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| **SUNY DOWNSTATE HEALTH SCIENCES UNIVERSITY**  **& NYC Health + Hospitals, Kings County**  *(If not applicable, delete one of the above lines and the “&”)*  **BROOKLYN, NY 11203**  **Consent for Research Participation** |
| Title: **[Title]**  Researcher(s): **[PI Name and others, if desired (optional)**  Researcher Contact Information: **[phone (required) and e-mail (optional)]**  Sponsor: **[Name of external sponsor (e.g., industry, company, or government entity) or delete this line if there is no external sponsor]** |

*HELPFUL TIPS:*

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| * ***Informed consent is a “PROCESS,” not just a FORM!!! This template focuses on the regulatory requirements for the “form.” Please review additional IRB Guidance on “Obtaining Legally Effective Informed Consent and HIPAA Authorization.*** * *The design of this “All-In-One” template is for all research types and includes built-in guidance.* * *There is another “SIMPLE” template available that can be used, but please refer to this template for complete guidance.* * *Refer to the IRB Guidance:* [*Obtaining Legally Effective Informed Consent and HIPAA Research Authorization*](https://research.downstate.edu/irb/policies.html)*.* * *The HIPAA Authorization language is included in this template which is the preferred approach; however, if a sponsor requires a stand-alone HIPAA authorization, please refer to the stand-along template on the IRB website.* * *If the research has an external sponsor, please consider using the sponsor’s model informed consent template, rather than this template. However, be sure to include all language required by local research context:*   + *Required HIPAA authorization language when a study involves Protected Health Information (PHI). Include the elements described in IRB-01 policy, including disclosures of research involving video/audio recording or pictures or images. Use the recommended language in template below or use the stand-alone HIPAA Authorization.*   + *Information for diagnostic (clinical) genetic testing*   + *Option to use coded (de-identified) specimens and/or information for future research*   + *Use of psychiatry notes (include separate HIPAA Authorization; template on website)*   + *All required signature lines, as applicable to the study*   + *Information regarding HIV education/testing, when applicable*   + *Information regarding payment for research participation, when applicable*   + *Optional authorizations (e.g., future contact to obtain or share information about genetic testing, sharing information/specimens for future research, future contact for other studies, release of medical information)* * *Items in italics or red are general instructions which must be deleted (or changed when applicable) before submitting the final form to the IRB.* * *Informed consent must present information in sufficient detail related to the research and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective research participant’s or surrogate’s understanding of the reasons why one might or might not want to participate. Change the suggested order of this template, as needed, to facilitate the process of informed consent.* * *To the extent possible, explain technical, medical, and scientific concepts in lay terms that are understandable to someone who is educated* ***from a 6th to 8th grade level****. Note that grade 6-8 reading level is a goal, but some required language may necessarily be worded at a higher reading level. The aim is still to provide comprehensive information; whenever possible, reducing the reading level should* ***NOT*** *entail eliminating information. Avoid long sentences and medical/technical jargon, and clearly define any technical terms whenever they are used. If the definitions of technical terms are lengthy, describe in separate sentences. The PI is encouraged to* [*test the readability within Microsoft Word*](https://support.office.com/en-us/article/test-your-document-s-readability-85b4969e-e80a-4777-8dd3-f7fc3c8b3fd2?redirectSourcePath=%252fen-us%252farticle%252ftest-your-document-s-readability-0adc0e9a-b3fb-4bde-85f4-c9e88926c6aa&ui=en-US&rs=en-001&ad=US)*.* * *Consider adding pictures, diagrams, tables, or charts if they will improve understanding.* * *Avoid or minimize passive voice to the extent possible.  Example of passive voice: “A summary of results will be sent to all study participants.”  Example of active voice: “We will send you a summary of the results.”* * *Pronouns matter. Write directly to the reader, as though you are explaining the facts in person.  Write in the second person (“you”), not in the first person (“I”). Avoid the frequent use of first-person pronouns (I, me, my, we, us, etc.).* * *When applicable, change the title in header (e.g., PARENTAL PERMISSION, HEALTHY VOLUNTEER INFORMED CONSENT, etc.).* * *Remove references to “NYC Health + Hospitals, Kings County” in the header and throughout this form if they are not involved in the research.* * *Use bold text and/or boxes around critical text for emphasis.* * *Include any requirements of any applicable federal, state, or local law.* * *Include any requirements of any applicable tribal law passed by the official governing body of an American Indian or Alaska Native tribe (e.g., Research focus on American Indians, Alaskan Natives, or indigenous people). NOTE: A Tribe may require their own tribal IRB approval, prior to submission to Downstate IRB* * *Please consider numbering the sections to help with the informed consent process.* |

**Key Information:**

*Provide a concise and focused summary of the key information that is most likely to assist a reasonable person in understanding the reasons why one might or might not want to participate in the research.*

**What should you know about this research?**

We (the researchers) are asking if you would like to be in a research study. Participation is **voluntary**, which means that only you can decide if this is right for you. It is your choice whether you want to be in this research. Your decision will not affect your services at Downstate (or list other sites).

This form will explain the following to help you decide whether to participate in the study or not:

* Why the study is being done.
* What will happen if you participate.
* Risks or discomforts that might happen.
* Benefits, if any.

To participate in the study is your choice and only up to you. You can choose not to take part. You can agree to take part and later change your mind. There are no penalties or loss of services or any benefits if you decide not to participate. And, please ask all the questions you want before you decide.

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

*[Insert a short, 1-2 sentence summary of the purpose of the research]*

This is a research study to (state purpose, if biomedical, consider the following or something similar: better understand [insert problem] (or) evaluate if new medication(s)/procedure(s) are safe/helpful in reducing/improving the [problem/clinical outcome].

*[When evaluating an investigational drug, biologic, or medical device, indicate it is not FDA approved.] Example:* [name of the product or device] is investigational, which means that it is not approved by the Food and Drug Administration (FDA).

You are being asked to be in this study because you are/have [describe reason or disease and/or inclusion criteria as applicable for the study].

**What happens if you decide to be in this study?**

If you decide to take part in this research study, the main procedures include [briefly outline in simple terms the procedures that are key to the research and are most likely to affect someone’s decision about whether to take part. Include a description of any experimental procedures.]

**How long will you be in the study?**

*[Insert a description of the duration of the participant’s participation, long-term follow-up/monitoring of participants via chart review, and length of the overall study]*

*Example:* You will be in this study for just one visit/6 months/3 years. We will collect information from your medical records for 12 months. This study will go on for three years.

**Are there any risks in being in this study?**

In simple language, explain the high-level or most common foreseeable risks **and** discomforts that are most likely to affect someone’s decision about whether to take part. *Note: Include the complete list of reasonably foreseeable risks in the DETAILED INFORMATION section of the consent form, including any foreseeable risks to a pregnant individual or a fetus for research involving pregnant individuals or individuals of childbearing potential.]*

*Example:* If you participate in this study, you might experience the following:

* List (e.g., side effect/adverse event/pain/medical complications/bruising, infection, etc.)
* List others

**Are there any benefits from being in this study?**

DO NOT LIST PAYMENTS, COMPENSATION, OR REIMBURSEMENT AS A BENEFIT.

You will not benefit from being in this research.

*-OR-*

No benefits are promised. Some anticipated benefits might include [describe any direct, known, proven, or therapeutic benefits of the research to the participant in a clear, balanced manner based on reliable information]. ADD, if applicable: The results of the research might benefit others in the future. Describe any possible future benefits to others or knowledge gained that might result from the research. Example: We hope to learn more about <describe> which may benefit others in the future.

*If sharing data or specimens, edit as applicable*: You will not receive any direct benefit from sharing your data and specimens. However, sharing your data and specimens may contribute to research that helps others in the future.

*Add to commercial studies to inform prospective participants about whether their data and specimens may contribute to products with commercial value. If research participants will receive any payments related to commercial or product development, adjust language in the last sentence to reflect this:* The use of your data and specimens may lead to new tests, drugs, devices, or other products or services with commercial value. These products or services could be patented and licensed. There are no plans to provide any payment to you should this occur.

**Do you have other options?** *[Delete if there are no alternatives]*

You do not have to participate in this study to receive treatment for your condition. There are treatments such as [if there are other treatments, insert here], or you can choose to have no treatment. The study doctor [or list other healthcare provider] will discuss alternatives with you and their risks and benefits.

**What other information should you know?** [Delete if not applicable]

[Include any additional information that may be crucial to know early that would affect the decision to participate. This may include large out of pocket expenses, participant responsibilities that may be burdensome, unusual privacy or confidentiality issues, or serious implications for future treatment (e.g., taking part in the study may limit options in the future).]

You should also consider the following before deciding whether to take part in this study: [describe].

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| The KEY INFORMATION (above) is meant to help you decide if you are interested in being in this study but does not include everything you need to know. If interested, please review the DETAILED INFORMATION (below). Ask any questions that you have. |

**Detailed INFORMATION:**

*Organize the information in sufficient detail relating to the research in a way that facilitates the prospective subject’s or legally authorized representative’s understanding of the reasons why one might or might not want to participate. Do not merely provide lists of isolated facts*.

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

*When requesting parent or legal guardian permission for a child, add the following (edit as needed, depending on the age range of the participants)*:

**If you are giving permission for a child to be in the study:**

The terms “you” and “your” mean your child and we are asking your permission for your child to be in this study. *Edit as needed and/or include one or more of the following:* If your child is older than 6, we will ask your child if they want to be in the study. If your child is between 7-12 we will also ask your child to sign an Assent Form to be in the study. If your child is between 13-17, we will also ask your child to sign this form to be in the study.

*When obtaining consent from a surrogate for a cognitively impaired adult, add the following:*

**If you are giving permission to participate for an adult who cannot make their own decision:**

The terms “you” and “your” mean the adult who cannot make their own decision. Please consider the wishes and beliefs or the best interests of this person. If this person can get back their ability to make their own decisions after you give your permission for this person to be in the study, they will be asked to give their permission to participate.

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

*Note: If fully described in the key information section summary above, delete this section. If more description is appropriate, consider augmenting this section with simple illustrations, diagrams, or figures if they aid in the explanation.*

**What does genomic research mean for my family?**

INCLUDE FOR NIH FUNDED STUDIES FOR GENOMIC RESEARCH.

For more information see: <https://www.genome.gov/about-genomics/policy-issues/Informed-Consent-for-Genomics-Research/Special-Considerations-for-Genome-Research#families>

Genetic studies provide information about you and your family members. Some conditions run in families and are passed on through genes, our biological information that is like a fingerprint. Because certain conditions and traits run in families and are inherited through genes, this study is recruiting biologically related family members. This study will compare family members who have [disorder] and family members who do not have [disorder]. You may learn something about your genome that relates to the health of your relatives. If so, your relatives might want to know so that they can decide whether to get tested or follow up in other ways. It is also possible that they might not want to know.

It is possible that we will learn that assumed family relationships are incorrect (such as learning that a child is adopted or has a different father). [Possibly] We will not give you these results. [OR] We will tell you these results only if they are relevant to your health.

**What does genomic research mean for your community?**

INCLUDE FOR NIH FUNDED STUDIES FOR GENOMIC RESEARCH.

For more information see: <https://www.genome.gov/about-genomics/policy-issues/Informed-Consent-for-Genomics-Research/Special-Considerations-for-Genome-Research#families>

This study has been developed in consultation with [representatives of the community, describe]. These community representatives have been/are involved in [describe their involvement]. [For a biobank/data repository] [Add if applicable] They have agreed that it is not likely to harm the community if we share your data with other researchers. Although we will not give researchers your name, we will give them basic information such as your race, ethnic group, geographic region, age range, gender identity, sex assigned at birth [specify demographic variables]. This information may help researchers in this study whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people in the same groups as you. However, it is also possible that research findings could be used inappropriately to support negative stereotypes, stigmatize, or discriminate against members of the same groups as you.

**What happens if you decide to be in this study?**

*If fully described in the key information section summary above, delete this section.*

*Example (edit as needed):* The following will happen if you decide to participate in this research:

* The study will take place in the SUNY Downstate Clinical and Translational Science Center.
* Five (5) teaspoons of your blood will be drawn for some lab tests and a physical exam will take place to make sure you are eligible to be in the study. You will also have a single chest x-ray. This visit will take about 30 to 60 minutes.
* After it is determined you can be in the study, you will be put into a study group by chance (like a coin toss). You have 1 out of 2 chances of being placed in each group. You cannot choose your study group.
* Depending on the group you are in, you will be given either the experimental drug called XYZ or a placebo (no active drug) that looks like the study drug.

XYZ is investigational, which means that it is not approved by the Food and Drug Administration (FDA).

* You will take the study drug or placebo two (2) times a day for four (4) months.
* You will complete a Quality-of-Life survey which takes about 30 minutes each time. This survey will be done on the first visit and every month for six (6) months. The survey will have questions about your general well-being and happiness about life.
* The study drug will not be available at the end of the study. However, after the study is complete, you may be eligible to participate in a follow-up study that allows you to take XYZ, even if you had the placebo. You will need to sign a separate consent form to participate in the new study.
* We will draw an additional five (5) teaspoons of your blood in the 2nd and 4th month for additional study tests.

We will ask your permission at the end of this form to store your specimens and information for future research. You do not have to agree to this.

* *Describe any information sought from other individuals or entities (e.g., participants caretaker, clinicians, etc.): Example:* We will ask your caretaker/clinician to give information about you.
* *Include if the study will or might (if known or anticipated) 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 study might include whole genome sequencing. Deoxyribonucleic acid, or DNA, is the material that makes up genes. Genes carry information that determines your traits, such as your hair color, eye color, and risk for certain disease. Genes contain the instructions that you need to develop, live, and reproduce. These instructions are found inside every cell and are passed down from parents to their children. Whole genome sequencing is the process of determining your complete DNA sequence, which is the order of DNA building blocks (nucleotides) in your genetic code. DNA sequencing determines the order of the four chemical building blocks - called "nucleotides" - that make up the DNA molecule. The four nucleotides are adenine (A), thymine (T), guanine (G) and cytosine (C). The order of these bases is what determines DNA's instructions, or genetic code.

*When appropriate for your research, include the following items:*

* *Describe where this study will be done.*
* *Provide a time-line description of the tests/ procedures that will be done, including screening procedures. You can use tables or charts if helpful to explain the schedule.*
* *Describe each group or arm.*
* *Identify all hospitalizations, outpatient visits, and telephone or written follow-up.*
* *Indicate the length and duration of visits and procedures.*
* *Identify all unapproved drugs, devices, tests, and procedures as experimental.*
* *Identify all approved drugs, devices, tests, and procedures being used in a novel fashion as experimental.*
* *If blood will be drawn, indicate how often and the amount in English units.*
* *Identify all questionnaires or diaries by name and explain what they involve and how long and how often they will need to be completed.*
* *For research on investigational drugs or devices, list any options for the subject to get the drug/device after the research, and who will pay for this.*
* *Describe any planned future research (extension or follow-up studies, analysis of specimens). Describe whether subjects will be asked to sign a separate consent form.*
* *Indicate whether the ­­­­­­­­study treatment will be available at the end of the study.*
* *Include any follow-up procedures. Any videotaping, photography, or audio recording must be noted.*

ADD THE FOLLOWING IF APPLICABLE

***RANDOMIZATION:*** *If the research involves random assignment describe this and the probability of assignment to each group.*

*For example, edit as needed:* You will be put into a study group by chance (like a coin toss/ like drawing straws). You have a one (1) out of two (2) or 50% chance of being placed in each group. You cannot choose your study group.

***BLINDING:*** *If the research involves blinding, include language describing a single or double blind, as appropriate.*

*For example:* During the study, you *Add/edit as applicable:* and the study doctor and others doing this research will not know which group you are in. *Add/edit as applicable:* Your study doctor and others doing this research can find out in case of an emergency.

***IND & IDE:*** *For studies conducted under an IND, IDE, or abbreviated IDE, state:* [Name of the product or device] is investigational, which means that it is not approved by the Food and Drug Administration (FDA).

*If applicable, explain whether the subject will be told clinically relevant research results, and if so, under what conditions.*

***GENOME SEQUENCING:*** *Example text for research which may involve whole genome sequencing or describe in more detail later in the document:*

The study includes genome sequencing (determining the order of DNA building blocks (nucleotides) in your genetic code).

