

Frankford Hospital
 Institutional Review Board
 Red Lion & Knights Road
 Mansion House – 3rd Floor
 Philadelphia, PA 19114

IRB REQUEST FOR WAIVER OF HIPAA AUTHORIZATION
 to Use or Disclose Documents, Records or Data Sources Containing Identifiable,
 Protected Health Information (PHI) for Research Purposes
 (Provide Original & 2 copies, unless full-board review is required)

Project Title			
Principal Investigator	Name	Phone:	
	Title	Email:	
	Address		
Primary Contact (if not Principal Investigator)	Name	Phone:	
	Title	Email:	
	Address		
IRB USE ONLY	<p>This project meets the IRB criteria for waiver of authorization: <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Printed Name: (Authorized IRB signatory)</p> <p>Authorized IRB Signature: _____ Date: _____</p>		

<p>REQUIRED INFORMATION</p> <p>The information must include a specific description of the procedure(s) and health information collected/used (e.g. surveys, record reviews, etc.), involving the human subjects in sufficient detail to demonstrate to the IRB reviewer that the research project/protocol meets the requirements for waiver of authorization and prospective informed consent. The information can be provided on this form or included as a separate addendum keeping the numbered heading scheme of this form.</p> <p>If you are only collecting or using – and <u>not</u> disclosing:</p> <ul style="list-style-type: none"> • <u>Indirect identifiers</u> (listed in the right hand column of the table noted below), the risk is considered minimal risk to privacy. If you disclose information containing indirect identifiers under a data use agreement then the disclosure is also deemed minimal risk by the IRB. • <u>Direct identifiers</u> (listed in the left-hand column of the table noted below), then you must provide a rationale for the collection and use of these identifiers. The following issues must be addressed if applicable: How will the collected data be kept secure? Will the direct identifiers be kept separate from the collected health information and separately secured? These are addressed in the numbered items below. <p>If you are collecting or using – and <u>will be</u> disclosing:</p> <ul style="list-style-type: none"> • <u>Direct identifiers</u>, the risk to privacy may be greater than minimal and full IRB review if required. In this circumstance you will need to describe additional privacy protections in question #8 below, in order to demonstrate to the IRB that the research will qualify as less than minimal risk.

Please provide the following information:

1. The objective (hypothesis) of the research project and a brief background for the study. If this is a new IRB submission please submit a **Research Application form**, two copies of the protocol summary and full protocol. If this is a request to amend a protocol, provide a copy of the amended protocol and IRB number.
2. The rationale for the use of the selected subject population, record set, archives or material and sources of information.
3. Describe the reasons why the research could not be practicably carried out without the waiver of authorization or consent to collect and/or use the protected health information.
4. Provide a rationale as to why the research described in the research protocol could not be practicably conducted without access to the health information.
5. The specific type of data to be collected and used and why this is considered the minimum necessary to conduct the analysis. (Must be specific and include a copy of a data collection sheet(s).) **Please complete the attached table: “Identifiable Information.”**
6. Does the recorded data contain either a direct identifier or a link to allow the re-identification of the individual?¹

<input type="checkbox"/> Yes	<input type="checkbox"/> No
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If yes, describe the procedures to protect the confidentiality and security of this linking data set and specific plans as to the time point at which the linking data set will be destroyed.

If the linking set will not be destroyed provide written assurance that access to the identifiable data for future research will not be done without prior IRB approval.

7. During the conduct of the research what is your plan to protect the identifiers from improper use and disclosure?
8. If you intend to disclose information containing direct identifiers listed below in the “Identifiable Information” table (left column), the risk to privacy may be greater than minimal and full IRB review is required. Please provide the Committee a rationale as to why the disclosure of the protected health information with these direct identifiers, is thought to involve no more than minimal risk to the rights, welfare and/or privacy of the individuals. Fully describe any additional privacy protections that will be put in place in order to protect the privacy of the individuals. Please submit an original and 19 copies of this form.

¹The code or other means of record identification should not be derived from or related to information about the research subject and should not otherwise permit re-identification of the subject.

Please complete the following checklist related to specific identifiers of the research subject or of relatives, employers, or household members of the research subject to be collected, used or disclosed.

