## Title of research study: (Insert title of research study here with VT IRB protocol number, if applicable.)

## Principal Investigator: (Required: insert name of principal investigator as well as contact information, phone number and e-mail required.)

**Other study contact(s):** *(Optional: insert names as well as contact information.)*

## Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form. (This is a required section according to the revised Common Rule. Use plain language and short sentences to keep all sections at the reading level of the intended study population. Please include only a brief summary in this key information section. This information can be formatted in different ways depending on the complexity of the activities and the number of subject populations. Please see [Examples of Key Information](https://www.research.vt.edu/content/dam/research_vt_edu/hrpp/files/guides/consent-form-key-information-section.pdf) for three examples.)

## Detailed Information: The following is more detailed information about this study in addition to the information listed above.

## Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at *(Insert contact information for the research team.)*

This research has been reviewed and approved by the Virginia Tech Institutional Review Board (IRB). You may communicate with them at 540-231-3732 or irb@vt.edu if:

* You have questions about your rights as a research subject
* Your questions, concerns, or complaints are not being answered by the research team
* You cannot reach the research team
* You want to talk to someone besides the research team to provide feedback about this research

## How many people will be studied?

We plan to include about \_\_\_\_\_ people in this research study.

*(If multisite study, state:)*

We plan to include about \_\_\_\_\_ people at this location out of \_\_\_\_\_ people in the entire study nationally *(or internationally).*

## What happens if I say yes, I want to be in this research?

*(Tell the subject what to expect using plain language. Whenever appropriate include the following items:)*

* *If procedures require more than one session, prepare a timeline, chart, or diagram to accompany descriptions of procedures and tests*
* *The length and duration of visits and procedures*
* *With whom will the subject interact*
* *Where the research will be done*
* *When the research will be done*
* *List experimental procedures and therapies that the subject will experience*
* *How often procedures or study activities will be performed*
* *All devices and equipment that will be used, including drawings or photos of non-routine devices that the subject will interact with or wear.*
* *If blood will be drawn, indicate the amount (in US units) and frequency*
* *If saliva or other specimens will be obtained and for what purpose*
* *If subjects might be students, explain which procedures are also part of the course or class and which are part of the research study only. If the only procedure is giving consent for the researcher to analyze course work or grades for research and publication purposes, state that clearly.*
* *When applicable, indicate that the subject will be contacted for future research, and if so, whether that is related to the current study or for new studies.*

## What happens if I say yes, but I change my mind later?

You can leave the research at any time, for any reason, and it will not be held against you.

*(Include if there are potential adverse consequences to withdrawing from the research. Otherwise delete.)*If you decide to leave the research, *(Describe the adverse consequences.)*

If you decide to leave the research, contact the investigator so that the investigator can *(Describe the procedures for orderly termination by the subject, if any.)*

*(Describe what will happen to data collected to the point of withdrawal. Describe whether subjects will be asked to explain the extent of their withdrawal and whether they will be asked for permission to collect data through interaction or collection of private identifiable information. For example, a subject may wish to withdraw from the experimental procedure because of unacceptable side effects, but may agree to undergo follow-up procedures and data collection.)*

## Is there any way being in this study could be bad for me? (Detailed Risks)

*(The risks of procedures may be presented in a table form.)*

*(Describe each of the following risks, as appropriate. If known, describe the probability and magnitude of the risk. For each risk, also describe how the researcher is minimizing or managing the risk and/or how the subject should respond if the risk were to occur.)*

* *Physical risks (e.g., potential for pain, discomfort, infection)*
* *Psychological risks (e.g., potential for stress, fear, discomfort, embarrassment)*
* *Privacy risks (e.g., potential for personal information being accessed, used or disclosed without the subjects’ knowledge or consent, breach of confidentiality/security)*
* *Legal risks (e.g., potential for disclosure of illegal activity, negligence)*
* *Social risks (e.g., potential for discrimination or stigmatization and disruption of personal and family relationships)*
* *Economic risks (e.g., potential for individuals to lose access to economic services, employment, insurability)*

*(If no risks have been identified state:)*There are no known risks to participating in this study.

