**IMPORTANT:** When completing this outline, you **must** use the [IRB Guidance: Research Plan](https://www.campbell.edu/about/leadership/provost/institutional-review-board/for-investigators/guidance-library-faq/) 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.

**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)**

Include brief background including literature review results with citations, discuss why novel inquiry is necessary, and if replicating research provide rationale.

1. **Aims**

List aims directly related to the research questions to be answered.

1. **Research Population, Recruitment Methods and Compensation**
2. Describe participant population:

* Rationale
* Inclusion/Exclusion Criteria
* Number of participants/records/biospecimens (required)
* Screening procedures to ensure only eligible participants are enrolled/consented

1. Recruitment Methods

* When, how, by who
* Recruitment materials used (attach documents to electronic New Protocol Submission Form)

1. Compensation/Reimbursement of Participants
2. Withdrawal of Participants
3. **Informed Consent Process** *Address consent/waivers for HIPAA, FERPA, deception and banking in addition to study consent, if applicable*
4. Informed Consent Process

* Describe the informed consent process, including:
* How the required elements of informed consent will be conveyed to the participant
* Where, when & how the consent process will take place
* Steps to ensure voluntary participation and reduce coercion or undue influence
* Who will conduct the consent process
* Refer to [IRB Guidance: Informed Consents and Waivers](https://www.campbell.edu/about/leadership/provost/institutional-review-board/for-investigators/guidance-library-faq/) for clarification on consenting requirements for Registration/Exempt review vs. Expedited/Full review.
* See [IRB SOP: Waiver or Alteration of the Informed Consent Process](https://www.campbell.edu/about/leadership/provost/institutional-review-board/for-investigators/policies-procedures/) for the criteria that must be met and information that must be included in this section to request consideration of a waiver of documentation from the IRB.
* Waiver or Alterations of the Informed Consent Process and Documentation of Consent require justifications to be provided for each criteria before the IRB can approve the Waivers or Alteration.

1. Methods used to facilitate understanding
2. Documentation of Consent

* Describe how the researcher plans to document that each participant has provided informed consent and/or assent. In certain circumstances, the IRB may waive the requirement to obtain a signed consent form based on specific criteria. See [IRB SOP: Waiver or Alteration of Documentation of Consent](https://www.campbell.edu/about/leadership/provost/institutional-review-board/for-investigators/policies-procedures/) for the criteria that must be met and information that must be included in this section to request consideration of a waiver of documentation from the IRB.

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.

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.

1. Materials

* Explain the attached all materials used in performance of procedures, 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.
* 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.)
* 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.).

**Note:** Please see [IRB Guidance: Identification in Research](https://www.campbell.edu/about/leadership/provost/institutional-review-board/for-investigators/guidance-library-faq/) for clarification regarding identified, de-identified, coded and anonymous data.

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, 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.

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).
* Roles and Research Duties
* Training and Oversight