|  |
| --- |
| **SUNY DOWNSTATE MEDICAL CENTER**  **& 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:*

|  |
| --- |
| * *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.* * *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 for the use of coded specimens and/or information for future research*   + *Use of psychiatry notes (include a separate HIPAA Authorization –see template on IRB 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.* * *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.* * *To the extent possible, explain technical, medical, and scientific concepts in lay terms that are understandable to someone who is educated to the* ***6th grade level****. 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.* * *To avoid IRB requests for modifications, please check the readability of the consent before finalizing the document. The PI is encouraged to use readability resources, such* [*Readability Formulas*](http://www.readabilityformulas.com/cgi-sys/suspendedpage.cgi) *or* [*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.”* * *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 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.* |

**Key Information for You to Consider:**

*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.*

*Include in all forms:*

Researchers are asking if you would like to be in a research study. The boxes below provide key information about this research to help you to consider whether to participate. Please consider all of the details on the pages that follow.

*When requesting parent or legal guardian permission for a child, add the following*:

If you are providing permission for a child to be in the study, the terms “you” and “your” refer to your child.

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

If you are deciding if an adult can be in this study, the terms “you” and “your” refer to the adult who cannot make the decision. Please consider the wishes and beliefs or the best interests of this person. If the participant’s ability to make decisions is regained after you give your permission for him/her to be in the study, he/she will be asked to provide his/her consent.

|  |  |
| --- | --- |
| **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 find out if the drug called ABCXYZ is safe and effective.  *[When evaluating an investigational drug, biologic, or medical device, indicate it is not FDA approved.]* |
| **What will happen to you during the study?** | *[Insert a high-level summary that explains the procedures and activities of the study and include a description of any experimental procedures.]*  When enrolled in this study, you will receive ABCXYZ in the Clinical and Translational Science Center at Downstate. You will be asked to complete surveys about your health and will have exams and procedures done for the study purposes. Each visit will last 2-3 hours. |
| **How long will you be in the research?** | *[Insert a description of the length of duration of the study participant’s participation]* |
| **Could being in this research harm you?** | *[Insert a description of any foreseeable risks and discomforts related to research participation. Include any foreseeable risks to a pregnant females or a fetus for research involving pregnant females or females of childbearing potential.]*  Some of the foreseeable risks and discomforts of your participation include [describe the most important risks in lay terms. Consider the most probable and/or highest magnitude of harm].  *[For greater than minimal risk research, add the following]:*  Taking part in this research may expose you to significant risks. Researchers may not know or understand all the risks at this time. Some people may experience side effect or discomfort, some of which may be serious. It is very important that you understand the risks of this research study before you decide to participate.  *[OPTIONAL, for minimal risk research, consider adding the following]:*  This research is no more than minimal risk, which means that there is no more expected risk to you than what you might experience during a typical day or during a routine physical exam. |
| **Will being in this study help you in any way?** | Researchers cannot promise that you will get any benefits from taking part in this research study. Some of the benefits that may be expected include *[Describe any direct, known, proven, or therapeutic benefits of the research to the participant in a clear, balanced manner based on reliable information. However, do not include theoretical or hypothetical benefits (e.g., those under the investigation). DO NOT LIST PAYMENTS, COMPENSATION, OR REIMBURSEMENT AS A BENEFIT.]*  *-OR-*  There is no benefit to you for participating in the study. *[Describe possible benefits to others and/or explanation of what the research hope to gain or learn]* |
| **Are there any costs to participate?** | *If there are no foreseeable costs, this should be specified:*  Researchers do not foresee any additional costs to you for your participation in the research.  *Describe any additional expenses that the participant will incur by taking part in the research. When applicable, include a discussion on transportation costs or loss of income for taking time off from work to be in a study.*  For clinical trials or studies involving patient care, use the text:  The care provider will bill you, your insurance carrier, or third party payer for the cost of routine care associated with the study. You will be responsible for any co-payments or deductibles as you would in the normal course of receiving standard care. Some insurance companies or third party payers will not cover the costs of care related to research.  Care providers will not charge for the costs of any of the procedures performed solely for the purpose of this research study. The materials or procedures performed solely for the purpose of research include <include applicable investigational study drug, device, or biologic, unless this is covered by insurance (e.g., deemed or qualifying clinical trial with Medicare patients), and any other items.> You may consult with the study team to explain the costs you may incur and if your insurance will pay.  *[For studies involving greater than minimal risk, include the following:]*  In the event of a research related injury, treatment is available at University Hospital Brooklyn or the provider of your choice, but it is not free of charge. |
| **How do researchers protect your information?** | *[Edit as applicable to the research.]*  Researchers will keep information about you in a secure location. Only those approved to have access will see your information. |
| **Will you get any test results?**  *[Delete if none]* | *[When applicable, include whether individually clinically relevant research results will be disclosed to a participant and if so, under what conditions]*  Laboratory tests performed for research purposes have no clear meaning for health care; however, test results from a certified clinical laboratory may be provided [upon request, at the end of the study, when the results may have a meaning for your health, or state the condition when results will be released].  You may talk to your healthcare provider to request diagnostic tests by a certified clinical laboratory. You may request genetic testing and professional genetic counseling. You may have to pay for those additional services. |
| **What other choices do you have besides taking part in this research?**  *[Optional if no alternatives]* | *[If there are no alternatives, delete this section OR state:]*  There are no alternatives to this research at this site. You may choose not to participate in this research study.  *[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 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.> |

**Additional Detailed Information:**

Please review the rest of this document for additional details before making a decision about whether to participate in this research.

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

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

*Briefly explain the purpose of the study.*

*[When evaluating an investigational drug, biologic, or medical device, indicate it is not FDA approved.]*

**What will happen to you if you decide to be in this study?**

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

*Give a detailed description of the research procedures, including any genetic or other testing.*

*When the study involves randomization, describe procedure in lay terms and the chance of being in each group (e.g., you have a 50:50 chance of being in each study group; like the flip of a coin).*

*Describe any experimental interventions, interactions, or procedures. Describe any drugs, biologics, or devices that are experimental.*

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

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

*Describe the duration of the research participation in this section or alternatively include the details in the next section along with the study procedures. The participants must be informed of their individual time commitment for participation in the total study, including long-term follow-up:* Your individual participation in the project will take approximately X minutes, hours, days, weeks, months, years, etc.

*You may also want to explain the total duration of the study:* This study should to take place for approximately X years, months, etc.

Include any follow-up procedures.

**Could being in this research harm you? (Detailed Risks)**

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

*Describe any foreseeable risks and discomforts related to research participation. Include any foreseeable risks to a pregnant females or a developing human fetus for research involving pregnant females or females of childbearing potential.*

*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:*

Genetic test results may reveal that you or a relative may develop a disease. Sharing this information may cause stress or genetic discrimination to you or others. Disclosing the results in error may create this risk.

The Genetic Information Nondiscrimination Act (GINA) is a law making it illegal for health insurance companies, group health plans, and most large employers to discriminate against you based on your genetic information. However, GINA does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Insurance companies may use your genetic information to evaluate whether a person can purchase a policy. An insurance carrier may request or require disclosure of your genetic test results.

*Include a statement that there may be research risks are currently unforeseeable, particularly for research that involves greater than minimal risk:*

There may be unknown risks or side effects of the research. If you develop a new condition or suffer an injury, please tell the study doctor right away.

*If applicable (e.g., for clinical trials or other high-risk research), add:*

If you need emergency care, dial 911 or go to the nearest emergency room.

**Is there any available compensation or medical treatment if injured in the study?**

*Delete this section if the study is no greater than minimal risk.*

*[For studies* ***without an external sponsor*** *that involve more than minimal risk, that have no sponsor, include the following:]*

Immediately call the study doctor if you experience an injury, adverse event (bad effect), emergency care, or hospitalization related to the research. The study doctor will help you obtain medical treatment. Treatment is available to you at this site or you could go to any other facility of your choosing. However, any treatment provided is not free of charge. You or your insurance company bills for these costs in the usual fashion. There are no funds set aside to compensate you for injuries or to pay for unfavorable outcomes such as lost wages or discomfort. For additional information, call the researchers listed on the top of the first page of this document.

