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| **SUNY DOWNSTATE MEDICAL CENTER**  **& NYC Health + Hospitals, Kings County**  *(if not applicable, delete one of the above lines and the “&”)*  **BROOKLYN, NY 11203**  **INFORMED CONSENT FORM** |
| **TITLE OF RESEARCH STUDY:**  **Location/Department:**  **Principal Investigator:**  **Sponsor:** [insert external sponsor (e.g., industry, company, or government entity) or delete this line] |

*HELPFUL TIPS:*

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| * *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, including NY state laws, such as the following:*   + *Required elements of informed consent described at* [*45 CFR 46.116*](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1116)   + *Required HIPAA authorization language, as described in IRB-01 policy or information in the template below.*   + *Information for diagnostic genetic testing*   + *Option for use of coded specimens for future research*   + *Access to HIV result (see Privacy Officer required language in template below)*   + *Use of psychiatry notes (include a separate HIPAA Authorization –see template on IRB website)*   + *Disclosures of research involving video/audio recording or pictures or images (see recommended language in template below).*   + *Include all required signature lines (examples are provided at the end of this template as well as a description of when each is required based on federal and NY regulations)* * *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 Legally Authorized Representative’s (LAR) 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 to 8th 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 the passive tense.* * *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.* |

**Introduction & 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.***

**This is a research study to find out if the drug called ABCXYZ is safe and effective.**

**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 legally authorized representative 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.**

**This form includes important information to help you decide if you want to be in a research study.**

**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.**

**This form describes some of the risks and discomforts of the study, including nausea, diarrhea, tiredness and weakness, fever, and muscle pain. You might feel uncomfortable answering some very personal questions about your health.**

**Below are some reasons why you might want to participate in the research:**

* **You may benefit from being in the study. Such benefits may 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.**
* **We cannot promise that you will get any benefits from taking part in this research study. However, possible benefits to others may include: (describe)**
* **You may receive more attention from your study doctor and closer follow-up.**
* **Add other reasons particular to the research.**

**Below are some reasons why you might not want to participate in the research:**

* **There is no benefit to you for participating in the study.**
* **Your participation may be inconvenient.**
* **You may have to take time off from work to participate in the research.**
* **It might be risky to you than alternatives. Be sure to understand the risks.**
* **Add for clinical studies: Being in a research study is different from being a patient. When you are a patient, you and your doctor have freedom in making decisions about your healthcare. When you are in a research study, the researcher will follow the rules of the research study as closely as possible, while monitoring your health.**
* **Describe any potential conflicts of interest of investigators**
* **Add other reasons particular to the research.**

**If you are interested in learning more about this study, please continue reading below.**

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

*Briefly explain the purpose of the study and the reason for participation in lay terms. (e.g., to see if X is safe and effective to treat Y, to see if the X can reduce the pain, or reduce the size of the tumor, or stop your irregular heart rate, to evaluate a different way of giving an approved drug). You could provide a summary of the research study with the hypothesis, objectives, and/or aims written in a manner that would be understandable to the research participants.*

This study is for people who \_\_\_\_\_\_\_\_\_\_\_. *(Fill in the condition or circumstance that makes someone eligible for the study. If including healthy volunteers add the following to the first sentence:* are healthy individuals.)

This research will help increase our knowledge about \_\_\_\_\_\_.

*Clinical equipoise exists when a clinician has no good basis for a choice between two or more standard of care options or when one is truly uncertain about the overall benefit or harm offered by the treatment to a patient. Consider adding the following statement, if you are comparing two arms that are in clinical equipoise:*

The purpose of this study is to see if <name the research article> is better or has fewer side effects than <name the research article>. *Describe any drug, device, or biologic used in the research and indicate whether it is approved by the Food and Drug Administration (FDA). See examples below.*

*If a specimen and/or data repository is involved for future research, please include the following (edit as needed):*

The purpose of this study is to collect and store your specimens <and information about you> for future research purposes. *Describe the purpose of any specimen/data repositories or genetic testing and/or adequately describe future research purpose(s) so that it would be reasonable for the research participant to understand the use of his/her specimens and if applicable, expect that his/her Protected Health Information (PHI) be involved in such future research. When applicable, fully disclose plans for “diagnostic genetic testing” on stored specimens. This information must be consistent with all other sections within this consent form.*

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

Up to XXX people will be screened to determine if they can be enrolled at Downstate Medical Center <and NYC Health & Hospital, Kings County>. We hope to enroll up to XXX people at this site <or: these sites>. *For multicenter studies, add:* XXX people, in total, are expected to be in the study at all the sites.

