SUNY DOWNSTATE Medical Center

# HOW TO COMPLETE THE HIPAA RESEARCH AUTHORIZATION FORM

The Research Authorization form will need to be carefully prepared by the Principal Investigator to ensure that the form covers the necessary uses and disclosures of protected health information (PHI). The person(s) preparing the Research Authorization form for the individual to sign must follow these instructions.

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

1. ***"Who will disclose, receive and/or use the information?"*** – Please list *every* person, class of persons or organization (including government agencies, companies, etc.) who might disclose, receive and/or use the information to which the form applies. Check the boxes on the form, as appropriate. *Please note, however, that the persons and organizations listed beside the boxes 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 not receive protected health information held by SUNY Downstate, create or use protected health information on the SUNY Downstate's premises for research purposes or disclose the protected health information to any other party.

2. ***"What information will be used or disclosed?"*** – 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."
Note that for any disclosure of HIV-related information for research purposes, the appropriate box must be checked and a description of the specific HIV-related information must be included. Recipients are prohibited from re-disclosing the information without the subject's authorization, unless permitted under state or federal law.

3. ***"What is the expiration date or event for this Research Authorization form?"***- The expiration date or event must related to the subject or the purpose of the use or disclosure. The statement "End of research study", "None" or similar language is sufficient if the authorization is for a use or disclosure of PHI for research, including for the creation and maintenance of a research database or research repository.

SUNY DOWNSTATE Medical Center

# RESEARCH AUTHORIZATION

*We understand that information about you and your health is personal and we are committed to protecting the privacy of that information. Because of this commitment, we must obtain your written authorization before we may use or disclose your protected health information for the research purposes described below. 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. A representative of SUNY Downstate is available to answer any questions regarding this authorization.*

Patient Name: _____ MR#: _____

Address: _____

_____

DOB: _____ Telephone#: _____ (Day) _____ (Eve)

1. **Who will disclose, receive and/or use the information?** The following person(s), class(es) of persons and/or organization(s) may disclose, use and receive the information, but they may only use and disclose the information to the other parties on this list, to the research subject or his/her personal representative or as required by law.

- ❑ Every research site for this study, including SUNY Downstate and each sites' research staff and medical staff
- ❑ Every health care provider who provides services to you in connection with this study
- ❑ Any laboratories, other individuals and organizations that analyze your health information in connection with this study in accordance with the study's protocol
- ❑ The following research sponsors: _____
- ❑ The United States Food and Drug Administration
- ❑ The members and staff of SUNY Downstate's affiliated Institutional Research Board/ Privacy Board
- ❑ Principal Investigator: _____
- ❑ Study Coordinator: _____
- ❑ Members of the Research Team: _____

  _____
- ❑ Members of the Research Foundation _____

  _____
- ❑ Contract Research Organization Name:

  _____
- ❑ Data Safety Monitoring Board/Clinical Events Committee
- ❑ Others (as described below):

  _____

  _____

  _____

  _____

2. **What information will be used or disclosed?** The appropriate boxes should be checked below and the descriptions should be in enough detail so that you (or any organization that must disclose information pursuant to this authorization) can understand what information may be used or disclosed.

- ❑ The entire research record and any medical records held by SUNY Downstate may be used and disclosed.

- ❑ 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.

- ❑ The following information:

_____

_____

_____

_____

3. **What is the expiration date or event for this Research Authorization form?** ____

_____

## SPECIFIC UNDERSTANDINGS

*By signing this research authorization 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 during the informed consent process and 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 SUNY Downstate.*
*This information may be re-disclosed if the recipient(s) described on this form is not required by law to protect the privacy of the information.*
*You have a right to refuse to sign this authorization. While your health care outside the study, the payment for your health care and your health care benefits will not be affected if you do not sign this form, you will not be able to participate in the research described in this authorization and will not receive treatment as a study participant if you do not sign this form.*
*If you sign this authorization, you will have the right to revoke it at any time, except to the extent that the hospital has already taken action based upon your authorization or needs the information to complete analysis and reports of data for this research. To revoke this authorization, please write to:*

*SUNY Downstate Medical Center*
*Research Foundation*
*450 Clarkson Ave.*
*Brooklyn, NY 11203*

*You have a right to see and copy the information described on this authorization form in accordance with our policies. You also have a right to receive a copy of this form after you have signed it.*

**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 re-disclosing 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) 870-8624 or the New York City Commission of Human Rights at (212) 566-5493. These agencies are responsible for protecting your rights.

By signing below, I acknowledge that I have read and accept all of the above.

_____ _____

Print Name of Patient Signature of Patient

_____

Date

If you are signing as a personal representative of the patient, read and sign below:

I, _____, hereby certify and attest that I am the duly authorized personal representative of _____ and that I have the lawful provisions set forth in this authorization and agree to the use and/or disclosure of the patient's information for the purposes set forth herein.

_____ _____

Print Name Signature

_____

Date

***THE SUBJECT OR HIS OR HER PERSONAL REPRESENTATIVE MUST BE PROVIDED WITH A COPY OF THIS FORM AFTER IT HAS BEEN SIGNED.***

**FOR SUNY DOWNSTATE USE ONLY:**

**Research Foundation Approval:** By signing below, I certify that this Research Authorization complies with SUNY Downstate's policy on *Uses and Disclosures for Research Purposes* and with the Health Insurance Portability and Accountability Act of 1996 and accompanying regulations.

_____ _____

Print Name of Research Foundation Administration Print Name of Principal Investigator

_____ _____

Signature of Research Foundation Administration Date