HIPAA APPLICATION – NON JHM

APPLICATION FOR DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES FROM A NON-JHM COVERED ENTITY

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

**I. Protected Health Information for Living Participants (For Decedents, go to Section V)**

1. **Identify the specific Covered Entity(ies) from which the PHI will be obtained:**

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

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| 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 |

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

1. 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

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| 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?   Approved Workforce Member from the Covered Entity providing the PHI.  Name:  JHSPH Researcher with documentation of approval from the Covered Entity providing PHI.  Name: |
| 1. **ACCESS TO RECORDS PREPARATORY TO RESEARCH**   **N/A**   * 1. Identifying Potential Participants: Who will access medical/billing records to find potentially eligible participants?   Approved Workforce Member from the Covered Entity providing the PHI.  Name:  JHSPH Researcher with documentation of approval from the Covered Entity providing PHI.  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.   Confirm  If 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 covered entity or, if electronic, go outside the covered entity’s 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 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.   Confirm   1. When will you destroy the identifiers? (Must be at earliest opportunity)      1. Identify the person or who will extract the data from the covered entity’s medical/billing records.      1. Provide a fully executed (signed) Data Use Agreement (DUA) from the Johns Hopkins University Research Administration (JHURA) with this application. IRB approval will not be finalized without this agreement.   Confirm that a DUA will be provided with the research submission.  Confirm |
| 1. **LIMITED DATA SETS AND DE-IDENTIFIED DATA SETS**   **N/A**   * 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) who will create the Limited Data Set or De-identified Data Set:   Name:   * 1. Confirm that a DUA will be provided with the research submission.   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 you intend to study.      1. Identify the person who will create the Data Set of Decedents-Only PHI.   Name:   1. Provide a fully executed (signed) Data Use Agreement from the Johns Hopkins University Research Administration (JHURA) with this application. IRB approval will not be finalized without this agreement. 2. Confirm that a DUA will be provided with the research submission.   Confirm   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.   Confirm |

**5. Confirm the following for all five categories of disclosure 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

Confirm

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Signature of Principal Investigator Date