**Request for Waiver of HIPAA Authorization**

FULL PROTOCOL TITLE**:**

PRINCIPAL INVESTIGATOR**:**

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| **This form should be used to request a waiver of HIPAA authorization*** A waiver is needed when an individual within a covered entity (such as the University of Pennsylvania Health System) seeks permission to use and/or disclose Protected Health Information (PHI) for a research project and an authorization for that use and/or disclosure will not be obtained from the research subject.
* In order to approve a waiver of Authorization at Penn, the IRB (serving as a Privacy Board) must determine that ALL the following criteria have been met:
1. The use or disclosure of the PHI involves no more than minimal risk to the privacy of individuals based on, at least, the presence of the following elements:
	1. An adequate plan to protect health information identifiers from improper use and disclosure. ([Click here](https://irb.upenn.edu/initial) to access IRB guidance on protection plans)
	2. An adequate plan to destroy identifiers at the earliest opportunity consistent with conduct of the research (absent a health or research justification for retaining them or a legal requirement to do so).
	3. Adequate written assurances that the PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.
2. The research could not practicably be conducted without the waiver or alteration.
3. The research could not practicably be conducted without access to and use of the PHI.

**This form is a supplement to the IRB application:**Please ensure that your HS-ERA application or separate protocol document provides the following information so that the IRB can complete a waiver determination:* The sources from which you will collect research data, including the names of any electronic medical record systems and research databases;
* The location where research data will be stored and how access to research data will be controlled; and
* What individuals or entities outside of the study team will receive study data.

*Please note that the receipt and analysis of a limited dataset under a data use agreement does not require a waiver of HIPAA authorization. However, if you are accessing identifiable information (such as the electronic medical record) in order to create a limited dataset, then a waiver of HIPAA authorization is likely required. If you have questions about whether this form is required for your research project, please contact the IRB prior to completing this form.*  |

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| 1. **Who should the IRB contact with questions?**
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| Name:  | Telephone:  |
| Penn Email:   |

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| 1. **General Information**
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| 1. Please choose the option below that best describes the data you will collect:

[ ]  The data being collected is fully retrospective (meaning all data is already in existence as of the time of this submission to the IRB)[ ]  The data being collected is both retrospective and prospective[ ]  The data being collected is prospective only (the data will be generated in the future after the time of submission to the IRB) |
| 1. Please specify the period of time from which data could be generated and included in your study:
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| From:  To:   |
| 1. Please indicate the approximate number of subjects (or eligible cases in a chart review study) that will have data included in your study:
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| 1. Please describe why the number of subjects and the date range of information identified above is the minimum amount reasonably necessary to achieve your research objective.
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| Protected Health Information to be collected or used* **“Use**”= the sharing, employment, application, utilization, examination, or analysis of PHI within a covered entity.
* **“Collection”** = recording, documenting, storing, abstraction of PHI
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| **Direct Identifiers** |
| * Names
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| * Street Address / Mailing information (anything more specific than City or Zip Code)
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| * Telephone numbers, including fax
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| * Electronic mail addresses
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| * Social security numbers
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| * Medical record numbers
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| * Health plan beneficiary numbers, or any other account numbers
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| * Certificate/license numbers, vehicle identifiers/serial numbers (including license plate)
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| * Implanted device identifiers and serial numbers
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| * Web Universal Resource Locators (URLs)
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| * Internet Protocol (IP) address numbers
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| * Biometric identifiers, including finger and voice prints or audio recordings
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| * Full face photographic images and any comparable image, including video recordings
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| **Indirect Identifiers** |
| * Geographic Identifiers such as City/Town and Zip Code [*Anything more specific is directly identifiable*]
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| * **All elements of dates** (except year) directly related to an individual (e.g. date of birth/ death/ admission/ discharge, etc.) and **all ages over 89 that are not aggregated** into a single category of age 90 or older
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| * Any other unique identifying number, characteristic or code *[This includes numbers or codes that combined with other information could make the data identifiable. An example includes an accession number assigned to a coded specimen when the researcher has access to a database that can identify an individual using that number]*
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| With some exceptions, the Privacy Rule imposes a **minimum necessary** requirement on all permitted uses and disclosures of PHI by a covered entity. This means that a covered entity must establish that the **PHI to be used and/or disclosed are limited to the minimum amount reasonably necessary** to achieve the purposes (e.g., necessary for the specific research) for which disclosure is sought. |
| 1. Please describe why the elements of PHI you are using and collecting are the minimum necessary to accomplish your research objective.
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| 1. **Data Disclosure**
* **“Disclosure**”= the sharing of PHI outside of a covered entity.

