MINUTES[1]

Virginia Commonwealth University IRB [panel name]

[Meeting Date]

ATTENDANCE

Name of Regular/Alternate Member[2]	Status (Member or Alternate)	If Voting Alternate, Member Substituting For	Present by Tele-conference?

Reporting of Expedited Reviews:

A report of completed review conducted via the Expedited procedure during *[date range]* was made available to the IRB. The IRB was asked if there were any questions about the reviews and *[no questions or comments were raised OR include description if there were any questions]*.

OTHER ATTENDEES[3]

Name of Attendee	Title/Role	Present by Tele-conference?

MEETING INFORMATION

Number of IRB members on the roster[4]:
Number required for quorum:
Meeting start time:
Meeting end time:

[1] This template satisfies AAHRPP elements I-9, II.1.D, II.1.E, II.2.D, II.2.E-II.2.E.2, II.5.B

[2] Document the attendance of any member (regular or alternate) in attendance who voted during the meeting. Any member (regular or alternate) who did not vote at least once during the meeting must be documented under "Other Attendees."

[3] Any non-voting individuals (including IRB staff, consultants, Investigators, etc.) in attendance at the meeting for any reason or any amount of time.

[4] Document the number of regular IRB members listed on HRP-601 - DATABASE - IRB Roster, not including alternates.

All members present by teleconference received all pertinent material before the meeting and were able to actively and equally participate in all discussions.

The Chair asked the board to declare any conflicts of interest with the posted agenda items.

The minutes from the *[enter meeting date and panel name]* IRB meeting were posted for IRB member consideration. The Chair asked whether there were any questions and *[no questions or comments were raised OR include description if there were any questions].*

ATTENDANCE KEY

Vote Type	Description
FOR:	Voting for the motion.
AGAINST:	Voting against the motion.
ABSTAIN:	Present for the vote, but not voting “For” or “Against.”
ABSENT:	Absent for discussion and voting for reasons other than a conflicting interest.
RECUSED:	Absent from the meeting during discussion and voting because of a conflicting interest.
SUBSTITUTION:	When regular members and their alternate(s) are listed in the ATTENDANCE table above and an alternate member substitutes for the regular member this identifies the name of the alternate to indicate which individual is serving as the voting member for this vote. May be deleted if there are no substitutions.

OTHER BUSINESS

1. Item
2. Item
3. Item

REVIEW OF PROTOCOLS

1. **Protocol Review:**

Type of Review:	*<Indicate Initial, Continuing, Modification>*
Title:	
Investigator:	
IRB ID:	
Funding:	*<Indicate "None" if there is none.>*
Grant Title:	*<Indicate "None" if there is none.>*
Grant ID:	*<Indicate "None" if there is none.>*
IND or IDE:	*<Indicate "None" if there is none.>*
Documents Reviewed:	

a. **Notes:**

<If approved, include statement that the IRB determined that all criteria for approval were met.>

b. **Consultant report:**

c. **Controverted issues and their resolution:** *<Indicate "None" if there is none.>*

d. **Level of risk:** Minimal Risk/Greater than Minimal Risk

e. **Determinations and findings that require documentation:** *<Append completed checklist(s) when applicable.>*

f. **Rationale for a significant/non-significant device determination per FDA:**

g. **Motion:**

h. **Modifications required to secure approval:**

Required Change	Reason

i. **Deferral/disapproval reasons and recommended changes:**

Recommendation	Reason

j. **Suspension/termination reasons and recommended changes:**

Recommendation	Reason

k. **Tabled reason:**

l. **VA documentation:**

m. **Vote:**

For:

Against:
Abstain:
Absent:
Recused:
Substitutions:

REVIEW OF REPORTABLE NEW INFORMATION

2. Reportable New Information:

Type of Review:	*<Indicate Unanticipated Problem Involving Risks to Subjects or Others, Serious Non-Compliance, Continuing Non-Compliance, Suspension of IRB Approval, Termination of IRB Approval>*
Title:	
Investigator:	
IRB ID:	
Funding:	*<Indicate "None" if there is none.>*
Grant Title:	*<Indicate "None" if there is none.>*
Grant ID:	*<Indicate "None" if there is none.>*
IND or IDE:	*<Indicate "None" if there is none.>*
Documents Reviewed:	

a. Notes:

b. Consultant report:

c. Controverted issues and their resolution: *<Indicate "None" if there is none.>*

d. Motion:

e. Required action(s):

Required Action(s)	Reason

f. Request for additional information:

Requested Information	Reason

g. Suspension/termination reasons and recommended changes:

Recommendation	Reason

h. Tabled reason:

i. VA documentation:

j. Vote:

For:
Against:
Abstain:
Absent:
Recused:
Substitutions:

POSSIBLE CONTINGENCIES FOR DETERMINATIONS AND PROTOCOL-SPECIFIC FINDINGS THAT REQUIRE DOCUMENTATION

Research Involving Pregnant Women or Neonates that is Not Otherwise Approvable (45 CFR §46.207)

Add the following contingencies when these reasons are met:

Required Change	Reason for Change
The research may proceed only after OHRP has reviewed and approved the research.	The research is conducted or funded by DHHS and requires OHRP approval.
The research may proceed only after the Director, Defense Research (DOD) and Engineering has reviewed and approved the research.	The research is conducted or funded by Department of Defense (DOD) and requires approval by the Director, Defense Research and Engineering.
The research may proceed only after organizational officials have conducted a review in accordance with the HRP-044 - SOP - Not Otherwise Approvable Research and approved the research.	The research is not conducted or funded by DHHS and requires an external review as an additional ethical protection.

Research Involving Prisoners as Subjects (45 CFR §46 Subpart C)

Add the following contingencies when these reasons are met:

Required Change	Reason for Change
The research may proceed only after OHRP has reviewed and approved the research.	The research is conducted or funded by DHHS and falls into the 45 CFR §46.306(2)(C), which requires OHRP approval.
The research may proceed only after OHRP has reviewed and approved the research.	The research is conducted or funded by DHHS and falls into the 45 CFR §46.306(2)(D) category and prisoners are assigned to control groups which may not benefit from the research, which requires OHRP approval.
The research may proceed only after the institution has certified to OHRP that the duties of the Board under this section have been fulfilled.	The research is conducted or funded by DHHS and OHRP requires certification of such research before it may proceed.
The research may proceed only after the Director, Defense Research and Engineering (DOD) has reviewed and approved the research.	The research is conducted or funded by Department of Defense (DOD) and falls into the 45 CFR §46.306(2)(C), which requires approval by the Director, Defense Research and Engineering.
The research may proceed only after the Director, Defense Research and Engineering (DOD) has reviewed and approved the research.	The research is conducted or funded by Department of Defense (DOD) and falls into the 45 CFR §46.306(2)(D) category and prisoners are assigned to control groups which may not benefit from the research, which requires approval by the

	Director, Defense Research and Engineering.
The research may proceed only after the institution has certified to the Director, Defense Research and Engineering (DOD) that the duties of the Board under this section have been fulfilled.	The research is conducted or funded by Department of Defense (DOD) and the Director, Defense Research and Engineering requires certification of such research before it may proceed.

Research Involving Children as Subjects (21 CFR §50.54/45 CFR §46.407)

Add the following contingencies when these reasons are met:

Required Change	Reason for Change
The research may proceed only after OHRP has reviewed and approved the research.	The research is conducted or funded by DHHS and requires OHRP approval.
The research may proceed only after the Director, Defense Research (DOD) and Engineering has reviewed and approved the research.	The research is conducted or funded by Department of Defense (DOD) and requires approval by the Director, Defense Research and Engineering.
The research may proceed only after Commissioner of Food and Drugs has reviewed and approved the research.	The research is FDA regulated and requires FDA approval.
The research may proceed only after organizational officials have conducted a review in accordance with HRP-044 - SOP - Not Otherwise Approvable Research and approved the research.	The research is not conducted or funded by DHHS and not FDA regulated, and requires an external review as an additional ethical protection.

Permission to Take Part in a Human Research Study

ICF version number: ***[insert ICF version number]***

Title of research study[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 a research study because _____. ***[Fill in the circumstance or condition that makes subjects eligible for the research.]***

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?

[Tell the subject the purpose of the research. Explain the background of the research problem. Explain any potential benefits to others.]

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

We expect that you will be in this research study 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)"***

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[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

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 benefits to others. If benefits from participation may not continue after the research has ended, describe them here. Monetary reimbursement for participation 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 benefits to others. Monetary reimbursement for participation is not a benefit.]***

[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 HRPP@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?

We expect about _____ people here will be in this research study 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 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.***

[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 an _____ ***[equal/one in three/etc.]*** chance of being given each treatment. ***[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; 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 may 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, this 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, 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)

[Delete this section if there are no risks or discomforts.]

[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.

[Include for research where the sponsor provides study-related agents/procedures at no cost to ALL subjects. Otherwise delete. Note: Detailed coverage analysis information is not required in this section.] The sponsor will provide the following study-related items/procedures for you at no cost during participation in the study: ***[Describe what is provided e.g. investigational drug/device.]***

[Include for research that may result in additional costs for all subjects. Otherwise delete.] Taking part in this research study may lead to added costs to you. ***[Describe what these costs are. Detailed coverage analysis information is not required in this section.]***

[Include for a clinical trial. Otherwise delete.] 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.

[Include for research that will collect/store data and samples for future research. Otherwise delete.]

We will do our best to protect your data and samples during storage and when they are shared. However, there remains a possibility that someone could identify you. There is also the possibility that people who are not supposed to might access your data and samples. In either case, we cannot reduce the risk to zero.

[Include for Veterans Administration (VA) research. Otherwise delete.] You will not be required to pay for care received as a subject, except that some veterans are required to pay co-payments for medical care and services provided by Veterans Administration (VA) and that these co-payment requirements will continue to apply to VA-provided medical care and services that are not part of this study.

[Include for Department of Defense (DoD) research where DoD-affiliated personnel are subjects and if the HSR includes a risk to their fitness for duty (e.g. health, availability to perform job, data breach).] This research project may impact your fitness for duty. Please seek command or Component guidance before participating.

[Include for Department of Defense (DoD) research, if applicable.] This research includes the potential risk of the loss of clearance, credentials, or other privileged access or duty.

[Include for Department of Defense (DoD) research that is greater than minimal risk.] For the duration of the study, you may be eligible for health care services for research-related injuries at a military treatment facility, and this eligibility for health care services extends beyond your participation in the study to such time after the study has ended. ***[Add additional information about how this organization will care for participants with research-related injuries, including injuries that are the direct result of activities performed by DoD-affiliated personnel]***

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 and other representatives of this organization. ***[Add to this list other organizations that may have access to the subject's records such as the Food and Drug Administration, when the research if FDA-regulated, the Department of Health and Human Services, when the research is conducted or funded by DHHS, the sponsor, contract research organization, sponsor's agent and other collaborating institutions. Include for Department of Defense (DoD) research that representatives of the DoD are authorized to review research records.]***

[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.]

[As employees of an institution of higher education in Virginia, VCU faculty and staff are all mandated reporters and are obligated to report child and elder abuse. If there is the potential for any participant to disclose that they may cause injury to themselves or others, you should state in this section that you are required by law to report that information to the appropriate authorities.

Note: When research is supported by the Department of Justice, in order to report child abuse, the researcher must obtain a separate consent to allow child abuse reporting. The National Institute of Justice provides a consent template for this purpose.]

[Example:] We will not tell anyone the answers your child/loved one gives us. However, if your child/loved one tells us that someone is hurting them, or that they might hurt themself or someone else, the law says that we must let people in authority know so they can protect your child/loved one.

[Example:] If you tell us that you may hurt yourself or someone else, the law says that we must let people in authority know.

[Include for NIH-funded studies or those receiving a CoC by request from NIH.] This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

[Include for Veterans Administration (VA) research that involves a certificate of confidentiality and information about the participant's participation will be included in the participant's VA medical record] Information about your study participation will be included in your VA medical record.

[If data or 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, and how long the date or specimens will be retained.]

[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 identifiable private information or identifiable 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. ***See the information*** found under ***"Will my data or samples be used for future research?"***

OR

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.

[Include for research where the sponsor may pay for medical expenses of the subject.] If the sponsor pays any of your medical expenses, we may be required to give the sponsor your name, date of birth, and Medicare ID or social security number.

[Include for a clinical trial. Otherwise delete.] 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 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 Web site will not

include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site 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 may also be given to officials and agencies within the criminal justice system when necessary and permitted by law.

Will my data or samples be used for future research?

[Include this section if data or specimens will be retained after the study for future research, add/modify the following text to explain where the data or specimens will be stored, who will have access to the data or specimens, and how long the data or specimens will be retained.]

This study is collecting data and samples from you. We would like to make your data and samples available for other research studies that may be done in the future. The research may be about similar diseases or conditions to this study. However, research could also be about unrelated diseases, conditions, or other types of research. These studies may be done by researchers at this institution or other institutions, including commercial entities. Your data and samples may be shared with researchers around the world. Our goal is to make more research possible. We plan to keep your data and samples for ***[Insert time frame as indicated in the study protocol]***. To get your data or samples, future researchers must seek approval from this institution and review by an IRB may be required.

[If the data and biospecimens are coded and can be linked back to the identity of the participant enter the following text.]

We will protect the confidentiality of your information to the extent possible. Your data and samples will be coded to protect your identity before they are shared with other researchers. Only the study team ***[or indicate who has the code key]*** will have a code key that can be used to link to your identifying information. The code key will be securely stored.

[If the data and biospecimens cannot be easily linked back to the identity of the participant enter the following text.]

Your name and identifying information will be removed from any data and samples you provide before they are shared with other researchers. Researchers cannot easily link your identifying information to the data and samples.

[Include when sharing of data and specimens will NOT be optional (e.g., where sharing is integral to the purpose of the study).]

Participating in this study means you agree to share your data and samples. You can change your mind later, but researchers might still use your data and samples if they have already been shared. If you do not want your data and samples used for other research studies, you should not participate in this study.

Can I be removed from the research without my OK?

[Delete this section if not applicable.]

[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 may be withdrawn, if appropriate.]***

[Include for research where this is a possibility. Otherwise delete.] 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?

[Include for sponsored research. Otherwise delete.] This research is being funded by ***[Insert name of sponsor]***. ***[Include for Department of Defense (DoD) research that the DoD or a DoD organization is funding the study.]***.

[Include for research involving more than minimal risk. Otherwise delete.]

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.

[Describe any compensation available for research related injury, if applicable.]

[Include for Veterans Administration (VA) research. Otherwise delete.] If you are injured or made sick from taking part in this research study, medical care will be provided. In general this medical care will be provided in VA medical facilities. This care will be provided at no cost to you. Contact the investigator for more information.

[Required for Veterans Administration (VA) research studies using a drug, biological product, device, or vaccine designed to treat, diagnose, cure or prevent COVID-19. This language must be included as is unless an exception is granted by the VA. Otherwise delete.] A new public health law under the Public Readiness and Emergency Preparedness Act (PREP Act) was issued by the Department of Health and Human Services on March 10, 2020. This law limits your ability to sue if you are in a COVID-19 research study. If this study uses a drug, device or vaccine designed to treat, diagnose, cure or prevent COVID-19, you cannot sue the manufacturers, the study sponsor, healthcare providers or other professionals involved in the study for injury or harm (i.e., getting hurt) unless the injury or harm was on purpose. You may be compensated for injury or harm through a Department of Health and Human Services program called the Countermeasures Injury Compensation Program (CICP). For more information about this program, please contact the Health Resources and Services Administration's CICP by phone at 855-266-2427 or online at https://www.hrsa.gov/cicp/about/index.html. VA will provide necessary medical treatment should you be injured by being in this study. You will be treated for the injury at no cost to you. This care may be provided by the local VAMC or arrangements may be made for contracted care at another facility. In case of research related injury resulting from this study, you should contact your study team. If you have questions about medical treatment for any study related injuries, you can call the operator at this VA Medical Center and ask for medical administration. *You still have the right to hold VA responsible for negligence that is not related to a COVID-19 research study.*

[Include for research studies using a drug, biological product, device, or vaccine designed to treat, diagnose, cure or prevent COVID-19. Otherwise delete.] Due to the coronavirus public health emergency, the federal government has issued an order that may limit your right to sue if you are injured or harmed while participating in this COVID-19 study. If the order applies, it limits your right to sue researchers, healthcare providers, any study sponsor, manufacturer, distributor or any other official involved with the study. However, the federal government has a program that may provide compensation to you or your family if you experience serious physical injuries or death. To find out more about this "Countermeasures Injury Compensation Program" please go to https://www.hrsa.gov/cicp/about/index.html or call 855-266-2427.

[Include if subjects will be paid. Otherwise delete.] If you agree to take part in this research study, we will pay you ***[indicate amount]*** for your time and effort. ***[Indicate if the amount is pro-rated for research visit completion.]***

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

[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: ***[Describe the important risks and potential benefits of the alternative procedures and courses of treatment.]***

[If this is a clinical research study that has the potential for clinical billing, is a clinical trial, or if research information will be placed in the participant's electronic health record at VCU Health, insert:] 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.

[Include when applicable.] Your information and samples (both identifiable and de-identified) may 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.

[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*** contact 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.

[When the research involves genetic testing or the collection of genetic information.] This research study involves genetic testing. The Genetic Information Nondiscrimination Act (GINA) prohibits health insurers or health plan administrators from requesting or requiring genetic information of you or your family members, or using such information for decisions regarding your eligibility for insurance or your premiums. However, this law does not provide the same protection for disability, life insurance, or long-term care insurance. GINA also prohibits most employers (with 15 employees or more) from using genetic information when making decisions on your employment, including decisions related to hiring, firing, promotion, pay, and job assignments. Information obtained through genetic testing may be susceptible to re-identification. The following safeguards will be used to help protect your information from re-identification: ***[indicate safeguards].*** Please contact your study doctor if you would like more information about GINA and how it protects you from genetic discrimination.

[If tests are done that require reporting of positive results to the Health Department (e.g. hepatitis, HIV, STDs, COVID) these must be mentioned, along with that information.] Your blood sample will be tested for ***[insert name of disease]***. Virginia state law requires the study staff to report the results of positive tests for [disease name] to a local public health agency.

[Include this section when sharing of data and specimens will be optional (e.g., for studies that have potential benefit)]

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].

The following information is required for all studies funded by the Department of Justice:

Private, identifiable information will only be used for research and statistical purposes. However, if you indicate future criminal intent, the researchers are required by law to report this to the authorities.

Project findings and reports prepared for dissemination will not contain information that can reasonably be expected to be identifiable. ***[If findings in a project cannot, by virtue of sample size or uniqueness of subject, be expected to totally conceal subject identity, this must be included in the informed consent.] [If the study is funded by the National Institute of Justice, insert:]*** At the end of the study, a copy of all the data (without any information that could identify you) will be submitted to the National Archive of Criminal Justice Data.

[Include amount, timing and plan for disbursement of any payment or incentive to participants, as applicable.]

Total payments within one calendar year that exceed $600 will require the University to report these payments annually to the IRS and you. This may require you to claim the compensation you receive for participation in this study as taxable income. VCU is required by federal law to collect your social security number. Your social security number will be kept confidential and will only be used to process payment.

[Include if appropriate:] Please be aware that the investigative team and the University may receive money for the conduct of this study.

[Include if appropriate:] ***Optional Procedures for the Study***

[Include the below paragraph if you intend to store/share data/leftover samples from this study for future research. Future research includes any research that may be performed that is outside of the perimeters of this study. Samples being stored until the end of the study for analysis related to this study are not considered future research.]

It is your choice whether or not to let researchers share your data and samples for research in the future. If you say “yes,” you can change your mind later. If you say “no,” you can still fully participate in this study. If you change your mind and no longer wish to have us store or share your data and samples, you should contact the investigator. We will do our best to honor your request and to get back any data and samples that have been shared with other researchers. However, there may be times we cannot. For example, if we do not have a way to identify your data and samples, we will not be able to get them back. In addition, if the data and samples have already been used for new research, the information from that research may still be used. We will destroy any samples we have or are able to get back.

Please initial ***[or sign depending on institutional practice]*** next to your choice:

_____YES, my data and samples may be used in other research studies

_____NO, my data and samples MAY NOT be used in other research studies

[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.

Signature of subject	Date
Printed name of subject	Date
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

[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
Printed name of person witnessing consent process	Date

Signature Block for Adult Unable to Consent

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

_____

Printed name of subject

_____

Signature of legally authorized representative Date

_____

Printed name of legally authorized representative

_____

Signature of person obtaining consent Date

_____

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

_____

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.

_____

Printed name of child

_____

Signature of parent or individual legally authorized to consent to the child's general medical care — Date

_____

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

☐ 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.

_____

Signature of parent — Date

_____

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

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

Printed name of person witnessing consent process

[Include the following HIPAA authorization, applicable. This template may be subject to further changes. Content may be modified as needed to meet regulatory requirements.]

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, Consultation 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.
- Others, specify:

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

PROTOCOL TITLE: Click or tap here to enter text.

INSTRUCTIONS[1]:

- *Use this template to prepare a document with the information from following sections.*
- *Depending on the nature of your study, some sections may not be applicable to your research. If so mark as "NA". For example, research involving a retrospective chart review may have many sections with "NA." For subsections, like 1.x or 8.x, you can delete it if it's not applicable.*
- *When you write a protocol, keep an electronic copy. You will need to modify this copy when making changes.*
- *As you are writing the protocol, remove all instructions in italics so that they are not contained in the final version of your protocol.*
- *For submission of a protocol specific to a participating Site as part of a Multi-Site Study, use HRP-508 - TEMPLATE - SITE SUPPLEMENT.*

PROTOCOL TITLE:

Include the full protocol title. Click or tap here to enter text.

PRINCIPAL INVESTIGATOR:

Name Click or tap here to enter text.
Department Click or tap here to enter text.
Telephone Number Click or tap here to enter text.
Email Address Click or tap here to enter text.

VERSION NUMBER/DATE:

Include the version number and date of this protocol. Click or tap here to enter text.

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.

[1] This template satisfies AAHRPP elements 1.7.B, I.8.B, I-9, II.2. A, II.2.I, II.3.A, II.3.B, II.3.C-II.3.C.1, II.3.D-F, II.4.A, III.1.C-F, II.2.D

Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.

Table of Contents

1.0 Study Summary

Protocol Information	Description
Study Title	Click or tap here to enter text.
Study Design	Click or tap here to enter text.
Primary Objective	Click or tap here to enter text.
Secondary Objective(s)	Click or tap here to enter text.
Research Intervention(s)/ Investigational Agent(s)	Click or tap here to enter text.
IND/IDE #	Click or tap here to enter text.
Study Population	Click or tap here to enter text.
Sample Size	Click or tap here to enter text.
Study Duration for individual participants	Click or tap here to enter text.
Study Specific Abbreviations/ Definitions	Click or tap here to enter text.

2.0 Objectives

2.1 Describe the purpose, specific aims, or objectives. Click or tap here to enter text.

2.2 State the hypotheses to be tested. Click or tap here to enter text.

3.0 Background

3.1 Describe the relevant prior experience and gaps in current knowledge. Click or tap here to enter text.

3.2 Describe any relevant preliminary data. Click or tap here to enter text.

3.3 Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge. Click or tap here to enter text.

4.0 Study Endpoints

4.1 Describe the primary and secondary study endpoints. Click or tap here to enter text.

4.2 Describe any primary or secondary safety endpoints. Click or tap here to enter text.

5.0 Study Intervention/Investigational Agent

5.1 Description: Describe the study intervention and/or investigational agent (e.g., drug, device) that is being evaluated. Click or tap here to enter text.

5.2 Drug/Device Handling: If the research involves drugs or device, describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.

- *If the control of the drugs or devices used in this protocol will be accomplished by using the Investigational Drug Service (IDS) pharmacy, please reference that in this section.*

Click or tap here to enter text.

5.3 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:*

Click or tap here to enter text.

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	

6.0 Procedures Involved

6.1 Describe and explain the study design. If you have any sub-groups, sub-studies, or retrospective collection of data and/or biospecimens, remember to address them here. If the study design involves placebos, deception, or washout periods, address that here. Click or tap here to enter text.

6.2 Provide a description of all research procedures being performed and when they are performed, including procedures being performed to monitor subjects for safety or minimize risks. Click or tap here to enter text.

6.3 Describe:

- *Procedures performed to lessen the probability or magnitude of risks.*
- *All drugs and devices used in the research and the purpose of their use, and their regulatory approval status.*
- *The source records that will be used to collect data about subjects. (Attach all surveys, scripts, and data collection forms.)*
- *Biospecimens to be collected, and whether you will collect them directly from participants for research only or from another source (e.g., another research study or pathology laboratory, either fresh or archived/diagnostic tissue). For specimens obtained directly from participants, include the amount collected, the collection schedule, and collection method.*
- *Genetic testing or genetic analysis of any biospecimens.*

Click or tap here to enter text.

6.4 What data will be collected during the study and how that data will be obtained.

- *List of data elements*
- *Surveys, Questionnaires, data collection forms, active or passive internet data collection, verbal responses, interviews, focus groups, audio/video recordings, photographs, educational assessments*

Click or tap here to enter text.

6.5 If there are plans for long-term follow-up (once all research related procedures are complete), what data will be collected during this period. Click or tap here to enter text.

6.6 For Humanitarian Use Device (HUD) uses provide a description of the device, a summary of how you propose to use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures. Click or tap here to enter text.

7.0 Data and/or Specimen Banking

7.1 If data and/or specimens will be banked for future use, describe where the specimens will be stored (e.g., VCU or external registry/repository), how long they will be stored, how the specimens will be accessed, and who will have access to the specimens. Click or tap here to enter text.

7.2 List the data to be stored and/or associated with each specimen. Click or tap here to enter text.

7.3 Describe the procedures to release data or specimens, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens. Click or tap here to enter text.

7.4 State whether participants may access their data/specimens for personal use, and if so how. Click or tap here to enter text.

7.5 State whether participants may withdraw their banked data/specimens from future research use. If yes, explain whether data/specimens would be destroyed or fully anonymized in response to a withdrawal request. If no, explain why (e.g., data/specimens are fully anonymized prior to banking). Click or tap here to enter text.

8.0 Sharing of Results with Subjects

8.1 Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how the results will be shared. Click or tap here to enter text.

9.0 Study Timelines

9.1 Describe:

- *The duration of an individual subject's participation in the study.*
- *The duration anticipated to enroll all study subjects.*
- *The estimated date for the investigators to complete this study (complete primary analyses).*

Click or tap here to enter text.

10.0 Inclusion and Exclusion Criteria

10.1 Describe how individuals will be screened for eligibility. Click or tap here to enter text.

10.2 Describe the criteria that define who will be included or excluded in your final study sample. Click or tap here to enter text.

10.3 If any specific population or segment of community will be targeted or excluded, describe this and provide justification. Click or tap here to enter text.

10.4 Indicate specifically whether you will include or exclude each of the following special populations: (You may not include members of the below populations as subjects in your research unless you indicate this in your inclusion criteria.)

- *Adults unable to consent*
- *Individuals who are not yet adults (infants, children, teenagers)*
- *Pregnant women*
- *Prisoners*

Click or tap here to enter text.

11.0 Vulnerable Populations

11.1 If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.

- *If the research involves pregnant women, review HRP-412 - CHECKLIST - Pregnant Women to ensure that you have provided sufficient information.*
- *If the research involves neonates of uncertain viability or non-viable neonates, review HRP-413 - CHECKLIST - Non-Viable Neonates or HRP-414 - CHECKLIST - Neonates of Uncertain Viability to ensure that you have provided sufficient information.*
- *If the research involves prisoners, review HRP-415 - CHECKLIST - Prisoners to ensure that you have provided sufficient information.*
- *If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research ("children"), reviewHRP-416 - CHECKLIST - Children to ensure that you have provided sufficient information.*
- *If the research involves decisionally impaired adults, review HRP-417 - CHECKLIST - Cognitively Impaired Adults to ensure that you have provided sufficient information.*

● *Check if the research involves any of the following groups:*

☐ *Wards of the State*
☐ *VCU/VCUHS students or trainees*
☐ *VCU/VCU Health System employees*
☐ *Active military personnel*
☐ *Student populations in K-12 educational settings or other learning environments*
☐ *Members of a federally recognized American Indian or Alaska Native tribe*

12.0 Number of Subjects

12.1 Indicate the total number of subjects to be accrued locally. If this is a multi-site study, provide both study-wide accrual goal and the number of participants to be accrued at each participating site. Click or tap here to enter text.

12.2 If applicable, distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures (i.e., numbers of subjects excluding screen failures.) Click or tap here to enter text.

13.0 Recruitment Methods

13.1 Describe when, where, and how potential subjects will be recruited. If applicable, describe procedures for oral or written communication with the prospective subject or legally authorized representative that will be done for purposes of screening, recruiting, or determining eligibility. If the study recruitment process is expected to include non-English speaking subjects, describe accommodations such as interpreters. Click or tap here to enter text.

13.2 Describe the source of subjects (e.g., community, recruitment registry [specify], health records). Click or tap here to enter text.

13.3 Describe the methods that will be used to identify potential subjects, including whether subjects self-identify in response to recruitment material or how contact information is obtained, and who will contact or approach subjects. If applicable, describe procedures for accessing records or stored identifiable biospecimens for purposes of screening, recruiting, or determining eligibility. Click or tap here to enter text.

13.4 Describe materials that will be used to recruit subjects, addressing when and how often they will be used. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)

Example recruitment materials that should be described and included:

- *E-mail invitations*
- *Phone solicitation scripts*
- *Flyers, mailed letter or newspaper/TV/radio ads*
- *TelegRAM announcements*
- *website text*
- *study-specific websites*
- *social media*
- *EPIC MyChart Patient Portal research study descriptions*

- *Psychology Research Participant Pool (SONA) study descriptions*
- *Scripts for announcements made to groups*

Click or tap here to enter text.

13.5 *Describe the amount and timing of any payments to subjects. See VCU Procurement Services for allowable payment methods.*

- *Explain whether subjects will be reimbursed for out of pocket expenses and/or receive payments related to their participation. Include specific information about the amount, timing and method of disbursement. Provide justification to support that the amount of payment and the disbursement procedures are neither coercive nor present undue influence to participants. Provide the reason for reimbursement.*
- *Confirm that credit for payment will accrue as the study progresses.*
- *Indicate whether there is any bonus paid for completion.*

Click or tap here to enter text.

14.0 Withdrawal of Subjects

14.1 *Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent.* Click or tap here to enter text.

14.2 *Describe any procedures for orderly termination.* Click or tap here to enter text.

14.3 *Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.* Click or tap here to enter text.

15.0 Risks to Subjects

15.1 *List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects' participation in the research. Include as may be useful for the IRB's consideration, a description of the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks. Describe any impact the study might have on students' opportunity to learn required educational content. Describe any interventions that may be perceived as offensive or embarrassing.* Click or tap here to enter text.

15.2 *If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.* Click or tap here to enter text.

15.3 *If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.* Click or tap here to enter text.

15.4 *If applicable, describe risks to others who are not subjects.* Click or tap here to enter text.

15.5 *Describe how the study design, inclusion/exclusion criteria, and any other relevant factors minimize risks of harm or discomfort.* Click or tap here to enter text.

16.0 Potential Benefits to Subjects

16.1 Describe the potential benefits that individual subjects may experience from taking part in the research. Include as may be useful for the IRB's consideration, the probability, magnitude, and duration of the potential benefits. Click or tap here to enter text.

16.2 Indicate if there is no direct benefit. Do not include benefits to society or others. Click or tap here to enter text.

17.0 Data Management* and Confidentiality

17.1 Describe the data analysis plan, including any statistical procedures or power analysis. Click or tap here to enter text.

17.2 Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission.

*Select all that apply to **paper** research material:*

☐ *Maintaining control of paper documents at all times, including when at off-campus location*

☐ *Storing paper documents in a secure location accessible only by study team*

☐ *Promptly transcribing, scanning, or abstracting data from paper into electronic platform and destroying the paper copy*

*Select all that apply to **electronic** research material:*

☐ *Use VCU-approved methods of data storage, transmission, and transfer (see https://dms.vcu.edu)*

☐ *Using individual logins/separate accounts on shared devices*

☐ *Using VCU approved data collection tools and apps (e.g., REDCap, Qualtrics)*

☐ *Consulting with VCU Information Security when using non-VCU approved data collection tools (https://ts.vcu.edu/askit/essential-computing/information-security/)*

*Select all that apply for research **biospecimens**:*

☐ *Maintaining control of specimens at all times, including when at off-campus location*

☐ *Storing specimens in a secure location only accessible only by study team*

☐ *Labeling specimens with subject ID or other coded information instead of direct identifiers*

☐ *Final destruction of specimens will be devoid of any identifiable information*

17.3 Describe any procedures that will be used for quality control of collected data. Click or tap here to enter text.

17.4 Describe how data or specimens will be handled study-wide:

- *What information will be included in that data or associated with the specimens?*
- *Where and how data or specimens will be stored?*
- *How long the data or specimens will be stored?*
- *Who will have access to the data or specimens?*
- *Who is responsible for receipt or transmission of the data or specimens?*
- *How data or specimens will be transported?*

Click or tap here to enter text.

17.5 If you plan to retain screening data collected by phone or other methods for people who decline to participate, describe this, including the rationale for retaining the information and for how long (e.g., end of the study). Click or tap here to enter text.

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

This section is required when research involves more than Minimal Risk to subjects.

18.1 Describe:

- *The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe. The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor. Indicate if this study will have a Data Safety Monitoring Board or a Data Safety Monitoring Plan.*
- *What data are reviewed, including safety data, untoward events, and efficacy data.*
- *How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).*
- *The frequency of data collection, including when safety data collection starts.*
- *Who will review the data.*
- *The frequency or periodicity of review of cumulative data.*

- *The statistical tests for analyzing the safety data to determine whether harm is occurring.*
- *Any conditions that trigger an immediate suspension of the research.*

Click or tap here to enter text.

19.0 Provisions to Protect the Privacy Interests of Subjects

19.1 Describe the steps that will be taken to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on whom they interact or whom they provide personal information.

Select any of the following that apply:

☐ *Conducting study activities in locations that maximize privacy*

☐ *Verifying identify before discussing personal information*

☐ *Asking the subject if they are comfortable answering in the location*

☐ *Asking the subject if they are comfortable with others present*

☐ *Offering alternate ways to respond (e.g., pointing, writing)*

☐ *Using generic signs on research rooms and spaces*

☐ *Some questions may be skipped*

☐ *Using Study IDs instead of direct identifiers*

☐ *Using mailing techniques that do not include study name or identifiers*

☐ *Working only in locations the study team can ensure privacy*

☐ *Storing study material in locations restricted to study team access*

☐ *Obtaining explicit parental permission before sharing photos/recordings of children*

19.2 Describe what steps you will take to make the 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. Click or tap here to enter text.

19.3 Indicate how the research team is permitted to access any sources of information about the subjects. Click or tap here to enter text.

19.4 Select all identifiers that will be collected at any time as part of this study (including for recruitment, data gathering, data analysis, etc.), even if the data will eventually be anonymized:

☐ *Names*
☐ *Geographic Locators Below State Level*
☐ *Social Security Numbers*
☐ *Dates (year alone is not an identifier)*
☐ *Ages over 89 (age under 89 is not an identifier)*
☐ *Phone Numbers*
☐ *Facsimile Numbers*
☐ *E-mail Addresses*
☐ *Medical Record Numbers*
☐ *Device Identifiers*
☐ *Biometric Identifiers*
☐ *Web URLs*
☐ *IP Addresses*
☐ *Account Numbers*
☐ *Health Plan Numbers*
☐ *Full Face Photos or Comparable Images*
☐ *License/Certification Numbers*
☐ *Vehicle ID Numbers*
☐ *Other Unique Identifier*
☐ *No Identifiers*
☐ *Employee V#*

20.0 Compensation for Research-Related Injury

20.1 If the research involves more than Minimal Risk to subjects, describe the available compensation in the event of research related injury. Click or tap here to enter text.