*For sponsored research, use their informed consent template or add the required language that indicates coverage of the costs of research related injury as outlined in the sponsor’s agreement. Contact Pre-Awards for additional information.*

**How many people will participate in this research study?**

*Include the anticipated enrollment number of individuals for the study, as this may influence potential participants’ decisions whether to enroll.*

*If screening, add:* Up to XXX people will be screened to determine if they can be enrolled at Downstate Medical Center <and NYC Health & Hospital, Kings County>.

*Include a statement about anticipated enrollment numbers:* The researchers hope to enroll up to XXX people at Downstate Medical Center <and NYC Health & Hospital, Kings County>.

F*or multicenter studies , add:* XXX people, in total, are expected to be in the study at all the sites.

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

If you have questions, concerns, complaints, or think the research hurt you, please contact the researcher(s) listed on the top of the first page.

This research is reviewed and approved by an Institutional Review Board (IRB). An IRB is a committee that provides ethical and regulatory oversight of human research. You may talk to the SUNY Downstate Medical Center IRB & Privacy Board by calling (718) 613-8480, if

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

**What happens to the information collected for this research?**

*CAUTION: THIS SECTION MUST BE COMPATIBLE WITH ANY OPTIONS ADDED FOR FUTURE RESEARCH AT THE END OF THE CONSENT FORM.*

*Add a statement about the type of information and/or specimens collected for the research.*

*Add a statement about storing coded materials if applicable. It is best practice to store coded materials rather than identifiable materials.*

Researchers will securely store your information <and specimens> in a coded format. The code can be used to link to materials back to you. Only the researchers approved by the IRB may have access to the code.

*If the research involves the collection of ‘identifiable private information’ or ‘identifiable specimens’ federal regulations requires one of the following:*

The researchers will not use or distribute your identifiable private information (and identifiable specimens) collected for this research for future research studies, even after removal of identifiers.

*-OR-*

Identifiers might be removed from the identifiable private information (and identifiable specimens) and after such removal, the information (and specimens) could be used for future research studies or distributed to another investigator for future research studies or distributed to another investigator without obtaining additional informed consent from you (or your authorized representative). The researchers would like your permission to share coded materials with other investigators. There is a section at the end of this consent to ask your permission to use or share your coded information (and coded specimens) for future research studies and provide more information about this. Researchers will only use or share your coded material obtained from this current research if you provide your permission to do so. Researchers will not share the key to the code with future researchers; therefore, the researchers doing future research cannot identify you.

***CAUTION: WHEN THE OPTION IMMEDIATELY ABOVE THIS NOTE IS USED, YOU MUST INCLUDE THE OPTIONAL AUTHORIZATION FOR FUTURE USE AT THE END OF THE FORM.***

**Does this study involve any diagnostic genetic testing?**

*Omit this section if there is no diagnostic genetic testing in the research.*

*For 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 or categories of persons or 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 for;*
* *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;  and*
* *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;  and*
* *a statement explaining the benefits and risks of consenting to future contact*

If the study includes obtaining clinical consent for the collection of diagnostic genetic information that is part of usual care, consider adding the following to cover the NY State requirements:

For this research, researchers will obtain the results of the diagnostic genetic testing that is part of your usual care. You will need to provide a separate consent for genetic testing for your usual care. The consent process will include specific information required by law. Please ask any questions that you may have. The clinician may provide information about counseling, the purpose of genetics test, or the meaning of the results.

