PROTOCOL TITLE:

**INSTRUCTIONS[[1]](#footnote-1):**

* *Use this template to prepare a document with the information from the following sections.*
* *Depending on the nature of your study, some sections may not be applicable to your research. If so mark as “NA”. For example, research involving a retrospective chart review may have many sections with “NA.” For subsections, like 1.x or 8.x, you can delete it if it’s not applicable.*
* *When you write a protocol, keep an electronic copy. You will need to modify this copy when making changes.*
* *As you are writing the protocol, remove all instructions in italics so that they are not contained in the final version of your protocol.*
* *For submission of a protocol specific to a participating Site as part of a Multi-Site Study, use HRP-508 - TEMPLATE - SITE SUPPLEMENT.*

**PROTOCOL TITLE:**

*Include the full protocol title.*

**PRINCIPAL INVESTIGATOR:**

*Name*

*Department*

*Telephone Number*

*Email Address*

**VERSION NUMBER/DATE:**

*Include the version number and date of this protocol.*

**REVISION HISTORY**

|  |  |  |  |
| --- | --- | --- | --- |
| **Revision #** | **Version Date** | **Summary of Changes** | **Consent Change?** |
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# Study Summary

|  |  |
| --- | --- |
| **Protocol Information** | **Description** |
| **Study Title** |  |
| **Study Design** |  |
| **Primary Objective** |  |
| **Secondary Objective(s)** |  |
| **Research Intervention(s)** |  |
| **Study Population** |  |
| **Sample Size** |  |
| **Study Duration for individual participants** |  |
| **Study Specific Abbreviations/ Definitions** |  |

# Objectives

* 1. *Describe the purpose, specific aims, or objectives.*
  2. *State the hypotheses to be tested.*

# Background

* 1. *Describe the relevant prior experience and gaps in current knowledge.*
  2. *Describe any relevant preliminary data.*
  3. *Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.*

# Study Endpoints

* 1. *Describe the primary and secondary study endpoints.*

# Study Intervention

*5.1* *Describe the study intervention that is being evaluated.*

# Procedures Involved

* 1. *Describe and explain the study design. If you have any sub-studies, or retrospective collection of data and/or biospecimens, remember to address them here. If the study design involves placebos, deception, or washout periods, address that here.*
  2. *Provide a description of all research procedures being performed and when they are performed, including procedures being performed to monitor subjects for safety or minimize risks.*
  3. *Describe:*
     + *Procedures performed to lessen the probability or magnitude of risks.*
     + *The source records that will be used to collect data about subjects. (Attach all surveys, scripts, and data collection forms.)*
  4. *What data will be collected during the study and how that data will be obtained.*
* *List of data elements*
* *Surveys, Questionnaires, data collection forms, active or passive internet data collection, verbal responses, interviews, focus groups, audio/video recordings, photographs, educational assessments*
  1. *If there are plans for long-term follow-up (once all research related procedures are complete), what data will be collected during this period.*

# Data and/or Specimen Banking

* 1. *If data and/or specimens will be banked for future use, describe where the specimens will be stored (e.g., VCU or external registry/repository), how long they will be stored, how the data/specimens will be accessed, and who will have access to the data/specimens.*
  2. *List the data to be stored and/or associated with each specimen.*
  3. *Describe the procedures to release data or specimens, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.*
  4. *State whether participants may access their data/specimens for personal use and if so how.*
  5. *State whether participants may withdraw their banked data/specimens from future research use. If yes, explain whether data/specimens from future research use. If yes, explain whether data/specimens would be destroyed or fully anonymized in response to a withdrawal request. If no, explain why (e.g., data/specimens are fully anonymized prior to banking).*

# Sharing of Results with Subjects

* 1. *Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject’s primary care physicians) and if so, describe how the results will be shared.*

# Study Timelines

* 1. *Describe:*
     + *The duration of an individual subject’s participation in the study.*
     + *The duration anticipated to enroll all study subjects.*