***DIAGNOSTIC GENETIC TESTING:*** *Follow guidance in this this section ONLY if there is diagnostic genetic testing in the research.*

*To comply with NY regulations, studies involving diagnostic genetic testing (e.g., any laboratory test of human DNA, chromosomes, genes, gene products, or DNA profile analysis to diagnose the presence of a genetic variation linked to a predisposition to a genetic disease or disability in the individual or the individual’s offspring), include the elements of informed consent described below.*

* *A general description of the test.*
* *A statement of the purpose of the test.*
* *A statement indicating that the individual may wish to obtain professional genetic counseling prior to signing the informed consent.*

*NOTE: Information about specific genetic test results on stored specimens cannot be disclosed to the individual or others without obtaining informed consent for the disclosure.*

* *The name of the person/ categories of persons/ organizations to whom the test results may be disclosed.*
* *A statement the only tests authorized on the specimen are performed and the specimen is destroyed at the end of the testing process or not more than sixty (60) days after the sample was collected, unless a longer period of retention is expressly authorized in the consent.*

*If the research permits such degree of specificity, include the following:*

* *A statement that a positive test result is an indication that the individual may be predisposed to or have the specific disease or condition tested for and may wish to consider further independent testing, consult their physician, or pursue genetic counseling.*
* *A general description of each specific disease or condition tested.*
* *The level of certainty that a positive test result for that disease or condition serves as a predictor of such disease.*
* *A description of the policies and procedures to protect patient confidentiality.*
* *A statement of the right to withdraw consent to use the specimen for future use at any time and the name of the organization that should be contacted to withdraw consent.*
* *A statement allowing individuals to consent to future contact for any or all purposes, including the following:*
* *research purposes*
* *provision of general information about research findings*
* *information about the test on their sample that may benefit them or their family members in relation to their choices regarding preventive or clinical care*
* *a statement explaining the benefits and risks of consenting to future contact.*

**Will you get any test results?** (Delete section if not applicable)

**For clinically validated tests**: Laboratory tests for this study will be done at a certified clinical laboratory. You may get your test results [specify when: by asking your study doctor/healthcare provider or others doing this research (or) at the end of the study (or) state the condition when results will be released].

**For research tests on specimens** (not performed in a CLIA or DOH certified lab): The results of study tests using your sample are not given to you. Results of the tests have no clear meaning for your health care.

Add if applicable, for reporting **incidental findings** (e.g., discovery of a tumor on an fMRI): If we find something of urgent medical importance to you *(describe the tests/imaging procedures)*, we will inform you or your clinician (with your permission). We expect that this will be a very rare event.

Add the following (or something similar) if **no results returned** to participants: In general, we will not give you the test results from the samples you give us. If we find something of urgent medical importance to you, we will inform you or your clinician (with your permission) although we expect that this will be a very rare event.

Add the following (or something similar) if **participants will receive aggregate results**: Once the study has been completed, we will send you a summary of all the results of the study and what they mean. We will not send you your individual results from this study.

**What will you learn from genetic test results?** (Delete section if not applicable; otherwise please edit as applicable)

Any genetic test results we return to you will first be verified in a clinical lab.

A genetic counselor or health professional who has training in genetics and counseling will explain the results to you.

[if applicable] Sometimes the meaning of results can be unclear or uncertain. It is important to understand that genetics research is changing quickly, and in many cases, we will not know for sure what the results mean for your future health.

[if applicable] Sometimes, even if you learn of a clear diagnosis, there will be no clear treatment.

[if applicable] Only certain genes will be analyzed, so we will not find all gene variants that cause disease. It may be possible that we discover you have a gene variant that is unrelated to the purpose of this study. If we believe that the information is of urgent medical importance, we will share this information with you.

**How long will you be in the study?**

*Note: If fully described in the key information section summary above, delete this section.*

**Can you leave the study after you start?**

*Always include:* Yes. You may change your mind and leave the study at any time. To withdraw from the study, please send a letter to the researchers (see name and address below) asking to leave the study:

[INSERT NAME AND ADDRESS OF PI TO RECEIVE THE NOTICE]

*Add if applicable:*

If you withdraw your permission to be in the study, you will not be allowed participate in other study-related procedures or activities.

The data collected before you withdraw from the study will still be used to maintain the integrity (truthfulness) of the data or to conduct investigations or report bad study outcomes or effects.

**Can you be removed from the study before it ends?**

*When appropriate, describe the consequences of a research participant’s decision to withdraw from a research study. Edit the following as needed:* The person in charge of this study can remove you from the study before it ends for any of the following reasons:

* You become pregnant
* We learn that the research is harmful
* Whenever it is determined that it is not in your best interest to continue
* You do not follow the instructions or adhere to the study requirements given to you
* You are not able to take medication as instructed
* You are not able to keep study appointments
* The research is cancelled by the FDA or Sponsor

**Could you be hurt or harmed in this study? (Detailed Risks)**

*Note: If risks are few and thus are fully described in the key information section summary above, delete this section.*

*Describe any foreseeable risks and/or discomforts related to the research participation, including any foreseeable risks to pregnant individuals, developing fetuses, or individuals of childbearing potential.*

*Describe the duration of the risks and discomforts. Note whether the risks and discomforts will go away when the study drug, device, or procedure is stopped.*

*Describe the side effects of any comparator drugs.*

*Describe any risks of washout, withholding treatment, or randomization.*

*Consider:*

* *Physical risks (for example, medical side effect)*
* *Psychological risks (for example, embarrassment, fear or guilt)*
* *Privacy risks (for example, disclosure of private information)*
* *Legal risks (for example, legal prosecution or being reported for child abuse)*
* *Social risks (for example, social ostracizing or discrimination)*
* *Economic risks (for example, having to pay money out-of-pocket for research or medical expenses, losing health insurance, or being unable to obtain a job)*

*It is unnecessary to list details of previous clinical trials.*

*Include for research that involves procedures whose risk profile is not well known, including all research involving an investigational product or for other greater than minimal risk studies for which the risks are currently unforeseeable:*

In addition to these risks, taking part in this study may harm you in unknown ways.

*Include for research that involves pregnant individuals or individuals of child-bearing potential and known risks to an embryo or fetus:*

*Include this section when enrolling individuals of childbearing potential, when individuals are screened for pregnancy test or when pregnant individuals are excluded or when pregnant individuals will be withdrawn from a study.*

The research study drug(s) (or indicate procedure) can harm an unborn fetus. Because of this, you should not become pregnant [If appropriate, include: or get someone pregnant] if you join this study.

Individuals who can get pregnant will have pregnancy test before enrolling and before certain procedures. If you join the study and have a positive pregnancy test, we will tell you about the test results and you will be withdrawn from the research. *Include when using this form to document parental permission and assent of a child between the ages of 13-18:*  If you are under 18, you must give your permission before we can share the results with a parent or guardian or anyone else. If you have a positive pregnancy test, we will ask you to leave the study. This means that even if we did not tell your parent or guardian, they might figure out you were pregnant. You will be referred to an adolescent healthcare provider who can discuss your options.

*Suggested wording for risk of blood draw (edit as needed):* During the blood draw, you may experience some discomfort or pain at the site where the needle enters the vein. There is small risk of bruising and a rare risk of fainting. Infection could occur; however, the person collecting your blood will use procedures to reduce the risk of an infection.

*If research involves genetic testing, add:* We have taken steps to safeguard your genetic testing information, so the risk of loss of confidentiality is small, however, if confidentiality is broken, results of genetic testing may become available to insurance carriers or employers that might use this information to discriminate against you. Someone with a known genetic condition or susceptibility to develop a disease or condition might be denied a job, promotion, or health or life insurance, because they are regarded as a health risk and therefore an economic risk. Carriers for a genetic disorder might be discriminated against and viewed as having the potential to have a child with a genetic condition. There is a federal law called the Genetic Information Nondiscrimination Act (GINA) that, in general, makes it illegal for health insurance companies, group health plans, and most employers (except those with less than 15 employees) to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

*Share any risk related to the plans for sharing data or specimens:* When we share your data and samples, there is a small risk that people may get access to it who are not supposed to. We will protect your data and samples as much as possible during storage and when they are shared. However, there is a small chance your identity could be shared with others.

***What should you do if you are injured being in this research?***

*Always include the following for research involving more than minimal risk or involving an intervention in medical care. Otherwise delete this section.*

For medical emergencies, call 911. If you are injured or get sick because of being in this study, call the study doctors immediately. The study doctor/healthcare provider will explain treatment options and tell you where to get treatment.

***Who will pay for your medical care if being in this research harms you?***

*Always include this section for research involving more than minimal risk or research involving an intervention in medical care.*

For non-sponsored or federally funded studies, include the following: SUNY Downstate <and Kings County, or other sites > makes <or make> no commitment to provide free medical care or payment for any bad or damaging results from participating in the study. Medical services will be billed at the usual charge and will be your responsibility or that of your third-party payer, but you are not stopped for seeking financial compensation for injury related to malpractice, fault, or blame on the part of those involved in the research study.

Include for sponsored studies:

The Sponsor of this study will pay for the direct and necessary costs of medical care related to injury from the study if injury is directly related to the study drug or device or study procedure. The sponsor is not offering to pay for any such costs that arise from a pre-existing condition, negligence or misconduct by you or that of the study personnel, or failure by the study personnel to follow the protocol or instructions. By accepting medical care or payment for medical expenses, you are not giving up any of your legal rights.

