**INFORMED CONSENT TO PARTICIPATE IN A RESEARCH REGISTRY**

**REGISTRY NAME:** [Insert the official name of the registry, as it is given in the IRB application]

**PRINCIPAL INVESTIGATOR/REGISTRY DIRECTOR:** [Insert the full name, title, and phone number of the VCU Principal Investigator or the registry director]

**SPONSOR:** [Insert the full name of the funding sponsor. If there is no sponsor for this research, delete this item]

*TEMPLATE INSTRUCTIONS: This template is designed for a stand-alone registry protocol.*

* Instructions and comments are indicated in blue boxes and [yellow highlighting].
* Delete the instructions and comments after reading and following.
* Required information is indicated in the instruction boxes. You may delete the optional sections and language if they are not applicable to your study.
* Example text should be edited to be appropriate for your study.
* Use lay language at an 8th grade reading level.
* If it is necessary to use technical terms, a lay definition of the term must be provided.
* Define all acronyms at first use.
* Page numbers must be included in the format “Page \_\_ out of \_\_\_\_”.
* Replace “disease name” with the actual disease or condition.
* If the study enrolls only children, consider replacing “you” with “your child” and “consent” with “parental permission”

*[Include if appropriate:] NOTE: In this consent form, “you” always refers to the research participant. [Include if this study will enroll decisionally impaired subjects:]* *If you are a legally authorized representative, please remember that “you” refers to the study participant. [Include if this study will enroll child subjects:]* *If you are a parent or legal guardian, please remember that “you” refers to the child study participant.*

**ABOUT THIS CONSENT FORM**

**The following text is relevant to all research studies and may be modified as appropriate.**

You are invited to participate in a research study. **It is important that you carefully think about whether being in this study is right for you and your situation.**

This consent form is meant to assist you in thinking about whether or not you want to be in this study. **Please ask the study staff to explain any information in this consent document that is not clear to you.** [Insert if applicable:] You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

**45 CFR 46.116 (b)(8):**“A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled”

**\*\*The following text is required for all studies and modifications are not recommended:**

Your participation is voluntary. You may decide to not participate in this study. If you do participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

**AN OVERVIEW OF THE STUDY AND KEY INFORMATION**

INSTRUCTIONS: This new section complies with the Final Revisions to the Common Rule (45 CFR 46), which are in effect as of January 19, 2018. **This is a required section for all studies and may not be waived.**

**45 CFR 46.116(a)(5)(i):** “Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist the prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.”

**45 CFR 46.116(b)(9):** “One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
 (i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
 (ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.”

As explained in guidance provided with the Final Rule (Federal Register Vol. 82, No. 12, January 19, 2017, page 7214), if the information included in this Overview section contains sufficient detail to also satisfy the required Basic and Additional Elements of informed consent, then the information included at the beginning does not need to be repeated later in the informed consent.

Sub-headers in this section are optional, but may improve reading comprehension.

**\*\*This is required information for all studies and may be modified as appropriate, but try to cover the same topics described below. If you are not collecting biospecimens for the registry, delete all references to such.**

To advance science, it is helpful for researchers to share information. They do this by putting data or biospecimens into one or more scientific databases (called registries or repositories), where it is stored along with information from other studies. Researchers can then study the information in other ways and combine information from many studies to learn even more.

* This consent form asks for permission to store and share your biospecimens and/or information in a research registry to help research studies in the future.
* The purpose of this registry is to collect and store [list the specific types of biospecimens and information that will be maintained] along with your [describe the identifiers that will be part of the registry (name, phone, email, etc.)]
	+ [Option A - If future research will be limited to specific types of studies/diseases, include:] These biospecimens and information will be used for future research about [describe what types of research will be permitted]
	+ [Option B - If there will be no restrictions on the types of future research, include:] The biospecimens and information will be available for any research question, such as research to understand what causes certain diseases (for example heart disease, cancer, or psychiatric disorders), development of new scientific methods, or the study of where different groups of people may have come from.
	+ [Include if applicable:] Your biospecimens may/will be used for future research that involves various types of genetic testing, including whole genome sequencing. This will be described more later in this consent form.
* Your information and/or biospecimens will be protected, but there is always a possibility that information could be accessed by individuals without authorization.
* Your participation in this registry will not give you any known benefit at this time. We do not anticipate learning any information that could clinically benefit you personally. It is hoped that the knowledge gained from research studies conducted using this registry will benefit people in the future.
* There is no limit on the length of time we will store your information/biospecimens. [Or describe the length of time that the registry will be maintained.]
* Identifiers might be removed from the information and biospecimens you provide in this study, and after that removal, the information/biospecimens could be used for other research studies by this study team or another researcher without asking you for additional consent.

**WHY IS THIS REGISTRY BEING CREATED?**

INSTRUCTIONS: Insert a concise overview (1-2 paragraphs) of the registry’s purpose written in lay language.

