***Tip:*** *The protocol number will be assigned automatically if you download the form from within IRB Protocol Management system.*

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.

**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](mailto: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.

***Rationale:*** *Allows for matching of study-related documents*

***Tip:*** *Should match what is listed in IRB Protocol Management*

***Don't be intimidated by the length of this form - much of it is explanatory notes!***

**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.

***Rationale:*** *Allows for matching of study-related documents*

***Tip:*** *Should match what is listed in IRB Protocol Management and in the header of this document*

**PRINCIPAL INVESTIGATOR:**

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

***Common error:*** *Listing a student (students cannot be PIs)*

***Rationale:*** *To approve the protocol, the IRB must ensure that the PI has the expertise to conduct the study (also includes reviewing the PI’s CV uploaded to IRB Protocol Management)*

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.

***Common error:*** *Leaving this blank when funding is reported elsewhere in IRB Protocol Management or supporting materials*

***Tip:*** *If no external funding will support this project, indicate “N/A”*

***Rationale:*** *To approve the protocol, the IRB must ensure that adequate resources exist to complete the study. OSP and HRPP must coordinate approvals for the release of funds.*

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.

***Tip:*** *This item and the revision history table are for version control and ensuring that the most current version of the protocol is being reviewed. In addition, this allows documentation of changes since the last submission.*

**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?** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

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# Study Summary

|  |  |
| --- | --- |
| **Study Title** | ***Common errors:*** *Leaving the table blank; providing inconsistent information in the table compared with the rest of the protocol*  ***Rationale:*** *Provides a quick overview for the pre-*  *review process* |
| **Primary Objective** | The primary outcome or goal of your research |
| **Secondary Objective(s)** | The secondary outcome(s) or goal(s) of your research  ***Tip:*** *If none, indicate “N/A”* |
| **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.

***Common errors:*** *Leaving blank; providing a non-specific or incomplete answer*

***Tip:*** *Your response should answer the question, “What are you trying to learn by doing this study?”*

***Rationale:*** *The IRB must ensure that the research design is appropriate for the questions of interest in order to minimize risks to participants to the extent possible by using sound research design. The research design should not unnecessarily expose subjects to risk.*

* 1. State the hypotheses to be tested.

Click here to provide a response.

***Tip:*** *For descriptive studies, indicate that there are no hypotheses being tested (i.e., “N/A”). For studies comparing groups or outcomes, state what you are testing (e.g., difference between groups; that people’s perceptions of a topic vary by age or other demographic factors).*

***Rationale:*** *The IRB must ensure that the research design is appropriate for the questions of interest in order to minimize risks to participants to the extent possible by using sound research design. Research design does not unnecessarily expose subjects to risk.*

# Background

***Common errors:*** *Leaving blank; providing a non-specific or incomplete answer. It is okay to cite references where appropriate. It is okay to indicate that there is no relevant prior research (though this would be rare).*

***Rationale:*** *Required to assess ethical criteria: 1) Risks to subjects are minimized to the extent possible by using sound research design. Research design does not unnecessarily expose subjects to risk (it is unethical to put subjects at even minimal risk to answer a question that has already been settled). 2) Risks to subjects are reasonable relative to anticipated benefits (if any) to subjects and to the importance of the knowledge that is reasonably expected to result from the research.*

* 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.

***Tip:*** *A concise summary about what is known and not known about the topic and how your research will help fill in that knowledge is important for all research projects.*

***Tip****: If you have preliminary data, please describe its origin and content, including any connection to previously reviewed IRB protocols. If none, indicate “N/A.”*

***Tip****: Think of this as the answer to the questions, “Why are you doing this project? What will your findings add to the knowledge in this area?”*

# Statistical Analysis Plan

***Common errors:*** *Leaving blank; providing a non-specific or incomplete answer*

***Rationale:*** *Required to assess ethical criteria: Risks to subjects are minimized to the extent possible by using sound research design*

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

Click here to provide a response.