**Are there any conflicts of interests reported for this study?**

*Omit this section when there are no significant financial interests (SFI) nor conflict of interest management plans (MP) applicable to the study. For more information, see* [*RFDMC-01: Research Conflict of Interest Policy.*](https://www.downstate.edu/coi/index.html)

Dr. <add name of investigator with SFI or MP>, an investigator on this study at SUNY Downstate Medical Center, is receiving funding from <source>. The outcome of this research study could be of interest to <list any party maintaining an interest in the outcomes>. This investigator does not participate in the recruitment, enrollment, or obtaining of informed consent for this research. The Downstate’s Financial Conflict of Interest Committee oversees the conflict of interest policies. In accordance with these policies, Downstate has determined that Dr. <add name of investigator with SFI or MP> interests create no significant risk to the welfare of participants in this study or to the integrity of the research. If you want more information about this, please contact Ms. Shoshana Milstein in the Financial Conflict of Interest Committee’s Office of Corporate Compliance at (718) 270-7470.

**What other choices do you have besides taking part in this research?**

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

*If there are no alternatives, delete this section OR state:*

There are no alternatives to this research at this site. You may choose not to participate in this research study. *If applicable:* There are no established 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 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 research study to receive <treatment outside of this study / hospice, palliative and/or comfort care / extra credit / benefits to which you are entitled / >.

**How do researchers protect your information?**

*Describe how the study maintains the confidentiality of participant data:*

The researchers will keep information about you in a secure location with limited access. The researchers will not reveal your identity in any publication or public presentation of the results of the study.

*Include if applicable:*

The researchers will destroy your information <and your specimens> after the study is complete. The researchers will not use the specimens or information for future studies; however, the researchers will keep information about you as long as required by regulations and institutional policy.

*Include the text below for research involving any Protected Health Information (PHI) also known as Individually Identifiable Health Information (IIHI):*

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.

*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 the following:*

* *A specific and meaningful description of the PHI to be used or disclosed. Example provided below.*
* *A description of each purpose for which the PHI is 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.*

For the purposes described in this form the research team will create, use or report PHI from your medical records or research records including <specify the health information in a specific and meaningful fashion (e.g. results from physical examinations, laboratory tests, x-rays, and other diagnostics medical procedures (be specific regarding tests, such as MRI, CT, psychological tests, etc.).

*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.*

The researchers will create, use or report PHI until the end of the research study or as otherwise specified on this form (-or-) for an indefinite time period *(insert one of these options or other specific expiration date or event).*

*Add/edit/delete as applicable, when the study involves the use of video/audio recordings/ pictures/images. Be sure to include statements to specifically indicate who has access to the recordings, how they are stored, for what purposes they will be used, and what happens to the recordings/files once the study has ended (i.e., destroyed after all necessary information is collected, kept for archival purposes).*

The researchers will obtain video/audio records/pictures/images 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.

Include the name or identification of the person(s) or class of person(s) who will disclose the PHI (e.g., UHB, UPB, NYC H+H, Kings County, other hospitals, practice groups, other individuals approved on this study by the IRB, etc.) **and** the internal or external persons or entities who will be receiving PHI.

***NOTE: List all entities for legal access the research participants’ health information.***

Research and administrative staff from SUNY Downstate Medical Center, University Hospital Brooklyn, University Physicians of Brooklyn, Inc, NYC Health +Hospitals/Kings County, <other hospitals, practice groups, other individuals approved on this study by the IRB, etc.> will use your protected PHI related to this research study.

Research and administrative staff from SUNY Downstate Medical Center, University Hospital Brooklyn, NYC H+H, Kings County, <other hospitals, practice groups, etc.> will share your PHI with the following persons or agencies for purposes related to the conduct of the research:

* The Institutional Review Board(s) that have oversight of this research.
* The research staff approved by the Institutional Review Board.
* Collaborating research sites, outside laboratories, cooperative study groups, or contracted research organizations that are approved by the Institutional Review Board
* The SUNY Downstate Medical Center 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. (delete if not applicable)
* 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 Institute of Health or other government agencies.
* The Data Safety Monitoring Board that reviews the safety of this study. (delete if not applicable)
* Your insurance companies. (delete if not applicable –this is only expected if a third-party payment is expected)

*Include a statement that the individual may revoke the authorization in writing at any time (except to the extent that a provider has acted in reliance of the authorization), and instructions on how to exercise such right.*

You can withdraw this authorization for the use or reporting of your PHI. You have to write to us to withdraw. To withdraw, please write to *(complete name and address of the PI or other person to receive the notice of withdrawal)*. If you withdraw, the researchers will stop collecting and accessing your PHI, but will collect and report any adverse event (bad effect) that you had in the study. Your PHI collected before you withdraw your authorization will still be used and reported. If you withdraw your authorization, you can no longer be in the study.

