INSTRUCTIONS FOR PROTOCOL:

A complete description of the planned research (i.e., protocol) must be submitted with initial applications for IRB review. The research protocol should provide the information needed for reviewers to determine that the regulatory and Human Research Protection Program (HRPP) policy requirements have been met. There is no required format or template; different sections and formatting may be used, provided the necessary information is included. Please use the sections below as a guide.

Note that **text in blue are instructions and points to consider;** do not use the blue text as an outline. Please delete the blue text and complete the section with study appropriate information.

GENERAL INFORMATION:

- Title of the Research Proposal
- Name of Principal Investigator
- Contact Information of Principal Investigator
- Version Date and Number of the Protocol (to be updated with changes)

OBJECTIVES:

The purpose of the study (research questions and / or study objectives) should be clearly stated. In experimental designs, objectives will be stated as hypotheses to be tested and specific aims.

BACKGROUND AND RATIONALE:

Summarize and synthesize the available research (including published data) to provide justification for the study. Evaluate prior research for relevance to the research question under study. When the proposed research is the first of its type to involve human participants, the results of relevant animal studies must be included. Discuss the anticipated results and potential pitfalls. Describe the significance of the research including potential benefit for individual participants or society at large. Discuss how public health and social welfare might be enhanced.

PROCEDURES:

The procedures should include the following sections and information:

- **Research Design**
    - The research design should be identified and should be appropriate to answer the research question(s) under study. Describe the type of research proposed (e.g. experimental, correlational, survey, qualitative) and specific study design that will

be used (e.g. pre-test /post-test control group design, cross-sectional design, prospective longitudinal cohort design, phase III double-blind randomized control group design).

- **Study Population**
    - **Target Population and Inclusion/ Exclusion Criteria:** Describe the participant population such as age range, gender and ethnic background. List the inclusion/exclusion criteria (characteristics that people must have to be included or unable to participate in the research).
    - **Participant Enrollment:** Define enrollment for the study and provide the number of participants planned to be enrolled.
    - **Recruitment and Screening Procedures:** Describe the plan (when, where, how) to identify potential participants, including database/ medical record review if applicable. Explain who will be identifying and reviewing potential participants. Describe how the population will be identified and how initial contact will be made. Provide information regarding access to the population (approvals to recruit when necessary).
        - Specify if any advertising/ recruitment materials that will be used. Upload and attach recruitment materials with your iRIS submission. Examples of recruitment:
            - PI/ study team will recruit his/her/their own employees/patients/students
            - PI/ study team will recruit individuals unknown to them (e.g. social network, posting flyers, direct approach)
            - PI/ study team will send letters to colleagues asking for referrals
            - PI/ study team will send letters to potential participants
        - Describe the screening process (confirming that potential participants meet inclusion/exclusion criteria). Explain what happens with screen failures and any data obtained from screen failures, if applicable.
- **Detailed Study Procedures:** Provide a thorough description of all study procedures, assessments and participant activities in a sequential format. Include methods for data collection. Describe how information will be captured (e.g. audio or video recorded, observations, note taking, etc.) Upload data collection documents/scripts/etc. as supporting documents with your submission. Include a timeline for participant evaluations and the duration of participant participation. Examples of types of studies and information to include:
    - **Behavioral Intervention Studies:**

        - Describe how the behavioral intervention with be developed or adapted for use
        - Describe how the intervention will be administered
        - Describe what the participant will be asked to do
    - **Survey/ Interview Studies:**
        - Describe survey/ interview methodology
        - Describe development or selection of questionnaire, including whether it is validated
    - **Focus Groups:**
        - Describe the process/ design of the focus group(s)
        - Describe whether information drawn from the focus group will be shared with group participants
    - **Studies that Use Medical Records, Data or Biospecimens:**
        - Identify the sources of research material
        - Describe what information (records, data, etc.) will be recorded and used
        - Detail whether the data and/or specimens are identifiable and list the exact HIPAA identifiers to be accessed and used
        - Describe how the data will be stored
        - Describe any approvals or permissions that are required for obtaining existing data, records or specimens, as applicable
        - Describe any specimens to be collected and the procedure for collecting and using them
        - Describe any plans for retaining specimens including how long they will be kept, how they will be stored, who will have access, and the tracking labeling system to be used
        - If data or specimens will be banked for future use, describe the process for providing researchers access
    - **Studies Involving use of Medical Devices or Drugs:**
        - Provide product details (name, manufacturer, etc.)
        - Describe route of administration, dosing, dosage regimen and duration
        - State whether device or drug is FDA approved for the purpose being studied
- **Participant Compensation:**
    - Describe any compensation to participants including amounts, payment schedule and type.
- **Participant Withdrawal:**

