**SUNY DOWNSTATE HEALTH SCIENCES UNIVERSITY**

**& NYC Health + Hospitals, Kings County**

*(if not applicable, delete one of the above lines and the “&”)*

**BROOKLYN, NY 11203**

**Information Sheet & HIPAA Authorization for Electronic Survey/Interview/Focus Group Session**

**Edit any of the following information as applicable to the study. Items in red are general instructions which must be deleted (or changed when applicable) before submitting the final form to the IRB. Please submit a MS Word version to the IRB or include this information within the e-mail script or electronic survey as applicable to the project. (Please delete all instructions/guidance once the document is finalized).**

**REMINDER: Include a HIPAA Waiver/HIPAA Alteration to request IRB approval to provide the HIPAA Authorization without obtaining the required signature.**

**Information for You to Consider:**

You are being invited to participate in a research study called state study’s title. This study is being done by name of Principal Investigator (PI) from SUNY Downstate Health Sciences University and NYC Health + Hospitals, Kings County (if not applicable, delete one of the above lines and the “and”). *If sponsored:* This study is sponsored by name of sponsor. You were selected to participate in this study because of briefly state study’s eligibility criteria (e.g. you are an elementary school teacher).

Please insert a short, 1-2 sentence summary of the purpose of the research, e.g., The main purpose of this study is (state purpose, such as:) to learn whether elementary school teachers prefer online/remote or in-person classroom teaching. The research will also…

If you agree to take part in this study, please complete an online survey/participate in an online focus group/interview. Briefly state what the survey/interview/ focus group entails such as: The survey/interview/focus group session with ask about your teaching preferences. We will ask some demographic questions such as your age, gender and race/ethnicity. Describe estimated time for participation, for example: It will take you approximately 10 minutes to complete the survey/participate in the focus group/interview.

There will not be any direct benefit to you from this research. The researchers, however, may learn more about (describe what information the researchers hope to learn).

There are minimal risks associated with this research, including loss of confidentiality (add if collecting identifiers). Add if applicable to focus group or interview session: We will discuss the ground rule of protecting other’s privacy; however, we cannot guarantee that everyone will understand the importance of confidentiality. Describe the electronic platform used (e.g., REDCap, Zoom, etc.) and indicate how privacy and confidentiality risks are mitigated, for example: We will obtain anonymous results through a Zoom interview. [or edit this section as appropriate, if identifiers will be retained with the study’s data.] Research records will be kept confidential to the extent allowed by law and may only be reviewed by those authorized by the SUNY Downstate Health Sciences University Institutional Review Board (IRB) & Privacy Board.

Your participation in this study is completely voluntary and you can withdraw at any time by simply exiting the survey. [If data for partially completed surveys for those who withdraw will be retained, disclose that here.] Choosing not to participate or withdrawing from the study will not result in a penalty or loss of benefits or services to which you are entitled. You are free to skip any question that you choose.

If you have questions about this project or if you have a research-related problem, you may contact the researcher, state name of researcher at telephone number or send an encrypted (secure) email to (insert e-mail).

This research is reviewed and approved by an Institutional Review Board (IRB). An IRB is a committee that provides ethical and regulatory oversight of human research. You may talk to the SUNY Downstate Health Sciences University IRB & Privacy Board by calling (718) 613-8480 or sending an encrypted (secure) e-mail to IRB@downstate.edu, if

* You have questions about your rights as a research participant
* Your questions, concerns, or complaints are not being answered by the research team,
* You cannot reach the research team,
* You want to talk to someone besides the research team, or
* You want to get information or provide input about this research

By accessing the survey link below you are indicating that you are at least 18 years old, have read this consent form and agree to participate in this study. Please print a copy of this page for your records.

**What Protected Health Information will be used or disclosed?**

Federal law protects your right to privacy concerning Protected Health Information (PHI). There are certain things you need to know. PHI is any information from your medical record or obtained from the study linked to you and that refers to your mental or health conditions in the past, the present or the future.

Include the name or identification of the person(s) or class of person(s) who will use or disclose the PHI. List all entities (including external sites to be approved by the Downstate IRB) that access the research participants’ health information.

By signing this form, you give permission to the researchers approved on this study at SUNY Downstate, University Hospital Brooklyn, University Physicians of Brooklyn, Inc, NYC Health +Hospitals/Kings County, <list other hospitals, practice groups, or institutions or individuals on this study, etc.> to use or disclose (release) your Health Informationthat identifies you for the research described within this form.

*Add an expiration date or event (this must be a certain date, or an event tied to the individual).* *For example, a statement that the authorization will expire on a specific date, after a specific amount of time, or upon occurrence of some event related to the research participant. (e.g., “until the completion of the research”) – be sure this expiration matches any other expiration dates or events described elsewhere in this form. NOTE: Be sure to include the time-period for any storage of information for the creation and maintenance of a research database or research repository or future research. This may be included in other relevant sections of the consent form. Example provided below.*

This authorization is valid on the date the form is signed until the research is complete (or enter date or event).

*Provide a specific and meaningful description of the PHI to be used or disclosed. Example provided below.*

*Note: The minimum necessary rule does not apply to Authorizations; however, Downstate encourages the investigators to limit the PHI to the minimal necessary PHI that is reasonably necessary to accomplish the purpose of the research.*

The Protected Health Information that we may create, use, report, or disclose (release) for this research includes:

* Health information collected during the research (delete if N/A)
* Medical records (delete if N/A)
* Results of physical examinations (delete if N/A)
* Medical history (delete if N/A)
* Laboratory tests (delete if N/A)
* X-rays, MRI, CT or other imaging tests (delete if N/A)
* Diagnostic medical procedures *(delete if N/A)*
* Psychological tests (delete if N/A)
* Information related to (name of particular condition) (delete if N/A)
* Communicable diseases (including HIV and AIDS) (delete if N/A)
* Alcohol/drug abuse treatment (delete if N/A)
* Mental health records (delete if N/A)
* All treatment records (delete if N/A)
* (describe other Health Information in a specific meaningful manner or delete if N/A)

*Add if collecting e-mail address during the research, including at the end of this form, prior to signature lines:*

The researchers will not use unsecure e-mail for any research communications involving PHI unless you specifically authorize us to do so.

*Provide a description of each purpose for which the PHI is to be used or disclosed. Example provided below (edit purposes as needed):*

This information will be used and/or given to others to:

* Do the research,
* To do clinical testing,
* To study the results, and
* To see if the research was done right.

*Include the name or identification of the person(s) or class of person(s) authorized to make the use or disclosure of PHI. For example, who will disclose the PHI? (e.g., UHB, NYC H+H, Kings County, other hospitals, practice groups, etc.). Include ALL names or other identification of ALL classes of persons who will have access to the health information, including those who are outside of Downstate. It is recommended that the classes of persons (e.g., researchers, administrators, etc.) be listed rather than names of these individuals, to make future amendments easier).*

The Protected Health Information listed above may be used by and/or disclosed (released) to:

* The Institutional Review Board(s) (IRB) that have oversight of this research.
* The researchers and their staff approved by the IRB.
* Collaborating research sites, outside laboratories, cooperative study groups, or contracted research organizations that are approved by the Institutional Review Board
* The SUNY Downstate and NYC Health +Hospitals/Kings County officials and other administrative staff who supervise the way research is done, such as auditors or monitors.
* The sponsor(s) of this study, including monitors and auditors. *(include if the monitors need access to health information or if the sponsor will own the research data, or when the trial follows GCP standards.*
* The Federal agencies that supervise the way research is conducted, such as the Department of Health and Human Services Office for Human Research Protections, the Food and Drug Administration*,* the National Institutes of Health or other government agencies.
* Data Coordinating Center(s). *(delete if N/A)*
* The Data Safety Monitoring Board that reviews the safety of this study. *(delete if N/A)*
* Your insurance companies. (*delete if N/A)*

*Always include:*

You may change your mind and revoke (take back) this authorization in writing at any time. To withdraw, please write to *(complete name and address of the PI or other person to receive the notice of withdrawal)*. Your Protected Health Information collected before you withdraw your authorization will still be used and reported to the extent that those noted above have taken action in reliance of this authorization, including as necessary to maintain the integrity of the research or to conduct investigations or to report adverse events (bad effects).

*Add if applicable:* If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

*Always Include a statement that treatment, payment, enrollment, or eligibility for benefits may not be conditioned on obtaining the authorization if such conditioning is prohibited by the Privacy Rule or, if conditioning is permitted, a statement about the consequences of refusing to sign the authorization. Note: The PI may condition healthcare on the provision of the authorization for research related treatment (e.g., clinical trial), in which case the provider may refuse to provide the research related healthcare if the research participant refuses to execute the authorization. Example provided below. This statement is required under the HIPAA regulations. Example provided below:*

You have a right to refuse to sign this form. If you do not sign this form, there will be no effect on your health care treatment, your enrollment for benefits, your payment for the health care outside of the study, or your health care benefits are not affected. However, you will not be able to participate in the research described in this consent form if you do not sign this form.

*When the research, for which the use or disclosure is made, involves a treatment add the following, if applicable:* To maintain the integrity of this research study, you generally will not have access to your personal health information related to this research until the study is complete. At the conclusion of the research and at your request, you generally will have access to your health information that [Downstate <add names of other institution(s)>] maintains in a designated record set, which means a set of data that includes medical information or billing records used in whole or in part by your doctors or other health care providers at [Downstate <add names of other institution(s)>] to make decisions about individuals. Access to your health information in a designated record set is described in the Notice of Privacy Practices provided to you by [Downstate <add names of other institution(s)>]. If it is necessary for your care, your health information will be provided to you or your physician.

*Add if applicable:*

The researchers cannot share with you some of the Protected Health Information obtained in this study during the research; however, it can be shared at the end of the study. This includes (information about which study arm you are participating in, etc.).

*Add if applicable:*

You have the right to get your patient information in your healthcare record. Test results from a certified clinical laboratory may be provided to you.

*Add/edit/delete as applicable when the study involves the use of video recording /voice recordings / photographs:*

The researchers will obtain video recording /voice recordings / photographs of you for research purposes. Only the research staff approved to be on this study may have access to these materials. These materials will be stored in a locked cabinet and used only for the research. The researchers will keep these materials only for as long as needed for this research. These materials will be (SELECT OR EDIT) destroyed after the required retention period has ended after the study is complete / stored for archival purposes and used only for the purposes approved by the Institutional Review Board / will be destroyed after the recording is transcribed.

If photographs of the face are taken, include the option for publication of face photos at the end of the consent form, if applicable to the study.

*Always include a statement about the potential for the PHI to be re-disclosed by the research team (e.g., to another organization) and no longer protected by the Privacy Rule. Example provided below:*

You need to know that some of the individuals or groups mentioned above who may receive your health information may not be required by federal privacy laws to protect your PHI. They may share your information with others without your permission if permitted by the laws governing them. *Add example, if applicable:* For example, the sponsor *(only if applicable, name the sponsor, the CRO, the DSMB, etc.)* does not have the same obligations as your research team and may no longer protect your PHI.

*If the grant/contract between the sponsor and the Research Foundation establishes continuing protections for the disclosed information, you may add such a statement here.*

*Include the following bullets when applicable to the research:*

The research team may share your Protected Health Information as required by law, for example, to:

* Comply with a court ordered subpoena, ***[CAUTION: remove this bullet if there is a Certificate of Confidentiality (CoC) for this study, including any NIH funded studies which automatically have a CoC. CoC is described in the All-In-One template and should be included within this document when applicable to the research.]***
* Report suspected child abuse or neglect,
* Report certain communicable diseases,
* Report a possible threat or harm to yourself or others, or
* Comply with other laws.

*Include if applicable to the research:*

If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

*Note: Unless waived by the IRB, when PHI is involved in a study, the individual’s signature and date, and if signed by a personal representative, a description of his or her authority to act for the individual (e.g., required when recruiting children or cognitively impaired adults). See signature lines at the end of the form.*

*Add the following when recruiting patients into a clinical trial involving an IND or IDE* ***OR*** *any research involving an NIH Certificate of Confidentiality:*

The researchers will file a copy of this consent in your medical record. The researchers will place a note in your medical record to let other healthcare providers know that you are participating in a clinical trial.

*Recommend (not require) including the following paragraph when researching HIV-related information as it may help ensure compliance with NY State regulations (NY PHL Section 2782(5)(a); NY PHL Section 2781(2)(e), 10 NYCRR 63.3(b)(5), 14 NYCRR 505.6(a)(ii)):*

Recipients of HIV-related information may not re-disclose your HIV-related information without your authorization unless permitted to do so under federal or state law.  You have a right to request a list of people who may receive or use your HIV-related information without authorization, as well as a list of any disclosures made pursuant to this research authorization.  For more information about HIV confidentiality, call the New York State Department of Health HIV Confidentiality Hotline at 1-800-962-5065; for more information regarding federal privacy protection, call the Office for Civil Rights at 1-800-368-1019. You may also contact the NYS Division of Human Rights at 1-888-392-3644.

*There are additional requirements for authorizations for using PHI for marketing purposes, sale of PHI, or for the use or disclosure of psychotherapy notes. Contact the IRB or Privacy Officer for additional information or refer to* [*http://www.downstate.edu/hipaa/hipaa\_policies.html*](http://www.downstate.edu/hipaa/hipaa_policies.html)

*Based upon Downstate policy* [*https://www.downstate.edu/hipaa/documents/hipaa-37-privacy-of-psychotherapy-notes-2018.pdf*](https://www.downstate.edu/hipaa/documents/hipaa-37-privacy-of-psychotherapy-notes-2018.pdf) *psychotherapy notes are defined as notes made by a mental health professional that document or analyze the contents of a conversation during a private counseling session. These notes are considered to be inappropriate for inclusion in the medical record, are intended to enable the mental health professional to recall the therapy discussion and are of little use to others not involved in the therapy. These notes are kept separate from the rest of the patient’s record. If an EMR is utilized, these notes are entered into a separate section that is not considered part of the designated record set. In contrast, behavioral medicine clinical notes (such as med prescribing/ monitoring, counseling session start & stop times, modalities/ frequency of treatment, results of clinical tests, other mental health info typically needed for treatment) are NOT considered ‘*psychotherapy *notes’ under HIPAA and would not require separate authorization.*

You may open the survey in your web browser by clicking the link below:
(ADD LINK)

If the link above does not work, try copying the link below into your web browser:
(ADD LINK)

This link is unique to you and should not be forwarded to others.