RUTGERS
Douglass Developmental Disabilities Center

Rutgers, The State University of New Jersey
25 Gibbons Circle/151 Ryders Lane
New Brunswick, NJ 08901

dddc.rutgers.edu
848-932-9137/4500
Fax: 732-932-8011/3095

PARENTAL PERMISSION TO PERMIT CHILD TO TAKE PART IN RESEARCH

TITLE OF STUDY: A Pilot Investigation of Emergent Multi-Class Imitation Training (EMIT)

Principal Investigators: Meghan Deshais, Ph.D., BCBA-D and Debra Paone, Ph.D., BCBA-D

STUDY SUMMARY: This consent form is part of an informed consent process for a study on the effects of a comprehensive protocol designed to teach imitation skills to your child. The information in this consent form will help you decide whether you want your child to take part in this research. It is your choice as to whether your child will participate in this research.

The purpose of the research is to examine the effectiveness of a comprehensive imitation training approach designed to quickly establish imitation skills in young children with ASD. If your child takes part in the research, he/she will participate in approximately ten 15-20 minute sessions per week. Sessions will be distributed across a minimum of 3 days per week. During sessions, a member of our study team will teach your child how to imitate different actions with objects, movements, and/or sounds. Initially, physical guidance will be used to teach your child how to imitate the modeled responses. This guidance will be faded gradually, as your child begins to respond correctly. Rewards, in the form of preferred items or social praise, will be delivered to your child following correct responses. As your child learns to imitate these models, he/she will be asked to imitate new actions with objects, movements, and/or sounds to determine if they have learned the skill of "doing what others do".

If you choose to have your child participate in this research, they will be asked to participate in approximately 10 sessions per week. Your child may participate in the study for a period of 3 to 15 months (approximately 30 to 150 total sessions). It is a requirement that you provide consent for your child's sessions to be videotaped for them to participate in this study. When possible, we will conduct your child's sessions at their school (with permission from teachers/school administrators), at their after-school program or therapy provider to make it convenient for your child to participate.

Your child will benefit from high-quality, evidence-based imitation training and assessment of imitation skills. Participants may encounter stress from acquiring skills, embarrassment associated with responding incorrectly, or fatigue. The time spent participating in the study may be a burden to some participants. It is also possible that your child does not benefit from participation.

Your child's alternative to taking part in the research study is not to take part in it. It is your choice as to whether your child will participate in the research.

The information in this consent form will provide more details about the research your child is being asked to take part in. If you have any questions now or at any time, you should feel free to ask and should expect to be given answers you completely understand. After all your questions have been answered and you wish to give consent for your child to participate in the study, you will be asked to digitally sign this consent form. You are not giving up any of your child's legal rights by permitting your child to take part in this research or by signing this parental permission form.

Who is conducting this research study?

Rutgers, The State University of New Jersey
25 Gibbons Circle/151 Ryders Lane
New Brunswick, NJ 08901

dddc.rutgers.edu
848-932-9137/4500
Fax: 732-932-8011/3095

Meghan Deshais is the Principal Investigator (PI) of this research. The PI has the overall responsibility for the conduct of the research. However, there are other individuals who are part of the study team. Meghan Deshais is the representative PI and may be reached at (848) 445-3928. She is located at Nelson Biological Laboratory, 152 Frelinghuysen Road, D313, Piscataway, NJ 08854. A member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Why is this study being done?
This study is being conducted to address a critical need to develop and evaluate interventions designed to teach generalized imitation to individuals with autism. Generalized imitation refers to an individual's ability to "do as others do" – even without prior exposure to the modeled responses. Generalized imitation plays a critical role in helping children to learn communication, play, social-emotional, self-help, and academic skills. There is currently no evidence-based imitation training protocols for practitioners designed to quickly establish generalized imitation in autistic children. This project aims to fill this crucial gap by using empirically based teaching procedures to teach generalized imitation to children with a diagnosis of autism.

Who may take part in this study and who may not?
Initial referrals to the study will include children aged 5 or under, with a diagnosis of autism and reported challenges imitating new models. Following the referral, assessments will be conducted to determine eligibility.

Children will be eligible to participate if they meet any of the following criteria:

- Motor Vocal Imitation Assessment - maximum score of 40 (score of 10 or under in 4 categories)
- Peabody Picture Vocabulary Test, 5th edition – maximum age equivalent of 2.6 years of age
- Demonstrates matching identical objects or pictures above chance levels

Children will be ineligible to participate if they meet any of the following criteria:
- Diagnosis of intellectual disability
- Diagnosis of motor conditions that impact motor function (e.g., cerebral palsy)
- Visual impairment
- Hearing impairment

Children will be withdrawn from the study if they consistently and persistently exhibit challenging behavior (e.g., uncooperative behavior, self-injurious behavior) during screening or research sessions. Caregivers of participants will be notified of the reason for their child's withdrawal from the study and will receive a written summary of (1) their child's assessment results and/or progress up to the point of withdrawal, and (2) clinical recommendations based on the child's performance in the study.

Why has my child been asked to take part in this study?
Your child is being asked to participate in this study because they are aged 5 and under, have demonstrated difficulty learning to imitate actions with objects, motor movements, or sounds modeled by another individual, and they have a diagnosis of autism.

How long will the study take and how many subjects will take part?
We anticipate screening 20-30 children and enrolling 6-10 children in the study. A minimum of ten sessions (15-20 min per session) will be conducted each week, with sessions distributed over a minimum

Rutgers, The State University of New Jersey
25 Gibbons Circle/151 Ryders Lane
New Brunswick, NJ 08901

dddc.rutgers.edu
848-932-9137/4500
Fax: 732-932-8011/3095

of three days per week. The study will be conducted over a period of two years, however, your child's participation in the study may range from 3 to 15 months.

What will be asked of me and my child if s/he takes part in this study?
Once the informed consent is obtained, we will conduct a screening appointment to determine if your child is eligible for the study. During the screening appointments, the study team will complete the following assessments:

1. Motor Vocal Imitation Assessment (MVIA)
2. Peabody Picture Vocabulary Test™ Fifth Edition (PPVT™-5)
4. Identity matching assessment

If your child meets the eligibility criteria described above, we will inform you that your child will be enrolled in the study. We will ask you to fill out a brief survey to obtain information about your child's age, race, and sex and to report any food allergies your child has.

We will also send you a copy of the Reinforcer Assessment for Individuals with Severe Disabilities (RAIS-D)[15] to complete. The purpose of the RAIS-D is to identify potential rewards that can be delivered to your child during the intervention.

At the start of the study, your child will be assigned to either the Emergent Multi-Class Imitation Training (EMIT) group or the waitlist group. If your child is assigned to the EMIT group, they will begin the study procedures immediately.

During the first phase of the study (pre-intervention sessions) we will present potential targets (different actions and sounds) to your child to identify responses for the study. We will also conduct preference assessments with your child. Preference assessments are commonly conducted in educational/therapeutic settings; they involve presenting potential items (e.g., toys, snacks) to children to see how they respond. Items that your child selects or enjoys playing with will be used as rewards during the intervention.

During the intervention, your child will participate in a minimum of ten sessions distributed over a minimum of three days per week. During each session, your child will work with a study staff member to learn how to imitate different responses, such as sounds, actions with objects, and gross motor movements. Study staff members working directly with your child will be bachelor, master, or doctoral-level practitioners. Bachelor and masters-level individuals will be trained and supervised by the PI or Co-Investigator (doctoral-level Board Certified Behavior Analysts).

Initially, physical guidance will be used to teach your child how to imitate these models. This guidance will be faded gradually, as your child begins to respond correctly. Rewards, in the form of preferred items or social praise, will be delivered to your child following correct responses. As your child is learning to imitate these models, he/she will be asked to imitate new actions, movements, and/or sounds (i.e., untrained models) that will not be taught using rewards or physical guidance. We are interested in examining the extent to which your child will imitate these new, untrained models, because of our teaching procedures.

Sessions will be recorded using a video camera and recordings will be stored on Microsoft Teams, a HIPAA compliant platform. Recordings will be used for data collection that may be difficult to capture in the moment and will allow for data collection by a second observer. It is a requirement that you provide consent for your child's sessions to be videotaped for them to participate in this study.

Rutgers, The State University of New Jersey
25 Gibbons Circle/151 Ryders Lane
New Brunswick, NJ 08901

dddc.rutgers.edu
848-932-9137/4500
Fax: 732-932-8011/3095

If your child is assigned to the waitlist group, he/she will be matched with a participant in the EMIT group. Participants will be matched using the scores and information obtained during the screening process. Participants in the waitlist control group will begin participating in the research sessions when their assigned matched study participant has completed his/her participation in the sessions.

All participants will be assessed using the Motor Vocal Imitation Assessment (MVIA) prior to and at the completion of the study. A professional who is not affiliated with the study will view video recordings of your child's MVIA before and after the study and rate their imitation skills in both videos.

What are the risks of harm or discomforts my child might experience by taking part in this study?
Procedures used in this study are designed to teach your child to imitate different types of modeled responses. If your child participates in this research, they may encounter stress from acquiring skills, embarrassment associated with responding incorrectly, fatigue, and time spent participating in the study may burden for some participants.

Are there any benefits to my child if s/he takes part in this study?
If your child participates in this research, they may benefit from high-quality, evidence-based imitation training. Your child may also benefit from regular assessment to monitor the emergence of generalized imitation. All individual results for your child will be shared with you and any professionals (identified by you) that work with your child. It is important for family members and clinicians to be informed about participant gains in new skills and to ensure that gains made during the study are maintained following the conclusion of the investigation. It is also possible that your child receives no direct benefit from participation.

What are my alternatives if I do not want to take part in this study?
Your child's alternative to taking part in the research study is not to take part in it. You may choose to not allow your child to take part in this study. It is your choice as to whether you want your child to take part in the study.

How will I know if new information is learned that may affect whether I am willing to allow my child to stay in the study?
Information regarding your child's progress will be shared at the completion of the study and upon request.

Will I receive the results of the research?
Results of the research will be shared with upon completion of the study or upon request.

Will there be any cost for my child to take part in this study?
Most participants will not incur any costs for participation because their child's sessions will be conducted at a collaborating site (i.e., school, clinic, or program that the child already attends). Therefore, additional transportation costs will not be incurred.

Will my child be paid to take part in this study?
Your child will not be paid to take part in this study.

How will information about my child be kept private or confidential?
All data that will be used in research, including assessment data, will be stored on a HIPAA compliant Microsoft Teams Channel. Access to the data in this system is restricted to only those individuals who are

Rutgers, The State University of New Jersey
25 Gibbons Circle/151 Ryders Lane
New Brunswick, NJ 08901

dddc.rutgers.edu
848-932-9137/4500
Fax: 732-932-8011/3095

directly involved with the study and part of the study team. Video recordings will also be stored on a HIPAA compliant Microsoft Teams Channel. When the study has closed, all data will be de-identified. All de-identified data and de-identified video recordings will be destroyed six years after the close of the study.

If your child's audio/visual recording will be used for the purpose of illustrating the procedures at a workshop/conference, we will ask for you to consent to the use of your child's image in that forum. If you do not provide consent for us to use your child's image, we will not use the video or alter the image (e.g., blur face) such that the child cannot be identified.

What will happen to my child's information data, recordings and/or images?
The results of the study may be shared at conferences or in a publication. If the results of the study are shared at a conference or workshop, pseudonyms will be used and identifying information will be omitted. Prior to sharing videos with your child's image at a conference, we will request your permission to do so. If you do not give us permission to share your child's image, we will not use the video or we will mask the identity of your child. When the study has closed, we will de-identify all of the data and video recordings. The de-identified data and de-identified video recordings will be destroyed six years after the study has closed.

What will happen if I do not wish my child to take part in the study or if I later decide that I do not wish my child to stay in the study?
It is your choice whether your child takes part in the research. You may choose to have your child take part, not to take part, or you may change your mind and withdraw your child from the study at any time. If you do not want your child to enter the study or decide to stop taking part, there is no penalty or loss of benefits to which your child is otherwise entitled. If you withdraw from the study, your child's data will not be shared with anyone.

Who can I call if I have questions?
If you have questions, concerns, problems, wish more information about your child taking part in the research, or if you feel your child may have suffered a research related injury, you can call Meghan Deshais at (848) 445-3928.

If you have questions, concerns, problems, information or input about the research or would like to know more about your rights as a research subject, you can contact the Rutgers IRB Director or the Rutgers Human Subjects Protection Program via phone at (973)972-3608 or (732)235-2866 or (732)235-9806 OR email irboffice@research.rutgers.edu, or write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.
.

RUTGERS
Douglass Developmental Disabilities Center

Rutgers, The State University of New Jersey
25 Gibbons Circle/151 Ryders Lane
New Brunswick, NJ 08901

dddc.rutgers.edu
848-932-9137/4500
Fax: 732-932-8011/3095

PARENTAL PERMISSION FOR CHILD

Parental Permission

I have read this entire form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form or this study have been answered.

I am the [ ] parent or [ ] legal guardian of _____ (print name of child) and I agree for my child to take part in this research study.

Parent or Legal Guardian Name (Print):_____

Parent or Legal Guardian Signature:_____ Date:_____

Signature of Investigator/Individual Obtaining Consent

To the best of my ability, I have explained and discussed the full contents of the study including all the information contained in this consent form. All questions of the research subject and those of his/her parent or legal guardian have been accurately answered.

Investigator/Person Obtaining Consent Name (Print):_____

Signature:_____ Date: _____

RUTGERS
Douglass Developmental Disabilities Center

Rutgers, The State University of New Jersey
25 Gibbons Circle/151 Ryders Lane
New Brunswick, NJ 08901

dddc.rutgers.edu
848-932-9137/4500
Fax: 732-932-8011/3095

ADDENDUM: CONSENT TO AUDIO-VISUALLY RECORD SUBJECTS

You have already agreed to have your child take part in a research study entitled, Emergent Multi-Class Imitation Training, conducted by Meghan Deshais. We are asking your consent to allow us to record both audio and video recording your child to be used for data collection of responses that may be difficult to capture in the moment and will allow for data collection by a second observer.

The sessions will be recorded using an iPad, laptop, or digital video camera. Recordings will be stored on Microsoft Teams, a HIPAA-compliant platform. Only those involved in the study will have access to the Microsoft Teams channel. If your child's audio/visual recordings will be used for the purpose of illustrating the procedures used in the study at a workshop/conference, we will ask for your consent to use of your child's image in that forum. If you do not provide consent for us to use your child's image, we will not use the video or alter the image (e.g., blur face) such that your child cannot be identified. Video recordings will be destroyed six years after the study has been completed.

Your signature on this form permits the investigator to use audio/video recordings of your child as described above during participation in the above-referenced study. The investigator will not use the recording(s) for any other reason than that/those stated in the consent form without your written consent.

AGREEMENT TO BE RECORDED

Subject Name (Print): _____

Parent/Legal Guardian Name (Print): _____

Parent/Legal Guardian Signature _____ Date _____

Investigator/Person Obtaining Consent Name (Printed): _____

Signature _____ Date _____