

You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study, you will be one of many other individuals who are being studied at Emory. For this study, you will be one of about 100 others.

Why is this study being done?

This study is being done to answer the question: Is it feasible for parents to perform interactive social behavioral assessments on their children. You are being asked to be in this research study because, through your participation, you will help us gather information that may lead to a better understanding of the feasibility and workload of social behavior assessments when performed by parents on their children.

Do you have to be in the study?

It is your decision to be part of this research study. You do not have to be in it. Your choice will not affect your access to care at Emory University or health care affiliates. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?

If you are eligible and want to be part of the study, you will participate for approximately 30 minutes by completing an interactive social behavior assessment on your child and filling out online questionnaires pertaining to your child's behaviors and developmental history and milestones. We are asking each parent participant to gather a ball and a book and then interact with his/her child in a particular way. We will ask them to observe the child's reactions (e.g., eye contact, smiling, and turn-taking) and answer a series of questions about the child's reactions. We will also ask about symptoms of anxiety and depression you experienced in the previous week.

To participate in this study, we are asking that you use a child's board book between 2 and 4 inches and a 3- to 4- inch ball. Ball can be larger than 4 inches across if necessary, but not be less than 3 inches across.

We are assuming that you can use materials that you already own or that these materials can be borrowed for the purpose of the assessment. It is assumed that you will have access to both a ball and a book, thus there will be no cost to you



How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question. Additionally, by participating in this study you will learn how psychologists observe social behavior moment by moment in young children.

What are the risks or discomforts I should know about before making a decision?

The study will take time. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, loss of privacy and breach of confidentiality could be risks. A full list of expected risks, their frequency and severity are in the “What are the possible risks and discomforts?” section of this document below.

Alternatives to Joining This Study

Since this is not a treatment study, the alternative is not to participate.

Costs

Assuming you will have access to a child’s board book between 2 and 4 inches and a 3- to 4-inch ball (Ball can be larger than 4 inches across if necessary, but not be less than 3 inches across), you WILL NOT have to pay for any of the study procedures (i.e., completing the online questionnaire).

There is more information in the cost section below.

What Should I Do Next?

Read this form, or have it read to you. Take time to consider this and talk about it with your family and friends. Because this is an online study, if you have questions about the study, even after reading the full consent form, you may decide not to participate. It is entirely your choice.



Emory University Consent to be a Research Subject

Title: Interactive Social Behavior Assessments Performed by Parents

Principal Investigator: Opal Ousley, PhD

Funding Source: Emory University Department of Neuroscience & Behavioral Biology

Introduction

You are being asked to be in a research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study. You can skip any questions that you do not wish to answer.**

Before making your decision:

- Please carefully read this form or have it read to you
- Take time to consider this and talk about it with your family and friends.
- Because this is an online study, if you have questions about the study, even after reading the full consent form, you may decide not to participate.

You can make a copy of this consent form, to keep, using your computer's screen shot function. Feel free to take your time thinking about whether you would like to participate. By signing this form you will not give up any legal rights.

Study Overview

The purpose of this study is to determine the feasibility and workload of parents performing interactive social behavioral assessments on their children.

Procedures

- If you chose to participate, you will answer questions from online questionnaires.
- You will answer online questionnaires via a program called REDCap, a HIPAA approved web-based application designed to support research and data gathering.
- Each parent participant will gather a ball and a book and then interact with his/her child in a particular way. We will ask them to observe the child's reactions (e.g., eye contact, smiling, and turn-taking) and answer a series of questions about the child's reactions.
- Questionnaires will assess general information, concerns about the child, social development scale, developmental history and milestones, and anxiety and depression experienced in the previous week.

Risks and Discomforts

Risks of this study may include boredom or fatigue from participation, loss of privacy and/or breach of confidentiality.

- To minimize fatigue, you will have the option to work as quickly or slowly as you would like, as long as you complete the study in one sitting. REDCap can "time out" if there is not continued responding.
- To minimize the risk of loss of privacy and breach of confidentiality, the REDCap program was chosen, which is a secure, HIPPA-compliant database.



Benefits

This study is not designed to benefit you directly. This study is designed to determine the feasibility and workload of parents performing social behavioral assessments on their children using provided assessment instructions. In the process you will also get to learn about how psychologists observe social behavior in young children.

Compensation

You will not be offered payment for being in this study.

Confidentiality

Certain offices and people other than the researchers may look at study records. Government agencies and Emory employees overseeing proper study conduct may look at your study records. These offices include the Office for Human Research Protections, the funder(s), the Emory Institutional Review Board, the Emory Office of Compliance. Emory will keep any research records we create private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

Study records can be opened by court order. They may also be produced in response to a subpoena or a request for production of documents.

Resources

Participating in this study will not generate any clinical information. If participation in this study raises any concerns you might have for your child, it is encouraged that you discuss these with your pediatrician. To find a pediatrician near you please access the link below. If you scroll down to the bottom of the provided website you will find a section designated for helping you locate a nearby pediatrician.

<https://www.healthychildren.org/English/Pages/default.aspx>

Storing and Sharing your Information

Your data from this study will not be shared with anyone outside this study, even if we take out all the information that can identify you.

We will not give you any individual results from the study of the data you give us. If we find something of urgent medical importance to you, we will inform you if you have provided your contact information, although we expect that this will be a very rare occurrence.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.



Contact Information

Contact our research coordinator, Jack Olson at jolson6@tulane.edu:

- if you have any questions about this study or your part in it
- if you have questions, concerns or complaints about the research

If Jack Olson cannot be reached, please contact Dr. Opal Ousley at ousley@emory.edu.

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at <http://www.surveymonkey.com/s/6ZDMW75>.

Consent and Authorization

Discoveries made in this study may lead to future research. If you wish to be contacted for other future studies conducted by our research team, please initial here: PLEASE PROVIDE YOUR INITIALS IN THE ONLINE FORM _____

Please provide your contact email if you wish to be contacted for future studies: PLEASE PROVIDE YOUR EMAIL USING THE ONLINE FORM

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in this research study. By signing this consent and authorization form, you will not give up any of your legal rights. Because this is an online study, we ask that you screenshot your consent form. Consent will be stored in electronic format in REDCap and you may request additional copies at any time within the study.

******PLEASE PROVIDE YOUR NAME AND SIGNATURE USING THE ONLINE FORM******

Name of Subject

Signature of Subject (18 or older and able to consent)

Date

Time



TO BE FILLED OUT BY STUDY TEAM ONLY

******THIS SECTION NOT APPLICABLE******

Name of Person Conducting Informed Consent Discussion

Signature of Person Conducting Informed Consent Discussion

Date

Time