The purpose of the Research Plan is to describe the proposed research in sufficient detail so that the Institutional Review Board (IRB) can determine if approval criteria for human subjects research defined in in federal regulations is met.

The Research Plan is a narrative of the study and is a living document to be maintained over the life of the protocol.

The following guidelines are designed to help researchers develop a comprehensive yet succinct Research Plan for inclusion with your New Protocol Submission. This document covers the following:

I. General Considerations

- This guidance is comprehensive to include aspects of research from varying disciplines. Do not be overwhelmed by the length of this guidance. Depending on your particular research the application can vary widely in length.
- Not all points will apply to all research.
- The IRB will consider what is appropriate to the proposed research.
- For each section, this guidance includes a description of why the information is important for IRB review (in *italics*).
- The Research Plan must be submitted with the new protocol submissions. Amendments and Continuing Progress Reviews require submission of a revised Research Plan reflecting any changes.
- There is no minimum or maximum length requirement. We encourage investigators to be succinct while including all required information in sufficient detail for the IRB to make appropriate determinations.
- Remember this form should be written in **lay terms** and define specific terms prior to using initials. Please double check your submission for completeness and accuracy prior to submission.

II. Instructions

- The Research Plan must provide **sufficient detail** for IRB reviewers to be able to understand and evaluate the research protocol.
- The focus of the Research Plan should be the activities taking place between the investigator(s) and the participants. Note that this is different from research plans develop for scientific review (e.g., grant reviews).
- The Research Plan must be written in such a way as to be understood by readers outside of the research field of expertise. Explain discipline specific terms, procedures, and concepts.
- The version date (located in the footer section) must be updated each time this Research Plan is revised whether or not the revisions are being requested by the IRB during the review process or being proposed by the investigator through the submission of an Amendment Submission.
- Refer to the appropriate ***Research Guidance Document found in Section IV: Additional Guidance for Special Topics*** for specific information that must be included in the Research Plan when research involves the following: biospecimens, multi-site research, international research, minimally-invasive/non-invasive procedures, minors/children as subjects, subjects with decreased decisional ability, and federally regulated clinical trials.

III. Research Plan Content

- When drafting the Research Plan, follow the format and use the section headings (i.e. A – J) provided below, refer to the bulleted items for section content. Do not submit the document in pdf format or in any other format (google documents) other than MSWord format.
- For each section, this guidance includes a description of why the information is important for IRB review (*in italics*).

A. Background and Rationale

In reviewing the protocol, the IRB must consider the rationale for the project and the importance of the knowledge that may reasonably be expected to result. This is one of the main ways in which the benefit of the research is shown. Please do not submit a background/rationale based on personal/anecdotal observations alone, rather include supportive literature. Emphasize what is new or novel in this proposal.

- **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.

B. Aims

The IRB must evaluate the objective of the research in order to determine whether the risks to participants are reasonable in relation to the importance of the knowledge that may be gained.

- **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.

C. Research Population, Recruitment Methods, and Compensation

In order to approve research, the IRB must determine that the selection of participants is equitable and reasonably related to the purpose and aims of the research. The IRB must also consider whether adequate safeguards are in place to minimize any risks that are unique to vulnerable populations (e.g., children, cognitively impaired persons, etc.). To make this determination, the IRB must review all methods and materials used to contact and recruit potential participants, including letters, flyers, emails, etc. Please only submit to the IRB when all materials are finalized.

1. Participant Population

- 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.
  - Describe how the research team member(s) are fluent in the language of the participants or if a translator will be used.
  - Describe how materials will be presented in the language understandable to participants (e.g. will translated materials be used?). If there is not written language, state this and explain translation.

- 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).

2. 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.
- If any part of the recruitment procedures involve a language other than English describe any differences in the recruitment procedures for non-English speaking participants.

- For research using academic records/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 Protected 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.

- For research involving treatment (e.g., behavioral intervention, educational intervention, medical intervention, etc.):
  - Describe how research treatment will be distinguished from regular treatment.
  - Indicate whether the individuals who will recruit participants have provided or will provide treatment or care to the prospective participants. If treatment providers/teachers also have a role in the research, you must describe measures to avoid or diminish undue influence.

3. Compensation/Reimbursement

- If there is the possibility that there will be costs to the participant or to a third party (e.g., an insurer), identify the specific expenses (e.g., drug tests, procedures, hospitalization, travel, etc.) and provide a justification for those costs.

- If participants are to receive compensation for their time, please describe the following or simply state no compensation will be offered:
  - The amount and nature of the compensation (e.g., cash, gift card, course credit, etc.).

- Explain how and when compensation will be provided, including payment schedules, whether or not compensation will be reduced if the participant does not complete all activities in the project, and how any proration will occur.
- Explain how the methods and amount of compensation is appropriate for the participant population and study activities (e.g., based on time commitment, number of project visits, travel expenses, age of participant population, etc.).

4. Withdrawal of Participants

- Describe any anticipated circumstances under which participants will be withdrawn from the research without their consent.
- Explain any procedures for orderly termination.
- Explain procedures that will be followed when participants withdraw from the research, including partial withdrawal from procedures with continued data collection.
- Describe what will happen to participant's data if they are withdrawn from the project.
- Explain how withdrawal of subjects will affect data analysis.

NOTE: Attach all recruitment materials used in the research to the appropriate Electronic Application Form.

D. Informed Consent Process

Informed consent is a process not just a form, and obtaining informed consent is a central protection for human participants. The IRB must ensure the informed consent process clearly discloses and facilitates the understanding of all information needed to make an informed decision to participate while promoting the voluntariness of participation. Please note that the informed process is more than obtaining a signed consent form.

Below are the key components of the informed consent process. In some cases, it may be appropriate to seek a waiver or alteration of informed consent or a waiver of documentation of informed consent from the IRB.

The informed consent process for registration and exempt research may not need to include all the required elements of informed consent in the Common Rule (45 CFR 45) regulations (as noted below), researcher should employ a consent process when interacting with participants even when conducting registration or exempt research. Understand the IRB will make the final determination on informed consent requirements.

Researchers are strongly encouraged to continue using the guidance information below and one of the IRB Informed Consent Form Templates. At minimum, the informed consent process for exempt research should disclosure of the following to participants:

- That the activity involves research.
- A description of the procedures.
- That participation is voluntary.
- Name and contact information of the Researcher and the IRB Office.

1. Informed Consent Process

- Describe the informed consent process, including:
  - How the required elements of informed consent will be conveyed to participants (i.e., informed consent documents, verbal script, online statement, letter, etc.).
  - Where, when, and how the informed consent process will take place (i.e., in-person in private room, phone/orally, video presentation etc.).
  - Any waiting period available between informing the prospective participant and obtaining the consent.
  - Any cultural considerations (e.g., tribal or group permission requirements, age of majority, technological limitations, etc.).
  - Steps that will be taken to ensure voluntary participation and to minimize the possibility of coercion or undue influence.
  - Which research personnel (e.g., PI, Investigator, resident, student, etc.) will conduct the consent process and how that person will be trained (e.g., previous experience or related training, one-on-one training with PI, etc.).
  - If multiple participant groups or consent procedures are to be included, these need to be clearly delineated.
- If a Legally Authorized Representative (LAR) and/or a Witness will be use, explain reason for using LAR. In certain circumstances, the IRB may approve a consent process which does not include, or which alters, some or all of the elements of informed consent or waive the requirements to obtain informed consent.
- In some circumstances, the IRB may approve a consent procedure that omits some or alters some or all of the elements of informed consent. If you are requesting a waiver or alteration of the informed consent process you must provide justification for the following criteria to be approved by the IRB:
  - The project involves no more than minimal risk to the subjects;
  - The project could not practicably be carried out without the waiver or alteration;
  - If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without

using such information or biospecimens in an identifiable format;

- The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

2. Facilitate Understanding

- Describe how the investigator will ensure that the participants understand all aspects of their involvement in the research (i.e., will participants be asked questions about the procedures, or encouraged to ask questions?).
- Describe any special provisions for individuals who might have trouble comprehending the consent information.
- If any participants do not speak English, describe:
  - Whether or not the researcher is fluent in the language.
  - Whether or not and how a translator will be used.
  - Whether or not translated consent materials will be used.
  - Whether or not there are any differences in the consent process for different populations based on the language they speak.
- Describe the process by which the investigator will ensure ongoing consent.