**Will you be updated about new study information?**

We will inform you in a timely manner of any significant new information that may affect you. Such information may help you decide if you want to stay in the study.

The researchers will also share any new information with you if it may affect your decision or ability to stay in the study.

**What other choices do you have besides participating in this study?**

*Note: If fully described in the key information section summary above, delete this section. If there are none, do not include this this section OR state:*

You may choose not to participate in this study. There are no alternatives to this study at this site. *If applicable:* There are no proven treatments for people with your disease.

*If alternatives are available, provide a disclosure of appropriate alternative procedures or courses of treatment that might be advantageous to the research participant. This allows the potential participant to understand how the research differs from the care they might otherwise receive.*

There are other choices such as *<describe alternatives such as: other clinical trials, appropriate medically recognized standard of care alternatives to a clinical trial, including any standard of care or “off label use of drug, approved by the Pharmacy, or other alternatives such as seeking clinical trials at other sites, seeking extra credit that can be earned by a student instead of becoming a research participant.*>. You do not have to agree to participate in this study to get <treatment outside of this study / hospice, palliative and/or comfort care / extra credit / benefits to which you are entitled / >.

**What costs are you responsible for paying in this study?**

If there are no foreseeable costs: It does not cost anything to be in the study.

When applicable, include a discussion on transportation costs or loss of income for taking time off from work to be in a study.

Include if *sponsor is paying for research activities:* The tests or procedures in this study are not part of your standard care and will be covered by the sponsor of this study.

*When a drug, device or assay is provided by a sponsor or company:* [Company Name] the manufacturer of [study drug, device, or assay] being used in this study is providing [study drug, device, or assay] at no cost [or at cost] to the researchers [or research participant].

Include if participant will be paying for standard of care medical expenses: The tests or procedures that would be provided to any patient with your condition, regardless of whether he/she was participating in the study, are considered standard care and will be billed to you or your private or public health insurance company. You will still be responsible for the cost of your usual ongoing medical care, including deductibles and co-payments. If you have any questions about what expenses are the responsibility of you or your health insurance provider, please contact a member of the study staff and/or your health insurance provider.

Include for a device study where the study device and procedures will be paid by the participant and insurance companies. Modify the language to match the actual billing requirements for study. Your private or public health insurance company (for example Medicare) will be billed for the study device, the procedure to implant the device, and any other necessary procedures required by the study. You will be responsible for paying for any co-payment, co-insurance or deductible.

If applicable, add: You may request professional genetic counseling. You may have to pay for those additional services.

If applicable, add: You or your insurance pay for the cost of clinical laboratory tests.

Add if applicable (edit as needed): Your doctor may request additional testing if this is needed for your care, and it will be billed to you or your insurance.

**Will you receive anything for being in this study?**

*If there are no gifts, rewards, compensation, or reimbursement, either delete this section or add:*

You will NOT be paid for taking part in this study.

*Note that if participants’ biospecimens may be used for commercial profit, this section cannot be deleted (see last sentence in this section, below.)*

*Include when applicable:* You will NOT receive any compensation for discoveries, patents or products developed from this research.

*Describe any gifts, rewards, compensation (payment), or reimbursement (e.g., in terms of expense, such as travel or inconvenience) provided.*

For taking part in this study, you may be paid up to a total of $\_\_\_\_\_. Your compensation will be broken down as follows:

*Describe payment schedule in terms of each activity and amount*

*Describe when payments will be made*

*Describe the amount of payment if the participant drops out*

*Investigators must obtain the* [*“SUNY RF Payment Consent”*](http://research.downstate.edu/irb/irb-electronic-submissions.html) *addendum form, when providing research participants RF payment(s) of either 1) $600 or more per calendar year OR 2) more than $100 per study visit.*

*Note: SUNY RF treats travel reimbursement as compensation to research participants and is included in the calculation of thresholds noted above. Receipts are not necessary because the RF treats all travel reimbursement as compensation.*

*If desired, submit a* [*“SUNY RF Payment Consent Waiver”*](http://research.downstate.edu/irb/irb-electronic-submissions.html) *to the* [*RF Operations Manager*](mailto:Joseph.Barabino@downstate.edu) *to request an exception for the use of the “SUNY RF Payment Consent” when all of the following are true: 1) total payments are less than $600 per calendar year, AND 2) giving indirect payments (e.g., cash funds, gift card, pre-paid cards), AND 3) giving more than a $100 per study visit. Submit the approved form with the IRB Application in lieu of the SUNY RF Payment Consent.*

*When the SUNY RF Payment Consent addendum is used, include the following:* The researchers will ask you to complete a SUNY RF Payment Consent form to receive payment(s) for participating in this study. See attached form for additional information.

*For payments made through NYC HH, Kings County, include the following language in this consent:*

You will receive compensation as part of your participation in this research study.  If you receive $600.00 or more per calendar year in income for any reason from NYC Health + Hospital, Kings County, they must report it to the Internal Revenue Service (IRS) and issue an IRS form 1099.   In order to receive reimbursement, you must supply the appropriate Social Security number for IRS reporting.

*Federal regulations require adding a statement that the research participant’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the research participant will or will not share in this commercial profit. An example is provided below and may be edited as needed:*

Your samples may be used for a commercial profit. You will not receive any of the profits.

**Do the researchers have any conflicts of interests that may affect your willingness to participate in the research?**

Disclose any *significant financial interests (SFI)*. Suggested text is provided below based on the situations described. Edit as needed. The IRB will consult with the Conflict-of-Interest Committee to approve or make additional edits as needed.

Always identify sponsor and salaries supported under funds: The National Institutes of Health [or list other sponsor or foundation] provide funding to conduct this study. Some of the funding pays part of the salary for [list all investigators as applicable to the funding].

When an investigator has stock in a company: Dr \_\_\_\_\_\_\_\_\_ owns stock in a company that is (performing research/marketing a product) in the same area as this study.

When an investigator owns a company: Dr. \_\_\_\_\_\_\_\_\_ is the researcher running this study and is a [founder and] co-owner of \_\_\_\_\_\_\_\_\_.  This company may develop a commercial product using data from this research. Because Dr. \_\_\_\_\_\_\_ has an investment in the company, the amount of money the investment is worth might be affected by the results of this study. This means that Dr. \_\_\_\_\_\_\_\_ could gain or lose money depending on the results of this study.

When an investigator is named on a biomedical patent or otherwise has proprietary rights or interests in any medical therapy, drug, device, or method used, tested or studies in this research protocol: Dr \_\_\_\_\_\_\_ has developed \_\_\_\_\_\_ which is a (therapy/drug/device/method) that is (used/tested/studied) in this research protocol. Dr. \_\_\_\_\_\_\_\_\_\_\_\_ has a personal financial interest in this (therapy/drug/device/method). Dr. \_\_\_\_\_\_\_ and SUNY Downstate may benefit financially if this (therapy/drug/device/method) does what they hope it will do.

When an investigator received an honoraria or travel reimbursement: Dr. \_\_\_\_\_\_\_\_\_ has received an honorarium (payment for professional services such as consulting or advising) [or travel reimbursement] during the past 12 months from the study sponsor.

Add when applicable: Research participants will not receive any payment or rights for discoveries, patents or products that may be developed from this research.

Always include: Dr. \_\_\_\_\_\_\_ does not participate in the enrollment or informed consent process for this study.

We provide this information in case it affects your willingness to participate in the study. Please ask the researchers or the study coordinator if more information is needed.

*Include if applicable for genomic research involving children and edit as needed:*

**How will researchers protect and share your information and specimens?**

Note: Remove the word “specimen(s) from header and text below if there are no specimens in the research.

We will protect the confidentiality of your information to the extent possible. The researchers will keep information about you in a secure location with limited access. If the results of this study are made public, information that identifies you will not be used.

When data or specimens are stored for future research, add, and edit as needed: This study is collecting data and specimens from you. We would like to make your data and specimens 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 aspects of health. These studies may be done by researchers at other institutions, including commercial entities. Our goal is to make more research possible to learn about health and disease. Your data and specimens will be stored [indicate the name of the institution where they will be stored, including any biobanks to be utilized]. We plan to keep your data and specimens for [indicate time frame (no more than 10 years for DNA samples) or “indefinitely,” or until “used completely,” etc.]. Your data and specimens may be shared with investigators around the world. However, access to the data and specimens is controlled by [indicate which entity has control]. To use your data and specimens, researchers must get approval and cannot try to identify you.

