**INSTRUCTIONS:**

* *Use this “TEMPLATE PROTOCOL (HRP-503)” to prepare a study protocol outlining your research plan.*
* *Depending on the nature of your study, some major sections might not be applicable to your research. If so, simply mark as “N/A.” For example, a simple survey might have many sections with “N/A.” For subsections (e.g., 1.x or 8.x) you can mark as “N/A”if you are certain that the subsection is not applicable.*
* *Once the IRB/HRPP approves your submission, your latest approved version of the protocol will be stored in the IRB Protocol Management online system.*
* *If your research plan changes and you need to modify the protocol, 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 in order 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” before making a change to any section. Protocol management will store the older versions of your protocol if the IRB or HRPP staff 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!**

**The completed protocol, once approved, should serve as complete documentation of your study, and will be useful in developing research output such as theses, dissertations, presentations, and journal articles.**

**PROTOCOL NUMBER:**

*Include the number assigned in Protocol Management (verify this has been added before submitting 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

**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;

**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 already or in the proposal phase?*: Click here to provide a response.

*Is Virginia Tech the primary awardee or the coordinating center of this grant or contract? 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* |
| **Study Design** | *e.g., your research design and statistical/analytic plan* |
| **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 Intervention(s)/ Investigational Agent(s)**  | *e.g., surveys, interviews, observations, collection of EEG data, behavioral interventions*  |
| **Study Duration for Individual Participants** | *How long will a participant spend in your study? If multiple sessions, list time required for each session plus total.*  |
| **Acronyms and Definitions**  |  |

# Objectives

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

Click here to provide a response.

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

**Rationale:** Required to assess approval criteria: Risks to subjects are minimized to the extent possible by using sound research design. Research design does 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 (e.g., 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:** Required to assess approval criteria: Risks to subjects are minimized 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 say there is no relevant prior research (though this would be rare).

**Rationale:** Required to assess approval 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 risk to answer a question which 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 your research.

* 1. *Summarize the relevant prior research on this topic and gaps in current knowledge within the field of study*:

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

* 1. *Describe any relevant preliminary data*:

Click here to provide a response.

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

* 1. *Based on the existing literature, provide the scientific or scholarly rationale for and significance of your research and how will it add to existing knowledge*:

Click here to provide a response.

**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?”

# Study Endpoints

* 1. *Describe the primary and secondary* ***study*** *endpoints. See links below for discussion of study endpoints and how they may differ from study objectives. These are most common in clinical trials but are sometimes applicable to other types of biomedical research, as well as social, behavioral, or educational research. See link below for a discussion.*

[*https://docs.google.com/document/d/1Wocz7K7a0hCQJPPO\_khh5l1SQQjhGDDGHzcOPRHR5Tw/edit?usp=sharing*](https://docs.google.com/document/d/1Wocz7K7a0hCQJPPO_khh5l1SQQjhGDDGHzcOPRHR5Tw/edit?usp=sharing)

Click here to provide a response.

**Rationale:** Required to assess approval criterion: Risks to subjects are minimized to the extent possible by using sound research design. (When will you end the study to avoid exposing additional participants to unnecessary risk?).

**Tip:** Study endpoints are study outcomes, the things you will be measuring as a result of the study intervention (e.g., weight loss or change in knowledge, behavior, or attitude). If you are not doing an intervention to change a particular behavior or outcome, you likely do not have any study endpoints, and it is okay to state N/A.

* 1. *Describe any primary or secondary* ***safety*** *endpoints. These should be included for all studies that are greater than minimal risk. (Minimal risk: The probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.)*:

Click here to provide a response.

**Rationale:** Required to assess approval criterion: Data are monitored for subject safety. (When will you end the study to avoid exposing additional participants to unnecessary risk?).

**Tip:** Indicate N/A for minimal risk studies. For greater than minimal risk studies, indicate what safety events or outcomes you will monitor.

# Study Design and Statistical Analysis Plan

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

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

* 1. *Describe the basic study design/approach (e.g., qualitative study using five focus groups of first year students to describe assimilation into the university community; randomized controlled trial of a behavioral change intervention to increase dietary intake of whole grains; pre- post-test evaluation of new pedagogical techniques to improve adult literacy)*:

Click here to provide a response.

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

* 1. *Describe corresponding data analysis plan/approach (e.g., content analysis of focus group transcripts; descriptive analysis followed by linear regression modeling; nonparametric analysis of pre- and post-test measures)*:

Click here to provide a response.

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

# Setting

* 1. *Describe the sites or locations where your research team will conduct the research. Consider each of the items listed below:*
		+ *Identify where your research team will identify and recruit potential subjects.*
		+ *Identify where the team will perform the research procedures.*
		+ *Describe the composition and involvement of any community advisory board(s).*
		+ *For research conducted in other locations, describe:*
			- *Site-specific regulations or customs affecting the research at those locations.*
			- *Local scientific and ethical review structure at those locations.*

*Examples include work in other cultures or ethnic groups (within or outside of the U.S.) and work with churches. The HRPP will provide additional guidance for international research.*

Click here to provide a response.

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

**Rationale:** Required to assess approval criteria: 1) There are adequate provisions to protect the privacy of subjects. 2) Selection of subjects is equitable. Is the setting going to yield appropriate subjects for the research?

**Tip:** The first two bullets should be addressed in every protocol. The last two bullets refer to rare situations.

# Study Intervention(s)/Investigational Agent(s)

*7.1 Describe the study interventions (including behavioral interventions) and/or investigational agents (e.g., drugs or devices) to be used in this study. Consider each of the items listed below:*

* + - *Drug/Device Handling: If the research involves drugs or devices, describe your plans to store, handle, and administer the drugs or devices so that they will be used only on subjects, and only by authorized investigators.*
		- *Describe whether any of the following will be used: microwaves, X-rays, DEXA scans, general anesthesia, or sedation*
		- *If control of the drugs or devices used in this protocol will be accomplished by following an established, approved organizational SOP (e.g., Research Pharmacy SOP for the Control of Investigational Drugs, etc.), please reference the SOP in this section.*

Click here to provide a response.

**Common errors:** Leaving blank when there is clearly a behavioral intervention described elsewhere in the protocol; leaving blank when the research involves human testing of a device intended for use in a clinical population.

**Rationale:** Required to assess whether an FDA determination is needed; required to determine research category(ies).

**Tip:** Think of this as the answer to the question, “How will you interact or intervene with participants?”Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., focus group, internet survey, or venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.

* 1. *List the name of all drugs (including any vitamins, supplements, herbs, or nicotine) to be used in the study. Indicate whether they have FDA approval, and list any limitations for their use*:

Click here to provide a response.

**Rationale:** Required to assess whether an FDA determination is needed.

**Tip:** Unless you are doing a drug trial, this is rare at Virginia Tech. Okay to state N/A.

* 1. *List all devices, how they will be used, their purpose in the study, and if they will be used in a manner consistent with their approved uses. If they will be used in ways that are not yet FDA approved, indicate whether they need an IDE or a determination that they are exempt from the IDE Determination. If a determination of significant risk or non-significant risk is needed for any of the devices, include the researcher’s recommendation for each of those devices*:

Click here to provide a response.

**Rationale:** Required to assess whether an FDA determination is needed.

**Tip:** Intended for biomedical devices such as MRI, blood pressure monitors, and thermometers. In most cases, such devices will be used in a manner consistent with their FDA-approved uses. If you are testing a device for a novel use (e.g., developing an app that connects with an existing medical device and then testing the combination in humans), please contact the HRPP for consultation.

* 1. *If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:*
		+ *Identify the holder of the IND/IDE/abbreviated IDE.*
		+ *Explain procedures followed to comply with sponsor requirements for FDA regulated research for the following:*

|  |  |
| --- | --- |
|  | ***Applicable to:*** |
| ***FDA Regulation*** | ***IND Studies*** | ***IDE studies*** | ***Abbreviated IDE studies*** |
| ***21 CFR 11*** | ***X*** | ***X*** |  |
| ***21 CFR 54*** | ***X*** | ***X*** |  |
| ***21 CFR 210*** | ***X*** |  |  |
| ***21 CFR 211*** | ***X*** |  |  |
| ***21 CFR 312*** | ***X*** |  |  |
| ***21 CFR 812*** |  | ***X*** | ***X*** |
| ***21 CFR 820*** |  | ***X*** |  |

Click here to provide a response.

**Tip:** This will be rare. Indicate N/A.

# Procedures Involved

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

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

* 1. *Describe and explain the study design*:

Click here to provide a response.

**Tip:** This section should be consistent with the design outlined in question 5.1. Provide sufficient additional details to explain why this study design is the best for your study question.

* 1. *Provide a description of:*
		+ *All research procedures being performed*
		+ *If the study has more than one procedure, session, and/or subject population, describe each procedure, session, and/or study population separately. For complex studies, you are encouraged to include a figure or chart.*

Click here to provide a response.

**Rationale:** Required to assess several approval criteria, including: 1) Risks to subjects are minimized to the extent possible by using sound research design; 2) there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data; 3) additional safeguards have been included in the study to protect the rights and welfare of subjects vulnerable to coercion or undue influence; 4) informed consent will be sought from each prospective subject or the subject’s legally authorized representative; 5) informed consent will be appropriately documented or appropriately waived.

**Tip:** This 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).

* 1. *Describe:*
		+ *Procedures or safeguards intended to reduce the probability and magnitude of risks. (For example: Reducing the risk of injury in a virtual reality study either by having the subjects sit during the study or by providing an obstacle-free space for walking.)*
		+ *Be sure to describe all drugs and devices used in the research, when they will be administered or used, and their purpose.*
		+ *Methods used to collect data about subjects. Please upload all data collection forms to Protocol Management. Some common examples are:*
		+ *Screening questionnaires*
		+ *Survey(s), including online surveys*
		+ *Demographic questionnaire(s)*
		+ *Interview guide(s), e.g., questions or pool of questions for semi-structured interviews*
		+ *Focus group guide(s)*
		+ *Other documents used to collect data*

Click here to provide a response.

**Common errors:** Leaving blank because you think that there are no risks. Incomplete responses that do not address all bullet points.

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

**Tip:** There should always be an answer here. Start with the third bullet, then the first bullet (which should make sense based on the Risks section (section 17). Then address the second bullet (which will be rare but should make sense based on answers in section 7).

* 1. *What data will you collect during the study and how you will obtain them? Please include descriptions of electronic data collection, database matching, and app-based data collection*:

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. *Who will transcribe or code audio and/or video recordings?*:

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 sometimes transcribe audio or video recordings as a service and are not otherwise engaged in the research, thus do not need to be listed in the personnel or collaboration sections.

**Tip:** If audio and video recordings are checked in section 9.5, there should be an answer here. If you are not recording or are not transcribing recordings, state N/A.

* 1. *Include a description of any deception to be used in the study. Include justification for the use of deception (why the deception is necessary), describe the debriefing process, and describe how the study meets all the following criteria for alteration of consent (deception is considered an alteration of informed consent):*
* *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 a waiver or alteration of informed consent can be granted in order to conduct the research using deception. Using deception means that a potential participant cannot be fully informed, thus violating 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.

* 1. *If the study involves long-term follow-up (once all research related procedures are complete), describe what data will be collected during the follow up period and when it will occur*:

Click here to provide a response.

**Rationale:** Important for determining when a study can be deemed to be closed to new enrollment.

**Tip:** Be sure to include this information in the consent materials so that participants will know to expect follow-up. Be sure to include any questionnaires and other data collection tools that will be used during this phase along with your protocol.

# Data and Specimen Long Term Storage and Use

* 1. *If you will store data or specimens for future use, describe where you will store the data or specimens, how long they will be stored, and how and by whom the data or specimens will be accessed*:

Click here to provide a response.

**Common error:** Leaving this blank or stating N/A when it is stated elsewhere in the protocol that data will be retained for future use.

**Rationale:** Required to assess approval criteria: 1) Risks to subjects are minimized to the extent possible by using sound research design; 2) there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

**Tip:** This question refers to all study data (or specimens). If data (or specimens) will be stored for future use, provide a thorough explanation of how, where, and for how long the data (or specimens) will be stored, who will have access to them, and for what purpose. This information must also be included in the informed consent documents.

* 1. *For specimens, list the data to be stored or associated with each specimen*:

Click here to provide a response.

**Tip:** If your study does not entail obtaining biospecimens from participants, state N/A. If specimens are obtained and stored for future use, indicate what data elements will be associated with them (e.g., participant identifiers, demographic data).

* 1. *Describe the procedures to release data or specimens outside of the research team, including the process to request a release, approvals required for release, who can obtain data or specimens, and what data will be provided with specimens*:

Click here to provide a response.

**Tip:** This question refers to all study data (or specimens). If data (or specimens) will be stored for future use, provide a thorough explanation of how, where, and for how long the data (or specimens) will be stored, who will have access to them, and for what purpose. This information must also be included in the informed consent documents.

* 1. *Describe the identifiers to be included with stored data or specimens, as well as any key or code that could be used to make them identifiable. Describe where the code will be stored, who will have access to it, and when it will be destroyed*:

Click here to provide a response.

**Common error:** Leaving this blank or stating N/A when it is stated elsewhere in the protocol that data are identifiable (or can be made identifiable).

**Tip:** This question also refers to all study data (or specimens). If data (or specimens) are identifiable or can be made identifiable, explain whether data (or specimens) will be stored with or without identifiers and how the identifiers can be linked back to the data (or specimens). This information must also be included in the informed consent documents.