# Subject Population

* 1. *Describe generally the individuals that will be included in your study.*
  2. *Describe any subject populations or segment of community that will be specifically targeted, or specifically excluded from your sample.*
  3. *Indicate specifically whether you will include or exclude any of the following special populations: (You may not include members of the below populations as subjects in your research unless you include them in the description of your subject population.)*
     + *Adults unable to consent*
     + *Individuals who are not yet adults (infants, children, teenagers)*
     + *Pregnant women*
     + *Prisoners*

# Vulnerable Populations

* 1. *If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.*
     + *If the research involves pregnant women, review HRP-412 - CHECKLIST - Pregnant Women to ensure that you have provided sufficient information.*
     + *If the research involves neonates of uncertain viability or non-viable neonates, review HRP-413 - CHECKLIST - Non-Viable Neonates or HRP-414 - CHECKLIST - Neonates of Uncertain Viability to ensure that you have provided sufficient information.*
     + *If the research involves prisoners, review HRP-415 - CHECKLIST - Prisoners to ensure that you have provided sufficient information.*
     + *If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research (“children”), review HRP-416 - CHECKLIST - Children to ensure that you have provided sufficient information.*
     + *If the research involves decisionally impaired adults, review HRP-417 - CHECKLIST - Cognitively Impaired Adults to ensure that you have provided sufficient information.*
     + *Check if the research involves any of the following groups:*

☐ *Wards of the State*

☐ *VCU/VCUHS students or trainees*

☐ *VCU/VCU Health System employees*

☐ *Active military personnel*

☐ *Student populations in K-12 educational settings or other learning environments*

☐ *Members of a federally recognized American Indian or Alaska Native tribe*

# Local Number of Subjects

* 1. *Indicate the total number of subjects to be accrued locally, if known. If this is a multi-site study, provide both study-wide accrual goal and the number of participants to be accrued at each participating site.*

# Recruitment Methods

* 1. *Describe when, where, and how potential subjects will be recruited. If applicable, describe procedures for oral or written communication with the prospective subject or legally authorized representative that will be done for purposes of screening, recruiting, or determining eligibility.* *If the study recruitment process is expected to include non-English speaking subjects, describe accommodations such as interpreters.*
  2. *Describe the source of subjects (e.g., community, recruitment registry [specify], health records).*
  3. *Describe the methods that will be used to identify potential subjects, including whether subjects self-identify in response to recruitment material or how contact information is obtained, and who will contact or approach subjects. If applicable, describe procedures for accessing records or stored identifiable biospecimens for purposes of screening, recruiting, or determining eligibility.*
  4. *Describe materials that will be used to recruit subjects, addressing when and how often they will be used. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)*

*Example recruitment materials that should be described and included:*

* *E-mail invitations*
* *Phone solicitation scripts*
* *Flyers, mailed letter or newspaper/TV/radio ads*
* *TelegRAM announcements*
* *website text*
* *study-specific websites*
* *social media*
* *EPIC MyChart Patient Portal research study descriptions*
* *Psychology Research Participant Pool (SONA) study descriptions*
* *Scripts for announcements made to groups*
  1. *Describe the amount and timing of any payments to subjects. See* [*VCU Procurement Services*](https://procurement.vcu.edu/i-want-to/pay-an-individual/compensate-a-research-participant/) *for allowable payment methods.*
* *Explain whether subjects will be reimbursed for out of pocket expenses and/or receive payments related to their participation. Include specific information about the amount, timing and method of disbursement. Provide justification to support that the amount of payment and the disbursement procedures are neither coercive nor present undue influence to participants. Provide the reason for reimbursement.*
* *Confirm that credit for payment will accrue as the study progresses.*
* *Indicate whether there is any bonus paid for completion.*

# Withdrawal of Subjects

* 1. *Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent.*
  2. *Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.*

# Risks to Subjects

* 1. *List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects’ participation in the research. Include as may be useful for the IRB’s consideration, a description of the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks. Describe any impact the study might have on students’ opportunity to learn required educational content. Describe any interventions that may be perceived as offensive or embarrassing.*
  2. *If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.*
  3. *If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.*
  4. *If applicable, describe risks to others who are not subjects.*
  5. *Describe how the study design and any other relevant factors minimize risks of harm or discomfort.*

