# Model Language for (HIPAA) Privacy Rule Authorization for Research Use of Protected Health Information

8/30/18

The following language may be embedded in the body of the consent form, or may be used as the basis of a free-standing form, separate from the research consent form.

**HIPAA Authorization: For Use of Protected Health Information for Research Purposes**

**What are the HIPAA Privacy Rule and PHI?**

The federal government has created a “Privacy Rule” under the Health Insurance Portability and Accountability Act (HIPAA). This Rule gives you the right to decide who can use and release your individually identifiable health information (also called “protected health information” or “PHI”) for the purpose of research.

PHI is health information about you that could be linked to your identity. This may include information about illness such as AIDs, treatment for alcohol and/or drug abuse, or mental health or psychiatric services.

This section, called an “authorization,” explains your rights under the Privacy Rule and how your PHI might be used and released to conduct this research study.

**Why do the researchers want to use your PHI?**

The purposes of using and releasing your PHI are to: 1) collect the information needed to complete this research study, 2) monitor (watch) the study to make sure it is done properly, and 3) answer research questions related to this study. By signing this document, you are authorizing your health care providers, the principal investigator and members of the research team to use and release your PHI for these purposes.

**What PHI do the researchers want to use or release?**

The following information may be used and/or released in order to perform this study:

* Information from your medical record, including information about your general health, the status of any disease, and the medical care provided to you;
* The results of laboratory and other tests;
* Information related to tissue and/or blood samples that have been collected from you; and
* Information that could identify you such as your name and medical record number.

*Researcher: Include information that applies specifically to this study.*

**Who may receive your PHI?**

Your PHI may be released to:

* The PI, co-investigators and study staff working on this project at UH with access;
* Researchers at other institutions that are collaborating on this project;
* Central laboratories that process tests performed under this study;
* The data coordinating center, and data and safety monitoring board ;

*Researcher: For the items above, list the specific names and/or roles of the individuals with access to PHI. Similarly, include the name of the laboratories or coordinating centers with access as well.*

* Government agencies that have oversight over this research such as the Department of Health and Human Services (DHHS);
* The sponsor of this study and their agents or designees;
* The University of Hawaii Human Studies Program and Institutional Review Boards (IRBs) at hospitals taking part in this study to make sure that your rights are protected.

*Researcher: Include information that applies specifically to this study.*

**Will your PHI be kept private?**

There is a possibility that your PHI may be released again by an entity that receives it. If your PHI is released by them to a 3rd party, the HIPAA Privacy Rule may no longer apply, and your PHI may no longer be protected by it.

The researchers and all others working as part of this study will keep all of your personal information private as required by law.

*Researcher: Insert specific steps that will be taken to minimize disclosure of PHI; for example, “As part of this study, participants will not be identified by name, and your social security number (other unique identifiers?) will not be recorded or released.”*

**What happens if you do not sign this authorization?**

Signing this authorization form is voluntary. If you do not sign this form, you will not be able to take part in this research study. This choice will not make a difference in your usual treatment or payments, and it will not affect your eligibility for health care or health benefits.

**What happens if you want to revoke your authorization?**

If you sign this form and enter the research study, you are free to change your mind and revoke (take away) your authorization at any time. To revoke your authorization, you must make this request in writing to the Principal Investigator at the address listed on page 1 of this form.

Beginning on the date you take away your authorization, no new PHI will be used or released for this research study. The Privacy Rule allows researchers to continue to use information that has already been collected. Under certain circumstances, your health care provider(s) may release additional PHI to the researchers. For example, if an adverse event (a bad side effect) related to the study is found, the researchers may need to review your medical record.

**How long will this authorization last?**

If you authorize the researchers to use your PHI, this authorization has no expiration date.

*Researcher: Include the date or event [e.g., end of this study] as applicable.*

**What are your rights to access your personal health information?**

You may see the information in your medical record. However, the information collected or developed under this study is kept separately, and it will not be available to you until the study is finished. If you wish to review your study records after the study is over, you should ask this from the researcher.

**Authorization to Use and Release Your Protected Health Information**

My signature below indicates that I have read this authorization form and that my questions have been satisfactorily answered. I understand that if, at any time, I have other questions, I can contact the Principal Investigator named on page 1 of this form. I further understand that I will be given a copy of this signed authorization form for my records.