

Application for Waiver of HIPAA Authorization

When to Use This Form:

Use this form to request a partial waiver of HIPAA authorization, or full waiver of HIPAA authorization. This form should be submitted in conjunction with a new IRB application or as an addendum to an already approved IRB study. This form must be completed electronically. The IRB will not accept handwritten forms

Please indicate what this request is for (mark all that apply)

* Waiver of HIPAA authorization *(Complete Section* A)
* Partial Waiver of HIPAA authorization *(Complete Section B)*

Principal Investigator:

Email Address (St. John’s email address required):

Phone:\_\_\_\_\_\_\_\_\_\_\_ Department: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Project Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Co-Investigators: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# HIPAA AUTHORIZATION

SECTION A: WAIVER OF HIPAA AUTHORIZATION

### Complete this section if you seek to obtain a waiver of HIPAA authorization to use and/or disclose protected health information. (Note: if you are conducting a chart review and are requesting a waiver of informed consent, you must also complete this section

### 1. Describe the risks to privacy involved in this study and explain why the study involves no more than minimal risk to privacy: Besides a potential breach of confidentiality, there is no risk of harm to the patients. There will be elements in place to reduce the risk of a breach of confidentiality.

2. What is your plan to protect identifiers from improper use or disclosure and to destroy them at the earliest time? Besides a potential breach of confidentiality, there is no risk of harm to the patients. There will be elements in place to reduce the risk of a breach of confidentiality. The Pl will report any unanticipated problems (within 5 business days) or protocol deviations (within 10 business days) to the NSLIJ IRB. Demographic and clinical data will be attained and recorded on Redcap that can only be accessed by the investigators to maintain patient confidentiality. Redcap will also automatically de-identify each patient.

3. Why is it not possible to seek subjects' authorization for use or disclosure of PHI? It is impractical to conduct this research if authorization for use or disclosure of PHI is required because we would need to contact all 35 individuals and ask them to come into the office. We have a limited span of time (1-2 months) to conduct this research and it may take well over half a year to get the consent of all the individuals.

4. Why is it not possible to conduct this research without use or disclosure of the PHI? In this research, we will not be disclosing any PHI to anyone outside of the study investigators. However, we will require the patients' PHI to access their charts and find information that is relevant to our research.

5. Will the PHI be disclosed in any way outside the Health System and your research team?

* Yes; To whom:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* No

## SECTION B: PARTIAL WAIVER OF HIPAA AUTHORIZATION FOR SCREENING/ RECRUITMENT REQUEST

If it is impracticable to obtain a potential subject's prior authorization (i.e., the researcher does not have access to patient records as s/he is not part of the covered entity), the researcher may ask the IRB to grant a partial waiver of the patient's authorization for screening/recruitment purposes.

1. Describe how data will be collected and used: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_-

Note: Information collected through a partial waiver for recruitment cannot be shared or disclosed to any other person or entity.

1. Why do you need the PHI? (Check all that apply)
   * Protected health information is required to determine eligibility
   * Identifiers are necessary to contact the individual to discuss participation
   * Other: Explain:
2. Explain why the research cannot be practicably conducted without the partial waiver? (Check all that apply)
   * I don't have access to the medical records/contact information of the targeted population
   * There is no treating clinician to assist in recruitment of the targeted study population
   * The targeted study population will not be exposed to advertisements/media, or any other institutional programs or activities that would provide the opportunity for screening/recruitment
   * Assistance from treating clinicians has been historically minimal, producing sub-par accrual
   * Other: Explain:

**Pl Signature**

I **attest the information provided on this form is true and accurate.**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_**

**Pl Printed Name PI Signature Date**