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STUDY INFORMATION:

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

Principal Investigator: Valentin Fuster, MD, PhD.

Physical Address: Mount Sinai Hospital, Division of Cardiology, Guggenheim Pavilion, 1190 Fifth Avenue, New York, NY 10029

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Phone: 212-659-9644

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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 your child or others. Participation is entirely voluntary. It is completely up to you whether or not you or your child takes part. You can also change your mind at any time and it will not affect your or your child's 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 throughout the five boroughs of New York City (NYC), and study how different backgrounds, and teachers' characteristics may affect the program's effectiveness and children's health. Your child's school has accepted to participate in our heart health promotion program. Known as the SI! Program-NYC, it is a four-month preschool program with health-based activities.

Your child may qualify to take part in this research study because your child is currently between ages 3 to 5 years old and attends a NYC preschool program that is participating in this program. 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 that are under contract with the city to provide preschool programing 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 and your child will be asked to do if you choose to participate in this study. It also describes the way we would like to use and share information about you and your child.

*Throughout this document "child" refers to a minor under applicable state law and "you" refers to any individual who may legally act on the minor's behalf (e.g. parent or legal guardian)

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 website will not include information that can identify you or your child. At most, the website will include a summary of the results. You can search this website at any time.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE:

Your and your child's participation in this research study is expected to last an average of 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 approximately 2500 children and their parents, and a minimum of 130 teachers.

DESCRIPTION OF WHAT'S INVOLVED:

If you agree to participate and permit your child's participation in this research study, the following information describes more specifically what may be involved.

Our trained Child Education Specialist will meet with your child for the assessment, at your child's school while he/she is in attendance, whenever possible, or at a Mount Sinai clinic or Mount Sinai mobile van. During the assessment, the Child Education Specialist will:

1. Measure your child's height and weight; and
2. Interview your child using questionnaires with pictures, to ask questions about food, exercise and emotions.

The assessment session is expected to last for a total of approximately 30 minutes. The entire study will last up to 4 years. You will be asked to bring your child in for three assessments: 1) before your child starts a 4-month, in-class heart health promotion education program; 2) shortly after the Program has ended, and 3) within 30 months after enrollment.

Whether or not you agree to have your child participate in this research study (assessment), all children ages 3 to 5 attending NYC schools that are participating in this study will receive the 4-month SI! Program-NYC in the classroom.

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USE OF YOUR AND YOUR CHILD'S DATA:

In the future, your and your child's information will be de-identified (the private identity information that is collected as part of this research will be removed). After this removal, the rest of 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 and your child's medical information. That means that a research project might be conducted 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 trainings, for presentation purposes in scientific meetings or congresses or as promotion of the project.

Further, do you agree to permit your child or the child in your care, to be videotaped or have their picture taken during the classroom educational activities or the assessments?

- **Do you agree your child to be videotaped? Initial your choice: Yes _____ No _____.**
- **Do you agree your child to be photographed? Initial your choice: Yes _____ No _____.**

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YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part, and permit your child to take part in this research study, you will be responsible for bringing your child for the three assessments described above: before and after the completion of the health promotion program, and within 30 months after enrollment (either at your child's school, when possible, or at a Mount Sinai clinic or Mount Sinai mobile van).

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COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

You and your child will not be paid for participating in this research study. Being in this research study will not lead to extra costs to you. If you agree to take part and to permit your child to take part in this research study, we will pay you up to a total compensation of not more than One Hundred Fifty Dollars ($150) for time and effort for bringing your child to the three assessments in the event that he or she cannot be assessed at school. Specifically, at the end of each assessment visit, we will pay you with either a gift card of up to Fifty Dollars ($50) if your child's assessment requires you to travel to Mount Sinai Clinic, or a gift card of up to Twenty-five Dollars ($25) if your child's assessment requires you to travel to a Mount Sinai mobile van located near the preschool. During the course of the study, we will also provide you and your child with small, non-monetary "thank you" gifts, such as T-shirts and stickers, for your child's attendance/participation in the assessments.

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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.

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POSSIBLE BENEFITS:

It is important to know that you and your child may not get any benefit from taking part in this research but your child's participation may help children like your child in the future. Even so, you and your child may benefit from participation in this research since you will receive the confidential results of your child's assessment, along with general medical counseling, and referral information, if necessary. This information may assist you in making health-related decisions for your child in the future. In that case, the potential health benefits to you and your child 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.

There are no direct risks to you or your child if you choose to participate. Still, 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 your responses and your child's responses and measurements will be stored de-identified and we will keep this information confidential.
- Psychological/emotional risks: there may be some questions you and your child are not used to answering that may or may not make you or your child uncomfortable. Your child may feel uncomfortable when we measure his/her height and weight. Our staff will be specially trained to help your child not to feel uncomfortable during the assessments. Please note, you and your child do not 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 take part and not to permit your child to take part in this research study without any penalty. The choice is totally up to you. The health promotion program is being implemented in your

child's school/classroom. You can, however, decline to have your child participate in assessments related to the curriculum. Your child's participation or non-participation in this research study (assessments) will no way affect your child's grades, academic standing, or any other status.

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IN CASE OF INJURY DURING THIS RESEARCH STUDY:

If you believe that you or your child 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.

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ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop you or your child's taking part in this research study at any time without any penalty. Doing so will not prevent your child from receiving the 4-month long, in-class heart health promotion education program that is a part of this research study. Withdrawing your child from participating will also not affect your or your child's ability to receive medical care at any of the Mount Sinai Health System hospitals or to receive any benefits to which you, or your child, are otherwise entitled.

If you decide to stop you or your child from 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 that you are calling about the CHSEI study and 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 you or your child to participate in the study anymore, we will no longer take your child's measurements nor ask you or your child to complete the child questionnaires with us. You can tell us you want to withdraw your child from the research study at any time without canceling the authorization to use you or your child's data.

If you decide you don't want your or your child's 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 or your child's identity, it won't be possible to retrieve them because no one will know who you or your child are. Data that have already been used will not be affected by your decision. Any data that are still linked to your or your child's identity by a code the researcher has will be withdrawn so that no future sharing of your or your child's data will take place.

Withdrawal without your permission: The Principal Investigator, the sponsor, or the institution may stop your and your child's 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 or your child's 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 or your child's involvement in the research study is discontinued, you will be notified by a member of the research staff.

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CONTACT INFORMATION:

If you have any questions, concerns, or complaints at any time about this research, or about your or your child's rights as a research participant, or you think the research has harmed you or your child, 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 saying that you are calling about the CHSEI study and 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 child's 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.

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 or your child's physician/researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As you and your child take part in this research project, it will be necessary for the research team and others to use and share some of your and your child's 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.

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What protected health information is collected and used in this study, and might also be shared with others?
As part of this research project, the research team involved in the research will collect your child's name, parent's address, zip code, telephone number and email, and your child's name and date of birth. During the study, the researchers will gather information by completing the questionnaires and measurements, as explained in the Description section of this consent.

Why is your and your child's protected health information being used?
Your personal contact information, and that of your child, is important so that we are able to contact you during the study. Your and your child's health 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 or your child 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 or your child 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 or your child's 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 child's 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 and your child's protected health information?

As part of the study, the Principal Investigator, study team and others in the Mount Sinai workforce may disclose your child's 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, 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, your child or 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 or your child 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 or your child's privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to inspect your or your child's 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 or your child's 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 child's name and other identifying information confidential.

For how long will Mount Sinai be able to use or disclose your and your child's protected health information?
Your authorization for use of your and your child's protected health information for this specific study does not expire.

Will you be able to access your or your child's records?
During your and your child's participation in this study, you will have access to your or your child's 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 or your child's medical record.

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

Can you change your mind?
You may withdraw your permission for the use and disclosure of any of your or your child's 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 and your child's protected information that was already collected if that information is

necessary to complete the study. Your child's health information may still be used or shared after you withdraw your authorization should you or your child have an adverse event (a bad effect) from being in the study. If you withdraw your permission to use your or your child's protected health information for research that means you or your child will also be withdrawn from the research study, but standard medical care and any other benefits to which you or your child are entitled will not be affected. You can also tell us you want to withdraw you or your child from the research study at any time without canceling the Authorization to use your or your child's 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 or your child's data that we have collected, you may follow the instructions of "USE OF YOUR OR YOUR CHILD'S DATA".

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 or your child's 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 or your child's 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 or your child's medical records are being reviewed, or your or your child's 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 child's 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 child's HIV-related information without authorization. If you or your child 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 child's rights.

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ADULT PARTICIPANT:
Your signature below documents your permission for you and the child named below to take part in this research and to the use and disclosure of your and your child's protected health information.

A signed and dated copy of this informed consent will be given to you.

Printed Name of Child: _____

_____	_____	_____	_____
Signature of parent/guardian	Printed Name of parent/guardian	Date	Time

- ❑ Parent
- ❑ Guardian (May provide permission only if legally authorized to consent to the child's general medical care.)

_____	_____	_____	_____
Signature of second parent/guardian	Printed Name of second parent/guardian	Date	Time

Note on Second Parent: If the IRB determined both parents must give permission unless an exception below applies, and if documented permission of the second parent of this child is not obtained, indicate the reason: (select one)

- ❑ Second parent is deceased
- ❑ Second parent is unknown
- ❑ Second parent is incompetent
- ❑ Second parent is not reasonably available
- ❑ Only one parent has legal responsibility for the care and custody of the child

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----------FOR IRB USE ONLY----------

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

Assent
- ❑ Obtained
- ❑ Not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.

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