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DEPARTMENT OF HEALTH

APPLICATION FOR WAIVER OF AUTHORIZATION
TO THE
PENNSYLVANIA DEPARTMENT OF HEALTH INSTITUTIONAL REVIEW BOARD

Purpose: A waiver is needed when an individual within a covered entity (such as the Pennsylvania Department of Health) 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.

To approve a waiver of Authorization at the Pennsylvania Department of Health, the IRB (serving as a Privacy Board) must determine that ALL the following criteria have been met:

- The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals based on the presence of the following elements:
  - An adequate plan to protect the PHI from improper use and disclosure;
  - An adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of research, unless there is justification for retaining the identifiers or such retention is required by law; and
  - Adequate written assurances that the PHI will not be reused or disclosed, except as required by law, for authorized oversight of the research or for other research for which the use or disclosure would be permitted by HIPAA regulations.
- The research could not practicably be conducted without the waiver and access to and use of the PHI.

This form is a supplement to the IRB application:
Please ensure that your 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.

***This form should be used to request a waiver of authorization**
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) to create a limited dataset, then a waiver of 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.

Date Waiver of Authorization was issued:
☐ Expedited Basis ☐ After deliberation of the full IRB

Study Information

Study Title:	
Name of Primary Investigator (PI):	IRB Protocol #:
PI Phone #:	PI Email address:

General Information

A. Please choose the option below that best describes the data you will collect:

☐ The data being collected is fully retrospective (all data is already "on the shelf" at the time of this request)

☐ The data being collected is both retrospective and prospective

☐ The data being collected is prospective only

B. Please specify the period from which data could be generated and included in your study:
From: To:

C. Please indicate the approximate number of subjects (or eligible cases in a chart review study) that will have data included in your study:

D. 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.

Identifiable Information to be Collected or Used

- Please use the checkboxes in sections A and B in the table below to indicate the types of information being collected and/or used as part of the research
- **"Use**" = the sharing, employment, application, utilization, examination, or analysis of PHI within a covered entity.

Please ensure that the listing of protected health information (PHI) to be used as selected below aligns with the PHI selected in the application.

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A. Direct Identifiers:

- ☐ Names
- ☐ Street Address / Mailing information (anything more specific than City or Zip Code)
- ☐ Telephone numbers, including fax
- ☐ Electronic mail addresses
- ☐ Social security numbers
- ☐ Medical record numbers
- ☐ Health plan beneficiary numbers, or any other account numbers
- ☐ Certificate/license numbers, vehicle identifiers/serial numbers (including license plate)
- ☐ Implanted device identifiers and serial numbers
- ☐ Web Universal Resource Locators (URLs)
- ☐ Internet Protocol (IP) address numbers
- ☐ Biometric identifiers, including finger and voice prints or audio recordings
- ☐ Full face photographic images and any comparable image, including video recordings

B. Indirect Identifiers:

- ☐ Geographic Identifiers such as City/Town and Zip Code [Nothing more specific can be included]
- ☐ 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
- ☐ Any other unique identifying number, characteristic or code [Please check this box if you are using 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]

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. Please describe why the elements of PHI selected from the list above are the minimum necessary to accomplish your research objective.

Data Disclosure

Are you planning to disclose any individual subject level data outside of The Pennsylvania Department of Health or outside of the covered entity that you are researching for?

If you are only sharing results or aggregated data, please answer No below.

☐ NO, I do not plan to disclose any individual subject level data outside of any of my covered entity. (If no, please proceed to section V.)
☐ YES, I do plan to disclose some or all individual subject level data outside of my covered entity.

1. Please review the identifiers you selected in the "Identifiable Information to be Collected or Used" section. In the box below, please list all intended recipients and the data elements each recipient will receive. Please ensure this list of intended recipients mirrors the data disclosure section in the HSERA application. 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)

Recipients	Data Elements

2. If the data you plan to disclose only contain indirect identifiers, the dataset qualifies as a "limited dataset" under HIPAA and the disclosure is permitted without subject Authorization, provided you obtain a Data Use Agreement (DUA). The following are considered indirect identifiers:

- Geographic identifiers such as city/town and zip code;
- All elements of dates; and
- 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.

3. If you are requesting a waiver to disclose any identifiers that are not considered indirect identifiers without obtaining subject Authorization, please provide your rationale for why this disclosure is necessary to achieve the research objective. **{Please Note: disclosure of direct identifiers without subject Authorization may be considered greater than minimal risk and may require convened IRB review}**

4. 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.

Minimal Risk Assessment

For a HIPAA waiver to be granted, the use of PHI must present no more than minimal risk to the privacy of individuals. The following must be addressed to establish that the use is no more than minimal risk:

- There must be an adequate plan to protect PHI from improper use and disclosure;
- There must be an adequate plan to destroy PHI at earliest opportunity consistent with conduct of the research; and
- Adequate assurances must be provided if PHI will not be reused or disclosed unless permitted.

A. Please provide a plan to protect the PHI from improper use and disclosure. If PHI will be disclosed, please include plans for protection of the data during transit 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."

B. 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 destruction. If you plan to have a separate linking set please describe how that will be maintained. 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 explain the reason 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.

☐ 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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Practicability
Please explain why the research could not practicably be done without access to this specific PHI and without disclosing this specific PHI:
Please explain why it is not practicable to obtain HIPAA Authorization individually from potential subjects:
Please note that HIPAA waiver requests for prospective data collection require additional justification 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.

Completed Waiver of Authorization forms should be submitted electronically to ra-healthresearch@pa.gov or mailed to Department of Health, Health Research Office, Health and Welfare Building, Room 833, 625 Forster St., Harrisburg, PA 17120-0701.