, UR, URA * 6.5 UP-PGH * 6.5.1 Residents-in-training * 6.5.2 Fellows-in-training * 6.5.3 Residents/Fellows graduated completing research requirements * 6.5.4 Nursing * 6.5.5 Other Researchers * 6.6 Non-UPM (NOTE: This category requires completion of *SECTION IV: AUTHORIZATION AND ACKNOWLEDGEMENT OF REVIEW* below) * 6.7 Others, please specify: | | | |
| 1. **Purpose of study** | * 7.1 Academic requirement (Thesis, Dissertation, Training Requirement) (NOTE: Indicate name/s of adviser/s and describe roles of adviser/s in item 26 below) * 7.2Independent research work * 7.3 Multi-institutional or multi-country collaboration (NOTE: Multi-site protocols may be endorsed for a single joint review[[3]](#footnote-3)) * 7.4Others (indicate): | | | |
| 1. **Study Title** |  | | | |
| 1. **Study Protocol Synopsis**   *Please write a synopsis of the study in the space provided, and indicate page where this may be found in the full study protocol or in annexes/appendices. Attach the full study protocol to this application. Make a diagrammatic workflow and attach it to the study protocol.* | | | | |
| * 1. **Technical Synopsis**      1. Social Value | *Please write a summary regarding social value of the study.* | | | |
| * + 1. Objectives/Expected output | *Please write the objectives of the study.* | | | |
| * + 1. Literature review rationalizing the design | *Please write a summary on the literature review rationalizing the design.* | | | |
| * + 1. Research design | *Please write a summary regarding the research design.* | | | |
| * + 1. Sampling design, sample size, site recruitment or accrual ceiling | *Please write the sampling design and sample size.* | | | |
| * + 1. Inclusion criteria, exclusion criteria, withdrawal criteria | *Please write the inclusion, exclusion and withdrawal criteria.* | | | |
| * + 1. Data collection and processing plan | *Please write a summary of the data collection and processing plan, including plans for data storage, duration of storage, and who has access to the stored data.* | | | |
| * + 1. Specimen collection and processing plan | *Please write a summary of the specimen collection and processing plan, including plans for specimen storage, duration of storage, access to the stored data, and details on biobank custodian and adherence to institutional guidelines for biobanking, and provision for sample and data removal and destruction for biobanked samples.* | | | |
| * + 1. Data analysis plan | *Please write a summary of the plan for data analysis including statistical basis for design, as applicable.* | | | |
| * + 1. Rationalization for choice of study site (Cross reference information with statements provided in the informed consent) | *Please indicate the specific study site/s and provide justification for the choice of site/s, including capacity of site to address known risks of study protocol, such as availability of equipment and facilities, as applicable.*  *Note that for multi-site protocols involving DOH hospitals, review is done by the Single Joint Review Ethics Board (SJREB). For further information on SJREB, you may visit DOH website accessible at https://www.doh.gov.ph/Single-Joint-Research-Ethics-Board-Forms.* | | | |
| * + 1. Duration of human participant involvement | *Please indicate duration of human participant involvement.* | | | |
| * 1. **Ethical Considerations**      1. Protection of privacy and confidentiality of research information including data protection plan | *The section on ethical considerations should be stated in the study protocol. Please write a summary on protection of privacy and confidentiality of research information including data protection plan.* | | | |
| * + 1. Vulnerability of research participants | *Please write a summary regarding vulnerability of research participants, as applicable.* | | | |
| * + 1. Risks of the study | *Please write a summary on measures regarding risks of the study, including social risks and issues for safety.* | | | |
| * + 1. Benefits of the study | *Please write a summary regarding benefits of the study, including a statement justifying a favorable benefit-risk ratio.* | | | |
| * + 1. Patient-related compensations/reimbursements/ entitlements | *Please write plans on patient-related compensations/reimbursements/entitlements.* | | | |
| * + 1. Informed consent process and recruitment procedures | *Please write a summary regarding process of recruitment and informed consent, including how potential participants will be identified and what information will be made available to the participants, who will obtain informed consent and how this will be done.* | | | |
| * + 1. Community considerations | *Please write a statement regarding community considerations, as applicable.* | | | |
| * + 1. Dissemination/data sharing plan | *Please write a summary regarding plans on dissemination and data sharing.* | | | |