20.2 For industry funded studies only, provide a memo from the Division of Sponsored Programs approving the consent form language for compensation for research-related injury. For all other funding sources, the template language from HRP-502 should be utilized in the consent form. Click or tap here to enter text.

21.0 Economic Burden to Subjects

21.1 Describe any costs that subjects may be responsible for because of participation in the research.

Select all that apply:

☐ *Participants will have no costs associated with this study*

☐ *Study related procedures that would be done under standard of care*

☐ *Study related procedures not associated with standard of care*

☐ *Administration of drugs/devices*

☐ *Study drugs or devices*

22.0 Consent Process

22.1 Indicate whether you will you be obtaining consent, and if so describe (describe for different groups if multiple):

- *Who will obtain informed consent*
- *Where the consent process will take place.*
- *How the consent process will be conducted (e.g., electronic, face-to-face, phone or video).*
    - *If electronic, choose platform(s) or explain other:*
        - ☐ *DocuSign Part 11 (FDA regulated studies)*
        - ☐ *DocuSign (standard platform for non-FDA regulated studies)*
        - ☐ *REDCap e-Consent*
        - ☐ *iMedConsent (Veterans Affairs studies)*
- *Any waiting period available between informing the prospective subject and obtaining the consent.*
- *Any process to ensure ongoing consent.*
- *Whether you will be following HRP-090 - SOP - Informed Consent Process for Research. If not, describe:*
    - *The role of the individuals listed in the application as being involved in the consent process.*
    - *The time that will be devoted to the consent discussion.*
    - *Steps that will be taken to minimize the possibility of coercion or undue influence.*
- *Steps that will be taken to ensure the subject's understanding*

Click or tap here to enter text.

Non-English Speaking Subjects

- *Indicate what language(s) other than English are understood by prospective subjects or representatives.*
- *If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate the language that will be used by those obtaining consent.*

Click or tap here to enter text.

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

- *Review HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process to ensure you have provided sufficient information for the IRB to make these determinations. Describe whether you are requesting to waive some elements of consent (describe which ones), or all elements of consent. Provide justification.*
- *If the research involves a waiver of the consent process for planned emergency research, please review HRP-419 - CHECKLIST - Waiver of Consent Process for Emergency Research to ensure you have provided sufficient information for the IRB to make these determinations.*
- *If the research involves deception, describe whether subjects prospectively authorize the deception and plans for de-briefing subjects.*

Click or tap here to enter text.

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

- *Describe the criteria that will be used to determine whether a prospective subject has not attained the 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., individuals under the age of 18 years.)*
    - *For research conducted in the state, review HRP-013 - SOP - LARs, Children, and Guardians to be aware of which individuals in the state meet the definition of "children."*
    - *For research conducted outside of the state, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of "children" in HRP-013 - SOP - LARs, Children, and Guardians.*
- *Describe whether parental permission will be obtained from:*
    - *Both parents 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 child.*
    - *One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.*

- *Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals' authority to consent to each child's general medical care.*
- *Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent. If not obtaining assent, include justification.*
- *When assent of children is obtained describe whether and how it will be documented.*

Click or tap here to enter text.

Cognitively Impaired Adults

- *Describe the process to determine whether an individual is capable of consent or assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require cognitively impaired adults to sign assent documents.*

Click or tap here to enter text.

Adults Unable to Consent

- *List the individuals from whom permission will be obtained in order of priority. (E.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child.)*
    - *For research conducted in the state, review HRP-013 - SOP - LARs, Children, and Guardians to be aware of which individuals in the state meet the definition of "legally authorized representative."*
    - *For research conducted outside of the state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of "legally authorized representative" in HRP-013 - SOP - LARs, Children, and Guardians.*
- *Describe the process for assent of the subjects. Indicate whether:*
    - *Assent will be required of all, some, or none of the subjects. If some, indicated, which subjects will be required to assent and which will not.*
    - *If assent will not be obtained from some or all subjects, an explanation of why not.*
    - *Describe whether assent of the subjects will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document*

and does not routinely require assent documents and does not routinely require subjects to sign assent documents.

Click or tap here to enter text.

Humanitarian Use Device (HUD)

- *For HUD uses provide a description of how the patient will be informed of the potential risks and benefits of the HUD and any procedures associated with its use.*

Click or tap here to enter text.

23.0 Process to Document Consent in Writing

23.1 Describe whether you will be following HRP-091 - SOP - Written Documentation of Consent. If not, describe whether and how consent of the subject will be documented in writing. Click or tap here to enter text.

23.2 If your 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, the IRB will generally waive the requirement to obtain written documentation of consent. Click or tap here to enter text.

23.3 (If you will document consent in writing, attach a consent document. If you will obtain consent, but not document consent in writing, attach a consent script. Review HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent to ensure that you have provided sufficient information. You may use HRP-502 - TEMPLATE CONSENT DOCUMENT to create the consent document or script.) Click or tap here to enter text.

24.0 Setting

24.1 Describe the sites or locations where your research team will conduct the research.

- *Identify where your research team will identify and recruit potential subjects.*
- *Identify where research procedures will be performed.*
- *Describe the composition and involvement of any community advisory board.*
- *For research conducted outside of the organization and its affiliates describe:*
    - *Site-specific regulations or customs affecting the research for research outside the organization.*
    - *Local scientific and ethical review structure outside the organization.*

Click or tap here to enter text.

25.0 Resources Available

25.1 Describe the resources available to conduct the research: For example, as appropriate:

- *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 consequence of the human 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.*

Click or tap here to enter text.

26.0 Multi-Site Research

26.1 Study-Wide Number of Subjects
If this is a multicenter study, indicate the total number of subjects to be accrued across all sites. Click or tap here to enter text.

26.2 Study-Wide Recruitment Methods

- *If this is a multicenter study and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) describe those methods. Local recruitment methods are described later in the protocol.*
- *Describe when, where, and how potential subjects will be recruited.*
- *Describe the methods that will be used to identify potential subjects.*
- *Describe materials that will be used to recruit subjects. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)*
- *If this is a multi-site study where you are the lead investigator, describe the processes to ensure communication among sites. See HRP-830 - WORKSHEET - Communication and Responsibilities. All sites have the most current version of the protocol, consent document, and HIPAA authorization.*
- *All required approvals (initial, continuing review and modifications) have been obtained at each site (including approval by the site's IRB of record).*
- *All modifications have been communicated to sites and approved (including approval by the site's IRB of record) before the modification is implemented.*

- *All engaged participating sites will safeguard data, including secure transmission of data, as required by local information security policies.*
    - *All local site investigators conduct the study in accordance with applicable federal regulations and local laws.*
- *All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.*

Click or tap here to enter text.

26.3 Describe the method for communicating to engaged participating sites (see HRP-830 - WORKSHEET - Communication and Responsibilities):

- *Problems (inclusive of reportable events).*
- *Interim results.*
- *The closure of a study.*

Click or tap here to enter text.

26.4 If this is a multicenter study where you are a participating site/investigator, describe the local procedures for maintenance of confidentiality. (See HRP-830 - WORKSHEET - Communication and Responsibilities.)

- *Where and how data or specimens will be stored locally?*
- *How long the data or specimens will be stored locally?*
- *Who will have access to the data or specimens locally?*
- *Who is responsible for receipt or transmission of the data or specimens locally?*
- *How data and specimens will be transported locally?*

Click or tap here to enter text.

PROTOCOL TITLE: Click or tap here to enter text.

INSTRUCTIONS[1]:

- *Use this template to prepare a document with the information from following sections.*
- *Depending on the nature of your study, some sections may not be applicable to your research. If so mark as "NA". For example, research involving a retrospective chart review may have many sections with "NA." For subsections, like 1.x or 8.x, you can delete it if it's not applicable.*
- *When you write a protocol, keep an electronic copy. You will need to modify this copy when making changes.*
- *As you are writing the protocol, remove all instructions in italics so that they are not contained in the final version of your protocol.*
- *For submission of a protocol specific to a participating Site as part of a Multi-Site Study, use HRP-508 - TEMPLATE - SITE SUPPLEMENT.*

PROTOCOL TITLE:

Include the full protocol title. Click or tap here to enter text.

PRINCIPAL INVESTIGATOR:

Name Click or tap here to enter text.
Department Click or tap here to enter text.
Telephone Number Click or tap here to enter text.
Email Address Click or tap here to enter text.

VERSION NUMBER/DATE:

Include the version number and date of this protocol. Click or tap here to enter text.

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.

[1] This template satisfies AAHRPP elements 1.7.B, I.8.B, I-9, II.2. A, II.2.I, II.3.A, II.3.B, II.3.C-II.3.C.1, II.3.D-F, II.4.A, III.1.C-F, II.2.D

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Table of Contents

1.0 Study Summary

Protocol Information	Description
Study Title	Click or tap here to enter text.
Study Design	Click or tap here to enter text.
Primary Objective	Click or tap here to enter text.
Secondary Objective(s)	Click or tap here to enter text.
Research Intervention(s)	Click or tap here to enter text.
Study Population	Click or tap here to enter text.
Sample Size	Click or tap here to enter text.
Study Duration for individual participants	Click or tap here to enter text.
Study Specific Abbreviations/ Definitions	Click or tap here to enter text.

2.0 Objectives

2.1 Describe the purpose, specific aims, or objectives. Click or tap here to enter text.

2.2 State the hypotheses to be tested. Click or tap here to enter text.

3.0 Background

3.1 Describe the relevant prior experience and gaps in current knowledge. Click or tap here to enter text.

3.2 Describe any relevant preliminary data. Click or tap here to enter text.

3.3 Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge. Click or tap here to enter text.

4.0 Study Endpoints

4.1 Describe the primary and secondary study endpoints. Click or tap here to enter text.

5.0 Study Intervention

5.1 Description: Describe the study intervention that is being evaluated. Click or tap here to enter text.

6.0 Procedures Involved

6.1 Describe and explain the study design. If you have any sub-studies, or retrospective collection of data and/or biospecimens, remember to address them here. If the study design involves placebos, deception, or washout periods, address that here. Click or tap here to enter text.

6.2 Provide a description of all research procedures being performed and when they are performed, including procedures being performed to monitor subjects for safety or minimize risks. Click or tap here to enter text.

6.3 Describe:

- *Procedures performed to lessen the probability or magnitude of risks.*
- *The source records that will be used to collect data about subjects. (Attach all surveys, scripts, and data collection forms.)*

6.4 What data will be collected during the study and how that data will be obtained.

- *List of data elements*
- *Surveys, Questionnaires, data collection forms, active or passive internet data collection, verbal responses, interviews, focus groups, audio/video recordings, photographs, educational assessments*

Click or tap here to enter text.

6.5 If there are plans for long-term follow-up (once all research related procedures are complete), what data will be collected during this period. Click or tap here to enter text.

7.0 Data and/or Specimen Banking

7.1 If data and/or specimens will be banked for future use, describe where the specimens will be stored (e.g., VCU or external registry/repository), how long they will be stored, how the specimens will be accessed, and who will have access to the data/specimens. Click or tap here to enter text.

7.2 List the data to be stored and/or associated with each specimen. Click or tap here to enter text.

7.3 Describe the procedures to release data or specimens, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens. Click or tap here to enter text.

7.4 State whether participants may access their data/specimens for personal use, and if so how. Click or tap here to enter text.

7.5 State whether participants may withdraw their banked data/specimens from future research use. If yes, explain whether data/specimens would be destroyed or fully anonymized in response to a withdrawal request. If no, explain why (e.g., data/specimens are fully anonymized prior to banking). Click or tap here to enter text.

8.0 Sharing of Results with Subjects

8.1 Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how the results will be shared. Click or tap here to enter text.

