# cid:image001.png@01CF191D.41D41DC0HIPAA APPLICATION – JHM

# APPLICATION FOR DISCLOSURE OF PROTECTED HEALTH INFORMATION FROM JOHNS HOPKINS MEDICINE (JHM) FOR RESEARCH PURPOSES

|  |  |
| --- | --- |
| PI Name |       |
| IRB Number |       |
| Study Title |       |

1. **Identify the specific JHM Covered Entity(ies)[[1]](#footnote-1) and JHM Departments from which the PHI will originate:**

|  |
| --- |
| **[ ]** 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, e.g. EHP**[ ]** JH University School of Nursing **[ ]** JH Home Health Services**[ ]** Other Hopkins Providers (specify):       List the specific JHM department(s) from which the PHI will originate:       |

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

|  |  |
| --- | --- |
| [ ]  Name | [ ]  Certificate or license numbers |
| [ ]  Geographic information smaller than State, including city, county, and zip code and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:(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 a zip code for all such geographic units containing 20,000 or fewer people is changed to 000. | [ ]  Vehicle identifiers and serial numbers, including license plate numbers |
| [ ]  All elements of dates except years (e.g., birth date, admission date, date of death, age by year if >89 years of age) | [ ]  Device identifiers and serial numbers |
| [ ]  Telephone numbers | [ ]  Web URLs  |
| [ ]  FAX numbers | [ ]  Internet Protocol (IP) address |
| [ ]  Email address | [ ]  Biometric identifiers, including finger and voice prints |
| [ ]  Social Security Number | [ ]  Full face photographic images and comparable images  |
| [ ]  Medical record numbers  | [ ]  Health Plan beneficiary numbers |
| [ ]  Account numbers  | [ ]  Any other unique identifying number, characteristic or code  |

|  |
| --- |
| **3**. Describe specifically the types of health information you will collect (e.g., diagnosis, test results, treatments, billing information, etc.) The IRB will review only those specific items you list here.     1. Identify in the section below which mechanism you wish the IRB/Privacy Board to approve to allow you to use the PHI you want in your study. **Note**: ***The JHSPH IRB approval is for the use of the PHI in research. That approval is separate and distinct from the actual permissions required to access medical/billing records. JHSPH researchers may not access JHM’s Epic or other PHI unless they have a joint appointment with the SOM with clinical responsibilities or are authorized as a HIPAA Workforce member Preparatory to Research (see second mechanism below)****.*

Check the box for each of the 5 mechanisms that apply to your research, or “N/A” for those that do not apply:* HIPAA Authorization: to ask participants to authorize access to their medical/billing records
* Preparatory to Research: to access medical records for limited purpose of identifying potentially eligible study participants
* HIPAA Waiver: to access PHI for secondary data analysis or program evaluation without a HIPAA Authorization
* Limited and De-identified Datasets: for secondary data analysis
* Representations for Decedents-only Research
 |

|  |
| --- |
| 1. **[ ]  PRIVACY AUTHORIZATION SIGNED BY STUDY PARTICIPANT**

**[ ]  N/A*** 1. What type of form do you plan to use?

[ ]  Combined consent/HIPAA authorization document [ ]  Stand-alone HIPAA Authorization/Medical Records Release form * 1. Once you have a signed HIPAA Privacy Authorization, who will access the medical/billing records to obtain the PHI described in Section 3, above?

[ ]  Center for Clinical Data Analysis (CCDA)[ ]  JHM Privacy Office Certified Honest Broker[[2]](#footnote-2)Name:       [ ]  JHM Entity that is the source of the data (includes JHM collaborating treating clinician - researcher)Name:       |
| 1. **[ ]  ACCESS TO RECORDS PREPARATORY TO RESEARCH**

**[ ]  N/A**Please respond to questions a, b, and c below.* 1. Identifying Potential Participants: Who will access EPIC/billing records to find potentially eligible participants?

[ ]  A JHHS credentialed workforce member Name:      [ ]  A JHSPH faculty, staff, or student working under the direction of a JHHS credentialed clinician, and who submits to the IRB a HIPAA Workforce Agreement co-signed by the JHHS credentialed clinician. Name:      [ ]  Other JHU- employed research personnel (including faculty and staff) working under the direction of a JHHS credentialed clinician, and who submits to the IRB a HIPAA Workforce Agreement co-signed by the JHHS credentialed clinician. Name:      [ ]  An Honest Broker certified and approved by the JHM Privacy Office.Name:      * 1. Recruitment: Once you have the names and contact information for potentially eligible participants, confirm that you will check with the treating clinician whether each potentially eligible patient is a good candidate for the study.

[ ]  ConfirmIf the treating clinician agrees that a patient is a good candidate for the study, please check all the HIPAA compliant methods of sending IRB approved communications to potential participants that you plan to use:[ ]  The **treating clinician** (not the researcher) will send an IRB approved communication to the patient informing them about the study and how to contact the study team.[ ]  The **treating clinician** who is not a researcher will provide patients with information about the study, including contact information for the researcher.[ ]  The **treating clinician** will be added to the study team and may delegate to the JHSPH researcher the actual sending of the IRB approved communication informing potential participants about the study, on the treating clinician’s behalf, and signed by the treating clinician.[ ]  The **treating clinician** who is not a researcher will direct the potential participant to the researcher’s designated space outside of the direct treatment space (e.g., conference room, table in waiting room, lobby space, etc.)* 1. Confirm the following required criteria for Preparatory to Research access to PHI to identify potentially eligible participants:
* You will only obtain the “minimum necessary PHI
* The PHI will not leave the JHM covered entity or, if electronic, go outside JHM firewalls
* The PHI will not be used or disclosed to anyone outside the approved recruitment plan
* Individuals who agree to join the study will sign a consent/authorization
* All PHI not associated with a signed Authorization will be destroyed after it has been used for recruitment purposes
* Any access to Epic or other medical/billing records preparatory to research **WILL NOT BE USED TO PULL INFORMATION FOR THE STUDY ITSELF**.