| * + 1. Terms of reference of collaborative study | *Please indicate terms of reference of collaborative study, as applicable, such as intellectual property agreements and similar concerns.* | | | |
| * + 1. Terms of available study-related insurance | *Please indicate the terms of available study-related insurance, as applicable.* | | | |
| 1. **Study Duration** | (in months) | | | |
| 1. **Use of special populations or vulnerable groups** | * 11.1 Children (under 18) * 11.2 Indigenous People * 11.3 Elderly * 11.4 People on welfare/social assistance * 11.5 Poor and unemployed * 11.6 Patients in emergency care * 11.7 Homeless persons * 11.8 Refugees or displaced persons * 11.9 Patients with incurable diseases * 11.10 Others (indicate): * 11.11 Not applicable | | | |
| 1. **Involvement of children and adolescents** | * 12.1 Children aged less than 7 years old * 12.2 Children aged 7 years old to less than 12 years old * 12.3 Children aged 12 years old to less than 15 years old * 12.4 Children aged 15 years old to less than 18 years old * 12.5 Not applicable | | | |
| 1. **Endorsing/College/ Unit/ Institution** | * 13.1 College of Allied Medical Professions * 13.2 College of Arts and Sciences * 13.3 College of Dentistry * 13.4 College of Medicine * 13.5 College of Nursing * 13.6 College of Pharmacy * 13.7 College of Public Health * 13.8 National Teacher Training Center for the Health Professions * 13.9 School of Health Sciences * 13.10 UPM-NIH (Put institute or office): <name of institute or office> * 13.11 UP-PGH (Put department and section): <name of department & section> * 13.13 Non-UPM (local): <name of institution> * 13.13 Non-UPM (foreign institution): <name of institution> | | | |
| 1. **Study site/s** | (NAME): | | | |
| **TYPE OF STUDY SITE** | | | |
| * 14.1 UPM unit * 14.2 Non-UPM with local IRB/ERB/ERC: <Indicate name of IRB/ERB/ERC> * 14.3Non-UPM without local IRB**/**ERB/ERC (NOTE: This category requires completion of *SECTION IV: AUTHORIZATION AND ACKNOWLEDGEMENT OF REVIEW* below) | | | |
| 1. **Funding agency:** | **(NAME):** | | | |
| **TYPE OF FUNDING AGENCY** | | | |
| * 15.1 UPM or UPM unit * 15.2 Investigator * 15.3 PHL Government agency/office/entity * 15.4 Multilateral Agency (UN agencies and other intergovernmental agencies) * 15.5 Private company or Non-governmental organization (NGO) * 15.6 Others (indicate): | | | |
| 1. **Study Budget** | NOTE: This refers to line item amounts. However, if a separate budget sheet is available, just indicate total amount and attach budget sheet | | | |
| 1. **Previous ethics approval or clearance issued by other sites** | * 17.1 Name of Institutional Review Board or Ethics Review Committee: * 17.2 Date of ethics approval: * 17.3 Date of expiration of ethics approval: * 17.4 Not applicable | | | |
| 1. **Principal Investigator** | <Title, Name, Surname> | | | |
| 1. **Birthday** | <dd/mm/yyyy> | | | |
| 1. **PI Address** | <Institutional Address> | | | |
| 1. **PI Telephone:** |  | | | |
| 1. **PI Facsimile:** |  | | | |
| 1. **PI Mobile:** |  | | | |
| 1. **PI Email:** |  | | | |
| 1. **Other Ongoing studies** | * 25.1 Title: * 25.1.1 UPMREB Code (if applicable): | | | * 25.3 Title: * 25.3.1 UPMREB Code (if applicable): |
| * 25.2 Title: * 25.2.1 UPMREB Code (if applicable): | | | * 25.4 Title: * 25.4.1 UPMREB Code (if applicable): |
| 1. **Other investigators with corresponding task description** *(add additional rows as applicable)* | Co-Investigator:  Task description (*Refer to pg 47-54 of NEGHHR 2017 for roles of investigators*): | | | |
| Co-Investigator:  Task description *(Refer to pg 47-54 of NEGHHR 2017 for roles of investigators)*: | | | |
| 1. **Submitted by:** | <Title, Name, Surname> | | | |
| Study designation |  | | |
| 1. **PI signature** |  | | | |

|  |  |  |
| --- | --- | --- |
| **SECTION II: SCIENTIFIC/TECHNICAL REVIEW APPROVAL ENDORSEMENT**  *This section should be signed by the Chair/Head of the Scientific/Technical Review committee/office that reviewed the scientific soundness of the study and issued the appropriate approval. Alternatively, results of Scientific/Technical Review disposition may be appended to this application, instead of completing this section, provided that the information required below had been appropriately addressed.* | | |
| STUDY PROTOCOL TITLE: | <with Version Number and Date> | |
| Principal Investigator: | <Title, Name, Surname> | |
| I confirm that the(NAME OF SCIENTIFIC/TECHNICAL REVIEW COMMITTEE/OFFICE) has reviewed and approved the following study protocol-related information: Objectives/Expected output supported by literature review; overall research design; sampling design, sample size, Inclusion/exclusion/ withdrawal criteria; data collection plan and specimen collection, processing, and storage as applicable; data analysis plan including statistical design/framework, as applicable. | | |
| Issuing committee/office: |  | |
| Head of committee/office: | <Title, Name, Surname> | |
| Signature: |  | Date of Signature: <dd/mm/yyyy> |
| **SECTION III: INSTITUTIONAL ENDORSEMENT**  *This section should be signed by the head of unit (administrative authority legally empowered to sign on behalf the unit such as Dean, Director, and the like) of the Principal Investigator. This section is required only for initial submission,* ***provided there are no changes in study protocol information below.*** | | |
| STUDY PROTOCOL TITLE: |  | |
| Principal Investigator: | <Title, Name, Surname> | |
| I confirm that I have read this Application and that the research will be implemented under the oversight of this Department/Institution in accordance with the conditions of approval by the University of the Philippines Manila Research Ethics Board. I also confirm that the Principal Investigator has an appointment or a student in good standing in this institution. | | |
| Issuing unit/college: |  | |
| Head of unit: | <Title, Name, Surname> | |
| Signature: |  | Date of Signature: <dd/mm/yyyy> |

|  |  |  |  |
| --- | --- | --- | --- |
| **SECTION IV: AUTHORIZATION AND ACKNOWLEDGEMENT OF REVIEW**  *This section should be completed by the signatory official who can sign on behalf of the institution that has oversight on the research site,* ***IF the research site is OUTSIDE the scope of authority of UPM****. If not applicable, put N/A in all fields. This section is required only for initial submission,* ***provided there are no changes in study protocol information below.*** *In case regional IRB will opt not to review, attach letter of endorsement.* | | | |
| STUDY PROTOCOL TITLE: |  | | |
| Principal Investigator: | <Title, Name, Surname> | | |
| Research Site Personnel: | <Title, Name, Surname> | | |
| Institutional Affiliation of Research Site Personnel: |  | | |
| Signature |  | Date of Signature: <dd/mm/yyyy> | |
| This is to certify that the **<NAME OF RESEARCH SITE>:**   1. Has no local Institutional Review Board/ Ethics Review Committee; and 2. Authorizes and acknowledges the University of the Philippines-Manila Research Ethics Board (UPMREB), located at the Room 126, National Institutes of Health, UP Manila, 623 Pedro Gil St, Ermita, Manila, to perform the ethical review of the abovementioned study protocol in accordance with international ethical standards and national regulatory requirements, and oversee the conduct of the research study which includes progress monitoring, adverse event monitoring, and site visits.   Responsibilities of the Site:   1. Monitoring of the site - continuing review, SAEs 2. Communicate reportable events to the UPMREB 3. Attend UPMREB meetings, if applicable | | | |
| Name of Research Site |  | | |
| Address of Research Site |  | | |
| Signatory Official | <Title, Name, Surname> | | |
| Position of Official |  | | |
| Signature |  | | Date of Signature: <dd/mm/yyyy> |

|  |  |  |
| --- | --- | --- |
| **SECTION V: DECLARATION OF CONFLICT OF INTEREST**  *This section should be signed by the Principal Investigator indicating disclosure of financial interest and arrangements.* | | |
| STUDY PROTOCOL TITLE: | <with Version Number and Date> | |
| FUNDING AGENCY/SPONSOR: |  | |
| *Check the applicable box/boxes of the declaration of conflict of interest, including the nature of significant conflict of interest, as applicable.*   * I declare that I have significant conflict of interests that are required to be disclosed as follows: * Significant financial Interests, defined in US 45 CFR Part 94 as receiving payments for services and/or equity more than more than $5000 (Note: This category is only for applications for which this regulation may apply. For information, refer to http://www.ecfr.gov) * Any financial arrangements entered into between the sponsor for the covered study and the clinical investigator involved in the conduct of the covered study, whereby the value of the compensation to the clinical investigator for conducting the study could be influenced by the outcome of the study;   (Attach details of investigator’s disclosable financial arrangements and interests, including the description of steps to minimize the potential bias of clinical study results by any of the disclosed arrangements or interests.)   * Any proprietary interest in the research for which this application is being made (patent, trademark, copyright, licensing) * Any significant personal/family interest (up to 4th civil degree by consanguinity or affinity) with the sponsor or the results of the study. * I declare that I do not have any significant conflict of interest in conducting the study, as listed above. | | |
| Principal Investigator: | <Title, Name, Surname> | |
| Institution: | <Name of Institution> | |
| Signature: |  | Date of Signature: <dd/mm/yyyy> |

1. To be issued upon RGAO registration [↑](#footnote-ref-1)
2. To be issued upon initial processing by UPMREB [↑](#footnote-ref-2)
3. Multi-site protocols involving at least three (3) sites in the Philippines with at least one (1) DOH hospital are endorsed to the Single Joint Research Ethics Board. [↑](#footnote-ref-3)