9.0 Study Timelines

9.1 Describe:

- *The duration of an individual subject's participation in the study.*
- *The duration anticipated to enroll all study subjects.*

10.0 Subject Population

10.1 Describe generally the individuals that will be included in your study. Click or tap here to enter text.

10.2 Describe any subject populations or segment of community that will be specifically targeted, or specifically excluded from your sample. Click or tap here to enter text.

10.3 Indicate specifically whether you will include or exclude any of the following special populations: (You may not include members of the below

populations as subjects in your research unless you indicate them in the description of your subject population.)

- *Adults unable to consent*
- *Individuals who are not yet adults (infants, children, teenagers)*
- *Pregnant women*
- *Prisoners*

Click or tap here to enter text.

11.0 Vulnerable Populations

11.1 If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.

- *If the research involves pregnant women, review HRP-412 - CHECKLIST - Pregnant Women to ensure that you have provided sufficient information.*
- *If the research involves neonates of uncertain viability or non-viable neonates, review HRP-413 - CHECKLIST - Non-Viable Neonates or HRP-414 - CHECKLIST - Neonates of Uncertain Viability to ensure that you have provided sufficient information.*
- *If the research involves prisoners, review HRP-415 - CHECKLIST - Prisoners to ensure that you have provided sufficient information.*
- *If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research ("children"), reviewHRP-416 - CHECKLIST - Children to ensure that you have provided sufficient information.*
- *If the research involves decisionally impaired adults, review HRP-417 - CHECKLIST - Cognitively Impaired Adults to ensure that you have provided sufficient information.*

  - *Check if the research involves any of the following groups:*

    ☐ *Wards of the State*
    ☐ *VCU/VCUHS students or trainees*
    ☐ *VCU/VCU Health System employees*
    ☐ *Active military personnel*
    ☐ *Student populations in K-12 educational settings or other learning environments*
    ☐ *Members of a federally recognized American Indian or Alaska Native tribe*

12.0 Local Number of Subjects

12.1 Indicate the total number of subjects to be accrued locally, if known. If this is a multi-site study, provide both study-wide accrual goal and the number of participants to be accrued at each participating site. Click or tap here to enter text.

13.0 Recruitment Methods

13.1 *Describe when, where, and how potential subjects will be recruited. If applicable, describe procedures for oral or written communication with the prospective subject or legally authorized representative that will be done for purposes of screening, recruiting, or determining eligibility. If the study recruitment process is expected to include non-English speaking subjects, describe accommodations such as interpreters.* Click or tap here to enter text.

13.2 *Describe the source of subjects (e.g., community, recruitment registry [specify], health records).* Click or tap here to enter text.

13.3 *Describe the methods that will be used to identify potential subjects, including whether subjects self-identify in response to recruitment material or how contact information is obtained, and who will contact or approach subjects. If applicable, describe procedures for accessing records or stored identifiable biospecimens for purposes of screening, recruiting, or determining eligibility.* Click or tap here to enter text.

13.4 *Describe materials that will be used to recruit subjects, addressing when and how often they will be used. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)*

Example recruitment materials that should be described and included:

- *E-mail invitations*
- *Phone solicitation scripts*
- *Flyers, mailed letter or newspaper/TV/radio ads*
- *TelegRAM announcements*
- *website text*
- *study-specific websites*
- *social media*
- *EPIC MyChart Patient Portal research study descriptions*
- *Psychology Research Participant Pool (SONA) study descriptions*
- *Scripts for announcements made to groups*

Click or tap here to enter text.

13.5 *Describe the amount and timing of any payments to subjects. See VCU Procurement Services for allowable payment methods.*

- *Explain whether subjects will be reimbursed for out of pocket expenses and/or receive payments related to their participation. Include specific information about the amount, timing and method of disbursement. Provide justification to support that the amount of payment and the disbursement procedures are neither coercive nor present undue influence to participants. Provide the reason for reimbursement.*

- *Confirm that credit for payment will accrue as the study progresses.*
- *Indicate whether there is any bonus paid for completion.*

Click or tap here to enter text.

14.0 Withdrawal of Subjects

14.1 Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent. Click or tap here to enter text.

14.2 Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection. Click or tap here to enter text.

15.0 Risks to Subjects

15.1 List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects' participation in the research. Include as may be useful for the IRB's consideration, a description of the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks. Describe any impact the study might have on students' opportunity to learn required educational content. Describe any interventions that may be perceived as offensive or embarrassing. Click or tap here to enter text.

15.2 If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable. Click or tap here to enter text.

15.3 If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant. Click or tap here to enter text.

15.4 If applicable, describe risks to others who are not subjects. Click or tap here to enter text.

15.5 Describe how the study design, inclusion/exclusion criteria, and any other relevant factors minimize risks of harm or discomfort. Click or tap here to enter text.

16.0 Potential Benefits to Subjects

16.1 Describe the potential benefits that individual subjects may experience from taking part in the research. Include as may be useful for the IRB's consideration, the probability, magnitude, and duration of the potential benefits. Click or tap here to enter text.

16.2 Indicate if there is no direct benefit. Do not include benefits to society or others. Click or tap here to enter text.

17.0 Data Management and Confidentiality

17.1 Describe the data analysis plan, including any statistical procedures or power analysis. Click or tap here to enter text.

17.2 Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls,

certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission.

*Select all that apply to **paper** research material:*

☐ *Maintaining control of paper documents at all times, including when at off-campus location*

☐ *Storing paper documents in a secure location accessible only by study team*

☐ *Promptly transcribing, scanning, or abstracting data from paper into electronic platform and destroying the paper copy*

*Select all that apply to **electronic** research material:*

☐ *Use VCU-approved methods of data storage, transmission, and transfer (see https://dms.vcu.edu)*

☐ *Using individual logins/separate accounts on shared devices*

☐ *Using VCU approved data collection tools and apps (e.g., REDCap, Qualtrics)*

☐ *Consulting with VCU Information Security when using non-VCU approved data collection tools (https://ts.vcu.edu/askit/essential-computing/information-security/)*

*Select all that apply for research **biospecimens**:*

☐ *Maintaining control of specimens at all times, including when at off-campus location*

☐ *Storing specimens in a secure location only accessible only by study team*

☐ *Labeling specimens with subject ID or other coded information instead of direct identifiers*

☐ *Final destruction of specimens will be devoid of any identifiable information*

17.3 Describe any procedures that will be used for quality control of collected data. Click or tap here to enter text.

17.4 Describe how data or specimens will be handled study-wide:

- *What information will be included in that data or associated with the specimens?*
- *Where and how data or specimens will be stored?*
- *How long the data or specimens will be stored?*
- *Who will have access to the data or specimens?*

- *Who is responsible for receipt or transmission of the data or specimens?*
- *How data or specimens will be transported?*

Click or tap here to enter text.

17.5 If you plan to retain screening data collected by phone or other methods for people who decline to participate, describe this, including the rationale for retaining the information and for how long (e.g., end of the study). Click or tap here to enter text.

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

This section is required when research involves more than Minimal Risk to subjects.

18.1 Describe:

- *The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe. The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor. Indicate if this study will have a Data Safety Monitoring Board or a Data Safety Monitoring Plan.*
- *What data are reviewed, including safety data, untoward events, and efficacy data.*
- *How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).*
- *The frequency of data collection, including when safety data collection starts.*
- *Who will review the data.*
- *The frequency or periodicity of review of cumulative data.*
- *The statistical tests for analyzing the safety data to determine whether harm is occurring.*
- *Any conditions that trigger an immediate suspension of the research.*

Click or tap here to enter text.

19.0 Provisions to Protect the Privacy Interests of Subjects

19.1 Describe the steps that will be taken to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on whom they interact or whom they provide personal information.

Select any of the following that apply:

☐ *Conducting study activities in locations that maximize privacy*

☐ *Verifying identify before discussing personal information*

☐ *Asking the subject if they are comfortable answering in the location*

☐ *Asking the subject if they are comfortable with others present*

☐ *Offering alternate ways to respond (e.g., pointing, writing)*

☐ *Using generic signs on research rooms and spaces*

☐ *Some questions may be skipped*

☐ *Using Study IDs instead of direct identifiers*

☐ *Using mailing techniques that do not include study name or identifiers*

☐ *Working only in locations the study team can ensure privacy*

☐ *Storing study material in locations restricted to study team access*

☐ *Obtaining explicit parental permission before sharing photos/recordings of children*

19.2 *Describe what steps you will take to make the 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.* Click or tap here to enter text.

19.3 *Indicate how the research team is permitted to access any sources of information about the subjects.* Click or tap here to enter text.

19.4 *Select all identifiers that will be collected at any time as part of this study (including for recruitment, data gathering, data analysis, etc.), even if the data will eventually be anonymized:*

☐ *Names*
☐ *Geographic Locators Below State Level*
☐ *Social Security Numbers*
☐ *Dates (year alone is not an identifier)*
☐ *Ages over 89 (age under 89 is not an identifier)*
☐ *Phone Numbers*
☐ *Facsimile Numbers*
☐ *E-mail Addresses*
☐ *Medical Record Numbers*
☐ *Device Identifiers*
☐ *Biometric Identifiers*
☐ *Web URLs*
☐ *IP Addresses*
☐ *Account Numbers*
☐ *Health Plan Numbers*

☐ *Full Face Photos or Comparable Images*
☐ *License/Certification Numbers*
☐ *Vehicle ID Numbers*
☐ *Other Unique Identifier*
☐ *No Identifiers*
☐ *Employee V#*

20.0 Compensation for Research-Related Injury

20.1 If the research involves more than Minimal Risk to subjects, describe the available compensation in the event of research related injury. Click or tap here to enter text.

20.2 For industry funded studies only, provide a memo from Division of Sponsored Program approving the consent form language for compensation for research-related injury. For all other funding sources, the template language from HRP-502 should be utilized in the consent form. Click or tap here to enter text.

21.0 Economic Burden to Subjects

21.1 Describe any costs that subjects may be responsible for because of participation in the research.

Click or tap here to enter text.

22.0 Consent Process

22.1 Indicate whether you will you be obtaining consent, and if so describe (describe for different groups if multiple):

- *Who will obtain informed consent*
- *Where the consent process will take place.*
- *How the consent process will be conducted (e.g., electronic, face-to-face, phone or video).*
- *Any process to ensure ongoing consent.*
- *Whether you will be following HRP-090 - SOP - Informed Consent Process for Research. If not, describe:*
    - *The role of the individuals listed in the application as being involved in the consent process.*
    - *The time that will be devoted to the consent discussion.*
    - *Steps that will be taken to minimize the possibility of coercion or undue influence.*
- *Steps that will be taken to ensure the subject's understanding*

Click or tap here to enter text.

Non-English Speaking Subjects

- *Indicate what language(s) other than English are understood by prospective subjects or representatives.*
- *If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate the language that will be used by those obtaining consent.*

Click or tap here to enter text.

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

- *Review HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process to ensure you have provided sufficient information for the IRB to make these determinations. Describe whether you are requesting to waive some elements of consent (describe which ones), or all elements of consent. Provide justification.*
- *If the research involves deception, describe whether subjects prospectively authorize the deception and plans for de-briefing subjects.*

Click or tap here to enter text.

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

- *Describe the criteria that will be used to determine whether a prospective subject has not attained the 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., individuals under the age of 18 years.)*
    - *For research conducted in the state, review HRP-013 - SOP - LARs, Children, and Guardians to be aware of which individuals in the state meet the definition of "children."*
    - *For research conducted outside of the state, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of "children" in HRP-013 - SOP - LARs, Children, and Guardians.*
- *Describe whether parental permission will be obtained from:*
    - *Both parents 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 child.*

- *One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.*

- *Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals' authority to consent to each child's general medical care.*
- *Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent. If not obtaining assent, include justification.*
- *When assent of children is obtained describe whether and how it will be documented.*

Click or tap here to enter text.

Cognitively Impaired Adults

- *Describe the process to determine whether an individual is capable of consent or assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require cognitively impaired adults to sign assent documents.*

Click or tap here to enter text.

