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|  | **University of Southern Philippines Foundation****RESEARCH ETHICS COMMITTEE** | Form No.  | **2A** |
| **Review Checklist** | Version No. | 2 |
| Code | 2023-USPF - REC 2A |
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| **STUDY PROTOCOL INFORMATION** |
| **Reference Number (OR):***(to be accomplished by USPF REC Staff)* |  |
| **USPF REC Code:***(to be accomplished by USPF REC Staff)* |  |
| **Study Protocol Title:** |  |
| **Principal Investigator/s:** |  |
| **Study Protocol Submission Date:***(to be accomplished by USPF REC Staff)* |  |
| **Verified Complete by:***(to be accomplished by USPF REC Staff)* |  |
| **Classification of Review:***(to be accomplished by USPF REC)* | **🞎 EXPEDITED****🞎 FULL BOARD****🞎 EXEMPTED** |
| **Classified by the:***(to be accomplished by USPF REC Staff)***🞎 USPFREC Chairperson****🞎 USPFREC Secretary** |  |

**USPFREC Forms submitted by the investigators (Type of Submission)**

* **USPFREC FORM 2B 2019** Printed Registration and Application Form
* **USPFREC FORM 2C 2019** Study Protocol Assessment Form
* **USPFREC FORM 2E 2019** Review of Resubmitted Protocol Form
* **USPFREC FORM 2F 2019** Study Protocol Amendment Submission Form
* **USPFREC FORM 3G 2019** Continuing Review Application Form
* **USPFREC FORM 3H 2019** Final Report Form
* **USPFREC FORM 3I 2019** Study Non-Compliance Report
* **USPFREC FORM 3J 2019** Early Study Termination Application Form
* **USPFREC FORM 3K 2019** Suspected Unexpected Serious Adverse Events/Reactions Report
* **USPFREC FORM 3L 2019** Queries Notification and Complaints

**Basic Documents (must submit for initial review)**

* Proof of financial research grant (*if applicable*)
* **USPFREC FORM 2A 2019** Review Checklist
* Study Protocol
* Data collection forms (instruments)
* Diagrammatic workflow
* CV of Primary Investigator and study team members
* Proof of payment of ethics review fee (*as applicable*)

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| A logo of university of southern philippines  Description automatically generated with low confidence | **University of Southern Philippines Foundation****RESEARCH ETHICS COMMITTEE** | Form No.  | **2A** |
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**Study-specific Documents (submit as needed)**

* **USPFREC FORM 2D 2019** 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) or Health Research Ethics Training Certificate of PI, Co-I and the rest of the study team (GCP is required for clinical trials)
* Recruitment advertisements (as needed by the study protocol)
* Other information or documents for participants (such as diaries, etc.)
* Material Transfer Agreement or Terms of Reference (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 UPMREB review is ongoing)
* Clearance or permit from respective regulatory authorities (such as FDA approval for clinical trials and DENR local transport permit, as applicable)
* Others (specify):