In the course of conducting research, all study personnel involved in the research, including the Principal Investigator (PI) (collectively, Research Staff), may need to obtain, create, use, and/or disclose individually identifiable information related to an individual’s health (Protected Health Information or PHI). Under the HIPAA Privacy Rule, the Covered Entity (i.e.: hospital; provider; health plan, etc.) or its Business Associate may disclose PHI to Research Staff without an individual’s authorization if the PI obtains approval from the Institutional Review Board (IRB). By completing this Application, the PI seeks the IRB’s approval to waive the requirement for an individual’s authorization to obtain PHI.

The IRB requires certain information in order to determine whether the criteria are met to permit a waiver of authorization under HIPAA. Please answer the following questions.

1. **Why do you request a waiver of authorization? (**e.g., to find patients that you will ask to be in your study, to conduct a secondary analysis of medical record data for encounter dates from mm/yyyy to mm/yyyy, to alter a HIPAA authorization to eliminate signature of the individual and date [i.e., to obtain a verbal HIPAA authorization])
2. **Describe the health information and identifiers (PHI) that are needed to conduct the research. First, describe the health information. Then review each identifier (A) through (Y) and mark an “X” to the left of the identifiers that are needed. Note that identifiers (X) and (Y) require you to add an additional description.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Describe the health information (e.g., specific tests, images, demographic information): | | | | |
|  | | | | |
|  | (A) Name |  |  | (M) Medical record numbers |
|  | (B) House number and street address |  |  | (N) Social security numbers |
|  | (C) City |  |  | (O) Health plan beneficiary numbers |
|  | (D) County |  |  | (P) Account numbers |
|  | (E) Precinct |  |  | (Q) Vehicle identifiers and serial numbers, including license plate numbers |
|  | (F) ZIP code |  |  | (R) Certificate/license numbers |
|  | (G) Telephone numbers |  |  | (S) Device identifiers and serial numbers |
|  | (H) Email addresses |  |  | (T) Full-face photographs and any comparable images |
|  | (I) Fax numbers |  |  | (U) Internet Protocol (IP) addresses |
|  | (J) Date of Birth |  |  | (V) Web Universal Resource Locators (URLs) |
|  | (K) Date of Death |  |  | (W) Biometric identifiers, including finger and voice prints |
|  | (L) Dates of Service (admission; discharge; surgery; test, etc.) |  |  | (X) Any other unique identifying number, characteristic, or code: ***Describe:*** |
|  |  |  |  | (Y) Any other information that could be used alone or in combination with other information to identify the individual who is a subject of the information. ***Describe:*** |

1. **Why is the information that you listed in #2 necessary for your research?** The HIPAA regulation requires reasonable efforts to limit PHI to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.
2. **List the source(s) of the health information and identifiers** (e.g., the Data Lake, patient records, etc.)
3. **Explain why the research could not practicably be conducted without a waiver.** (e.g., the inclusion/exclusion criteria are complex/time sensitive and patients will not know whether they meet the criteria; the study team has tried unsuccessfully to recruit subjects through flyers or provider referrals; the study team does not provide direct patient care for the subjects and the secondary analysis requires access to data from an extended time frame such that patients may have moved or died)
4. **Where will the PHI be stored?** (e.g., [REDCap](https://www.umassmed.edu/it/security/research-and-clinical-data-access/research-data-storage/), [UMass Chan research drive](https://www.umassmed.edu/it/security/research-and-clinical-data-access/research-data-storage/), UMass Chan OneDrive, UMass Chan Teams, locked folder for paper records when not in use)
5. Members of the Research Staff, the Covered Entity that holds the PHI (e.g., UMMH), and oversight bodies (e.g., FDA, NIH, UMass Chan Human Research Protection Program) will have access to the PHI. **List any additional people/entities that may access the PHI or indicate in your response that there are none. IMPORTANT:** PHI obtained under a waiver of HIPAA authorization may not be reused or disclosed to any person or entity other than those listed here, except as required by law; for authorized oversight of this research study; or as specifically approved for use in another study by an IRB.
6. **When will the identifiers be destroyed?** The identifiers must be destroyed at the earliest opportunity, unless you provide a justification for retaining the identifiers longer or retention is required by law. (E.g., once the study closes to enrollment, three years after study closure, etc.)
7. **How will the identifiers be destroyed?** (e.g., Research Staff will shred paper files; Research Staff will contact IT to overwrite files containing identifiers; Research Staff will export REDCap fields that do not contain any of the 18 HIPAA identifiers and the REDCap project will be destroyed; etc.)
8. **Provide a plan for completing the required** [**accounting of disclosures**](https://www.umassmed.edu/ccts/research-resources/privacy-and-security/) (e.g., If the use/access/disclosure involves 49 or fewer patients, complete the Accounting for Use/Disclosures form for each patient as you go. If the use/access/disclosure involves 50 patients or more, complete the Accounting of Research Disclosures-Summary Form as soon as IRB approval for the HIPAA waiver is granted. Not sure you’ll reach the 50-patient mark? Start with individual accounting and then switch to the summary form when you reach 50. Be sure to coordinate with external sites to complete the required Accounting if your HIPAA waiver extends beyond UMMH.) The PI is ultimately responsible for completing the required accounting of research disclosures for any PHI released under a waiver. Access to the relevant forms is available at <https://www.umassmed.edu/ccts/research-resources/privacy-and-security/>, and additional information regarding these obligations is available by contacting UMass Chan Medical School’s Office of Management privacy and compliance group at 508-856-8326 or privacyandcompliance@umassmed.edu or the UMass Memorial Medical Center Privacy Office at (844) 744-9212.

When the PI named below is logged into eIRB with their UMass Chan credentials and submits this form to the IRB, the PI attests to the following:

* The information that I have provided in this Application is accurate and all Research Staff will comply with the HIPAA regulations and the information in this Application.
* Protected Health Information for which a Waiver of Authorization has been requested will not be reused or disclosed to any person or entity other than those listed in this Application, except as required by law, for authorized oversight of this research study, or as specifically approved for use in another study by an IRB.

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| --- | --- |
| **Principal Investigator**: |  |
| **IRB Study ID #**: |  |
| **Protocol Title**: |  |