**DO NOT DELETE OR ALTER ANY PART OF THIS FORM**

|  |  |
| --- | --- |
| **Principal Investigator:** | [REQUIRED FIELD] |
| **Study Title:** | [REQUIRED FIELD] |
| **IRB #:** |  |

|  |
| --- |
| **ADDENDUM: HIPAA AUTHORIZATION** |

**Instructions:**

* Read the guidance provided below before answering the questions.
* Do not leave questions/required fields blank; write or check "**N/A**" if not applicable.

**Guidance:**

* **HIPAA:** The Health Insurance Portability and Accountability Act (HIPAA) is a complex regulation that affects many researchers at the Washington State University.

The HIPAA Privacy Rule protects most “individually identifiable health information” held or transmitted by a covered entity or its business associate, in any form or medium, whether electronic, on paper, or oral. The Privacy Rule calls this information protected health information (PHI).

* **Protected health information is information which relates to:**
* The individual’s past, present, or future physical or mental health or condition;
* The provision of health care to the individual; or
* The past, present, or future payment for the provision of health care to the individual, and that identifies the individual or for which there is a reasonable basis to believe can be used to identify the individual. Protected health information includes many common identifiers (e.g., name, address, birth date, social security number) when they can be associated with the health information listed above.

[Protected Health Information](https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html#protected) is defined as any of the 18 HIPAA recognized identifiers **in combination with** health information.

* **HIPAA recognized identifiers:**
* Names
* All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geocodes, except for the initial three digits of the ZIP code if, according to the current publicly available data from the Bureau of the Census:
* The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; and
* The initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people is changed to 000
* All elements of dates (except year) for dates that are directly related to an individual, including birth date, admission date, discharge date, death date, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
* Telephone numbers
* Fax numbers
* Device identifiers and serial numbers
* Email addresses
* Web Universal Resource Locators (URLs)
* Internet Protocol (IP) addresses
* Social security numbers
* Medical record numbers
* Biometric identifiers, including finger and voice prints
* Health plan beneficiary numbers
* Full-face photographs and any comparable images
* Account numbers
* Certificate/license numbers
* Vehicle identifiers and serial numbers, including license plate numbers
* Any other unique identifying number, characteristic, or code

|  |
| --- |
| **SECTION 1.**  **REQUESTING HIPPA AUTHORIZATION** |

1. **Is this research requesting HIPPA authorization?**

**No**

**Yes**

***If yes****,* ***complete (a-f).***

1. **Please indicate which HIPAA recognized identifiers will be collected:**

**Names**

**Addresses/geographic subdivisions**

**Elements of dates**

**Telephone numbers**

**Fax numbers**

**Device identifiers and/or serial numbers**

**Email addresses**

**Web Universal Resource Locators (URLs)**

**Internet Protocol (IP) addresses**

**Social security numbers**

**Medical record numbers**

**Biometric identifiers**

**Health plan beneficiary numbers**

**Full-face photographs and/or any comparable images**

**Account numbers**

**Certificate/license numbers**

**Vehicle identifiers and/or serial numbers**

**Any other unique identifier (*please specify)*:** [Required field]

1. **Name of entity providing PHI:** [Required field]
2. **Describe how the PHI will be used and how access to PHI will further the research aims:** [Required field]
3. **If participant samples/data are received from a source outside of WSU, will you send results back to the provider(s) or entity(ies)? *(select one)***

**N/A**

**No, I will not send results back to the provider(s) or entity(ies)**

**Yes, I will send aggregate results to the provider(s) or entity(ies).**

**Yes, I will send results to the provider(s) that are linked to identifiable individuals.**

1. **Does the provider or entity intend to link your data to identifiable individuals?**

**N/A**

**No**

**Yes**

|  |
| --- |
| **SECTION 2. INVESTIGATOR’S RESPONSIBILITIES AND ASSURANCES** |

**By signing bellow, you agree to the to the following:**

* I am providing written assurance that the information is essential to the research and access to the information will be limited to the greatest extent possible, allowable under the Privacy Regulations.