*0ne of the next 4 options is required when the research is federally funded/supported OR when the HIPAA regulations do NOT apply (e.g., PHI is not used or disclosed); otherwise delete this section.*

**OPTION 1** (INCLUDE THE SECTION AT END OF CONSENT TO REQUEST SHARING OF SPECIMENS IN THE FUTURE; OTHERWISE USE OPTION 2, 3, or 4 BELOW):

Your data and specimens will have a code that links to your identifying information. The code key will be kept in a locked location separate from your information. The code key can only be accessed by people who have permission*.* There is a section at the end of this form to ask your permission now to use or share your information and specimens for future research studies or distributed to another investigator for future research without additional future consent.  If you agree now, your name or other identifying information will not be on any data or specimens we share with others for future research.

**OPTION 2:** We will not use or share your identifiable information and identifiable specimens collected for this research study for any future research studies, even after your identifiers are removed.

**OPTION 3:** Use this, if the data and biospecimens are completely delinked from identifiers and cannot be linked back to the participant: Your name and identifying information will not be on any data and specimens you provide. Investigators cannot link your identifying information to the data and specimens.

**OPTION 4:** Use this when sharing of data and/or biospecimens will not be optional (e.g., for studies where sharing is integral to the purpose of the study, such as a data or specimen repository): Participating in this study means you agree to share your data and specimens. You can change your mind later, but researchers may still use your data and specimens that have already been shared. If you do not want your data and specimens used for other projects, you should not participate in this study.

**What Protected Health Information will be used or disclosed?**

Federal law protects your right to privacy concerning Protected Health Information (PHI). There are certain things you need to know. PHI is any information from your medical record or obtained from the study linked to you and that refers to your mental or health conditions in the past, the present or the future.

Include the name or identification of the person(s) or class of person(s) who will use or disclose the PHI. List all entities (including external sites to be approved by the Downstate IRB) that access the research participants’ health information.

By signing this form, you give permission to the researchers approved on this study at SUNY Downstate, University Hospital Brooklyn, University Physicians of Brooklyn, Inc, NYC Health +Hospitals/Kings County, <list other hospitals, practice groups, or institutions or individuals on this study, etc.> to use or disclose (release) your Health Informationthat identifies you for the research described within this form.

*Add an expiration date or event (this must be a certain date, or an event tied to the individual).* *For example, a statement that the authorization will expire on a specific date, after a specific amount of time, or upon occurrence of some event related to the research participant. (e.g., “until the completion of the research”) – be sure this expiration matches any other expiration dates or events described elsewhere in this form. NOTE: Be sure to include the time-period for any storage of information for the creation and maintenance of a research database or research repository or future research. This may be included in other relevant sections of the consent form. Example provided below.*

This authorization is valid on the date the form is signed until the research is complete (or enter date or event).

*Provide a specific and meaningful description of the PHI to be used or disclosed. Example provided below.*

*Note: The minimum necessary rule does not apply to Authorizations; however, Downstate encourages the investigators to limit the PHI to the minimal necessary PHI that is reasonably necessary to accomplish the purpose of the research.*

The Protected Health Information that we may create, use, report, or disclose (release) for this research includes:

* Health information collected during the research (delete if N/A)
* Medical records (delete if N/A)
* Results of physical examinations (delete if N/A)
* Medical history (delete if N/A)
* Laboratory tests (delete if N/A)
* X-rays, MRI, CT or other imaging tests (delete if N/A)
* Diagnostic medical procedures *(delete if N/A)*
* Psychological tests (delete if N/A)
* Information related to (name of particular condition) (delete if N/A)
* Communicable diseases (including HIV and AIDS) (delete if N/A)
* Alcohol/drug abuse treatment (delete if N/A)
* Mental health records (delete if N/A)
* All treatment records (delete if N/A)
* (describe other Health Information in a specific meaningful manner or delete if N/A)

*Add if collecting e-mail address during the research, including at the end of this form, prior to signature lines:*

The researchers will not use unsecure e-mail for any research communications involving PHI unless you specifically authorize us to do so.

*Provide a description of each purpose for which the PHI is to be used or disclosed. Example provided below (edit purposes as needed):*

This information will be used and/or given to others to:

* Do the research,
* To do clinical testing,
* To study the results, and
* To see if the research was done right.

*Include the name or identification of the person(s) or class of person(s) authorized to make the use or disclosure of PHI. For example, who will disclose the PHI? (e.g., UHB, NYC H+H, Kings County, other hospitals, practice groups, etc.). Include ALL names or other identification of ALL classes of persons who will have access to the health information, including those who are outside of Downstate. It is recommended that the classes of persons (e.g., researchers, administrators, etc.) be listed rather than names of these individuals, to make future amendments easier).*

The Protected Health Information listed above may be used by and/or disclosed (released) to:

* The Institutional Review Board(s) (IRB) that have oversight of this research.
* The researchers and their staff approved by the IRB.
* Collaborating research sites, outside laboratories, cooperative study groups, or contracted research organizations that are approved by the Institutional Review Board
* The SUNY Downstate and NYC Health +Hospitals/Kings County officials and other administrative staff who supervise the way research is done, such as auditors or monitors.
* The sponsor(s) of this study, including monitors and auditors. *(include if the monitors need access to health information or if the sponsor will own the research data, or when the trial follows GCP standards.*
* The Federal agencies that supervise the way research is conducted, such as the Department of Health and Human Services Office for Human Research Protections, the Food and Drug Administration*,* the National Institutes of Health or other government agencies.
* Data Coordinating Center(s). *(delete if N/A)*
* The Data Safety Monitoring Board that reviews the safety of this study. *(delete if N/A)*
* Your insurance companies. (*delete if N/A)*

*Always include:*

You may change your mind and revoke (take back) this authorization in writing at any time. To withdraw, please write to *(complete name and address of the PI or other person to receive the notice of withdrawal)*. Your Protected Health Information collected before you withdraw your authorization will still be used and reported to the extent that those noted above have taken action in reliance of this authorization, including as necessary to maintain the integrity of the research or to conduct investigations or to report adverse events (bad effects).

*Add if applicable:* If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

*Always Include a statement that treatment, payment, enrollment, or eligibility for benefits may not be conditioned on obtaining the authorization if such conditioning is prohibited by the Privacy Rule or, if conditioning is permitted, a statement about the consequences of refusing to sign the authorization. Note: The PI may condition healthcare on the provision of the authorization for research related treatment (e.g., clinical trial), in which case the provider may refuse to provide the research related healthcare if the research participant refuses to execute the authorization. Example provided below. This statement is required under the HIPAA regulations. Example provided below:*

You have a right to refuse to sign this form. If you do not sign this form, there will be no effect on your health care treatment, your enrollment for benefits, your payment for the health care outside of the study, or your health care benefits are not affected. However, you will not be able to participate in the research described in this consent form if you do not sign this form.

*When the research, for which the use or disclosure is made, involves a treatment add the following, if applicable:* To maintain the integrity of this research study, you generally will not have access to your personal health information related to this research until the study is complete. At the conclusion of the research and at your request, you generally will have access to your health information that [Downstate <add names of other institution(s)>] maintains in a designated record set, which means a set of data that includes medical information or billing records used in whole or in part by your doctors or other health care providers at [Downstate <add names of other institution(s)>] to make decisions about individuals. Access to your health information in a designated record set is described in the Notice of Privacy Practices provided to you by [Downstate <add names of other institution(s)>]. If it is necessary for your care, your health information will be provided to you or your physician.

*Add if applicable:*

The researchers cannot share with you some of the Protected Health Information obtained in this study during the research; however, it can be shared at the end of the study. This includes (information about which study arm you are participating in, etc.).

*Add if applicable:*

You have the right to get your patient information in your healthcare record. Test results from a certified clinical laboratory may be provided to you.

*Add/edit/delete as applicable when the study involves the use of video recording /voice recordings / photographs:*

The researchers will obtain video recording /voice recordings / photographs of you for research purposes. Only the research staff approved to be on this study may have access to these materials. These materials will be stored in a locked cabinet and used only for the research. The researchers will keep these materials only for as long as needed for this research. These materials will be (SELECT OR EDIT) destroyed after the required retention period has ended after the study is complete / stored for archival purposes and used only for the purposes approved by the Institutional Review Board / will be destroyed after the recording is transcribed.

If photographs of the face are taken, include the option for publication of face photos at the end of the consent form, if applicable to the study.

*Always include a statement about the potential for the PHI to be re-disclosed by the research team (e.g., to another organization) and no longer protected by the Privacy Rule. Example provided below:*

You need to know that some of the individuals or groups mentioned above who may receive your health information may not be required by federal privacy laws to protect your PHI. They may share your information with others without your permission if permitted by the laws governing them. *Add example, if applicable:* For example, the sponsor *(only if applicable, name the sponsor, the CRO, the DSMB, etc.)* does not have the same obligations as your research team and may no longer protect your PHI.

*If the grant/contract between the sponsor and the Research Foundation establishes continuing protections for the disclosed information, you may add such a statement here.*

*Include the following bullets when applicable to the research:*

The research team may share your Protected Health Information as required by law, for example, to:

* Comply with a court ordered subpoena, ***[CAUTION: remove this bullet if there is a Certificate of Confidentiality (CoC) for this study, including any NIH funded studies which automatically have a CoC. CoC is described in next section.]***
* Report suspected child abuse or neglect,
* Report certain communicable diseases,
* Report a possible threat or harm to yourself or others, or
* Comply with other laws.

*Include if applicable to the research:*

If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

*Note: Unless waived by the IRB, when PHI is involved in a study, the individual’s signature and date, and if signed by a personal representative, a description of his or her authority to act for the individual (e.g., required when recruiting children or cognitively impaired adults). See signature lines at the end of the form.*

*Add the following when recruiting patients into a clinical trial involving an IND or IDE* ***OR*** *any research involving an NIH Certificate of Confidentiality:*

The researchers will file a copy of this consent in your medical record. The researchers will place a note in your medical record to let other healthcare providers know that you are participating in a clinical trial.

*Recommend (not require) including the following paragraph when researching HIV-related information as it may help ensure compliance with NY State regulations (NY PHL Section 2782(5)(a); NY PHL Section 2781(2)(e), 10 NYCRR 63.3(b)(5), 14 NYCRR 505.6(a)(ii)):*

Recipients of HIV-related information may not re-disclose your HIV-related information without your authorization unless permitted to do so under federal or state law.  You have a right to request a list of people who may receive or use your HIV-related information without authorization, as well as a list of any disclosures made pursuant to this research authorization.  For more information about HIV confidentiality, call the New York State Department of Health HIV Confidentiality Hotline at 1-800-962-5065; for more information regarding federal privacy protection, call the Office for Civil Rights at 1-800-368-1019. You may also contact the NYS Division of Human Rights at 1-888-392-3644.

*There are additional requirements for authorizations for using PHI for marketing purposes, sale of PHI, or for the use or disclosure of psychotherapy notes. Contact the IRB or Privacy Officer for additional information or refer to* [*http://www.downstate.edu/hipaa/hipaa\_policies.html*](http://www.downstate.edu/hipaa/hipaa_policies.html)

*Based upon Downstate policy* [*https://www.downstate.edu/hipaa/documents/hipaa-37-privacy-of-psychotherapy-notes-2018.pdf*](https://www.downstate.edu/hipaa/documents/hipaa-37-privacy-of-psychotherapy-notes-2018.pdf) *psychotherapy notes are defined as notes made by a mental health professional that document or analyze the contents of a conversation during a private counseling session. These notes are considered to be inappropriate for inclusion in the medical record, are intended to enable the mental health professional to recall the therapy discussion and are of little use to others not involved in the therapy. These notes are kept separate from the rest of the patient’s record. If an EMR is utilized, these notes are entered into a separate section that is not considered part of the designated record set. In contrast, behavioral medicine clinical notes (such as med prescribing/ monitoring, counseling session start & stop times, modalities/ frequency of treatment, results of clinical tests, other mental health info typically needed for treatment) are NOT considered ‘psychotherapy notes’ under HIPAA and would not require separate authorization.*

**Certificate of Confidentiality:**

Include for NIH funded study or when a Certificate of Confidentiality (CoC) covers non-NIH funded studies.For more information on CoCs and their limitations, see the NIH CoC [FAQs](https://humansubjects.nih.gov/coc/faqs) on this topic or <http://grants.nih.gov/grants/policy/coc/>

NOTE: The CoC is automatically granted for all NIH funded research. There is no need to apply for a CoC when the NIH funds the research. If the study is not NIH funded and a CoC is needed, the study team must apply for the CoC with the NIH.

This study 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.

IMPORTANT REMINDER TO STUDY TEAM (DELETE THIS NOTE): A copy of the signed informed consent document which includes the CoC disclosure language must be filed in the medical record to prevent unintentional disclosure by Health Information Management (HIM) pursuant to a request that does not require patient authorization (e.g., court subpoena).

**What information about this study is available to the public?**

*Include the following statement verbatim for an “Applicable Clinical Trial”, as defined by FDA Amendments Act of 2007 (FDAAA), otherwise delete this section.*

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 website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Always include specifically for genomic testing with children; edit as applicable for other types of studies with children.

**What will happen when your child becomes an adult?**

As a part of the study, your child's samples, genomic data, and health information will be stored and used for future research. When your child reaches age 18, we will try to contact him or her to ask whether he or she wants to continue to participate in research. If we cannot find your child, we will remove identifying information, and continue to include his or her samples, genomic data, and health information in research.

*Clarify other types of research activities will stop when a child reaches age 18 if consent is not obtained once the child becomes an adult. (e.g., use of identifiable data, follow-up interactions/interventions, review of medical records etc.).*

We may learn information relevant to your child's or your family's health. For example, if [tailor example based on the plans for returning results]. If this happens, we will tell you only information directly related to diseases and disorders that affect your child. Your child can request additional information when he or she is 18.

**Who can you talk to about the research?**

Contact the researcher listed on the first page if you have questions, concerns, complaints, or get hurt.

The SUNY Downstate Health Sciences University (Downstate) Institutional Review Board & Privacy Board (IRB) oversees this research. You may send an encrypted (secured) e-mail to the IRB at [irb@downstate.edu](mailto:irb@downstate.edu) or you may call (718) 613-8480 to speak to someone in the IRB for any reason, such as:

* You have questions about your rights.
* 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 want to get more information.
* You want to provide your input about this research.

**----------------------------------------------------------------------------------------------------------------------**

**OPTIONAL RESEARCH:**

*Add one or more of any of the following sections, when applicable to the research:*

We are asking your permission to participate in some optional activities below. Your decision will not affect your participation in the current study.

*You must include the box below when the research involves diagnostic genetic testing.*

|  |  |
| --- | --- |
| **May we contact you in the future to share information related to diagnostic genetic testing or to obtain more related information about you?**  We need your permission to contact you to explain the results of diagnostic genetic tests or to obtain more related information from you. We will not disclose the results of the genetic tests to anyone without first obtaining your written consent. | |
| **Initial next to your choice below:** | |
| *\_\_\_\_\_ (initials)* | YES, you may contact me in the future to share information related to diagnostic genetic testing or to obtain more related information about me. |
| *\_\_\_\_\_ (initials)* | NO, do not contact be in the future to share information related to diagnostic genetic testing or to obtain more related information about me. |

*Add for data and sample storage through data repositories and biobanks and edit as applicable:*

**REMINDER: The section below is REQUIRED when Option 1 is selected from “How will researchers protect and share your information and specimens?”**

|  |  |  |
| --- | --- | --- |
| **May we share your de-identified information (and de-identified specimens) for future research?**   * It is your choice whether to let researchers share your data and specimens for research in the future. If you say “yes,” you can change your mind later, but your data and specimens might still be used if they have already been shared. If you say “no,” you can still fully participate in this study. * Adjust language as applicable to the study to describe what will happen if the participant changes their mind about storage and sharing: You can change your mind about sharing your data and specimens at any time. If you change your mind, please contact the study team to let us know not to share your data and specimens going forward. We will do our best to retrieve all your data and biospecimens that have already been shared, but it may not be possible. For example, if some research with your data and specimens has already been done, the information from that research may still be used. We will not know which data and specimens are yours if the identifying information was removed. Also, if the data and specimens have been shared already with other researchers, it might not be possible to get them back. * Researchers will remove information from your materials that can identify you so that other researchers doing future research will not know about you. Such materials may include: <describe> * Future research may include: <adequately describe indication(s)/purpose(s) so that it would be reasonable for the research participant to expect that his/her materials could be used or disclosed for such future research> * *Add if retaining DNA samples:*  DNA samples will be maintained for as long as they are useful for research purposes but not past 10 years*,* after which time the DNA will be destroyed. *NOTE: Modify as needed. New York State law requires the retention period be explicit in the consent and prohibits retaining DNA samples (not the data) past a period of ten (10) years.* | | |
| **Initial next to your choice below:** | |
| *\_\_\_\_\_ (initials)* | YES, use my data and specimens in other research studies. |
| *\_\_\_\_\_ (initials)* | NO, do not use my data and specimens in other research studies. |