*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.*

You have a right to refuse to sign this form. If you do not sign this form, your health care treatment, your enrollment for benefits, your payment for the health care outside of the study, and 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.

*Include if applicable:*

The researchers cannot share with you some of the PHI obtained in this study during the course of 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.).

*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*

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. 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 or edit to be consistent with the Certificate of Confidentiality language (see next section):*

As required by law, the research team may share your PHI with the relevant agency to:

* Report suspected child abuse or neglect,
* Report certain communicable diseases,
* Report a possible threat or harm to yourself or others,
* Comply with a court ordered subpoena, or,
* Comply with other laws.

*Include the following for international clinical trials that follow the ICH GCP(E6) guidelines, or whenever applicable to the study:*

The researchers will grant direct access to your original medical and research records to monitors, auditors, the Institutional Review Board (IRB), and regulatory authorities for the purpose of verification of clinical trial procedures or data. The researchers provide access without violating your confidentiality, to the extent permitted by the applicable laws and regulations. When signing this written informed consent form, you are authorizing such access.

*Add if the study involves genetic information or testing:*

The researchers will not give your genetic information to anyone unless you authorize it. The researchers will not use your genetic information to set the terms of your employment or make any decisions to hire, promote, or fire you. Please be aware that laws do not protect you against genetic discrimination by companies that sell insurance.

*Add the following when recruiting patients into a clinical trial involving an IND or IDE or when there is a 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.

*Note: 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* [*SUNY Downstate HIPAA (Health Insurance Portability and Accountability Act) Policies and Forms*](http://www.downstate.edu/hipaa/hipaa_policies.html)*.*

*If the EU General Data Protection Regulation (GDPR) is applicable to this study, please work with the sponsor, Privacy Officer, or the Office of Compliance and Audit Services (OCAS) to include the appropriate GDPR disclosures within this consent or an addendum. The IRB will work with OCAS to confirm all required disclosures are included. Examples for when GDPR applies to the research include the following:*

1. *The study includes outreach and recruitment of individuals who are located in the European Economic Area (EEA), which is 28 EU member states and three additional countries (Liechtenstein, Iceland, and Norway),*
2. *Downstate and/or NYC H+H, Kings County is the site for a study involving the EEA and has the role of primary research site and/or lead investigator, or*
3. *Downstate and/or NYC H+H, Kings County collects and/or processes Personal Data (as defined by GDPR) in the EEA in connection with the study (including incidental collection of personal data on a mobile app while a research participant is travelling in the EEA).*

**Is this research covered by a Certificate of Confidentiality?**

*Include for NIH funded study or when a Certificate of Confidentiality 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/*](http://grants.nih.gov/grants/policy/coc/)

***IMPORTANT REMINDER: 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).***

A **Certificate of Confidentiality** from the National Institutes of Health covers this research. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use.

This certificate prevents disclosure of protected information, documents, or biospecimens to anyone else who is not connected with the research; however, the Certificate of Confidentiality does not prevent disclosure as required by federal, state, or local law when required to share your information with the relevant agency for reporting the following:

* Suspected elder or child abuse or neglect
* Certain communicable diseases
* Possible threat or harm to yourself or others

The Certificate does not cover disclosures for which you have consented, including your medical treatment. The Certificate does not cover disclosures used for other scientific research, as allowed by federal regulations protecting research participants.    
  
*Include the following for federally or state funded/conducted studies, otherwise delete:*

The Certificate does not prevent disclosure of information to the [add US or State Agency/Department sponsor(s)] for the purposes of auditing or conducting a program evaluation.

*Include the following for FDA regulated clinical investigations, otherwise delete:*

The Certificate does not prevent disclosure of information necessary to meet the requirements of the federal Food and Drug Administration (FDA).

*Keep for all studies:*

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must first authorize the researchers to release it.

