NewYork-Presbyterian/Queens

Theresa & Eugene M. Lang Center for Research & Education

Request for a Waiver of Consent and Waiver of Authorization under HIPAA

(Incomplete or Incorrect Forms will be returned and may delay the IRB review process. If you require assistance in completing this form, please contact the IRB office at 718-670-2914**)**

Principal Investigator (PI) Information

PI Name:		
PI Department:		
PI Email:	PI Telephone:	Spectra:

Protocol Information

Title:	**IRB File #:**

Waiver of Consent ☐ **N/A**

Describe why this research involves no more than minimal risk to the subjects:		
Describe why this consent waiver will not adversely affect the rights and welfare of the subjects.		
Describe why this research could not be carried out without a waiver of consent.		
Will subjects be provided with any information on this study after participation? If so, what information will they be given?	Yes ☐	No ☐

HIPAA-Waiver of authorization to use and disclose protected health information (PHI) ☐ **N/A**

Describe the protected identifiable health information that will be accessed under this waiver (see below for Identifiers that are protected):			
Who will have access to the information?			
In what form will the information be maintained? ☐ **Paper** ☐ **Electronic** ☐ **Both**			
If the information is in paper format, describe the precautions you are taking to protect the identifiers from improper use and disclosure:			NA ☐
If information is in an electronic medium, are passwords required?	NA ☐	Yes ☐	No ☐

Is access to the information restricted to only those who have a need to know for performance of their job?	Yes ☐	No ☐
Is this electronic system used to transmit data outside of your site?	Yes ☐	No ☐
If information is transmitted, what safeguards does your system have to prevent inadvertent access to this data?		
When do you plan to destroy the identifiers? (Identifiers must be destroyed at the earliest opportunity.) ☐ End of Study ☐ _____ years after the end of the study. ☐ Other (please specify):_____		
Other than you and your research staff, who else will have access to this information?		
Please explain how your research meets the criteria for a waiver: **(Both Q1 & Q2 must be answered)** 1. Explain why this research cannot be practicably be carried out without a Waiver of Authorization under HIPAA:		
2. Explain why this research cannot practicably be conducted without collecting the participants' PHI.		

By signing this statement, I am providing written assurance that only information essential to the purpose of this research will be collected, and access to the information will be limited to the greatest extent possible. Protected health information will not be re-used or disclosed to any other person or entity.

_____
Principal Investigator's Name (Print)

_____ _____
Principal Investigator's Signature Date

HOW TO KNOW IF YOUR STUDY IS USING PROTECTED HEALTH INFORMATION

(HIPAA Definitions and the 18 Protected Health Identifiers (PHI)

1. **HIPAA Authorization:** Obtaining permission from an individual for release of their protected health information (PHI) for research purposes. AHIPAA Authorization contains certain elements required by the HIPAA Privacy Rule (e.g., how, why and to whom PHI will be used or disclosed) and is required in all NYP/QUEENS informed consent documents. The NYP/QUEENS IRB requires that informed consent documents contain the NYP/QUEENS IRB approved HIPAA language (Please contact the IRB office at extension 1194 if you require this template)

   If a research study is using PHI and applying for a waiver of consent, a request for Waiver of authorization to use and disclose protected health information (PHI) must also be completed.

2. **Protected Health Information (PHI):** Information in any format that identifies an individual, including demographic information collected from an individual that can reasonably be used to identify the individual. Additionally, PHI is information created or received by a health care provider, health plan, employer, or health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual.

3. **Identifiers:** Under the HIPAA Privacy Rule "identifiers" include the following:
   - Names
   - Geographic subdivisions smaller than a state (except the first three digits of a zip code if the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people and 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, and 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 older)
   - 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 Resource Locators (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 (excluding a random identifier code
   - for the subject that is not related to or derived from any existing identifier

4. **De-identified:** Information that has certain identifiers (see "identifiers") removed in accordance with 45 CFR 164.514 is no longer considered to be Protected Health Information.