# Registration and Application Form

**For Initial Review and Resubmission**

*Please print in A4 size paper*

**SECTION 1. APPLICATION INFORMATION**

|  |  |  |
| --- | --- | --- |
| 1.1. Study Protocol Code[[1]](#footnote-1): | Reference Number: |       |
| UPLB REB CODE: |       |
| 1.2. Study Title |  |
| 1.3. Type of Submission | [ ]  | Initial Review |
|  | [ ]  | 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 |
|  |  |  |
| 1.4. Date of Submission: | 1 January 2000 |
|  |  |
| 1.5. Type of study: | [ ]  | Communication Arts |
|  | [ ]  | Development Communication |
|  | [ ]  | Economics |
|  | [ ]  | Extension Education |
|  | [ ]  | Human/Family Studies |
|  | [ ]  | Rural Sociology |
|  | [ ]  | Environmental Science |
|  | [ ]  | Urban/Environmental Planning |
|  | [ ]  | Human Ecology |
|  | [ ]  | Management |
|  | [ ]  | Development Studies |
|  | [ ]  | Agriculture |
|  | [ ]  | Biology |
|  | [ ]  | Forestry |
|  | [ ]  | Nutrition |
|  | [ ]  | Public Health |
|  | [ ]  | Engineering |
|  | [ ]  | Biobanks, Registries, and Databases |
|  | [ ]  | Others, please specify:       |
|  |  |  |
| 1.6. Category of Investigator | [ ]  | UPLB Faculty/REPS |
| [ ]  | UPLB Undergraduate Student |
| [ ]  | UPLB Graduate Student (MS, PhD) |
| [ ]  | Others, please specify:       |
|  |  |
| 1.7. Purpose of study | [ ]  | Academic requirement (Thesis, Dissertation, Training requirement)  |
|  | [ ]  | Independent research work |
|  | [ ]  | Multi-institutional or multi-country collaboration |
|  | [ ]  | Others, please specify:      |
| 1.8. Endorsing/College/ Unit/ Institution |       |

**SECTION 2. RISK ASSESSMENT**

* 1. Please indicate if your research involves people from the following population:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| YES | [ ]  | POSSIBLY | [ ]  | NO | [ ]  | Children/minors (under 18) |
| YES | [ ]  | POSSIBLY | [ ]  | NO | [ ]  | Indigenous People |
| YES | [ ]  | POSSIBLY | [ ]  | NO | [ ]  | Pregnant women |
| YES | [ ]  | POSSIBLY | [ ]  | NO | [ ]  | Elderly |
| YES | [ ]  | POSSIBLY | [ ]  | NO | [ ]  | People on welfare/social assistance |
| YES | [ ]  | POSSIBLY | [ ]  | NO | [ ]  | Economically disadvantaged and unemployed |
| YES | [ ]  | POSSIBLY | [ ]  | NO | [ ]  | Patients in emergency care |
| YES | [ ]  | POSSIBLY | [ ]  | NO | [ ]  | Homeless persons |
| YES | [ ]  | POSSIBLY | [ ]  | NO | [ ]  | Refugees or displaced persons or populations involved in disaster situations |
| YES | [ ]  | POSSIBLY | [ ]  | NO | [ ]  | Patients with serious illnesses or incurable diseases |
| YES | [ ]  | POSSIBLY | [ ]  | NO | [ ]  | Persons with disability(ies) |
| YES | [ ]  | POSSIBLY | [ ]  | NO | [ ]  | Persons in conflict with the law |
| YES | [ ]  | POSSIBLY | [ ]  | NO | [ ]  | Persons deprived of liberty |
| YES | [ ]  | POSSIBLY | [ ]  | NO | [ ]  | Persons living with HIV or AIDS |
| YES | [ ]  | POSSIBLY | [ ]  | NO | [ ]  | Others, please specify:      |

* 1. Please identify the foreseeable risks in the study, including the likelihood, and severity. Please take note that different people may experience different risks differently (refer to the *Guidance on Assessment and Mitigation of Risks in Research Involving Human Participants*).

| **TYPE OF RISK** | **AFFECTS WHO** | **LIKELIHOOD** | **SEVERITY** | **CATEGORY** |
| --- | --- | --- | --- | --- |
| **Participant** | **Researcher** | **OTHER** | **Unlikely** | **Seldom** | **Occasional** | **Likely** | **Definite** | **Insignificant** | **Minor** | **Moderate** | **Critical** | **Catastrophic** | **Low** | **Medium** | **High** | **Extreme** |
| **DISCOMFORT**: which can involve body and/or mind: e.g. minor side-effects of medication, discomfort related to measuring blood pressure, and mild anxiety induced by an interview.  |
|       | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
|       | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
|       | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| **PHYSICAL HARMS**: including potential for injury, illness, pain, chemical exposure, infection.  |
|  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
|  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| **PSYCHOLOGICAL HARMS**: including feelings of worthlessness, distress, guilt, anger or fear related, for example, to disclosure of sensitive or embarrassing information.  |
|  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
|  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| **DEVALUATION OF PERSONAL WORTH**: including being humiliated, manipulated or in other ways treated disrespectfully or unjustly.  |
|  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
|  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| **SOCIAL HARMS**: including damage to social networks or relationships with others; discrimination in access to benefits, services, employment or insurance; social stigmatization.  |
|  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
|  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| **ECONOMIC HARMS**: including the imposition of direct or indirect costs on participants.  |
|  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
|  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| **LEGAL HARMS**: including discovery and prosecution of criminal conduct; mandatory reporting requirements.  |
|  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
|  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| **REPUTATIONAL HARMS** including loss of reputation and credibility to any and all parties, and to the research findings.  |
|  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
|  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| **CIRCUMSTANCES OF VULNERABILITY:** including all dynamic circumstances of relational asymmetry in the research context (i.e. cognitive, juridic, deferential, medical, allocation, infrastructural, social) that make a person(s) more susceptible to harm (Kipnis, 2001; Luna, 2019; Racine & Bracken‐Roche, 2019) |
|  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
|  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| **OTHER RISKS** |
|  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
|  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |

* 1. Please describe the risks identified in the study including the affected group (participants, researcher, etc.), likelihood, and severity.

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|       |

* 1. Please describe the mechanisms to manage or minimize the risks identified.

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* 1. Please indicate the potential benefits of the research.

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**SECTION 3. DETAILS OF THE RESEARCH**

|  |  |
| --- | --- |
| 3.1. Study Title: |       |
| 3.2. Technical Study Protocol Synopsis*Please write a synopsis (maximum 500 words) of the study in the space provided. Attach the full study protocol to this application. Make a diagrammatic workflow and attach it to the study protocol. Outline the research in* ***simple language*** *the following components of the research:***Technical Synopsis**1. Objectives/Expected output
2. Literature review rationalizing the design
3. Research design
4. Sampling design, sample size
5. Inclusion criteria, exclusion criteria, withdrawal criteria
6. Data collection plan
7. Specimen collection and processing plan (including plans for specimen storage and duration of storage)
8. Data analysis plan (including statistical basis for design, as applicable)
9. Rationalization for choice of study site (including capacity of site to address known risks of study protocol, such as availability of equipment and facilities, as applicable) (Cross reference information with statements provided in the informed consent)
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| 3.3. Study Duration (in months):      |
| Start date: 1 January 2000 | End date:1 January 2000 |
|  |  |
| 3.4. Data Collection Methods (tick all that apply). *Attach a copy of data collection instrument.* |
| [ ]  | Interviews | [ ]  | Focus Group Discussion |
| [ ]  | Hard copy surveys | [ ]  | Online surveys |
| [ ]  | Online/transactional tracking | [ ]  | Observation |
| [ ]  | Social media monitoring | [ ]  | Specimen collection (blood, saliva, tissue, etc.) |
| [ ]  | Sensory Evaluation | [ ]  | Documents and records |
| [ ]  | Others, please specify:       |
|  |  |
| 3.5 Study Site | [ ]  | UPLB unit |
|  | [ ]  | Non-UPLB unit with local research ethics committee |
|  | [ ]  | Non-UPLB unit without local research ethics committee |
|  |  |
| 3.6. Study participants |
|  |
| 3.6.1. Describe the participants to be included in the study. If the research involves collection of secondary data, indicate where/from whom the data will be extracted and what will it include.  |
|       |
| 3.6.2. Describe the participant inclusion and exclusion criteria. |
|       |
| 3.6.3 Describe how the [Sex and gender Equity in Research (SAGER) guidelines](https://researchintegrityjournal.biomedcentral.com/articles/10.1186/s41073-016-0007-6) were applied in this research. |
|       |
|  3.7Recruitment |
| 3.7.1. Describe the recruitment process. Provide the explanation on how the sample size was arrived at and how potential participants will be identified. Briefly describe how, by whom, and from where the participants will be recruited. |
|       |
| 3.7.2. Describe any recruitment materials to be used. *Attach a copy of the recruitment posters/materials.* |
|       |
| 3.7.3. Will the participants receive any compensation for participation? If yes, describe the nature of compensation, frequency, and justification for the value of the compensation. If not, explain why compensation is not appropriate. |
|       |
| 3.8. Consent |
| 3.8.1. Describe in detail how informed consent will be obtained and recorded. *Attach a copy of the consent in English and local language.* |
|       |
| 3.8.2. If the research will take place in a community or an organization, describe how the community or organizational consent will be obtained and recorded. *Attach a copy of the consent in English and local language.* |
|       |
| 3.8.3. If the research involves children or those who are not competent to give consent, please describe the process of obtaining consent from this population. |
|       |
| 3.9. Participant Withdrawal |
| 3.9.1. Describe how the participants will be informed of their right to withdraw from the study. |
|       |
| 3.9.2. If there is incentive or compensation, describe how will this be affected if the participant choses to withdraw.  |
|       |
| 3.9.3. Describe what will happen to the collected data of the withdrawn participant.  |
|       |
| 3.10. Confidentiality, Data Privacy, and Storage |
| 3.10.1. Describe the steps to be employed to ensure the confidentiality and anonymity of the data/specimen collected.  |
|       |
| 3.10.2. Describe the measures of data security including where the data/specimen will be stored and who has access to the data/specimen.  |
|       |
| 3.10.3. Indicate how long the data/specimen will be stored. |
|       |
| 3.10.4. Outline how the data and/or specimen will be disposed of. |
|       |
| 3.11. Results Dissemination |
| 3.11.1. Describe how will the participants be informed about the outcomes of the study.  |
|       |
| 3.11.2. Describe how, where, and to whom the results will be disseminated (e.g., publication, conference presentation, etc.) |
|       |
|  |
| 3.12. Funding and Collaboration |
| 3.12.1. Study Budget:  |       |
| 3.12.2. Please choose from the following: |
| [ ]  | FUNDED | Funding Agency:      | Funding Number:      |
| [ ]  | APPLIED FOR FUNDING | Funding Agency:      | Start Date of Grant:1 January 2000 |
| [ ]  | UNFUNDED | Describe:       |
|  |  |
| 3.12.3. Please describe the terms of reference for collaborative studies. |
| 3.13. Previous ethics approval or clearance issued by other sites (N/A if not applicable). |
| Name of Ethics Review Committee: |       |
| Date of Ethics Approval: | 1 January 2000 |
| Date of Expiration of Ethics Approval: | 1 January 2000 |