*If applicable, provide a list of exclusion criteria that may be relevant to potential participants, in order to make an informed decision regarding their participation in the study. In certain ethical circumstances, you may wish to exclude participants who do not want future contact, for example if you anticipate needing to notify them for incidental findings.*

*If applicable, describe any prohibitions to the use of certain medications, supplements, biologics, or devices.*

*Indicate whether participants can or cannot participate in other research studies.*

**What is the duration of your participation in the research, including any follow-up?**

*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.

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

*Tell the research participant what to expect. Give a detailed description of the research procedures, investigational drugs, biologics, or devices, hospitalizations, outpatient visits, and total duration of a research participation (e.g. your involvement in the study will be for one study visit).*

*If the study includes multiple visits by the research participant, describe them in chronological order. For repeated procedures in different visits, describe them once and then state which visits they are performed.*

*If there is a need to describe procedures or schedules in detail, consider including those in an addendum. Distinguish carefully the use of drugs and/or procedures done as part of the standard of care from drugs and procedures used exclusively for research purposes. Alternatively, indicate only those drugs and/or procedures given specifically for the research.*

*Describe the process for specimen collection.*

*If blood is drawn, indicate the amount in teaspoons or tablespoons and the frequency of the procedure. State the total amount of blood that collected for the entire study. The amount of blood collected should be described using teaspoons or tablespoons (5 cc = 1 teaspoon; 15 cc = 1 tablespoon)*

*If the study will involve the administration of questionnaires/surveys, briefly state what they entail and state the approximate length of time it will take to complete.*

*Outline what the research participant must do to comply with the protocol, including taking research drugs or maintaining or using research devices, any follow-up visits. Include the number of study visits, maintenance of diaries, medical or dietary restrictions.*

*Provide a brief description of the type of questions asked within questionnaires. In addition, inform participants they may review the survey tools prior to agreeing to participate (if appropriate).*

*Describe how placement occurs for one study arm over another and include a description of the randomization procedure and the chance of being in each arm.*

*In lay terms, describe any blinding process that is used.*

*It may be helpful to provide charts or graphics to simplify the participants’ understanding.*

*If describing every procedure would make the consent too long, please provide a general description of the procedures in this consent and providing a consent addendum describing all study procedures. Removing procedural details from the consent will reduce length, enhance understanding, and allow more focus on risks and benefits.*

*Describe any follow-up visits and/or phone calls.*

*Provide a listing or chart of planned study visits, if possible.*

*Include when applicable:*

You must tell your study doctor about any of the following:

* New medications that you take.
* New medical conditions that occur
* Any adverse (bad effect) that you experience

*Add if applicable:*

Dr.\_\_\_\_\_\_\_\_\_ will be your study doctor, if you agree to be in this study.

*Add/edit as applicable:*

If necessary, we will contact your personal health care provider during the study and follow-up after your study participation has ended. We may need to ask you for your provider’s contact information if we do not have it already.

*Include the following when applicable for the research or if controlled substances are provided or prescribed to outpatients for future use (e.g., this is not required for IV therapy under in house observation):*

Do not leave the research drug where others can see or access them.  Do not share the study drug with anyone. Only you can directly request study medications or refills.

*Describe any washout period. You may edit the example below:*

As part of the study procedure, the medication you normally use for your condition will/may *(choose one option)* be stopped for up to \_\_\_\_ *(days/weeks/months).* You will/may *(choose one option*) receive no medication/medication at a dose to help your condition. Thus, you will/may *(choose one option)* have an increase in symptoms including \_\_\_\_\_\_\_ (i.e. for schizophrenia: agitation, hallucinations; for hypertension: high blood pressure, nausea, lightheadedness, etc.). (*Please include steps to monitor subjects as they undergo this washout period).*

**Does the research involve identifiable private information or identifiable specimens?**

*Include one of the following statements:*

We WILL collect your identifiable private information AND identifiable specimens.

We WILL collect your identifiable private information. We WILL NOT collect any identifiable specimens.

We WILL NOT collect your identifiable private information, but we WILL collect your identifiable specimens.

We WILL NOT collect any identifiable private information or identifiable specimens from you.