*(Include for research that may result in additional costs to the subjects. Otherwise delete.)* Taking part in this research study might lead to added costs to you. *(Describe what these costs are and whether they will be reimbursed. Examples could include travel, child care.)*

## What happens to the information collected for the research?

We will make every effort to limit the use and disclosure of your personal information, including research study and medical records, only to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the IRB, Human Research Protection Program, and other authorized representatives of Virginia Tech. *(Add to this list other organizations that may have access to the subject’s records such as the Food and Drug Administration [FDA], when the research if FDA-regulated, the Department of Health and Human Services [HHS], when the research is conducted or funded by HHS, the sponsor, contract research organization, sponsor’s agent and other collaborating institutions.)*

*(Describe any limitations on confidentiality based on possible legal issues. For example, if the research team is likely to uncover abuse, neglect, or reportable diseases, explain that this information may be disclosed to appropriate authorities.)*

*(If data, including specimens, will be retained after the study for future research, explain where the data or specimens will be stored, who will have access to the data or specimens, how long the data or specimens will be retained, and whether they will include identifiers.)*

*(If identifiable private information or identifiable specimens will be collected during the research, add one of the following statements:)*

If identifiers are removed from your private information or samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

*OR*

*(This option will rarely be used.)* Your information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.

*(Please describe the planned uses for the research results. Revise the following statement as appropriate.)* The results of this research study may be presented in summary form at conferences, in presentations, reports to the sponsor, academic papers, and as part of a thesis/dissertation.

*(Include if a HIPAA authorization is required. Otherwise delete.)* Federal law provides additional protections of your medical records and related health information. These are described in an attached document.

*(Include for research involving prisoners. Otherwise delete.)*If you are a prisoner, your medical records might also be given to officials and agencies within the criminal justice system when necessary and permitted by law.

## Can I be removed from the research without my OK?

*(Include for research where this is a possibility. Otherwise delete.)*The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include *(Describe reasons why the subject could be withdrawn, if appropriate.)*

*(Include for research where this is a possibility. Otherwise delete.)*We will tell you about any new information that might affect your health, welfare, or choice to stay in the research.

## What else do I need to know?

*(Include if this project is funded. Otherwise delete.)* This research is being funded by *(Insert name(s) of funder)*.

*(If as a result of the research project, the investigator determines that the subject should seek counseling or medical treatment, a list of local services should be provided.)*

*(If applicable, inform subjects:)*Any expenses accrued for seeking or receiving medical or mental health treatment will be your responsibility and not that of the research project, research team, or Virginia Tech.

*(Include if subjects will be paid. Otherwise delete.)* If you agree to take part in this research study, we will reimburse you $\_\_\_\_\_\_\_\_ *(indicate amount)* for expenses *(itemize)*. You will also receive $\_\_\_\_\_ for your time and effort. *(If you will pay additional incentives for participation, add:)*In addition, if you complete the study, you will receive $\_\_\_\_.*(Include descriptions of any additional incentives for participation. Include amounts and schedule. Indicate if the amount is pro-rated for research visit completion. For complicated payment plans, include a chart. Tell participants method of payment, such as ClinCard, gift cards [specify business], cash, check.)*

*(If compensation will include a drawing, include the following. Odds are usually described as “one in X”, depending on the number of subjects and the number of drawings.)*You can choose to be included in a drawing for $\_\_\_\_\_. The odds of receiving $ \_\_\_\_\_ are one in \_\_\_. *(depending on the total number of subjects)*

*(Include for Department of Defense [DOD] research that includes military personnel where subjects will be paid – this is rare. Otherwise delete.)*Military personnel should check with their supervisor before accepting payment for participation in this research.

*(Future use for commercial purposes, include when applicable and alter to match the type of data being collected. Otherwise delete. If you do not inform subjects about this possibility, you will not be able to use information and samples for this purpose without additional consent.)*Your information and samples (both identifiable and de-identified) might be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans *(or replace with plans when using identifiable information/samples)* to tell you, or to pay you, or to give any compensation to you or your family.

*(Select either “will” or “will not”. When applicable, include whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions)*We (will/will not)offer to share your individual test results with you. You may accept or decline these results.

*(Omit the signature page if there is no written documentation of consent. If electronic consent will be obtained, add the text that will be used in place of the signature page. If verbal consent will be obtained, include the script that will be used to obtain consent.)*

**Signature Block for Capable Adult** *(contact HRPP for questions about adults not capable of providing consent)*

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| Your signature documents your permission to take part in this research. We will provide you with a signed copy of this form for your records. | | |
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