**45 CFR 46.116(b)(1):** “A statement that the study involves research [and] an explanation of the purposes of the research”

**\*\*This is required information for all studies and may be modified as appropriate.**

The purpose of this research registry is to [insert short discussion of the general scope and purpose of the registry.]

[If conducting the study in a prison setting with research project involving prison staff or inmates as participants, also include a description of the anticipated uses of the results of the research.] The results of this study will be used to \_\_\_.

**WHAT WILL HAPPEN IF I PARTICIPATE?**

INSTRUCTIONS: Include in this section a full and complete description of the study procedures explained from the participant’s perspective. After reading this section, the participant should have a good understanding of what they will experience and be asked to do during the study.

1. Include information about timing and duration of activities, locations where activities will take place, and what uncommon procedures will be like. Also include a description of any secondary data that will be collected about participants.
2. Include only information about the research activities in this study, not activities that would be done for usual care regardless of participation in study. Explain what aspects of usual care will be altered or omitted because of the study.
3. As appropriate, and particularly for complex studies, include study schemas, study calendars or other tables, figures or graphics to assist the subject in understanding what will be asked of them.
4. Use lay language to facilitate the participant’s understanding. Do not copy technical language from the IRB application or a grant.
5. If the study involves genetic research, be sure to explain what genetic information will be used, generated, or obtained.

**45 CFR 46.116(b)(1):** “the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental”

**45 CFR 46.116 (c)(6):** “The approximate number of subjects involved in the study”

**\*\*This is required information for all studies and may be modified as appropriate.**

If you decide to participate, you will be asked to do the following things: [customize as appropriate]

1. Visit [location] \_\_ times for study visits that will last for \_\_\_ hours
2. Have [insert volume in teaspoons or tablespoons] of your blood drawn \_\_ times
3. Have an MRI/EKG/ultrasound/CT \_\_ times
4. Take surveys and answer questions about [describe general topics]
5. Give permission for the researchers to collect information about [describe general topics] from your [describe the data source such as medical records, educational records, title of another research study, etc.].
6. The investigators will also collect information from your medical records about [insert a description of what types of information will be abstracted]. Medical record information will be collected during your participation in the study and for 5 years after your last study visit.

INSTRUCTIONS: Insert the language of either Option A or Option B if the study will collect biospecimens. If there is any chance that whole genome sequencing (i.e. sequencing of a human germline or somatic specimen with the intent to generate the genome or exome of that specimen) could be done in this study or future research studies, insert Option A.

**45 CFR 46.116(c)(9):** “For research involving biospecimens, 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).”

**\*\*This is required information for all studies that collect biospecimens and may be modified as appropriate.**

[Option A – Studies that will or might perform whole genome sequencing, insert:] This study or other studies in the future [will or might] use your biospecimens to sequence all or part of your DNA.

*Deoxyribonucleic acid (DNA) is the “blueprint” or “recipe” that gives the body’s cells instructions on how to do their jobs. Scientists can use a test called whole genome sequencing to determine the order of all or part of the molecules that make up your DNA, like reading all the letters in a book. Sequencing is usually done to look for changes in the molecules of DNA that may cause health problems.*

[Option B – Studies that will not perform whole genome sequencing, insert:] This study and other studies in the future will not use your biospecimens to sequence all or part of your DNA.

INSTRUCTIONS: Include one (1) of the following template paragraphs that discuss what kinds of future research could be done with the registry materials. Customize this language as appropriate.

**Specific consent:**

Sometimes, it may be appropriate to seek consent for more narrowly defined research uses of participant biospecimens and data. This consent approach may increase participation of people who have concerns about privacy or do not want their biospecimens and data used for research on certain topics.

**Unrestricted consent:**

Participants can be asked to agree to storage of their biospecimens and/or data and to the use of their biospecimens/data in future unspecified research ("general research use"). Unrestricted consent maximizes the utility of collected biospecimens and/or data.

[Specific consent for sharing:] Your information and biospecimens will be stored at [VCU] by [full name of investigator who will oversee the registry] and could be used for other research studies about [list specific types of studies/diseases].

[Unrestricted consent for sharing] Your information and biospecimens will be stored at [VCU] by [full name of investigator who will oversee the registry] in one or more scientific databases, and shared with other researchers. The biospecimens and information will be available for any research question, such as research to understand what causes certain diseases (for example heart disease, cancer, or psychiatric disorders), development of new scientific methods, or the study of where different groups of people may have come from.

**Data Submission to an NIH-Designated Controlled-Access Database or Repository**

For NIH-funded research, investigators are frequently expected to obtain consent for future uses and broad sharing of data and/or biospecimens, particularly genomic and phenotypic data. Template language may be available at the funding institute or center’s website. Customize as appropriate.

[If this or future studies might contribute to an NIH registry, repository or database:] Your individual biospecimens/genomic data/health information could be put in a controlled-access database at the National Institutes of Health (NIH) in the future and stored there indefinitely. Controlled-access means that only researchers who apply for and get permission from the NIH to use the information for a specific research project will be able to access the information. Your data will not be labeled with your name or any other information that could be used to identify you. However, it is possible that the information from your genome, when combined with information from other public sources could be used to identify you, though we believe it is unlikely that this will happen. Researchers approved to access information in the database will agree not to attempt to identify you.

**Will I be contacted by other researchers in the future?**

[Customize this section as appropriate:] Most future research studies involving this registry will only use the information stored in this registry, and therefore will not require further involvement or additional informed consent of participants. However, information from this registry may be used to identify people who may be eligible to participate in future research studies that relate to a particular disease, condition, or treatment and for which additional information is needed that is not in the registry.

If you would like to be contacted for future studies, please initial the optional consent to contact below to authorize the registry to give out your contact information to the relevant study team so they may contact you. The researchers would fully explain the new research study and you would have to give your informed consent to that study before you could participate

If you participate in this registry, you are not required to participate in any future research study. You can also remove permission for the VCU registry to contact you about future studies at any time by contacting the Registry Director identified at the top of this document.

*Optional Permission:* I give permission for the registry staff to share my contact information with other researchers who need additional information or are conducting research that might interest me.

YES \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ NO \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**How long will I be in the registry?**

Your active participation in this study while contributing biospecimens/information will last up to [insert length of time], and your biospecimens/information will be stored in the registry for [insert length of time] and used for future research studies. Approximately [insert how many total] individuals will participate in this registry. [Or state: An unlimited number of subjects will participate in this registry at VCU.

**Include the following paragraph if the registry involves children. It may be modified to reflect this study’s plan for re-consenting children in the registry who reach the age of majority.**

[Example:] When your child reaches age 18, we will try to contact him or her to ask whether they want to continue to participate in this research registry. If we cannot find your child, we will remove all identifying information, and continue to use their biospecimens, genomic data and health information in research.

**WHAT ALTERNATIVES ARE AVAILABLE?**

INSTRUCTIONS: Insert a concise overview (1-2 paragraphs) of the alternatives or other options that would be available to individuals who do not participate in this study. Identify any other procedures that would be available to individuals as well as other treatment options for individuals who do not participate in this study.

**45 CFR 46.116(b)(4):** “A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject”

**\*\*This is required information for all studies and may be modified as appropriate.**

Your alternatives are to not participate in this study or to participate in a different registry if one is available. You do not have to participate in this study to be treated for [disease name].

[If participants have an alternative way of completing a study procedure (e.g. filling out a paper instead of an online questionnaire, going to a different location for a test, having a MRI instead of a CT, etc.), describe that option.]

**WHAT RISKS AND DISCOMFORTS COULD I EXPERIENCE FROM BEING IN THE STUDY?**

INSTRUCTIONS: Include in this section a full and complete description of all reasonably foreseeable risks and discomforts the participant might experience. It is not acceptable to say that there are no risks.

**45 CFR 46.116(b)(2):** “A description of any reasonably foreseeable risks or discomforts to the subject”

**\*\*This is required information for all studies and may be modified as appropriate.**

1. Include only risks of the research activities in this study, not the risks of activities that would be done for usual care or for other purposes (e.g. normal education, routine psychiatric care, quality improvement, etc.) regardless of participation in study.
2. Include physical, psychological, social, and research data risks. The information in this section should be a lay description of the risks given in the IRB submission.
3. Please use lay language (the non-technical meaning), rather than a medical term (ex, use “bruising” instead of “contusion”)
4. The NCCN Informed Consent Language (ICL) database is a comprehensive resource to assist researchers and clinical operations personnel with writing and amending informed consents for study participants. **For standardized lay language descriptions of risks and events associated with clinical research, see:** [**https://www.nccn.org/clinical\_trials/informed\_consent.aspx**](https://www.nccn.org/clinical_trials/informed_consent.aspx).

[List risks of all other research and biospecimens collection procedures]

[Example:] Blood draws may cause pain, bleeding, and/or bruising. You may faint and could develop an infection at the site where blood is drawn.

[Example:] Urine collection involves no anticipated physical risks.

[Applicable to all registries:] Participation in research might involve some loss of privacy or confidentiality. There is a small risk that someone outside the research study could see and misuse information about you.

[Example:] Questionnaires may contain questions that are [sensitive/personal/upsetting/offensive/disturbing/etc.] in nature. You may refuse to answer any question that makes you feel uncomfortable.

[Example:] This study will ask you questions about personal topics that might be embarrassing to talk about and that could affect your family relationships if this information were to become known outside of the study. You will also be asked about illegal activities, which could have legal and financial consequences if this information were to become known outside of the study.

