ADAPT: Approach to Dance for Autism

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THE MOUNT SINAI HEALTH SYSTEM
PERMISSION FORM FOR A CHILD TO PARTICIPATE IN A RESEARCH STUDY AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION

Study ID: STUDY-24-00144
Form Version Date: 05Apr2024

STUDY INFORMATION:

Study Title: ADAPT: Approach to Dance for Autism through Personalized Teaching

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

Lead Researcher (Principal Investigator): Alexander Kolevzon, MD

Physical Address: 1428 Madison Avenue, E Level, Seaver Autism Center

Mailing Address: 1425 Madison Avenue, 4th Floor, Rm 4-32, New York, NY, 10029

Phone: 212-659-8752

SUMMARY OF THIS RESEARCH STUDY:

This document explains a research study you might be interested in allowing your child to join. Participation in the study is voluntary. You can agree to 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 your child to take part if you understand the study and if all of your questions about the research study are answered. If you allow your child to join the study, the research team must share any new information with you that may change your mind about your child taking part.

The purpose of this research study is to examine if a ballet dance program can help improve some motor, psychological, and social manifestations of Autism Spectrum Disorder.

If you choose to allow your child to take part, your child will be asked to

- Meet with Dr. Kolevzon and other study staff
- Provide written informed consent, and your child may be asked to provide verbal consent if they are able to
- Attend one ballet class a week for 12 weeks for 45 minutes per class
- Watch videos that show the movements that will be taught 3 times per week
- Complete several caregiver questionnaires about your family’s demographics and your child’s motor and social skills, sleep, emotional well-being, and behavioral symptoms

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- These questionnaires will be completed before the start of the program and throughout the study. These may be completed during your child’s ballet class or at a different time that is more convenient for you.
- There are no costs associated with participating. You will receive Metrocards to cover transportation costs for the child participant and one parent, and all dance apparel will be provided.

If you choose to allow your child to take part, the main risks to your child are minimal risks of fatigue and physical discomfort from dancing in the ballet class. Though unanticipated, physical injury is also possible. A team of medical students will be in the room and doctors on call. The research team will do everything possible to prevent this risk. The research team is using a ballet curriculum that has been specifically designed for children with Autism Spectrum Disorder and has been used for over a decade. We will have enough staff who are trained in the ballet curriculum to support every child’s needs. If your child shows signs of fatigue, discomfort, or injury, they have the option of sitting out of some or all of the class. There is always a risk of losing private information. The research team has procedures in place to prevent this risk and will keep the name of you and your child separate from all other information collected.

Your child may benefit from taking part in this research. Some potential benefits are:

- Improved motor skills such as coordination, balance, proprioception and core strength
- Improved self-esteem
- Improved executive function such as sequencing
- Improved social skills
- Improved behavior

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

STUDY PARTICIPATION:

Your child may qualify to take part in this research study because they have autism spectrum disorder and are between 7-12 years old.

Your child’s participation in this research study is expected to last until they finish the 12 week ballet program.

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There are 24 people expected to take part in this research study at the Icahn School of Medicine.

Funds for conducting this research study are provided by the Seaver Autism Center and the American Psychiatric Association Foundation.

DESCRIPTION OF WHAT IS INVOLVED:

If you agree to allow your child to take part in this research study, here is what may be involved:

- You will be asked to give written informed consent.
- The ballet class and all other questionnaires will be completed at Ballet Academy East (1651 3rd Ave 3rd fl, New York, NY 10128) or online.
- Prior to the start of the first ballet class, you will be sent some videos that show the movements that will be taught. You are encouraged to view these videos at least 3 times a week with your child.
- In September 2024, you will complete the first set of questionnaires that ask about your child’s motor, psychological, and social skills. These questionnaires should take no more than one hour to complete.
  - After, your child will begin a 12 week ballet program. This ballet program is experimental. Your child will attend a ballet class once a week for a 45 minute class.
  - Depending on the group your child is assigned to, your child will start the ballet program right away or in January 2025
  - On weeks 4,8, and 12 of the ballet program, you will complete questionnaires that ask about your child’s motor and social skills, behavior, sleep, and emotional well-being. These forms will be completed while your child is in the ballet class or online and should take no more than 45 minutes to complete.
  - If your child is assigned to the waitlist group, you will complete the questionnaires on weeks 4, 8, and 12 of the waitlist period and again during the ballet program.
  - At week 12, you will also complete a questionnaire that asks about your family’s demographics. You will complete this demographic questionnaire only one time.
  - All these procedures are part of research. Research is different from you and your child’s clinical care and will not impact the care that your child receives at Mount Sinai.
  - Trained members (medical student volunteers) of the research team and clinicians at the Seaver Autism Center will work with you and your child throughout the study

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Randomization

There will be two groups in this study. One group will start the ballet program right away. The other group will be on a waitlist and start the ballet program in January 2025. No one, not you, or anyone from your medical team or from the research team will be able to choose what group your child is assigned to. It will be by chance, like flipping a coin. Your child will have a(n) equal chance of being given each study procedure.

Future Contact:

The researchers may wish to use your personal contact information to contact you in the future. Do you give the researchers permission to **contact you** in the future to request the collection of additional information about your child, discuss how your child's private information, study data and/or samples might be used, or discuss possible participation in another research study?

