

IRB Request for Waiver of HIPAA Authorization

Grant #		Responsible Org.
Project Title		
Principal Investigator	Name	Phone
	Title	E-mail
	Address	
Primary Contact (if not Principal Investigators)	Name	Phone
	Title	E-mail
	Address	

A. Provide the following information:

- The objective (hypothesis) of the research project and a brief background for the study. If this is a new IRB submission please submit an IRB application. If this is a request to amend an approved protocol, submit a modification form, a copy of the revised protocol, and IRB number.**
- The rationale for the use of the selected subject population, record set, archives or material and sources of information.**
- 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.**
- Provide a rationale as to why the research described in the research protocol could not be practicably conducted without access to the health information.**
- 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."***
- Does the recorded data contain either a direct identifier or a link to allow the re-identification of the individual?¹**
 Yes No
 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.
- During the conduct of the research what is your plan to protect the identifiers from improper use and disclosure?**
- 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 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.**

B. Complete the following checklist:

¹ The 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.
Version: November 11, 2010

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)
		Names		
		Street Address, Apartment #, Precinct, or other geocode more geographically specific than zip code.		
		City/Town, State and Zip Code <i>To be considered de-identified, only the first three digits of the zip code may be used</i>		
		All elements of dates (except year) for dates directly related to an individual (e.g. date of birth/death, dates of admission/discharge etc.)		
		Ages less than 90 and a single aggregated category for "90 or older"		
		Ages 90 or greater and data are not aggregated into a single category of "90 or older"		
		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 and serial numbers, including license plate numbers		
		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		
		None of the Direct Identifiers noted above will be collected		None of the Indirect Identifiers noted above will be collected

Definitions

“De-identified Data” Data that is “de-identified” under HIPAA is not regulated by HIPAA and may, accordingly, be used or disclosed for research and other purposes without patient authorization. Data is “de-identified” under HIPAA if the following identifiers of the individual or of relatives, employers, or household members of the individual are removed:

- **Names**
- **All geographic subdivisions smaller than a State**, including street address, city, county, precinct, zip code, and their equivalent geo-codes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census, (a) the geographical unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; and (b) the initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
- **All elements of dates (except year)** for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or order.
- **Telephone numbers**
- **Fax numbers**
- **Electronic mail addresses**
- **Social security numbers**
- **Medical record numbers**
- **Health plan beneficiary numbers**
- **Account numbers**
- **Certificate/license numbers**
- **Vehicle identifiers and serial numbers, including license plate numbers**
- **Device identifiers and serial numbers**
- **Web Universal Resources (URLs)**
- **Internet Protocol (IP) address numbers**
- **Biometric identifiers, including finger and voice prints**
- **Full face photographic images and any comparable images**
- **Any other unique identifying number, characteristic, or code**, except that a code may be assigned to allow information de-identified by removal of all above information to be re-identified provided that: (a) the code is not derived from or related to the information from and the individual and is not otherwise capable of being translated so as to identify the individual; and, (b) the code is not used for any other purpose nor disclosed to any outside entity

“Disclosure” means the release, transfer, provision of access to, or divulging of protected health information by any means to persons or entities outside of FIGHT or other covered entity.

“Limited data set” Members of a covered entity may use or disclose data contained in a “limited data set” for research purposes, without obtaining individual authorization.. A “limited data set” excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual:

- *Names*
- *Postal address information, other than town or city, State, and zip code*
- *Telephone numbers*
- *Fax numbers*
- *Electronic mail addresses*
- *Social security numbers*
- *Medical record numbers*
- *Health plan beneficiary numbers*
- *Account numbers*
- *Certificate/license numbers*
- *Vehicle identifiers and serial numbers, including license plate numbers*
- *Implanted device identifiers and serial numbers*
- *Web Universal Resource Locators (URLs)*
- *Internet Protocol (IP) address numbers*
- *Biometric identifiers, including finger and voice prints*
- *Full face photographic images and any comparable image*

“Protected Health Information (PHI)” Protected health information (PHI) is defined under the HIPAA regulations as information that is a subset of health information, including demographic information collected from an individual, and: (1) is created by a health care provider, health plan, employer, or health care clearinghouse; and (2) relates to the past, present or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual; and (i) that identifies the individual; or (ii) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

“Use” means to collect, share, employ, apply, utilize, examine, or analyze PHI within Philadelphia FIGHT.

Investigator’s Responsibilities

The Principal Investigator (PI) has the ultimate responsibility for the protection of the privacy rights and welfare of human subjects and the ethical conduct of this research project. The PI is obligated to comply with all FIGHT 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 Philadelphia FIGHT 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.
- Forbidding attempts to re-identify the subjects from the data collected under this waiver, and attempts to contact the subjects or their family members.