BROWN

THE BROWN UNIVERSITY
AUTHORIZATION TO USE
PROTECTED HEALTH INFORMATION (PHI) IN RESEARCH

Title of the Study:_____

Protocol Number:_____

Principal Investigator:_____

The Privacy Law, Health Insurance Portability & Accountability Act (HIPAA), protects individual identifiable health information also known as Protected Health Information, or "PHI." This law requires a signed authorization (or agreement) in order for researchers to be able to use your PHI for research purposes in this study. This authorization states how this information will be used and with whom it may be shared.

If you provide your permission and sign this form, you are allowing _____ to provide PHI about you from your medical record(s). The PHI may include several aspects of your medical records such as visit notes, dates and reasons of visits for medical treatment, x-rays, or other medical testing or laboratory results.

Your medical records may also include information regarding certain health issues, which require your specific permission for release. The following information will only be released with your permission. Please note **your initials** on the line next to each statement you agree with:

_____I agree to the release of information regarding drug and alcohol abuse, diagnosis or treatment.

_____I agree to the release of HIV/AIDS testing information.

_____I agree to the release of genetic testing information.

_____I agree to the release of information pertaining to mental health diagnosis or treatment.

Who may receive, use and share my PHI as part of this Study?

If you provide permission, Brown University Investigators and research staff will receive and use your PHI for this research study. The Brown University research team may also share your PHI with other researchers, the study sponsor or other staff or researchers involved in the design of the study, in order to perform the research. Other Brown University staff and faculty not involved in the study directly may be aware that you are participating in a research study and have access to your information as part of Brown's obligations to support and maintain required standards of the protection of research participants and compliance with regulations and policies.

These other staff and faculty may include:

- Members and staff of Brown University's Institutional Review Board (IRB), and staff associated with Human Research Protections Program (HRPP)
- Other staff associated with the Brown University Office of the Vice President for Research (OVPR)
- Brown University data safety/data security monitoring personnel
- Other Brown University offices as applicable

Your health information may also be shared with federal and state agencies that have oversight of the study or to whom access is required under the law. These may include the following:

- Food and Drug Administration
- Office for Human Research Protections
- National Institutes of Health

All Brown University research staff and other Brown staff mentioned above are obligated to protect your privacy and your personal information. Your PHI may be disclosed to other authorized entities or representatives outside of Brown University associated with the research study. Though such entities would also have safeguards in place to protect your information, Brown University cannot guarantee the confidentiality of your information for those entities.

Does my permission expire?

Your permission/this authorization will expire on_____, unless you change your mind before that date and cancel your permission in writing.

Can I cancel my permission?

You can cancel your permission at any time. If you would like to cancel your permission and prevent any further release of your PHI, please contact the study Investigator, _____ in writing, at [STATE: "email address", "mailing address".]

- Withdrawal of authorization will not affect treatment, payment or enrollment in any health plans or affect your eligibility for benefits.
- When you withdraw authorization, investigators may only use and disclose your PHI already collected for this research study.
- Withdrawal of authorization may also mean that you may not be allowed to continue to participate in the study.

What happens if I decide not to sign this authorization?

You have the right to refuse to sign this authorization. Your health care outside of the study, payment for your health care, and your health care benefits will not be affected if you choose not to sign this form.

You may not be able to take part in this study if you do not sign this form. If this is the case, the study team will let you know at the time this form is presented to you.

- If you sign this authorization, you may change your mind at any time. Researchers may continue to use information collected up until the time that you formally changed your mind. If you change your mind, your permission must be withdrawn in writing.

Contacts for Questions

If you have any questions relating to your privacy rights, please contact the Brown IRB /Human Subjects Research Protections Program (HRPP) at 401-8363-3050 or IRB@Brown.edu.

Signature

Signing your name below means you understand that you are allowing permission for the study to obtain, use, and share your Protected Health Information (PHI). You will be given a copy of this signed form.

Signature_____
(Subject or Legally Authorized Representative)

Print Name _____ Date_____ Time _____ AM/PM

_____ *(If legal representative, also print relationship to subject)*