
HIPAA IRB Form 4
(7/14 Revision)

APPLICATION FOR IRB WAIVER OF HIPAA PRIVACY AUTHORIZATION

To grant a waiver of the HIPAA Privacy Authorization requirement, the IRB must determine that your project involves no more than minimal risk to the privacy of individual participants and meets all of the criteria listed in the Privacy Rule.

- ***Submit this form if you will access identifiable records (e.g., medical, research, billing records) without written authorization***
 - *To abstract identifiable information for research,*
 - *To create a limited data set, or*
 - *To de-identify data for use in research (unless the data sources are limited to your own patients or research subjects). Data are identifiable unless fully de-identified according to the HIPAA standard (see page 3) and you can't re-identify the data subjects.*
- ***Do not submit this form if you will access or receive de-identified data only, and will have no ability to re-identify data subjects.***
- ***Do not submit this form if you are receiving or sending (but not creating) a limited data set (use the Hopkins data use agreement instead).***

PLEASE NOTE: If the IRB approves this application, approval does not include permission to contact individuals whose records are reviewed. You may not use any information in the requested records to recruit subjects without separate IRB approval of the recruitment plan described in the eIRB application. Except as permitted in an IRB-approved recruitment plan, PHI may not be presented, published, or otherwise disclosed to third parties under an approved HIPAA waiver.

IRB Application Number (if available): **IRB_00052743**

Research Project Title: **CEIRS: Human Influenza Surveillance of Health Care Centers in the United States and Taiwan**

Principal Investigator: **Andrea Dugas, MD PhD**

Department/School: **Department of Emergency Medicine**

A. Data collection points (*check at least one*):

Data collection form has been uploaded in the eIRB application (required for retrospective chart reviews)

Minimum amount of data necessary to determine inclusion/exclusion criteria as defined in the protocol

I plan to collect or access the following data:

This HIPAA waiver is to identify potential study subjects. We will evaluate basic clinical data (e.g. demographics, comorbidities, risk factors, and presenting symptoms), treatment data (e.g. antibiotics or antivirals) and laboratory results (e.g. influenza tests).

- B. Describe the source(s) of the information (e.g., EPR, records from previous study, pathology archive) that you want to access:

We would evaluate the chart from the patient's Emergency Department visit using EPIC, including the medical record, pathology and laboratory results. Additionally, referring physicians who identify potential patients for the study are a source of information.

- C. Describe the plan to destroy the participant identifiers at the earliest opportunity consistent with the conduct of research, unless retention is required for reasons of health, research, or law. Please explain if the participant identifiers will be stored or retained and the length of time they will be stored or retained:

If a patient declines to participate in the study, no PHI will ever be recorded. If a patient agrees to participate, they will undergo a written consent process, and their PHI will be handled as described in remainder of this application.

- D. Explain why the research could not practicably be conducted without the waiver:

Collection of this data would not be practical without a waiver because patients will be screened for inclusion and exclusion criteria before we obtain written consent.

- E. Explain why the research could not practicably be conducted without access to and use of the identifiers (PHI):

The initial data collected in the proposed research are necessary to determine study eligible Emergency Department patients, i.e., to review who meets study inclusion and exclusion criteria.

- F. In applying for waiver of the HIPAA authorization requirement, you are assuring the IRB that the identifiers you request will not be used for any other purpose or disclosed to any other person or entity (apart from research team members listed in this application), except as required by law, for authorized oversight of the research study, or for use in future IRB-approved research.

AGREEMENT:

By electronically submitting this form, you agree that you and your research team will comply with Johns Hopkins HIPAA policies and the use and disclosure restrictions described above. *Specifically, you acknowledge and agree that you may share PHI obtained under a HIPAA waiver only with IRB-approved members of your study team, and you assume responsibility for all uses and disclosures of the PHI by members of your study team.*

This application form does not replace the requirement to submit an application for Human Subjects Research to the JHM IRBs for an individual research project.

Definitions of HIPAA Terms

De-identified Data: To “de-identify” data under the Privacy Rule safe harbor, you must ensure the following:

- (1) Each of the data elements listed below is removed from the data; **AND**
- (2) You do not know that any recipient of the data could re-identify a data subject, using the information alone or in combination with other publicly-available information.

Data elements that must be removed:

- Names
- Geographic subdivisions smaller than a state (including street, city county, precinct), except first three digits of the zip code if, according to current Bureau of Census data:
 - (1) The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people, and
 - (2) The initial three digits of ZIP code for all such geographic units containing 20,000 or fewer people are changed to 000.
- All elements of dates (except year) for dates directly related to an individual, and all ages over 89 and elements of date (including year) indicative of such age, except that ages and elements may be aggregated into a single category of age 90 or older.
- Telephone numbers;
- Fax numbers;
- E-mail addresses;
- Social security numbers;
- Medical record numbers;
- Health plan beneficiary numbers;

- Account numbers;
- Certificate/license numbers;
- Vehicle identifiers and serial numbers, including license plate numbers;
- Device identifiers and serial numbers;
- Web Universal Resource Locators (URLs);
- Internet protocol address numbers;
- Biometric identifiers, including voice and finger prints;
- Full face photographic images and any comparable images;
- Any other unique, identifying number characteristic, or code, except for a unique code that meets the following criteria:
 - (1) Is not derived from any other code (e.g., MRN or SSN) and is not used for any other purpose; and
 - (2) Persons using the data for research have no access to the code key and the key is held by a source that is not part of the research team. An investigator (or her study team members) may not create the code for de-identified data that she will use in her own research.