The following is optional, but recommended for future contact for other studies:

|  |  |
| --- | --- |
| **May we contact you to invite you to consider other research studies?**   * Your decision will not affect your participation in the current study. * The study team may contact you to see if you are interested in other studies. | |
| **Initial next to your choice below:** | | |
| *\_\_\_\_\_ (initials)* | YES, you may contact me to invite me to consider other research studies. | |
| *\_\_\_\_\_ (initials)* | NO, do not contact me to invite me to consider other research studies. | |

*(DELETE IF THIS STUDY DOES NOT INCLUDE GENOMICS RESEARCH) nih suggested language for genomics research THIS SECTION MUST BE COMPATABLE WITH any CERTIFICATation PROVIDED TO NIH*

*For more information see:* [*https://www.genome.gov/about-genomics/policy-issues/Informed-Consent-for-Genomics-Research/Special-Considerations-for-Genome-Research*](https://www.genome.gov/about-genomics/policy-issues/Informed-Consent-for-Genomics-Research/Special-Considerations-for-Genome-Research)

|  |  |
| --- | --- |
| **May the researchers store and share your samples, genomic data, and health information with other researchers?**  The samples 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. Your decision will not affect your participation in the current study.  If you agree, portions of your samples, genomic data, and health information will be stored for an unlimited period of time to be used in future research.  [If appropriate] As part of this project, your samples will be used to create cell lines that will keep reproducing and can be used for many purposes. We will store the cell lines and other samples and data in a "cell bank," so that other researchers and companies can apply to use the cell lines in their own research. The cell bank will only release cell lines to researchers and others under certain conditions.  You should also know the following:   * It may be possible that your identity can be learned, even though your name will not be connected to the data, and even though the data will be well-protected. Confidentiality cannot be guaranteed, and re-identified data could potentially be used to discriminate against you or stigmatize you or your family or groups. There may be unknown risks to you if you are identified. * You will not receive any direct benefits from any research on de-identified samples or data. * The Certificate of Confidentiality do not apply for the protection of the summary results for the larger group of participants.   [Specify the terms of release established by the repositories, such as IRB approval or approval by a governance committee.]  Unrestricted access databases: The information from this study will be freely available in a public, unrestricted database that anyone can use. [For example], the public database will include information on hundreds of thousands of genetic variations in your DNA code, as well as your ethnic group, gender identity, sex assigned at birth. The only health information included will be whether you had [disease X] or not. This public information will not be labeled with your name or other information that could be used to easily 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.  Controlled access databases: Your individual genomic data and health information will be put in a controlled-access database. This means that only researchers who apply for and get permission to use the information for a specific research project will be able to access the information. Your genomic data and health information will not be labeled with your name or other information that could be used to identify you. Researchers approved to access information in the database will agree not to attempt to identify you.  [For Genomic Summary Results (GSR) under unrestricted access]: Although researchers will not be able to access information specific to you without permission, it will be generally possible to access some summary-level information about all the participants included in a dataset (including you), or across multiple datasets, without applying for permission. This information may be shared through the scientific literature or through other public scientific resources, such as data repositories that provide unrestricted access to the information. Some examples of information that may be shared includes how different genes are associated with different traits or diseases across the many participants in a dataset, or how often certain gene changes are seen across participants from many studies. The risk of anyone identifying you with this information is very low.  [For 'Sensitive' GSR under controlled-access]: Although researchers will not be able to access information specific to you without permission, some summary-level information about all the participants included in a dataset (including you) may be shared through the scientific literature. Some examples of information that may be shared includes how different genes are associated with different traits or diseases across the many participants in a dataset, or how often certain gene changes are seen across participants. The risk of anyone identifying you with this information is very low. | |
| **Initial next to your choice below:** | |
| *\_\_\_\_\_ (initials)* YES.  *\_\_\_\_\_ (initials)* NO. | May we collect your specimens, health information, and genomic information to study [state specific research project]? |
| *\_\_\_\_\_ (initials)* YES.  *\_\_\_\_\_ (initials)* NO. | May we share your specimens, health information, and genomic information with other researchers to study [state specific disease or disorder]? |
| *\_\_\_\_\_ (initials)* YES.  *\_\_\_\_\_ (initials)* NO. | May we share your specimens, genomic data, and health information with other researchers for future research projects related to other topics? |
| **Researchers might want to ask you to participate in additional studies. In some cases, you might be a particularly good candidate for a particular study because of your health history or genomic information. Initial next to your choice below:** | |
| *\_\_\_\_\_ (initials)* YES.  *\_\_\_\_\_ (initials)* NO. | May we contact you in the future to get your permission to use your samples, health information, and genomic information for additional studies? |
| *\_\_\_\_\_ (initials)* YES.  *\_\_\_\_\_ (initials)* NO. | May we contact you in the future to ask your permission for additional samples or follow-up information about your health or medical care? |

*Optional:*

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| **Do you authorize the release of your medical information from another provider for use with this research?**  Your authorization allows researchers to share a copy of this consent with your outside healthcare provider. The researchers may need to re-contact you or your personal representative for additional authorization. | |
| **Initial next to your choice below:** | |
| *\_\_\_\_\_ (initials)* | YES. Indicate the names of the providers you authorize the release of your medical information to us:  Provider Name: Provider Telephone:  Provider Name: Provider Telephone:  Provider Name: Provider Telephone: |
| *\_\_\_\_\_ (initials)* | NO. |

**Does this research provide education about HIV/AIDS or require consent for HIV testing?**

*Edit as applicable, when obtaining consent for HIV testing for research purposes or use an alternative approach (e.g., documented oral consent, or general medical consent) that meets the requirements of NYS Public Health Law, Article 27F. For additional information, please see:* [*https://www1.nyc.gov/site/doh/providers/health-topics/aids-hiv-obtaining-patient-consent.page*](https://www1.nyc.gov/site/doh/providers/health-topics/aids-hiv-obtaining-patient-consent.page)

The researchers provide HIV/AIDS related information on testing, transmission, treatment, and safety and are asking for your permission to test you for HIV.

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| **Consent for HIV testing:**  I have been given information regarding HIV testing, how HIV can be transmitted, that there is treatment for HIV/AIDS, how to keep myself and others safe from HIV infection, that testing is voluntary and can be done anonymously, how my HIV-related information will be kept confidential and what laws protect people with HIV/AIDS discrimination. I understand the results will be documented in my medical chart.  I may revoke (take back) my consent orally or in writing at any time. As long as this consent is in force, Downstate (and/or NYC Health + Hospital, Kings County, or provide name of other facility where the research takes place) may conduct additional tests on me without asking me to sign another consent form. In those cases, my provider will tell me if other HIV tests will be performed and will make a note in my medical record. | |
| **Initial next to your choice below:** | |
| *\_\_\_\_\_ (initials)* | YES. Consent for HIV-related testing remains in effect until I revoke it, or until the following date: \_\_/\_\_/\_\_. |
| *\_\_\_\_\_ (initials)* | NO. I do not want an HIV test. |

Include the following if the study includes participants who lack the capacity to consent, but are capable of designating a surrogate:

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| --- |
| **Designated Consent:**  [If the study includes participants who lack the capacity to consent but can designate a surrogate]  I designate \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (OR a previously designated legal guardian/named power of attorney) to make decisions about my participation in this research project.  [If participants are at high risk of losing capacity to consent]  If my [e.g., dementia, illness, etc.] progresses to the point that I cannot answer questions about whether to participate in the study:  You may continue to use the samples and data you have already collected from me:  *\_\_\_\_\_ (initials)* YES  *\_\_\_\_\_ (initials)* NO  You may collect new samples or data from me, just as described in this consent form:  *\_\_\_\_\_ (initials)* YES  *\_\_\_\_\_ (initials)* NO  I designate \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (OR a previously designated legal guardian/named power of attorney) to make decisions about my participation, consistent with what I have agreed to here. |

Add the following (or something similar) if participants have option to receive individual results, edit as needed:

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| **As they become available, do you want us to contact you and ask whether you want to receive your genetic results?** | |
| *\_\_\_\_\_ (initials)* | YES. I want to receive my genetic test results.  Initial below to indicate what type(s) of results would you like to receive:  \_\_\_\_\_ (initials) Results about genetic risks that might affect your future health, even if you cannot do anything about it.  *\_\_\_\_\_ (initials)* Results about genetic risks that you can do something about, like start a new medication or have preventive screening.  *\_\_\_\_\_ (initials)* Results that might be important to your family members or for your plans to have future children (if relevant).  *\_\_\_\_\_ (initials)* All genetic test results, including any of the above. |
| *\_\_\_\_\_ (initials)* | NO. I do not want to receive my genetic test results. |

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| **Do you want to be contacted by other researchers with results from studies using your samples, genomic data, and health information?** | |
| *\_\_\_\_\_ (initials)* | YES. |
| *\_\_\_\_\_ (initials)* | NO. |

Include the following if the study includes photographs of the face:

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| **Can the researchers publish photographs of your face in a publication or poster that describes the results of the research?**  The researchers would like to publish the photographs of a few (not all) of the participants in this study.  With your authorization, the researchers may publish your photographs including a full-face image (with or without censoring your eyes) in a medical journal or a poster at a scientific meeting.  Your decision will not affect your participation in the current study. If you choose no, you may still participate, and the researcher will not use your photograph in any publication or poster. | |
| **Initial next to your choice below:** | |
| *\_\_\_\_\_ (initials)* | **YES.** It is OK to use my photographs (including a **full-face image with my eyes uncensored**) in a medical journal or a poster at a scientific meeting. |
| *\_\_\_\_\_ (initials)* | **YES**. It is OK to use my photographs in a medical journal or a poster at a scientific meeting **BUT I would like my eyes censored.** |
| *\_\_\_\_\_ (initials)* | **NO**. Do NOT use my photographs (including a full-face image with my eyes censored or uncensored) in a medical journal or a poster at a scientific meeting. |

**Signatures:**

***Instructions: Use only the required boxes based on the research and delete all others.***

1. ***Lines should be added for the Names (no signature nor date) for the following individuals, when applicable for the research:***
   1. ***Child under 13.***
   2. ***Cognitively impaired adult.***
2. ***Lines should be added for the Names, Signatures, and Dates, as indicated below, when applicable for the research:***
   1. ***Child providing assent.*** *In general, add to consent for assent ages 13-17; otherwise, use an assent document for ages 7-12.*
   2. ***Parent or Legal Guardian.*** *Required when enrolling a child, under the age of 18.*
   3. ***2nd Parent or Legal Guardian (if applicable).*** *Required for category 406 & 407 research.*
   4. ***Emancipated Minor.*** *An emancipated minor is defined as either a person who is 16 years or older and living independently from his/ her parents or a minor who is a parent him/herself.*
   5. ***Married Minor.***
   6. ***Independent Consent Monitor****. Required when enrolling an Emancipated Minor [when the research does not involve a clinical treatment (e.g., "survey" on HIV or STD) for an emancipated minor], Married Minor, or a Ward. An Independent Consent Monitor may not be a member of the research team.*
   7. ***Adult Research Participant.*** *For adults who are 18 years of age or older*
   8. ***Personal Representative (Legally Authorized Representative).*** *Required when obtaining surrogate consent for enrolling adults who are cognitively impaired.*
   9. ***Interpreter.*** *Required when there are plans to enroll participants with individuals who have Limited English Proficiency or communicate with sign language.*
   10. ***Witness.*** 
       1. *Required for the following situations:*
          1. *When obtaining consent/permission from research participants, parents/guardians, or personal representatives with Limited English Proficiency.*
          2. *When obtaining consent/permission from research participants, parents/guardians, or personal who understand English, but cannot read English.*
          3. *When obtaining permission from the personal representative of a cognitively impaired adult.*
       2. *A witness is recommended (not required) for clinical trials that involve investigational drug, biologic, or device.*
   11. ***Impartial Witness.*** 
       1. *Required for a Clinical Trial that follows ICH-GCP requirements when enrolling non-English reading research participants. May be required by a sponsor for enrolling other vulnerable populations such as cognitively impaired adults.*
       2. *Recommended for any situation that requires a “witness” as indicated above.*

***ADDITIONAL NOTES REGARDING SIGNATURES****:*

1. *Remove all signature blocks from the template below that are not required by the study. To do this, highlight the rows that should be deleted, by placing the cursor over the row and* ***left click****.* ***Right click*** *once highlighted, then select “delete” option.*
2. *If a 2nd parent/legal guardian signature is not required, remove these rows from the template.*
3. *When a witness is required, as indicated above, choose only one type (e.g., witness, or impartial witness).*
4. *Template signature blocks are provided for the witness and investigator when remote consent is anticipated. Use one or the other blocks, not both.*

*Please note that electronic signatures (e.g., e-signatures captured with software or computer equipment) are not permitted for FDA regulated Clinical Investigations, unless the IRB has confirmed 21 CFR part 11 compliance.*

You have read this document and were told of the risks and benefits (if any) and a member of the research team answered questions to your satisfaction. A member of the research team will answer any future questions. You voluntarily agree to join the study and know that you can withdraw from the study at any time without penalty. You do not waive any legal rights by signing this form.

**You will receive a signed copy of this form to keep.**

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print the Name of the Child**  **(Under the age of 18 only)**  Check if the Child is a Ward.  *When enrolling a Ward, an Independent Consent Monitor must sign this consent form below.* | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of the Child providing assent.**  **(ages 13-17 only)** | \_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print Name Minor**  Check type of minor:  \*Emancipated Minor\*\*  Married Minor\*\*  \*An emancipated minor is defined as either a person 16 years or older and living independently from his/ her parents or a minor who is a parent him/herself.  \*\*An Independent Consent Monitor must also sign this consent form below. | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of Minor** | \_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print Name of Parent or Legal Guardian** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of Parent or Legal Guardian** | \_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |
| **Check box to indicate reason for not obtaining 2nd Parent or Legal Guardian, if applicable:**  2nd parent/legal guardian is not reasonably available, deceased, unknown, or incompetent.  Only one parent has legal responsibility for the care and custody of the child. | | |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print Name of 2nd Parent or Legal Guardian** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of 2nd Parent or Legal Guardian** | \_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print Name of Independent Consent Monitor**  (Required when enrolling a Minor without Parental Permission or when enrolling a Child who is a Ward)  An Independent Consent Monitor may not be a member of the research team. | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of Independent Consent Monitor** | \_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print the Name of the Adult Research Participant**  (18 years of age or older) | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of the Adult Research Participant** | \_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print the Name of the Adult Research Participant for whom you are providing permission to be in the study.**  (18 years of age or older)  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print Your Name as the Surrogate and indicate your relationship to the research participant:**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | You are being asked to decide if someone else can be in this research. Please think of this person’s wishes, beliefs, and interests. We will obtain her/his consent if (s)he becomes able to decide later.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of Surrogate** | \_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print Name of Interpreter**  (Applicable when the person authorizing the research has limited English proficiency or uses sign language)  *NOTE: The interpreter may also serve as a witness, impartial witness, or impartial consent monitor, when applicable.* | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of Interpreter (if applicable)** | \_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |
| ***Completed by Witness (required for surrogate consent, remote consent, or when obtaining consent from a non-English speaking participant):***  Check if consent was obtained remotely (e.g., conference call, Doxy.Me, MS Teams).  Check to confirm participant agreed to participate in the study and signed the informed consent form(s) and all questions were answered.  Check if participant could not sign the consent form but signaled consent to participate and describe (i.e., gave thumbs up): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| ***Completed by Witness (required for surrogate consent, or when obtaining consent from a non-English speaking participant):***  Check to confirm participant agreed to participate in the study and signed the informed consent form(s) and all questions were answered.  Check if participant could not sign the consent form but signaled consent to participate and describe (i.e., gave thumbs up): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print Name of Witness** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of Witness** | \_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print Name of Impartial Witness**  An impartial witness cannot be a member of the research team. | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of Impartial Witness** | \_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |
| ***Completed by the Investigator obtaining informed consent (including remote consent option, when applicable):***  In addition to advising the person authorizing the research about any appropriate alternatives to research participation, I have offered an opportunity for further explanation of the risks and discomforts which are, or may be, associated with this research, and to answer any further questions.  Check to confirm participant agreed to participate in the study and signed the informed consent form(s) and all questions were answered.  *Check options pertaining to remote consent if applicable:*  Check if consent was obtained remotely (e.g., conference call, Doxy.Me, MS Teams).  Check if the informed consent document signed by the participant was not retained, due to contamination of the document by infectious material. A copy signed by the Witness and Investigators and retained for the research record.  Check to confirm participant was asked to mail, fax, or e-mail a copy (including photo) of the signed consent form to the research team. If copied by smart phone camera photo, at least a photo of the signature page was requested. | | |
| ***Completed by the Investigator obtaining informed consent:***  In addition to advising the person authorizing the research about any appropriate alternatives to research participation, I have offered an opportunity for further explanation of the risks and discomforts which are, or may be, associated with this research, and to answer any further questions.  Check to confirm participant agreed to participate in the study and signed the informed consent form(s) and all questions were answered.  . | | |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print Name of Investigator Obtaining Informed Consent** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of Investigator Obtaining Informed Consent** | \_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |