Family-Based Interoceptive Exposure for Avoidant Restrictive Food Intake Disorder
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STUDY INFORMATION:

Study Title: Family-Based Interoceptive Exposure for Avoidant Restrictive Food Intake Disorder

Study site(s): Icahn School of Medicine at Mount Sinai

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SUMMARY OF THIS RESEARCH STUDY:

This document explains a research study you and your child might be interested in joining. Participation in the study is voluntary. You can agree to join and allow your child to join or not. Your decision will not limit your child's ability to receive care at Mount Sinai. You should only agree for you and your child to take part if you understand the study and if all of your questions about the research study are answered. If you join and allow your child to join the study, the research team must share any new information with you that may change your mind about you and your child taking part.

The purpose of this research study is to find ways that adolescents diagnosed with avoidant-restrictive food intake disorder (ARFID) can learn to eat more flexibly. This study includes testing an intervention, called Mindfulness-Based Interoceptive Exposure (MBIE). A similar treatment called interoceptive exposure (IE) has been used in adolescents with low-weight eating disorders in our program, and this type of treatment may help reduce anxiety about eating by targeting the experience of disgust. MBIE will expand on this idea for adolescents with ARFID, using mindfulness skills that focus on what you see and feel in the moment and practice with exposures to different foods with the aim to improve symptoms and the ability to tolerate different foods.

This study includes parent and child participation for the duration of the study. If either you or your child decide not to participate, neither of you will be eligible for the study. Participation in this study will include you and your child completing 20 weekly therapy sessions and 5 assessments over 6-months and a final assessment 3-months after therapy ends.

If you both choose to take part, your child will be asked to complete the following:

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- Baseline Visit (2 hours) – will assess study eligibility
- Therapy (20 hours) – 20 weekly sessions including you and your child
- Follow-ups – Assessments will occur after the 5th, 10th, 15th, and 20th therapy sessions and 3-months after therapy ends. You will complete surveys at these visits.
- Families will be paid $200 total for the baseline visit and the 5 follow-up assessments

If you and your child choose to take part, the main risks to both of you include (1) the potential for becoming upset or anxious when discussing your child's health and eating disorder symptoms or your experiences with them and (2) loss of private information.

You and your child may benefit from taking part in this research. One potential benefit includes the possibility of a reduction of symptoms associated with ARFID. There is a possibility you or your child do not experience direct benefit from participating but, regardless, will be helping future treatment of eating disorders.

Instead of taking part in this research, your child may also seek standard treatment for ARFID.

If you and your child are interested in learning more about this study, please continue to read below.

STUDY PARTICIPATION:

You and your child may qualify to take part in this research study because they have been diagnosed with Avoidant Restrictive Food Intake Disorder, they are between the ages of 12-18, and speak English.

You and your child's participation in this research study is expected to last 9 months.

There are 57 parent/child pairs expected to take part in this research study at the Eating and Weight Disorders Program at the Icahn School of Medicine at Mount Sinai.

Funds for conducting this research study are provided by the National Center for Complementary and Integrative Health (NCCIH).

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. At most, the website will include a summary of the results. You can search this website at any time.

DESCRIPTION OF WHAT IS INVOLVED:

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If you agree to take part, and allow your child to participate, in this research study, the following information describes what may be involved:

All research visits and therapy sessions and will take place at the Eating and Weight Disorders Program office. Remote sessions are also available via a HIPPA compliant Zoom.

Baseline Visit:

The baseline visit includes completing the consent process and assessing your child's eligibility for the study. It will take approximately 2 hours to complete. If preferred, they may complete the consent process separately, before beginning baseline procedures, to allow for more time to consider participation.

- The research team will review and sign this consent form with your family. During the consent process, you and your child will be given as much time as needed to ask question and consider your participation before proceeding with the baseline procedures.
- As part of the baseline assessment, your child will complete the following:
  - Research staff will take physical measurements of height and weight.
  - A member of the study staff will ask questions about their eating, medical status, medications, and eating/weight history to determine if they are eligible.
  - A laboratory meal test, which includes drinking a strawberry yogurt shake.
  - Two computer tasks, which include rating foods on level of disgust and responding to emotion images (i.e., happy faces).
  - Online surveys that will ask additional questions about eating patterns and experiences.
- You will be asked to complete online surveys asking questions about your experience with your child having ARFID.
- As part of this baseline process, research staff will collect your child's primary care doctor's contact information and ask for permission for them to participate and do not have symptoms that suggest a higher level of care, like inpatient treatment. If they qualify for the study after completing the baseline, your child will be enrolled in the MBIE treatment, described below.

Therapy:

The Mindfulness-Based Interoceptive Exposure (MBIE) intervention will be led by a trained clinician and includes 20 sessions of weekly therapy. The MBIE intervention is a form of family therapy, so your attendance is needed at each of these visits.

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The MBIE treatment tries to help your child increase tolerance to food, eating situations, and other feeding challenges (e.g., texture) via mindfulness, (i.e. increasing non-judgmental awareness and learning skills to tolerate disgust). MBIE increases acceptance of disgust related to food by decreasing avoidance, and focuses on tolerating distressing or undesired internal experiences. Several of the initial sessions will include eating a food during the appointment. The intervention also includes education, mindfulness practice of different skills, and counter-conditioning. Each session will include measuring weight and assigning homework to practice the skills at home. The final few sessions will focus on recognizing change, planning for future obstacles, and developing a plan to continue working on expanding food choices and mindful awareness. The first session will last 1.5 hours and the others will be 1 hour each.

All sessions will be video recorded in order to ensure that the therapy is provided as intended. In order to participate in the study, you must agree to the video recordings. Videos will be stored for seven years following data analysis of study data per Mount Sinai policy.

Follow-ups:

During the treatment intervention, you and your child will be scheduled for 5 follow-up visits. These procedures will be conducted in the same manner as those completed at baseline; and they will be conducted immediately following therapy sessions. The specific tasks for each assessment point are described below:

- Assessment after therapy session 5 (10 minutes): This assessment includes online surveys for you and your child.
- Assessment after therapy session 10 (1 hour): This assessment includes your child drinking a strawberry yogurt shake and online surveys for you and your child.
- Assessment after therapy session 15 (10 minutes): This assessment includes online surveys for you and your child.
- Assessment after therapy session 20 (1 hour): This is the final assessment and includes your child drinking a strawberry yogurt shake, and online surveys for you and your child.
- Final Assessment 3 months after therapy ends (20 minutes): This assessment includes online surveys for you and your child.

USE OF YOUR DATA AND/OR SAMPLES:

The researchers would like your permission to keep you and your child's de-identified study data to use or share in future studies. You both can still be part of the study if you do not allow us to use or share

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them. Please select Yes or No to each of the questions below. To decline all future uses/sharing please select 'No' each time.

(1) Will you allow the researchers to store you and your child's de-identified data to use in future research studies?

Please initial your choice: Yes_____ No_____

If you select No, please stop here and move to the next section, **'Your Responsibilities If You Take Part in This Research'** section below."

If yes, please continue to the next question and tell us how you and your child's de-identified study data may be used in future research studies.

(2) Do you give the researchers permission to keep you and your child's de-identified data, so they could use them in future studies that are **directly related** to the purpose of the current study?

Please initial your choice: Yes_____ No_____

(3) Do you give the researchers permission to keep you and your child's de-identified data indefinitely, so they could use them for future studies that are **not related** to the purpose of the current study (for example a different area of research)?

Please initial your choice: Yes_____ No_____

(4) From time to time, researchers outside of medicine and related sciences would like to use de-identified data. This might be in the fields such as anthropology, human origins, mapping human migration patterns. Do you give permission for researchers **outside the field of medicine** to use you and your child's de-identified data?

Please initial your choice: Yes_____ No_____

If the future research, related to unrelated to this research, you and your child's data will be anonymized and will be done without knowing that the data came from you personally.

(5) Do you give permission to have you and your child's de-identified data given **to other researchers,** including those at Mount Sinai, other medical or scientific institutions and for-profit companies, for use in research within the limits you have chosen above?

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Please initial your choice: Yes_____ No_____

(6) Do you give permission to have portions of you and your child's de-identified data deposited in large public databases (repositories) for use in research with the limits you may have chosen above? Please read the paragraphs below which explains repositories, then initial your choice:

To do more powerful research, it is helpful for researchers to share information they get from studying human samples. They do this by putting it into one or more scientific databases, where it is stored along with information from other studies. Researchers can then study the combined information to learn even more about health and disease. If you agree to take part in this study, some of your unidentifiable study data and health information might be placed into a National Data Archive (NDA). There are many different kinds of scientific databases; some are maintained by Icahn School of Medicine at Mount Sinai or another institution, some are maintained by the federal government, and some are maintained by private companies. The NDA is a biomedical informatics system and data repository created by the National Institutes of Mental Health – part of the U.S. Department of Health and Human Services (DHHS), an agency of the U.S. Government – to assist biomedical researchers working to develop a better understanding of mental health and/or develop more effective methods to diagnose, treat, and prevent mental health disorders.

Any researcher who wants to study the information must apply for permission to use the database. Different databases may have different ways of reviewing such requests. Researchers with an approved study may be able to see and use you and your child's unidentifiable information, along with that from many other people. Researchers will always have a duty to protect your privacy and to keep your information confidential, but there are risks associated with data collection and sharing. They are described in more detail in the risks section.

Data entered into NDA will be kept confidential, with NDA being designed for access by researchers only. Data provided to NDA as part of your participation in this research study will not be linked directly to you or your child's identity – i.e. your name will be separated from the data. If you do not consent to sharing your data with NDA, you and your child will still be eligible to participate in this study.

During the process of removing your personally identifiable information to make you and your child's data anonymous, a computer-generated ID will be used called a Global Unique Identifier. This cannot be linked back to your identity. This will ensure that any data collected from you and your child is linked to one unique ID, so the National Data Archives can make sure your data is secure and is not accidentally duplicated if you take part in research at multiple sites.

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Please initial your choice: Yes _____ No _____

Whether or not you have allowed us to share your de-identified data with a National Data Archive, the researchers at Mount Sinai will keep data collected about you and your child during this research study to use in future research studies consistent with the wishes you expressed above.

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to allow your child to take part in this research study, you and your child will be responsible for the following things: make sure to attend all scheduled study visits and inform the research team as soon as possible if cancelling or rescheduling an appointment or withdrawing from the study.

In addition, please inform the research team immediately if there are any medical/mental health changes that might require treatment, as these changes may impact eligibility to participate in the study. If either you or your child are withdrawn, it will end participation for the both of you.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

If you agree to take part in this study, you/your child will be paid $200 ($150 for your child and $50 for parents) for your time and effort. You could choose to give the entire portion to your child if you wish. It can take up to 6 weeks *to prepare and give you a check for study participation.* If you do not get a check by then, you can first contact the research team. If further assistance is needed, please contact Mount Sinai's Program for the Protection of Human Subjects at (212) 824-8200.

You and your child will receive partial payment if you do not complete the entire protocol:

- Baseline: $10 for you, $30 for your child
- Session 5 assessment: $5 for you, $15 for your child
- Session 10 assessment: $10 for you, $30 for your child
- Session 15 assessment: $5 for you, $15 for your child
- Session 20 assessment: $10 for you, $30 for your child
- Final assessment: $10 for you, $30 for your child

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 happens if you receive payments that equal $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:

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There is a chance this study may benefit your child, but this is not guaranteed. Others may benefit from what researchers learn from the study. Possible benefits to your child include a reduction of symptoms associated with avoidant/restrictive food intake disorder (ARFID). MBIE is a treatment currently being tested in the study, and participants of this study will receive treatment at no cost. There is a possibility your child doesn't experience direct benefit from participating but, regardless, they will be helping future treatment of eating disorders. Indirect benefits to future patients, researchers, clinicians, and health care planners could include valuable information about ways to improve outcomes in adolescents with ARFID. Evaluating effective interventions in the treatment of adolescent ARFID is of the utmost importance in order to improve the outcome in this disorder.

POSSIBLE RISKS AND DISCOMFORTS:

During this study you or your child may become upset, tired, anxious, or uncomfortable during visits. If this happens, a member of the research team will be available to speak to you or your child, offer comfort, and ask if you want to continue in the study. You or your child may take a break or decline to complete a particular task like a questionnaire. Because this intervention involves both the parent(s) and the child, if your child ends participation in the study, your participation in the study will end also.

During the study you or your child may reveal previously unknown symptoms, including suicidality, a psychiatric disorder, abuse, or neglect that could pose a safety or medical risk. Discovery of information or symptoms that could pose a medical or safety risk needs to be addressed by the research team. In the case of active suicidality, a licensed psychologist/psychiatrist will evaluate, and if necessary, additional care will be identified. In the case of abuse or neglect, this would be reported in accordance with state laws.

Group Risks - Although you and your child's name will not be given to other researchers, basic information such as your race, ethnic group, and sex may be shared. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people of the same race, ethnic group, or sex as you. However, they could also be used to support harmful stereotypes or discrimination. Privacy Risks - Your name and other information that could directly identify you or your child (such as an address, date of birth, or social security number) will never be placed into a database.

Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.

OTHER OPTIONS TO CONSIDER:

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You and your child may decide not to take part in this research study. If you decide not to take part, this will not affect the clinical care you or your child receive at Mount Sinai. The choice is totally up to you and your child. Instead of being in this research study, your choices include: treatment for ARFID as available in the community or in the EWDP. You do not have to participate in this study for your child to receive treatment for their eating disorder. MBIE is not a treatment that is currently available in the community since it is a treatment made specifically for this study by clinicians in our program.

IN CASE OF INJURY DURING THIS RESEARCH STUDY

If you or your child is injured or made sick from taking part in this research study, you will get medical care. Generally, it will be billed to you or your child's insurance. You will be responsible for all treatment costs not covered by your child's insurance, including deductibles, copayments, and coinsurance. This does not prevent you from seeking payment for injury related to malpractice or negligence. You can contact the Lead Researcher for more information.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop you and your child's participation in this study at any time. No matter what you choose, your child's care and benefits through Mount Sinai will not be negatively impacted.

If you decide to stop participation in the study, please contact the Lead Researcher or the research staff.

You may also withdraw your permission for the researchers to use and share any of you or your child's protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page. Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected if that information is necessary to complete the research study. You and your child's health information may still be used or shared after you withdraw your authorization if your child has an adverse event (a bad effect) from taking part in the research study.

If you decide you don't want you or your child's data and/or samples to be used for research anymore, you can contact the researcher and ask to have the data withdrawn or labeled so that they will not to be used in additional projects or shared. If you or your child's data have already been shared with researchers, those researchers will be asked to stop using them. However, if any data have already been shared without you or your child's identity or a linking code, it won't be possible to retrieve them. Data that have already been used will not be affected by your decision. If you or your child's data

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have already been deposited in an external repository, the study team will request that the data be removed.

Withdrawal without your consent: The Lead Researcher, the funder or Mount Sinai may stop you or 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 research team have not been followed, the Lead Researcher believes it is in you 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 permission.

CONTACT INFORMATION:

If you or your child have any questions, concerns or complaints at any time about this research, or you think the research has harmed you or your child, please contact the office of the research team and/or the Lead Researcher at phone number 212-659-8756.

If there is an emergency, please call 911 or go to the emergency room. Let the emergency room staff know that your child is in a research study so they can contact the Lead Researcher if needed.

DISCLOSURE OF FINANCIAL INTERESTS:

Researchers sometimes get paid for consulting or doing work for companies that produce drugs, biologics or medical devices. If you or your child have questions regarding industry relationships, you are encouraged to talk to the Lead 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 part of this study, some of you and your child's private and/or protected health information will be obtained, used, and shared with your permission. There is a Federal Health Insurance Portability and Accountability Act (HIPAA) that makes sure this is done correctly and safely.

What is protected health information (PHI)?
PHI is the combination of two things:

1. PHI contains information that identifies you. It will be used to contact you and link you to your health information, like name, date of birth, medical record number, and address.

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2. PHI also contains health information, including information about your mental and physical health from your visits to doctors or hospitals, or from study visits.

Every time you visit a hospital or your doctor, PHI is created and recorded in your medical record by your healthcare providers. In the same way, the PHI created as part of this study will be linked to who you are and your medical information.

What PHI is collected and used in this research study, and might also be shared with others?

As part of this study, the research team at the hospital(s) involved in the research will collect you and your child's name, address, telephone numbers, date of birth, e-mail addresses, social security number, and life history of information regarding emotional and psychological difficulties. The researchers will also get information from your child's medical record related to their treatment in the EWDP.

During the study, the researchers will gather information by:

- Reviewing and/or taking a medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.).
- Completing the tests, procedures, questionnaires, and interviews explained in the description section of this consent.
- Reviewing medical records maintained by the EWDP.

Why are you and your child's PHI being used?
Researchers need the information that identifies you so they can contact you during the study. They need your health information and the results of any tests and procedures being collected as part of this study to answer the questions posed in the study. The purpose of the study is discussed earlier in this consent form. Before researchers analyze the data, they remove any information that would let others know who you are or that you took part in the study. If researchers publish or present study results at scientific meetings, lectures, or other events, their presentations would not include any information that would let others know who you are, unless you give separate permission to do so.

The Lead Researcher may also use and share the results of these tests and procedures with other healthcare providers at Mount Sinai who are involved in your care or treatment. 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 Mount Sinai Program for the Protection of Human Subjects is responsible for overseeing research on human participants and may need to see your information.

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- If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.
- I*f the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.*

Who, outside Mount Sinai, might receive you or your child's PHI?
As part of the study, the Lead Researcher, research team and others in the Mount Sinai workforce may disclose your PHI, 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 Lead Researcher.)

- The United States Department of Health and Human Services (DHHS) and the Office of Human Research Protection (OHRP) (the government organization that is responsible for protecting human research participants).
- The sponsoring government agency and/or their representatives who need to confirm the accuracy of the results submitted to the government or the use of government funds: NCCIH
- A Data Safety Monitoring committee that will monitor the study on an ongoing basis for safety.

In almost all disclosures outside of Mount Sinai, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. Some records and information disclosed may be identified with a unique code number. The Lead Researcher 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 Institutional Review Board (IRB) allows it after determining that there would be minimal risk to your privacy. The Certificate of Confidentiality obtained from the Department of Health and Human Services will not be used to prevent disclosure to local authorities of child abuse and neglect, or harm to self or others. 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, *OHRP, 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.* The results of this research may be published. However, your name and other identifying information will be kept confidential.

For how long will Mount Sinai be able to use or disclose you and your child's PHI?
Authorization for use of your PHI for this specific study does not expire.

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Will you be able to access you and your child's 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 research team is not required to release research information to you that is not part of your medical record.

Do you need to give the researchers permission to obtain, use or share you and your child's PHI?
NO! If you decide not to let the research team obtain, use or share your PHI, 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 or your child change your mind?
If you decide to stop being in the study, please contact the Lead Researcher or the research staff. The research team may ask you whether they can continue to collect information from your medical record. You will also have to decide if you wish to limit the continued use of the information collected during the study. Under US privacy laws you may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page.

Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected, but only to complete this research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from taking part in the research study.

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 PHI.

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, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If researchers are reviewing your medical records or asking questions about your medical history or conditions, it is possible that they may learn information related to your HIV status. If that is the case, the following information concerns you. If researchers are not reviewing your medical records or asking questions about your medical history or conditions, then you may ignore the following section.

Notice Concerning HIV-Related Information
If you are authorizing the release of you or your child's 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

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may receive or use you or your child's HIV-related information without authorization. If you or your child experiences 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) 416-0197. These agencies are responsible for protecting your child's rights.

Certificate of Confidentiality: To further protect you or your child's privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services. This is intended to ensure that you and your child's identity as a participant in this research study will not have to be disclosed as a result from a subpoena, for the purpose of identifying you or your child in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings other than to the FDA or OHRP as identified above.

The research staff will not share any of you or your child's personal information or study data with anyone who is not a member of the research team, including any family members or friends, other than those identified above. However, you should know that if it is learned that your child or someone else is threatened with serious harm, such as a child or an elderly person being abused, the research team may notify the appropriate authorities if necessary to protect you, your child, or others. A Certificate of Confidentiality does not prevent you, your child, or a member of your family from voluntarily releasing information about your child or their involvement in this research. This means that you, your child and your family must also actively protect your child's privacy. If an insurer or employer learns about your child's research participation, and you agree that they can have your child's research information, then the researchers may not use the Certificate of Confidentiality to keep this information from them.

How the Institutional Review Board (IRB) can help you:

This research has been reviewed and approved by an Institutional Review Board (IRB). You may reach a representative of the Mount Sinai Program for Protection of Human Subjects at telephone number (212) 824-8200 during regular work hours (Monday-Friday, 9am-5pm, excluding holidays) for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- 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 participant.
- You want to get information or provide input about this research.

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ADULT PARTICIPANT:
Your signature below documents your permission for you as well as the child named below to take part in this research study and to the use and disclosure of you and your child's protected health information. A signed and dated copy 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*

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

_____	_____	_____	_____
Signature of Consent Delegate	Printed Name of Consent Delegate	Date	Time

WITNESS SECTION:
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 parent(s)/guardian(s), and that permission was freely given by the parent(s)/guardian(s).

_____	_____	_____	_____
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.

*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)

----------FOR IRB USE ONLY----------
Rev 11.11.2022 (Amendment 1-03.09.2023)

Effective Date: 4/30/2024
End Date:4/29/2025