## Permission to Take Part in a Human Research Study

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| --- |
|  |
| IRB Approval Date |

## Title of research study[[1]](#footnote-1): [insert title of research study here with protocol number, if applicable]

## Investigator: [insert name of principal investigator]

## 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.

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

We invite you to take part in this protocol because you have condition and this is in your best interest.

## What should I know about 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?

This protocol is being done to provide treatment for patient XX.

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

We expect that you will be on this protocol for \_\_\_\_\_\_\_\_ ***[hours/days/months/weeks/years, until a certain event]***.

You will be asked to \_\_\_\_\_\_\_\_\_ ***[include a high level summary of the procedures that will be done. For example: You will be given an investigational drug and asked to be asked to come for 3 study visits. You will give a total of 3 blood samples and fill out questionnaires asking about how you feel.]***

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 identify the most important risks, e.g., emotional distress resulting from a series of questions in a social-behavioral research project or 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]***

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?

We cannot promise any benefits to you from your taking part in this research. However, possible benefits include improvement of your disease/condition.

## [Include for research involving prisoners] Taking part in this research study will not improve your housing or correctional program assignments. Your 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 voluntary. You can decide to participate, not participate, or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

***[Include if there are alternatives other than participating.]*** Instead of being in this research study, your choices may include: ***[List alternatives procedures. For student subject pools describe alternatives for course credit. For clinical trials describe the options that you would normally offer patient. If applicable, include supportive care as an option.]***

***[Include if there are no alternatives other than participating.]*** Your alternative to participating in this research study is to not participate.

## 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 an Institutional Review Board (“IRB”). You may talk to them at (804) 828-0868 or ORSP@vcu.edu if:

* 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.
* You have questions about your rights as a research subject.
* You want to get information or provide input about this research.

## How many people will be studied?

This protocol is only available for the single patient.

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

***[Tell the subject what to expect using lay language and simple terms. Whenever appropriate include the following items:]***

* ***A time-line description of the procedures that will be performed. If practical, prepare a time-line chart or schematic to accompany descriptions of procedures and tests for research that require more than 1 or 2 steps/visits***
* ***The drugs or biologics that will be given to the subject***
* ***All devices that will be used***
* ***All hospitalizations, 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***
* ***With whom will the subject interact***
* ***Where the research will be done***
* ***When the research will be done***
* ***List experimental procedures and therapies and identify them as such***
* ***How often procedures 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***
* ***Whether the research will (if known) or might include whole 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.***

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

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; it will not be held against you.

If you stop being in this protocol, already collected data may not be removed from the records. You may be asked whether the investigator can collect data from your routine medical care.

## 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, if appropriate. If known, describe the probability and magnitude of the risk.]***

* ***[Physical risks***
* ***Psychological risks***
* ***Privacy risks***
* ***Legal risks***
* ***Social risks***
* ***Economic risks]***

***[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 may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

***[Include for research that involves pregnant women or women of child-bearing 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 may also hurt a pregnancy or fetus in ways that are unknown. These may be a minor inconvenience or may 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.

The sponsor will provide the following study-related items/procedures for you at no cost during participation in the study:

* Study drug

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. You remain responsible for all deductibles, co-pays, and balances under your insurance. 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. A member of the study team can talk to you about what procedures would be considered standard care and the coverage of those costs.

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

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB, the Food and Drug Administration and other representatives of this organization.

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.

The sponsor, monitors, auditors, the IRB, the Food and Drug Administration 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 may publish the results of this research. However, we will keep your name and other identifying information confidential.

***[Include for research involving prisoners. Otherwise delete.]*** If you are a prisoner, your medical records may 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?

The person in charge of the protocol can remove you from the protocol without your approval. Possible reasons for removal include

* If you are not able to comply with required visits to monitor your safety
* If we can not get in contact with you for required safety follow ups

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

## What else do I need to know?

This protocol is being funded by ***[Insert name of company providing the drug]***.

If you are injured by, or become ill, from participating in this study, please contact your study doctor immediately. Medical treatment is available at the Virginia Commonwealth University Health System (VCU Health System). Your study doctor will arrange for short-term emergency care at the VCU Health System or for a referral if it is needed.

Fees for such treatment may be billed to you or to appropriate third party insurance. Your health insurance company may or may not pay for treatment of injuries or illness as a result of your participation in this study. To help avoid research-related injury or illness, it is very important to follow all study directions.

***[Include for research involving prisoners 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 physician.

***[Include for a clinical trial.]*** Instead of being in this research study, your choices may include: ***[include alternatives.]*** The important risks and possible benefits of these alternatives include:

It will be noted in your protected electronic health record at VCU Health that you are in this study. Information about the study including any medications you may receive, will be included in the record. This information is protected just as any of your other health records are protected.

***[When applicable, include whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and for research involving biospecimens.]*** Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers ***will/will not*** *c*ontact you to let you know what they have found. If the researchers return genetic test results to you, it may be because they think you could have a health risk and want to recommend that the test should be re-done by a certified clinical laboratory to check the results. If this happens, then you may want to get a second test from a certified clinical laboratory, consult your own doctor, or get professional genetic counseling. You may have to pay for those additional services yourself.

***The following information is required if the study is conducted in a prison setting involving prison staff or inmates as participants:***

***[Describe any exceptions to any guarantees of confidentiality required by federal or state law. For example, a researcher may not guarantee confidentiality when the subject indicates intent to commit future criminal conduct or harm himself/herself, or, if the subject is an inmate, indicates intent to leave the facility without authorization] If you tell us [outline exceptions], then we are required to report that information to [insert name of prison].***

***[There are three signature pages attached to this template consent. Use the signature page or pages appropriate for your study. The IRB recommends that you make separate consent documents for each signature page to be used.]***

***[Omit the signature page if there is no written documentation of consent.]***

**Signature Block for Capable Adult**

Your signature documents your permission to take part in this research.

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Signature of subject Date

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Printed name of subject Date

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Signature of person obtaining consent Date

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Printed name of person obtaining consent

**Signature Block for Adult Unable to Consent**

Your signature documents your permission for the named subject to take part in this research.

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Printed name of subject

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Signature of legally authorized representative Date

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Printed name of legally authorized representative

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Signature of person obtaining consent Date

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Printed name of person obtaining consent IRB Approval Date

***[Add the following block if you will document assent of the subject.]***

Assent

☐ Obtained

☐ Not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.

***[Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects.]***

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of witness to consent process Date

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Printed name of person witnessing consent process

**Signature Block for Children**

Your signature documents your permission for the named child to take part in this research.

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Printed name of child

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Signature of parent or individual legally authorized Date

to consent to the child’s general medical care

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Printed name of parent or individual legally authorized Date  
to consent to the child’s general medical care

☐ Parent

☐ Individual legally authorized to consent to the child’s general medical care (See note below)

**Note:** Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child’s general medical care. Contact legal counsel if any questions arise.

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Signature of parent Date

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Printed name of parent

If signature of second parent not obtained, indicate why: (select one)

☐ The IRB determined that the permission of one parent is sufficient. **[Delete if the IRB did not make this determination]**

☐ Second parent is deceased

☐ Second parent is unknown

☐ Second parent is incompetent

☐ Second parent is not reasonably available

☐ Only one parent has legal responsibility for the care and custody of the child

***[Add the following block if you will document assent of children]***

Assent

☐ Obtained

☐ Not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.

***[Add the following block to all consents]***

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of person obtaining consent and assent Date

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Printed name of person obtaining consent IRB Approval Date

***[Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects.]***

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of witness to consent process Date

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Printed name of person witnessing consent process

**Virginia Commonwealth University Health System (****VCU Health)**

**Research Subject** **HIPAA Authorization Form**  
**for Use or Disclosure of Protected Health Information (PHI)**  
**(In accordance with HIPAA Act 45** **CFR 160 and 164)**

Research study title:

RAMS-IRB number:

**What is the purpose of this form?**

Federal privacy laws protect the use and release of your protected health information (“PHI”). Under these laws, VCU Health cannot release your protected health information for research purposes unless you give your permission. Your information will be released to the research team, which includes the researchers, people hired by VCU Health or the sponsor to do the research, and people with authority to oversee the research. If you decide to give your permission and participate in the study, you must sign this form and the Consent Form. This form describes the different ways that VCU Health can share your information with the researcher, research team, sponsor, and people with oversight responsibility. The research team will use and protect your information as described in the Consent Form. However, once your health information is released by VCU Health, it may not be protected by federal privacy laws and might be shared with others. If you have questions, ask a member of the research team.

By signing this form, you give us permission to use or disclose your requested PHI (itemized below) for the conduct and oversight of the above-mentioned research study.

**What Personal Health Information will be released?**

If you give your permission and sign this form, you are allowing **VCU Health** to release the following medical records containing your Personal Health Information. Your Personal Health Information includes health information in your medical records, financial records and other information that can identify you.

* Entire Medical Record
* Inpatient Records
* Progress Notes
* Consultation
* Discharge Summary
* History & Physical Exams
* Operative Reports
* Abstract of Record\*
* Lab & Pathology Reports
* Radiology Reports
* Psychological Tests
* Other Test Reports
* Emergency Dept. Records
* Outpatient/Ambulatory Clinic Records
* Radiology Images
* Diagnostic Photographs, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Financial records
* Other (describe): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\* An abstract of the record includes: History & Physical Exams, Operative Reports, Consultations and Discharge Summary Reports, and Diagnostic Reports (including Lab, Pathology, & Imaging).

The information used/disclosed pursuant to this authorization will not include psychotherapy notes, but may include detailed mental health information, HIV/AIDS information and/or information regarding alcohol or substance abuse consistent with 42 CFR 2.52.

**People that will Use or Disclose your PHI:** the following person(s), class(es) of persons, and/or organization(s) may disclose, use, and receive the information, but they may only use and disclose the information to the other parties on this list, to the research subject or his/her personal representative, or as otherwise permitted or required by law.

* The Principal Investigator and the research staff and any other people and groups authorized to help conduct the study.
* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, the study sponsor for this research study. The sponsor may also use your PHI to collect and analyze the results of the research and may have other people and groups help conduct, oversee, and analyze the study. These people will use your PHI.
* Every health care provider who provides services to you in connection with this study.
* Any laboratories and other individuals and organizations that analyze your health information in connection with this study in accordance with the study’s protocol.
* The Virginia Commonwealth University Institutional Review Board.
* Any government agencies that regulate research including: the Office for Human Research Protections, The Food and Drug Administration, Medicare, Medicaid, and other regulatory agencies.
* Data and Safety Monitoring Boards / Ethics Committees, research monitors and reviewers.

You do not have to sign this authorization form. If you do not sign, you may not participate in the above-mentioned research study. VCU Health providers shall not condition treatment on the receipt of this authorization, and you may still receive non-research related treatment. This Authorization to release your personal health information expires when the research ends, and all required study monitoring is over.

**Revoking your Authorization:**

You may change your mind and revoke (take back) this Authorization at any time. If you revoke your authorization, the researchers will not collect any more of your PHI. But they may use or pass along the information you already gave them so they can follow the law, protect your safety, or make sure the research is done properly. The information used or disclosed pursuant to this Authorization may be subject to re-disclosure by the recipient of the information and may then no longer be protected by the federal privacy regulations. This authorization for use and disclosure for research purposes indicated above is valid until the end of the study or until/unless you revoke this authorization**.**

If you do wish to revoke authorization you must write to: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_,

**Participant**

If you agree to the use and release of your Personal Health Information, please print your name and sign below. You will be given a signed copy of this form**.**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Participant's Name (print)--*required*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Participant’s Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date

**Parent or Legally Authorized Representative**

If you agree to the use and release of the above-named Participant's Personal Health Information, please print your name and sign below.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Parent or Legally Authorized Representative’s name (print)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Parent or Legally Authorized Representative’s Signature

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date

**Witness**

***If this form is being read to the Participant because they cannot read the form, a witness must be present and is required to print their name and sign here:***

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Witness’ Name (print)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Witness’ Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date

**Interpreter**

***This section must be completed if an interpreter is used during the authorization process because the subject does not speak English.***

By signing below, you confirm that the information in this form has been fully explained to the potential subject in a language they understand and all their questions have been answered.

***If the interpreter speaks with the participant over the phone, write the interpreter's ID # on the signature line below.***

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Interpreter Name (print)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Interpreter’s Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date

1. This template satisfies AAHRPP elements I.1.G, I.4.A, I-9, II.3.C-II.3.C.1, II.3.E, II.3.F, II.4.B, III.1.F, III.1.G [↑](#footnote-ref-1)