# Potential Benefits to Subjects

* 1. *Describe the potential benefits that individual subjects may experience from taking part in the research. Include as may be useful for the IRB’s consideration, the probability, magnitude, and duration of the potential benefits.*
  2. *Indicate if there is no direct benefit. Do not include benefits to society or others.*

# Data Management and Confidentiality

* 1. *Describe the data analysis plan, including any statistical procedures or power analysis.*
  2. *Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission.* *If the study will code the research data by replacing subjects’ names and/or other identifiers with assigned subject IDs, describe the following:*
     + *How subject IDs will be generated/assigned (e.g., random, sequential)*
     + *Whether a key will be retained linking subject IDs to identifiers, and if so where the key will be stored, who has access to key, and when key will be destroyed*

*Select all that apply to* ***paper*** *research material:*

☐ *Maintaining control of paper documents at all times, including when at off-campus location*

☐ *Storing paper documents in a secure location accessible only by study team*

☐ *Promptly transcribing, scanning, or abstracting data from paper into electronic platform and destroying the paper copy*

*Select all that apply to* ***electronic*** *research material:*

☐ *Use VCU-approved methods of data storage, transmission, and transfer (see https://dms.vcu.edu)*

☐ *Using individual logins/separate accounts on shared devices*

☐ *Using VCU approved data collection tools and apps (e.g., REDCap, Qualtrics)*

☐ *Consulting with VCU Information Security when using non-VCU approved data collection tools (https://ts.vcu.edu/askit/essential-computing/information-security/)*

*Select all that apply for research* ***biospecimens****:*

☐ *Maintaining control of specimens at all times, including when at off-campus location*

☐ *Storing specimens in a secure location only accessible only by study team*

☐ *Labeling specimens with subject ID or other coded information instead of direct identifiers*

☐ *Final destruction of specimens will be devoid of any identifiable information*

* 1. *Describe any procedures that will be used for quality control of collected data.*
  2. *Describe how data or specimens will be handled study-wide:*
     + *What information will be included in that data or associated with the specimens?*
     + *Where and how data or specimens will be stored?*
     + *How long the data or specimens will be stored?*
     + *Who will have access to the data or specimens?*
     + *Who is responsible for receipt or transmission of the data or specimens?*
     + *How data or specimens will be transported?*
  3. *If you plan to retain screening data collected by phone or other methods for people who decline to participate, describe this, including the rationale for retaining the information and for how long (e.g., end of the study).*

# Provisions to Monitor the Data to Ensure the Safety of Subjects

***This section is required when research involves more than Minimal Risk to subjects.***

* 1. *Describe:*
     + *The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe. The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor. Indicate if this study will have a Data Safety Monitoring Board or a Data Safety Monitoring Plan.*
     + *What data are reviewed, including safety data, untoward events, and efficacy data.*
     + *How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).*
     + *The frequency of data collection, including when safety data collection starts.*
     + *Who will review the data.*
     + *The frequency or periodicity of review of cumulative data.*
     + *The statistical tests for analyzing the safety data to determine whether harm is occurring.*
     + *Any conditions that trigger an immediate suspension of the research.*

# Provisions to Protect the Privacy Interests of Subjects

* 1. *Describe the steps that will be taken to protect subjects’ privacy interests. “Privacy interest” refers to a person’s desire to place limits on whom they interact or whom they provide personal information.*

*Select any of the following that apply:*

☐ *Conducting study activities in locations that maximize privacy*

☐ *Verifying identify before discussing personal information*

☐ *Asking the subject if they are comfortable answering in the location*

☐ *Asking the subject if they are comfortable with others present*

☐ *Offering alternate ways to respond (e.g., pointing, writing)*

☐ *Using generic signs on research rooms and spaces*

☐ *Some questions may be skipped*

☐ *Using Study IDs instead of direct identifiers*

☐ *Using mailing techniques that do not include study name or identifiers*

☐ *Working only in locations the study team can ensure privacy*

☐ *Storing study material in locations restricted to study team access*

☐ *Obtaining explicit parental permission before sharing photos/recordings of children*

* 1. *Describe what steps you will take to make the subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. “At ease” does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures.*
  2. *Indicate how the research team is permitted to access any sources of information about the subjects.*
  3. *Select all identifiers that will be collected at any time as part of this study (including for recruitment, data gathering, data analysis, etc.), even if the data will eventually be anonymized:*

☐ *Names*

☐ *Geographic Locators Below State Level*

☐ *Social Security Numbers*

☐ *Dates (year alone is not an identifier)*

☐ *Ages over 89 (age under 89 is not an identifier)*

☐ *Phone Numbers*

☐ *Facsimile Numbers*

☐ *E-mail Addresses*

☐ *Medical Record Numbers*

☐ *Device Identifiers*

☐ *Biometric Identifiers*

☐ *Web URLs*

☐ *IP Addresses*

☐ *Account Numbers*

☐ *Health Plan Numbers*

☐ *Full Face Photos or Comparable Images*

☐ *License/Certification Numbers*

☐ *Vehicle ID Numbers*

☐ *Other Unique Identifier*

☐ *No Identifiers*

☐ *Employee V#*

# Compensation for Research-Related Injury

* 1. *If the research involves more than Minimal Risk to subjects, describe the available compensation in the event of research related injury.*
  2. *For industry funded studies only, provide a memo from Division of Sponsored Program approving the consent form language for compensation for research-related injury. For all other funding sources, the template language from**HRP-502 should be utilized in the consent form.*

# Economic Burden to Subjects

* 1. *Describe any costs that subjects may be responsible for because of participation in the research.*

# Consent Process

* 1. *Indicate whether you will you be obtaining consent, and if so describe (describe for different groups if multiple):*
     + *Who will obtain informed consent*
     + *Where will the consent process take place.*
     + *How the consent process will be conducted (e.g., electronic, face-to-face, phone or video). If electronic, describe platform.*
     + *Any process to ensure ongoing consent.*
     + *Whether you will be following HRP-090 - SOP - Informed Consent Process for Research. If not, describe:*
       - *The role of the individuals listed in the application as being involved in the consent process.*
       - *The time that will be devoted to the consent discussion.*
       - *Steps that will be taken to minimize the possibility of coercion or undue influence.*
       - *Steps that will be taken to ensure the subject’s understanding.*

***Non-English Speaking Subjects***

* + - *Indicate what language(s) other than English are understood by prospective subjects or representatives.*
    - *If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate the language that will be used by those obtaining consent.*

***Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)***

* + - *Review HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process to ensure you have provided sufficient information for the IRB to make these determinations. Describe whether you are requesting to waive some elements of consent (describe which ones), or all elements of consent. Provide justification.*
    - *If the research involves deception, describe whether subjects prospectively authorize the deception and plans for de-briefing subjects.*

***Subjects who are not yet adults (infants, children, teenagers)***

* + - *Describe the criteria that will be used to determine whether a prospective subject has not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted. (E.g., individuals under the age of 18 years.)*
      * *For research conducted in the state, review HRP-013 - SOP - LARs, Children, and Guardians to be aware of which individuals in the state meet the definition of “children.”*
      * *For research conducted outside of the state, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of “children” in HRP-013 - SOP - LARs, Children, and Guardians.*
    - *Describe whether parental permission will be obtained from:*
      * *Both parents 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.*
      * *One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.*
    - *Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals’ authority to consent to each child’s general medical care.*
    - *Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent. If not obtaining assent, include justification.*
    - *When assent of children is obtained describe whether and how it will be documented.*

***Cognitively Impaired Adults***

* + - *Describe the process to determine whether an individual is capable of consent or assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require cognitively impaired adults to sign assent documents.*

***Adults Unable to Consent***

* + - *List the individuals from whom permission will be obtained in order of priority. (E.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child.)*
      * *For research conducted in the state, review HRP-013 - SOP - LARs, Children, and Guardians to be aware of which individuals in the state meet the definition of “legally authorized representative.”*
      * *For research conducted outside of the state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of “legally authorized representative” in HRP-013 - SOP - LARs, Children, and Guardians.*
    - *Describe the process for assent of the subjects. Indicate whether:*
      * *Assent will be required of all, some, or none of the subjects. If some, indicated, which subjects will be required to assent and which will not.*
      * *If assent will not be obtained from some or all subjects, an explanation of why not.*
      * *Describe whether assent of the subjects will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require subjects to sign assent documents.*

# Process to Document Consent in Writing

* 1. *Describe whether and how consent of the subject will be documented in writing.*
  2. *If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent.*
  3. *(If you will document consent in writing, attach a consent document. If you will obtain consent, but not document consent in writing, attach a consent script. Review HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent to ensure that you have provided sufficient information. You may use HRP-502 - TEMPLATE CONSENT DOCUMENT to create the consent document or script.)*

# Setting

* 1. *Describe the sites or locations where your research team will conduct the research.*
     + *Identify where your research team will identify and recruit potential subjects.*
     + *Identify where research procedures will be performed.*
     + *Describe the composition and involvement of any community advisory board.*
     + *For research conducted outside of the organization and its affiliates describe:*
       - *Site-specific regulations or customs affecting the research for research outside the organization.*
       - *Local scientific and ethical review structure outside the organization.*

# Resources Available

* 1. *Describe the resources available to conduct the research: For example, as appropriate:*
     + *Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?*
     + *Describe the time that you will devote to conducting and completing the research.*
     + *Describe your facilities.*
     + *Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated consequence of the human research.*
     + *Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.*

# Multi-Site Research

(Delete this section if this is not a Multi-Site Research Study.)

* 1. *Study-Wide Number of Subjects*

*If this is a multicenter study, indicate the total number of subjects to be accrued across all sites.*

* 1. *Study-Wide Recruitment Methods*
     + *If this is a multicenter study and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) describe those methods. Local recruitment methods are described later in the protocol.*
     + *Describe when, where, and how potential subjects will be recruited.*
     + *Describe the methods that will be used to identify potential subjects.*
     + *Describe materials that will be used to recruit subjects. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)*
     + *If this is a multi-site study where you are the lead investigator, describe the processes to ensure communication among sites. See HRP-830 - WORKSHEET - Communication and Responsibilities. All sites have the most current version of the protocol, consent document, and HIPAA authorization.*
     + *All required approvals (initial, continuing review and modifications) have been obtained at each site (including approval by the site’s IRB of record).*
     + *All modifications have been communicated to sites and approved (including approval by the site’s IRB of record) before the modification is implemented.*
     + *All engaged participating sites will safeguard data, including secure transmission of data, as required by local information security policies.*
     + *All local site investigators conduct the study in accordance with applicable federal regulations and local laws.*
     + *All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.*
  2. *Describe the method for communicating to engaged participating sites (see HRP-830 - WORKSHEET - Communication and Responsibilities):*
     + *Problems (inclusive of reportable events).*
     + *Interim results.*
     + *The closure of a study*
  3. *If this is a multicenter study where you are a participating site/investigator, describe the local procedures for maintenance of confidentiality. (See HRP-830 - WORKSHEET - Communication and Responsibilities.)*
     + *Where and how data or specimens will be stored locally?*
     + *How long the data or specimens will be stored locally?*
     + *Who will have access to the data or specimens locally?*
     + *Who is responsible for receipt or transmission of the data or specimens locally?*
     + *How data and specimens will be transported locally?*

1. This template satisfies AAHRPP elements 1.7.B, I.8.B, I-9, II.2. A, II.2.I, II.3.A, II.3.B, II.3.C-II.3.C.1, II.3.D-F, II.4.A, III.1.C-F, II.2.D [↑](#footnote-ref-1)