Authorization to Use and Disclose Protected Health Information for Research

Principal Investigator ("**PI**"): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PI's Phone Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title of Study: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ("**Study**")

Institutional Review Board (IRB) #:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ University Health project #:\_\_\_\_\_\_\_

Privacy laws, including the Health Insurance Portability and Accountability Act ("HIPAA"), protect the use and disclosure of protected health information about you (“PHI”), and generally requires your permission to use and disclose your PHI for research purposes.

To participate in this Study, you must give the research team permission to collect PHI about you and use and share that information with others by signing this Authorization.

What protected health information about me may be used or shared for this Study?

*[Name or other identification of specific health care provider(s) or description of classes of persons, e.g., all doctors, all health care providers, research team]* (“Research Team”) at *[name of covered entity or entities]* will use and disclose your PHI, including the PHI they collect for the Study. It also includes information in your medical records such as:

*[Provide a description of information to be used or disclosed for the research project (e.g. all information in a medical record, results of physical examinations, medical history, lab tests, or certain health information indicating or relating to a particular condition)]*

PHI may include records relating to mental health care, communicable disease, HIV/AIDS, and/or treatment of alcohol/drug abuse.

How will protected health information about me be used for the research?

Protected health information about you will be used to:

*[Describe planned uses (e.g., conduct the study and perform the research, storing/using PHI for future research).]*

Who will receive the protected health information about me?

The health information listed above may be used by and/or disclosed for research, quality assurance, and data analysis to:

* Data coordinating centers that will receive and process PHI;
* Sponsors who want access to PHI or who will actually own the research data; and/or
* Institutional Review Boards or Data Safety and Monitoring Boards.
* *[List any and all additional persons to whom PHI may be disclosed (e.g. research collaborators, outside entity)]*.

The Research Team may also share protected health information about you with federal and state agencies that have oversight of the Study or to whom access is required under the law. These may include, but are not limited to:

* The Food and Drug Administration (“FDA”).
* Regulatory agencies in the U.S. and other countries.
* The Office for Human Research Protections.
* Public Health Authorities.

Once the Research Team discloses your protected health information as described in this Authorization, it may no longer be protected by HIPAA and other privacy laws and recipients could possibly use or re-disclose it in ways other than those listed here.

Will I be able to see my Study records?

You have a right to see and make copies of the protected health information collected about you for the Study. However, by signing this Authorization you agree that you may not be able to see or copy this information until the sponsor has completed all work related to this Study.

When does this Authorization to use my protected health information expire?

This authorization will not expire unless you change your mind and withdraw it in writing. There is no set date at which your information will be destroyed or no longer used.

Am I required to sign this Authorization?

No. However, if you choose not to sign this Authorization, you may not take part in this Study. If you decide not to authorize the use and disclosure of your PHI for the Study, your decision will have no impact on your ability to receive care at University Health and will have no impact on any other benefits to which you would otherwise be entitled.

Can I change my mind about giving permission to use my protected health information?

You may change your mind at any time. If you take back your permission, the Research Team may still keep and use any patient information about you that they already have. But they can’t obtain more health information about you for this research unless it is required by a federal agency that is monitoring the research.

To withdraw your permission, you must write to Barbara Zubeck, Chief Compliance Officer, at barbara.zubeck@uhkc.org, stating that you are withdrawing this Authorization.

Who can answer any additional questions that I have?

If you have any questions relating to your rights under HIPAA and other applicable privacy laws, please contact barbara.zubeck@uhkc.org. If you have any questions relating to the Study, please contact the PI.

By signing this form, you agree that your research-related health information can be used and shared as described above. You will receive a copy of this Authorization after you have signed it.

|  |  |
| --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature of participant or participant's personal representative | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Printed name of participant or participant's personal representative\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature of minor child’s assent to participate | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_If applicable, a description of the personal representative's authority to sign for the participant\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date |