**SECTION 4. RESEARCHER INFORMATION**

4.1. Principal Investigator

|  |  |
| --- | --- |
| Title:      | Name:      |
| Department/College:       |
| Institutional Address:      |
| Email:      | Mobile Phone:      | Landline:      |
| Degree program (if applicable):      |
| Student Number (if applicable):      |
| Describe your research experience: |
|       |

4.2. Faculty Supervisor (if PI is a student)

|  |  |
| --- | --- |
| Title:      | Name:      |
| Department/College:       |
| Institutional Address:      |
| Email:      | Mobile Phone:      | Landline:      |
| Areas of expertise:       |

4.3. Co-investigators

|  |  |
| --- | --- |
| Title:      | Name:      |
| Department/College:       |
| Institutional Address:      |
| Email:      | Mobile Phone:      | Landline:      |
| Research experience:       |
| Tasks in the research:      |

|  |  |
| --- | --- |
| Title:      | Name:      |
| Department/College:       |
| Institutional Address:      |
| Email:      | Mobile Phone:      | Landline:      |
| Research experience:       |
| Tasks in the research:       |

|  |  |
| --- | --- |
| Title:      | Name:      |
| Department/College:       |
| Institutional Address:      |
| Email:      | Mobile Phone:      | Landline:      |
| Research experience:       |
| Tasks in the research:       |

4.4. Other ongoing studies of the principal investigator

|  |  |
| --- | --- |
| Title:      | Title:      |
| UPLB REB Code:      | UPLB REB Code:      |
| Title:      | Title:      |
| UPLB REB Code:      | UPLB REB Code:      |

**SECTION 5. DECLARATION**

This section is applicable to the whole research team (including supervisors and co-investigators). Please reproduce this page as needed.

I certify that (*tick all that apply*):

|  |  |
| --- | --- |
| [ ]  | All information above is correct and complete; |
| [ ]  | The research will be conducted following the national and international ethical guidelines applicable to my study; |
| [ ]  | I will immediately report any incident that needs ethical review such as change in protocol, reportable negative event, and/or serious adverse events; |
| [ ]  | I have appropriate qualifications to conduct this research;  |
| [ ]  | I have no conflict of interest in any form (financial, proprietary, professional) with sponsor, the study, co-Investigators, or the site; |
| [ ]  | I have personal/family financial interest in the results of the study;Please specify nature of interest:       |
| [ ]  | I have proprietary interest in the research for which this application is being made (patent, trademark, copyright, licensing);Please specify nature of interest:       |
| [ ]  | I have significant financial Interests as defined in US 45 CFR Part 94 (Note: This category is only for applications for which this regulation may apply. For information, refer to <http://www.ecfr.gov>).Please specify nature of interest:       |

Submitted by:

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Name | Signature | Date |

**SECTION 6. ENDORSEMENT**

|  |
| --- |
| 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: 1 January 2000 |
| 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: | <with Version Number and Date> |
| 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 Los Baños Research Ethics Board (UPLB REB). I also confirm that the Principal Investigator has a regular appointment in this institution. |
| Issuing unit/college: |       |
| Head of unit: | <Title, Name, Surname> |
| Signature: |  | Date of Signature: 1 January 2000 |
| 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 UPLB and the PI is non UPLB personnel. 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: | <with Version Number and Date> |
| Principal Investigator: | <Title, Name, Surname> |
| 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 Los Baños Research Ethics Board (UPLB REB), located Los Baños, Laguna 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. |
| Name of Research Site |       |
| Address of Research Site |       |
| Signatory Official | <Title, Name, Surname> |
| Position of Official |       |
| Signature |  | Date of Signature: 1 January 2000 |

1. *To be issued upon initial processing by UPLB REB* [↑](#footnote-ref-1)