**“Covered Entities”** **at Penn**: Any transfer of data between the entities listed online [HERE](https://irb.upenn.edu/mission-institutional-review-board-irb/guidance/other-elements-research) or to places outside of those entities (including to other Penn entities not listed here) constitutes a disclosure.  |
| 1. Are you planning to disclose (share) any individual subject level data outside of Penn or outside of the covered entity within Penn that you work for? *[If you are only sharing analyzed results or aggregated data, please answer No.]*

[ ]  **NO**, I do not plan to disclose (share) any individual subject level data outside of my covered entity. **(IF NO, SKIP TO SECTION V.)**[ ]  **YES**, I do plan to disclose some or all individual subject level data outside of my covered entity. **(IF YES, complete section IV, B)** |
| 1. **Disclosures**
2. Please review the identifiers you selected in the HSERA application Procedures Page, Protected Health Information/Data Protection. In the box below, please list all intended recipients and the data elements each recipient will receive. Please ensure this list of intended recipients aligns with the HSERA application Procedures Page, Data Disclosure section. If no identifiers will be included, please answer “None.” *(If you intend to disclose to more than 5 recipients, please provide a supplemental table as an additional attachment to your application)*
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| Recipients | Data Elements |
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| 1. If the data you plan to disclose only include indirect identifiers, the dataset qualifies as a “limited dataset” under HIPAA and the disclosure is permitted without subject Authorization provided you obtain a [Data](http://www.upenn.edu/researchservices/Forms%20and%20Agreements.html) Use Agreement (DUA). The following are considered indirect identifiers:
* Geographic identifiers such as city/town and zip code
* All elements of dates and all non-aggregated ages over 89
* Any other unique identifying number characteristic or code

[ ]  Please check this box to confirm that you will obtain a DUA before disclosing any limited datasets outside of the covered entity. *Please note that if the data you will share contains no direct or indirect identifiers, a data use agreement is not required but may be executed if desired. A DUA can be executed by the Office of Research Services through use of their research inventory system. Look for the log-in to the research inventory system at the link in the left navigation bar at the following site:* [*www.upenn.edu/researchservices*](http://www.upenn.edu/researchservices) |
| 1. If you are requesting a waiver to disclose any *direct identifiers* (e.g., name, MRN, etc.) without obtaining subject authorization, please provide rationale for why this disclosure is necessary to achieve the research objective. **[Please Note: The IRB does not recommend the disclosure of direct identifiers outside of the institution. Disclosure of direct identifiers without subject Authorization may be considered greater than minimal risk and may require convened IRB review]**
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| * 1. Please explain how the recipient will protect the PHI from improper use and disclosure. This should explain how the data will be stored and secured as well as provide confirmation that it is in compliance with their institutional policies.
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| 1. For all disclosures, please explain why the data you are asking to disclose qualifies as the minimum necessary you need to disclose to accomplish the study objectives.
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| 1. **Minimal Risk Assessment**

The use of PHI must present no more than minimal risk to the privacy of individuals.  |
| 1. **Please provide a plan to protect the PHI from improper use and disclosure.**
	* If you plan to have a separate linking set, please describe how that will be maintained.
	* In the event that PHI will be disclosed, please include plans for protection of the data during transmission and plans for secure storage of PHI by the recipient.
	* If this plan for storage is already described in the subject confidentiality section of your HSERA application, please answer “see the Subject Confidentiality Section of the HSERA application.”
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| 1. **Please describe your plan to destroy identifiers at the earliest opportunity consistent with the conduct of the research.**
	* Please be sure your response covers the specific planned time point for and method of destruction.
	* If you plan to share identifiers with external recipients, their planned time point for destruction of identifiers must also be included.
	* If you have no plans to destroy identifiers, please provide the rationale for retaining the identifiers and confirm that any use of the identifiable data for future research will only be used under an IRB approved protocol.
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| 1. **[ ]** By checking this box, I affirm that PHI will not be reused or disclosed in a manner different from what is outlined in this request unless permitted by appropriate privacy board review.
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| 1. **Practicability**
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| 1. Please explain why the research could not practicably be done without access to this specific PHI and without disclosing this specific PHI:
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| 1. Please explain why it is not practicable to obtain HIPAA Authorization individually from potential subjects:
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| ***NOTE: HIPAA waiver requests for prospective data collection require additional rationale as to why it would be impracticable to obtain HIPAA authorization from subjects or their legally authorized representative (LAR), given that prospective data collection may involve an opportunity to interact with the subject and obtain HIPAA authorization. If you have questions about a waiver request for prospective data collection, please contact the IRB staff prior to submission of your protocol.*** |