**Include the following sub-section if the registry or a future usage protocol could involve genetic analyses. Modifications are not recommended.**

**Genetic Risks:**

This registry/Future research studies that use your biospecimens or information may involve genetic analysis. If known to employers or insurance companies, the results of genetic tests might affect a person's ability to obtain a job or health or life insurance. If this information were released, it could be misused. Such misuse could be distressing, and it could cause you or your family members to have difficulty obtaining insurance coverage and/or a job.

A federal law called the Genetic Information Nondiscrimination Act (GINA) makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. However, this legal protection still may not keep someone from trying to discriminate against you in this way. This law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

**45 CFR 46.116(c)(5):** “A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject”

**\*\*** **Include the following sub-section if the study is longitudinal or interventional. Modifications are not recommended.**

**Unknown or Unforeseeable Risks**

The researchers will let you know about any significant new findings (such as additional risks or discomforts) that might make you change your mind about participating in the study.

**WHAT ARE THE BENEFITS OF BEING IN THE REGISTRY?**

INSTRUCTIONS: Include in this section a full and complete description of any benefits participants may reasonably expect to experience as well as a description of the benefits to others from the scientific knowledge to be gained.

**45 CFR 46.116(b)(3):** “A description of any benefits to the subject or to others that may reasonably be expected from the research”

**\*\*This is required information for all studies and may be modified as appropriate.**

**\*\*For simple studies, if a full description of the benefits is given in the Overview above, then this section can be deleted.**

This registry is not likely to benefit you. However, we hope the information learned from this study will provide more information about \_\_\_\_.

[If this study will include prisoners as subjects, insert:] If you are or should become involuntarily detained, confined or incarcerated (in a jail, prison, or alternative facility), you should be aware that your participation in this research project will have no effect on consideration of sentencing, length of sentence, or parole.

**45 CFR 46.116(c)(8):** “A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions”

**\*\* The following text is required for all studies and may be modified as appropriate.**

In general, we will not give you any individual results from the study. We do not anticipate learning any information that could personally benefit you. [Insert if applicable:] However, if we or other researchers find something of medical importance to you, we will inform you, [or explain another method of communicating the information] although we expect that this will be a very rare occurrence. [Insert if participants will receive aggregate results:] Once the study has been completed, we will send you a summary of all of the results of the study and what they mean.

**WHAT ARE THE COSTS?**

INSTRUCTIONS: Include in this section a description of all costs that the participant will be responsible for paying. Clinical research studies may use their cost coverage analysis to determine which items are billed to the patient.

**45 CFR 46.116(c)(3):** “Any additional costs to the subject that may result from participation in the research”

**\*\*This is an optional section. It applies only to studies where there will be costs to the participant and may be modified as appropriate.**

[Example:] You and your insurance plan will need to pay for the costs of medical care you get as part of the study, just as you would if you were getting the usual care for your condition. This includes:

* The costs of tests, exams, procedures, and drugs that you get during the study to monitor your safety, and to prevent and treat side effects.
* The costs of getting study drug ready and giving it to you
* Your insurance co-pays and deductibles.

[Example:] You and your insurance plan will not have to pay for exams, tests, and procedures done for research purposes only or that are covered by the study. This includes:

* The extra blood draws in this study done at every study visit
* The biopsy for testing \_\_\_\_ at the beginning of the study.

**WILL I BE PAID TO PARTICIPATE IN THE REGISTRY?**

INSTRUCTIONS: Include in this section a description of any planned compensation that will be given to participants. Use straightforward language and include the amount paid per visit.

**\*\*This is an optional section. It applies only to studies that plan to compensate or pay participants and may be modified as appropriate.**

[Example:] You will be paid $\_\_\_\_\_ in cash/by check/by gift card for each study visit, and if you complete all scheduled study visits, you will have received a total of $\_\_\_\_. If you withdraw before the end of the study, you will be paid $\_\_\_\_\_ per completed study visit.

[Include if compensating participants:] Total payments within one calendar year that exceed $600 will require the University to annually report these payments 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.

**45 CFR 46.116(c)(7):** “A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit”

**\*\*The following text is required for all studies that collect biospecimens and modifications are not recommended.**

You will not be paid for any future research studies that use the information or biospecimens in the registry. The information and biospecimens stored as part of this registry could lead to discoveries or inventions in the future that may be of value to VCU or to other organizations. You will not receive any money or other compensation that may come from products that are developed from the information or biospecimens stored in the registry. [Or, if the participant will share in profits, replace the last sentence with an explanation of the payment to be given.]