***Tip****: This should be a high-level description of the study design and analytic approach.*

***Tip****: If you are unsure of what to describe here, please consult a statistician or data analyst who can help you determine the appropriate analyses for your research question and data collected.*

# Procedures Involved

***Common errors:*** *Leaving blank; providing a non-specific or incomplete answer*

***Rationale:*** *Required to assess ethical criterion: Risks to subjects are minimized to the extent possible by using sound research design.*

* 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.

***Tip:*** *This section should be consistent with the research design. Provide sufficient details to explain why this study design is the best for your study question. Deception in research is rare and must be robustly justified. Think carefully about whether the proposed deception is absolutely necessary. Deception can vary from incomplete disclosure of study purpose to the use of an undisclosed research intervention*

***Rationale:*** *Required to assess several approval and ethical criteria, including: 1) Risks to subjects are minimized to the extent possible by using sound research design; 2) there are adequate privacy protections for participants, including maintaining confidentiality of data; 3) additional safeguards included in the study to protect the rights and welfare of subjects vulnerable to coercion or undue influence; 4) participants are provided with an information sheet or an informed consent document, if appropriate; 5)if applicable, informed consent will be sought from each prospective subject or the subject’s legally authorized representative and appropriately documented or appropriately waived.*

***Tip:*** *This section is the heart of the protocol. It should describe everything participants are expected to do and all steps in the process. Begin with recruitment, end with when participation is complete. If studying more than one group, be clear about what each group will do. Include amount of time for various study-related tasks. This should be complete enough that it can be used by study team members as guidance to ensure consistency among participants and research staff.*

***Bonus tip:*** *This section should be as long as needed to explain clearly and comprehensively what your research activities entail. It will serve as the start of your study standard operating procedures (SOPs).*

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. |

***Tip:*** *The content from these forms should not be inserted here. The forms should be uploaded in Protocol Management.*

* 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/>).

Click here to provide a response.

***Rationale:*** *Required to assess approval criterion: There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.*

***Tip:*** *There should always be an answer here.*

* 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.

***Rationale:*** *Used to ensure that any engaged researchers are included as project personnel. “Engaged” researchers are those who interact or intervene with human subjects or identifiable data. Transcriptionists who only transcribe audio or video recordings as a service and are not otherwise engaged in the research do not need to be listed in the personnel or collaboration sections.*

***Tip:*** *If audio and video recordings are checked in section 5.4, there should be an answer here. If you are not recording or are not transcribing recordings, state N/A.*

* 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](mailto: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

***Rationale:*** *Required to assess ethical criterion: Selection of subjects is equitable. (Consider the involvement of vulnerable subjects, selection criteria, as well as enrollment, procedures.)*

* 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.

***Tip:*** *Describe how you will determine if potential subjects are eligible to participate in your study. For example, if participants must be 18 years of age or older, how will you determine that (for minimal risk studies, this could be simply self-report on a screening question before consent)?*

***Bonus tip:*** *If you are planning to enroll Virginia Tech students, please see* [*Guidance for Researchers using Student Data or Students as Research Participants*](https://www.research.vt.edu/content/dam/research_vt_edu/hrpp/files/guides/guidance-for-conducting-research-with-students.pdf)*.*

* 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.

***Tip:***  *Be specific. If you will recruit online, you should include the reach (e.g., U.S. only or international).*

* 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.

***Rationale:*** *The IRB must assess whether the burdens and benefits of the research are equitable to ensure that people who happen to be in close proximity or easily accessible are not overused in research, especially when the benefits of the research will not apply to them.*

* 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.

***Common error:*** *Not reviewing this list carefully and neglecting to provide a response appropriate for your population*

***Rationale:*** *Required to assess approval and ethical criterion: Additional safeguards have been included in the study to protect the rights and welfare of subjects vulnerable to coercion or undue influence.*

***Tip:*** *Minors: If you do not plan to include minors, please include an age criterion in section 6.1. If you are using this template, it is likely you will exclude minors. If your research does involve minors make sure to include the appropriate consent or assent template. If you are unsure which one to include contact the Human Research Protection Program at* [*irb@vt.edu*](mailto:irb@vt.edu)*.*

***Bonus tip:*** *Pregnancy: Women who are pregnant or of childbearing age can be included in most studies at Virginia Tech. If your study involves only surveys, interviews, or focus groups, there should be no reason to exclude pregnant women. Any exclusion of pregnant women from minimal risk studies should be justified.*

* 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.

***Common error:*** *Indicating that you do not yet know how many subjects you will enroll in your study. To begin your study, you must know how many subjects you need to adequately examine your research question.*

***Rationale:*** *Required to assess ethical criterion: Risks to subjects are minimized to the extent possible by using sound research design.*

***Tip:*** *You must provide an answer to this question before your protocol can be reviewed. If your study involves multiple procedures (with different populations) or multiple populations (with the same procedures), please indicate the number of subjects you will enroll for each.*

# Recruitment Methods

***Common errors:*** *Leaving blank or providing incomplete or vague answers*

***Rationale:*** *Required to assess ethical criterion: Selection of subjects is equitable. (Consider the purpose and setting of the research and recruitment, enrollment, and payment procedures.)*

* 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.

***Tip:*** *This must always be answered. Be specific. If you will be working within a certain school district, name the district (not just a rural school system in Southwest Virginia).*

* 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.

***Common errors:*** *Attaching items titled Sample Flyer, Example Email, Draft Recruitment Script instead of the final versions.*

***Tip:*** *This question must always be answered. Be specific. Include the FINAL copies of recruitment materialsInclude the contents of the “subject line” for email recruitment materials.*

***Bonus tip:*** *In your recruitment materials, avoid overemphasizing compensation (e.g., different font, larger font, bold font, exclamation points). Do not refer to a raffle, sweepstakes, or winning. Use "drawing" and "selected." Include the odds of being selected. For example, "All participants will be eligible for a drawing for a $50 Amazon gift card. The odds of being selected are 1 in 50 because we plan to enroll 50 participants." Please see our* [*Flyer Template*](https://www.research.vt.edu/content/dam/research_vt_edu/hrpp/files/templates/vt_flyer_template.docx) *and our* [*SOP – Payment to Research Participants*](https://www.research.vt.edu/content/dam/research_vt_edu/hrpp/files/sops/sop-hrpp-092.1-payments-to-research-participants.pdf)*.*

# Risks to Participants

***Common error:*** *Indicating “N/A” or stating that the study has no risk.*

***Rationale:*** *Required to assess ethical criteria: 1) Risks to subjects are minimized by using procedures, which are consistent with sound research design and which do not unnecessarily expose subjects to risk; 2) risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.*

* 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.

***Tip:*** *Review the explanatory materials above and address them completely. Research that involves some of these risks might require additional information.*

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

Click here to provide a response.

***Common errors:*** *Leaving blank because you think that there are no risks*

***Rationale:*** *Required to assess ethical criterion: Risks to subjects are minimized to the extent possible by using sound research design.*

***Tip:*** *There should always be an answer here. It is possible as a minimal risk study that the only risk involved is to confidentiality and/or privacy, but there should be safeguards in place for any risk.*

***Bonus tip:*** *For surveys, questionnaires, focus groups, and educational tests that do not contain any sensitive information that would put participants at financial, social, psychological, or other risk, it is sufficient to state that participation is voluntary, participants are not required to participate, and individuals can stop participating without negative consequences. These safeguards ensure participant autonomy by eliminating the risk of pressure or coercion from the research team.*

* 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.

***Rationale:*** *Required to assess ethical criteria: 1) Risks to subjects are minimized to the extent possible by using sound research design; 2) risks are reasonable given potential benefits and knowledge gained.*

***Tip:*** *If there are no risks to others, indicate “N/A.”*

# Potential Benefits to Participants

***Common Errors:*** *Mentioning compensation as a benefit or outlining benefits to society. Compensation is not considered a study benefit. The regulations prohibit the IRB from considering broad benefits to society in the risk:benefit analysis for individual participants, although the IRB does use these broad societal benefits when considering whether the study risks and study methods are ethically sound.*

***Rationale:*** *Required to assess ethical criterion: Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.*

***Tip:*** *This is about the individual participant. If there are no direct benefits to individual participant, as is often the case in research, indicate “N/A.”*

* 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

***Common errors:*** *Incomplete or cursory statements about how data will be stored and managed.*

***Rationale:*** *Required to assess approval criteria: 1) risks to subjects are minimized to the extent possible by using sound research design; 2) risks are reasonable given potential benefits and knowledge gained; 3) there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.*

* 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.

***Tip:*** *It is unethical to put people at risk (even minimal risk) for poor quality data from which any benefits are unlikely to accrue. Quality control and validity of the data are important in order to achieve the benefits of the research. Achieving the benefits is essential because you have put subjects at risk (or discomfort, inconvenience, etc.) and not achieving the benefits would mean that the risk was in vain.*

* 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.

***Common error:*** *Stating that data will be held securely, without details about how they will be secured/protected. Indicating that data will be stored on a student's (or faculty member’s) personal computer with no details on access, security, archiving, etc., or attention to university data security policies.*

***Tip:*** *Be complete here. Consult with departmental IT if necessary. In many cases the greatest risk in a study is related to a breach of data.*

***Bonus tip:*** *Become familiar with Virginia Tech policies with regard to research data: 7010 Policy for Securing Technology Resources and Services, 7105 Policy for Protecting University Information in Digital Form, and 13015 Ownership and control of research results.*

* 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](mailto: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.

***Common error:*** *Indicating that the data will be stored indefinitely with no details about how they will be stored and secured, who will have access, and what will be their final disposition (e.g., when will the dataset be de-identified, put into a public repository, or destroyed).*

***Rationale:*** *Required to assess approval criterion: there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.*

***Tip:*** *Be complete here. Consult with departmental IT if necessary. In many cases the greatest risk in a study, even after completion, is related to a breach of data.*

***Bonus tip:*** *Become familiar with Virginia Tech policies with regard to research data: 7010 Policy for Securing Technology Resources and Services, 7105 Policy for Protecting University Information in Digital Form, and 13015 Ownership and control of research results.*

# Provisions to Protect the Privacy Interests of Participants

***Rationale:*** *Required to assess approval criterion: there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.*

* 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.

***Rationale:*** *Required for university compliance with Title IX.*

***Tip:*** *Ensure that your Title IX training is up-to-date and that you understand whether you are a mandatory reporter. If working with a prisoner population, there may be different reporting requirements that you should be familiar with and additional information might be needed. Please review the* [*HRP-415 CHECKLIST: Prisoners*](https://www.research.vt.edu/sirc/hrpp/resources/checklists.html) *to review the criteria for approval for research that involves prisoners.* *.*

# 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.

***Tip:*** *Implied consent is when a participant agrees to participate in the research without signing a form. The instructions may state that by checking a box or starting the survey the participant agrees to participate in the study.*

* 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.

***Tip:*** *Indicate “N/A” when all participants will speak or understand English.*

* 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](mailto: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.

***Rationale:*** *Required to assess against ethical criteria: 1) informed consent will be sought from each prospective subject or the subject’s legally authorized representative; 2) informed consent will be appropriately documented or appropriately waived. Must also ensure that the consent process meets all requirements and that the consent documents contain all required elements.*

***Tips:*** *Include both parental permission (“consent”) form as well as child assent form, where assent is appropriate (e.g., older child, teen).*

* 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.

***Rationale:*** *Used to determine whether an alteration of the consent process can be granted in order to conduct the research using deception. Using deception means that a potential participant cannot be fully informed which violates a subject’s autonomy to make an informed decision regarding participation.*

***Tip:*** *Deception in research is rare and must be robustly justified. Think carefully about whether the proposed deception is absolutely necessary. Deception can vary from incomplete disclosure of study purpose to the use of an undisclosed research intervention. The third bullet is important for providing justification for the deception.*