[ ]  Confirm |
| 1. **[ ]  HIPAA WAIVER**

**[ ]  N/A** ***NOTE:  If you intend to use a LIMITED DATA SET, you do not need a HIPAA Waiver for that purpose.***1. Check off the purpose for which you seek the waiver.

[ ]  For study recruitment because it is impracticable to have the clinician with a treatment relationship with the potential participants involved in the recruitment contact. *[Note: The IRB will grant a waiver for recruitment in rare circumstances; its expectation is that the researcher’s activities will follow the recruitment requirements provided in the Preparatory to Research section, above.]* [ ]  For secondary data analysis or a broad program evaluation. 1. Explain why the research could not practicably be conducted **without the waiver**. Explain why you cannot obtain a signed Privacy Authorization. Be as specific as possible.

     1. Explain why the research could not practicably be conducted **without access to/use of the PHI**. Be as specific as possible.

     1. Confirmthat the use of PHI pursuant to the waiver involves no more than minimal risk to the privacy of the study participant.

[ ]  Confirm1. Confirm that if you plan to enroll, or do enroll, 49 or fewer participants from JHM, you will “track” the disclosures of PHI to you, as required, in the SPH Johns Hopkins HIPAA Compliance System. The database may be accessed at: [https://cfapps2.jhsph.edu/SPH-JH-HIPAA-Compliance/](https://nam02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fcfapps2.jhsph.edu%2FSPH-JH-HIPAA-Compliance%2F&data=04%7C01%7Cjpettit%40jhu.edu%7Caa1e00a0f9874936695b08d90ff81cfb%7C9fa4f438b1e6473b803f86f8aedf0dec%7C0%7C0%7C637558380569684262%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=r%2FLETXtGkbTrwFMrLv%2Fr3NhUYtjNCIW55V4%2BDQIpXO0%3D&reserved=0).

[ ]  Confirm1. When will you destroy the identifiers? (Must be at earliest opportunity)

      1. Identify the person or entity (Honest Broker or CCDA, or other JHM entity providing the data) who will extract the data from the JHM medical/billing records.

     1. For studies using JHM clinical records:  I certify that I have reviewed the **JHM Privacy Office Data Protection Attestation** and agree to be bound by its terms.

[ ]  Not applicable[ ]  Confirm |
| 1. **[ ]  LIMITED DATA SETS AND DE-IDENTIFIED DATA SETS**

**[ ]  N/A****Complete this section if you intend to use a Limited Data Set or De-Identified Data Set produced by a JHHS Certified Honest Broker, the Center for Clinical Data Analysis (CCDA),** **other approved JHHS data provider, or another JHM Entity that is the source of the data.*** 1. Check off the kind of data set you plan to use:

[ ]  Limited Data Set**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 or any other geographic subdivision, such as state, county, city, precinct and their equivalent geocodes except street addresses; and
* Ages in years, months, days, or hours (with ages >89 aggregated into a single category of 90 or older).

[ ]  De-identified Data Set* 1. Identify the person (Honest Broker) or entity (CCDA or other approved JHHS data provider, or JHM entity providing the data) who will create the Limited Data Set or De-Identified Data set:

Name:       * 1. For studies using JHM clinical records:  I certify that I have reviewed the **JHM Privacy Office Data Protection Attestation** and agree to be bound by its terms.

[ ]  Not applicable[ ]  Confirm |
| 1. **[ ]  REPRESENTATIONS FOR DECEDENTS-ONLY RESEARCH**

**[ ]  N/A**1. Please describe the research purposes for which you need to examine records/specimens of deceased individuals.

      1. Please identify the source of the records/specimens of deceased individuals.

      1. Identify the person (Honest Broker) or entity (CCDA or other approved JHHS data provider, or JHM entity providing the data) who will create the Data Set of Decedents-Only PHI.

Name:      1. Confirm the following:
	* 1. The use or disclosure of PHI is sought solely for research on the PHI of decedents. No living individuals will be included.
		2. If the IRB requests it, the researcher will provide documentation as to the death of the individuals.
		3. The PHI is necessary for the research purposes.
		4. The PHI will be obtained through the CCDA, an Honest Broker, or other JHM entity via a JHHS Credentialed HIPAA Workforce Member.
		5. For studies using JHM clinical records:  I certify that I have reviewed the **JHM Privacy Office Data Protection Attestation** and agree to be bound by its terms.

[ ]  Confirm |

1. **Confirm the following for all five categories of disclosures of PHI above:**

**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 Johns Hopkins Medicine HIPAA Privacy Office.

[ ]  Confirm

     \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_      \_

Signature of Principal Investigator Date

1. An updated list of Johns Hopkins Medicine covered entities may be found at:

http://intranet.insidehopkinsmedicine.org/privacy\_office/about\_hipaa/. [↑](#footnote-ref-1)
2. *An honest broker is a neutral third party authorized by the JHM Privacy Office to access PHI to abstract datasets for research purposes. JHSPH has only one such person.* [↑](#footnote-ref-2)