**WHAT HAPPENS IF I AM INJURED OR BECOME SICK BECAUSE I TOOK PART IN THE STUDY?**

**45 CFR 46.116(b)(6):** “For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained”

**\*\* This is a required section for all greater than minimal risk studies and modifications are not recommended. Modified text will need to be reviewed by the Office of Sponsored Programs to ensure consistency with the grant contract.** This section is not required, and generally not appropriate, for expedited research.

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.

**CAN I STOP BEING IN THE REGISTRY?**

You can stop being in this research registry at any time. Leaving the registry will not affect your medical care, employment status, or academic standing at VCU or VCU Health. Tell the study staff if you are thinking about stopping or decide to stop.

In the future, if you decide that you don’t want to be part of this registry, you can request that your information/biospecimens be removed and destroyed by contacting [name of investigator who should be contacted (e.g. the PI at VCU)]. However, information that has already been shared with other researchers will continue to be used.

**45 CFR 46.116(c)(2):** “Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent”

**\*\*The following information is required if there are any anticipated circumstances under which the investigator might stop a participant from continuing in the study (early withdrawal) and may be modified as appropriate.**

Your participation in this registry may be stopped at any time by the study staff without your consent. The reasons might include:

* you are found to not be eligible for the study [delete not applicable]
* the sponsor has stopped the study [delete if the study is unfunded]
* administrative reasons require your withdrawal
* [insert any other reasons why the study team would take a participant out of the study]

[If this study will include prisoners as subjects, insert:]

If you are or should become involuntarily detained, confined or incarcerated (in a jail, prison, or alternative facility) during your active participation in this study, you should be aware that your continuation will need to be reconsidered given your status as a prisoner.

**HOW WILL INFORMATION ABOUT ME BE PROTECTED?**

INSTRUCTIONS: Include in this section a description of how the study staff will keep research data secure and identify all individuals and groups who may access the data.

**45 CFR 46.116(b)(5):** “A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained”

**\*\* This is required information for all studies and modifications are not recommended:**

VCU has established secure research databases and computer systems to store information and to help with monitoring and oversight of research. Your information may be kept in these databases but are only accessible to individuals working on this study or authorized individuals who have access for specific research related tasks. Identifiable information in these databases are not released outside VCU unless stated in this consent or required by law. Although results of this research may be presented at meetings or in publications, identifiable personal information about participants will not be disclosed.

Personal information about you might be shared with or copied by authorized representatives from the following organizations for the purposes of managing, monitoring and overseeing this study:

* The study Sponsor, representatives of the sponsor and other collaborating organizations [delete if there is no Sponsor]
* Representatives of VCU and the VCU Health System/VCU Dental Care
* Officials of the Department of Health and Human Services or the Federal Food and Drug Administration [reference to the FDA may be deleted if this is not an FDA regulated study]
* [If research is conducted in foreign countries include the following statement:] This research is also being conducted in foreign countries, so personal information pertaining to you may be shared or copied by authorized agents of governmental agencies in those countries.

[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, [insert if applicable: 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.

**\*\*The following paragraph is required for all clinical trials and may not be modified.**

For more information on CT.gov reporting and a decision tool to decide if your study is a clinical trial, see <https://cctr.vcu.edu/support/consultation/clinical-trials-gov/>

A description of this clinical trial will be available on [http://www.ClinicalTrials.gov](http://www.clinicaltrials.gov/), as required by U.S. Law. This Web site will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Web site at anytime.

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.

**\*\*The following information is required if there is the potential for you to discover suspected child or elder abuse during the course of the study and may be modified as appropriate.**

[Example:] We will not tell anyone the answers your child/loved one gives us. But, 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.

**[If tests are done that require reporting of positive results to the Health Department (e.g. hepatitis, HIV, STDs, COVID, see** [**https://www.vdh.virginia.gov/surveillance-and-investigation/commonwealth-of-virginiastate-board-of-health/**](https://www.vdh.virginia.gov/surveillance-and-investigation/commonwealth-of-virginiastate-board-of-health/)**), these must be mentioned, along with that information.**

[Example:] 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.

**\*\*The following text is required if the study will include prisoners as subjects and may be modified with caution.**

If you are or should become involuntarily detained, confined or incarcerated (in a jail, prison or alternative facility), you should be aware that confidentiality regarding your status as a prisoner cannot be guaranteed. Personal information about you might be shared with or copied by authorized representatives of the prison facility and/or prison system.

All research involving human participants conducted within the Bureau of Prison system must comply with additional requirements established by the Bureau of Prisons in order to be approved by the IRB. Consent requirements are outlined in 28 CFR 512.16.

**\*\*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]

Certificate of Confidentiality

**\*\*This sub-section is required for all studies funded in whole or in part by the NIH that are automatically granted a Certificate of Confidentiality (CoC) and for all non NIH-funded studies that will voluntarily seek a CoC (all human subject research qualifies). Modifications are not recommended.**

**For studies applying to the NIH for a certificate of confidentiality - enter the information below in your online CoC application (**[**https://grants.nih.gov/policy/humansubjects/coc.htm**](https://grants.nih.gov/policy/humansubjects/coc.htm)**):**

 **Name of Institutional Official\* - Tina Cunningham**

 **Email Address of Institutional Official\* - tlcunningham2@vcu.edu**

 **Phone Number of Institutional Official - (804) 828-6772**

**For studies applying to another agency or department for a CoC, see instructions at** [**https://research.vcu.edu/forms/**](https://research.vcu.edu/forms/) **under the VCU IRB accordion.**

To help us protect your privacy, we have obtained [or insert: will apply for] a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

[If you intend to make voluntary disclosure about things such as child abuse, intent to hurt self or others, or other voluntary disclosures, insert:] The researchers may share information about you or your participation in the research project without your consent if: [State here the conditions under which voluntary disclosure would be made, such as child or elder abuse or neglect, or harm to self or others.]

**HOW WILL MY EDUCATIONAL RECRODS BE USED IN THIS REGISTRY?**

INSTRUCTIONS: Access to educational records is regulated by the Family Educational Rights and Privacy Act (FERPA), which stipulates generally that schools must have written permission from the parent or eligible student in order to release any information from a student’s education record. For more information about FERPA requirements, contact [VCU Records and Registration](https://rar.vcu.edu/records/family-educational-rights-and-privacy-act/).

For research uses of education records, there are several options for how data can be accessed. If, after consultation with VCU Records and Registration, the “written, signed consent” FERPA pathway will be used, then the consent form must specify:

For research uses of education records, the consent must specify:

* The records to be released
* Reasons for the release
* Parties to whom records may be released
* Notice that, upon parental or adult student request, the school will provide him/her with a copy of the records disclosed
* Notice that, upon parental request, the school will provide the student with a copy of the records disclosed

**The following language is required if the study involves obtaining identifiable (directly or indirectly identified) education record information and may be modified as appropriate. Alternatively, a stand-alone FERPA consent form is available on the VCU Records and Registration website that could be used instead.**

As part of this research, we will ask you to share identifiable information from your educational records, which is protected by the Family Educational Rights and Privacy Act (FERPA). The following types of information will be used for the conduct of this research: [list the specific types of educational records/information to be released (e.g. test grades, GPA, homework, writing samples, etc.)]. This educational information will be released to the Principal Investigator and the research staff [if information may be released to other persons or groups, list them here]. Upon request, the school will provide you with a copy of the records disclosed.

**HOW WILL MY HEALTH INFORMATION BE USED AND SHARED DURING THIS STUDY?**

INSTRUCTIONS: **This section includes all of the required elements of valid HIPAA Authorization.** Include this section if the study will collect Protected Health Information (PHI) from either secondary data or direct report from participants.

**\*\*This is an optional section that applies only to studies accessing, using, or maintaining PHI AND if the study’s HIPAA pathway is “Signed Authorization Combined with Consent.” Remove this section if a separate HIPAA Authorization form will be used. Modifications are not recommended.**

VCU researchers can ensure all of the HIPAA authorization requirements are being met by utilizing this template language as directed. Researchers also have the option to draft their own authorization language. If drafting your own language, this section is required to include 8 elements in order for the authorization to be valid.

For more information, see the HIPAA in Research accordion at <https://research.vcu.edu/human-research/hrppirb/hrpp-policies-and-guidance/>

As part of this research study, we will ask you to permit us to access existing information from your healthcare records. [Include if applicable: New health information will also be placed in your health records from study-related tests, procedures, visits, and/or questionnaires.] This type of information is considered “Protected Health Information” that is protected by federal law.

**What type of health information will be used or shared with others during this research?**

[Double click on the boxes to insert a check mark. Or, you may delete the table and list in paragraph form:]

The following types of information may be used for the conduct of this research:

|  |  |  |
| --- | --- | --- |
| [ ]  Complete health record | [ ]  Diagnosis & treatment codes | [ ]  Discharge summary |
| [ ]  History and physical exam | [ ]  Consultation reports | [ ]  Progress notes |
| [ ]  Laboratory test results | [ ]  Medical imaging reports  | [ ]  Imaging films/scans/pictures |
| [ ]  Photographs, videotapes | [ ]  Billing records | [ ]  Itemized bill |
| [ ]  Drug or alcohol abuse | [ ]  Hepatitis B or C tests |
| [ ]  Mental or behavioral health  | [ ]  Sexually transmitted diseases |
| [ ]  Other physical or mental health information (specify):       |

**Who will use or share protected health information about me?**

VCU and VCU Health/VCU Dental Care are required by law to protect your identifiable health information. By signing this document, you authorize VCU and VCU Health/VCU Dental Care to use and/or share your health information for this research. The health information listed above may be used by and/or shared with the following people and groups to conduct, monitor, and oversee the research:

|  |  |
| --- | --- |
| * Principal Investigator and Research Staff
 | * Study Sponsor [delete if none]
 |
| * Health Care Providers at VCU Health/VCU Dental Care
 | * Data Coordinators [delete if none]
 |
| * Institutional Review Boards
 | * Research Collaborators [delete if none]
 |
| * Government/Health Agencies
 | * Data Safety Monitoring Boards [delete if none]
 |
| * Others as Required by Law
 |  |

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

**When will this authorization (permission) to use my protected health information expire?**

[Insert ONE of the following options:]

[Option 1:] This authorization will expire when the registry is closed.

[Option 2:] This authorization will expire when [specify other expiration date].

### Statement of Privacy Rights

You may change your mind and revoke (take back) the right to use your protected health information at any time. However, even if you revoke this authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you revoke this Authorization you may no longer be allowed to participate in the research study. To revoke this Authorization, you must write to the Principal Investigator at [insert VCU PI’s full name and mailing address].

**WHO SHOULD I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?**

INSTRUCTIONS: Include in this section the names and contact information for

1. The VCU Principal Investigator
2. The study doctor to contact if injury occurs (if different from the VCU PI), and
3. The person/office at VCU to contact with questions about rights as a participant.

**45 CFR 46.116(b)(7):** “An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject”

**\*\*This is required information for all studies**

Provide at least 2 methods of directly contacting the PI (e.g., phone, email, pager). For greater than minimal risk treatment studies, a 24-hour phone number should be provided.

In addition to the PI, other relevant contact people may be listed in order of priority. Other contact persons might include the student/trainee investigator carrying out the project, a medically responsible investigator, or a research coordinator.

**The following language applies to all research studies and modifications are not recommended:**

The investigator and study staff named below are the best person(s) to contact if you have any questions, complaints, or concerns about your participation in this research:

**[Insert name and two forms of contact information of VCU Principal Investigator.]**

 and/or

**[Insert name and two forms of contact information of additional contact person/people for study]**

If you have general questions about your rights as a participant in this or any other research, or if you wish to discuss problems, concerns or questions, to obtain information, or to offer input about research, you may contact:

Virginia Commonwealth University Office of Research

800 East Leigh Street, Suite 3000, Box 980568, Richmond, VA 23298

Phone: (804) 827-2157

<https://research.vcu.edu/human-research/hrppirb/research-participants/>

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

**STATEMENT OF CONSENT [AND/OR PARENT/LEGAL GUARDIAN PERMISSION]**

I have been provided with an opportunity to read this consent form [permission form] carefully. All of the questions that I wish to raise concerning this study have been answered. By signing this consent form [permission form], I have not waived any of the legal rights or benefits to which I [and/or my child] otherwise would be entitled. My signature indicates that I freely consent to participate [and/or give permission for my child to participate] in this research study. I will receive a copy of the consent form [permission form] for my records.

INSTRUCTIONS: Access to educational records is regulated by the Family Educational Rights and Privacy Act (FERPA), which stipulates generally that schools must have written permission from the parent or eligible student in order to release any information from a student’s education record. For more information, see <https://rar.vcu.edu/records/family-educational-rights-and-privacy-act/> or contact VCU Records and Registration.

**The following language is required if the study involves obtaining identifiable educational record information and may not be modified.**

FERPA Statement:

Under the Family Educational Rights and Privacy Act (FERPA) of 1974, updated January 2009, I understand that my educational records cannot be released without my written permission. I authorize the release of my academic records from Virginia Commonwealth University for the purpose of this study. I understand that I have the right to rescind this release agreement of my academic records at any time.

INSTRUCTIONS: Include one or more signature blocks depending upon what type of participants will be enrolled. **VCU requires that the following three signature lines are included in all consent documents unless a waiver of consent documentation is approved in the IRB application**:

1. **Subjects or the subject’s legally authorized representative** must sign and date the consent form, as required by 46.117(a).
2. **The person conducting the informed consent discussion** must sign and date the consent form, as required by the VCU IRB and to meet International Conference on Harmonization (ICH) guidelines.
3. **The Principal Investigator or equally qualified Sub-Investigator** must sign and date consent forms, which is required by the VCU IRB because it is the responsibility of the investigator to ensure that consent is obtained from each subject as required.

**Try to format the signature lines so that the entire signature block fits on a single page.**

**Delete this block of signatures if the study does not enroll adult participants.**

**Signature Block for Enrolling Adult Participants**

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

Adult Participant Name (Printed)

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

Adult Participant’s Signature Date

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

Name of Person Conducting Consent Discussion (Printed)

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

Signature of Person Conducting Consent Discussion Date

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

Principal Investigator Signature (if different from above) Date

**Delete this block of signatures if the study does not enroll decisionally impaired adult participants.**

**Signature Block for Enrolling Decisionally Impaired Adult Participants**

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

Name of Adult Participant (Printed)

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

Name of Legally Authorized Representative (Printed) Relationship to Participant

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

Legally Authorized Representative Signature Date

INSTRUCTIONS: Assent should be obtained from the adult participant whenever possible to show respect for their autonomy.For decisionally impaired adults who are capable of providing assent, it may be appropriate to verbally explain the study to them using this consent document and appropriate language. In this situation, the adult participant’s assent should be documented on the following line.

**STATEMENT OF ASSENT BY ADULT PARTICIPANT**

The person doing this research study has explained what will happen to me if I participate in this study. My signature below means that I want to be in this study. I can decide not to be in this study if I do not want to. Nothing will happen to me if I do not want to participate.

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

Adult Participant’s Signature Date

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

Name of Person Conducting Consent/Assent Discussion (Printed)

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

Signature of Person Conducting Consent/Assent Discussion Date

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

Principal Investigator Signature (if different from above) Date

**Delete this block of signatures if the study does not enroll children OR if a separate Parental Permission Form will be developed.**

INSTRUCTIONS: For research conducted under **Children’s Categories 404 and 405**, the IRB will determine whether one or two parents/guardians must sign the parental permission form. It is recommended that the form allow signature lines for 2 signatories even if only 1 parent/guardian is required to sign.

“Parent” means a child's biological or adoptive parent.

“Guardian” means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

**Signature Block for Enrolling Child Participants - Parent/Guardian Permission**

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

Name of Child/Youth Participant

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

Name of First Parent/Legal Guardian (Printed)

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

**Required** First Parent/Legal Guardian Signature Date

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

**Optional**Second Parent /Legal Guardian’s Signature Date

INSTRUCTIONS: Both parents are required to sign the parental permission form in the following situations:

1. For research conducted under **Children’s Category 406**
EXCEPTION: The second 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

2. For research conducted with **nonviable neonates** after delivery [45 CFR 46.204(c)(5)]
EXCEPTION: The second parent is unable to consent because of unavailability, incompetence, or temporary incapacity
EXCEPTION: The father’s consent need not be obtained if the pregnancy resulted from rape or incest

3. For research that **involves pregnant women AND** **holds out the prospect of direct benefit solely to the fetus** [45 CFR 46.204(e)]
EXCEPTION: The father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest

**REPLACE the “Optional Second Parent/Legal Guardian” signature line above with the following Required Parent/Legal Guardian lines:**

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

Name of Second Parent/Legal Guardian (Printed)

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

**Required** Second Parent /Legal Guardian’s Signature Date

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

Name of Person Conducting Parental Permission Discussion (Printed)

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

Signature of Person Conducting Parental Permission Discussion Date

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

Principal Investigator Signature (if different from above) Date

**Delete this block of signatures if the study does not enroll children, children will not provide written documentation of assent, or if a separate Assent Form will be developed.**

INSTRUCTIONS: For older child participants (i.e. 8th grade or older) and depending on the nature of the study, it may be appropriate to verbally explain the study to the youth using the parental permission form and age-appropriate language. In this situation, assent should be documented in this form**.**

**Signature Block for Enrolling Child Participants (Ages \_\_-\_\_) – Assent by Child**

**STATEMENT OF ASSENT BY CHILD PARTICIPANT**

The person doing this research study has explained what will happen to me if I participate in this study. My signature below means that I want to be in this study. I can decide not to be in this study if I do not want to. Nothing will happen to me if I do not want to participate.

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

Child Participant’s Signature Date

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

Name of Person Conducting Assent Discussion (Printed)

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

Signature of Person Assent Discussion Date

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

Principal Investigator Signature (if different from above) Date

**Delete this block of signatures if the study will only enroll English-speaking participants OR if the consent document will be translated.**

INSTRUCTIONS: In order to provide equitable access to research, it may be appropriate to enroll subjects who are not fluent in English (LEP) using the “short form consent” process.

* The short form process is intended for situations where the likelihood of encountering eligible LEP individuals is small (i.e., <5% of the patient population typically served). If the targeted population is anticipated to include 5% or more of LEP subjects, investigators should submit translated consent forms to the VCU IRB for approval.

**Signature Block for Short Form Consent – Limited English Proficiency Participants**

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

Name of Participant (Printed)

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

Witness or Interpreter’s Signature Date

*(NOTE: The witness may be the interpreter or a family member of the LEP subject who can speak both English and the participant’s language. The witness cannot be the member of the study team conducting the consent process.)*

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

Name of Person Conducting Consent/Assent Discussion (Printed)

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

Signature of Person Conducting Consent/Assent Discussion Date

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

Principal Investigator Signature (if different from above) Date