* 1. *Please select the identifiers you will obtain (whether directly from participants or from another source), including but not limited to:*

|  |
| --- |
|[ ]  *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) for dates 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*  |
|[ ]  *User name 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 explain. |

***Common errors:*** *Not checking the video and audio boxes when it is stated elsewhere that video or audio data will be collected.*

***Rationale:*** *Required to assess approval criterion: There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. Also required for granting a HIPAA waiver.*

# Sharing of Results with Subjects

* 1. *Describe whether you will share results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) with subjects or others (e.g., the subject’s primary care physician). If so, describe how you will share the results and include this information as part of the consent document. Upload materials you will use to explain the results to subjects*:

Click here to provide a response.

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

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

**Tip:** It is not required (and in some cases not allowable) to share research results with participants, so if you are not planning to, simply state N/A. If you plan to share results with participants, describe the process here as well as in the consent documents.

# Study Timelines

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

**Rationale:** Often used at the time of continuing review or progress report to assess whether adequate progress is being made, which is necessary to ensure that risks are minimized and benefits are maximized.

**Tip:** Be sure to address all three points.

* 1. *Describe:*
		+ *The duration of an individual subject’s participation in the study (for example, 1 hour, 2-4 weeks, 3-5 years).*
		+ *The amount of time expected to enroll all study subjects (weeks, months, years, etc.)*
		+ *The amount of time expected for the investigators to complete this study including primary data analyses.*

Click here to provide a response.

# Inclusion and Exclusion Criteria

**Rationale:** Required to assess approval criterion: Selection of subjects is equitable. (Consider the purpose and setting of the research, involvement of vulnerable subjects, selection criteria, as well as recruitment, enrollment, and payment procedures.)

* 1. *Describe how you will screen individuals for eligibility. When will screening occur and what procedures will you use? Upload any screening scripts or surveys to Protocol Management*:

Click here to provide a response.

**Tip:** If there are any eligibility requirements (and there almost always are), describe the screening process here. 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 by self-report in the form of a screening question prior to consent)?

* 1. *Describe the eligibility criteria that define who will be included and who will be excluded from enrollment for each procedure of your study. Include any geographic criteria (e.g., Virginia Tech undergraduate students, a national sample of adults with engineering degrees, minors aged 8-12 in the New River Valley, university faculty in Virginia and Paris, France)*:

Click here to provide a response.

**Tip:** If there are any eligibility requirements (and there almost always are), describe them here.

* 1. *Indicate specifically whether you will include or exclude each of the following special populations: (You may not include members of these populations as subjects in your research unless you indicate them in the description of your subject population.)*
		+ *Minors, as defined by state law where the study is performed (infants, children, teenagers)*
		+ *Pregnant women (can be included in minimal risk studies by mentioning in section 13.1)*
		+ *Prisoners (including all incarcerated individuals)*
		+ *Adults not capable to consent on their own behalf*

Click here to provide a response.

**Tip:** Minors: If you do not plan to include minors, then there should be an age criterion in section 12.2. Pregnancy: Women who are pregnant or of childbearing age can be included in most studies at Virginia Tech. If you decide to exclude pregnant women because there are risks to the woman or fetus, list the risks in section 17 and indicate how you will assess pregnancy in the procedures section (8.2).

# Vulnerable Populations

* 1. *If the research involves individuals who are vulnerable to coercion or undue influence, please describe additional safeguards you will include to protect their rights and welfare. Consider the applicable items listed below:*
		+ *If the research involves Virginia Tech students, indicate whether these are students of any of the investigators. If so, describe whether the activities will take place during class time as part of the curriculum and the steps you will take to reduce the possibility that students feel obliged to participate in order to improve their course grade. The HRPP can provide further guidance as needed. Describe whether you will request access to student records (e.g., SAT, GPA, GRE scores).*
		+ *If the research involves employees of Virginia Tech or the research sponsor, describe steps you will take to ensure that the employees are freely participating and describe how their data will be protected from inspection by their supervisors.*
		+ *If the research involves Virginia Tech NCAA athletes, you must obtain approval from the athletic department.*
		+ *For research involving Montgomery County Public Schools, you must obtain county approval (after obtaining contingent Virginia Tech approval). Other locales have different requirements; please check on these and describe here. Approval is typically granted by the superintendent, principal, and classroom teacher (in that order). Approval by an individual teacher is insufficient. School approval, in the form of a letter or a memorandum should be uploaded as a supporting document.*
		+ *If the research involves pregnant women, review “CHECKLIST: Pregnant Women (HRP-412)” to ensure that you have provided sufficient information in this protocol.*
		+ *If the research involves prisoners, review “CHECKLIST: Prisoners (HRP-415)” to ensure that you have provided sufficient information in this protocol.*
		+ *If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research (minors), review the “CHECKLIST: Minors (HRP-416)” to ensure that you have provided sufficient information in this protocol.*
		+ *If the research involves cognitively impaired adults, review “CHECKLIST: Cognitively Impaired Adults (HRP-417)” to ensure that you have provided sufficient information in this protocol.*

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 criterion: Additional safeguards have been included in the study to protect the rights and welfare of subjects vulnerable to coercion or undue influence

**Tips:** Read each bullet carefully, and address the concerns if you plan to enroll that population. Referenced checklists can be found at <https://www.research.vt.edu/sirc/hrpp/resources/checklists.html>.

# Number of Subjects

* 1. *Indicate the total number of subjects to be enrolled and how this number was determined (e.g., sample size calculation [show], number of available subjects 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 approval criterion: Risks to subjects are minimized to the extent possible by using sound research design.

**Tips:** 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.

* 1. *If this is a multi-site study, indicate the number of subjects to be enrolled at this site and the total to be enrolled from all sites*:

Click here to provide a response.

**Rationale:** Used to determine whether a central IRB or other IRB-reliance agreements are necessary with other institutions as required by the regulations.

**Tips:** This question is refers to collaborative, multi-site studies where researchers from different institutions will be collecting data from their respective locations. It does not include a single research team from the same institution collecting data from multiple sites. If you are unsure, please contact HRPP.

* 1. *If applicable, indicate the number of potential subjects you expect to screen for enrollment, and the number of subjects you will need to complete the research procedures*:

Click here to provide a response.

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

**Tip:** Not all of the potential subjects you screen for enrollment will be eligible for your study, so you will have to approach more people than your target enrollment number. You should indicate here how many potential subjects you think you will have to approach and/or screen in order to meet your enrollment target.

* 1. *If the study has more than one procedure, indicate the total number of subjects to undergo each procedure separately*:

Click here to provide a response.

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

**Tip:** If your study involves a survey and a focus group, for example, these are separate procedures and the total number of subjects in each activity.

# Recruitment Methods

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

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

* 1. *Describe when, where, and how you will recruit potential subjects*:

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 the source of subjects (for example, clinic patients with specific conditions, students in the library, community members at a gathering, or members of a local gym)*:

Click here to provide a response.

***Tip***: *This must always be answered. Be specific.*

* 1. *Describe the methods that you will use to identify potential subjects*:

Click here to provide a response.

**Tip:** This must always be answered. Be specific. For example, posting on SONA (SONA posting would have to be uploaded as part of the recruitment materials).

* 1. *Describe materials that you will be use to recruit subjects. Attach 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., attach the final wording and graphics to be used.*
* *For email recruitments, please include the subject line.*
* *For advertisements meant for audio 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 compensation to subjects. Separate compensation 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.

**Tip:** This must always be answered. Be specific. Include the FINAL copies of recruitment materials. An amendment will be needed if these documents are later changed. Include 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 or 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."

# Withdrawal of Subjects

* 1. *Describe circumstances under which you anticipate subjects could be withdrawn from the research without their consent*:

Click here to provide a response.

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

**Tip:** Withdrawal of subjects without their consent is usually a result of a safety concern or due to non-response to follow-up activities (if applicable). Outline here what might cause a subject to be removed from the study by the investigator(s).

* 1. *If applicable, describe any procedures for orderly termination (e.g., discontinuation of a study drug or debriefing after a behavioral intervention)*:

Click here to provide a response.

**Rationale:** Required to assess approval criterion: Risks to subjects are minimized to the extent possible by using sound research design. If a study involves deception (rare), and a subject is withdrawn by investigators, all reasonable effort must be made to debrief participant. There are rare circumstance where disclosure of the deception might pose more risk than non-disclosure. Consult with the HRPP on this part of the study if needed.

**Tip:** Describe how a participant will be notified of early withdrawal and what steps will be taken to ensure an orderly and safe termination.

* 1. *Describe procedures that you will follow when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection (e.g., participant declines to continue with regular blood draws, but continues with periodic behavioral questionnaires)*:

Click here to provide a response.

**Tip:** Consider this possibility at the start of your study and prepare for contingencies. Participants should be informed of these as part of the consent process. Be sure to describe any adjustments to compensation based on study withdrawal or partial completion of study activities.

# Risks to Subjects

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

***Rationale:*** *Required to assess approval 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 subjects related the subjects’ participation in the research. Include for the IRB’s consideration a description of the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, privacy, and economic risks. Do not indicate “No risk” or “N/A.” Instead, for studies with very low risk (e.g., anonymous online questionnaire on a mundane topic) indicate “The investigators are not aware of any risks from participation in this study.” or “No more than risks than are found in everyday life.” The example consent form presents a tabular method for risk information, which you can also use here. Common risk types include:*
* *Physical (e.g., potential for pain, discomfort, infection)*
* *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 subjects’ knowledge or consent, breach of confidentiality/security)*
* *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.

