|  |  |
| --- | --- |
| **Title:** |  |
| **REC Protocol No.:** |  |
| **Principal Investigator:** |  |
| **Sponsor:** |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Department:** |  | **Contact No./Email:** |  |
| **Co-Investigator(s):** |  | **Contact No./Email:** |  |
| **Total No. of Participants:** |  | **No. of Study Sites:** |  |
| **Sponsor:** |  | **Contact no./Email:** |  |
| **Duration of the Study:** |  | **Status:** | [ ] **New** [ ] **Amended** |
| **Type of the Study****(highlight only):**  | Intervention Epidemiology Observational/ClinicalDocument Review Individual Based StudySocial Survey Others, Specify Genetics |

|  |
| --- |
| *Description of the Study in brief. Mark whatever applies to the study.* |
| [ ] Randomized [ ] Drug [ ] Use of Genetic Materials[ ] Double Blind [ ] Medical Device [ ] Multi-Center Study[ ] Single Blind [ ] Vaccine [ ] Global Protocol[ ] Open Label [ ] Diagnostic [ ] Sponsor Initiated [ ] Observational [ ] Questionnaires [ ] Investigator Initiated |

(***Indicate the protocol page number where the description is found. Write N/A if not applicable****)*

|  |  |  |
| --- | --- | --- |
| 1. **OBJECTIVE OF THE STUDY**
 |  | Page No. |
| 1. **DESCRIPTION OF THE STUDY SUBJECTS/ PARTICIPANTS**
 |  |  |
| 1. **RATIONALE/ BRIEF BACKGROUND OF THE STUDY**
 |  |  |
| 1. **STUDY DESIGN/ METHODOLOGY**
 |  |  |
| 1. **DESCRIBE YOUR SAMPLE POPULATION AND SAMPLE SIZE?**
 |  |  |
| 1. **ARE YOU USING A PLACE? IF YES WHY?**
 |  |  |
| 1. **DESCRIBE THE METHOD OF RANDOMIZATION IF USING CONTROL ARMS**
 |  |  |
| 1. **DATA ANALYSIS PLAN OR STATISTICAL PLAN**
 |  |  |
| 1. **EXPECTED STUDY OUTCOME**
 |  |  |
| 1. **DESCRIBE THE RISKS ASSOCIATED WITH THE STUDY**
 |  |  |
| 1. **DESCRIBE THE BENEFITS OF THE STUDY**
 | **RISK LEVEL**[ ] High Risk[ ] Moderate Risk[ ] Low Risk |  |
| 1. **INCLUSION CRITERIA**
 |  |  |
| 1. **EXCLUSION CRITERIA**
 |  |  |
| 1. **WITHDRAWAL CRITERIA**
 |  |  |
| 1. **DOES YOUR STUDY INVOLVE THE FOLLOWING?**
 | [ ] Pregnant Women[ ] Fetuses or neonates[ ] Prisoners [ ] Children [ ] Employee[ ] Student | [ ] Person with mental disabilities[ ] Economically disadvantaged[ ] Educationally disadvantaged persons[ ] Others,\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
| 1. **HOW ARE STUDY SUBJECTS/ PARTICIPANTS PROTECTED FROM HARM, RISK OR INJURIES**
 |  |  |
| 1. **HOW DO YOU ENSURE VOLUNTARY, NON-COERCIVE RECRUITMENT OF SUBJECTS OR PARTICIPANTS?**
 |  |  |
| 1. **WHAT IS YOUR QUALIFICATION/S AND EXPERIENCE TO CONDUCT THIS STUDY?**
 |  |  |
| 1. **WHAT WILL YOU GET FOR CONDUCTING AND/OR COMPLETING THIS STUDY?**
 |  |  |
| 1. **NAME ALL YOUR STUDY SITE/S**
 |  |  |
| 1. **DID YOU CONDUCT A COMMUNITY CONSULTATION? IF YES, WHY?**
 |  |  |
| 1. **DID YOU INVOLVE LOCAL RESEARCHERS AND/OR COMMUNITIES IN THE PROTOCOL PREPARATION? IF YES, WHY? WILL THEY BE PART OF THE IMPLEMENTATION?**
 |  |  |
| 1. **WILL YOUR STUDY CONTRIBUTE TO LOCAL CAPACITY BUILDING? IF YES, HOW / IF NO, WHY?**
 |  |  |
| 1. **WILL THIS STUDY BENEFIT LOCAL COMMUNITIES? IF YES, HOW? IF NO, WHY?**
 |  |  |
| 1. **HOW WILL YOU SHARE THE STUDY RESULTS?**
 |  |  |
| 1. **WILL YOU USE BLOOD TISSUE SAMPLES? IF YES, HOW WILL IT BE STORED/ WILL YOU SEND IT ABROAD? HOW?**
 |  |  |

**IMPORTANT:** Does your study entail Human Subject or need Human Participation for data gathering? If YES, continue with the succeeding items/ questions. (*Indicate the protocol page number where the description is found. Write NA if not applicable.)*

|  |  |  |
| --- | --- | --- |
| 1. Does your Inform Consent state that the procedures are primary intended for research? If NO, why?
 |  |  |
| 1. How and when do you plan to obtain the Inform Consent?
 |  |  |
| 1. What are important contents of your Inform Consent Document?
 |  |  |
| 1. What information provided in the proposal/protocol consistent with those in the consent form?
 |  |  |
| 1. What are the related risks mentioned in the consent form?
 |  |  |
| 1. What words, or phrase in the Inform Consent document are written in technical, complex or scientific names?
 |  |  |
| 1. Is the Consent translated into local language/ dialect? If NO, why?
 |  |  |
| 1. How do you protect your study subjects/ participants?
 |  |  |
| 1. Are the different types of consent form (assent, patient representative) appropriate to the type of study participants? If NO, why?
 |  |  |
| 1. Are names and contact numbers from research team and the ISU-IREB in the informed consent? If NO, why?
 |  |  |
| 1. Does the ICF mention privacy and confidentiality protection? If NO, why?
 |  |  |
| 1. Are the references properly indexed? Is the APA 7th Edition Indexing method properly executed?
 |  |  |

*The End…*