**Name:** [REQUIRED FIELD]

**Date:** [REQUIRED FIELD]

**Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

*It is important that you understand that you could face criminal and/or civil liabilities for noncompliance. Please use the template below for your research. Information in the authorization should* ***not*** *conflict with the consent form.*

****

Human Research Protection Program (HRPP) - Office of Research Assurances

PO Box 643143 Neil Hall 427 Pullman, WA 99164-3143

Telephone: (509)335-7646 Email: [irb@wsu.edu](mailto:irb@wsu.edu) Web site: [www.irb.wsu.edu](http://www.irb.wsu.edu)

|  |  |
| --- | --- |
| **Principal Investigator:** | [REQUIRED FIELD] |
| **Study Title:** | [REQUIRED FIELD] |
| **IRB #:** |  |

|  |
| --- |
| **HIPAA AUTHORIZATION FORM** |

**By signing bellow, you agree to the to the following:**

By law, researchers must protect the privacy of health information about you. In this form the word “you” means both the person who takes part in the research and the person who gives permission for another person to be in the research. Researchers may use, create, or share your health information for research only if you let them. This form describes what researchers will do with your information. Please read it carefully. If you agree with it, please sign your name at the bottom. You will get a copy of this form after you have signed it.

If you sign this form, information will be shared with the people who conduct the research. In this form, all these people together are called “researchers.” Their names will appear on the research consent form that you sign.

The researchers will use the health information only for the purposes named in this form as described below:

1. **What “health information” includes:**

* All information about you that is collected during the research study. This might include the results of tests or exams that become part of the study records; diaries and questionnaires that you might be asked to fill out as part of the study and other records from the study.
* All health information in your medical records that is needed for this research study. These might include the results of physical exams, blood tests, x-rays, diagnostic and medical procedures and your medical history.

1. **What the researchers may do with health information:**

* The researchers may use and create health information about you for the study.
* They may also share your health information with certain people and groups. These may include:
* The sponsor of the study and its representatives
* Government agencies, review boards, and others who watch over the safety, effectiveness, and conduct of the research.
* Other researchers when a review board approves the sharing of the health information.
* Your health insurer if they are paying for care provided as part of the research study.
* Others, if the law requires.
* **The listed sponsors are identified as:** [REQUIRED FIELD]

1. **Removing your name from health information:**

* The researchers may remove your name (and other information that could identify you) from your health information. No one would know the information was yours.
* If your name is removed, the information may be used, created, and shared by the researchers and sponsor as the law allows. (This includes other research purposes.) This form would no longer limit the way the researchers use, create, and share the information.

1. **How the researchers protect health information:**

* The listed researchers will follow the limits in this form. If they publish the research, they will not identify you unless you allow it in writing. These limitations continue even if you take back this permission.
* **The listed researchers are identified as:** [REQUIRED FIELD]

1. **After the researchers learn health information:**

* The limits in this form come from a federal law called the Health Insurance Portability and Accountability Act. This law applies to your doctors and other health care providers.
* Once the researchers get your health information, this law may no longer apply. However, other privacy protections will still apply.

1. **Storing your health information:**

* Your health information may be added to a database or data repository. This permission will end when the database or data repository is destroyed.
* You do not have to sign this permission (“authorization”) form. If you do not, you may not be allowed to join the study. You may change your mind and take back your permission at any time.
* **To take back your permission, contact the study manager (name, contact method):** [REQUIRED FIELD]
* If you do this, you may no longer be allowed to be in the study. The researchers will keep any information in the study record they already collected.
* Your authorization will expire when the goals of the study have been met.
* **The listed research goals are identified as:** [REQUIRED FIELD]
* During the study, you will not be allowed to see your health information that the researchers may place in your medical record. After the study is finished, you may see this information.

1. **Signature:**

* If I have not already received a copy of the Privacy Notice, I may request one. If I have any questions or concerns about my privacy rights, I should contact the WSU IRB at: [irb@wsu.edu](mailto:irb@wsu.edu).
* I am the subject or am authorized to act on behalf of the subject. I have read this information, and I will receive a copy of this form after it is signed.
* I agree to the use, creation, and sharing of my health information for purposes of this research study

**Research subject/legal representative name:** [REQUIRED FIELD]

**Relationship to subject:** [REQUIRED FIELD

**Date:** [REQUIRED FIELD]

**Signature (required): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**PI name:** [REQUIRED FIELD]

**Date:** [REQUIRED FIELD]

**Signature (required): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**