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

We will securely store your information <and specimens> with an identification linking code.  Only the researchers of this current study will have access to these materials and only they can use the code to link the materials back to you.

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

We 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). We would like your permission to share coded materials with other investigators. At the end of this consent, we will ask your permission to use or share your coded information (and coded specimens) for future research studies and provide more information about this. We will only use or share your coded material obtained from this current research if you provide your permission to do so. We 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, AS REQUIRED UNDER THE HIPAA REGULATIONS.**

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

*For studies involving genetic testing (or possible genetic testing) for diagnostic purposes (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 taken, 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 of 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, we 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.

Consider including the following statements if “research genetic testing” (i.e., not FDA approved or tested in a certified laboratory) is involved:

Research tests will not help make decisions about your health care. We will not provide you with any research results. Add, edit, or delete, as applicable: We do not provide genetic counseling for research tests. You can obtain professional genetic counseling if you wish.

*REMINDER: In the optional section of the consent form at the end of the form, include the option to request future contact to obtain or share information related to diagnostic genetic testing from a CLIA or New York State certified laboratory.*

**Which procedures are experimental?**

*Describe any experimental interventions or interactions.*

*Indicate whether research specimens are collected in addition to specimens collected for medical treatment.*

*Identify any procedures, drugs, biologics, or devices that are experimental and indicate they are experimental or not approved by the FDA. You may also indicate which procedures, drugs, biologics, or devices are for standard clinical care, if related to the research.*

**What are the possible risks and discomforts of the research?**

*Risks may be physical, psychological, social, legal and economic.*

*Describe any foreseeable risks and discomforts related to research participation.*

*Describe any foreseeable risks and discomforts related to any other individuals (e.g., radiation risk to family members that may be in close proximity to the participant after radiation exposure.)*

*Describe the risks for each procedure or drug clearly in lay terms. When possible, quantify and group the risks into categories such as expected, occasional, or rare and describe them as such. Quantify these categories - i.e., expected = more than 3 in 10, occasional = 1 in 10, rare = less than 1 in 20. Be sure to list ALL foreseeable risk (including side effects), no matter how rare.*

*It is usually best to present the risks in tabular format or as a bulleted list rather than as a paragraph.*

*Include any foreseeable risk to an unborn child (developing fetus), if a woman in the study (or a participant’s partner) is pregnant or becomes pregnant.*

*For studies involving possible reproductive risks, please include a section that includes the following:*

* *State any known risks in pregnancy, to either the mother, developing fetus, or child.*
* *State that there may be unforeseeable (unanticipated) risks to the participant (or to the embryo or developing fetus) if the participant is pregnant or becomes pregnant during the study.*
* *If relevant, include the required methods of birth control.*
* *Describe what action will occur in the event of pregnancy, e.g., follow-up of pregnancy outcome, immediate withdrawal from the study, etc.*
* *Describe if there is any effect on sperm count or the motility of sperm or other reproductive risks associated with fathering a child.*
* *Describe if there are any known risks to gametes.*
* *Include a statement that some risks may be unforeseeable.*

*Include any reproductive risks for BOTH male and female research participants.*

*If long-term safety studies (such as bench and animal testing) are not completed, explain that researchers have not completed studies that may identify potential risks, for example, whether the research article may cause cancer or birth defects.*

*Suggested wording for risk of blood draw (edit as needed):*

During the blood draw, you may experience some discomfort or pain at the where the needle enters the vein. There is small risk of fainting. Infection could occur; however, we will take all available precautions to prevent an infection by using sterile techniques.

*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.

There is a law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans, and most large employers 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. Insurance companies may use the information to evaluate whether a person can purchase a policy. An insurance carrier may request or require disclosure of your genetic test results.

*Suggested wording when usual care procedures are not part of the study:*

The risks of the usual care you receive while in this study are not risks of the research. Those risks are not included in this consent form. You may talk with your health care providers about the risks of usual care.

*You may add the following or similar statement when evaluating standard of care arms with clinical equipoise:*

The researchers believe that the risks and benefits of taking the standard of care options are the same. If you have any questions about the usual risk of care, please ask your care provider.

*If a repository is involved, describe the risk, such as:*

We protect your specimens and information as described in this form; however, there is a small likelihood of a breach of your privacy.

*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.

