|  |
| --- |
| **SUNY DOWNSTATE HEALTH SCIENCES UNIVERSITY**  **& NYC Health + Hospitals, Kings County**  *(if not applicable, delete one of the above lines and the “&”)*  **BROOKLYN, NY 11203**  **Consent for Research Participation** |
| Title:  Researcher(s):  Researcher Contact Information:  Sponsor: |

**Key Information for You to Consider:**

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

Edit any of the following sections as applicable to the study:

|  |  |
| --- | --- |
| **What is the purpose of this research?** | We are asking if you want to be in this sub-study for one of the following reasons:   * 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. * 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. |
| **What will happen to you during 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. |
| **How long will you be in the research?** | Participation will take place for approximately X days, weeks, months, years, etc. |
| **Could being in this research harm you?** | 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. |
| **Will being in this study help you in any way?** | 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 costs to participate?** | Researchers do not foresee any additional costs to you for your participation in the research. |
| **How do researchers protect your information?** | Researchers will keep information about you in a secure location. Only those approved to have access will see your information. |

**Additional Detailed Information:**

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

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

*Add any additional risks not noted above. If none, delete this section.*

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

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

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

* You have questions about your rights as a research participant
* Your questions, concerns, or complaints are not being answered by the research team,
* You cannot reach the research team,
* You want to talk to someone besides the research team, or
* You want to get information or provide input about this research.

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

*CAUTION: THIS SECTION MUST BE COMPATIBLE WITH ANY OPTIONS ADDED FOR FUTURE RESEARCH AT THE END OF THE CONSENT FORM. See* [*All-In-One Consent Template*](http://research.downstate.edu/irb/irb-electronic-submissions.html) *for more details.*

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

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

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

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

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

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

*-OR-*

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

***CAUTION: WHEN THE OPTION IMMEDIATELY ABOVE THIS NOTE IS USED, YOU MUST INCLUDE THE OPTIONAL AUTHORIZATION FOR FUTURE USE AT THE END OF THE FORM.*** *See* [*All-In-One Consent Template*](http://research.downstate.edu/irb/irb-electronic-submissions.html) *for more details.*

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

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

*If genetic testing is done, please refer to* [*All-In-One Consent Template*](http://research.downstate.edu/irb/irb-electronic-submissions.html) *for more details.*

**How do researchers protect your information?**

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

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

*Include if applicable:*

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

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

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

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

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

*Provide the following:*

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

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

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

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

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

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

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

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

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

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

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

* The Institutional Review Board(s) that have oversight of this research.
* The research staff approved by the Institutional Review Board.
* Collaborating research sites, outside laboratories, cooperative study groups, or contracted research organizations that are approved by the Institutional Review Board
* The SUNY Downstate Medical Center and NYC Health +Hospitals/Kings County officials and other administrative staff who supervise the way research is done, such as auditors or monitors.
* The sponsor(s) of this study. (delete if not applicable)
* The Federal agencies that supervise the way research is conducted, such as the Department of Health and Human Services Office for Human Research Protections, the Food and Drug Administration*,* the National Institute of Health or other government agencies.
* The Data Safety Monitoring Board that reviews the safety of this study. (delete if not applicable)
* Your insurance companies. (delete if not applicable –this is only expected if a third-party payment is expected)

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

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

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

You have a right to refuse to sign this form. If you do not sign this form, your health care treatment, your enrollment for benefits, your payment for the health care outside of the study, and your health care benefits are not affected. However, you will not be able to participate in the research described in this consent form if you do not sign this form.

*Include if applicable:*

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

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

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

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

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

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

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

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

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

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

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

*Add the following when recruiting patients into a clinical trial involving an IND or IDE or when there is a Certificate of Confidentiality:*

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

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

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

*Note: There are additional requirements for authorizations for using PHI for marketing purposes, sale of PHI, or for the use or disclosure of psychotherapy notes. Contact the IRB or Privacy Officer for additional information or refer to* [*SUNY Downstate HIPAA (Health Insurance Portability and Accountability Act) Policies and Forms*](http://www.downstate.edu/hipaa/hipaa_policies.html)*.*

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

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

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

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

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

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

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

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

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

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

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

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

*Keep for all studies:*

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

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

**What additional information should I know?**

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

**Signatures:**

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

You will receive a signed copy of this document.

*If other types of signatures are anticipated (e.g., pregnant minor, parent or legal guardian, independent consent monitor, surrogate, interpreter, impartial witness, etc.), please see* [*All-In-One Consent Template*](http://research.downstate.edu/irb/irb-electronic-submissions.html) *for guidance.*

|  |  |  |
| --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print the Name of the Adult Research Participant**  (18 years of age or older) | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of the Adult Research Participant** | \_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print Name of Investigator Obtaining Informed Consent** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of Investigator Obtaining Informed Consent** | \_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |