**Instructions:**

* Keep an electronic copy. You will need to modify this copy when making changes.
* All referenced checklists, templates, and policies, can be found on the IRB website.
* **Remove all instructions in italics so they are not contained in the final version of your protocol.**
* Depending on the nature of your study, some sections may not be applicable to your research. If so mark as “N/A”. Do not deletethe section headers.
* *When you save and upload this document, add the protocol version date to the title.*

**PROTOCOL TITLE:**

**PRINCIPAL INVESTIGATOR:**

Name

Department

Telephone Number

Email Address

**STUDY SUMMARY:**

*Please provide a brief summary of the study in the table below.*

|  |  |
| --- | --- |
| **Research Site** |  |
| **Purpose/Objective** |  |
| **Research Intervention(s)/ Interactions** |  |
| **Clinical Trials NCT#** |  |
| **Study Population** |  |
| **Type of Consent** |  |
| **Sample Size** |  |
| **Study Duration for individual subjects** |  |
| **Funding Source** |  |

**REVISION HISTORY:**

***\*This table should only be used during submission of an Amendment application to the IRB.***

|  |  |  |  |
| --- | --- | --- | --- |
| **Version #** | **Version Date** | **Summary of Changes** | **Consent Change?** |
|  |  |  |  |
|  |  |  |  |

**OBJECTIVES:**

*Describe the purpose, specific aims, objectives, and/or hypotheses.*

**BACKGROUND:**

*Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how this project will add to existing knowledge.*

*Describe any relevant preliminary data or knowledge to be built upon in this study. Examples of issues to address are cultural expectations, political conditions, economic conditions, disease prevalence/incidence, environmental factors.*

*Include any other non-research rationale for the work, if this study is a mix of non-research and research.*

*Note: this section should be limited to only information directly related to the research questions and objectives. Do not include your thesis/dissertation proposal.*

**STUDY POPULATION:**

*Describe generally the individuals that will be included in your study. Describe any subject populations that will be specifically targeted.*

*Describe the criteria that define who will be included or excluded in your final study sample.*

*Indicate whether you will include or exclude each of the following special populations:*

* *Adults unable to consent*
* *Individuals who are not yet adults (infants, children, teenagers)*
* *Pregnant women*
* *Prisoners*
* *Vulnerable Populations*

*Community Participation: For studies aimed at addressing issues that affect a certain community or group: How, if at all, will this study involve people from the target community in the design of the study? Conduct of the study? How will the results of the research be shared with the participants and/or the target community/ies?*

**VULNERABLE POPULATIONS:**

*If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.*

*Vulnerable populations may include:*

* *Prisoners*
* *Pregnant Women/Fetuses*
* *Children/Neonates*
* *Cognitively/Decisionally impaired adults*
* *Your own students/employees*
* *Undocumented immigrants*
* *Illiterate individuals*
* *Individuals experiencing addictions/substance abuse*
* *Domestic violence victims*

*Additional safeguards include (but not limited to) considerations involving:*

* *Recruitment: Where/how precisely does recruitment to the study take place? Are participants recruited separately or in the presence of a Parent/LAR/Advocate?*
* *Assent/Permission Process: Does this take place separately or in the presence of a Parent/LAR? How will you tailor the assent process to the developmental stages and capacity of the children you seek to enroll? Describe this process in detail and how you are documenting it. A formal assent process with documents uploaded for 7-17 year old participants is the expectation. If any participants are under 7 years old, provide a description of how the study will be verbally explained to them, as appropriate.*
* *Data Collection: Explain how the method of data collection is appropriate for this population. Describe whether it is appropriate for interactions/interventions to occur alone with the participant.*

**SAMPLE SIZE:**

*Briefly describe the anticipated total number of participants. If there will be multiple study sub-groups, describe how many participants you plan to enroll in each sub-group.*

*Provide a justification for the sample size – explain why this number of participants is needed to answer your research questions.*

**RESEARCH SITE/LOCATIONS:**

*A research site is defined as a location or place where the research procedures will be conducted by the researchers. Examples: lab space at WSU, schools, community centers, public venues, online, etc.*

