|  |
| --- |
| **SUNY DOWNSTATE MEDICAL CENTER**  **& NYC Health + Hospitals, Kings County**  *(if not applicable, delete one of the above lines and the “&”)*  **BROOKLYN, NY 11203**  **HIPAA RESEARCH AUTHORIZATION** |
| **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 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 HIPAA authorization language, as described in IRB-01 policy or information in the template below.*   + *Access to HIV result (see Privacy Officer required language in template below)*   + *Use of psychiatry notes (include a separate HIPAA Authorization –see template on IRB website)*   + *Disclosures of research involving video/audio recording or pictures or images (see recommended language in template below).*   + *Include all required signature lines (examples are provided at the end of this template as well as a description of when each is required based on federal and NY regulations)*   + *If the following information is not included in a companion consent/information sheet, be sure to include it within this form:*     - *Purpose of the use or disclosure of PHI*     - *Description of whether the research includes identifiable private information or identifiable specimens*     - *Optional consent/authorization for use of identifiable data or specimens for future research* * *Items in italics or red are general instructions which must be deleted (or changed when applicable) before submitting the final form to the IRB.* * *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)*.* * *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.* |

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

*Always include this section when there is no companion informed consent document that describes the purpose of the research (e.g., exempt research, IRB waives informed consent, journal requiring authorization for a case study, institution not engaged in human research, etc.). Omit this section when there is already a companion informed consent document or information sheet that describes the purpose of the study.*

*Briefly explain the purpose of the study and the reason for participation in lay terms.*

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

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

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

*If applicable, provide a list of exclusion criteria that may be relevant to potential participants, in order to make an informed decision regarding their participation in the study.*

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

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

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

*Always include this section when there is no companion informed consent document that describes whether identifiable private information or identifiable specimens are involved in the research (e.g., exempt research, IRB waives informed consent, journal requiring authorization for a case study, institution not engaged in human research, etc.). Omit this section when there is already a companion informed consent document or information sheet that describes whether identifiable private information or identifiable specimens are involved in the research.*

*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.**

**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 below <add description of the purpose for the use or disclosure>, 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 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 that 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.*

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

**OPTIONAL RESEARCH ACTIVITIES**

*Always include this section when there is no companion informed consent document that describes optional research activities (e.g., exempt research, IRB waives informed consent, journal requiring authorization for a case study, institution not engaged in human research, etc.). Omit this section when there is already a companion informed consent document or information sheet that describes 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 requesting approval to contact a secondary party or personal representative, for example to try to contact a participant that is lost to follow-up or to obtain information about them such as their death or current status.*

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

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

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

*Add or delete as applicable:*

**CONTACT INFORMATION:**

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

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

**Signatures**

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

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

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

|  |  |  |
| --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print the Name of the Child**  **(Under the age of 18 only)**  *Include if applicable for the research:*  Check if the Child is a Ward.  *When enrolling a Ward, an Independent Consent Monitor must sign this consent form below.* | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of the Child providing assent**  **(ages 13-17 only)** | \_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |

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

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

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

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

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

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

|  |  |  |
| --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print Name of 2nd Parent or Legal Guardian (if applicable)**  Check:  Parent  Legal Guardian  Not applicable because the 2nd parent/legal guardian is not reasonably available, deceased, unknown, or incompetent.  Not applicable because only one parent has legal responsibility for the care and custody of the child. | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of 2nd Parent or Legal Guardian (if applicable)**  I have read this form and all of my questions about the research have been answered to my satisfaction.  By signing, I acknowledge reading the consent and accept all the above. I voluntarily permit the child named above to participate in this research study. | \_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |

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

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

|  |  |  |
| --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print Name Minor**  Check type of minor:  Emancipated Minor\*  Married Minor  Pregnant Minor  Minor for Research Not Requiring Parental Consent  \*An emancipated minor is defined as either a person 16 years or older and living independently from his/ her parents or a minor who is a parent him/herself.  An Independent Consent Monitor must also sign this consent form below. | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of Minor**  I have read this form and all of my questions about the research have been answered to my satisfaction.  By signing, I acknowledge reading the consent and accept all the above. I voluntarily participate in this research study. | \_\_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |

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

|  |  |  |
| --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print Name of Minor**  Check:  Emancipated Minor\*  Married Minor  Pregnant Minor  Minor for Research Not Requiring Parental Consent  \*An emancipated minor is defined as either a person 16 years or older and living independently from his/ her parents or a minor who is a parent him/herself. | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of Minor**  I have read this form and all of my questions about the research have been answered to my satisfaction.  By signing, I acknowledge reading the consent and accept all the above. I voluntarily participate in this research study. | \_\_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |

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

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

|  |  |  |
| --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of Independent Consent Monitor**  (Required when enrolling a Minor without Parental Permission or when enrolling a Child who is a Ward)  An Independent Consent Monitor may not be a member of the research team. | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature of Independent Consent Monitor**  I was present during the entire consent process. The person authorizing the research voluntarily provided their consent. The investigator answered all questions. The consent process was adequate, and the information accurately convened. | \_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Date Signed** |

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

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

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

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

|  |
| --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print the name of the adult 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 applicable:*

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