

Parental Consent Form

Project Title: The Development of Self-Regulation in Early Childhood Study

Principal Investigator: Jamie Lawler, Ph.D., Eastern Michigan University

Co-Investigator: Angela Staples, Ph.D., Eastern Michigan University

Invitation to participate in research

You and your child are invited to participate in a research study. In order to participate, you must be at least 18 years old and your child must be 3 or 4 years old (36-59 months old) and be free of significant developmental disabilities including autism spectrum disorder. Your family must be eligible for Head Start or the Great Start Readiness Program (family income at 250% federal poverty guidelines or below) to take part in this study.

Participation in research is voluntary. Please ask any questions you have about participation in this study.

Important information about this study

- The purpose of the study is to examine the development of children's capacity to control their behavior, attention, and emotions across early childhood.
- Participation in this study involves two sessions one week apart involving questionnaires, parent-child activities, and games. The first session takes approximately 60-75 minutes, while the second session takes approximately 90 minutes. We will also keep in touch with your family to conduct follow-up assessments.
- We will ask you and your child to wear an activity recording bracelet between the two sessions and will collect saliva from your child several times at the second session.
- At each session, we will ask you to complete some online questionnaires.
- Risks of this study include potential loss of confidentiality and potential emotional distress or upset caused by sensitive survey questions and/or tasks.
- The investigator will protect your confidentiality by using a coded subject identifier, meaning that your personally identifiable information will be kept separately from the data.
- Participation in this research is voluntary. You and your child do not have to participate, and if you and your child decide to participate, you or your child can stop at any time.

What is this study about?

The purpose of the study is to examine the development of children's capacity to control their behavior, attention, and emotions across early childhood.

What will happen if my child and I participate in this study?

Participation in this study involves:

- Visit 1
 - Completing questionnaires
 - A parent and child interactive play activity
 - Game-like computer tasks for your child to complete
 - This visit should take approximately 60-75 minutes
- Between visits
 - Completing a sleep diary
 - You and your child will wear an activity recording bracelet
- Visit 2
 - Completing questionnaires
 - A parent and child interactive play activity
 - Game-like tasks for your child to complete
 - Five saliva collections from your child
 - Brief videos for your child to watch
 - This visit should take approximately 90 minutes
- Follow-up
 - We will keep in contact with you so that we can schedule additional visits to repeat the above procedure again in 12 months.
 - We will also send an online survey for you to complete in about 18 months
 - At the time of your online follow-up, with your permission, we will also ask your child's teacher to complete some questionnaires.

We would like to video record you and your child for this study. If you and your child are video recorded, it will be possible to identify you both through your voices/images. If you do not agree to allow you and your child to be video recorded, you will not be eligible to participate in this study.

What types of data will be collected?

We will collect data about your thoughts and feelings, your history of stressors (including any past experiences of abuse and trauma), and demographic information, including your racial or ethnic origin. We will also collect data about your child including your report of his or her behavior and functioning, his or her past experiences of adversity, his or her personality, his or her self-control abilities, and demographic information including his or her racial or ethnic origin. We will also collect actigraphy data, which measures you and your child's sleep and activity level. Finally, we will collect saliva samples from your child, which will be used to measure cortisol, a chemical that the body produces when a person is in a new or stressful situation.

What are the anticipated risks for participation?

Some of the survey questions are personal and may make you feel uncomfortable. You do not have to answer any questions that make you uncomfortable or that you do not want to answer. If you are upset, please inform the investigator immediately. You may discontinue your participation at any time.

Additionally, there are tasks in the sessions that may cause children to become frustrated or disappointed. These tasks, however, are designed to mimic events that children are likely to experience in their everyday lives. For example, your child may experience some difficulty while playing a puzzle game. These events are brief and you will be nearby if your child needs you. Should you decide that your child is too uncomfortable at any time, you may stop the session. If we believe that your child needs or wants us to, we will also stop the study.

There are no physical risks associated with providing a saliva sample or wearing the activity-recording bracelet. These methods shouldn't cause your child discomfort in any way.

Finally, an additional risk of participation in this study is a potential loss of confidentiality.

Are there any benefits to participating?

You and your child will not directly benefit from participating in this research.

Benefits to society include greater understanding of the factors that contribute to the development of self-control. The study has the potential to inform interventions designed to promote self-control in young children.

How will my and my child's information be kept confidential?

We plan to publish the results of this study. We will not publish any information that can identify you or your child.

We will keep you and your child's information confidential by using a coded identifier, meaning that your personally identifiable information will be kept separately from the data. Your information including video recorded information, will be stored in a password-protected file on a password-protected computer and/or in a locked filing cabinet in a locked office. We will store you and your child's information for at least three years after this project ends, but we may store the information indefinitely. If we still have your child's identifiable information when your child turns 18, we will contact your child to obtain their consent to retain their information going forward.

We will make every effort to keep you and your child's information confidential, however, we cannot guarantee confidentiality. The principal investigator and the research team will have access to the information you provide for research purposes only. Other groups may have access to your child's research information for quality control or safety purposes. These groups include the University Human Subjects Review Committee, the Office of Research Development, or federal and state agencies that

oversee the review of research, including the Office for Human Research Protections and the Food and Drug Administration. The University Human Subjects Review Committee reviews research for the safety and protection of people who participate in research studies.

If, during your child's participation in this study, we have reason to believe that elder abuse or child abuse is occurring, or if we have reason to believe that you or your child is at risk for being suicidal or otherwise harming themselves or anyone else, we must report this to authorities as required by law. We will make every effort to keep you and your child's research information confidential. However, it may be possible that we have to release your or your child's research information. If this were to occur, we would not be able to protect your and your child's confidentiality.

Storing study information for future use

We will store your and your child's information to study in the future. Your and your child's information will be labeled with a numeric code and not your names. You and your child's information will be stored in a password-protected or locked file and will be stored indefinitely. We may share your and your child's information with other researchers without asking for your permission, but the shared information will never contain information that could identify you or your child. We will send your de-identified information by email and only upon request.

What are the alternatives to participation?

The alternative is not to participate.

Are there any costs to participation?

Participation will not cost you or your child anything.

Will I be paid for participation?

You will be compensated with a \$20 gift card for the first session. One week later, you will be compensated with a \$40 gift card for the second session of this study. Additionally, you can earn \$20 and \$40 respectively for completing sessions 1 and 2 at follow-up, 12 months from now. Finally, if you complete the online follow-up survey that will sent by email in 18 months, you will receive a \$20 gift voucher by email.

Your child will not be paid to participate in this research study, but he or she will receive several small prizes for participation.

Study contact information

If you or your child has any questions about the research, you can contact the Principal Investigator, Jamie Lawler, at jlawler1@emich.edu or by phone at 734-487-0123. For questions about you or your

child's rights as a research subject, contact the Eastern Michigan University Human Subjects Review Committee at human.subjects@emich.edu or by phone at 734-487-3090.

Voluntary participation

Participation in this research study is your and your child's choice. Your child's dissent will be respected. You and your child may refuse to participate at any time, even after signing this form, with no penalty or loss of benefits to which you and your child are otherwise entitled. You and your child may choose to leave the study at any time with no loss of benefits to which you and your child are otherwise entitled. If you and your child leave the study, the information you and your child provided will be kept confidential. You and your child may request, in writing, that your and your child's identifiable information be destroyed. However, we cannot destroy any information that has already been published.

Statement of Consent

I have read this form. I have had an opportunity to ask questions and am satisfied with the answers I received. I give my consent to for my child and I to participate in this research study.

Signatures

Name of Parent

Name of Child

Signature of Parent

Date

I agree for my child and I to be video recorded for this study.

Signature of Parent

Date

I have explained the research to the parent and answered all his/her questions. I will give a copy of the signed consent form to the parent.

Name of Person Obtaining Consent

Signature of Person Obtaining Consent

Date