*Indicate that all required permissions and/or approvals are already obtained or will be obtained at each research location prior to project implementation. Please keep in mind that if you will be doing research in K-12 schools, some school systems require an additional research review process.*

*If your study will collect data through or from online/internet sources, please describe specifically which survey platforms or websites you plan to use for data collection (e.g., Qualtrics survey panels, Amazon Mechanical Turk, internet chat rooms and support groups, etc.). If you will be doing research using online activities, explain whether you anticipate your participants might be located outside the United States.*

**INTERNATIONAL RESEARCH:**

*If your research will take place outside the United States, please explain:*

*Will you obtain review by an IRB/research ethics committee located in the country where you will be doing research? Some countries do not have IRBs/research ethics committees, and in some countries the IRBs only review biomedical research – we understand that IRB review in another country is not always possible, but expect that review by an IRB/research ethics committee be obtained whenever possible in the country where research will take place – it is your responsibility to determine whether there is an IRB/research ethics committee that can review your research in the countries where you plan to collect data.*

*What sociocultural factors could affect the consent process in the countries/regions where you will do research? For example, are there low rates of literacy, are there cultural customs that require consent from a community or family leader, etc.?*

*Are there any mandatory reporting laws that apply to your research (e.g., mandatory reporting of child abuse and neglect?)*

*NOTE: If you plan to collect data* ***from individuals located in the European Economic Area****, you must take into consideration the General Data Protection Regulations (GDPR). This includes surveys/questionnaires that will be fielded with individuals in the European Economic Area. Some crowdsourcing platforms and survey panels include participants from the EEA countries – if you plan to use a crowdsourcing platform/survey panel that could include individuals in EEA countries, you must specify whether you will set the study qualifications to only include U.S. residents or not.*

*NOTE: If you will be collecting data that are sensitive, you must use good* ***data security practices*** *to collect, store, and transport your data. Keep in mind that officials in other countries, as well as U.S. Customs and Border Protection, could potentially try to access data stored on a phone, laptop, or other device.*

**PROCEDURES INVOLVED:**

*Describe recruitment methods:*

* *Describe when, where, and how potential participants will be recruited.*
* *Describe the source of participants.*
* *Describe the methods that will be used to identify potential participants.*
* *Describe materials that will be used to recruit participants. (Attach copies of these documents.)*

*Describe and explain the study design.*

*Provide a description of all research procedures being performed and when they are performed, including procedures being performed to monitor participants for safety or minimize risks.*

*If your study will have multiple phases or sequential aims, please describe each phase and whether you are only seeking IRB approval for certain phases of the study at this time.*

*We need to know how you will collect all of your study data and in what order data collection will occur. If the study involves multiple conditions where each condition involves different procedures, please provide a table or diagram that breaks down the procedures by condition and in chronological order.*

*Describe:*

* *The source records that will be used to collect data about participants.* 
  + *Attach copies of all surveys, focus group questions, data collection forms, scripts, etc. If unable to attach data collection instruments due to copyright requirements, include description of the instrument.*
* *What data, specifically, will be collected during the study and how that data will be obtained.*
  + *If there are plans for long-term follow-up (once all research related procedures are complete), what data will be collected during this period.*
* *Does the research design require subjects to be deceived?*
  + *Describe and justify need for deception.*
  + *Describe plan to debrief participants after study participation is completed.*
* *Will the subjects be exposed to any stress?*
  + *Describe and justify need for stress.*
* *Procedures performed to lessen the probability or magnitude of risks.*

*If you will be using any attention check measures and/or performance bonuses/incentives, you must describe them and explain what happens if a participant fails the attention checks or does not qualify for a bonus/incentive.*

*Confidentiality:*

* *Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission.*

**AUDIO/VIDEO RECORDING/PHOTOGRAPHY:**

*If applicable, describe:*

* *the type of recording/photography being utilized*
* *why the type of recording is necessary to the research*
* *how the recordings/photograph(s) will be utilized in the research (e.g., data analysis only)*
* *how and where the recordings/photograph(s) are stored, who has access to them, and if/when they will be destroyed.*
* *describe processes for transcribing audio/video recordings. Will audio-recordings be destroyed after transcription? If so, how long after transcription? If not, how will they be kept secure?*
* *If video-recordings will be used beyond the current research procedures for educational/presentation purposes.*

*If audio/video-recording is mandatory for participation, a rationale must be provided here and the consent form must include this detail.*

**INCOMPLETE DISCLOSURE/DECEPTION:**

*If you will be using incomplete disclosure (withholding information about the study purpose during the consent process because disclosing the study purpose in detail could significantly impact the validity of your study results) or deception (purposely misleading participants by providing them with overt misdirection or false information about some aspect of the research during the consent process), describe the incomplete disclosure or deception and provide a rationale explaining why it is necessary to the research.*

*Because deception and incomplete disclosure alter the information presented during the consent process, the debriefing process serves as the remedy by completing the consent process. If debriefing is appropriate, explain how you will conduct the debriefing process.*

*NOTE: If you plan to alter the consent process because you are using deception or incomplete disclosure as a research technique, you must request an alteration of the consent process.*

**STUDY TIMELINES:**

*Describe:*

* *The duration of an individual subject’s participation in the study.*
* *The duration anticipated to enroll all study subjects.*
* *The estimated date for the investigators to complete this study’s’ primary analyses.*

**SHARING OF RESULTS WITH PARTICIPANTS:**

*Describe whether results (study results or individual subject results) will be shared with participants.*

*Describe how the results will be shared If applicable.*

**WITHDRAWAL OF SUBJECTS:**

*Describe anticipated circumstances under which participants will be withdrawn from the research without their consent.*

*Describe procedures that will be followed when participants withdraw from the research, including partial withdrawal from procedures with continued data collection.*

**PROVISIONS FOR DATA MONITORING TO ENSURE THE SAFETY OF SUBJECTS:**

*If you are using surveys/questionnaires/focus groups and any portion thereof could be upsetting to subjects, describe the nature of the questions and how you will refer subjects for counseling or other assistance. Include a plan for the study team developing criteria for which answers indicate distress, reviewing the answers before the subject leaves the study visit, and a plan for treatment or referral.*

*Describe the plan to monitor and evaluate the information collected regarding risks or harms to determine whether participants and others remain safe – the frequency of monitoring should be appropriate to the sensitivity of the data and level of risk. For example, if participant responses could suggest likelihood of intent to harm self or others, what is your plan for monitoring severity and how will you respond if a participant indicates intent to harm? If directly assessing this data, someone on the research team must be appropriately qualified.*

**CONSENT PROCESS:**

*Consent is not merely a document – it is a process, in which the participant gains an understanding of the research procedures and the potential study benefits and risks in order to make an informed, voluntary decision on whether to participate in a research study.*

*Describe the process you will use to obtain informed consent (written, oral/verbal, online, etc.) from participants, including where and when the consent process will occur. If consent will be obtained in different ways for different participant groups or study phases, describe the consent process that will be used for each participant group and/or study phase.*

*If applying for a waiver of informed consent (i.e. no consent), please address how your request meets the following criteria:*

* *The research involves no more than minimal risk to the subjects.*
* *The waiver or alteration will not adversely affect the rights and welfare of the subjects.*
* *The research could not practicably be carried out without the waiver or alteration (impracticability normally requires justification beyond inconvenience or cost)*
* *Whenever appropriate, the subjects will be provided with additional information about their participation in the research (often not necessary).*

**RESOURCES AVAILABLE:**

*Describe the resources available to conduct the research:*

* *Justify the feasibility of recruiting the required number of suitable participants within the agreed recruitment period.* 
  + *For example, how many potential participants do you have access to? What percentage of those potential participants do you need to recruit?*
* *Describe the time that you will devote to conducting and completing the research.*
* *Describe your facilities.*
* *Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated consequences of the human research.*
* *Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.*

**REFERENCES:**

*Add references*