|  |
| --- |
| **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 & AUTHORIZATION TO USE PROTECTED HEALTH INFORMATION****FOR PREGNANT INDIVIDUALS** |
| **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:*

|  |
| --- |
| * *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 for 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.*
* *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.***

**We are asking if you want to be in this sub-study for one of the following reasons:**

1. **You reported to the study team that you became pregnant while you were participating in the main research study. Your participation in the main study ended in order to minimize the unknown risk to a developing fetus.**
2. **Your partner reported to the study team that you became pregnant while he was participating in the main research study.**

**We are asking you to sign this consent in order for us to obtain the information about your pregnancy and its outcome from your medical and obstetric records.**

**The purpose of collecting information about your pregnancy and baby is to gather data that may eventually help determine whether <name of the investigational drug(s) or biologic(s)> has any harmful effects.**

***If it is conceivable that an investigator would need to obtain consent from a surrogate (legally authorized representative) for a cognitively impaired pregnant woman, add the following, otherwise delete this paragraph:* 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 this sub study.**

**This form describes some of the risks and discomforts of the study, including a potential loss of privacy. 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:**

* **The information that you provide may increase our scientific understanding and will help to provide information that may inform future patients.**
* **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.**
* **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 will happen to you if you decide to be in the study?***

If you sign this form, the study doctor and the study staff will collect information about your pregnancy and baby from you, from your partner, or from your medical records.

Information collected may include: *(include relevant information)*

* *last menstrual period,*
* *history/number of previous pregnancies and outcomes,*
* *medications taken during pregnancy,*
* *any medical complications experienced during pregnancy,*
* *any procedures during the pregnancy (lab tests, ultrasound),*
* *family history of any birth defects, genetic disorders, developmental disorders, pregnancy complications, spontaneous abortion and multiple births,*
* *the outcome of pregnancy, and how the baby is delivered,*
* *date of birth, status of baby at birth (length, weight, APGAR scores), and whether the baby is healthy or, if not healthy, what the health problem is,*
* *any of your partner’s relevant medical history such as familial birth defects, genetic or chromosomal disorders, or medication use, if available in your obstetric record*

*Edit as applicable:*

Information will be collected until childbirth *(every 3 months or up to 3 times in a full-term pregnancy)* or termination of the pregnancy.

*Edit as applicable:*

Your individual participation in the project will end approximately X days, weeks, months, years, etc.after the delivery of your baby.

*Edit as applicable:*

The main study and this sub study should to take place for approximately X years.

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

Agreeing to provide personal health information about yourself and about your baby may result in a loss of privacy, since persons other than the investigator(s) might view any records about you, or your pregnancy, or your baby. In order to protect the privacy of the study data, it will be sent to the sponsor with your study identification number. Other identifiers will not be provided.

**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.

**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 (e.g., surveys, etc.)*

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

**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 in the sub study.*

*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.

*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.

**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 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>.

**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 whenever 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).

**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.

***Will it cost me money to be in this study?***

You will not be charged or compensated for providing this medical information. This authorization form is simply to collect medical information related to your pregnancy and the outcome of your pregnancy. There are no tests, procedures or extra doctor visits involved. You or your insurance company will be responsible for payment of any costs resulting from your pregnancy or the birth of your child, as well as any other medical care that you might have in relation to your pregnancy, or the birth of your child.

**What additional information should I know?**

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.

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.*

We may contact your healthcare provider to obtain information about you or your baby. We may need to ask you to provide additional permission to obtain this information.

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

**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.

|  |  |  |
| --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Print the Name of the Pregnant Research Participant**  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Signature of the Pregnant 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 pregnant women 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.*

|  |
| --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Print the name of the pregnant woman for whom you are providing permission to be in the study** |

|  |  |  |
| --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**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.*

|  |  |  |
| --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**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***

|  |  |  |
| --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**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.*

|  |  |  |
| --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**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:*

|  |  |  |
| --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**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 there are plans to recruit cognitively impaired pregnant women:*

|  |  |  |
| --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**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** |

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

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