* 1. *Indicate the measures you will use to minimize risks and monitor subjects for safety. (e.g., asking a subject at regular intervals to rate how they are feeling from 1 to 10, or to slowly crouch in order to check their balance.)*

Click here to provide a response.

**Tip:** For low risk studies (e.g., an online survey), it is okay to indicate N/A.

* 1. *If applicable, indicate which procedures might have risks to the subjects that are currently unforeseeable. This will be rare, and usually applicable when testing a new drug or device or a new use of an existing drug or device*:

Click here to provide a response.

**Rationale:** Required to assess approval 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. Also important for studies that are subject to FDA regulations.

**Tip:** Very rare, so okay to say NA for most studies.

* 1. *If applicable, indicate which procedures might have risks to an embryo or fetus should the subject be or become pregnant*:

Click here to provide a response.

**Rationale:** Required to assess approval 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; 3) selection of subjects is equitable.

**Tip:** If not applicable to your study, indicate N/A. Should be consistent with other responses related to inclusion or exclusion of pregnant women or women of childbearing age.

* 1. *If applicable, describe risks to others who are not subjects (e.g., collection of sensitive health data that might affect sexual partners if disclosed, mandatory reporting of abuse, DNA testing that might affect family members or relationships)*:

Click here to provide a response.

**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.

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

# Potential Benefits to Subjects

**Common Errors:** Mentioning compensation as a benefit, or outlining benefits to society.

**Rationale:** Required to assess approval 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 that individual subjects might experience from participating in the research. Include the probability, magnitude, and duration of the potential benefits, as this will be useful to the IRB’s risk:benefit analysis. Do not include benefits to society or others. Do not list monetary or non-monetary compensation for participation, as this is not a benefit These should be included in section 2 or 3 of this document*:

Click here to provide a response.

* 1. *If applicable, specify that there are no anticipated direct benefits for participants*:

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 for quality control to ensure validity of collected data*:

Click here to provide a response.

**Tip:** It is unethical to put people at risk for poor quality data from which any benefits would be 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. *Describe any existing data or biospecimens you will obtain as part of this study. Include:*
		+ *Variables or samples to be obtained*
		+ *Source of the data or specimens*
		+ *Your authorization to access or receive the data or biospecimens*
		+ *Whether the data or biospecimens are publicly available*
		+ *Whether the data or specimens you receive will contain identifiers*

Click here to provide a response.

**Common error:** Leaving this blank or indicating NA when it is stated elsewhere in the protocol that existing data will be used or matched to other data.

**Rationale:** Required to determine research categories and to justify consent waivers in some cases.

**Tip:** This question also refers to any existing data (or biospecimens) to be used as part of the study. If you will be collecting existing data about or using stored specimens for enrolled participants, they must consent to this as part of the consent process.

**Bonus tip:** If your study involves only existing data, complete an existing data protocol instead (form available HRPP website).

* 1. *Describe the steps that you will take to handle and secure study data during data collection, storage, use, and transmission. Include information about training of study staff, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, separation of identifiers and data, etc.*:

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’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. *For multi-site studies, describe how data or specimens will be handled and secured for each site (e.g., central or disseminated data storage, data coordinating center)*:

Click here to provide a response.

**Tip:** This will take some legwork to obtain adequate answers from other sites.

* 1. *Describe the plan for data disposition following the conclusion of the study (e.g., long term maintenance of data, data destruction methods).*
		+ *What information will be included in the long term storage of data or specimens?*
		+ *How long will the data or specimens be stored?*
		+ *Where and how data or specimens will be stored?*
		+ *Who will have access to the data or specimens during long term storage?*
		+ *Who is responsible for receipt or transmission of the data or specimens?*
		+ *How will data or specimens be shared or transported?*
		+ *When and how will personal identifiers be destroyed?*

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 Subjects

**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 subjects’ 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)*:

Click here to provide a response.

* 1. *Describe steps that you will take to make 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 (e.g., use of a same gender investigator to place sensors on the torso, a private changing area if clothing must be changed, sensitivity when discussing pregnancy testing with subjects, 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 how you plan to access existing sources of information about the subjects (e.g., medical records, grades) and how you will protect participant privacy through the data security plan*:

Click here to provide a response.

**Tip:** Ensure that this plan isconsistent with section 19.2. If you will be collecting existing data about enrolled participants, they must consent to this as part of the consent process.

* 1. *Describe any required reporting that might occur as a result of your research questions, study populations, and data collection methods. Examples for 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.

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

*Safety monitoring is required* *when research involves greater than minimal risk and is sometimes appropriate for other studies.*

* 1. *Describe:*
		+ *The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe (e.g., periodic reporting to the IRB, establishing a data monitoring committee, reporting data monitoring committee findings to the IRB and the sponsor).*
		+ *What data you will review, including safety data, unexpected events, and data that show the ability to produce the intended results.*
		+ *How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with subjects).*
		+ *The frequency of data collection, including when safety data collection starts.*
		+ *Who will review the safety data and with what frequency.*
		+ *The statistical tests for analyzing the safety data to determine whether harm is occurring.*
		+ *Any conditions that will trigger an immediate suspension of the research (e.g., a serious adverse event).*

Click here to provide a response.

**Rationale:** Required to assess approval criterion: The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects

**Tip:** Most common in biomedical clinical trials, but might be appropriate in other research that is greater than minimal risk.

# 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, if any*:

Click here to provide a response.

**Tip:** This section is for studies that are deemed to be greater than minimal risk. Indicate whether any compensation or medical treatments are available if injury occurs and, if so, what they consist of, or where further information can be obtained. If compensation for injury related to research participation is unavailable, indicate so here and in the informed consent documents.

* 1. *Provide a copy of contract language, if any, relevant to compensation for research-related injury. At Virginia Tech, this is most common for sponsored research*:

Click here to provide a response.

**Rationale:** Need to ensure consistency between contract language, what the IRB has been told, and what participants have been told.

**Tip:** Ensure consistency with what was stated in section 22.1.

# Economic Burden to Subjects

* 1. *Describe any costs that subjects might be responsible for because of participation in the research, including any uncompensated costs for items such as transportation, missed work, and childcare*:

Click here to provide a response.

**Rationale:** Potential costs to participants must be disclosed in the informed consent documents when applicable.

**Tip:** If no potential additional costs are anticipated, state N/A.

# Consent Process

* 1. *Indicate the process by which you will obtain consent for study participation. Please upload all consent, parental permission, and assent forms, documents, and scripts referenced in this section to Protocol Management.*

*Describe the following:*

* + - *Where the consent process will take place (e.g., clinic waiting area, classroom, online)*
		- *The time interval between sharing the consent information with the prospective subject and obtaining consent. For lab, interview, and focus group studies, the Virginia Tech IRB prefers that subjects have at least 24 hours to review the consent form and study information before the appointment where consent will be obtained. For simple online survey studies, you can typically present the consent information immediately before subjects begin participation.*
		- *If applicable, processes to ensure ongoing consent or assent (e.g., for multiple sessions; for research in which a minor will turn 18 during the study; for longitudinal research with minors who will later be asked to provide or affirm their assent).*
		- *Please review “SOP: Informed Consent Process for Research (HRP-090)” for recommended procedure. Describe your process, being sure to include:*
			* *The name and role of all study personnel who will be trained and certified by the PI to conduct the consent process*
			* *The time that will be devoted to the consent discussion*
			* *Steps that you will take to minimize the possibility of coercion or undue influence*
			* *Steps that you will take to gauge or ensure the subjects’ understanding*

Click here to provide a response.

**Common errors:** Using an outdated consent template that does not include all of the required elements of consent under the Revised Common Rule. Omitting the Key Information section or having it be too brief or vague. "Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject … in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension."

**Rationale:** Required to assess approval 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.

**Tip:** Consent documents are used to inform potential participants about the details of the study and must be written in plain language at a level that reflects the reading ability of your potential participants. Consent templates are available at [https://www.research.vt.edu/sirc/hrpp/resources/templates.html.](https://www.research.vt.edu/sirc/hrpp/resources/templates.html) Consent documents must be in final form when submitted with protocol for IRB review. They must be amended if changes are needed during conduct of the study.

**Bonus tip:** Consent for some low risk studies (e.g., a one-time online survey) can be an abbreviated statement covering the purpose, the study activities, the time commitment, letting participants know that participation is voluntary and they can quit at any time, along with a final affirmation of consent. If sensitive data are being collected in these low risk studies, additional statements about privacy and data confidentiality should also be included.

**Bonus tip:** Consent is an ongoing process; it does not begin and end with the consent form. Be sure to describe the entire consent process, including any re-consent for longitudinal or multi-part studies, studies where minors will age to age-of-consent, or where persons might develop impaired decision-making capacity (e.g., dementia).

***Non-English Speaking Subjects***

* + - *Indicate what language(s) other than English are understood by prospective subjects or representatives.*
		- *If non-English speakers will be recruited, describe the process you will use to ensure that the oral and/or written consent information provided will be in a language that they understand.*
		- *If you translate consent forms and study materials, please provide a certified translation of the form as well as the certification document.*
		- *Indicate the spoken language that study personnel obtaining consent will use. Describe how you will assess fluency of personnel obtaining consent to ensure that the translation is accurate.*

Click here to provide a response.

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

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

* + - *Review the “CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)” to ensure you have provided sufficient information for the IRB to make these determinations (i.e., that it meets the criteria for a waiver or alteration of the consent process).*

Click here to provide a response.

**Rationale:** Required to assess consent process criterion: Requirements for waiver and alteration. In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that:

* + 1. *The research involves no more than minimal risk to the subjects;*
1. *The research could not practicably be carried out without the requested waiver or alteration;*
2. *If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;*
3. *The waiver or alteration will not adversely affect the rights and welfare of the subjects; and*
4. *Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.*

**Tip:** Checklist can be found at: <https://www.research.vt.edu/sirc/hrpp/resources/checklists.html>.

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

* + - *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).*
			* *For research conducted in Virginia, review “SOP: Legally Authorized Representatives, Minors, and Guardians (HRP-013)” to determine which individuals in the state meet the definition of “minor.”*
			* *For research conducted outside of the state, please describe the legal requirements for the definition of “minor.”*
		- *Describe the process for obtaining parental permission.*
			* *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 subject.*
			* *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 minors will 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. However, 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?*
		- *Attach parental permission and minor assent forms or scripts in Protocol Management.*

Click here to provide a response.

**Rationale:** Required to assess against approval 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).

***Adults Unable to Consent***

* + - *Describe the process you will use to determine whether an individual adult is capable of consent.*
		- *List the individuals from whom you will obtain permission in order of priority (e.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and non-minor child).*
			* *For research conducted in the Virginia, review “SOP: Legally Authorized Representatives, Minors, and Guardians (HRP-013)” to determine which individuals in the state meet the definition of “legally authorized representative.”*
			* *For research conducted outside of Virginia, please describe the legal requirements for obtaining permission from a legally authorized representative in the state where the research will occur.*
		- *Describe the process for assent of the subjects.*
			* *Indicate whether you will require assent from all, some, or none of the subjects. If some, indicate which subjects will be required to assent and which will not.*
			* *If you will not obtain assent from some or all subjects, please provide justification for not obtaining assent.*
			* *Describe whether and how you will document assent.*

Click here to provide a response.

**Rationale:** Required to assess against approval 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 representative permission (“consent”) form as well as subject assent form, where assent is appropriate (e.g., person with intermittent decision-making capacity).

# Process to Document Consent in Writing

***Rationale:*** *Required to assess against process criteria: 1) Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject’s legally authorized representative; 2) informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject’s legally authorized representative (unless signature is waived by the IRB). Each participant must receive a written copy of the informed consent documents.*

* 1. *Consult “SOP: Written Documentation of Consent (HRP-091)” for recommended procedures, and describe whether and how consent of the subject will be documented in writing*:

Click here to provide a response.

* 1. *If the 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, you can request that the IRB waive the requirement to obtain written documentation of consent (e.g., consent to participate is indicated by pressing a button for an online questionnaire – after the consent information is presented and before the questionnaire begins)*:

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**Rationale:** Required to assess consent process criterion: An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:

1. *That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern; OR*
2. *That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.*

**Tip:** Briefly describe your justification for a waiver of written documentation of consent (e.g., this study is no more than minimal risk, and participants will be remotely accessing the questionnaire. They will press a button to indicate consent after being provided the consent information.)

* 1. *If you will document consent in writing, attach a consent document with places for signatures. If you will obtain consent, but not document consent in writing, please attach the consent script or text. Review “CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)” to ensure that you have provided sufficient information. You should use “TEMPLATE CONSENT DOCUMENT (HRP-502)”to create the consent document or script*:

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**Rationale:** Required to assess approval 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.

**Tip:** Attach final versions of consent documents and any scripts that will be used to facilitate the consent process. Checklist can be found at <https://www.research.vt.edu/sirc/hrpp/resources/checklists.html>and Consent Form templates can be found at <https://www.research.vt.edu/sirc/hrpp/resources/templates.html>.

# Resources Available

* 1. *Describe the resources available to conduct the research. For example, as appropriate:*
		+ *Describe the PI’s availability to supervise the research.*
		+ *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 or unanticipated consequence of participation in the 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 (e.g., training plans, detailed study notebooks).*

Click here to provide a response.

**Rationale:** It is unethical to expose participants to risk in an under-resourced study with little likelihood of success. If you need a very specific research population, and there are very few of that population in the area, then you might not be able to meet target enrollment. Those who have already participated may have done so in vain if the research cannot be completed.

# Multi-Site Research

*Contact the HRPP for multi-site research (involving multiple institutions) and the details required for this section will be provided. Otherwise, indicate N/A.*

Click here to provide a response.

**Tip:** Contact the HRPP early in the process if you think your study will involve co-investigators or colleagues at institutions other than Virginia Tech. We will provide the additional questions for this section.