

Parent/Guardian Consent Form

NCT number: TBD

Date: August 1, 2024 (last reviewed by IRB; original approval March 18, 2022)



Cleveland State University

Consent Form/Parental or Guardian Consent Form

Dear Parent or Guardian:

I, Dr. Kelle DeBoth Foust, Associate Professor in Occupational Therapy at Cleveland State University, am asking your permission for you and your child to participate in a research study. For more information, please contact me at (216) 687-3628 or k.deboth@csuohio.edu.

The purpose of this study is to understand if teaching kids and their caregivers about emotions and coping skills leads to feelings of better social support, resilience, and hope. We call this “Building Resilience.” The resilience group focuses on mindfulness techniques, learning to cope with stress and challenges, building relationships, and social supports. The focus of this resiliency training program is to provide education and introduce tools needed to overcome challenges. The intent is to improve your and/or your child’s quality of life.

Your child will be placed into one of two groups to start, the Resilience Group or the Play Group. The Play group will focus on school readiness skills such as coloring, listening and working together. The Resilience group participate in the program to work on emotions and coping skills. Your child will be in both groups, but it will be random which group they do first. Each group is 8 weeks long. The total program is 16 weeks.

Children in the resilience group will work with the occupational therapist or her assistant in a group setting. They will work with a few other children twice a week, for one hour over an 8 week period. During this time they will engage in 3-4 activities. First, a warm up or icebreaker. Second, they will participate in structured group activities such as games, watching child-friendly videos, and drawing or making crafts. Each activity focuses on resilience and emotion-teaching theme. Lastly, children will discuss what they learned that day. Observational assessments will be used and the data will be collected by either Dr. Kelle DeBoth or her occupational therapy student assistant, Kelsey DeLisio. They will be introduced to your children at the beginning of the school year. They will do brief assessments throughout the 8 week period as well as leading the small group sessions.

Adults will work with the occupational therapist or her assistant in a group setting with a few other caregivers three times, for one hour over an 8 week period. During this time, you will engage in 3-4 structured activities, including an icebreaker or introduction to the topic, structured activities such as adult-centered games, learning new skills, and discussions, and finally a discussion of what was introduced that day. You will be asked to complete a few questionnaires for the program. These will be given to you before the program begins and after the program ends. These questionnaires should not take more than 30 minutes each time. These will assess things such as problem solving, coping skills, and stress. Children will also complete a few

questionnaires while you complete yours. These will assess things such as problem solving, coping skills, and stress.

Adults and children will be given a short homework assignment each week, and you will be asked to complete the assignment before returning to group the following week. This might be a worksheet to complete with your child or a video to watch together.

This is a pilot study. This means we are trying something different, and it builds on a program we did here in 2022. I hope the results will support use of this resiliency program for even more children. I intend to present and publish the results of the study. The results will be reported as a whole. That means there is no way for anyone to identify anything about you or your child specifically. This includes any test scores or results. The name and specific location of the preschool will not be included publication. This will help to protect your child's identity.

There are minimal psychological and social risks related to participation in this study. It is also possible that you or your child may not enjoy participating in group. Your child may also have difficulty learning to work with a new adult in the classroom. Although these risks are unlikely, you and your child will have the option not to participate should they occur. In addition, every effort will be made to be sure you and your child feel comfortable and enjoy the group sessions. If you or your child are uncomfortable or stressed at any time, you can contact the PI, Dr. Kelle DeBoth. The PI will help you identify resources available to cope with stress, such as community clinics and/or social work. You can contact the PI at 412-401-5143 with concerns, or by email at k.deboth@csuohio.edu. You may also contact Bradie Williams, Clinical Director, with concerns at bwilliams@ywcafcleveland.org. Finally, toll-free emotional support provided by the Ohio Department of Mental Health and Addiction Services is available 24/7 by calling their hotline at 1-800-720-9616.

There may also be a risk of confidentiality data breach, which can happen in any study. Every step will be taken to prevent this from happening. All data collected is password-protected and encrypted, and any information used in future papers will not have any identifying data about you. There is no direct benefit for you or for your child for participating in this project. Your child may, however, enjoy the social connection with their classmates, the activities, and time spent with the therapists. You may also enjoy your time spent in group.

Reporting Child Abuse or Neglect – Ohio Revised Code

Because the PI is a health care provider, the PI and her assistant are required to report child abuse or neglect. The Ohio Revised Code section 2151.421 requires a report to child protective services or law enforcement for cases of suspected abuse or neglect.

COVID-19

COVID-19 is a highly contagious virus. It has been linked to severe illness, and in rare cases, death. This is particularly true for individuals over the age of 60. It is also true for those with compromised immune systems. The research team is using reasonable measures following Centers for Disease Control (CDC) guidelines. This is intended to minimize potential exposure to COVID-19. Given the highly contagious nature of COVID-19, exposure avoidance cannot be guaranteed.

I understand that my participation in this research may increase my risk of exposure to COVID-19. I accept this risk. I assume full responsibility for any associated medical care or treatments. I waive any claim against the State of Ohio for such medical care or treatment. I waive any claim against Cleveland State University, its Trustees, officers, or employees for any such care or treatment. I understand I am not waiving my right to claim and collect compensation related to malpractice, fault or blame on the part of the researchers. I will notify a member of the research team should I test positive for COVID-19 within 14 days of research participation. I understand and will follow COVID-19 safety. I understand that this may include wearing a mask and social distancing while participating in groups. For general CDC guidance for COVID-19, please visit the following site: <https://www.cdc.gov/coronavirus>

You can choose not to participate in this study. There are no costs associated with participating in this study. All needed materials will be provided to you.

Your consent and your child's participation are voluntary. Your child can withdraw at any time. You may also withdraw your child or yourself at any time. There is no consequence for not participating.

Please read the following: ***"I understand that if I have any questions about my child's rights as a research subject, I can contact the Cleveland State University Institutional Review Board at (216) 687-3630."***

There are two copies of this form. After signing them, keep one copy for your records. Please return the other copy to your child's school. Thank you in advance for your support.

I agree to allow my child to participate, please sign below and check the box that you are 18 years of age or older.

I am 18 years of age or older

Parent's Signature: _____

Child's Name: _____ (Please Print)

Date: _____

I agree to participate in the above research study.

Parent's Signature: _____

Date: _____

OR:

I opt-out of participating in the above research study, but agree for another caregiver to take part in the study with my child.

Parent's Signature: _____

Date: _____

Investigator Signature: _____

Date: _____