- Describe procedures that will be followed when participants withdraw during data collection. Describe the process for participants to withdraw from the study after participation is complete, if applicable.
- Describe conditions under which the investigators might withdraw a participant from the study.
- Describe what will happen to data obtained from withdrawn participants.

STUDY DATA DETAILS:

This section should provide specific details around study data including the following information:

- **Data Management Procedures and Confidentiality:**
  - Describe what will happen with the data (electronic, paper, recordings, etc.) from the time it is collected until the data are permanently de-identified or destroyed
  - If applicable, describe who will have access to the data and how the data will be handled/ maintained securely
  - Considerations for securely storing fata include:
    - Paper records are locked in a secure location
    - Electronic records are stored on a password protected or encrypted computer as appropriate based on sensitivity of data
    - Identifiers are stored separately from consent forms as well as study data
    - For identifiable data, a coding system will be used to store data without identifiers, with the link stored separate
  - Provide specific information regarding where identifiable data and consent forms will be stored
  - If data will be transferred outside of Geisinger, describe procedures for data transfer
  - Describe plans for destroying the data or other handling once study is completed (Please note the following minimum research record retention requirements:
    - Study records must be kept for at least 3 years after study completion
    - Federally-funded study records must be kept for at least 3 years after the final reports are submitted
    - Signed consent/authorization, stand-alone authorization forms or documentation of verbal authorization must be kept for 6 years to comply with HIPAA requirements.

        - FDA requires studies including investigational drugs or devices must be kept for 2 years after the last marketing approval or withdrawal of approval request
    - Describe how the confidentiality of the study data will be maintained
    - If greater than minimal risk study, describe the data and safety monitoring plan for the project and upload any supporting documents
- **Data Analysis/ Statistical Considerations:**
    - Provide a brief sample size calculation or description of sample size calculation. Include methods and assumptions such as loss to follow-up, as appropriate.
    - Describe the statistical analysis plan
    - If a study uses qualitative rather than quantitative methods, describe qualitative analysis
    - Describe how the data will be examined and statistically analyzed to answer study objectives

EXPECTED RISKS/ BENEFITS:

- **Potential Risks**
    - State any physical, psychological, social, economic, or legal risks and access their likelihood and seriousness. Examples include:
        - Is there a potential for participants to become upset as a result of the research procedures and thus require psychological or medical attention?
        - Is there a potential for emotional stress or fatigue?
        - Is there potential for loss of confidentiality and how serious would loss of confidentiality be? Consider breach of confidentiality or privacy as a risk for all study participants
        - Is there risk of physical harm from the intervention?
        - Could the research create potential social stigmatization or legal action by authorities if research information became known outside of the research team?
        - Are there potential risks to the participants related to the political, social, or economic context in which they live?
        - Are there economic burdens the participants will encounter from participating in the research?
    - State the plan for preventing or minimizing risks (e.g. screening to assure appropriate selection of participants, sound research design, de-identification of data, safety monitoring and reporting)

- **Benefits**
    - Describe the potential benefits that individual participants may experience from taking part in the research
    - If there is no direct benefit, acknowledge that and describe the anticipated social benefit to the research

BIBLIOGRAPHY

Include a reference list of literature cited to support the protocol

APPENDIX

Management of Multi-Site Research Where Geisinger/AtlantiCare is the Lead Site

Describe study activities that will be conducted at each site if they differ between sites.

Describe the plans for management of study activities, reporting requirements and communication across sites, including, for example:

- Unanticipated problems involving risks to participants or others
- Modifications to study protocol, procedures, documents
- Interim study results