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

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| --- | --- | --- | --- | --- |
| **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/Clinical  Document Review Individual Based Study  Social Survey Others, Specify Genetics | | | |

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| --- |
| *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****)*

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| --- | --- | --- | --- |
| 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.)*

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| 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…*