
STUDY INFORMATION:

Study Title: Children's Health & Socioeconomic Implications (CHSEI)

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SUMMARY OF THIS RESEARCH STUDY:

In medicine there are many unanswered questions. A "research study" is when scientists try to answer a question about something that we don't know enough about. Participation in a research study may or may not directly help you or others. Participation is entirely voluntary. It is completely up to you whether or not you take part. You can also change your mind at any time about your participation and it will not affect your ability to get medical care within the Mount Sinai Health System.

The purpose of this research study is to learn more about heart disease prevention through health promotion. Early childhood represents an opportunity to promote healthy habits and prevent future development of heart disease. We are expanding a heart health promotion education program to preschool children who live within the five boroughs of New York City (NYC). Also, we want to study how different backgrounds, and teachers' characteristics, may affect the program's effectiveness and children's health. Your school has agreed to participate in our heart health promotion program, known as the SI! Program-NYC. The SI! Program-NYC is a four-month preschool program with health-based activities.

You may qualify to participate in this research study because you are currently a teacher of children between the ages of 3 to 5 years who work in a school that has accepted to teach the SI! Program-NYC. We are targeting schools/centers (e.g., NYC Early Education Centers, District schools, Pre-K Centers, and Charter Schools) within the five boroughs of NYC under contract with/or operated by New York City to provide preschool programming for children ages 3 to 5.

If you are interested in learning more about this study, please continue to read below. This form explains why we are doing this study and what you will be asked to do if you choose to be in this study. It also describes the way we would like to use and share information about you.

PARTICIPATION IN THIS RESEARCH STUDY:

This research study will be fully explained to you by a member of the study team. Feel free to ask all the questions you want before you decide whether or not to participate. If new information arises, a research team member will promptly give you information that may or may not make you change your mind about participating.

Funds for conducting this research are provided by the Vicky and Joseph Safra Foundation and the Mother Cabrini Health Foundation.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE:

Your participation in this research study is expected to last about 30 months after enrollment. The number of people expected to take part in this research study at the participating NYC preschool programs across the five boroughs is approximate 2,500 children and their parents, and a minimum of 130 teachers.

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DESCRIPTION OF WHAT'S INVOLVED:

If you agree to participate in this research study, the following information describes what may be involved for you. A research team member will administer questionnaires about your background information, motivation, stress, and food and exercise habits. Our trained research team member will measure your blood pressure, your height, and your weight.

The questionnaire and measurements are expected to take approximately 20 minutes to complete. The assessments administered at the school when possible for a total of three times: at the beginning of the SI! Program-NYC, at four months after completing the program, and within 30 months after enrollment. In the event that you cannot be assessed at school, you may have to travel to Mount Sinai clinic or Mount Sinai mobile van for your assessments.

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USE OF YOUR DATA:

In the future, your identifiable information may be removed from the private information that is collected as part of this research. After this removal, the information could be used for future research studies or shared with other research teams for future research studies. You will not be informed of the details of specific research that is done with your medical information. That means that a research project might be done that you would not consent to if provided with the details of that research project.

The research will not involve mandatory audio/video recording or photography of research participants. However, some recording(s) or pictures may be taken for possible use as a teaching tool during teaching training, for presentation purposes in scientific meetings or congresses, or as promotion of the project.

Do you agree to permit yourself to be videotaped or photographed during the classroom educational activities or the assessments?

- **Videotaped: Yes or No (circle one). Initials**_____
- **Photographed: Yes or No (circle one). Initials**_____

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study, in that case, responsible for meeting three times with our research staff: at the beginning of the study, after the completion of the health promotion program, as well as about 30 months after enrollment (either at your school, if possible, or at a Mount Sinai clinic or Mount Sinai mobile van) to 1) Complete the teachers' questionnaires about motivation, stress, and health; and 2) Measure your height, weight, and blood pressure.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

You will not be paid for participating in this research study. Being in this research study will not lead to extra costs to you.

Pursuant to NYC DOE regulations, no payments may be distributed to NYC DOE teachers participating in this study. In the alternative, in the event that the questionnaires and measurements cannot be completed at the school, compensation, not to exceed a total of One Hundred Fifty Dollars ($150), for time and effort will be paid for the times you are required to travel to either a Mount Sinai Clinic or to a Mount Sinai Mobile van in order to complete your questionnaires and have your measurements taken. Specifically, at the end of each assessment visit, we will pay up to Fifty Dollars ($50) if your assessment requires you to travel to Mount Sinai Clinic or up to Twenty-five Dollars ($25) if your assessment requires you to travel to a Mount Sinai mobile van in a location near the preschool. These payments may be donated directly to the entire school or to a specific classroom project through online sites such as DonorsChoose.org and Adopt a Classroom. For teachers at Community Based Organizations (CBO) their CBO's leadership will be consulted in order to determine how they prefer this compensation to be distributed to their teaching staff who are participants in the study

Tax law may require the Mount Sinai Finance Department to report the amount of payment you receive from Mount Sinai to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally, this reporting would take place if you receive payments that equal Six Hundred Dollars ($600) or more from Mount Sinai in a calendar year. You would be responsible for the payment of any tax that may be due.

POSSIBLE BENEFITS:

It is important to know that you, as the participating teacher, may not get any benefit from taking part in this research. Even so, you may benefit from participation in this research since you will receive the confidential results of your assessments, along with general medical counseling and referral information if necessary. You may learn information about your current health and health condition(s) that may help you make health-related decisions for you in the future. In that case, the potential health benefits to you may continue even after the study has ended.

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REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

Participating in research may present a range of risks, depending upon the study. We do not think that the risks associated with taking part in this study are greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests. Risks and discomforts may be of a physical, social, financial, emotional, or psychological nature, and there may be risks related to confidentiality of information, or risks from procedures.

Some risks might be:

- Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk. We will work with anonymized data. Anonymization is a data processing technique that removes or modifies personally identifiable information (e.g. take a name and turn it into a randomly generated code); it results in anonymized data that cannot be associated with an individual in any manner. All of your responses and measurements will be stored de-identified, and we will keep this information confidential.
- Psychological/emotional risks: there may be some questions you may not be used to answering that may or may not make you uncomfortable, or may feel discomfort when we measure your height, weight, and blood pressure. Our staff will be specially trained to help you not to feel uncomfortable and will remind you that you don't have to answer a question if you don't want to.

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OTHER POSSIBLE OPTIONS TO CONSIDER:

You may decide not to participate in this research study without any penalty. The choice is totally up to you. This will not affect you from potentially being approached for participation in the health promotion educational program. Your participation or non-participation in this research study will in no way affect your academic standing, or any other status. Please keep in mind that the educational materials about healthy habits will still be applied in your classroom.

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IN CASE OF INJURY DURING THIS RESEARCH STUDY:

If you believe that you have suffered an injury related to this research as a participant in this study, you should contact the Principal Investigator, or the research staff, at 212-659-9644.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this research study at any time without any penalty. This will not affect your ability to receive medical care at any of the Mount Sinai Health System hospitals or to receive any benefits to which you are otherwise entitled.

If you decide to stop being in the research study, please contact the Principal Investigator, or the research staff, at 212-659-9644. If you can't reach us, please leave a message you are calling about the CHSEI study, leave your phone number and we will contact you as soon as possible. From the time you notify us that you have changed your mind and do not want to participate in the study anymore, we will no longer take your measurements nor ask you to complete the teacher questionnaire. You can tell us you want to withdraw from the research study at any time without canceling the authorization to use your data.

If you decide you don't want your data to be used for research anymore, you can contact the Principal Investigator, or the research staff, at 212-659-9644 following the same instructions. If any data have already been shared without your identity, it won't be possible to retrieve them because no one will know who you are. Data that have already been used will not be affected by your decision. Any data that are still linked to your identity by a code the researcher has will be withdrawn so that no future sharing of your data will take place.

Withdrawal without your permission: The Principal Investigator, the sponsor, or the institution may stop your involvement in this research study at any time without your permission. This may be because the research study is being stopped, the instructions of the study team have not been followed, the investigator believes it is in your best interest, or for any other reason. If data have been stored as part of the research study, they too, can be destroyed without your consent. In the event that your involvement in the research study is discontinued, you will be notified by a member of the research staff.

CONTACT INFORMATION:

If you have any questions, concerns, or complaints at any time about this research, or you think the research has harmed you, please contact the office of the research team and/or the Principal Investigator, at 212-659-9644. If you can't reach us, please leave a message that you are calling about the CHSEI study, leave your phone number and we will contact you as soon as possible.

This research has been reviewed and approved by an Institutional Review Board. An Institutional Review Board, or IRB, is a committee organized to protect the rights and welfare of people involved in research. You may reach a representative of the Program for Protection of Human Subjects at the Icahn School of Medicine at Mount Sinai at telephone number (212) 824-8200 during standard work hours for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System if:

- Your questions, concerns, or complaints are not being answered by the research team.

- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

In addition, you may contact: Institutional Review Board, New York City Department of Education by phone at (212) 374-3913, by mail at 52 Chambers Street, Room 310, New York, NY 10007, or by email to MAzar@schools.nyc.gov.

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DISCLOSURE OF FINANCIAL INTERESTS:

Sometimes, physicians/researchers receive payments for consulting or similar work performed for industry. Effective September 2014 Mount Sinai reviews only payments to an individual totaling more than Five Thousand Dollars ($5,000) a year per entity when determining potential conflicts of interest. If you have questions regarding industry relationships, we encourage you to talk your physician/researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

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MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As you take part in this research project it will be necessary for the research team and others to use and share some of your private protected health information. Consistent with the federal Health Insurance Portability and Accountability Act (HIPAA), we are asking your permission to receive, use and share that information.

<u>What protected health information is collected and used in this study, and might also be shared with others?</u>
As part of this research project, the research team at the hospital(s) involved in the research will collect your name, address, zip code, telephone number, and e-mail. During the study, the researchers will gather your socioeconomic/demographic information from the teacher questionnaires that you complete, as explained in the Description section of this consent.

<u>Why is your protected health information being used?</u>
Your personal contact information is important so that we are able to contact you during the study. Your information being collected as part of this research study will be used for the purpose of this study as explained earlier in this consent form. The results of this study could be published or presented at scientific meetings, lectures, or other events, but would not include any information that would let others know who you are, unless you give separate permission to do so. The Principal Investigator may also use and share the results of these tests and procedures to treat you in collaboration with others in the Mount Sinai Health System. The research team and other authorized members of The Mount Sinai Health System ("Mount Sinai") workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example, the School's Program for

the Protection of Human Subjects is responsible for overseeing research on human subjects, and may need to see your information. If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.

Who, outside Mount Sinai, might receive your protected health information?

As part of the study, the Principal Investigator, study team and others in the Mount Sinai workforce may disclose your protected health information, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Principal Investigator.)

-The United States Department of Health and Human Services and the Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, Toll-free Tel. (866) 447-4777, Email OHRP@HHS.gov.

- Institutional Review Board, New York City Department of Education, 52 Chambers Street, Room 310, New York, NY 10007, Tel. (212) 374-3913, Email: irb@schools.nyc.gov.

- The sponsors of this study, the Vicky and Joseph Safra Foundation, 546 Fifth Avenue, New York, NY 10036-5000; and the Mother Cabrini Health Foundation, 777 3rd Ave 23rd floor, New York, NY 10017, including persons or organizations working with or owned by the sponsors, may review your data for accuracy, but may not copy information with your name on it.

In all disclosures outside of Mount Sinai, you will not be identified by name, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law. Some records and information disclosed may be identified with a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the law requires it, or rarely if the Institutional Review Board allows it after determining that there would be minimal risk to your privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, when applicable, the monitors, auditors, the IRB, the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

For how long will Mount Sinai be able to use or disclose your protected health information?

Your authorization for use of your protected health information for this specific study does not expire.

Will you be able to access your records?

During your participation in this study, you will have access to your medical record and any study information that is part of that record. The investigator is not required to release to you research information that is not part of your medical record.

Do you need to give us permission to obtain, use or share your health information?

NO! If you decide not to let us obtain, use or share your health information, you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?

You may withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use your protected information that was already collected if that information is necessary to complete the study. Your health information may still be used or shared after you withdraw your authorization if you should have an adverse event (a bad effect) from being in the study. If you withdraw your permission to use your protected health information for research that means you will also be withdrawn from the research study, but standard medical care and any other benefits to which you are entitled will not be affected. You can also tell us you want to withdraw from the research study at any time without canceling the Authorization to use your data. Note that this section refers to protected information, such as zip code, address or phone number, that allow us to contact you during the study. To withdraw your permission for the use of your data that we have collected, you may follow the instructions of "USE OF YOUR DATA" on page 3. If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your protected health information. It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, even if your information will no longer be protected by federal regulations, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If as part of this research project your medical records are being reviewed, or a medical history is being taken, it is possible that HIV-related information may be revealed to the researchers. If that is the case, the following information concerns you. If this research does not involve any review of medical records or questions about your medical history or conditions, then the following section may be ignored.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 306-5070. These agencies are responsible for protecting your rights.

ADULT PARTICIPANT:
Your signature below documents your permission to take part in this research and to the use and disclosure of your protected health information. A signed and dated copy of this informed consent will be given to you.

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Signature of subject	Printed Name of Subject	Date	Time

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

_____	_____	_____	_____
Signature of consent delegate	Printed Name of consent delegate	Date	Time

WITNESS SECTION:
When a witness is required to observe the consent process, it should be documented below (for example, when subject is illiterate, visually impaired, or this document accompanies a short form consent).

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

_____	_____	_____	_____
Signature of Witness	Printed Name of Witness	Date	Time