**SUNY Downstate IRB & Privacy Board**
**FORM 8-18: HIPAA Waiver**
(Version 04.20.2022)
Instructions: 1) Open form in Adobe Reader. 2) Use Fill & Sign tool to complete. 3) Confirm any preformatted fields are correct. 4) Save file. 5) Submit completed form to IRB.
*Note: Free Adobe Reader available at: www.adobe.com*

A. Project Title:

B. Principal Investigator:

C. Type of request (check up to 3 applicable boxes):

☑ **Full HIPAA Waiver**

☐ **Partial HIPAA Waiver** (for recruitment purposes). A HIPAA Authorization will be obtained at the time of enrolling research participants.

☐ **HIPAA Alteration:** This is a request to waive one or more of the required elements of the HIPAA Authorization form (e.g., signature). If checked, include description of waived element(s) below:

D. ☐ (Optional) check this box, if this request also applies to a waiver of the entire process of informed consent under the Common Rule. *Note: This box should be unchecked for Exempt applications, as informed consent does not apply under the Common Rule.*

The following criteria must be met to waive the informed consent process:

- The research involves no more than minimal risk to the research participants;
- The research could not practicably be carried out without the requested waiver or alteration;
- If the research involves the use of identifiable private information or identifiable specimens, the research could not practicably be carried out without using such information or specimens in an identifiable format;
- The waiver or alteration will not adversely affect the rights and welfare of the participants;
- Whenever appropriate, the research participants, legally authorized representatives, or personal representatives will be provided with additional pertinent information after participation.

☐ Check if N/A, or otherwise when applicable, describe below how the research participants will be provided with additional pertinent information after participation (explain process to debrief participants involved in deception research and/or attempt contacting participants if life threating results are found, etc.):

E. Indicate all study procedures used in the research to confirm the study involves no more than minimal risk to the participants or their privacy (check all that apply):

- ☐ Blood collection from participants
- ☐ Focus group, survey, or interview research
- ☐ Record, data, document, or non-invasive specimen collection for research purposes
- ☐ Remnants of specimens collected for routine clinical care or analysis that would otherwise be discarded (i.e., left over clinical specimens to be discarded into waste)
- ☐ Collection of video, voice, digital, or image recording data made for research purposes
- ☐ Collection of data through non-invasive means routinely done in clinical practice
- ☐ Mobile applications that track data in accordance with data security requirements
- ☐ Other:

F. Explain why this waiver/alteration will not adversely affect the rights and welfare of participants:

- ☐ Research involves minimal risk to the participants
- ☐ Data will be de-identified and destroyed upon completion of project
- ☐ Data securely maintained with link to the source for validation purpose or future research
- ☐ Other:

G. Study Populations:

If there is more than one study population (or groups/study arms) in the study, please describe the population(s) (or groups/study arms) for which this waiver pertains.
*Note: A separate HIPAA Waiver form MUST be submitted when the responses in this form are different for another population or group.*

- ☑ Check box if this request applies to all study participants. Otherwise, uncheck this box and describe the study population(s) for which this waiver applies (e.g., healthy control, patients screened from medical records, specific study arm, population or group, etc.)

H. Protected Health Information (check identifiers accessed, collected, or used for research):

- ☐ Names
- ☐ Street address
- ☐ City
- ☐ County
- ☐ Precinct
- ☐ Zip code or partial zip code
- ☐ Dates
- ☐ Telephone numbers
- ☐ Fax numbers
- ☐ E-mail addresses
- ☐ Social security numbers
- ☐ Medical record numbers
- ☐ Vehicle identifiers and serial numbers (including license plates)
- ☐ Device identifiers and/or serial numbers
- ☐ Web Universal Resource Locators (URL's)
- ☐ Internet Protocol (IP) address numbers
- ☐ Biometric identifiers, including finger and voice prints
- ☐ Full face photographic images and any comparable images
- ☐ Health plan beneficiary numbers
- ☐ Account numbers
- ☐ Certificate/ license numbers
- ☐ Other unique identifying number, characteristic or code, or another HIPAA identifier listed in Policy HIPAA-6 (describe):

1. Briefly describe the PHI for which you are requesting access. List, in detail, the health information that is to be collected for the research activity:

2. PHI Source:
- ☐ Hospital/Medical/Clinical records
- ☐ Pathology records
- ☐ Radiology records
- ☐ Other (describe):
- ☐ Previously collected research data
- ☐ Previously collected survey/interview data
- ☐ Billing records

3. List entity that will release or disclose the PHI to the investigators:

SUNY Downstate; IF APPLICABLE, ADD/EDIT SITE INFORMATION: Kings County (KC) investigators will have access to PHI from KC patients. KC investigators may share coded or de-identified data with Downstate investigators.

