**HIPAA Waiver of Research Authorization Form**

|  |  |  |  |
| --- | --- | --- | --- |
| **Principal Investigator:** | Click or tap here to enter text. | **WVU Protocol Number:** | Click or tap here to enter text. |
| **Protocol Title:** | Click or tap here to enter text. | | |

**Disclosure or Use of Information**

|  |  |  |  |
| --- | --- | --- | --- |
| **It is the responsibility of the Principal Investigator to ensure that West Virginia University, as required, has on file a written account of all records accessed under this waiver of research authorization.** *Note: Disclosure means the release, transfer, provision of access to, or divulging information, in any manner, outside the entity holding the information.* | | | |
| 1. **What entity will disclose the information? Who will receive the information and how will it be used?** | | | |
| Click or tap here to enter text. | | | |
| 1. **List all variables that will be recorded for the purposes of research (i.e. blood pressure, weight, age, etc.).** | | | |
| Click or tap here to enter text. | | | |
| 1. **Will HIPAA identifiers only be viewed, and not recorded, as part of this research?**  **Yes**  **No** 2. **If no, what Private Health Information (PHI) will be viewed, used, or disclosed? Please select all that apply.** | | | |
| |  |  | | --- | --- | | Name | Geographic information smaller than state (i.e. zip code) | | Phone Number | Email Address | | Fax Number | Social Security Number (SSN) | | Health plan beneficiary numbers | Medical Record Number (MRN) | | Certificate/license numbers | Vehicle Identifiers and Serial Numbers | | Device Identifiers | Web Universal Resource Locators (URLs) | | Internet Protocol (IP) address numbers | Biometric identifiers, including finger and voice prints | | Account Number | Full Face photographic images and any comparable | | Other identifying number, characteristic, or code | Other (Please Describe): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | Elements of dates (except year) directly related to an  individual, including birth date, admission date, discharge  date, date of death; 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 | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Note: A unique identifying number, characteristic, or code does not mean the unique code assigned by the investigator to code the data. | | | | |
| 1. **Will the protocol involve any of the following?** | | | |
|  | Mental Health Information  Alcohol/Drug Treatment |  | Reportable Infectious Disease Information  Genetic Testing |
| 1. **Who will have access to, or use of, the PHI?** | | | |
| Click or tap here to enter text. | | | |
| 1. **How will the PHI be used or disclosed for the purposes of the research protocol (i.e. recruitment of subjects)?** | | | |
| Click or tap here to enter text. | | | |
| 1. **Please describe the data security measures that will be used to protect the PHI:** | | | |
| Click or tap here to enter text. | | | |
| 1. **When and how do you plan to destroy the PHI?** | | | |
| Click or tap here to enter text. | | | |
| 1. **Why would the research be impracticable without the waiver of research authorization?** | | | |
| Click or tap here to enter text. | | | |
| 1. **Indicate what will determine the termination of this waiver:**   Study termination  Specific Date: Click or tap to enter a date.  Other: Describe the circumstances that will determine the end date of this waiver. | | | |

**Statement of the Investigator**

*With respect to the waiver, you are only allowed to review the relevant minimum necessary information required in order to complete the study. For an IRB to approve a waiver of HIPAA authorization for research, it must determine that the following criteria have been met as required by 45 CFR 164.512(i). Please check all applicable criteria given below:*

The use or disclosure of the PHI involves no more than minimum risk to the privacy of individuals, based on, at least, the presence of all the following elements:

An adequate plan to protect the identifiers from improper use and disclosure.

An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of research unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted by the HIPAA Privacy Rule.

The research could not practicably be conducted without the Waiver of Research Authorization.

The research could not practicably be conducted without access to and use of the PHI.

***Note*:** *If an IRB determines that all criteria are not met, the IRB cannot approve the waiver.*

|  |  |
| --- | --- |
|  | **Investigator Certification**  By selecting this box, the investigator agrees that the Request for Waiver of Research Authorization meets with all the above given criteria and affirms that the information given in this request is accurate to the best of his/her knowledge. The investigator agrees to abide by the terms presented in the above given information. |

|  |
| --- |
| **HSC ITS Data Protection Notice** |
| It is recommended that you contact the HSC ITS department (304-293-3631) regarding confidentiality and security of the data. Per HSC ITS, all data containing PHI, PII or other confidential/sensitive/controlled data must be stored and processed using an approved WVU HSC managed network server or an approved WVU cloud location.  WVU desktop computers, mobile devices (laptops, usb drives, iOS and Android devices), online survey tools (qualtrics) and cloud storage (OneDrive, Google Drive, Dropbox, Box, iCloud, etc.) are not approved systems for storage of data that is sensitive or data requiring compliance controls such as NIST, HIPAA, FISMA protected data.  Please work with HSC ITS on an approved data storage location for all controlled data.  Depending on storage and processing needs, internal fees may apply to support projects. |