



Institutional Review Board Office

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**JHSPH IRB HIPAA Application for Disclosure
 of Protected Health Information
 Through Authorization, Waiver, or Limited
 Data Set**

PI Name		IRB Number
Study Title		
Date		

SECTION A: ACCESSING PROTECTED HEALTH INFORMATION (PHI)

How will you access the Protected Health Information (PHI) you want to use in your study?
 Choose all that apply.

- i. Directly from the study participant (choose form of Authorization below)
 - With a signed IRB Approved combined Consent/Authorization Form
 - With a signed stand-alone HIPAA Authorization Form
 - With a signed Medical Record Release/Authorization Form
- ii. With an IRB approved HIPAA waiver of the requirement to obtain a signed privacy authorization (*complete Section D, below*)
 - Directly from the participant using an oral consent process
 - Directly from the participant's clinical care provider
 - From an existing clinical/billing/insurance record
 - From an existing research database
- iii. By receiving or creating a limited data set, and signing a Data Use Agreement (*complete Section E, below*)

SECTION B: DESCRIBING PHI AND ITS SOURCE

1. Select the personal identifiers you seek to access/use in your research project.

<input type="checkbox"/> Name	<input type="checkbox"/> Certificate or license numbers
<input type="checkbox"/> Geographic information smaller than State	<input type="checkbox"/> Vehicle identifiers and serial numbers including license plate
<input type="checkbox"/> Elements of dates (birth date, admission date, date of death, ages >89 years of age)	<input type="checkbox"/> Device identifiers and serial numbers

<input type="checkbox"/> Telephone numbers	<input type="checkbox"/> URLs
<input type="checkbox"/> FAX numbers	<input type="checkbox"/> IP address numbers
<input type="checkbox"/> Electronic mail address	<input type="checkbox"/> Biometric identifiers
<input type="checkbox"/> Social Security Number	<input type="checkbox"/> Full face photographic images and comparable images
<input type="checkbox"/> Medical record numbers	<input type="checkbox"/> Health Plan beneficiary numbers
<input type="checkbox"/> Account numbers	<input type="checkbox"/> Any other unique identifying number, characteristic or code

2. Will you access PHI from a non-Hopkins covered entity?
 Yes No
 If yes, identify the covered entity(ies):

3. Will you access PHI from a Hopkins covered entity?
 Yes No
 a. If yes, identify the Hopkins covered entity(ies) below. Check all that apply.
 The Johns Hopkins Hospital The Johns Hopkins Bayview Medical Center
 Howard County General Hospital JH Community Physicians
 Suburban Hospital Sibley Memorial Hospital
 All Children’s Hospital JH Pharmaquip
 JH Pediatrics at Home Priority Partners Managed Care Organization
 JH University School of Medicine Johns Hopkins Employee Health Plans
 JH University School of Nursing JH Home Health Services
 Other Hopkins Providers (specify):

b. List the specific JH department(s) from which you will access PHI:

4. Describe the types of health information you will collect (e.g. diagnosis, test results, treatments, etc.).

5. How will you access the PHI?
 Directly from the participant or clinician
 Paper records
 Electronic medical records
 Electronic download of data

SECTION D: WAIVER OF HIPAA PRIVACY AUTHORIZATION

(Complete this section ONLY if you are requesting a waiver)

1. Are you requesting a waiver of HIPAA Authorization or a waiver of signature for an oral consent/authorization process?
 Yes No (If no, skip this section)
2. **Explain** why the research and/or recruitment could not practicably be conducted without the waiver. Be as specific as possible.
3. **Explain** why the research and/or recruitment could not practicably be conducted without access to/use of the PHI. Be as specific as possible.

NOTE: If you are obtaining PHI from a Johns Hopkins covered entity for fewer than 50 participants:
You must "track" this disclosure from the covered entity's health records to you in the SPH JH HIPAA Compliance System. Contact the IRB Office to register for the database. The database may be accessed at <https://cfapps.jhsph.edu/SPH-JH-HIPAA-Compliance/>.

4. Will the **JHSPH** researchers access the PHI directly from an electronic record system?
 No, the covered entity will extract the data and provide it to us.
 Yes, we will abstract the PHI from the electronic system.
 - Identify the electronic system:
 - Identify the name of the researcher who will access the electronic record system:

*The research team represents that it has the covered entity's permission to extract the records and will **access and extract only the records described in the research application and in this HIPAA application for disclosure of PHI**. If the source of the data is a Johns Hopkins covered entity, a **Business Associate Agreement (BAA)** will be in place.*

SECTION E: LIMITED DATA SET

(Complete this section ONLY if you will use a Limited Data Set)

1. Do you intend to use a Limited Data Set?
 Yes No (If no, skip this section)

Note: A limited data set may include **only** the following identifiers:

- Dates, such as admission, discharge, service, DOB, DOD;
- City, state, five digit or more zip code; and
- Ages in years, months, days, or hours.

If you check **yes**, you must enter into a **Data Use Agreement (DUA)** with the covered entity to gain access to the data.

2. Will the JHSPH researchers access an electronic record system to extract the PHI and create the limited data set?

No, the covered entity will extract the data and provide it to the research team.

Yes, the JHSPH researchers will access an electronic record system to create the limited data set.

- Identify the electronic system:
- Identify the name of the researcher who will access the electronic record system:

*The research team represents that it has the covered entity's permission to extract the records and will **access and extract only the records described in the research application and in this HIPAA application for disclosure of PHI**. If the source of the data is a Johns Hopkins covered entity, a **Business Associate Agreement (BAA)** will be in place.*

If you will access identifiable data from the covered entity and create the limited data set yourself, you will also enter into a Business Associate Agreement (BAA) with the covered entity.

Please complete the [BAA/DUA Investigator Request Form](#) and contact the JHSPH IRB Office at jhsph.irboffice@jhu.edu to discuss entering into Business Associate Agreements and Data Use Agreements.

SECTION F: TRAINING AND IDENTIFIERS

1. Who on the study team will have access to the PHI? Please provide all names.

2. When will you destroy the identifiers? (Must be at earliest opportunity)

3. Confirm the following: The PHI will not be reused or disclosed to any other person or entity, except:

- As required by law
- For authorized oversight of this research
- For other research for which use or disclosure of PHI is permitted under HIPAA. I will not proceed with any such use without consultation with the HIPAA Privacy Office.

Confirm