3. Documentation

- Describe how the researcher plans to document that each participant has provided informed consent and/or assent.
- Federal regulations and the CFVHS IRB require the documentation of informed consent, in writing, unless the IRB has approved a waiver or alteration of the documentation of the informed consent. Generally, the IRB does not grant a waiver for documentation for Expedited or Full Board (Non-Exempt) research.

  The IRB may waive the requirement for the Principal Investigator to obtain a signed and dated consent document for some or all subjects, if it finds one of the following justified in the Research Plan:

  - That the only record linking the subject and the project would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the project, and the subject's wishes will govern; or
  - That the project presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the project context; or

- That the subjects are members of a distinct cultural group or community in which signing forms is not the norm. This is limited to minimal risk research projects and requires an appropriate alternative method for recording that informed consent was obtained.

4. Additional Considerations

If the research involves:

- **Minors** (those under the age of majority) or individuals of diminished capacity:
  - Describe the capacity of the participant and their ability to assent.
  - Describe how assent to participate will be obtained and documented.
    - If a waiver of assent or waiver of assent documentation is being requested, provide justification.
  - Explain how the permission of the parent(s), guardian(s), or legally authorized representatives (LARs) will be obtained and documented.
    - If a waiver of permission or waiver of permission documentation is being requested, provide justification.
- **Deception:**
  - Explain how participants will be deceived and why it is necessary for the project.
  - Deception is an alteration of informed consent; provide justification for how the use of deception meets the criteria for alteration of informed consent.
  - Deception can be used in research involving **benign behavioral interventions** among adult participants if least one of the following criteria is met:
    - The identity of the participants cannot readily be ascertained, directly or through identifiers linked to the participants, or
    - Disclosure of the participant's responses outside of research would not reasonably place the participants at risk of criminal or civil liability ore be damaging to the participants' financial standing, employability, educational advancement, or reputation, or
    - The identity of the participants can readily be ascertained, and the IRB conducts a limited IRB review.

  The participant must authorize the deception through a prospective agreement in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research. Prospective agreement does not require the use of an informed consent document.

- Describe the debriefing process and provide script.

- **Protected Health Information and HIPAA:**
  HIPAA applies to Protected Health Information (PHI). PHI is individually identifiable health information that is created or maintained by a covered entity (health care providers, hospitals, physician offices, health care clearing houses, health care plans), or their business associate(s).)

  If your research does not involve the use of medical record information maintained by a covered entity and/or if the information generated from research will not be placed into the medical record, then HIPAA may not apply.

  Attach your completed Appendix A – Use of PHI Form to your electronic protocol submission form addressing the following:

  - If the research involves the use of protected health information from a covered entity, describe how authorization from participants to access and use their information will be obtained (i.e. signed HIPAA authorization form, informed consent which includes HIPAA authorization).
    - If requesting a waiver of authorization, please complete the appropriate sections of Appendix A – Use of PHI form.

E. Methods, Materials, and Analysis

The project design, methods and procedures must be adequately described, in order for the IRB to understand all activities in which human subjects will participate. The IRB must also be able to differentiate those procedures that are performed for research purposes from those that are performed for routine/standard care/practice/normal education or evaluation. It is not sufficient to simple state methods (e.g., "all subjects will be asked to donate blood"), rather include all details especially related to involvement and risks for the participant (e.g., who collects the blood, where, when, how much, by which procedure, how it is processed, saved, analyzed, etc.)

NOTE: The focus of this section is on methods and procedures. Risks must be discussed later in Section F.

Attach the appropriate appendices and all surveys, questionnaires, data collection tools, educational materials, etc. to the appropriate Electronic Application Form. Please do not submit links to these documents. The IRB requires permanent (paper or electronic documentation) documents.

Describe the project design and research methods used to meet the project aims and objectives stated above (e.g., on-line survey, open ended interview, randomized controlled trial, participant observation, field based research, lab/task based, etc.).

- Please write the methods section out in the perspective of the participants: What will they be asked to do and when?
- Remember to collect the minimum amount of identifiable information or

potentially identifiable information as possible to achieve research goals.

- If there will be multiple groups of participants completing different sets of activities/tasks, clearly delineate the activities to occur for each group.
- Describe in chronological order all research activities/procedures involving participants. 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.
    - Depending on the complexity or number of procedures or steps, consider inserting a table or attaching an inventory list of procedures, interventions measures and/or questionnaires.
    - If the research involves any procedures include the following:
        - The justification for the use of the procedures.
        - The qualifications of project personnel to conduct the procedures.
    - If using deception, discuss rationale/need of the deception, , what that deception entails, and when and how the debriefing process will occur.
- Include an estimate of the time each participant will spend completing the activities (in minutes or hours), the number of sessions the participant will engage in, and the total length of participation (in days, weeks, months, or years) from the beginning to the end of the project.
- If follow-up with participants is planned, discuss the procedures and under what circumstances follow-up will occur. Describe the methods of data collection and recording that will be utilized in the project (i.e., hand-written notes, survey platform, computer programs, videotapes, audiotapes, photographs, etc.).
    - For research using the internet as a source of information or survey tool. describe the following:
        - Describe if you will be:
            - Recruiting subjects over the internet
            - Observation of internet activity
            - Collecting data over the internet
            - Informed Consent obtained over the internet
            - Describe the process and how it is documented.
        - Describe mechanisms you will use to protect the confidentiality of

information collected over the internet.

- If an internet survey platform used:
  - How and when data will be removed from the survey platform (Qualtrics is currently the IRB approved survey platform)
  - If collection of data is identified or anonymous
  - Procedures or software settings used to remove identifiers if data is collected anonymously
  - Provide the company name and describe their security and retention policies.
  - Attachment of survey in the final survey platform format to the appropriate electronic application form. Although it is recommended that you include the link to the actual survey, this does not replace the need to submit a document (Word or pdf) containing the survey. The IRB requires a permanent document.

- Describe the specific locations where the activities will be conducted (i.e., in what labs, clinics, field sites, or online platforms will the procedures occur?). The investigator must determine if additional local, State and/or international policies and regulations are applicable to the research and include this information in the Research 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.
  - Describe how the data will be reported (e.g., aggregated, anonymously, pseudonyms for participants, etc.)

F. Potential Research Risks or Discomforts to Participants and Minimization of Risks

In order to approve the research, the IRB must consider the risks posed to participants by the research and any efforts to mitigate those risks. The IRB needs to determine that the risks have been both minimized and are reasonable in relation to the anticipated benefits to participants as well as to the importance of the knowledge that may be gained. The IRB will also consider whether the informed consent process provides potential participants with an accurate and fair description of the risks or discomforts. All research has risks.

- 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.)

- For each identified risk, explain the following:
  - Likelihood of the risk occurring.
  - Magnitude of the effects the risk would have should they occur.
  - **Mechanisms included in the study design to minimize the risks.** How the risk will be disclosed in the informed consent process.
- If the protocol involves treatment or intervention, describe the “standard of care” or “normal educational practice” and describe how the risks of the research interventions or treatments compare to this standard.
- Although the IRB is primarily concerned with risks to participants, some studies may also carry risks for others and/or research personnel. Please identify these risks, if present, and explain how risks will be mitigated.

G. Data and Safety Monitoring Plan, if applicable.

- When appropriate, describe any provisions for data and safety monitoring for the progress of the research and the safety of the patients.
  - If there is a separate Data and Safety Monitoring Plan (DSMP), state this and attach to the appropriate Electronic Application Form.
  - If there is an established Data and Safety Monitoring Board/Committee (DSMB/C) to monitor the progress of the research and the safety of participants, clearly indicate this. The frequency and operations of the DSMB/C should be covered in the DSMP.

H. Participant Privacy, Data Disposition, and Data Confidentiality

In order to approve research, the IRB must determine that there are adequate provision in place to protect the privacy of subjects and maintain the confidentiality of research

records and data collected.

1. **Privacy**
    - Describe the steps that will be taken to promote the protection of participants' privacy (mechanisms used to reduce the risk of loss of 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.
        - Privacy guidelines developed by relevant professional associations and scholarly disciplines (e.g., oral history, anthropology, psychology).
        - Steps to ensure access to the minimum amount of information necessary to complete the project.
        - Information that is obtained about individuals other than the "target participants," and whether such individuals meet the regulatory definition of "human participant" (e.g., a participant provides information about a family member for a survey).
    - 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.
2. **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.). In addition, consider the following:
        - Any other information collected to facilitate the research (i.e., contact information for recruitment).
        - Collection of audio/video/digital recordings or photos are considered identifiable information.
        - Any existing data and its level of identification (i.e., obtaining data from another source coded, or identifiable, etc.).
3. **Confidentiality**
    - Describe the steps that will be taken to secure data and/or specimens for the

research and describe mechanisms used to prevent the loss of confidentiality.

