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| **SUNY DOWNSTATE HEALTH SCIENCES UNIVERSITY**  **& NYC Health + Hospitals, Kings County**  **BROOKLYN, NY 11203**  **Pregnancy Follow-Up with HIPAA Authorization** |
| Title:  Researcher(s):  Researcher Contact Information:  Sponsor: |

*HELPFUL TIPS:*

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| * *This “SIMPLE” template does not include general guidance. Please refer to the “All-In-One” template for more detailed guidance, which is available in Step 8 at:* [*https://research.downstate.edu/irb/electronic-submission.html*](https://research.downstate.edu/irb/electronic-submission.html) * *Remove all guidance and instructional text before submitting to the IRB.* |

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

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

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

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

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

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

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

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 to minimize the unknown risk to a developing fetus .
* Your partner reported to the study team that you became pregnant while participating in the main research study.

We are asking you to sign this consent 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 happens if you decide to be in this study?**

Include a description of the procedures to be followed, and identification of any procedures that are experimental.

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

*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,
* whether the baby received care in a neonatal intensive care unit (NICU)
* race, ethnic group, geographic region, age range, gender identity, sex assigned at birth [specify demographic variables].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

*If clinical genetics testing is conducted, refer to the “All-In-One” template for more detailed guidance.*

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

Participation will take place for approximately X days, weeks, months, years, etc.

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

Describe any reasonably foreseeable risks or discomforts to the participant.

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.

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

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

No. Researchers do not foresee any additional costs to you for your participation in the research.

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

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

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

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

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

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

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

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

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

*Include the following HIPAA Authorization language when PHI is used or disclosed in the study:*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

*Always include:*

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

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

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

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

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

*Add if applicable:*

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

*Add if applicable:*

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

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

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

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

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

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

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

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

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

* Comply with a court ordered subpoena, ***[CAUTION: remove this bullet if there is a Certificate of Confidentiality (CoC) for this study, including any NIH funded studies which automatically have a CoC. CoC is described in the All-In-One template and should be included within this document when applicable to the research.]***
* Report suspected child abuse or neglect,
* Report certain communicable diseases,
* Report a possible threat or harm to yourself or others, or
* Comply with other laws.

*Include if applicable to the research:*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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**OPTIONAL RESEARCH:**

Delete if not applicable

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

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

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print Name of Research Participant** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of Research Participant** | \_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print Name of Investigator Obtaining Informed Consent** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of Investigator Obtaining Informed Consent** | \_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |