Waiver of Health Insurance Portability and Accountability Act (HIPAA) Authorization

IRB Number: 1306045-1

Project Title: Adenoma prevalence, characteristics, and outcomes on screening colonoscopy in patients with HIV in an Urban Safety Net Hospital and Urban University Hospital

Principal Investigator: Savanna Thor DO, MPH

☒ **Check this box, if this request will also apply to a waiver of the informed consent process.**
Note: If checked, the Application for Waiver of Informed Consent Requirements is not needed; however, this only applies to waivers of the entire process of informed consent.

If the above box is checked, the following criteria are met:

- 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 is federally supported or conducted and involves the use of identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
- The waiver or alteration will not adversely affect the rights and welfare of the participants;
- Whenever appropriate, the research participants or LARs will be provided with additional pertinent information after participation (e.g., debriefing research participants involved in deception research).

  When applicable, describe how the research participants will be provided with additional pertinent information after participation: _____ ☐ N/A

Type of request (check all 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 of the required elements of the HIPAA Authorization form (e.g., signature) and the element is described below.**

Complete the following:

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: _____ ☒ N/A – applies to all research participants.
Note: A separate request form may be made for each study population, or each population can be specifically described in each section below.

I. Provide a description of the PHI (IHII) for which use or access is necessary for the research:

a. **Briefly describe the protected health information for which you are requesting access. List, in detail, the health information that is to be collected for the research activity:** Please see Appendix 1 of the research protocol for a detailed list of variables that will be collected for each patient there are at least 50. Briefly, patients who have HIV and have had a screening colonoscopy at both DMC and KCH will be reviewed. We will be looking at the nature of their HIV and the nature of the colonoscopy results for every patient.

b. **What is the source of the health information (e.g., medical record, etc):** The source of patient information will be the medical record at Downstate we will be using Health Bridge and at Kings County we will be using Quadramed.

Note: Identify the covered entity or covered component that will release or disclose PHI (IHII) to the researcher.

c. **Explain why this health information is the minimum necessary to meet the research objectives:** We want to determine if there is a corellation between HIV disease status and the type of adenoma discovered on colonoscopy. Therefore it is important to collect many detailes regarding both of these concepts including CD4 count and viral load.

d. **Indicate where protected health information (PHI) or Individually Identifiable Health Information (IIHI) will be stored, and 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.):** There will be two excels created for data collection; one excel will be at Downstate kept on one computer in the GI suite. Another excel will be at Kings County kept on one computer in the GI suite. These excels will only be accessible to the team members listed on the IRB application. The excels will be kept on the computers hardrives which are only accessible to medical residents and not to general users of the computer. Furthremo the excels will be password protected and restricted so that copies will not be made; only team members will know the password to edit the excel.

e. **Does the use or disclosure of the PHI involve any risk to the privacy of individuals?** ☐ Yes ☒ No
If yes, describe: _____

f. **Identify anyone outside of the Downstate Medical Center or Kings County Medical Center who will use or receive PHI (e.g., researchers from other institutions collaborating on this research, research sponsors):** No one outside of the list mentioned in the IRB application will have access to the data.

II. 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:

a. Plans to protect the identifiers from improper use and disclosure: As mentioned above only team members will have access to PHI. The only reason the PHI will be used it to review patient data via the medical record number and for no other reason. It will not be distributed or copied.

b. Either (i) or (ii) must be provided:

i. Describe an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research: Once the variables are collected for each patient the respective patients MRN will be deleted and a code will be given to that data. Therefore by the end of the data collection phase all MRNs will be deleted and replaced with a code. This way during the the data collection phase, no MRNs will be used.

-OR-

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

c. The PI's e-signature in IRBNet affirms that PHI (IHII) 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 Medical Center's policies:

i. DMC Policy HIPAA-28: Uses and Disclosures for research Purposes

ii. DMC HIPPA-32 policy: Uses and Disclosures Requiring Patient Authorization

III. **Explain why the research cannot practicably be carried out without the waiver or alteration:** This is a retrospective chart review, and the ability to complete the chart review rests on the ability to have acess to charts.

IV. **Explain why the research could not practicably be conducted without access to, and use of, the PHI (IIHI):** The PHI holds all the answers to our research questions; we need the details of the patients HIV and their colonoscopy information the research cannot be conducted.

IRB/PRIVACY BOARD APPROVAL:
If this waiver is approved either by expedited or full board procedures as indicated in the IRB approval letter, the Downstate Medical Center IRB 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.*