**HIPAA Authorization**

|  |  |
| --- | --- |
| **Title of Study:** | Insert Title of Research StudyInsert Study Number |
| **Principal Investigator:** | Name of the Principal InvestigatorDepartment of Principal InvestigatorApplicable NYU School or CollegeAddressPhone Numbers |
| **Emergency Contact:** | Insert Emergency Contact Insert Phone Number/Pager, etc. |

***INSTRUCTIONS FOR PREPARING THE RESEARCH AUTHORIZATION FORM:***

***Please note that this shaded gray section is for instruction purposes only. Delete all of the text blocked in gray, when you are ready to prepare your Research Authorization Form. After you delete the instructions shaded in gray on the first and second page, the remaining pages of the document will shift up automatically. To enter the H# into the Header just click twice on the gray text. To exit the header, just click twice on the main text of the document.***

***As explained more fully in NYU Langone Health Investigator’s Guide, a covered entity may permit the use and disclosure of protected health information pursuant to a completed and signed Research Authorization form. This form will need to be carefully prepared by the Principal Investigator to ensure that the form covers all the uses and disclosure necessary for the research.***

***This form is required by all researchers with IRB approved studies that require consent. If you will be consenting subjects after April 14, 2003, you will need to complete this form and use it as an attached addendum with your current approved IRB consent document.***

***The document will be used with your existing approved IRB consent document and you will submit one copy to the IRB office to place on file***

***It is important to remember that each study participant will be required to sign and date the research authorization.***

***Additional Instructions:***

***Please note that if your study does not involve HIV related information you may delete the following text:***

***HIV-related information, which includes any information indicating that you have had an HIV-related test, or have HIV infection, HIV-related illness or AIDS, or any information which could indicate that you have been potentially exposed to HIV.***

***Notice Concerning HIV-Related Information***

***If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is prohibited from redisclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (212) 480-2493 or the New York City Commission of Human Rights at (212) 306-7450. These agencies are responsible for protecting your rights.***

***If you study does not have a sponsor or is not using a contract research organization, you can delete the bulleted information requesting this information.***

***If your study does not have any other possible recipients of protected health information, you may delete the bullet requesting this information.***

***IT IS THE RESPONSIBILITY OF THE RESEARCH STAFF TO ENSURE THAT THE COVERED ENTITY HAS ON FILE A WRITTEN ACKNOWLEDGMENT OF RECEIPT BY THE SUBJECT OF THE COVERED ENTITY’S NOTICE OF PRIVACY PRACTICES. IF THE SUBJECT HAS NOT ALREADY DONE SO, HE OR SHE MUST SIGN SUCH AN ACKNOWLEDGMENT BEFORE PARTICIPATING IN THE STUDY.***

***1. “Who may use and share information in connection with this study?” –Please note that the persons and organizations listed beside the bullets are not intended to be all-inclusive. If a person or organization is not included on the research authorization form, that person or organization may neither receive protected health information held by the hospital nor create or use protected health information on the hospital’s premises for research purposes, and that person or organization may be unable to disclose the protected health information to any other party.***

***2. “What information will be used or shared with others in connection with this study?” – Describe the protected health information in a way that allows both the prospective subject, and any person or organization that must disclose information pursuant to this authorization, to understand what records may be used or disclosed. For example, acceptable descriptions would be “laboratory results from July 2002,” “all laboratory results,” or “results of MRI performed in July 2002.”***

***Where to Direct Questions about This Form. Any questions about the Research Authorization form should be directed to the Director of the NYU Langone Health IRB at 212.263.4110.***

Federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study—in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

**What information may be used or shared with others in connection with this study?**

All information in your research record for this study may be used and shared with those individuals listed in this document. Additionally, information in your medical record that the research team believes may be important to the study may be accessed by those listed here. This includes, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, and diaries.

*[Note: Genetic testing, HIV results, substance abuse treatment and mental health records may require different consents or language under applicable law.]*

**Who may use and share information in connection with this study?**

The following individuals may use, share, or receive your information for this research study:

* The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
* The study sponsor: *[specify name(s) of study sponsors. Delete this item if an NYU Langone Health department is the only study sponsor]*
* Governmental agencies responsible for research oversight (e.g., the U. S. Food and Drug Administration or FDA).
* Health care providers, including your doctors and others who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.
* Other study sites involved in the research
* *[Specify other non-NYU Langone persons/entities as applicable, for example:*
* *Contract research organizations*
* *Central research laboratories*
* *Study related committees/boards/centers (Data & Safety Monitoring Board, Endpoint Committees, Clinical or Data Coordination Centers, etc.)]*
* *[If you are in a cancer study that receives federal funding, the National Cancer Institute (NCI) may require that we report some identifiable information about your participation. You may contact the NCI if you have questions about how this information is used.]*
* *[Specify the following if recruitment or other study activity occurs at NYC Health +Hospitals/Bellevue, etc.]*
* H+H personnel responsible for the support or oversight of the study at *[list Bellevue or other applicable H+H locations].*

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

**What if I do not want to give permission to use and share my information for this study?**

Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

**Can I change my mind and withdraw permission to use or share my information?**

Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

**How long may my information be used or shared?**

Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

This form provides that authorization and helps us make sure that you are properly informed of how this information will be used or disclosed. Please read the information below carefully before signing this form. If you have questions about this form you may contact the NYU Langone Health IRB at 212-263-4110.

|  |
| --- |
| **When you sign this form**, you authorize the use and/or disclosure of your protected health information described above. The purpose for the uses and disclosures you are authorizing is to conduct the research project explained to you to ensure that the information relating to that research is available to all parties who may need it for research purposes. Your information may also be used as necessary for your research-related treatment, to collect payment for your research-related treatment (when applicable), and to run the business operations of the hospital. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Name of Subject (Print) |  | Signature of Subject |  | Date |
|  |  |  |  |  |
| Name of Person Obtaining Authorization (Print) |  | Signature of Person Obtaining Authorization |  | Date |

***[The following sections provide signature blocks necessary for other types of research including:***

* *Studies where it is necessary to use an authorized subject representative*
* *Studies involving subjects who cannot read*

*Select or delete a given section and its signature block as applicable for your specific study.]*

***[For studies using authorized subject representatives:***

*Use the authorization signature line only for studies that are approved by the IRB to permit subject representatives to authorize a subject’s participation in research. Delete if not applicable.]*

For subjects unable to give authorization, the authorization to collect and use protected health information is given by the following authorized subject representative:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Name of Authorized Subject Representative (Print) |  | Signature of Authorized Subject Representative |  | Date |

Select the category that best describes the above Authorized Subject Representative:

[ ]  Court-appointed guardian

[ ]  Health care proxy

[ ]  Durable power of attorney

[ ]  Family member/next of kin; for this category describe relationship below:

**Witness to Consent of a Subject Who Cannot Read or Write**

Statement of Witness

I represent that the HIPAA Authorization was presented orally to the subject in the subject’s own language, that the subject was given the opportunity to ask questions, and that the subject has indicated his/her authorization by (check box that applies).

[ ]  Subject making his/her own “X” above in the subject signature line

[ ]  Subject showed approval for participation in another way; describe:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Name of Witness (Print) |  | Signature of Witness |  | Date |