4. Why is the PHI the minimum necessary to meet the research objectives?

EDIT AS NEEDED: We are accessing only the required PHI needed to meet the objectives of the research. No additional PHI is needed.

5. Where and how will PHI be stored securely?

EDIT AS NEEDED: Downstate PHI will be securely stored behind the Downstate firewall or locked cabinets. PHI at Kings County (KC)will be securely stored based on KC policy. Include the following as applicable to the study: (a) where the identifiable information will be stored, (b) who has access to the storage area, (c) what password protections are enabled, and (d) how access will be monitored.

6. Who will have access (this list must be inclusive, i.e., sponsor, OHRP, FDA, data safety monitoring boards, research team as listed on the associated IRB application etc.):

EDIT AS NEEDED: Only the investigators approved by the IRB will have access. OHRP and FDA and monitoring staff from the sponsor may have access to PHI on an as needed basis.

7. Date range of records: From: START DATE To: END DATE OR UN-ENDED

8. Including the primary risk of breach of confidentiality, describe the risks to the privacy of individuals involving the use or disclosure of the PHI:

EDIT AS NEEDED TO INCLUDE ALL RISKS: The primary risk is breach of confidentiality; however, the data will be protected as described below. ADD, IF NEEDED: Other risks may include_____; these risks are mitigated by _____

9. Identify anyone outside of the research site who will use or receive PHI (e.g., researchers from other institutions collaborating on this research, research sponsors).

☑ Check if N/A, otherwise describe below:

I. The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:

1. Plans to protect the identifiers from improper use and disclosure:

EDIT AS NEEDED: The research team complies with all institutional policies regarding privacy and security. Specific data security and privacy measures are described in the IRB application for this study.

2. Provide either (a) or (b):

(a). Describe an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research:

EDIT OR DELETE, AS NEEDED: After the study is completed, data will be stripped of all HIPAA identifiers listed in Policy HIPAA-6. After the study is completed, all data will be destroyed in accordance with applicable information security and privacy policies.

**-OR-**

(b). Provide a health (i.e., individual care) or research justification for retaining the identifiers or describe how retention of the identifiers required by law:

EDIT OR DELETE, AS NEEDED: All data will be securely stored for the minimum retention period required by federal regulations or longer, including up to a period of at least X years (X should be 10 years, if practicable).

J. Explain why the research cannot practicably be carried out without the waiver or alteration:

K. Explain why the research could not practicably be conducted without the PHI:

**PI Attestation:**

PHI will not be disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information is otherwise approved by the IRB or permissible under Downstate policies, including: 1) Policy HIPAA-28: Uses and Disclosures for research Purposes, and 2) HIPAA-32 policy: Uses and Disclosures Requiring Patient Authorization. Any suspected or confirmed breach or loss of PHI will be immediately reported to the IRB and HIPAA Privacy Office.

***PI MUST e-sign:*** *1) Open form in Adobe Reader. 2) Use Fill & Sign tool to complete. 3) Confirm all responses are correct. 4) Click on Red Signature tab to sign. 5) Save file. Note: Free Adobe Reader available at: www.adobe.com*

**THE SECTION BELOW IS FOR INTERNAL (IRB) USE ONLY**

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**Downstate IRB and Privacy Board Approval:** If this waiver is approved either by expedited or full board procedures as indicated in the IRB approval letter, the Downstate IRB and Privacy Board has determined that (unless otherwise indicated) the waiver requested herein and the use of the PHI/IIHI requested and described above, satisfies the required criteria for waiver of authorization under the Health Insurance Portability and Accountability Act of 1996 and implementing regulations:

- *The use or disclosure does not involve more than minimal risk to the individual because there is an adequate plan to protect the "identifiers."*
- *There is an adequate plan to destroy the "identifiers" at the earliest opportunity or there is a health (i.e., individual care) or research justification for retaining the identifiers or their retention is required by law.*
- *There are adequate written assurances that protected health information will not be reused or disclosed to any other person or entity, except (1) as required by law, (2) for authorized oversight of the research project, or (3) for other research for which the use or disclosure of protected health information is otherwise permissible under Downstate Medical Center's policy.*
- *The research could not practicably be conducted without the waiver.*
- *The research could not practicably be conducted without access to and use of the protected health information.*

Approval Review Type: ◯ Full Board ◉ Expedited procedure

**IRB/Privacy Board Certification:**

(IRB Member or Privacy Officer Signature)