### Human Subjects Research Protocol Application

|  |  |
| --- | --- |
| **SECTION 1: PROJECT TITLE** | |
| *Project Title (If application is part of a grant submission title must match the grant title exactly)* | *Sponsor Agency (if part of a grant)* |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **SECTION 2: PRINCIPAL INVESTIGATOR AND KEY PERSONNEL** | | | | | | | |
| *Name of Principal Investigator:* | | | | *Department:* | | | |
| *Phone Number:* | | | *Email:* | | | | |
| *University Position:*  Faculty Administrator/Staff Student Other (describe below) | | | | | *Degree Earned/Grade Level (if student)* | | |
| *Other (describe your position)* | | | | | | | |
| *Certification:*  CITI Training Completed  Yes  No | | | *If Yes, Date of Certification:* | | | *Faculty, Master’s Level and Doctoral Students:*  *CV Attached* | |
| **\*Faculty Advisor Information (only complete if Principal Investigator is a student).** | | | | | | | |
| *Name of Faculty Advisor:* | | | | *Department:* | | | |
| *Phone Number:* | | | *Email:* | | | | |
| **Please list Co-Investigators and other Key Research Personnel. This includes all individuals who will have responsibility for the consent process, data collection from subjects or subject’s records, databases or follow up research subjects or research data.** | | | | | | | |
| *Name* | *Department* | *Project Role* | | | | | *Date of Certification* |
|  |  |  | | | | |  |
|  |  |  | | | | |  |
|  |  |  | | | | |  |

|  |
| --- |
| **\*SIGNATURE APPROVAL INFORMATION** |
| *With the implementation of the IRBNet System all signatures are now electronic. Please consult the Investigator Submission Guide for instructions on how to sign your IRB Application Package and Share your package for appropriate signature. Please refer to the chart below to determine who should sign your IRB Application Package. Faculty Advisors are expected to sign off, certifying that they have reviewed the submission for completeness and accuracy. Chair/Dean/VP signatures are required only to certify that the signor is aware that research is being undertaken by a direct report, however, they have no responsibility for the quality of the submission.*   |  |  | | --- | --- | | **Status of Principal Investigator** | **Approval By** | | Student | Faculty Advisor | | Faculty Member | Department Chairperson | | Chairperson | Dean | | Administrator/Staff | Area Vice-President | |

|  |
| --- |
| **SECTION 3: PROJECT PURPOSE AND INTRODUCTION** |
| *3.1 Identify the purpose of this study in one or two sentences.* |
| *3.2 In one or two paragraphs provide an introduction to the study: include your rationale for conducting this study as well as any references to related research that might provide clarifying or supporting background information. Use lay language at a level an 8th grade student would understand.* |

|  |
| --- |
| **SECTION 4: RESEARCH PARTICIPANT INFORMATION** |
| *4.1 Number of research participants to be enrolled. Please make sure you do not underestimate the number of participants to be enrolled. In the case of survey provide the number of surveys you will be sending. In the case of available data, please estimate the number of participants’ data. Use an appropriate method to evaluate how many subjects are needed to complete this study. Enrolling more participants than approved is a violation of regulations.*  ***Enter the proposed number of participants:*** |
| *4.2 Please describe targeted participant populations. Identify particular demographic characteristics required in the proposed participant population (such as age, gender, and race).* |
| *4.3 Will the participants be characterized as any of the following* ***vulnerable populations****? (check all that apply)*  Physically handicapped Mental Health Subjects  Prisoners HIV-Positive  Use of database with identifiers Substance Abuse  Pregnant Women Medical Subjects  ***If any of the boxes are checked please answer 4.4.*** |
| *4.4 Choosing a vulnerable population requires consideration of the extent to which a proposed subject population is already burdened by poverty, illness, disability, etc., in deciding whether they are the appropriate population for the proposed study. Please explain the reason for using the subject population and describe the procedures you will be using to ensure appropriate consent is obtained, free of coercion (without deception) and the rights to privacy and confidentiality is respected.* |
| *4.5 Inclusion of Children*  Does this study require the inclusion of children as research participants? Yes No  *If you answered yes to the above question, the use of children must meet one of the criterions for risk/benefit assessment according to regulations. The IRB defines minimal risk to be a level of risk associated with the daily activities of a normal, healthy, average child. Risks beyond minimal include all harms, discomforts, indignities, embarrassments, and potential breaches of privacy and confidentiality.*  Minimal Risk  Greater than minimal risk, but holds prospect of direct benefit  Greater than minimal risks, no prospect of direct benefit to subjects, but likely to yield generalizable knowledge of the subject’s disorder or condition.  *Explain how the above criterion is met for this study.* |
| *4.6 Will any of the participants be from an institution or organization other than Saint Joseph's University?*  Yes No  *If you answered yes, please indicate the name of the institution and provide a letter of support from the official responsible for granting access to the participants.*  *Name of institution or organization:* |

|  |
| --- |
| **SECTION 5: RECRUITING**  **PLEASE ANSWER ALL QUESTIONS** |
| *5.1 How will you gain access to the targeted population?* |
| *5.2 What will be done to protect individual’s privacy in this process?* |
| *5.3 What is the proposed method of recruitment/advertisement? (i.e. advertising, letters, online invitation, investigator attendance at event/meeting)* ***Attach proposed recruitment scripts/materials to your submission.*** |

|  |
| --- |
| **SECTION 6: STUDY DESIGN AND METHODOLOGY**  **PLEASE ANSWER ALL QUESTIONS** |
| *6.1 What is the nature and length of interaction with the research participants? Imagine you are a participant in the research and walk us through the process from start to finish, detailing all methods.* |
| *6.2 Where will the research take place and who will be present?* |
| *6.3 Will participants be assigned to groups?* Yes No *If yes, explain the assignment procedure.* |
| *6.4. How will research instruments be distributed and collected?* ***Attach copies of all questionnaires, interview guides, surveys, etc. to your packet.*** |
| *6.5 Will deception be used in any way?*  YesNo  *If yes, please explain how and justify its use.* |
| *6.6 Will participants be compensated? If yes, please explain why and give amount and type of compensation.* |

|  |
| --- |
| **SECTION 7: CONSENT PROCEDURES** |
| *7.1 Check all of the applicable consent procedures that apply to your study. Consent templates may be found under “Forms and Templates” in IRBNet.* ***Attach copies of all proposed Consent Forms to your packet.***  Written and Signed  Web Survey Consent  Oral/Verbal (include a copy of the script to be used)  Audio/Video Recording (requires specific consent from participants)  Parental Consent (minors under the age of 8)  Assent and Parental Permission Form if applicable (minors between the ages of 8 – 17)  Waiver of Signed Consent  Waiver of Documented Consent (answer additional questions below) |
| If you wish to request a waiver of informed consent requirement you must answer the following:   |  |  | | --- | --- | | A. The research in its entirety involves no greater than minimal risk. | True  False | | B. The waiver of informed consent will not adversely affect the rights and welfare of the subjects. | True  False | | C. It is not practicable to conduct the research without the waiver. | True  False | | D. Whenever appropriate subjects will be provided with additional pertinent information after their participation. | True  False | | Please describe the reason why the waiver is necessary: | | |
|  |
| *7.2 Describe the means via which potential participants will be given informed consent.* |

|  |
| --- |
| **SECTION 8: RISKS AND BENEFITS** |
| *8.1 Does the research involve risk or harm to participants?* Yes No **(*If no skip to 8.4)***  *If yes, please describe the nature and degree of the risk or harm.* |
| *8.2 Explain the rationale for exposing participants to risk/harm, and the steps that will be taken to minimize the risk. Include specific contact or referral information for agency or support services to be provided to participants (this information needs to be included on the consent form).* |
| *8.3 If a vulnerable population group is being used please explain the additional steps being taken to reduce risk/harm to the participant.* |
| *8.4 Describe the anticipated benefits of this research for individual subjects. If the research has no direct benefit for the subjects participating in the research please state this in your response.* |
| *8.5 Describe the anticipated benefits to the society, if any, and if so, how benefits outweigh risks.* |

|  |
| --- |
| **SECTION 9: DATA CONFIDENTIALITY** |
| *9.1 Will you record (other than signed Consent) any direct identifiers (i.e., audio/video, names, social security numbers, addresses, email address, telephone numbers, etc)?*  Yes No |
| ***If Yes****, explain, and justify why it is necessary to record findings with identifiers. If there is a coding system which you will use to protect against disclosure of these identifiers, please include the system in your explanation. Also, include the provisions you have taken to maintain confidentiality of data.*    ***If No,*** *Skip to Section 10.* |
| *9.2 Where will the data be stored and in what format (such as paper, digital, electronic records, video, audio, etc.).* |
| *9.3 Describe security methods that will be used for protecting the data.* |
| *9.4 How long will the data be kept?* |
| *9.5 How will the data be destroyed?* |

|  |
| --- |
| **SECTION 10: INTENTED USE OF DATA** |
| *10.1 How will the research results be documented, reported and/or presented?* |

|  |
| --- |
| **SECTION 11: CONFLICT OF INTEREST** |
| *11.1 Investigators are required to disclose Conflicts of Interest on the application for initial IRB review and approval. The investigator must disclose whether he/she or members of his/her immediate family receives financial or other compensation from the study sponsor and/or whether the investigator or members of their immediate families have a significant financial interest in the sponsoring entity. If the answer is “yes” to either question, the investigator must (1) complete the Conflict of Interest Form and provide a description of the relationship between the investigator and/or immediate family with the sponsor of the research, (2) include a statement in the informed consent form that addresses the conflict of interest, or (3) state why such a statement in the informed consent is not necessary for the protection of human subjects.*  *Conflict of Interest Disclosure for (includes immediate family):*  *Principal Investigator*  Yes  No  *Co-Investigator*  Yes  No  *If you answered yes for either questions you* ***must*** *complete a Conflict of Interest Form for each Investigator and include with your IRB Package.* |

|  |
| --- |
| **SECTION 12: INVESTIGATOR’S ASSURANCE** |
| 1. *I recognize that as the Principal Investigator it is my responsibility to ensure that this research and the actions of all project personnel involved in conducting the study will conform to the IRB approved protocol, IRB requirements/policies, and all applicable HHS regulations.* 2. *I recognize that it is my responsibility to ensure that valid informed consent/assent has been obtained from all research subjects or their legally authorized representatives. I will ensure that all project personnel involved in the process of consent/assent are trained properly and are fully aware of their responsibilities relative to the obtainment of informed consent/assent according to the IRB guidelines and applicable federal regulations.* 3. *I will inform the IRB of any unanticipated adverse event or injury no later than two (2) business days following the time it becomes known that a SJU subject suffered and adverse event/injury.* 4. *I will not initiate any change in protocol without IRB approval except when it is necessary to reduce or eliminate a risk to the subject, in which case the IRB will be notified as soon as possible.* 5. *I will maintain all required research records on file and I recognize that the IRB is authorized to inspect these records.* 6. *I will inform the IRB immediately of any significant negative change in the risk/benefit relationship of the research as originally presented in the protocol and approved by the IRB.* 7. *I understand that IRB approval is valid for a maximum period of three (3) years with continuing review by the IRB required at least annually in order to maintain approval status. After (3) years, a full review is to be conducted.* 8. *I will inform the IRB immediately if I become aware of any violations of HHS regulations (45CFR46), or IRB requirements for the protection of human subjects.* 9. *I understand the failure to comply with all applicable HHS regulations, IRB requirements/policies, and the provision of the protocol as approved by the IRB may result in suspension or termination of my research.* 10. *I certify that the information provided in this application is correct and complete.*   **Attestation of Principal Investigator**  Please type your name:       Date: |