Adults Unable to Consent

- *List the individuals from whom permission will be obtained in order of priority. (E.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child.)*
    - *For research conducted in the state, review HRP-013 - SOP - LARs, Children, and Guardians to be aware of which individuals in the state meet the definition of "legally authorized representative."*
    - *For research conducted outside of the state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of "legally authorized representative" in HRP-013 - SOP - LARs, Children, and Guardians.*
- *Describe the process for assent of the subjects. Indicate whether:*
    - *Assent will be required of all, some, or none of the subjects. If some, indicated, which subjects will be required to assent and which will not.*
    - *If assent will not be obtained from some or all subjects, an explanation of why not.*

- *Describe whether assent of the subjects will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require subjects to sign assent documents.*

Click or tap here to enter text.

23.0 Process to Document Consent in Writing

23.1 Describe whether you will be following HRP-091 - SOP - Written Documentation of Consent. If not, describe whether and how consent of the subject will be documented in writing. Click or tap here to enter text.

23.2 If your 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, the IRB will generally waive the requirement to obtain written documentation of consent. Click or tap here to enter text.

23.3 (If you will document consent in writing, attach a consent document. If you will obtain consent, but not document consent in writing, attach a consent script. Review HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent to ensure that you have provided sufficient information. You may use HRP-502 - TEMPLATE CONSENT DOCUMENT to create the consent document or script.) Click or tap here to enter text.

24.0 Setting

24.1 Describe the sites or locations where your research team will conduct the research.

- *Identify where your research team will identify and recruit potential subjects.*
- *Identify where research procedures will be performed.*
- *Describe the composition and involvement of any community advisory board.*
- *For research conducted outside of the organization and its affiliates describe:*
  - *Site-specific regulations or customs affecting the research for research outside the organization.*
  - *Local scientific and ethical review structure outside the organization.*

Click or tap here to enter text.

25.0 Resources Available

25.1 Describe the resources available to conduct the research: For example, as appropriate:

- *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 consequence of the human 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.*

Click or tap here to enter text.

26.0 Multi-Site Research

26.1 Study-Wide Number of Subjects

If this is a multicenter study, indicate the total number of subjects to be accrued across all sites. Click or tap here to enter text.

26.2 Study-Wide Recruitment Methods

- *If this is a multicenter study and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) describe those methods. Local recruitment methods are described later in the protocol.*
- *Describe when, where, and how potential subjects will be recruited.*
- *Describe the methods that will be used to identify potential subjects.*
- *Describe materials that will be used to recruit subjects. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)*
- *If this is a multi-site study where you are the lead investigator, describe the processes to ensure communication among sites. See HRP-830 - WORKSHEET - Communication and Responsibilities. All sites have the most current version of the protocol, consent document, and HIPAA authorization.*
- *All required approvals (initial, continuing review and modifications) have been obtained at each site (including approval by the site's IRB of record).*
- *All modifications have been communicated to sites and approved (including approval by the site's IRB of record) before the modification is implemented.*
- *All engaged participating sites will safeguard data, including secure transmission of data, as required by local information security policies.*

- *All local site investigators conduct the study in accordance with applicable federal regulations and local laws.*

- *All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.*

Click or tap here to enter text.

26.3 Describe the method for communicating to engaged participating sites (see HRP-830 - WORKSHEET - Communication and Responsibilities):

- *Problems (inclusive of reportable events).*
- *Interim results.*
- *The closure of a study.*

Click or tap here to enter text.

26.4 If this is a multicenter study where you are a participating site/investigator, describe the local procedures for maintenance of confidentiality. (See HRP-830 - WORKSHEET - Communication and Responsibilities.)

- *Where and how data or specimens will be stored locally?*
- *How long the data or specimens will be stored locally?*
- *Who will have access to the data or specimens locally?*
- *Who is responsible for receipt or transmission of the data or specimens locally?*
- *How data and specimens will be transported locally?*

Click or tap here to enter text.

VCU Research and Innovation

Template for Not Human Subject Research (NHSR) Determination Requests

INSTRUCTIONS:

- *Use this template to prepare a document with the information from the following sections to request a determination of Not Human Subjects Research from the VCU IRB.*
- *Depending on the nature of your activity, some sections may not be applicable to your project. If so, mark as "NA."*

PROJECT TITLE:

Include the full project title

PROJECT LEAD(S):

Name
Department
Telephone Number
Email Address

NOTES:

- The IRB can only make this determination prior to the beginning of the research activity. The IRB will not make a determination after the activity has already begun.
- The IRB Office uses HRP-310 - WORKSHEET - Human Research Determination to make its Human Research determinations. Please consult that worksheet as a guide for the information you provide in Section 3.0 if you choose to submit to the IRB.
- Complete Section 3.0 below and create a new study in RAMS-IRB. Upload this completed template in lieu of a Protocol and submit for IRB Office review.
- If, while reviewing this determination form, you discover that an activity is Human Research, consult HRP-103 - Investigator Manual for instructions on how to submit a new study to the VCU IRB.
- VCU ONETRAC Protocol Review Oversight Committee (PROC) approval is required for studies involving research with VCUHS patients, facilities, or data regardless of NHSR determination prior to IRB submission. For guidance, see https://onetrac.vcu.edu/

Contents

1.0 Definitions for Human Research

Review the following definitions to determine whether your activity is Human Research. Note that publication is not a determining factor for whether an activity is Human Research requiring review and approval by the IRB.

1.1 **"Human Research"** (according to DHHS): The definition includes two components:

a. "Research": A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

b. Human Subject": A living individual about whom an investigator (whether professional or student) conducting research (1) obtains information or biospecimens through Intervention or Interaction with the individual, and uses, studies or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. For the purpose of this definition:

i. Intervention: Physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
ii. Interaction: Communication or interpersonal contact between investigator and subject.
iii. Private Information: Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record).
iv. Identifiable Private Information: Private Information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
v. Identifiable Biospecimen: A biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

If your activity does not meet both of these components, then it is not Human Research according to DHHS. Please see below for the FDA definition.

1.2 **"Human Research"** (according to FDA): The definition includes two components:

a. **"Research"**: Any experiment that involves a test article and one or more Human Subjects, and that meets any one of the following:

i. Must meet the requirements for prior submission to the US Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act meaning any use of a drug other than the use of an approved drug in the course of medical practice;
ii. Must meet the requirements for prior submission to the US Food and Drug Administration under section 520(g) of the

Federal Food, Drug, and Cosmetic Act meaning any activity that evaluates the safety or effectiveness of a device; OR

iii. Any activity the results of which are intended to be later submitted to, or held for inspection by, the US Food and Drug Administration as part of an application for a research or marketing permit.

b. **"Human Subject":** An individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.

If your activity is not research or is research that does not involve human subjects, it is not Human Research according to FDA.

If your activity does not meet either DHHS or FDA definitions for "Human Research" you are not required to submit to the IRB Office for review or approval. See the appendix for examples of activities that are generally considered not to be Human Research. If you are unsure whether your activity constitutes Human Research, or require documentation of the IRB's determination of research, complete and submit this template via RAMS-IRB.

2.0 Description of Activity

Project Information	Description
Brief background and Rationale for the non-research project.	
Purpose (may include goals and objectives) of the activity	

3.0 Type of Project

- Quality Improvement / Quality Assurance / Lean Six Sigma
- Program Evaluation
- Evidence-Based Practice
- Course-related Activity
- Case Report
- Oral History
- Scholarly Activity (e.g., journalism, biography, literary criticism, legal research, historical scholarship)
- Other or Uncategorized (please specify):

4.0 Procedures

4.1 Describe the procedures used to obtain information from the individuals with whom you will interact or intervene for this activity, including communication or interpersonal contact with individuals and physical procedures, if any.

5.0 Data and/or Specimen Collection

5.1 Describe the data/specimens you will collect and how they will be analyzed, if applicable. Specify whether the data/specimens may be directly linked to individuals, indirectly linked through a code, or not linked at all to individuals (you will not have a link to the code).

5.2 Describe the procedures used to obtain the data/specimens, if applicable.

6.0 HIPAA

6.1 Indicate which of the following applies to this project concerning protected health information (PHI):

- Not applicable: I am not using or accessing PHI for this project
- I am using PHI consistent with VCU's Notice of Privacy Practices for treatment, payment or health care operations purposes
- I am requesting an internal Data Use Agreement for this **research** activity on a limited data set obtained from VCUHS that **does not involve human subjects** as no direct identifiers will be collected
    - Upload a signed Data Use Agreement with submission

A limited data set is described as health information that excludes certain, listed direct identifiers (see below) but that may include city; state; ZIP Code; elements of date; and other numbers, characteristics, or codes not listed as direct identifiers. The direct identifiers listed in the Privacy Rule's limited data set provisions apply both to information about the individual and to information about the individual's relatives, employers, or household members. The following identifiers must be removed from health information if the data are to qualify as a limited data set:

1. Names. 2. Postal address information, other than town or city, state, and ZIP Code. 3. Telephone numbers. 4. Fax numbers. 5. Electronic mail addresses. 6. Social security numbers. 7. Medical record numbers. 8. Health plan beneficiary numbers. 9. Account numbers.		10. Certificate/license numbers. 11. Vehicle identifiers and serial numbers, including license plate numbers. 12. Device identifiers and serial numbers. 13. Web universal resource locators (URLs). 14. Internet protocol (IP) address numbers. 15. Biometric identifiers, including fingerprints and voiceprints. 16. Full-face photographic images and any comparable images.

Source: https://privacyruleandresearch.nih.gov/pr_08.asp

7.0 Appendices

7.1 Examples of activities that are generally considered not to be Human Research. Note that publication is not a determining factor for whether an activity is Human Research.

Program Evaluation/Quality Assurance Review/Quality Improvement Project:
The activity is limited to program evaluation, quality assurance, or quality improvement activities designed specifically to evaluate, assure, or improve performance within a department, classroom, or hospital setting.

Note: The purpose of a QA study is to assure known quality. The purpose of Program Evaluation (PE) is to assess that a program is doing what it is intended to do. Generally QI is designed for the purpose of improving the quality of a service, a program, a process, etc.

A QA, QI or PE study should present NO CHANGE in RISK to participants. These studies are mechanisms to assure that a service, a program or process functions optimally. Such projects are usually for internal auditing purposes only.

If you can answer "yes" to all of the following questions, the activity is most likely not human research:

1. Will you simply monitor an existing process for which there will be no manipulation of the existing process?
2. For biomedical or Social Behavioral QA or PE studies, will physicians or caregivers (parents, teachers, therapists, etc.) provide usual and customary care regardless of the conduct of the study?
3. Does the study involve collection of data to which the investigator routinely has access as part of his or her responsibilities within the institution to monitor data associated with, for example: treatment, cost containment, performance, or compliance?

Note that an evaluation, assurance review, or improvement project designed specifically for a particular setting may yield useful information for similar entities, and may still not meet one of the definitions for Human Research in Section 1.0.

Case Report:
A case report is a detailed report of the diagnosis, treatment, response to treatment, and follow-up after treatment of an individual patient. A case series is a group of case reports involving patients who were given similar treatment. Case reports and case series usually contain demographic information about the patient(s), for example, age, gender, ethnic origin.

When information on more than three patients is included, the case series is considered to be a systematic investigation designed to contribute to generalizable knowledge (i.e., research), and therefore submission is required to the IRB. Note that HIPAA or other state or local laws may still apply to this activity.

Course-Related Activity:

The project is limited to one or more course-related activities designed specifically for educational or teaching purposes where data are collected from and about students as part of routine class exercises or assignments and otherwise do not meet either of the definitions of Human Research in Section 1.0.

Note that some course-related activities, even those conducted by students, may yield information suggesting additional investigation or analysis. If an additional activity entails Human Research, then it must be submitted to the IRB for review.

Journalistic or Documentary Activity (including Oral History):
The activity is limited to investigations or interviews (structured or open-ended) that focus on specific events (current or historical), views, etc. Such investigations or interviews may be reported or published in any medium, e.g., print newspaper, documentary video, online magazine.

Research Using De-identified Information:
The activity is limited to analyzing private data that have been provided to the investigator without any accompanying information by which the investigator could identify the individuals. Note that HIPAA regulations still apply to limited data sets that may not otherwise be considered identifiable per DHHS regulations.

Research Using Health Information from Deceased Individuals:
This activity is limited to analyzing data (identifiable or not) about deceased individuals. Note that deceased individuals cannot be Human Subjects according to DHHS, but they may be Human Subjects according to FDA. Please review the definitions above for clarification. Note also that HIPAA or other state or local laws may still apply to this activity. Please consult the entity from which you received or accessed the information contained in the report for further guidance.

Instrument/Questionnaire Development:
This activity is limited to interacting with individuals in order to obtain feedback on the types of questions which could or should be used to develop an instrument or questionnaire. The focus is on the development and construction of a data collection tool and not on the individuals who are providing the feedback on the questions being developed. This will be true even when the feedback may be specifically sought from an identified group of people most likely to be affected by the topic of the instrument, survey or questionnaire. The instrument/questionnaire development process will apply to many aspects of reliability and validity testing of the instrument or questionnaire. Note that once the process gets to the level of testing discriminant, concurrent or predictive validity, the activity may need to be reclassified as human subject research.

Note that if the participant is asked to provide additional information unrelated to instrument/questionnaire construction, such as demographic information, that will be analyzed as part of a research study, the project may need to be submitted to the IRB for review.

SCHOOL PERMISSION TO CONDUCT RESEARCH

<Note to investigator: Use this form to obtain permission from schools at which your research is conducted.>

<Date>

Dear Institutional Review Board:

The purpose of this letter is to inform you that I give <*Name of Principal Investigator*> permission to conduct the research titled <*Title of Research Study*> at <*Name of School*>. This also serves as assurance that this school complies with requirements of the Family Educational Rights and Privacy Act (FERPA) and the Protection of Pupil Rights Amendment (PPRA) (see back for specific requirements) and will ensure that these requirements are followed in the conduct of this research.

Sincerely,

<*Name of Signatory*>
<*Title of Signatory*>

Template Revision:
February 1, 2024

- The right of a parent of a student to inspect, upon the request of the parent, a survey created by a third party before the survey is administered or distributed by a school to a student. Any applicable procedures for granting a request by a parent for reasonable access to such survey within a reasonable period of time after the request is received.
- Arrangements to protect student privacy that are provided by the agency in the event of the administration or distribution of a survey to a student containing one or more of the following items (including the right of a parent of a student to inspect, upon the request of the parent, any survey containing one or more of such items): Political affiliations or beliefs of the student or the student's parent. Mental or psychological problems of the student or the student's family. Sex behavior or attitudes. Illegal, anti-social, self-incriminating, or demeaning behavior. Critical appraisals of other individuals with whom respondents have close family relationships. Legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers. Religious practices, affiliations, or beliefs of the student or the student's parent. Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program).
- The right of a parent of a student to inspect, upon the request of the parent, any instructional material used as part of the educational curriculum for the student. Any applicable procedures for granting a request by a parent for reasonable access to instructional material received.
- The administration of physical examinations or screenings that the school or agency may administer to a student.
- The collection, disclosure, or use of personal information collected from students for the purpose of marketing or for selling that information (or otherwise providing that information to others for that purpose), including arrangements to protect student privacy that are provided by the agency in the event of such collection, disclosure, or use.
- The right of a parent of a student to inspect, upon the request of the parent, any instrument used in the collection of personal information before the instrument is administered or distributed to a student. Any applicable procedures for granting a request by a parent for reasonable access to such instrument within a reasonable period of time after the request is received.

VCU Research and Innovation

Permission for Emergency OR Non-Emergency Single Patient Treatment with an Unapproved Test Article

Dr. _____ ***[Name of physician]*** is offering to treat you, your child (in which case the word "you" will refer to "your child" throughout this document), or your representative (in which case the word "you" will refer to the person you are representing) with _____ ***[Name of unapproved drug, device, or biologic]*** because you have a serious condition called _____ and there are no standard Food and Drug Administration (FDA)-approved treatments available to you for treatment.

Read this document carefully. You may want to discuss your options with your doctors, family, friends, and others before deciding on whether to receive this treatment. Please ask questions about anything you do not understand.

What you should know about this experimental treatment

- This treatment has not been approved by Food and Drug Administration.
- This treatment is considered experimental and research. ***[delete "and research" for uses of devices]***
- Someone will explain this treatment to you.
- Whether or not you get this treatment is completely voluntary and up to you.
- You can choose not to get this treatment or agree to get this treatment now and later change your mind without penalty or loss of benefits to which you are otherwise entitled.
- If you do change your mind, contact your doctor right away.
- Whatever you decide it will not be held against you.
- Feel free to ask all the questions you want before you decide.

How long will this experimental treatment last?

We expect that the experimental treatment will last _____ ***[hours/days/months/weeks/years, until a certain event]***.

What happens if I get this experimental treatment?

[Tell the patient what to expect using lay language and simple terms]

Is there any way this experimental treatment could be bad for me?

[Describe the risks of the treatment]

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

If you are or become pregnant, this treatment may hurt your baby or your pregnancy in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

Getting this treatment may lead to added costs to you. You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. Insurance may not pay for this treatment because it is considered experimental.

Can this experimental treatment help me?
We cannot promise that this treatment will benefit you. The goal of this treatment is to _____. ***[Describe the potential benefits of the treatment]***

What happens if I say yes, but I change my mind later?
You can stop the experimental treatment at any time; it will not be held against you. If you stop treatment, information that was already collected may still be shared with the FDA. You may also be asked if you want to provide further information from your routine medical care.

Can from the experimental treatment be stopped without my OK?
[Include only for Compassionate Use of a Device or Single Patient Expanded Access of a Drug where this is a possibility. Otherwise delete.] The person in charge of the experimental treatment or the sponsor can stop the treatment without your approval. Possible reasons for stopping the experimental treatment include ***[describe reasons why the subject may be withdrawn from the treatment, if appropriate.]***

What else do I need to know?
Efforts will be made to limit your personal information, including 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 Institutional Review Board (IRB-an ethics committee that reviews this experimental treatment), representatives of this organization, the sponsor, and the Food and Drug Administration. In addition, your insurance company and/or the medical staff directly involved in your medical care may have access to your identity and information about your use of the experimental treatment. If the result of this treatment is published, your personal identifying information will not be used. Your information will not be used or distributed for future research studies.

If you are injured or made sick from taking part in this treatment, medical care will be provided. Generally, this care will be billed to you or your insurance. Depending on the circumstances, this care may be provided at no cost to you. ***[Insert the name of the institution]*** does not plan to pay for medical care for research-related injury. Contact the doctor for more information. ***[NOTE: HIPAA Authorization is not required because this does not meet the HIPAA definition of research.]***

During your treatment, if we learn any new information about the risks or benefits of the investigational treatment, the doctor will let you know.

Who can I talk to?
If you have questions, concerns, or complaints, or think the treatment has hurt you talk to your doctor at _____ ***[Insert contact information].***

This treatment is subject to oversight by an Institutional Review Board. If you have questions about your rights or any unresolved question, concern, or complaint, talk to them at (804) 828-0868 or HRPP@vcu.edu.

Your signature documents your permission to take part in this experimental treatment.

_____
Printed name of patient

_____
Signature of patient, legally authorized representative, parent, or guardian of child Date

_____
Printed name of legally authorized representative, parent, or guardian of child (if applicable)

_____
Signature of person obtaining consent Date

_____
Printed name of person obtaining consent

VCU Research and Innovation

Permission to Take Part in a Human Research Study

You are being asked to take part in a research study[1].

Before you agree to take part, someone will explain to you:

- Why you are being invited to take part in a research study
- What you should know about the research study
- Why this research is being done
- How long the research will last and what you will need to do
- Any ways being in this study could be bad for you
- Any ways being in this study could help you
- What happens if you do not want to be in this research
- Who you can talk to
- How many people will be studied
- What happens if you say yes, you want to be in this research
- What your responsibilities are if you take part in this research
- What happens if you say yes, but you change your mind later
- What happens to the information collected for the research
- Whether you can be removed from the research without your OK
- Anything else you need to know

Who can I talk to?

- If you have questions, concerns, or complaints, or think the research has hurt you, you can talk to the research team at (555) 555-1213 or researchteam@organization.org.
- This research has been reviewed and approved by an Institutional Review Board. You may talk to them at (804) 828-0868 or HRPP@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

When applicable, someone will explain to you:

- Whether you will get treated or paid if injured
- The possibility of unknown risks
- When you may be taken off the research without your agreement
- Added costs from taking part
- What will happen if you stop taking part
- Steps to safely stop taking part
- When new information will be told to you
- The number of people expected to take part
- That the Food and Drug Administration may inspect the records
- What happens to collected data if you stop taking part
- An explanation of www.ClinicalTrials.gov

[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.]

[1] This template satisfies AAHRPP element I.1.G

Signature Block for Capable Adult

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

_____

Signature of subject Date

_____

Printed name of subject

_____

Signature of witness to consent process Date

_____

Printed name of person witnessing consent process

Signature Block for Adult Unable to Consent

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

_____

Printed name of subject

_____

Signature of legally authorized representative Date

_____

Printed name of legally authorized representative

_____

Signature of witness to consent process Date

_____

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.

_____

Printed name of child

_____

Signature of parent or individual legally authorized to consent to the child's general medical care — Date

_____

Printed name of parent or individual legally authorized 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.

_____

Signature of parent — Date

_____

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

Signature of witness to consent process Date

Printed name of person witnessing consent process

INSTRUCTIONS:

- *Use this template to provide local study site information when the main study protocol is provided by a study sponsor (e.g., for an industry-sponsored drug study), or when the researcher must use another non-standard protocol template that does not include all of the elements of the VCU template protocols (HRP-503-TEMPLATE PROTOCOL or HRP-503a-TEMPLATE SBS PROTOCOL).*
- *Depending on the nature of your study, some sections may not be applicable to your research. These should be marked with "NA". Do not delete section headings.*
- *For any requested information below that is already fully addressed in the main protocol, simply note the section number/page number of the main protocol. When doing so, note that it is important for the study team to evaluate whether the main protocol section includes sufficient local detail requested in this Site Supplement. It is not sufficient to simply say "see protocol" in the Site Supplement as this does not provide sufficient detail to the Human Research Protection Program.*
- *Attach the entire sponsor's protocol. Unless otherwise specified, provide only site-specific information below.*
- *When you write a single site supplement, keep an electronic copy. You will need to modify this copy when making changes. When you make changes, use the Track Changes feature.*
- *When relying on an external IRB, changes must be submitted to the Site Supplement and submitted in the RAMS-IRB reliance application in accordance with HRP-103 Investigator Manual (see "What are my obligations as investigator when relying on an external IRB?").*

PROTOCOL TITLE:

Include the full protocol title. Click or tap here to enter text.

PRINCIPAL INVESTIGATOR:

Name Click or tap here to enter text.
Department Click or tap here to enter text.
Telephone Number Click or tap here to enter text.
Email Address Click or tap here to enter text.

VERSION NUMBER/DATE:

Include the version number and date of this site supplement. Click or tap here to enter text.

Revision History

Revision #	Version Date	Summary of Changes	Consent Change?

Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
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Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.

Table of Contents

1.0 Study Summary

Protocol Information	**Description** Click or tap here to enter text.
Study Title	Click or tap here to enter text.
Study Design	Click or tap here to enter text.
Primary Objective	Click or tap here to enter text.
Secondary Objective(s)	Click or tap here to enter text.
Research Intervention(s)/ Investigational Agent(s)	Click or tap here to enter text.
IND/IDE #	Click or tap here to enter text.
Study Population	Click or tap here to enter text.
Sample Size	Click or tap here to enter text.
Study Duration for individual participants	Click or tap here to enter text.
Study Specific Abbreviations/ Definitions	Click or tap here to enter text.

●

2.0 Study Intervention/Investigational Agent

2.1 If the research involves drugs or device, describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.

- *If the control of the drugs or devices used in this protocol will be accomplished by using the Investigational Drug Service (IDS), please reference that in this section.*

Click or tap here to enter text.

2.2 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:*

Click or tap here to enter text.

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*	

●

3.0 Data and Specimen Banking

3.1 The sponsor's protocol may require banking data or specimens for future use and both storage and use will be determined by the sponsor. If additional data or specimens will be banked locally for future use, describe where the specimens will be stored, how long they will be stored, how the specimens will be accessed, and who will have access to the specimens. Click or tap here to enter text.

3.2 List the data to be stored or associated with each specimen banked locally. Click or tap here to enter text.

3.3 Describe the procedures to release locally banked data or specimens, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens. Click or tap here to enter text.

3.4 State whether participants may access their data/specimens for personal use, and if so how. Click or tap here to enter text.

3.5 State whether participants may withdraw their banked data/specimens from future research use. If yes, explain whether data/specimens would be destroyed or fully anonymized in response to a withdrawal request. If no, explain why (e.g., data/specimens are fully anonymized prior to banking). Click or tap here to enter text.

4.0 Sharing of Results with Subjects

4.1 Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how it will be shared. Click or tap here to enter text.

5.0 Inclusion and Exclusion Criteria

5.1 Describe any inclusion or exclusion criteria that will differ for your local site compared to the sponsor's protocol. For example, if the sponsor's protocol allows the enrollment of children but your site will not enroll children, indicate that here. Click or tap here to enter text.

6.0 Vulnerable Populations

6.1 *If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.*

- *If the research involves pregnant women, review HRP-412 - CHECKLIST - Pregnant Women to ensure that you have provided sufficient information.*
- *If the research involves neonates of uncertain viability or non-viable neonates, review HRP-413 - CHECKLIST - Non-Viable Neonates or HRP-414 - CHECKLIST - Neonates of Uncertain Viability to ensure that you have provided sufficient information.*
- *If the research involves prisoners, review HRP-415 - CHECKLIST - Prisoners to ensure that you have provided sufficient information.*
- *If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research ("children"), review HRP-416 - CHECKLIST - Children to ensure that you have provided sufficient information.*
- *If the research involves decisionally impaired adults, review HRP-417 - CHECKLIST - Cognitively Impaired Adults to ensure that you have provided sufficient information.*
- *Check if the research involves any of the following groups:*

  ☐ *Wards of the State*
  ☐ *VCU/VCUHS students or trainees*
  ☐ *VCU/VCU Health System employees*
  ☐ *Active military personnel*
  ☐ *Student populations in K-12 educational settings or other learning environments*
  ☐ *Members of a federally recognized American Indian or Alaska Native tribe*

7.0 Local Number of Subjects

7.1 *Indicate the total number of subjects to be accrued locally.* Click or tap here to enter text.

7.2 *If applicable, distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures (i.e., numbers of subjects excluding screen failures.)* Click or tap here to enter text.

8.0 Local Recruitment Methods

This section is for recruitment methods under the control of the local site and not central recruitment managed by the sponsor.

8.1 *Describe when, where, and how potential subjects will be recruited.* Click or tap here to enter text.

8.2 *Describe the source of subjects (e.g., community, recruitment registry [specify], health records).* Click or tap here to enter text.

8.3 *Describe the methods that will be used to identify potential subjects including whether subjects self-identify in response to recruitment material or how contact information is obtained, and who will contact or approach subjects.* Click or tap here to enter text.

8.4 *Describe materials that will be used to recruit subjects, addressing when and how often they will be used. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)* Click or tap here to enter text.

8.5 *Describe the amount and timing of any payments to subjects. See VCU Procurement Services for allowable payment methods.* Click or tap here to enter text.

9.0 Withdrawal of Subjects

9.1 *Describe procedures that will be followed locally, if different than the sponsor's protocol, when subjects withdraw from the research.* Click or tap here to enter text.

10.0 Data Management and Confidentiality

10.1 *Describe the local procedures for maintenance of confidentiality. See https://dms.vcu.edu for VCU-approved methods of electronic data storage transmission, and transfer.*

- *Where and how data or specimens will be stored locally?*
- *How long the data or specimens will be stored locally?*
- *Who will have access to the data or specimens locally?*
- *Who is responsible for receipt or transmission of the data or specimens locally?*
- *How data and specimens will be transported locally?*

Click or tap here to enter text.

10.2 *If you plan to retain screening data collected by phone or other methods for people who decline to participate, describe this, including the rationale for retaining the information and for how long (e.g., end of the study).* Click or tap here to enter text.

11.0 Provisions to Protect the Privacy Interests of Subjects

11.1 *Describe the steps that will be taken to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on whom they interact or whom they provide personal information.* Click or tap here to enter text.

11.2 Describe what steps you will take to make the 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. Click or tap here to enter text.

11.3 Indicate how the research team is permitted to access any sources of information about the subjects. Click or tap here to enter text.

11.4 Select all identifiers that will be collected at any time as part of this study (including for recruitment, data gathering, data analysis, etc.), even if the data will eventually be anonymized:

- ☐ *Names*
- ☐ *Geographic Locators Below State Level*
- ☐ *Social Security Numbers*
- ☐ *Dates (year alone is not an identifier)*
- ☐ *Ages over 89 (age under 89 is not an identifier)*
- ☐ *Phone Numbers*
- ☐ *Facsimile Numbers*
- ☐ *E-mail Addresses*
- ☐ *Medical Record Numbers*
- ☐ *Device Identifiers*
- ☐ *Biometric Identifiers*
- ☐ *Web URLs*
- ☐ *IP Addresses*
- ☐ *Account Numbers*
- ☐ *Health Plan Numbers*
- ☐ *Full Face Photos or Comparable Images*
- ☐ *License/Certification Numbers*
- ☐ *Vehicle ID Numbers*
- ☐ *Other Unique Identifier*
- ☐ *No Identifiers*
- ☐ *Employee V#*

12.0 Compensation for Research-Related Injury

12.1 If the research involves more than Minimal Risk to subjects, describe the available compensation in the event of research related injury. Click or tap here to enter text.

12.2 For industry funded studies only, provide a memo from the Division of Sponsored Programs approving the consent form language for compensation for research-related injury. For all other funding sources, the template language from HRP-502 should be utilized in the consent form. Click or tap here to enter text.

13.0 Economic Burden to Subjects

13.1 Describe any costs that subjects may be responsible for because of participation in the research, e.g., fuel, parking, childcare. Click or tap here to enter text.

14.0 Consent Process

14.1 Indicate whether you will you be obtaining consent, and if so describe:

(describe for different groups if multiple):

- *Who will obtain informed consent*
- *Where the consent process will take place.*
- *How the consent process will be conducted (e.g., electronic, face-to-face, phone or video).*
    - *If electronic, choose platform(s) or explain other:*
        - ☐ *DocuSign Part 11 (FDA regulated studies)*
        - ☐ *DocuSign (standard platform for non-FDA regulated studies)*
        - ☐ *REDCap e-Consent*
        - ☐ *iMedConsent (Veterans Affairs studies)*
- *Any waiting period available between informing the prospective subject and obtaining the consent.*
- *Any process to ensure ongoing consent.*
- *Whether you will be following HRP-090 - SOP - Informed Consent Process for Research. If not, describe:*
    - *The role of the individuals listed in the application as being involved in the consent process.*
    - *The time that will be devoted to the consent discussion.*
    - *Steps that will be taken to minimize the possibility of coercion or undue influence.*
    - *Steps that will be taken to ensure the subject's understanding.*

Click or tap here to enter text.

Non-English Speaking Subjects

- *Indicate what language(s) other than English are understood by prospective subjects or representatives.*
- *If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate the language that will be used by those obtaining consent.*

Click or tap here to enter text.

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

- *Review HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process to ensure you have provided sufficient information for the IRB*

to make these determinations. Describe whether you are requesting to waive some elements of consent (describe which ones), or all elements of consent. Provide justification.

- *If the research involves a waiver of the consent process for planned emergency research, please review HRP-419 - CHECKLIST - Waiver of Consent Process for Emergency Research to ensure you have provided sufficient information for the IRB to make these determinations.*
- *If the research involves deception, describe whether subjects prospectively authorize the deception and plans for de-briefing subjects.*

Click or tap here to enter text.

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

- *Describe the criteria that will be used to determine whether a prospective subject has not attained the 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., individuals under the age of 18 years.)*
  - *For research conducted in the state, review HRP-013 - SOP - LARs, Children, and Guardians to be aware of which individuals in the state meet the definition of "children."*
  - *For research conducted outside of the state, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of "children" in HRP-013 - SOP - LARs, Children, and Guardians.*
- *Describe whether parental permission will be obtained from:*
  - *Both parents 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 child.*
  - *One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.*
- *Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals' authority to consent to each child's general medical care.*
- *Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent. If not obtaining assent, include justification.*
- *When assent of children is obtained describe whether and how it will be documented.*

Click or tap here to enter text.

Cognitively Impaired Adults

- *Describe the process to determine whether an individual is capable of consent or assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require cognitively impaired adults to sign assent documents.*

Click or tap here to enter text.

Adults Unable to Consent

- *List the individuals from whom permission will be obtained in order of priority. (E.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child.)*
  - *For research conducted in the state, review HRP-013 - SOP - LARs, Children, and Guardians to be aware of which individuals in the state meet the definition of "legally authorized representative."*
  - *For research conducted outside of the state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of "legally authorized representative" in HRP-013 - SOP - LARs, Children, and Guardians.*
- *Describe the process for assent of the subjects. Indicate whether:*
  - *Assent will be required of all, some, or none of the subjects. If some, indicated, which subjects will be required to assent and which will not.*
  - *If assent will not be obtained from some or all subjects, an explanation of why not.*
  - *Describe whether assent of the subjects will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require subjects to sign assent documents.*

Click or tap here to enter text.

15.0 Process to Document Consent in Writing

15.1 Describe whether you will be following HRP-091 - SOP - Written Documentation of Consent. If not, describe whether and how consent of the subject will be documented in writing. Click or tap here to enter text.

16.0 Setting

16.1 Describe the local sites or locations where your research team will conduct the research.

- *Identify where your research team will identify and recruit potential subjects.*
- *Identify where research procedures will be performed.*
- *Describe the composition and involvement of any community advisory board.*
- *For research conducted outside of the organization and its affiliates describe:*

- *Site-specific regulations or customs affecting the research for research outside the organization.*
- *Local scientific and ethical review structure outside the organization.*

Click or tap here to enter text.

17.0 Resources Available

17.1 Describe the resources available to conduct the research. For example, as appropriate:

- *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 consequence of the human 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.*

Click or tap here to enter text.

VA Minutes Supplement

Additional Veterans Administration (VA) Requirements

For an Unanticipated Problem Involving Risks to Subjects or Others the IRB's determination as to whether:

- The incident, experience, or outcome <is/is not> unexpected and related to the research or possibly related to participation in the research and indicative of the research placing subjects or others at substantively greater risk of harm than was previously known or recognized (i.e., whether the incident, experience or outcome constituted an actual Unanticipated Problem Involving Risks to Subjects or Others) OR there is insufficient information to determine whether the incident is an Unanticipated Problem Involving Risks to Subjects or Others.
- A protocol modification <is/is not> warranted.
- A consent document modification <is/is not> warranted.
  <If a consent document modification is warranted:>
  - Previously enrolled subjects <must be/do not have to be> notified of the modification.
    <If previously enrolled subjects must be notified:>
    - Such notification must take place <when>.

Such notification must be documented by <how>.

For Serious Non-Compliance or Continuing Non-Compliance, the IRB's determination as to whether:

- Serious Non-Compliance or Continuing Non-Compliance <did/did not> occur.
  <If Serious Non-Compliance or Continuing Non-Compliance did occur:>

Remedial actions <are/are not> needed to resolve present and/or future compliance. <If remedial actions are needed, describe.>

For external suspensions or terminations of research, the IRB's determination as to whether:

- The suspension or termination <was/was not> A result of a local adverse event(s), local non-compliance, or other local issue(s).

Local action <is/is not> required to ensure the safety, rights, or welfare of local research subjects, personnel, or others or the effective of the local HRPP.