**Request for Alteration/Waiver of HIPAA Authorization Form**

This form is to request an alteration or waiver of Authorization to use and/or disclose Protected Health Information (PHI)

|  |  |
| --- | --- |
| **Principal Investigator:** | Enter name |
| **IRB Protocol Number** | IRB will insert |
| **Project Title** | *Enter title* |

***Under the federal HIPAA privacy rule, research use or disclosure of an individual’s protected health information (PHI) requires the individual/s authorization unless the IRB determines the use or discloser qualifies for a waiver.***

**Requesting a partial waiver of HIPAA (pre-screening/recruitment)**

**Requesting a full waiver of HIPAA between dates:**

Click her to enter a date and Click here to enter a date

* **Indicate the identifiers for which you are seeking a waiver of Authorization:**

|  |  |
| --- | --- |
| Name | Account Number |
| Address *(e.g.: Zip-code, other geographical designation, etc.)* | Certificate/license number |
| Dates related to an individual *(e.g., Date of admission, birth, surgery, etc.)* | Any vehicle or devise serial |
| Telephone Number | Device identifiers or serial numbers |
| Fax number | Web URL |
| Email address | Internet protocol (IP) address |
| Social security number | Finger or voice prints |
| Medical record number | Photographic images |
| Health plan beneficiary number | Other: *Enter here any characteristic that would uniquely identify the individua*l |

* **Under the federal regulations, the investigator may obtain only the minimum necessary PHI to achieve the goals of the research.**
* Is the PHI described in the previous question the minimum necessary to achieve the goals of the research

Yes  No – *please explain here*

* Describe why patient identifying information is needed to complete this research.

Click here to enter text.

1. **The use or disclosure of the protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:**
2. Provide a plan to protect the identifiers from improper use and disclosure.

Identifiable information will **not** be used or disclosed by anyone other than the research team.

Identifiable information will be used or disclosed to: Click here to enter text.

* Detail how this will be accomplished including limitations of physical or electronic access to the information and other protections.

Click here to enter text.

Confidentiality agreements with study staff.

Policies and procedures relating to privacy and confidentiality.

Initial and continuing staff education on the HIPAA Privacy & Security Rule and/or subject privacy and confidentiality.

Other: *please explain here.*

1. **Identifiers must be destroyed at the earlies opportunity. When and how will identifiers of subjects be destroyed?**

Identifiers will be destroyed with the study records, as defined by federal, state laws and regulations, as well as, institutional policy.

Identifiers will be destroyed after health information has been collected for the study and a code (containing no HIPAA Identifiers or derivative(s) thereof) has been assigned to the study data.

Identifiers will not be destroyed. *Provide a health, research, and/or regulatory/legal justiction for retaining the identifiers as well as a timeframe here*

Other: *please explain here*

* Describe how long identifiers will be kept for in relations to study length and data collection and analysis.

Click here to enter text.

1. **What steps have been taken to ensure that the PHI will not be reused or disclosed to any other person or entity?**

Limited access to only individuals who need to know the information

Electronic safeguards where only study staff has access to electronic study information.

*Insert description of the electronic safeguards in place (e.g., password protections, data encryption, firewall, etc.*

Physical safeguards where only study staff has access to areas with study information.

*Insert description of the physical safeguards in place (e.g., locked cabinets, locked filing room, security system, etc. her)*

Other: *please explain here*

1. **Describe why the research could not be completed without the waiver or alteration.**

*Practicability (feasibility) should not be determined solely by considerations of convenience, cost, or speed.*

Scientific validity would be compromised if Authorization is required.

Sample size is so large that including only those samples/records/data for which Authorization can be obtained would prohibit conclusions to be drawn or bias the sample such that conclusions would be skewed.

Subjects for whom records will be reviewed will not be available to come to the study site to sign an Authorization.

Subjects for whom records will be reviewed are no longer being followed and/or are lost to follow-up.

Ethical concerns would be raised if Authorization is required.

A possibility exists of creating additional risks to privacy by linking otherwise de-identified data with nominal identifiers in order to contact individuals to seek Authorization.

A risk exists of inflicting psychological, social, or other harm by contacting individuals or families.

Study related to completed care only.

Other: Click or tap here to enter text.

* Please describe and provide additional details or supporting information.

Click here to enter text.

1. **Describe why the study could not be completed without access to and the use of the protected health information**.

Click here to enter text.

* **Do you plan to use the waiver from the CU IRB to justify disclosure or use of PHI from a non-CU covered entity?**

Yes  No

If yes,

* **What covered entity or entities will disclose or use the PHI:**

Click here to enter text.

* **What PHI will the entity or entities disclose or use?**

Click to enter text.

*If the IRB approves this request for waiver, the PI can forward the IRB-issued waiver to the non CU covered entity as documentation of the waiver of authorization for the disclosure of PHI to CU. Please note the entity may or may not accept the IRB’s waiver and may request an additional review.*

**I attest that protected health information (PHI) collected for purposes of this research study will not be reused or disclosed to any other person or entity, except (i) as required by law, (ii) for authorized oversight of the research study, or (iii) other research for which a waiver of HIPAA Authorization has been obtained or as otherwise permitted under 45 CFR 164.512.**

*Attach this form to the* [*Initial/New Protocol Electronic Applications Form*](https://cphsadmin.wufoo.com/forms/zkthc20k1gury/)*.*