- 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?
    - Justify, how, and why the code key will be retained or when and how the code key will be destroyed.
- If participant identities will be disclosed as a result of this research (e.g., attributing a direct quote, etc.), provide:
    - Justification for appropriateness of direct identification.
    - Parameters for disclosure (e.g., will participants be allowed to review prior to dissemination).
    - How permissions from participant will be solicited including restrictions.
- Describe storage and transfer including:
    - How the data will be collected and stored, including format, (e.g., audio/visual recordings or photographs, hard/paper 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 and if they data is identified provide justification for retaining the information in an identified manner.
    - The security of the area where data will be stored (e.g., locked office, password protected computer, encryption, firewalls, virus detection, etc.).
    - Specific location where information/materials are stored and maintained.

  All research source documents must be maintained for a minimum of **3 years** or **6 years** if HIPAA applies following **project closure** and must be readily available for IRB or other agency inspections, if applicable.
- Describe any intent for future use of data beyond this research, if applicable, including:
    - If other researchers will be permitted access/use of the data, after the data

has been de-identified or identified if this project is a banking project.

- How data will be maintained and stored.
- How participant permissions for the future use will be obtained and tracked.

- Is the use of a Data Use Agreement (DUA) or Materials Transfer Agreement (MTA) required to conduct the research?
- If seeking a Certificate of Confidentiality through NIH, this needs to be stated.

I. Potential Benefits of the Research

In order to approve research, the IRB must determine that the anticipated benefits to research participants and the knowledge researchers expect to gain are reasonable in relation to the potential risks.

- Describe any anticipated benefits that may result from the research. There must be at least a benefit to society, science, and humanity; potential generalizable knowledge. Consider the following and include all that apply:
  - 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. Please note that most research has no direct benefits. For example, a study aimed to test the efficacy of a new educational approach, cannot promise students their learning/grades will benefit from participating.
  - Guard for therapeutic misconception when describing benefits
  - Benefits to the general participant population.
  - General benefits of the research to society, science, and humanity; potential generalizable knowledge.

NOTE: Compensation for participation is not a benefit and should not be included in this section.

J. Investigator Research Qualifications, Roles and Training

In order to approve this research, the IRB needs to determine that research personnel are adequately trained and knowledgeable regarding the project procedures and the protection of human research participants. Address only training and knowledge beyond required human subject research protection training for the IRB.

1. Investigator Qualification

- 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).
- Include copies of CVs of all Investigators if the research is federally funded. If the research is not federally funded include a copy of the Principal Investigator only.

2. Roles and Research Duties

- Describe the roles and the associated research activities/duties. For example: students will consent participants and administer surveys.
- Note: Do not list individual names. Limit roles to Principal Investigator, Investigator(s), Faculty, Resident(s), Student(s). This information should be included on the Research Personnel Form.

3. Training and Oversight

- Describe how the study personnel will be adequately trained to conduct research activities in accordance with the approved protocol and in compliance with federal regulations and CFVHS policy.
- Describe any specific training or expertise required for procedures proposed in this research. Explain all of the following;
  - Training standards or requirements that must be met.
  - Who will be providing the training?
  - How will training be tracked/documented?

4. Translator

- If a translator will be used for any aspects of the research, provide the translator's name and qualifications for translation (e.g., native speaker, student of the language, etc.).

IV. Appendices to the Research Plan

Complete the applicable appendices and attach to the appropriate Electronic Application Form. If the following appendices do not apply to the research, do not include. Appendices become part of the Research Plan and are required with each subsequent submission

- Appendix A – HIPAA – Use of PHI

V. Additional Guidance on Special Topics

Collaborative/Multi-Site Research

Include the following information in your Research Plan when research activities are conducted at more than one site.

When CFVHS is relying/deferring to another Coordinating Site/IRB of Record, upload the following documents in the New Protocol Electronic Application Form

- IRB Institutional Authorization Agreement Request form, Investigator Attestation for Ceded Projects, Letters of Support, the IRB-approved protocol in lieu of a Research Plan, approved consent form or documentation of consent waiver for each research site.
- Institutional Authorization Agreement, if ready.
- Investigator's CV's and Qualifications.
- Protocol or procedure manual(s) to be used by any of the research sites, if applicable.
- Central data collection and management plan, if applicable.

Collaborative/Multi-Site Information

Please clarify the following in your **IAA/IIA Request Form** when CFVHS is not the Coordinating Site/IRB of record:

1. If the project is being implemented as an identical protocol at multiple sites (US or Internationally) under the direction of multiple Principal Investigators*.
2. If different activities are being conducted from one site to the next under the direction/supervision of different Principal Investigators*.
3. Include approximately how many total sites are participating in this project.
    - If the project is supported by any federal grants, contracts or subcontracts provide a list of the FWA# for each site.
4. Provide the name and address of the Coordinating Site/IRB of Record. If there is no coordinating site provide a justification.
5. Clarify if this research will be reviewed by a local IRB or ethic committee in each setting or a Central IRB.
    - Include the name, address, and contact information for each IRB or local ethics or the Central IRB committee cited.
6. It is important for the investigator to identify a person or persons (other than members of the research team) who can stand by to answer questions or handle complaints at CFVHS.
7. Clarify is all the subjects will be fluent in English.
    - If subjects are not fluent in English provide the following information:
        - The language these subjects speak and describe how communication will take place with subjects in each setting. *For example: Co-Investigator is fluent in Armenian and will be responsible for all interactions and all communications.*
        - If consent forms are to be used with non-English speaking subjects, clarify how translations will be obtained. All translated consent forms must be submitted to the IRB.
        - Describe how consent will be obtained from subjects in each setting.

International Research

Include the following information in your Research Plan when research activities are conducted in other countries.

International Information

Please clarify the following in your research plan:

1. Provide different countries and in what types of settings (rural, urban, etc.) will the research be conducted. *The term "setting" refers to the specific physical international location.*
2. Describe the cultural norms in this/these setting(s) with respect to research, individual autonomy, consent, age of majority, etc. in detail.
3. Describe how the investigators will ensure that subjects understand the nature of the research in each setting.
4. Describe the investigator's qualifications to conduct research in this setting.
5. If investigator's will be collaborating with local persons (e.g., researchers, universities, community leaders, etc.) list and describe collaborators.
6. It is generally recommended that research projects conducted in different countries obtain local IRB review and are conducted with a local principal investigator.
7. It is important for the investigator to identify a person or persons (other than the research team) who can stand by to answer questions or handle complaints in each setting. List who will service this function at each site.
8. Clarify is all the subjects will be fluent in English.
    - If subjects are not fluent in English provide the following information:
        - The language these subjects speak and describe how communication will take place with subjects in each setting. *For example: Co-Investigator is fluent in Armenian and will be responsible for all interactions and all communications.*
        - If consent forms are to be used with non-English speaking subjects, clarify how translations will be obtained. *All translated consent forms must be submitted to the IRB*.
        - Describe how consent will be obtained from subjects in each setting.

Minors/Children as Subjects

Include the following information in your Research Plan when research activities involve the use of minors/children as subjects.

Use of Minors/Children as Subjects

Please clarify the following in your research plan:

1. The age range of the children.
2. The location where children will participate such as:
   - Home
   - School (K-12 grade)
     - Indicate if you have obtained permissions from the school district, school principal and teacher.
   - Hospital/clinic/doctor's office
   - Non-medical College or University setting
   - Other, please specify

Allowable Categories for Use of Minors/Children in Research

Please indicate in your Research Plan which category below best represent the degree of risk to benefit to which the children in the project will be exposed and explain your choice.

1. **Category 1**: The proposed research poses risks no greater than that ordinarily encountered in daily life or during the performance of routine physical or psychologic examinations or tests (i.e., minimal risk).
2. **Category 2**: The proposed research poses a greater than minimal risk with the potential for direct benefits to subjects, i.e., the benefit to the subject is at least as favorable as alternative approaches.
3. **Category 3**: The proposed research poses a greater than minimal risk with no potential for direct benefit to individuals, but likely to yield vital generalizable knowledge about the subject's conditions.
4. **Category 4:** The proposed research does not meet the criteria in the above categories but presents an opportunity to understand, proven, or alleviate serious problems affecting he health or welfare of children. *This requires the Secretary of the Department of Health and Human Services approval, in addition to IRB approval.*

Parental Permission

In general, permission from both parents is required for research involving children unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. For Categories 1 & 2, however, the IRB may find that the permission of one parent is sufficient.

Please indicate in your Research Plan which what type of parental permission will be obtained from the parents from the list below:

- Permission will be obtained from both parents where possible
- Permission from only one parent is being requested
- Waiver of parental permission is being requested

If the research is being conducted in a group setting (e.g., day camp, day care, classrooms, boy/girl scouts), explain what provisions have been made for children whose parents have not given permission for them to participate.

Assent from Children

Adequate provisions must be made for soliciting the assent of children when in the judgment of the IRB the children are capable of providing assent and for soliciting the permission of their parents or guardians.

1. Indicate whether the children participating in the research are generally capable of providing assent; evaluate age, maturity and psychological state of the children involved by indicating the following:
   - All are capable
   - None are capable
   - Some are capable
     - Proved a detailed explanation.
   - No assent will be obtained
     - Proved a detailed explanation.
2. Describe the assent process, including what information will be provided to the subjects.
3. Describe how assent will be documented.

Subjects with Decreased Decisional Ability

Include the following information in your Research Plan when research involves subjects with decreased decisional ability.

"Decreased decisional ability" refers to persons who show decreased ability to understand, communicate, reason, and/or decide. The impairment may be due to disorders of psychiatric, organic (including those suffering from delirium or degenerative brain diseases), developments (e.g., mental retardation), substance misuse (e.g., those under the influence of or dependent on drugs or alcohol), or other nature that affects cognitive or emotional functions.

Subjects with Decreased Decisional Ability

Please clarify the following in your research plan:

1. Describe the subjects with decreased decisional ability that you intend to include in the research.
   The decision-making capacity of individual subjects should not be assumed because of a condition or diagnosis.
2. Provide an explanation for why these subjects are necessary for the research to be conducted.
3. If any of the subjects are institutionalized provide the name of the institutional setting, type of setting and provide documentation of permission from the institution.

Subjects with Decreased Decisional Ability

Please clarify the following in your research plan that the risks to subjects with decreased decisional ability fall within the federal definition of "minimal risk".

If the risks do not meet the definition of "minimal risk" then describe the direct benefits to the individual subjects.

Consent

Please clarify the following in your research plan:

1. Describe how individual subjects' ability to provide informed consent will be determined.
   The decisional ability of individual subjects should be determined through the use of a standardized measure or by consultation with a qualified professional. Describe the procedures, the assessment criteria, or instruments to be employed, and the qualifications of the assessors, and why they are appropriate for the subjects' conditions and the nature of the project.
2. Where it has been determined that a subject lacks the decisional ability to provide informed consent, describe the provisions for obtaining consent from the subject's legally authorized representative (LAR).
   When a subject in an ongoing project loses his/her decisional ability (whether transiently or irreversibly), the IRB considers that subject's participation in the project to be ended until a legally authorized representative consents to continuation on behalf of the subject – so long as that consent is documented within a relatively brief period of time (e.g., weeks).
3. If the LAR provides consent, describe how the assent of the subjects' will be obtained and documented.

4. If the subjects are likely to regain decisional ability, describe how and when their decisional ability will be assessed.
5. Explain if it is likely that some subjects who initially gave consent will lose their decisional ability during the course of the project.
6. Describe the procedures to be used to monitor the individual subject's ability during the course of the project.
7. Describe what your plans for obtaining consent from the subjects' LAR will be, if a subject who previously consent to participate, loses their decisional ability during the project.

Minimally-Invasive or Non-Invasive Procedures

Include the following information in your Research Plan when research activities involve minimally-invasive or non-invasive procedures.

Collection of Blood
Please clarify the following in your research plan:

If blood is collecting/using blood samples by finger stick, heel stick, ear stick or venipuncture please include the appropriate following statements:

- All subjects (100%) from which we collect blood will be healthy, non-pregnant, adults who weight at least 110 pounds.
- Blood amounts drawn will be limited to 550 ml in an 8-week period, with no more than 2 draws per week.
- Blood amounts drawn will be limited to 50 ml (or 3 ml per kg) in an 8-week period, with no more than 2 draws per week.

If your research does not meet the above statements then your research does not meet IRB approval criteria. Please contact the IRB for further instructions.

Collection of Biospecimens by Non-Invasive Procedures
Please clarify the following in your research plan the type of specimens collected by non-invasive means from the below:

- Hair or nail clippings collected in a non-disfiguring manner
- Deciduous teeth at time of exfoliation or clinically-indicated extraction
- Permanent teeth at time of clinically-indicated extraction
- Urine, excreta, or external secretions (including sweat)
- Uncannulated saliva collected in unstimulated or minimally-stimulated fashion
- Placenta removed at delivery
- Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor
- Supra- or subgingival dental plaque or calculus collected in routine-care fashion
- Mucosal or skin cells collected by buccal scraping or swab, skin swab, or mouth washings
- Sputum collected after saline mist nebulization
- Other-please describe

Other Non-Invasive Procedures
Please clarify the following in your research plan:

If you will use data collected by means of non-invasive means employed in clinical practice please list and describe each procedure.

The following procedures cannot be considered "non-invasive" for this question:

- *General anesthesia or sedation*
- *Any form of ionizing radiation (x-rays) or microwaves*
- *Use of medical device that has not been market-approved or cleared*

If research involves collecting/using data from voice, video, or image records, describe the recording media to be employed.

Biospecimens in Research

Include the following information in your Research Protocol when conducting research involving biospecimens.

When the research team will be collecting biospecimens from human subjects for the research project:

Please include the following information regarding the collection of biospecimens from human subjects for RESEARCH purposes *(table has been provided as an example you may provide the information in written format)*.

Type of Biospecimen	Volume/Size per sample	Estimated total # of samples	Estimated total # samples for this project

When conducting research with the use of previously collected biospecimens:

Include the following information:

1. For what purpose were the biospecimens originally collected (list all that apply)?
   - Clinical pathology specimens
   - Discard material
   - Different research project
   - Local bank, if so, list the CFVHS IRB Protocol Number
   - Other, please specify and provide details
2. Are some of the biospecimens publicly available?
   "Publicly available" means that the specimens are unidentified and available to the general research community without conditions.
   - If publicly available, include a brief description in the Research Plan and attach the public description of the public access database and its access criteria for IRB documentation in the appropriate Electronic Application Form.
3. **NOTE:** if all biospecimens are publicly available and are de-identified your research may qualify as Not Human Subjects Research. Do you plan to use/analyze biospecimens and related clinical data created before the date of IRB submission (retrospective records) *(i.e., NO additional cases created after that date, and NO opportunity to include follow-up information created after that date)*?
   - If "yes," provide the data for the earliest biospecimens you will access.
4. Do you plan to access biospecimens created after the date of IRB submission (prospective records)?
   - If "yes," please explain how will records be obtained:

- Using informed consent; or
- Other, provide clarification.

5. Provide an estimate of the total number of biospecimens (number of persons and number of specimens) that you intend to access for the project. Explain how you determined the number of biospecimens to include in the project.

6. If you will be collecting clinical information about the specimens, what information will you collect? (include all that apply)
   - Patient diagnosis;
   - Patient symptoms or signs;
   - Patient lab values;
   - Patient course of illness;
   - No clinical or health information corresponding to the biospecimen; or
   - Other: include details.

Storage Location and Conditions

Include where biospecimens will be stored *(provide building, room, locked freezer, etc.)* and, if collecting associated clinical data, where will be stored.

Clinical Trials

1. For a project that meets the definition of a clinical trial and is federally funded, one IRB informed consent form used to enroll subjects must be posted on a publicly available Federal Web site that has a repository for such informed consent forms.

2. Describe in this section of the Research Plan where the consent form will be posed and acknowledge the required timeframe for posting (e.g., clinicaltrials.gov or the regulations.gov document portal). NOTE: the investigator will be responsible for demonstrating at the time of continuing review, progress reporting, and/or closure of the project that this requirement has be satisfied.

3. Registration in clinicaltrials.gov is required for studies that meet the definition of an "applicable clinical trial" (ACT) as defined in section 402(j) of the PHS Act. These include any controlled clinical investigations (other than phase 1 investigations) of any U.S. Food and Drug Administration (FDA)-regulated drug or biological product for any disease or condition.