Direct Identifiers		Identifiable Information	Indirect Identifiers (Limited Data Set)	
Used/ Collected (check if yes)	Disclosed (check if yes)		Used/ Collected (check if yes)	Disclosed (check if yes)
<input type="checkbox"/>	<input type="checkbox"/>	Names		
<input type="checkbox"/>	<input type="checkbox"/>	Street Address, Apartment #, Precinct, or other geocode more geographically specific than zip code.		
		City/Town, State and Zip Code (Note: for the records to be considered de-identified only the first three digits of the zip code can be used ²)	<input type="checkbox"/>	<input type="checkbox"/>
		All elements of dates (except year) for dates directly related to an individual (e.g. date of birth/death, dates of admission/discharge etc.)	<input type="checkbox"/>	<input type="checkbox"/>
		Ages less than 90, and "90 and above" for those over 90.	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	Telephone numbers, including fax		
<input type="checkbox"/>	<input type="checkbox"/>	Electronic mail addressed		
<input type="checkbox"/>	<input type="checkbox"/>	Social security numbers		
<input type="checkbox"/>	<input type="checkbox"/>	Medical record numbers		
<input type="checkbox"/>	<input type="checkbox"/>	Health plan beneficiary numbers, or any other account numbers		
<input type="checkbox"/>	<input type="checkbox"/>	Certificate/license numbers, & vehicles identifiers and serial numbers, including license plate numbers		
<input type="checkbox"/>	<input type="checkbox"/>	Implanted device identifiers and serial numbers		
<input type="checkbox"/>	<input type="checkbox"/>	Web Universal Resource Locators (URLs)		
<input type="checkbox"/>	<input type="checkbox"/>	Internet Protocol (IP) address numbers		
<input type="checkbox"/>	<input type="checkbox"/>	Biometric identifiers, including finger and voice prints or any audio recordings		
<input type="checkbox"/>	<input type="checkbox"/>	Full face photographic images and any comparable image, including video recordings		
<input type="checkbox"/> None of the Direct Identifiers noted above will be collected.			<input type="checkbox"/> None of the Indirect Identifiers noted above will be collected.	

²The first three digits of the zip code may be used as the population in that region is greater than 20,000. If the geographic unit is less than 20,000 only state may be used.

INVESTIGATOR'S ASSURANCE

I certify that the information provided in this request for Waiver of HIPAA Authorization is complete and correct.

I understand that as Principal Investigator, I have ultimate responsibility for the protection of the privacy rights and welfare of human subjects and the ethical conduct of this research project/protocol. I agree to comply with all FH policies and procedures, as well as with all applicable federal, state and local laws regarding the protection of human subjects in research, including, but not limited, to the following:

- Permitting performance of the project only by qualified personnel according to the research project/protocol.
- Maintaining of a copy of all questionnaires, survey instruments, interview questions, data collection instruments, and information sheets for human subjects for at least three years following termination of the project unless otherwise necessary to protect subject confidentiality as described in the project/protocol.
- Acquiring the necessary review by the FH IRB if substantial changes are made in the research project/protocol or if any change is made which may result in the research no longer meeting the criteria for waiver.
- Maintaining as secure any protected health information collected for this research project/protocol, and not sharing access to such information with any individual without prior review and approval of the IRB and/or privacy officer unless such subset has been created to exclude all identifiable demographic information as defined in this document, or unless additional data use agreements have been obtained for distribution of limited data sets.
- Maintaining and accounting of disclosures as required under the HIPAA privacy regulations. This accounting will include, at a minimum:
 - The date, or range of dates, of disclosure
 - The name of the entity or person to whom the information was disclosed
 - If available, the address of the entity or person to whom the information was disclosed
 - A brief description of the PHI disclosed
 - A brief statement explaining the purpose for the disclosure or, in lieu of this statement, a copy of the written request that caused the disclosure.
- Forbidding attempts to re-identify the subjects from the date collected under this waiver, and attempts to contact the subjects or their family members.

I have completed the required educational program on ethical principles and regulatory requirements in human subjects research and HIPAA as necessary prior to initiating the research.

Signature: Principal Investigator noted above

Date