The Certificate of Confidentiality does not prevent disclosure for any purpose you have authorized within this informed consent document.

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

**Can your participation end early?**

*Omit this section, if it is not applicable to the study.*

*When appropriate, describe the consequences of a research participant’s decision to withdraw from a research study. Edit the following as needed:*

Your participation in the research study may end for any of the following reasons:

* If you are a female who becomes pregnant
* If the research becomes harmful
* Whenever it is determined that it is not in your best interest to continue
* If you do not follow the instructions or adhere to the research requirements given to you by the study doctor or study staff
* You do not take medication as instructed
* You do not keep study appointments

**What additional information should I know?**

The researchers will inform you of any significant new information that may affect you in a timely manner. Such information may help you decide if you want to stay in the study. The researchers will share any new information with you if it affects your ability to stay in the study.

*Federal regulations require adding the following information when applicable to the research:*

* + *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;*
  + *For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).*
  + *Information about NIH Genomic Data Sharing Policy, when applicable. Consult NIH policy for guidance on informed consent requirements and include appropriate disclosures in the risk and confidentially section of this consent. Some references which may be helpful are provided below, but this is not inclusive of all NIH policy:*
    - [*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)
    - [*https://osp.od.nih.gov/wp-content/uploads/NIH\_GDS\_Policy.pdf*](https://osp.od.nih.gov/wp-content/uploads/NIH_GDS_Policy.pdf)
    - [*https://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html#protection*](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html#protection)
    - [*https://osp.od.nih.gov/wp-content/uploads/GDS\_Points\_to\_Consider\_for\_Institutions\_and\_IRBs.pdf*](https://osp.od.nih.gov/wp-content/uploads/GDS_Points_to_Consider_for_Institutions_and_IRBs.pdf)
  + *Any requirements of any applicable federal, state, or local law.*
  + *Any requirements of any applicable tribal law passed by the official governing body of an American Indian or Alaska Native tribe.*

**Will you receive anything for being in the research?**

*If there are no gifts, rewards, compensation or reimbursement, add:*

You will NOT receive any gifts, rewards, compensation, or reimbursement for your participation in this research study.

*Include when applicable:*

You will NOT receive any type of rights 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.*

You will receive the following for your participation: <describe amounts for **each** activity and the **total** for the duration of the project>

*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:*

We 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 H+H, 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.

**Will the research obtain additional information about you from others?**

*Describe any information sought from other individuals or entities.*

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

**OPTIONAL RESEARCH ACTIVITIES**

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

This section provides a description of optional research activities. Please indicate if you agree or do not agree with the options below. Your decision will not affect your participation in the current study.

*Reminder: Include the box below when the research involves diagnostic genetic testing.*

|  |  |
| --- | --- |
| **Can the researchers contact YOU (and only you) in the future to obtain or share information related to diagnostic genetic testing?**  After completing diagnostic genetic tests, the researchers would like to be able to contact you in order to get more information needed for this research and/or to explain the results of this research study. Under New York State law, you must provide your consent to such future contact. The risks of allowing us to contact you are that the researchers may have information that causes some emotional distress, but the benefits are that researchers may have information that could help you in your medical planning and decision-making.  If you allow us to contact you in the future, the researchers will not disclose your medical information or the results of the genetic tests of the research study to anyone for any reason without your further specific written informed consent. If the researchers think your family members could benefit from knowing genetic information about you during this research study, the researchers may ask for your permission to contact them and would explain our reason to you for wanting to do so. | |
| **Please initial the ONE option that you choose below:** | |
| *\_\_\_\_\_ (initials)* | YES. |
| *\_\_\_\_\_ (initials)* | NO. |

**REMINDER: The section below is REQUIRED to use information/specimens for future research.**

**CAUTION: This section must also be compatible with the section “What happens to the information collected for this research?”**

|  |  |  |
| --- | --- | --- |
| **May the researchers share your coded information (and coded specimens) for future research?**   * The researchers will only use or share your coded material obtained from this current research if you provide your permission. * The researchers approved for this current study will code your materials and have access to the key to the code. * The researchers doing future research with coded materials without access to the key to the code cannot identify you. * The following materials may be used in the future research: <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 or edit or omit:*  The researchers in charge may share your coded specimens or information with other researchers or institutions. This could happen if the researchers in charge believe that sharing will allow important scientific research or due to a relocation of the research. * *Add or edit or omit:*  Your coded specimens <and information> will be maintained for as long as they are useful for research purposes *<or provide specific time-period, (e.g., 30 days after testing),* after which time the specimen and information will be destroyed *<or deidentified>*. *NOTE: Per New York State law: If retaining the DNA samples (not data) past a period of ten (10) years explicitly state the retention period.* * *Make slight edits if needed for consistency with other areas of the consent:* Future research will only take place under one or more of the following conditions:   + it is authorized by you within this consent or a future consent,   + it is reviewed and approved by an institutional review board (IRB), which is responsible for protecting your rights and welfare, or   + your data is stripped of all identifiers (including codes linked to you). | | |
| **Please initial the ONE option that you choose below:** | |
| *\_\_\_\_\_ (initials)* | YES.  *Note: You still have the right to withdraw this authorization later. If you withdraw, the researchers will stop using your information/ specimens for the future use, but they will use and report on the information/ specimens already collected before you withdraw to maintain the integrity of the study. If you withdraw, researchers cannot guarantee but will attempt to withdraw information/specimens already shared with others.* |
| *\_\_\_\_\_ (initials)* | NO. |

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

|  |  |
| --- | --- |
| **May the researchers contact you after your participation in this research is over to invite you to consider other research studies?**   * Your decision will not affect your participation in the current study. * The study team would like to contact you to let you know about other studies, which you may be interested in participating. * The researchers would provide additional information about the other research at the time of contact, as they may not know about it at this time. | |
| **Please initial the ONE option that you choose below:** | | |
| *\_\_\_\_\_ (initials)* | YES. | |
| *\_\_\_\_\_ (initials)* | NO. | |

*Optional:*

|  |  |
| --- | --- |
| **Do you authorize the release of your medical information from another provider for use with this research?**  After your participation is complete, the researchers may need to request your medical records from another healthcare provider. With your authorization, the researchers will share a copy of this consent with your outside healthcare provider. However, when required, the researchers may still need to re-contact you or your personal representative for additional authorization to release the medical records to us. | |
| **Please initial the ONE option you choose:** | |
| *\_\_\_\_\_ (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.

|  |  |
| --- | --- |
| **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 my consent orally or in writing at any time. As long as this consent is in force, Downstate Medical Center (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. | |
| **Please initial the ONE option that you choose 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. |

**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. ***Pregnant Minor.***
   7. ***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, Pregnant Minor, or a Ward. An Independent Consent Monitor may not be a member of the research team.*
   8. ***Adult Research Participant.*** *For adults who are 18 years of age or older*
   9. ***Personal Representative (Legally Authorized Representative).*** *Required when obtaining surrogate consent for enrolling adults who are cognitively impaired.*
   10. ***Interpreter.*** *Required when there are plans to enroll participants with individuals who have Limited English Proficiency or communicate with sign language.*
   11. ***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*
   12. ***Impartial Witness.*** 
       1. *Required for a Clinical Trial that follows ICH-GCP requirements when enrolling non-English reading research participants.*
       2. *Recommended for any situation that requires a “witness” as indicated above.*

You have read this document and were told of the risks and benefits 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 document.

|  |  |  |
| --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **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\*\*  Pregnant 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** |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print Name of 2nd Parent or Legal Guardian (if applicable) or check one of the boxes below:**  Not applicable because the 2nd parent/legal guardian is not reasonably available, deceased, unknown, or incompetent.  Not applicable because only one parent has legal responsibility for the care and custody of the child. | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of 2nd Parent or Legal Guardian (if applicable)** | \_\_\_\_\_\_\_\_\_\_\_\_  **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:**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **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** |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **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** |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print Name of Investigator Obtaining Informed Consent** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of Investigator Obtaining Informed Consent** | \_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |