The purpose of a research protocol is to document your research question(s) and describe how you will address it. Documenting your research plan will help you articulate the necessary steps for a reproducible and replicable study. This protocol template has been designed to guide researchers through ethical and methodologic considerations in developing a research plan. It will be useful in developing research output such as theses, dissertations, presentations, and journal articles. It will help ensure that you are developing and designing an ethically sound and scientifically valid study. Additional resources are available in the [resource](https://www.research.vt.edu/sirc/hrpp/resources.html) section of the Human Research Protection Program website. The [Tips](https://www.research.vt.edu/sirc/hrpp/resources/templates.html) document provides additional details for each section along with helpful tips.

**INSTRUCTIONS:**

* Use this “TEMPLATE PROTOCOL (HRP-503a)” to prepare a study protocol outlining your research plan for research that only involves **surveys, questionnaires, focus groups, or educational tests**. Do not use for intervention, observational, or biomedical/clinical research.
* If your research involves minors, please, contact the human research protection program at irb@vt.edu to discuss your research plans to ensure you are using the correct template, as there are specific federal requirements for research with minors.
* Depending on the nature of your study, some sections and subsections might not be applicable to your research. If so, simply indicate “N/A.”
* Once the IRB or HRPP approves your submission, your approved version of the protocol will be stored in the IRB Protocol Management online system.
* If your research plan changes, you might need to modify your protocol and submit an amendment. Please review our guidance on amendments for exempt research the [Exempt Guidance for Amendments in PM](https://www.research.vt.edu/sirc/hrpp/resources/guides.html) to determine if an amendment is required.
	+ If an amendment is required, please submit an amendment to Protocol Management with the requested modifications. Download your current protocol from Protocol Management and indicate the changes/revisions using the track changes feature to make review of the modifications easier to follow. If you are unable to use track changes, please create a new paragraph wherever you need to make a change and indicate “Amendment: Date.” Protocol Management will store the older versions of your protocol if the IRB or HRPP need to compare them during the review.

**PROTOCOL TITLE:**

Include the full protocol title.

Click here to provide a response.

**PROTOCOL NUMBER:**

Include the number assigned in Protocol Management (verify this has been added before submitting the protocol to HRPP).

Click here to provide a response.

**PRINCIPAL INVESTIGATOR:**

Full Name and Degrees: Click here to provide a response.

Department: Click here to provide a response.

Telephone number: Click here to provide a response.

Email address: Click here to provide a response.

**FUNDING:**

Sponsor(s): Click here to provide a response.

Funded or in the proposal phase? Click here to provide a response.

Is Virginia Tech the primary awardee or the coordinating center for the funding? If not, list the primary institution: Click here to provide a response.

**VERSION NUMBER/DATE:**

Include the version number and date of this protocol. Versions should start at 1.0.

Click here to provide a response.

**REVISION HISTORY:**

Use this table to keep track of changes.Add more rows as needed.

|  |  |  |  |
| --- | --- | --- | --- |
| **Revision #** | **Version Date** | **Brief Summary of Changes (i.e., the different sections)** | **Consent Change?** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**Table of Contents**

[1.0 Study Summary 4](#_Toc82686689)

[2.0 Objectives 4](#_Toc82686690)

[3.0 Background 4](#_Toc82686691)

[4.0 Statistical Analysis Plan 4](#_Toc82686692)

[5.0 Procedures Involved 5](#_Toc82686693)

[6.0 Participant Population 7](#_Toc82686694)

[7.0 Recruitment Methods 8](#_Toc82686695)

[8.0 Risks to Participants 9](#_Toc82686696)

[9.0 Potential Benefits to Participants 9](#_Toc82686697)

[10.0 Data Management and Confidentiality 10](#_Toc82686698)

[11.0 Provisions to Protect the Privacy Interests of Participants 11](#_Toc82686699)

[12.0 Consent Process 12](#_Toc82686700)

# Study Summary

|  |  |
| --- | --- |
| **Study Title** |  |
| **Primary Objective** | The primary outcome or goal of your research |
| **Secondary Objective(s)** | The secondary outcome(s) or goal(s) of your research  |
| **Study Population** | To whom will you be generalizing your findings? |
| **Sample Size** | How many people will you recruit for your study? |
| **Research Design**  | Survey, questionnaire, focus groups, or educational tests  |
| **Analytic Approach** | Qualitative, quantitative, or mixed methods |
| **Acronyms and Definitions**  |  |

# Objectives

* 1. Describe the purpose, specific aims, and objectives of this study.

Click here to provide a response.

* 1. State the hypotheses to be tested.

Click here to provide a response.

# Background

* 1. Summarize published (or available unpublished) literature to build a rational for the research question(s), study objectives, and research design. If none are available, include a statement that there is no available research data. This section must provide a justification for the conduct of this study based on existing knowledge and should include your research question.

 Click here to provide a response.

# Statistical Analysis Plan

* 1. Describe the statistical methods that will be used to analyze the data you collect.

 Click here to provide a response.

# Procedures Involved

* 1. Provide a description of:
		+ All research procedures being performed. Start with recruitment and end with when participation is complete.
		+ Include the estimated duration of participant’s participation (i.e., how long will it take participants to complete survey(s), questionnaire(s), focus group(s), or educational test(s)?).
		+ If the research involves deception include a justification (why it is necessary) and describe the debriefing process. You will need to request and justify an alteration of the consent process in section 12.2.

 Click here to provide a response.

Please select the methods that you will use to collect data about participants. Upload all data collection forms to Protocol Management.

|  |  |
| --- | --- |
| [ ]  | Screening questionnaire(s) |
| [ ]  | Survey(s), including online survey(s) |
| [ ]  | Demographic questionnaire(s) |
| [ ]  | Interview guide(s) or question(s) |
| [ ]  | Focus group(s) |
| [ ]  | Other, please specify**:** Click here to provide a response. |

* 1. What data will you collect during the study and how you will obtain them? Please include the name of the software and descriptions of electronic data collection, database matching, and app- or device-based data collection. If third party software will be used, please provide the name of the software, and indicate if you have confirmed that the software has been approved for use (see [https://vt.cobblestone.software/public/).](https://vt.cobblestone.software/public/)

Click here to provide a response.

* 1. Will your research involve any audio and/or video recordings?

[ ]  Yes, respond to question 5.4

[ ]  No, skip to question 5.5

* 1. Who will transcribe or code audio and/or video recordings? If third party software will be used, please provide the name of the software, and indicate if you have confirmed that the software has been approved for use (see <https://vt.cobblestone.software/public/>).

Click here to provide a response.

* 1. Please select the identifiers you will obtain (whether directly from participants or from another source). The collection of social security numbers, student records, including grades and assignments, may require approval from Virginia Tech data stewards prior to use. Please contact the Privacy and Data Protection Program at prdp@vt.edu for information on additional approvals*.*

|  |  |
| --- | --- |
| [ ]  | Name |
| [ ]  | Geographical subdivisions smaller than a state, including street address, city, county, precinct, zip code, and equivalent geocodes (note, the initial three digits of a zip code are not considered identifiable) |
| [ ]  | Elements of dates (except year) directly related to an individual, including birth date, admission date, discharge date, date of death, and single year of age over 89 and all elements of dates (including year) indicative of such age (note, such ages and elements may be aggregated into a single category of age 90+) |
| [ ]  | Phone numbers |
| [ ]  | Fax numbers |
| [ ]  | Electronic mail addresses (e-mail) |
| [ ]  | Social Security numbers |
| [ ]  | Medical record numbers |
| [ ]  | Health plan beneficiary numbers |
| [ ]  | Account numbers |
| [ ]  | Certificate/license numbers |
| [ ]  | Vehicle identifiers and serial numbers, including license plate numbers |
| [ ]  | Device identifiers and serial numbers |
| [ ]  | Web Universal Resource Locators (URLs) |
| [ ]  | Internet protocol (IP) address numbers |
| [ ]  | Biometric identifiers, including finger and voice prints (audio recording) |
| [ ]  | Full face photographic images and any comparable images (including video recording) |
| [ ]  | Student record number or identification number  |
| [ ]  | Student grades or classroom assignments |
| [ ]  | Username for online or computer accounts |
| [ ]  | Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data)**:** Click here to provide a response. |

# Participant Population

* 1. Provide a general description of the individuals who will be included in your study (e.g., Virginia Tech undergraduate students, a national sample of adults with engineering degrees) and how you will screen them for eligibility.

Click here to provide a response.

* 1. Provide the geographic location of where you will recruit participants (e.g., New River Valley; Blacksburg, VA; Paris, France).

Click here to provide a response.

* 1. Describe any populations or groups that you will target for inclusion in or exclusion from your sample. Please indicate why these groups have been selected and how your participant selection is equitable.

Click here to provide a response.

* 1. Will your research involve individuals who are vulnerable (pregnant women, minors, prisoners, adults with decisional impairment, students, and individuals who are economically or socially disadvantaged)? Pregnant women should be included in minimal risk studies that pose no risk to the woman or fetus.

[ ]  Yes, respond to question 6.5

[ ]  No, skip to question 6.6

* 1. Please specify which vulnerable populations you are including and provide justification for including these individuals. Describe additional safeguards you will include to protect their rights and welfare.

Click here to provide a response.

* 1. Indicate the total number of participants to be enrolled and how this number was determined (e.g., sample size calculation [show], number of available participants in a finite pool, number of tests funding award would allow).

 Click here to provide a response.

# Recruitment Methods

* 1. Describe when, where, and how you will recruit potential participants. If recruitment will be online, include the name(s) of participant management system (e.g., Ripple), the social media platform or online forums that you will use, include web address and contact information (for example MTURK, Facebook, Twitter, or Reddit). If recruitment will be in person include the specific location(s) (e.g., students in the library, community members at a gathering, or members of a local gym) and the methods that you will use to identify potential participants.

Click here to provide a response.

* 1. Describe materials that you will be used to recruit participants. Use the Worksheet on Advertisements [HRP 315.1](https://www.research.vt.edu/content/dam/research_vt_edu/hrpp/files/worksheets/hrp-315-worksheet-advertisements.docx) as a guide. Attach final copies of these documents with this protocol in Protocol Management and be sure to include the IRB protocol number on each document.
* For flyers, attach the final copy of printed flyers.
* For Virginia Tech News, Facebook postings and ads, newspaper ads, websites, MTurk/SONA/online survey systems, etc.
* For email recruitments, please include the subject line as well as the text.
* For advertisements meant for audio or video broadcast, please submit the wording of the advertisement prior to taping (to avoid having to re-record with approved language) and submit the final recorded version for IRB review before use.
* Describe any payment to participants. Please review [HRP 092.1](https://www.research.vt.edu/content/dam/research_vt_edu/hrpp/files/sops/sop-hrpp-092.1-payments-to-research-participants.pdf) *Payment to Research Participants* to ensure you are following the most recent guidance. Separate payments into appropriate categories, such as reimbursement for expenses, time and effort, and additional incentives for study participation. For each category, specify the amount (including any pro-rated amount), schedule, and method of payment.

Click here to provide a response.

# Risks to Participants

* 1. List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the participants related to their’ participation in the research. Include a description of the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, privacy, reputational, and economic risks. **Do not indicate “no risk” or “N/A.”** Instead, for studies with very low risk (e.g., anonymous online survey on a mundane topic) indicate “The investigators are not aware of any risks from participation in this study.” or “No more than risks that are found in everyday life.” Common risk types include:
* Psychological (e.g., potential for stress, discomfort, and/or embarrassment)
* Social (e.g., potential for discrimination or stigmatization and disruption of personal and family relationships)
* Legal (e.g., potential for disclosure of illegal activity, negligence)
* Privacy (e.g., potential for personal information being accessed, used, or disclosed without the participants’ knowledge or consent, breach of confidentiality/security)
* Reputational (e.g., loss of stature in the community, in business, or negative media coverage)
* Economic (e.g., potential for individuals to lose access to economic services, employment, insurability)

Click here to provide a response.

* 1. Describe procedures or safeguards intended to reduce the probability and magnitude of risks.

Click here to provide a response.

* 1. If applicable, describe risks to others who are not participants (e.g., mandatory reporting of abuse, unflattering results generalized to identifiable or vulnerable communities):

Click here to provide a response.

# Potential Benefits to Participants

* 1. Describe the potential benefits individual participants might experience from participating in the research. Include the probability, magnitude, and duration of the potential benefits. Do not include benefits to society or others. Do not list monetary or non-monetary compensation for participation, as this is not a benefit. If there are no anticipated direct benefits for participants, please state that below.

Click here to provide a response.

# Data Management and Confidentiality

* 1. Describe procedures that you will use to ensure the validity of collected data.
* How will you prevent the data from being inadvertently changed?
* How will data be accessed by the study team?
* How will you prevent those not on the study team from accessing the information?
* How will you back up your data to protect them from loss?
* How will you ensure that all copies of the data will remain at Virginia Tech when there is a change in study personnel?

Click here to provide a response.

* 1. From the list below check all the processes you will use to handle and secure study data during collection, storage, use, and transmission. Describe the process in the text field. Keep in mind that data is owned by Virginia Tech and must be stored on the university’s resources. Helpful resources are available on the Privacy and Research Data Protection Program [website](https://www.research.vt.edu/sirc/prdp/resources.html). Include information about:

[ ]  Training of study staff

[ ]  Authorization of access

[ ]  Password protection

[ ]  Encryption

[ ]  Physical controls

[ ]  Separation of identifiers and data

[ ]  Equipment or devices data to be used to collect or store data

[ ]  Other, specify below

Click here to provide a response.

* 1. Do you plan to store data online or in the cloud?

[ ]  Yes, respond to question 10.4

[ ]  No, skip to question 10.5

* 1. Please indicate the location of storage and any software used to access or input data. Please ensure that the data storage and software have been approved for use for Virginia Tech. You can review the list of approved software and data storage services at <https://vt.cobblestone.software/public/>. If you need assistance determining an appropriate location for your data or confirming software or storage have been approved, please contact the Privacy and Research Data Protection Program at prdp@vt.edu.

Click here to provide a response.

* 1. Does your research involve collaborators from other institutions or organizations?

[ ]  Yes, respond to question 10.6

[ ]  No, skip to question 10.7

* 1. For collaborative projects, describe how data will be handled and secured. If a central storage mechanism will be used, please indicate which institution is hosting the data:

Click here to provide a response.

* 1. Describe the plan for data disposition following the conclusion of the study (e.g., long-term archive of data, data destruction).
		+ How long will the data be stored?
		+ Where and how data will be stored?
		+ What information will be included in the long-term storage of data?
		+ When and how will personal identifiers be destroyed?
		+ Who will have access to the data during long term storage?
		+ Will you make the data available through a public or curated archive? Are you obligated to do so by a sponsor/grant agreement?

Click here to provide a response.

# Provisions to Protect the Privacy Interests of Participants

* 1. Describe the steps that you will take to protect participants’ privacy interests. “Privacy interest” refers to a person’s desire to place limits on with whom they interact or to whom they provide personal information (e.g., collecting the minimal amount of private information required to complete the study, protecting the data once it is obtained, obtaining a Certificate of Confidentiality).

Click here to provide a response.

* 1. Describe steps that you will take to make participants feel at ease with the research situation in terms of the questions being asked. “At ease” does not refer to physical discomfort, but the sense of intrusiveness a participant might experience in response to questions, making it clear on surveys that participants can discontinue at any time, not asking questions about private or sensitive issues unless necessary for the research.

Click here to provide a response.

* 1. Describe any required reporting that might occur because of your research questions, study populations, and data collection methods. Examples of required reporting in the Commonwealth of Virginia and Virginia Tech include:
	+ **Any** suspicions (e.g., circumstantial, disclosed) of child abuse (physical, emotional, sexual) and neglect
	+ Sexual discrimination and/or sexual violence that involves a student
	+ Disclosure or signs of intention to harm oneself (i.e., suicidal ideation and/or plan)
	+ Disclosure or signs of desire to harm others (i.e., homicidal ideation and/or plan)
	+ Suspected abuse, neglect, or exploitation of vulnerable adults (e.g., individuals with a disability, elderly persons)

Click here to provide a response.

# Consent Process

* 1. Indicate the process by which you will inform participants about the study and determine their voluntary decision to participate. If consent is implied that process should be described here. Please upload the information sheet and scripts referenced in this section to Protocol Management.

Click here to provide a response.

* 1. Does your research involve Non-English speaking participants?

[ ]  Yes, respond to question 12.3

[ ]  No, skip to question 12.4

* 1. Indicate what language(s) other than English are understood by prospective participants or representative and describe the process you will use to ensure that the information will be provided in a language that they understand.

Click here to provide a response.

* 1. Does your research involve participants who are not yet adults (minors: infants, children, teenagers)?

[ ]  Yes, respond to question 12.5

[ ]  No, skip to question 12.6

* 1. Describe the criteria that you will use to determine 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., in Virginia, individuals under the age of 18 years). Make sure you include the appropriate consent or assent template. If you are unsure which one to include contact the HRPP at irb@vt.edu. The inclusion of children includes some restrictions and additional information might be needed.
* For research conducted in Virginia, review “SOP: Legally Authorized Representatives, Minors, and Guardians ([HRP-013](https://www.research.vt.edu/content/dam/research_vt_edu/hrpp/files/sops/sop-hrpp-013.1-lars-minors-and-guardians.pdf))” to determine which individuals in the state meet the definition of “minor.”
* For research conducted outside of the Virginia, please describe the legal requirements for that state’s or locality’s definition of “minor.”

Describe the process for obtaining parental permission. Federal requirements state that:

* Permission from one parent is acceptable for studies that involve no greater than minimal risk OR involve greater than minimal risk but present the prospect of direct benefit to the minor participant.
* Permission from both parents is required in all other cases (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 minor).

Describe whether you will obtain permission from individuals other than parents or legally authorized representatives, and if so, who will be allowed to provide permission. Describe the process you will use to determine these individuals’ authority to consent to the minor’s general medical care.

* Indicate whether you will obtain assent from all, some, or none of the minors. If you will obtain assent from some minors, indicate which minorswill be required to assent. Consider chronological age and intellectual capacity when determining who will be required to provide assent (e.g., infants are unable to assent, while teenagers are likely able to read and sign an assent form).
* When assent of minors is obtained, describe whether and how you will document it. Will minors sign an assent form or give verbal assent?

Click here to provide a response.

* 1. For research that involves deception describe how the study meets all of the following criteria for an alteration of the consent process:
* The research involves no more than minimal risk to the subjects
* The alteration will not adversely affect the rights and welfare of the subjects
* The research could not practicably be carried out without the alteration/deception
* (Optional but encouraged in most cases) Subjects will be provided with additional pertinent information after participation (i.e., debriefing for studies involving deception)

Click here to provide a response.