

**Mercy College**

**Appendix D**

**Use Of Protected Health Information (PHI) Accessed,**

**Used or Disclosed from a Covered Entity**

|  |
| --- |
| **Protocol Title:** Click here to enter text. |
| **IRB Protocol # (if amendment):** Click here to enter text. |
| **Principal Investigator (PI):** Click here to enter text. |
| **Date of submission:** Click here to enter text. |

|  |
| --- |
| Complete this form when the proposed research includes plans to access, use, or disclose Protected Health Information (PHI). The Privacy Rule permits several methods by which PHI may be used in research.  |
| Part 1: To use PHI in research you must have approval through one of the following methods:1. An authorization signed by the research participant which meets HIPAA requirements;
2. An IRB waiver of the HIPAA authorization requirement;
3. An IRB alteration of the HIPAA authorization requirement; or
4. Use of a limited data set under a data use agreement.

Check below to indicate which method of approval you are proposing:

|  |  |
| --- | --- |
| [ ]  | Research participants in this study will sign an Authorization to Use or Disclose Protected Health Information for Research Purposes. Refer to the “HIPAA Authorization” (Authorization to Use Protected Health Information in Research) form/template to be presented to the study participant for review and to provide permission for access to their PHI. Be sure to compete HIPAA Authorization form/template with the required information and include it with the IRB submission application.  |
| [ ]  | I wish to obtain an IRB waiver of the authorization requirement. *Complete parts 2 & 3 of this appendix.* |
| [ ]  | I wish to obtain an IRB alteration of the authorization requirement. *Complete parts 2 & 3 of this appendix.* |
| [ ]  | I will access a Limited Data Set by signing a data use agreement with the party that releases the PHI. An Authorization or documentation of a waiver or alteration of Authorization is not required for a Mercy College researcher to receive a Limited Data Set when the data is accompanied by a Data Use Agreement from the PHI providing institution. A limited data set must have all the identifiers listed below removed from the data. It is the responsibility of the researcher and the party releasing the PHI to have in place and maintain a copy of a data use agreement which meets HIPAA requirements. A copy of the data use agreement must be included with the IRB submission. *Skip to Part 3 of this appendix.*The following identifiers must be removed to create a limited data set:

|  |  |
| --- | --- |
| * Names
* Postal address information other than town/city, state, and zip
* Telephone number
* Fax number
* Email address
* Social security number
* Medical record number
* Health plan number
 | * Account numbers
* Certificate or license numbers
* Vehicle identification/serial numbers, including license plate numbers
* Device identification/serial numbers
* Universal resource locators (URLs)
* Internet protocol addresses (IPs)
* Biometric identifiers
* Full face photographs and comparable images
 |

 |

 |
| **PART 2: Request for IRB Waiver or Alteration of HIPAA Authorization****Check below to indicate which IRB action you are requesting:** [ ]  Partial Waiver (recruitment purposes only) [ ]  Full Waiver (entire research study) [ ]  Alteration (permission is requested to alter/remove some of the required elements of authorization).  If an alteration is being requested, what are you requesting to alter/remove? Click here to enter text. |
| A. |

|  |
| --- |
| Provide information below about the PHI accessed in the research under the waiver/alteration. Please check all that apply: |
| [ ]  | Names | [ ]  | Medical Record numbers |
| [ ]  | Addresses (including any part of street address, city, state, or zip code) | [ ]  | Health plan beneficiary |
| [ ]  | Dates directly related to an individual (except year), please list: Enter text. | [ ]  | Device identifiers and serial numbers |
| [ ]  | Age information for those over 89 | [ ]  | Account numbers |
| [ ]  | Telephone and/or fax numbers | [ ]  | Certificate/license numbers |
| [ ]  | Email addresses | [ ]  | Biometric identifiers — including finger and voice prints. |
| [ ]  | Web URLs | [ ]  | Full face photographic images and any comparable images. |
| [ ]  | Internet protocol (IP) address numbers | [ ]  | Vehicle identifiers and serial numbers, including license plate numbers |
| [ ]  | Social Security Numbers | [ ]  | Any other unique identifying number, characteristic, or code (please describe below): |
| Enter unique identifiers. |
|  |

 |
| B. | The research could not practicably be conducted without access to and use of the PHI noted above **and** the research could **NOT** practicably be conducted without the waiver or alteration.[ ]  **Yes \*** [ ]  **No \*(If No, stop here, a waiver is not applicable )**  |
| C. | The use and disclosure of the PHI identified above involves no more that minimal risk to the privacy of individuals based on the presence of all the following (please check each item to confirm): |
| [ ]  | a. An adequate plan to protect health information identifiers from improper use and disclosure. |
| [ ]  | b. An adequate plan to destroy identifiers at the earliest opportunity consistent with conduct of the research (absent a health or research justification for retaining them or a legal requirement to do so). |
| [ ]  | c. Adequate written assurances that the PHI will not be reused or disclosed to (shared with) 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 the PHI would be permitted under the Privacy Rule. |
| [ ]  **Yes \*** [ ]  **No \*(If No, stop here, a waiver is not applicable)** |
| D. | Explain why a waiver or alteration (instead of written authorization) is needed to conduct the research.Click or tap here to enter text. |
|  | **PART 3: Investigator Signature**By signing this form, the Principal Investigator (PI) assures 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 study, or other research for which the use or disclosure of PHI would be permitted. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature of Principal Investigator Date Click or tap to enter a date. |