**IMPORTANT:** When completing this outline, you **must** use the ***IRB Research Plan Guidance*** document for the content necessary to develop a comprehensive yet succinct Research Plan. Using the guidance to complete this outline will help facilitate timely IRB review. Understand that **the assigned IRB reviewer will know if you used the Research Plan Guidance document** when reviewing your Research Plan. An existing protocol/research plan for a grant, class project etc. cannot replace this research plan. However, you are encouraged to copy and paste text from these documents into relevant sections below. Please verify that all required information is included prior to submitting.

* Text in blue may be removed and is only provided as guidance.

**Project Title:** *Title*

**Protocol Number:** Enter protocol number. If this is a new submission and has not yet been assigned a protocol number enter “TBD” and update during subsequent revisions once a number has been assigned.

**Principal Investigator:** Name

1. **Background and Rationale (short summary)**
   * **Briefly** describe the background (i.e. literature review) and rationale for this study (i.e., why is the study needed?). Explain the relevance of the project to previous and/or continuing work in the field.
   * Discuss why novel inquiry is necessary. If there is a gap in knowledge, explain how it is anticipated that this research will address the gap.
   * If this research is intended to replicate previous research, provide rationale.
   * Provide citations appropriately.

1. **Aims**

* **Clearly** outline the aims, objectives, purpose, and/or research question(s).
* **Only** include the purpose/aim/objective/research questions, no other information or rationale. The research questions should flow from section A above.
* If relevant, hypotheses can be included.

1. **Research Population, Recruitment Methods and Compensation**
2. **Participant Populations:**

* Describe the participant population:
* Provide the rationale and/or justification for including the participant population. When including any vulnerable populations in the project (see below) explain why inclusion of this population is necessary to accomplish the research aims.
  + - Minors (under the age of 18)
    - Subjects with decreased decisional ability
    - Students
    - Employees
    - Persons with mental, psychiatric or emotional disabilities
    - Persons with physical disabilities
    - Economically or educationally disadvantaged
    - Elderly – age 70 and over
    - Limited or non-reader
    - Nursing home residents
    - Poor and/or uninsured
    - Visually/hearing impaired
    - Other
* For record reviews or use of biospecimens previously collected indicate the type of records used; academic records, health records or biospecimens.
* List **all** inclusion criteria such as age range, race or ethnicity, gender, language, and condition, etc.

* List **all** exclusion criteria and **rationale** for these exclusions.
* Discuss how individuals/records/biospecimens will be screened for eligibility. Screening procedures should be completed ***prior*** to consenting of subjects. In most cases, screening data is not recorded/saved. If you plan to record/save this data justify why this is needed and how the confidentiality of this data is protected.
  + Address whether or not participants are fluent in English and/or if any of the project activities (i.e. recruitment, consent, assessments, etc.) will be carried out in a language other than English. If you are only including subjects that are English proficient provide justification.

* State the number of participants/records/biospecimens needed for the project, including the following:
* Provide the targeted number of individuals to be included in the research. ***If more than one groups, provide numbers needed for each group and total number for the entire project.*** Ranges are acceptable (i.e. 20-25 individuals, survey distributed to 200 people and expected 65% response rate).
  + Provide justification for targeted numbers (e.g. power analysis, etc.).
  + Keep in mind the need to recruit extra individuals to allow for attrition.
  + Keep in mind that over-recruitment may create non-compliance. Is your method of recruitment/consent set up so it prevents over-recruitment? (e.g., online recruitment for online questionnaires may yield many more participants than planned/needed).

1. **Recruitment Methods**

* Describe the process and/or method by which participants will be recruited for the research, including the following:
* When and how will each step of recruitment occur (i.e., initial contact, introductions, follow-ups, etc.)?
* Describe how the participant population is accessed. Discuss relevant permissions (e.g., access to listservs, online databases, access to HIPAA or FERPA covered information, etc.).
* List any recruitment materials that will be used, such as advertisements, flyers, or verbal scripts, etc. If there are no written recruitment materials, explain. These materials must be attached to the IRB electronic application form.
* Explain which research roles (e.g., PI, Investigator, Resident, Student, etc.) will recruit participants and how they will be trained.
* Describe any screening tests and or procedures that will be used to ensure that potential participants are eligible to participate.
* For research using health records or biospecimens describe the process or method for accessing such records or biospecimens and who owns the information and is allowed to release such information.
* Include if the research team will access Personally Identified Information (PII) or Private Health Information (PHI) covered records to obtain information or will the team be provided with de-identified information/report. If receiving de-identified information, indicate who has access the information and can provide in a de-identified manner. For PHI, de-identified means it does not contain any of the 18 PHI identifiers. *Please note that this may qualify as Not Human Subjects Research.*

1. Compensation/Reimbursement of Participants:

1. Withdrawal of Participants:
2. **Informed Consent Process** *Address consent/waivers for HIPAA, FERPA, deception and banking in addition to study consent, if applicable*
3. Informed Consent Process: (all research projects must have an informed consent process)

* Describe the informed consent process, including:
* How the required elements of informed consent will be conveyed to the participant (such as the use of a CFVHS informed consent template form, verbal script, etc.)
* Where, when & how the consent process will take place; clarify privacy & confidentiality surrounding the process is ensured
* Steps to ensure voluntary participation and reduce coercion or undue influence
* Who will conduct the consent process
* *Exempt Research may use the following types of informed consent without requesting a Waiver/Alteration of the Consent Process, if applicable:*
* *Recruitment email consent template*
* *On-line consent template*
* *Verbal consent template*
* *Project Information Sheet template*
* *No consent*

* *Waiver or Alterations of the Informed Consent Process for Non-Exempt Research require the investigator proved rationale and justification for the criteria below, for the IRB to grant a Waiver/Alteration of the Consent Process:*
  + *The research involves no more than minimal risk to the participants*
  + *The research could not practicably be carried out with the requested waiver or alteration (note; lack of time is not an acceptable justification)*
  + *If the research involves using identifiable private information/biospecimens, the research could not practicably be carried out without using such information/biospecimen in an identifiable format*
  + *The waiver or alteration will not adversely affect the rights and welfare of the participants*
  + *Whenever appropriate, the participants or LARs will be provided with additional pertinent information after participation.*

*The use of Recruitment email consent template, On-line consent template, Verbal consent template and Project Information Sheet are all types of Altered Consent Documents.*

1. Methods used to facilitate understanding of the participant:
2. Documentation of Consent

* Describe how the researcher plans to document that each participant has provided informed consent and/or assent, such as signature and date on the consent document. Indicate that subjects will receive a copy of the informed consent.

* *Waiver of the Documentation of Consent for research requires the investigator to provide rationale and justification for at least one of the criteria below, for the IRB to grant a Waiver of Documentation of the Consent Process:*
* *The only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality.*
* *The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.*
* *If the participant or LAR are members of a distinct cultural groups or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.*

1. **Methods, Materials and Analysis**
2. Project design

* Project design: (such as on-line survey, open-ended interview; randomized intervention, etc.)
* Project procedures/methods in chronological order with estimated times for each procedure, location of procedures/activities. Include justification for procedures.
* Please write the methods section out in the perspective of the participants: What will they be asked to do and when?

This should walk the reader step-by-step through the research

activities and include a description of the research procedures and instruments.

* Include the title and descriptions of any measures, questionnaires, tasks, tests, and/or procedures. Titles need to be used consistently throughout the description(s).
* The description must include whether these research activities or procedures are standard practice in the field or designed for this specific study.
* Provide a justification of procedures and include duration/time to complete, locations and who will conduct the procedures, etc.

1. Materials

* Explain any attached materials used in performance of procedures or activities and for the collection of research data/information.

1. Data analysis plan

* Explain how the data will be analyzed/studied (i.e., quantitatively or qualitatively and what statistical test are planned), how the interpretation will address the research questions, and how the research will be disseminated.

1. Data reporting plan

* Describe how the data will be reported (e.g., aggregated, anonymously,

pseudonyms for participants, etc.)

1. **Potential Research Risks or Discomforts to Participants, Minimization of Risks**
2. Describe any reasonably foreseeable risks of harm or discomforts for individuals and/or groups that may result from participation in the research. While risks associated with participation may not be expected, most protocols carry some risk. Risk of breach of confidentiality is present in almost all studies. Consider the following:

* Information risks (e.g., loss of privacy and/or breach of confidentiality). Even when data is coded or de-identified, combination of certain information may re-identify participants.
* Psychological or emotional risks (e.g., fear, stress, confusion, guilt, loss of self-esteem, depression, triggering of past emotional experiences).
* Social risks (e.g., social stigma, chance of being ostracized or shunned), economic risks (e.g., change in employment or insurability).
* Physical risks or harms (e.g., fatigue, pain or discomfort, potential injury, illness or disease, or death, side effects and contraindications of drugs or substances used in research).
* Legal risks (e.g., risk of persecution, mandatory reporting).
* Genetic privacy risk (e.g., stigmatization, self-stigmatization, limits to insurance coverage or employability, misattributed paternity, etc.)

1. For each identified risk, explain the following:

* Likelihood of the risk occurring.
* Magnitude of the effects the risk would have should they occur.
* How the risk will be minimized, include specific mechanisms to reduce these risks.
* How the risk will be disclosed in the informed consent process.

1. When appropriate, describe any provisions for data and safety monitoring for the progress of the research and the safety of the patients.
2. **Participant Privacy, Data identification level Data Confidentiality and data storage**
3. Privacy

* Describe the steps that will be taken to promote the protection of participants’ privacy. Consider the following:
* The methods used to identify and contact potential participants
* The settings in which an individual will be interacting with an investigator.
* The appropriateness of all personnel present for research activities.
* The methods used to obtain information about participants.
* The sensitivity of the requested information:
* In relation to the potential privacy risks of the information.
* In relation to options for participants to disclose identity.
* Describe what personal or identifiable information will be obtained to facilitate the research and as part of data collection. If participant data will be collected without identifiers, please state this.

1. Level of data identification and protection

* Describe what data will be collected, including the level of identification when it is collected **and** when it is stored (identifiable, coded, de-identified, anonymous s, etc.). Note that coded data with a key is considered identifiable, unless the PI and research team cannot access the key. If the project team has access to the key, then the information is identifiable until they key is destroyed.
* Any other information collected to facilitate the research (i.e., contact information for recruitment).
* Collection of audio/video/digital recordings or photos
* Any existing data and its level of identification (i.e., obtaining data from another source coded, or identifiable, etc.).

1. Confidentiality

* Describe the steps that will be taken to secure data and/or specimens for the research.
* Describe if participants’ private information will be coded (i.e., identifying information has been replaced with a number, pseudonym, etc.), include:
* How the key to decipher the code (i.e., list linking participant’s names with pseudonyms or participant number) will be stored?
* Who will have access to the code key?
* If, how, and why the code key will be retained.
* Describe storage and transfer including:
* How the data will be collected and stored (specific location), including format, (e.g., audio/visual recordings or photographs, hard or electronic copy, identifiable or de-identified).
* Security during transmission and sharing between researchers and participants.
* Who will have access to data (e.g., training of staff, authorization of access)?
* Who is responsible for receipt or transmission of the data or specimens?
* How will data or specimens will be transported?
* How long the records will be kept after the study is completed.
* The security of the area where data will be stored (e.g., locked office, password protected computer, encryption, firewalls, virus detection, etc.).

1. **Potential Benefits of the Research (to participant as well as society/science)**

* Describe any anticipated benefits that may result from the research. Consider the following:
* Direct benefits that may result from participation (e.g., psychological or emotional benefits, learning benefits, physical benefits, diagnostic or therapeutic benefits, etc.). If there are no direct benefits to participants, clearly state this.
* General benefits of the research to society, science and humanity; potential generalizable knowledge.
* You must indicate a benefit.

1. **Investigator Qualifications, Roles, and Training**

* Proved a brief description for all key research personnel (i.e., Principal Investigator, Investigator(s), residents, students or any other research personnel with responsibility for project oversight and research design.
* Academic background.
* Research experience.
* Experience with the proposed participant population.
* Experience with the proposed procedures and methodology.
* For students, include any applicable coursework (e.g., research methodology courses).
* Provide the Principal Investigator’s CV.
* Roles and Research Duties
* Training and Oversight