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**INSTITUTIONAL REVIEW BOARD**

**Application for Expedited or Full Review**

Research or projects that do not qualify as being Exempt from IRB review require more detailed information about study procedures. You can download this document and insert responses directly into the sections and subsections. If items within a section are not applicable, indicate with N/A.

# Section 1: Study Personnel

* Full name and contact information of SMU Principal investigator
* Define all members of the research team and their roles and affiliations.
* Include in the Attachments Section, evidence of current human subjects training (CITI training certificates within 3 years)

# Section 2: Review Type and General Information

* **Date of Submission:**
* **Review Type**: Choose either:

* + Full Review *or*
  + Study Eligible for Expedited Review

***Indicate which expedited category*** (choose one)

**Category 1:** Clinical studies of drugs and medical devices.

**Category 2:** Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.

**Category 3:** Prospective collection of biological specimens for research purposes by noninvasive means.

**Category 4:** Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.

**Category 5:** Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). *NOTE*: *Some research in this category may be exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.*

**Category 6:**Collection of data from voice, video, digital, or image recordings made for research purposes. *NOTE*: *Some research in this category may be exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.*

**Category 7:** Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. *NOTE*: *Some research in this category may be exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.*

* **Data Being Gathered**: Select all that apply
  + Data captured via email or the internet
  + Data captured through interview procedures
  + Photography, video or voice-recordings of subjects
  + Surveys, questionnaires, and/or assessments or tests
  + Use of existing data and/or artifacts
  + Human blood, cells, tissues or body fluid
  + Investigational Drugs, Reagents, Chemicals or Biologic Products
  + Investigational Equipment
  + Includes members of a vulnerable population
    - Minors (under 18)
    - Pregnant women and/or Fetuses
    - Prisoners
    - Individuals with impaired decision-making capacity
* **Location** of where data will be collected (choose all that apply)
  + Within SMU
  + Other US location
  + International location
  + Virtual
  + Telephone
  + Other (explain)
* **Funding** (choose all that apply and explain details)
  + None
  + SMU internal funding
  + External Grants or Contracts (public, corporate or foundation) or Donors
    - Explain including whether grantor has any connection to the research

# Section 3: Protocol Information

* **Purpose of the study**
  + Provide a brief explanation of the study (< 300 words) in lay terms including general study purpose and rationale.
  + **List research questions and/or hypotheses**
* **Study design** (select from list or choose other and describe the design)
  + Quantitative
  + Qualitative
  + Mixed Methods
  + Evaluation or Case Study
  + Experimental
  + Other (explain)

# Section 4: Study Procedures

* Is this a **multicenter study**?
  + Yes
  + No
  + If yes, is SMU acting as the coordinating center for other sites?
  + If yes, will SMU be participating in all parts/procedures/arms of the study?
    - *If not participating in all parts/procedures/arms, explain what SMU will NOT be participating in.*
* *Note: Inquire to IRB Administrator regarding guidelines for research involving multiple IRBs; cooperative agreements and authorization.*
* **Describe in chronological order**, the **events and activities** providing detailed information about **all study procedures** and who will conduct each.
  + If any interviews, questionnaires, surveys or focus groups will be conducted, explain and include copies of all data collection instruments in the Attachments Section.
  + Indicate frequency and estimated duration of visits or sessions or completion of surveys as well as the anticipated total time commitment for participants in the study.
  + If proposed research involves use of existing data/specimens, describe how data/specimens will be acquired.
  + **Provide an overall estimated time frame for when the study will be completed including subject recruitment, time needed for data collection, any subject follow-up, data analysis and publication.**

# Section 5: Subject Population

* **Expected age** range of subjects.
* **Estimated maximum number of subjects** planned for the study including initial recruitment numbers.
* **IF applicable, provide rationale for involvement of potentially vulnerable subjects** to be entered into the study including minors, pregnant women, prisoners, or decision impaired individuals.
* Does your study specifically target **SMU students or employees**?
  + Yes
  + No
  + *If yes, additional risk mitigation steps must be described in the Risk section of the protocol.*
* **Subject Recruitment**
  + **Describe how potential participants will be identified** for recruitment.
  + **Describe how potential subjects will learn about the research.** (e.g., flyer, email, social media post, telephone etc.)
  + Attach recruitment scripts and/or flyers etc.
* **Subject Population Inclusion and Exclusion Criteria**
  + **Indicate inclusion criteria**.
    - *Inclusion criteria are characteristics that the prospective participants must have if they are to be included in the study. Criteria focus on the key characteristics of the target population under study. Commonly, inclusion criteria involve demographic, clinical, or geographic characteristics such as age, race, educational level, occupational or work experience, primary residence, physical activities, medical, psychosocial or emotional conditions.*
  + **Indicate exclusion criteria.**
    - *Exclusion criteria are those additional characteristics of potential participants who meet the inclusion criteria that could interfere with the success of the study or increase their risk for an unfavorable outcome. Common exclusion criteria could be those individuals who indicate unwillingness to fully participate with study procedures (ie: being recorded during an interview); have high likelihood of missing follow-up appointments; have comorbidities that could bias study results or increase their risk for adverse events*.
  + ***IF women, minorities, or minors are excluded,*** *provide clear compelling rationale for the exclusion*.
* **Subject Compensation**
  + Explain any form of compensation for study subjects including dispensing gift cards or drawings for prizes.

# Section 6: Risks and Discomforts

* *Note: No research can be considered totally risk free; e.g., a potential risk of breach of confidentiality. The lowest level of risk is described as “no more than minimal risk”. Even the minimal risks need to be described. Focus on how the subjects will perceive the risks of participating in the study.*
* **Choose** one of the following:
  + **No greater than minimal risk**: the probability and magnitude of harms or discomforts anticipated during the research are not greater, in and of themselves, than those ordinarily encountered in daily life or during performance of routine physical or psychological exams or test.
    - Examples of minimal risks:
      * Physical exams, routine psychological tests
      * Surveys or interviews about non-sensitive topics
      * Research involving existing data, records, or specimens with sufficient confidentiality practices
  + **Greater than minimal risk**: the probability and magnitude of harms or discomforts anticipated during the research are greater, in and of themselves, than those ordinarily encountered in daily life or during performance of routine physical or psychological exams or test BUT these risks are considered acceptable when weighed against the anticipated benefits and the importance of the knowledge to be gained from the research.
* **Describe the potential risks and include the strategies and procedures that will be used to reduce the risk.** 
  + - Examples for mitigating risk include providing breaks to reduce fatigue, holding interviews in private spaces away from casual observers, redacting private information (names) and using pseudonyms to protect identity.
* Describe how any **adverse effects** of participation will be handled?
  + - Example: providing resources for emotional distress
* Describe any **subject deceit** involved in the proposed research providing explanation and rationale.
  + - If no deceit involved, this would not be applicable

# Section 7: Benefits/Alternatives

* Describe any **potential benefits** to the individual subject, group of subjects and society in general.
  + *IF individual subjects will not benefit directly from study procedures, this should be stated along with explanation of overall societal benefit.*
* Describe any **alternative treatments and procedures** available to the subjects should they choose not to participate in the study.
  + *IF no such alternatives exist; state that “the alternative is nonparticipation”.*
  + *For studies involving existing data or record reviews, a description of alternatives is not applicable.*

# Section 8: Procedures to Maintain Confidentiality

*Note: Federal regulations require that study data and any consent documents be kept by the PI for a minimum of three (3) years and HIPAA documents be kept for a minimum of six (6) years after the completion of the study.*

**Anonymity is a condition in which the identity of individual subjects is not known to the researchers.**

* **Subject Identity**
  + **Explain whether your data was collected anonymously (e.g. by survey)**
  + **Explain confidentiality procedures to protect subject identity and provide anonymity of subjects in sharing research findings**
    - Examples
      * collected data was de-identified and code names created
      * records were stripped of any identifying information
      * following transcription of interviews, voice recordings will be destroyed
  + *IF data or specimens are being shared* outside of the research team, **explain who will receive the materials and describe specific measures to protect the shared participant data.**
* **Data Security**
  + **Select at least two of the following safeguards for each type of data records (electronic and hardcopy)**
    - **Electronic Data**
      * Encrypted and password protected
      * Secure network
      * Data collected anonymously
      * Data de-identified by PI or research team
      * Coded, with the master list kept separate from the data files
    - **Hardcopy Data**
      * Locked suite
      * Locked office
      * Locked file cabinet
      * Data collected anonymously
      * Data de-identified by PI or research team
      * Coded, with the master list kept separate from the data files
      * 24 hour personnel supervision
  + *If needed, add any additional explanations about confidentiality practices*

# Section 9: Informed Consent

*Note: Federal regulations require that informed consent be provided and obtained from individuals prior to their participation unless the IRB grants a waiver of consent. There is a clear distinction between the researcher “providing informed consent” and obtaining “acknowledgement from the subject” of their consent to participate. Acknowledgement can be gathered in various ways: verbal consent to participate in an interview, electronic consent by clicking acceptance on an electronic survey form; signing either physically or electronically a consent form. Risks of the study as well as the potential for breach of security to captured consent documents must be considered.*

* **Describe how the subjects will be informed** of the purpose, procedures, risks and benefits of the study.
* **Describe communication methods** to respond to subject questions about the study procedures prior to their consent.
* **Describe how subject consent will be obtained** and acknowledged.
* *If* ***non-English speaking subjects*** *are involved, how will the information be translated and communicated?*
* *If* ***minors*** *are involved, prepare a child’s Assent form as well as a parent/guardian Informed Consent form.*
* **Include in the Attachments Section**: Informed Consent document and if applicable, Assent.

# Section 10: HIPAA

*Note: Studies that receive or create protected health information (PHI) are subject to HIPAA regulations. PHI is health information with one or personal identifiers.*

* **Choose one:**
  + **No health information** is being accessed, received, or collected. HIPAA does not apply

* + **Yes, health information is being accessed, received or collected**. HIPAA applies.
* **If HIPAA applies, locate the *HIPAA Guidelines* and complete either the *HIPAA Authorization form* or *Waiver of HIPAA Authorization* form and add as an attachment.**

# Section 11: Potential Conflict of Interest

*Note: Federal regulations require the indication of whether you, your spouse or dependent children or any investigator participating in the study have, or anticipate having, any income from or financial interest in a sponsor of this protocol, or a company that owns/licenses the technology being studied or any other entity which may affect the outcome of this research.*

* + *Financial interests include but is not limited to consulting; speaking or other fees; honoraria; gifts; licensing revenues; other research agreements; or equity interests (including stock, stock options warrants, partnership and other equitable ownership interests.*
* **Check one of the following**
  + No financial interest or financial interest less than or equal to $5K.
  + Potential Financial Conflict of Interest
    - Indicate who has the conflict of interest

*NOTE: IF you select potential financial conflict of interest, a Conflict of Interest Disclosure form must be added as an attachment. Financial disclosure statements must be in incorporated into the consent document.*

* ***Inquire to the IRB Administrator for Conflict of Interest Disclosure form****.*

**Section 12: Attachments**

**Required (check all that are included with submission; have each attachment properly identified)**

* **Recruitment notices**; email communication script; project flyers
* **Data collection instruments** (survey items, interview protocol, observation tools
* Any **materials to be distributed to subjects** during study procedures
* **Letters of support** from institutions or agencies where data is being collected
* **Informed Consent** documents
* **Human subjects training** (CITI training documents completed within past 3 years)
* *If available*, a full proposal with reference list, **however** appendixes containing any of the above need to be attached separately