## 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 name 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 an appropriate reading level of the intended population. Please include only a brief summary in this key information section. For simple studies [e.g., one session, one procedure], this information can be presented in a single paragraph that addresses the content of the subheadings below. For more complex studies [e.g., multiple session, multiple procedures], use the subheadings below.)

## Why am I being invited to take part in a research study?

We invite you to take part in a research study because \_\_\_\_\_\_\_\_\_\_\_\_\_. *(Fill in the circumstance or condition that makes subjects eligible for the research. For example: you are between the ages of 18-25 and are a candidate for one of the treatments of interest.)*

## What should I know about being in a research study?

* Someone will explain this research study to you
* Whether or not you take part is up to you
* You can choose not to take part
* You can agree to take part and later change your mind
* Your decision will not be held against you
* You can ask all the questions you want before you decide

## Why is this research being done?

*(Tell the subject the purpose of the research. Summarize the background of the research problem. Summarize any potential benefits to society or others. For example: Several treatment methods are currently used to treat this condition. The reason we are doing this research is to compare two of these methods in order to determine if one is more effective than the other at treating the condition.)*

## How long will the research last and what will I need to do?

We expect that your participation in this research study will last \_\_\_\_\_\_\_\_. *(Include hours/days/months/weeks/years, until a certain event. For example: two months or until you leave the hospital.)*

You will be asked to \_\_\_\_\_\_\_\_\_ *(Include a high level summary of the procedures that will be done. For example: wear a heart rate monitor and exercise vigorously for 20 minutes three times per week.)*

More detailed information about the study procedures can be found under, **“What happens if I say yes, I want to be in this research?”**

## Is there any way being in this study could be bad for me?

*(This beginning section of the consent form should briefly identify the most important risks, e.g., similar to the information that a physician might deliver in the clinical context in telling a patient how sick, e.g., the chemotherapy drugs will make them, but with a particular emphasis on how those risks are changed by participating in the study. If risks are very minor such as filling out an online questionnaire, say “Risks are no more than would be expected in everyday life.” For example: There is a risk that you may become nauseous or dizzy.)*

More detailed information about the risks of this study can be found under **“Is there any way being in this study could be bad for me? (Detailed Risks)”.**

## Will being in this study help me in any way?

*(This beginning section of the consent form should identify one or more likely benefits resulting from participation in the study. In doing so, you should not overemphasize the benefits. If you need to discuss benefits in additional detail, add an additional section later in the consent document.)*

*(Include if there are benefits to participation. Otherwise delete.)*We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. *(First describe any direct benefits to the subject, then any potential benefits to society or others, such as contributing to the knowledge base in your field. If benefits from participation may not continue after the research has ended, describe them here. Do not list monetary reimbursement for participation, as this is not a benefit.)*

*(Include for a study with no benefits to participation. Otherwise delete.)* There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. *(Describe any potential benefits to society or to others, such as contributing to the knowledge base in your field. Monetary reimbursement for participation is not a benefit. For example: the medical community gaining a better understanding of how to best prevent the condition.)*

## (Include for research involving prisoners.) Taking part in this research study will not improve your housing or correctional program assignments. Taking part in this research study will not improve your chance of parole or release.

## What happens if I do not want to be in this research?

Participation in research is completely up to you. You can decide to participate or not to participate.

*(Include if there are alternatives other than participating. Otherwise delete.)* Instead of being in this research study, your choices may include: *(List alternatives procedures.)*

*(For clinical trials, describe the options that you would normally offer a patient. If applicable, include supportive care as an option.)*

*(Include if some or all of the subjects might be Virginia Tech students. Otherwise delete.)*If you are a student, the decision whether to participate or not participate will have no effect on your grades or relationship with Virginia Tech.

## 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:)*

* *A timeline description of the procedures that will be performed. If practical, prepare a timeline chart or schematic to accompany descriptions of procedures and tests for research that require more than one or two steps/visits*
* *The drugs or biologics that will be given to the subject*
* *All devices that will be used*
* *All outpatient visits and telephone or written follow-up*
* *The length and duration of visits and procedures*
* *If blood will be drawn, indicate the amount (in English units) and frequency*
* *If saliva or other specimens will be obtained and for what purpose*
* *With whom will the subject interact*
* *Where the research will be done*
* *When the research will be done*
* *List experimental procedures and therapies in terms of what the subject will experience*
* *How often procedures or study activities will be performed*
* *What is being performed as part of the research study*
* *What is being performed as part of standard care*
* *What procedures are part of regular medical care that will be done even if the subject does not take part in the research*
* *If this research involves students, explain which activities are a normal part of the course or activity under investigation and which are part of the research study*
* *Whether the research will or might include large scale genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen)*
* *When applicable indicate that the subject will be contacted for future research.*

*(Include for a clinical trial that involves randomization. Otherwise delete.)*The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have a/an \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *(equal/one in three/etc.)* chance of being given *(the treatment, the sugar pill, etc.)*

*(For double-blinded research add)* Neither you nor the study doctor will know which treatment you are getting.

*(For single-blinded research add)*You will not be told which treatment you are getting, however your study doctor will know.

## What are my responsibilities if I take part in this research?

*(Delete this section if the research is not a clinical trial.)*

If you take part in this research, you will be responsible to:*(Describe any responsibilities of the subject.)*

## 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.)*

*(Include for FDA-regulated research. Otherwise delete.)*If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. *(Note: The consent document cannot give the subject the option of having data removed.)*If you agree, these data will be handled the same as research data. *(Note: If a subject withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the investigator must not access for purposes related to the study the subject’s medical record or other confidential records requiring the subject’s consent. However, an investigator may review study data related to the subject collected prior to the subject’s withdrawal from the study, and may consult public records, such as those establishing survival status.)*

*(For research that is not FDA-regulated)*If you stop being in the research study *(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)*

*(Include for research that involves procedures whose risk profile is not well known, including all research involving an investigational product. Otherwise delete.)* In addition to these risks, this research might hurt you in ways that are unknown. These might be a minor inconvenience or might be so severe as to cause death.

*(Include for research that involves pregnant women or women of childbearing potential and procedures that involve risks to an embryo or fetus or whose risk profile in pregnancy is not well known. Otherwise delete.)* The procedures in this research are known to hurt a pregnancy or fetus in the following ways: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. *(Omit the previous sentence if there are no known risks.)*The research might also hurt a pregnancy or fetus in ways that are unknown. These might be a minor inconvenience or might be so severe as to cause death. *(Omit the previous two sentences for research whose risk profile in pregnancy is well known.)*You should not be or become pregnant *(include as applicable “or father a baby”)*while on this research study.

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

*(Include for clinical trial or if applicable. Otherwise delete. If this study includes regular medical care that you would ordinarily get without being part of a study.)* You and your insurance company will be charged only for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

## 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 disposition of the research results. Revise the following statement as appropriate.)* The results of this research study may be presented in summary form at conferences, in presentation, reports, academic papers, and as part of a thesis/dissertation.

*(Include for research where the sponsor might pay for medical expenses of the subject.)*If the sponsor pays any of your medical expenses, we might be required to give the sponsor your name, date of birth, Insurance ID number, or social security number.

*(Include for a clinical trial. Otherwise delete.)*The sponsor, monitors, auditors, the IRB, the FDA will be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access. We might publish the results of this research. However, we will keep your name and other identifying information confidential.

*(Include for FDA-regulated controlled drug and device trials [except Phase I drug trials] and FDA-regulated pediatric post-market surveillance trials of devices. Otherwise delete.)*A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

*(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?

*(If this project is funded, include:)* 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.)*

*(Include for research involving more than minimal risk. Otherwise delete.)* If you need medical care because of taking part in this research study, contact the investigator and medical care will be made available. Generally, this care will be billed to you, your insurance, or other third party.Virginia Tech has no program to pay for medical care for research-related injury.

*(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, for example, parking, bus fare).* You will also receive $\_\_\_\_\_\_\_ for your time and effort *(If you will pay additional incentives for participation add: )* In addition, if you join/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 schemes, 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 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.

*(Include for research involving incarcerated persons where there may be a need for follow-up examination or care after the end of participation. Otherwise delete.)* If you are released from jail before you finish this research study, you should take steps to get insurance or Medicaid coverage. Regular office visits and standard treatment will be billed to you or your health insurance. You may continue in the research study after your release from prison. If you move out of the area, we will help you make arrangements to be followed by a healthcare provider.

*(Include for a clinical trial.)*Instead of being in this research study, your choices may include:*(Include alternatives. For example, you could get the usual/existing treatment for your condition)* The important risks and possible benefits of these alternatives include: *(Describe the important risks and potential benefits of the alternative procedures and courses of treatment.)*

*(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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