Please initial your choice: Yes_________ No__________

If "Yes", please indicate your preferred method of contact: (initial all that apply)

[ ] Email [ ] Phone [ ] Letter [ ] Text

USE OF YOUR DATA AND/OR SAMPLES:

In addition to being used to complete this research study, your child's personal information (such as, name, address, date of birth) and study data may also be used and shared for additional (future) research. Before anything is shared, all of your child's identifying personal information will be removed and it will be replaced with a code. Researchers are not planning on giving you or your child the details of any of this future research nor the results. That means that a research project might be done that you would not consent to your child's participation if provided with the details of that research project. If you do not want any future research to be done with your child's data, even with your child's identity removed, please do not sign this consent form or permit your child to take part in the study.

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to allow your child to take part in this research study, you/your child will be responsible for the following things: Attending a ballet class once a week for 12 weeks, watching videos 3 times per week, and completing all questionnaires.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

You and your child will not be paid for taking part in this study. Being in this study will not cost you anything extra.

If you agree to permit your child to take part in this study, you and your child will be paid with a Metrocard for time and effort. This Metrocard should cover all transportation costs for the ballet class and any additional study visits if needed. Your child will also be given any dance apparel necessary to participate.

Tax law may require the Mount Sinai Finance Department to report the amount of payment you/your child receives from Mount Sinai to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally, this happens if you/your child receives payments that equal $600 or more from Mount Sinai in a calendar year. You/Your child would be responsible for the payment of any tax that may be due.

POSSIBLE BENEFITS:

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:

- Your child's motor skills such as, but not limited to balance, coordination, proprioception, and core strength, may improve
- Your child's self confidence may improve

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- Your child’s social skills may improve
- After research has ended, the ballet classes provided at no cost during the study may not be available for free, or at all, when the research ends.

Possible benefits to others include:

- Your child’s participation in the ballet program may help us understand if or how a ballet program can help other children with autism spectrum disorder.

POSSIBLE RISKS AND DISCOMFORTS:

- Minimal risk of your child feeling embarrassed or nervous in the dance class.
- Minimal risk of experiencing fatigue and discomfort when completing questionnaires.
- Minimal risk of physical injury during ballet classes
- Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.

OTHER OPTIONS TO CONSIDER:

You may decide not to allow your child to take part in this research study. If you decide not to allow your child to take part, this will not affect the clinical care your child receives at Mount Sinai. The choice is totally up to you.

IN CASE OF INJURY DURING THIS RESEARCH STUDY

If you believe that being in this research study has harmed your child, you should contact the Lead Researcher. Their contact information is listed at the beginning of this consent form.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop 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.

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If you decide to stop your child from being 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 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. 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 your child's data to be used for research anymore, you can contact the researcher and ask to have your child's data withdrawn so that they will not to be used in additional projects or shared. If 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 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 your child's data have already been deposited in an external repository, the study team will request that your child's data be removed.

Withdrawal without your consent: The Lead Researcher or Mount Sinai may stop 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 your child's best interest, or for any other reason. If data and/or samples have been stored as part of the research study, they too can be destroyed without your permission.

CONTACT INFORMATION:

If you have any questions, concerns or complaints at any time about this research, or you think the research has harmed your child, please contact the office of the research team and/or the Lead Researcher at 212-659-8752

DISCLOSURE OF FINANCIAL INTERESTS:

Researchers sometimes get paid for consulting or doing work for companies that produce drugs, biologics or medical devices. If you 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 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.

<u>What is protected health information (PHI)?</u>
PHI is the combination of two things:

1. PHI contains information that identifies your child. It will be used to contact you and link your child to their health information, like name, date of birth, medical record number, and address.
2. PHI also contains health information, including information about your child's mental and physical health from your child's visits to doctors or hospitals, or from study visits.

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

<u>What PHI is collected and used in this research study, and might also be shared with others?</u>
As part of this study, the research team at the hospital(s) involved in the research will collect your child's name, address, telephone number, birth date, email and medical record number.

During the study, the researchers will gather information by:

- Reviewing and/or taking your child's 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 mental health records. We will review your child's mental health record to confirm a diagnosis of ASD and review any new treatments or medications that have been started during the study's duration.

<u>Why is your child's PHI being used?</u>
Researchers need the information that identifies your child so they can contact you during the study. They need your child's health information and the results of any tests and procedures being collected

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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 your child is or that your child 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 your child is, 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 child's care or treatment. The research team and other authorized members of The Mount Sinai Health System ("Mount Sinai") workforce may use and share your child's 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 child's information.
- If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your child's 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 your child's PHI?
As part of the study, the Lead Researcher, research team and others in the Mount Sinai workforce may disclose your child's 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).

In all disclosures outside of Mount Sinai, your child 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 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 your child without your permission, unless the law requires it, or rarely if the Institutional Review Board (IRB) allows it after determining that there would be minimal risk to your child's privacy. It is possible that a sponsor or

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their representatives, a data coordinating office, a contract research organization, may come to inspect 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, *OHRP, as well as the Food and Drug Administration (FDA) will be granted direct access to 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.* The results of this research may be published. However, your child's name and other identifying information will be kept confidential.

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

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

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

Can you change your mind?
If you withdraw your permission for your child to be 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 child's 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 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, but only to complete this research study. Your child's 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 child's 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 child's information to continue to protect your confidentiality.

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

Notice Concerning HIV-Related Information
If you are authorizing the release of 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 may receive or use 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.

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.

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- You have questions about your child's rights as a research participant.
- You want to get information or provide input about this research.

ADULT PARTICIPANT:

Your signature below documents your permission for the child named below to take part in this research study and to the use and disclosure of this 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:

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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.

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IRB Approved

Effective Date: 10/4/2024
End Date:5/27/2025