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| State Law ConsiderationsState laws impose additional requirements to research conducted in Pennsylvania and New Jersey. Please fill out the sections below as applicable.  |
| Pennsylvania*This section applies to patients who receive health services within the state of Pennsylvania* | If not applicable, check the box [ ]  |
| 1. **Does the study involve the use or collection of HIV status or HIV related data (e.g., HIV antiviral medications)?**

[ ]  **NO**[ ]  **YES:** Please note that Pennsylvania statute 35 P.S. 7607(A) states that research personnel cannot access or collect confidential HIV related information for research purposes ***without prospective consent*** from the individual, ***if he/she is not involved in a person’s clinical care*** (e.g., the researcher must be the patient’s care provider): <http://codes.findlaw.com/pa/title-35-ps-health-and-safety/pa-st-sect-35-7607.html> 1. [ ]  Please confirm you are the patients’ treating clinician OR
2. Provide a plan for prospective consent and HIPAA authorization in HSERA.
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| 1. **Does the study involve the use or collection of data from** mental health facility records**?**

[ ]  **NO**[ ]  **YES:** Please note that Pennsylvania statute generally precludes a waiver of consent for the use of data from the health records of a mental health facility: [www.pacode.com/secure/data/055/chapter5100/s5100.31.html](http://www.pacode.com/secure/data/055/chapter5100/s5100.31.html). *Provide a plan for prospective consent/HIPAA authorization process in HSERA.*  |
| 1. **Does the study involve the use or collection of data pertaining to *drug*/*alcohol* *use, addiction,* or *dependence*?**

[ ]  **NO**[ ]  **YES:** Please note that Pennsylvania statute precludes a waiver of consent for the use of any ***identifiable*** patient records related to ***drug* or *alcohol* *use, addiction,* or *dependence***: [www.health.state.pa.us/pdf/act63.pdf](http://www.health.state.pa.us/pdf/act63.pdf). Please delineate your plans below: [ ]  The data will be de-identified and not linked to a code nor participant identifiers. [ ]  Prospective consent/HIPAA authorization will be obtained. |
| New Jersey*This section applies to patients who receive health services within the state of New Jersey including Princeton Health and any affiliated sites.*  | If not applicable, check the box [ ]  |
| 1. **Does the study involve the obtaining a DNA biospecimen or genetic information from records of patients?**

[ ]  **NO**[ ]  **YES:** Please note that NJ state law precludes a waiver for obtaining and retaining ***identifiable*** genetic information. Likewise, a DNA sample from an individual who is the subject of a research project must be destroyed promptly upon completion of the project or withdrawal of the individual from the project, whichever occurs first. **A waiver is only permitted when the genetic information/ biospecimens are de-identified with no link to identifiers.** Please delineate your plans below: [ ]  Genetic information/DNA samples will be de-identified and not linked to a code nor participant identifiers. The DNA sample will be destroyed promptly upon completion of the project or withdrawal of the individual from the project. [ ]  Prospective consent/HIPAA authorization will be obtained. |
| 1. **Does the study involve the use or collection of data from** mental health records**?**

[ ]  **NO**[ ]  **YES:** Please note that NJ Statute (N.J.A.C. 10:37-6.53) precludes a waiver of consent for the use of any ***identifiable*** mental health data from mental health records. Please delineate your plans below: [ ]  The data will be de-identified and not linked to a code nor participant identifiers. [ ]  Prospective consent/HIPAA authorization will be obtained. |