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

*Note: If there are any conflicts of interests, briefly describe this in the Key Information section on the first page of the consent, in addition to completing this section.*

*Describe any conflicts of interests (e.g., financial, leadership, ownership, etc.) or if none, state:*

The researchers do not have any financial relationships or interests in this research. There are no conflicts of interest.

*For sponsored studies, when there are no COI management plans for any significant financial interests, please consider adding the following or something similar:*

The Sponsor of this study is paying the study team and/or SUNY Downstate Medical Center and NYC Health & Hospital, Kings County for doing this study. The study doctors do not have any financial relationship with the sponsor. The Sponsor does not base the payments on the results of the study.

*Please inform the participant of any financial relationships or interests that are associated with the research, such as payments for services, equity interests or intellectual property rights. Include the source of funding and funding arrangements for the research, or information and management of any financial arrangement or interest (e.g., stock in the study sponsor, patent on the investigational product) of an institution or an investigator. When a potential or actual financial conflict exists, have another individual who does not have a potential or actual conflict of interest involved in the consent process, especially when a potential or actual conflict of interest could influence the tone, presentation, or type of information presented during the consent process or using independent monitoring of the consent process.*

*The financial conflict of interest (fCOI) committee reviews significant financial interests (SFI) and develops a management plan for the SFI. The fCOI committee or IRB may require a specific statement to the informed consent form. The PI can propose such a statement using the template below:*

Dr. \_\_\_\_\_\_\_\_, an investigator on this study at SUNY Downstate Medical Center, is receiving funding from \_\_\_\_\_\_\_\_\_\_\_\_\_\_. The outcome of this research study could be of interest to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. The Downstate’s Financial Conflict of Interest Committee oversees the conflict of interest policies. In accordance with these policies, Downstate has determined that Dr. \_\_\_\_\_\_\_\_\_\_ 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 information do you need to know about pregnancy?**

*Delete this section if not needed.*

*Provide any information regarding pregnancy testing and/or birth control requirements. If this information is not applicable, then omit this section from your consent form. If the protocol will enroll minors, the Assent Form must include information to inform the minor of pregnancy testing and if sharing results with parents/legal guardian. The PI may submit a separate assent form for pre- and post-menarche research participants.*

*Include the following language if you intend to collect information about the subject’s pregnancy or birth, please use the following language as applicable.*

**For Female Research Participants:**

*Delete this section if not needed.*

Immediately tell the study doctor if you think you might be pregnant.

If the pregnancy continues, we will discontinue the study drug (or list other applicable interventions) and we will ask you to complete follow-up research visits.

We would like to collect information about your pregnancy and your child’s birth, such as \_\_\_\_\_\_\_\_\_\_\_\_\_*. (For example, estimated gestational age, sex, weight, length, and Apgar scores of child).*

**For Male Research Participants:**

*Delete this section if not needed.*

*Note: If there are plans to collect information from partners of males that may get pregnant, please include the “Pregnancy Follow-Up Consent” with the IRB submission. A template is available on the Downstate IRB website.*

Immediately tell the study doctor if you think your partner might be pregnant. We would like to collect information about your child’s birth, such as \_\_\_\_\_\_\_\_\_\_\_\_\_*. (For example, estimated gestational age, sex, weight, length, and Apgar scores of child).*

Please let your partner know that she may volunteer to be in a follow-up study. The follow-up study is for the collection of information about her pregnancy. If your partner does not want to participate, it will not affect your or your partner’s or your child’s medical care or research participation in any way. Your partner may call Dr. \_\_\_\_\_ at \_\_\_\_\_\_\_\_\_\_\_\_\_ for more information.

**Optional Follow-Up Study:**

*Delete this section if not needed.*

If we need to access your child’s medical records for the research purposes, we may need to obtain a separate consent from you. This follow-up study of your child’s medical records is optional, and you do not have to agree to participate. This will not affect your or your partner’s or your child’s medical care, or research participation in any way.

**What are the possible benefits of being in the study?**

*Note: This section may be deleted if all the possible benefits are described in the key information on page 1; however, if keeping this section, be sure it is consistent with the key information section.*

There is no benefit to you for participating in the study.

*-OR-*

We cannot promise that you will get any benefits from taking part in this research study. However, possible benefits to others may include <describe>.

**Are there any alternatives to the research?**

*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.*>

**What information do we keep private and confidential?**

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

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

*Include if applicable:*

We will destroy your information <and your specimens> when the study is complete. We will not use the specimens or information for future studies; however, we 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:*

We 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*
* *a description of each purpose for which the PHI is to be used or disclosed*

*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.*

We 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 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: All entities must be listed to legally 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, we will stop collecting and accessing your PHI, but we 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.*

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:*

We 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.

