**Purpose:** This appendix is designed to provide information to the IRB when using Protected Health Information (PHI).

**Instructions:** Complete and attach this supplement to your research plan if (a) you are **conducting** research at a HIPAA covered institution, or (b) a HIPAA covered entity or if you will be **accessing** “Protected Health Information.”

* This appendix is a part of the Research Plan and must be included with each Research Plan submission.
* Respond to every question on this form. Incomplete forms will be returned and will result in a delay of your project being reviewed.
* Save this form to your computer before proceeding.

|  |
| --- |
| **Part 1: General Information** |
| Principal Investigator (PI): | Name | Version Date: | Enter date |
| Student Name: | Name | Protocol Number: | number |
| Project Title: | *Title* |

|  |
| --- |
| **Part 2: Definitions** |
| * The HIPAA Privacy Rule established the conditions under which protected health information may be used or disclosed by covered entities for research purposes
* ***Protected Health Information (PHI):*** Individually identifiable health information held by a health care provider or health plan covered by HIPAA (e.g., Campbell University Community Care Clinic, PT Pro Bono Clinic, etc.)
* In the course of conducting research, research may obtain, create, use and/or disclose individually identifiable health information. Under the Privacy Rule, covered entities are permitted to use and disclose protected health information for research with individual authorization, or without individual authorization under limited circumstances set forth in the Privacy Rule. Research Use/Disclosure without Authorization.
 |
| **Part 3: Protected Health Information (PHI)** |
| 1. **Describe the PHI and how it will be obtained for this research:**
 |
| Enter text here |

|  |  |
| --- | --- |
| **Part 3: HIPAA Authorization** | [ ]  **N/A** |
| * Complete the applicable sections below. If not applicable, check “N/A”
 |
| A Privacy Rule Authorization is an individual’s signed permission to allow a covered entity to use or disclose the individual’s protected health information (PHI) that is described in the Authorization for the purpose(s) and to the recipient(s) stated in the Authorization. Please complete this section if an Authorization will be obtained from individuals for the use and/or disclosure of their PHI. |
| [ ]  **Authorization will be obtained**Researchers requesting HIPAA Authorization can either:* Include language in their regular informed consent form *(the IRB biomedical consent templates contain HIPAA Authorization language)*; or
* Can include a separate authorization form during the consent process; or
* If the PHI is owned by an external institution and patients have previously signed a HIPAA authorization form, allowing their PHI to be used for research (e.g., Walgreens waiver, etc.).

In any scenario, HIPAA Authorization must be written in plain language and include six core elements and three required statements.Additional information and an Authorization Template can be found on the IRB website.Attach a copy of the Authorization (or consent form) that will be used for this research to the **New Protocol Electronic Application Form.** |
| **Part 4: Waiver Request** | [ ]  **N/A** |
| The HIPAA Privacy Standard at 45 CFR 164.512(i) requires that certain criteria be met in order to grant a waiver of individual authorization for research uses of Protected Health Information. In addition to these criteria, the federal Common Rule (45 CFR 46.116(d)) stipulates that “whenever appropriate, the subjects will be provided with additional pertinent information after participation.” |
| This request is for (chose one): |
| [ ]  **Total Waiver**When you request a total waiver of the HIPAA Authorization, you are requesting permission to access, use or disclose a research subject’s PHI for your research project without seeking the subject specific authorization for that use or disclosure. |
| [ ]  **Partial Waiver**When a partial waiver is requested, you may request that certain required elements of the HIPAA authorization be altered or that the HIPAA authorization be waived for a portion of the project. *For instance, you may request a waiver for subject identification or recruitment purposes but not for enrollment purposes.* *For example, you may request a waiver of the HIPAA authorization requirement so that a treating physician may obtain verbal permission from the patient/parent so that the physician can notify the investigator of the patient’s/parent’s interest in the project. Once the investigator has discussed the project with the interested patient/parent, they will consent the participant and parent and obtain a full authorization.* |

|  |  |
| --- | --- |
| **Part 4: Waiver Request** | [ ]  **N/A** |
| **Specify what you are requesting the waiver (total or partial) for:** |
| Enter text here. |
| 1. **Does the use or disclosure of PHI involve no more than a minimal risk to the privacy of the individual? Indicate whether the research meets the following criteria:**
 |
| [ ]  Yes [ ]  No | 1. There is a plan to protect the identifiers from improper use and disclosure (e.g., encryption of electronic files, other confidentiality procedures, etc.)
 |
| [ ]  Yes [ ]  No | 1. There is a plan to destroy identifiers at the earliest opportunity consistent with the conduct of the research unless there is a health or research justification for retaining the identifiers or as otherwise required by law
 |
| [ ]  Yes [ ]  No | 1. Adequate written assurances that the protected health information will not be reused or disclosed to another person or entity, except as required by law, for authorized oversight of the research project, or other research for which the use or disclosure of PHI would be permitted can be provided (e.g., agreement with covered entity for disclosure of PHI, etc.)
 |
| 1. **Describe the plan to protect the identifiers (names, addresses, email addresses, social security numbers, medical record numbers, photos, and other identifying information, etc.) from improper use and disclosure:**
 |
|  Explain here |
| 1. **Describe the plan to destroy the identifiers at the earliest opportunity, or provide justification for retaining the identifiers:**
 |
| Explain here |
| 1. **Will a waiver adversely affect the privacy of the individual?**
 |
| [ ]  Yes [ ]  No | If “no”, please explain in the textbox below:Explain here |
| 1. **Could the research be practicably done without the waiver?**
 |
| [ ]  Yes [ ]  No | If “no”, please explain in the textbox below:Explain here |
| 1. **Could the research practicably be done without access to, use or disclosure of the PHI identified below?**
 |
| [ ]  Yes [ ]  No | If “no”, please explain in the textbox below:Explain here |
| 1. **Please identify the PHI that will be used under this waiver request.**
 |
| List identifiers here |
| 1. **Are the privacy risks to individuals whose PHI will be used or disclosed reasonable in relation to the anticipated benefit, if any, to the individuals?**
 |
| [ ]  Yes [ ]  No | Describe the risk/benefit analysis relating to the waiver request:Explain here |
| 1. **Will the Principal Investigator be the only member of the research team who will access, use or disclose PHI?**
 |
| [ ]  Yes [ ]  No | If “no”, name all the individuals who will have access to PHI during the research project, including students. |
|

|  |  |
| --- | --- |
| **Name** | **Job Description/Role in Project** |
| Name | Enter text here |
| Name | Enter text here |
| Name | Enter text here |
| Name | Enter text here |
| Name | Enter text here |
| Name | Enter text here |

 |
| **Part 5: Limited Data Set** | [ ]  **N/A** |
| A covered entity is permitted to use or disclose PHI for research purposes if it provides a *limited data set* and enters into a data use agreement with the recipient.Please complete this section if the PHI used or disclosed for this research is part of a limited data set and will be or is covered by a data use agreement.[ ]  **The PHI used or disclosed for this research is/will be part of a limited data set**A *limited data set* is protected health information from which direct identifiers have been removed that may be used and disclosed for research purposes pursuant to a data use agreement.Please attach a copy of the data use agreement that will be applied to this limited data set to the New Protocol Electronic Application Form. |