*The Downstate Privacy Officer requires the following paragraph to use or disclose HIV-related information:*

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.

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

We 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. We 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:*

We will not give your genetic information to anyone unless you authorize it. We 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:*

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

*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)*.*

*The EU General Data Protection Regulation (GDPR), effective 25 May 2018, is a data privacy law applies to certain EU research, including the transfer of private data between countries. For assistance with determining whether the GDPR regulations apply to this study, please contact the Privacy Officer or OCAS or see:* [*https://www.eugdpr.org/*](https://www.eugdpr.org/) *or* [*https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN*](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN)

*If the EU General Data Protection Regulation (GDPR) is applicable to this study, please work with the sponsor, Privacy Officer, or 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.*

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

*Note: A Certificate of Confidentiality (CoC) does not prevent disclosure as required by federal, state, or local law when required for agency reporting, such as suspected child abuse or neglect, elder abuse, certain communicable diseases, reporting possible threats or harms, reporting required events to Food and Drug Administration (FDA) or Office of Human Research Protections (OHRP).*

*The NIH policy for issuing a CoC applies to NIH funded studies, including those commencing or are ongoing on or after 12/13/16. The intent of a CoC is to prohibit disclosure of sensitive, identifiable information in response to legal demands. The general applicability applies to any of the following types of NIH funded research:*

* *All human research (including exempt research) when individuals can be readily identified.*
* *Research involving identifiable biospecimens.*
* *Research that generates individual-level human genomic data from biospecimens, or the use of such data.*
* *When it is possible to deduce the identity of an individual from research that involves information about an individual.*

*NIH no longer provides a paper certificate for studies with NIH awards. The award itself is confirmation that CoC protections are in place. Researchers may still request a CoC for other research. 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/)

*Include the following language for studies with a CoC, otherwise delete:*

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.

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 HIM pursuant to a request that does not require patient authorization (e.g. court subpoena).

**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.*

*Include the following for all studies, involving more than minimal risk:*

Immediately call the study doctor if you experience an injury, adverse event, 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.

You do not give up any legal rights by signing this consent form, such as seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research.

*For* ***non-sponsored*** *research, include the following:*

No additional funds have been set aside to cover compensation for a potential study-related injury.

*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.*

**Who may you contact if you have any additional questions?**

|  |  |
| --- | --- |
| **questions about:** | **May be directed to:** |
| * The research * Research related injury * How to withdraw from a study | **ENTER NAME(S)**  **Telephone: (718) XXX-XXXX**  **Pager:** **(718) XXX-XXXX** |
| * Your rights * Privacy rights * Concerns to be directed to an institutional representative who is not part of this research study | **SUNY Downstate Medical Center**  **Institutional Review Board: (718) 613-8480** |

**Is participation in the research voluntary?**

Being in this study is voluntary. You may refuse to participate or discontinue your participation at any time in this study without penalty or loss of benefits to which you are otherwise entitled.

**Is a description of the clinical trial available on the ClinicalTrials.gov website?**

*Include the following statement verbatim for an “Applicable Clinical Trial”, as defined 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?**

*Edit as needed:*

Your participation in the research study may end 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 your study doctor’s instructions or adhere to the research requirements
* You do not take medication as instructed
* You do not keep appointments

*When appropriate, describe the consequences of a research participant’s decision to withdraw from a research study and the procedures for orderly termination of participation by the subject.*

*When withdrawal from a research study may adversely affect the participant, explain the recommended withdrawal procedures in order to ensure the participants’ safety and specifically state why they are important to their welfare and describe any potential adverse effects of premature termination of the research intervention.*

*If applicable, explain whether or how early withdraws impact future compensation or reimbursements.*

*When applicable describe the procedures for orderly termination of research participation.*

*Include statement about whether or not the investigator retains information obtained during active participation when a participant is withdrawn from a study. However, the researchers must retain information for an FDA regulated clinical investigation.*

**Are there additional costs to participate in the study?**

*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 non-patient care studies (e.g., surveys, etc.), use the following text:*

We do not bill for the costs of any of the procedures performed solely for the purpose of this research study.

*Bill research-related services appropriately (i.e. do not bill erroneously to a third party payer and instead bill to sponsor of the study or to an internal fund).  Investigators from other sites must comply with their institutional policies and federal regulations and may contact their institutional representatives with questions.*

*For clinical trials or studies involving patient care, use the text:*

We 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.

We 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 >

• <list other items>

• <list other items>

We offer medical services at the usual charge for treatments for a research injury.

We will bill for medical expenses for treatments for a research injury. We cannot pay for unfavorable outcomes such as lost wages or discomfort.

You may consult with the study team to explain the costs you may incur and if your insurance will pay.

**What additional information should I know?**

Describe the process for informing participants’ or their healthcare providers of the test results of incidental or secondary findings.

*Include the following text for research studies where knowledge of risk is limited (e.g., first use in humans, novel therapies, new molecular entities, complex studies with significant risk) or for international research studies:*

We 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. We will share any new information with you if it affects your ability to stay in the study.

*Include when applicable:*

The results of this research study may help clinicians make informed decisions about patients in the future. If you want the results of this research once completed, please talk to your research doctor.

*Add 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;*
  + *A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to research participants, and if so, under what conditions; or*
  + *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).*
  + *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>

*State the total amount participants will be compensated or reimbursed if they complete all study visits.*

*When research participants anticipate receipt of $600 compensation or more (not including travel reimbursements) during the calendar year the income must be reported to the IRS. The PI may use a third-party vendor process, such as a gift or credit card company, to provide funds to the participant and require the vendor to complete the mandatory IRS reporting requirements; however, when the RF is reporting to the IRS and paying funds, include the* ***“SUNY –RF Payment Form for Compensation for Research Participation”*** *AND include the following language in this consent:*

We will ask you to complete a form to receive payment(s) for participating in this study. See attached form for additional information.

*If the above described payment is 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, we 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 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.

|  |  |
| --- | --- |
| **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, we 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 we may have information that causes some emotional distress, but the benefits are that we may have information that could help you in your medical planning and decision-making.  If you allow us to contact you in the future, we 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 we think your family members could benefit from knowing genetic information about you during this research study, we 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. |

|  |  |
| --- | --- |
| **May we share your coded specimens (and coded information) for future research?**   * We 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 will therefore have access to the key to the code. The code to the materials will not be shared with other researchers doing future research, therefore, the researchers doing future research 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 past a period of ten (10) years explicitly state the retention period.* * Unless legally permissible or authorized, any new research cannot take place unless it is reviewed and approved by an institutional review board (IRB), which is responsible for protecting your rights and welfare. | |
| *\_\_\_\_\_ (initials)* | **Please initial, if you agree with the above. If you do not initial, we will not use your information <and specimens> for future research.**  If you initial this box to authorize use for future research, you have the right to later decide to withdraw this authorization. If you withdraw, we will stop using your information/ specimens for the future use, but we will use and report on the information/ specimens already collected before you withdraw to maintain the integrity of the study. |

|  |  |
| --- | --- |
| **May we 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. * We would provide additional information about the other research at the time of contact, as we may not know about it at this time. * This research <would / would not / may or may not> be related to this current research. | |
| *\_\_\_\_\_ (initials)* | **Please initial, if you agree to us contacting you after your participation in this research is over to invite you to consider other research studies.** |

|  |  |
| --- | --- |
| **Do you authorize the release of your medical information from another provider for use with this research?**  After your participation is complete, we may need to request your medical records from another healthcare provider. With your authorization, we will share a copy of this consent with your outside healthcare provider. However, when required, we 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. |

*Add the section below, if you are requesting approval to contact a secondary party or personal representative, for example to try to contact a participant that is lost to follow-up or to obtain information about them such as their death or current status.*

***NOTE: The PI MUST request a waiver of informed consent within the IRB application to collect contact information below.***

|  |
| --- |
| If we may contact your personal representative to obtain information about you, such as <describe>, please provide their contact information below.  **Please let your family member or friend know you are providing their information for this purpose.**  Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Address (if known): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Phone Number: (\_\_\_\_\_\_\_\_) \_\_\_\_\_\_\_\_\_\_- \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  E-Mail: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Relationship: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  *\_\_\_\_\_ (initials)* |

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

*Add or delete as applicable:*

**CONTACT INFORMATION:**

*Before signing this form, please provide your contact information:*

|  |  |
| --- | --- |
| Address:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Telephone:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (daytime)  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (evening)  Email Address (optional):  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Signatures**

*Instructions: Use only the required boxes based on the research and delete all others. Make minor edits as needed, depending on the exact nature of the study.*

Please read this consent form carefully. Ask any questions you have before you decide. The study doctor will answer your questions. Take your time. You may consult with your family, friends, or other professionals.

*Use the following boxes when enrolling only children (including neonates, wards). If the research includes recruitment of children who are Wards, be sure to include the Independent Consent Monitor signature box.*

|  |  |  |
| --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print the Name of the Child**  **(Under the age of 18 only)**  *Include if applicable for the research:*  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** |

*Add if recruiting children under the age of 13 when the above box is not used.*

|  |
| --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print the name of the child for whom you are providing permission to be in the study**  Check if the Child is a Ward.  *When enrolling a Ward, an Independent Consent Monitor must also sign this consent form below.* |

|  |  |  |
| --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print Name of Parent or Legal Guardian**  (Required when enrolling a child, under the age of 18)  Check:  Parent  Legal Guardian | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of Parent or Legal Guardian**  I have read this form and all my questions about the research have been answered to my satisfaction.  By signing, I acknowledge reading the consent and accept all of the above. I voluntarily permit the child named above to participate in this research study. | \_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |

*Use the following box when enrolling* ***children*** *(including neonates and wards) when a 2nd signature is required.*

***A 2nd signature is required for the following types of research:***

* *Research involving greater than minimal risk and no prospect of direct benefit to individual child participant, but likely to yield generalizable knowledge about their disorder or condition.*
* *Research involving greater than minimal risk and no prospect of direct benefit to the individual child participant and unlikely to yield generalizable knowledge; but which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children Note: This type of study may require additional approval by OHRP and/or FDA.*
* *Research involving enrollment of a child as a normal control.*
* *When required by a sponsor.*

|  |  |  |
| --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print Name of 2nd Parent or Legal Guardian (if applicable)**  Check:  Parent  Legal Guardian  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)**  I have read this form and all of my questions about the research have been answered to my satisfaction.  By signing, I acknowledge reading the consent and accept all the above. I voluntarily permit the child named above to participate in this research study. | \_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |

*In general, the IRB makes their determination as to whether parental consent is required for research depending on whether the research is about clinical procedures for which parents do not have to provide consent under NY state laws. For example, if the research involves clinical treatment for which parental consent is not required (e.g., HIV or STD treatment) then parental consent would not necessarily be required for the research.  However, if the research does not involve a clinical treatment (e.g., "survey" on HIV or STD), then either parental consent is required or the IRB could grant a waiver of parental consent along with requiring an independent monitor as an additional protection.*

*Use the following box when requesting a waiver of parental consent to enroll married, emancipated, or pregnant minor. Be sure to use include the signature box for the independent monitor as well.*

|  |  |  |
| --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print Name Minor**  Check type of minor:  Emancipated Minor\*  Married Minor  Pregnant Minor  Minor for Research Not Requiring Parental Consent  \*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**  I have read this form and all of my questions about the research have been answered to my satisfaction.  By signing, I acknowledge reading the consent and accept all the above. I voluntarily participate in this research study. | \_\_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |

*Use the following box when the research involves research about clinical procedures for which parents do not have to provide consent under NY state laws. For example, if the research involves clinical treatment for which parental consent is not required (e.g., HIV or STD treatment). An Independent Consent Monitor is not required for this type of research.*

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print Name of Minor**  Check:  Emancipated Minor\*  Married Minor  Pregnant Minor  Minor for Research Not Requiring Parental Consent  \*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. | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of Minor**  I have read this form and all of my questions about the research have been answered to my satisfaction.  By signing, I acknowledge reading the consent and accept all the above. I voluntarily participate in this research study. | \_\_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |

*Use the following box when enrolling a minor when requesting a waiver of parental consent (see above) or when enrolling Wards.*

*Note: When applicable, an Independent Consent Monitor may also serve as an impartial witness or an interpreter.*

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature 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**  I was present during the entire consent process. The person authorizing the research voluntarily provided their consent. The investigator answered all questions. The consent process was adequate, and the information accurately convened. | \_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |

*Use the following box when enrolling adults with capacity to provide consent.*

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print the Name of the Adult Research Participant**  (18 years of age or older) | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of the Adult Research Participant**  I have read this form and all my questions about this research have been answered to my satisfaction. I volunteer to participate in this research study. | \_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |

*Use the following boxes when obtaining surrogate consent for enrolling adults that are cognitively impaired:*

*Note: The informed consent process must comply with institutional policy. For research at Downstate, this includes Policy CONS-01. Only one person from the list below, from the class of highest in priority may authorize the research when persons in prior classes are not reasonably available. The surrogate must be willing and competent to act. The person who is designated may designate another person on the list to be surrogate, as long as no one in the class higher in priority objects. However, if one surrogate does not provide consent, the investigator must honor that decision and not seek consent from another surrogate on the list.*

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print Name of Surrogate and indicate your authority to sign:**  Healthcare Agent (legal guardian) with authority to provide consent to healthcare decisions  Guardian authorized to decide about health care, pursuant to Article 81 of the NYS Mental Hygiene law  Spouse or domestic partner (provided there is no legal separation)  Adult child (son or daughter)  Parent  Adult sibling (brother or sister)  Close adult friend (must be 18 years or older and present a signed statement of relationship to a patient/participant) | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of Surrogate**  I have read this form and all of my questions about the research have been answered to my satisfaction. By signing, I accept all the above and voluntarily authorize the research participant named above to participate in this research study, based on my understanding of his/her wishes and beliefs or the best interests of this person. | \_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |

*Add the “Interpreter” signature box when there are plans to enroll participants with Limited English Proficiency or when sign language is used. For more information see additional* [*IRB Guidance*](http://research.downstate.edu/irb/irb-policies.html) *on the “process” for obtaining legally effective informed consent and HIPAA Authorization. This is needed on the English version of the consent, regardless of whether it will be translated or if the “short-forms” will be used.*

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **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)**  I have provided interpreter services to convey all the information on this form to the person authorizing the research. I have assisted the investigator explaining the research study and have assisted in answering all questions to the satisfaction of the subject. I am satisfied that the research participant understands this information and is voluntarily participating in this study.  *May include, only for non-FDA regulated research:*  Check this box if the Interpretation took place over the phone by a translation service. ***FAX a copy of this form with Interpreter signature to the research team to (718) \_\_\_-\_\_\_\_\_.***  *May include, only for FDA regulated research:*  Check this box if the Interpretation took place over the phone by a translation service.***Mail the original source document with Interpreter signature to the research team.*** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |

*Use the following box for a* ***Witness*** *in the following situations:*

* *When obtaining consent/permission from research participants, parents/guardians, or personal representatives with* ***Limited English Proficiency****.*
* *When obtaining consent/permission from research participants, parents/guardians, or personal who understand English, but* ***cannot read English****.*
* *When obtaining permission from the personal representative of a* ***cognitively impaired adult****.*
* *A witness is recommended (not required) for clinical trials that involve* ***investigational drug, biologic, or device***

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print Name of Witness** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of Witness**  I was present (physically or by phone or video conference) during the entire consent process. The person authorizing the research voluntarily provided their consent. The investigator answered all questions. The consent process was adequate and the information accurately convened. | \_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |

*Use the following box for an* ***Impartial Witness*** *for a Clinical Trial that follows* ***GCP requirements*** *when enrolling non-English reading research participants.*

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print Name of Impartial Witness**  An impartial witness cannot be a member of the research team. | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of Impartial Witness**  I was present during the entire consent process. The person authorizing the research voluntarily provided their consent. The investigator answered all questions. The consent process was adequate, and the information accurately convened. | \_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |

*Always include:*

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print Name of Investigator Obtaining Informed Consent** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of Investigator Obtaining Informed Consent**  In addition to advising the person authorizing the research about any appropriate alternatives to research participation, I offered an opportunity to answer any questions and further explain the risks and discomforts associated with this research. | \_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |

*Add if applicable:*

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print Name of Investigator Obtaining Informed Consent** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of Investigator Obtaining Informed Consent from a Participant Who Regained Ability to Provide Consent**  I obtained informed consent from the research participant after he/she regained his/her ability to provide consent. In addition to advising the person authorizing the research about any appropriate alternatives to research participation, I offered an opportunity to answer any questions and further explain the risks and discomforts associated with this research. | \_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print Name of Investigator** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of Investigator**  The research participant did not regain capability to provide written informed consent. Surrogate consent continues. | \_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print Name of Investigator** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of Investigator**  The research participant was withdrawn from the study. | \_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |