Informed Consent Form

Title: Examination of Differential Valuation of Leisure Items and Attention as Reinforcers by Children with Autism

NCT Number: NCT03152383

Date of IRB Approval: April 1, 2020

You Are Being Asked to Be in a Research Study

What Is a Research Study?

The main purpose of research studies is to gain knowledge. This knowledge may be used to help others. Research studies are not intended to benefit you directly, though some might.

Do I Have to Do This?

No. Being in this study is entirely your choice. If you decide to join this study, you can change your mind later on and withdraw from the research study.

Taking part in a study is separate from medical care. The decision to join or not join the research study will not affect your status as a patient.

What Is This Document?

This form is an informed consent document. It will describe the study risks, procedures, and any costs to you.

This form is also a HIPAA Authorization document. It will describe how your health information will be used and by whom.

Signing this form indicates you are willing to take part in the study and allow your health information to be used.

What Should I Do Next?

1. Read this form, or have it read to you.
2. Make sure the study doctor or study staff explains the study to you.
3. Ask questions (e.g., time commitment, unfamiliar words, specific procedures, etc.)
4. If there will be medical treatment, know which parts are research and which are standard care.
5. Take time to consider this, and talk about it with your family and friends.

Emory University and Children's Healthcare
Consent to be a Research Subject / HIPAA Authorization

Title: Examination of Differential Valuation of Leisure Items and Attention as Reinforcers by Children with Autism

Principal Investigator: Nathan A. Call, Ph.D.

Sponsor: National Institute of Health (NIH)

Introduction
You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of 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.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:
- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

What is the purpose of this study?
The purpose of this study is to compare how children with and without autism value social attention and toys. Typically developing (TD) children and children with other developmental delays are also being asked to participate in the study. We want to compare the preferences of the two groups.

What will I be asked to do?
Your child will be asked to do an action, such as pressing a button. When they do this they will get either an item or attention from a study team member. At first, they will only be required to press the button once. But after the first time, they will be required to press it more and more before they can get the item or attention. Your child will not receive attention or access to items while they are working. Eventually, most children stop responding. We will determine when your child is done working when they go for 1 minute without pressing the button. Sessions will end after 30 minutes if your child keeps working without stopping. This study will examine how many times your child will respond for items and attention. Your child will not be forced to respond. They may choose not to respond at all. In between each session, your child will take a short break. The amount of time required for participation in the study will vary. This depends on your child's responding and availability.

Children with autism will be asked to come back for an additional appointment one week after they complete the assessment of how they value attention and toys. We will repeat the same assessment to see if children respond the same way at different times. Some children will be asked to come back for daily appointments for 2-6 weeks and receive an intervention designed to increase the child's interest in interacting with people, communication skills, and ability to follow instructions. The intervention will involve spending time with a research team member. They will play games with your child and do other activities they like. The goal is to create a positive relationship between your child and the staff

member. We want to see if this can make your child more interested in social activity. For those children, we will repeat the same assessment after receiving treatment to see if there is a change. We will also complete some additional measures to see if there are other changes in your child's social skills and interests.

If your child has not already had testing done at the Marcus Autism Center to confirm a diagnosis, they will undergo characterization measures to ensure they qualify for the study. If your child has already had testing done at the Marcus Autism Center, please let us know if the Marcus Assessment Core can share the test results with us.

- ❑ I **decline** to have my child's test results shared.
  _____ Initial

- ❑ I **consent** to have my child's test results shared.
  _____Initial

Video recording

Video recordings of all sessions will be taken as part of your child's participation. These videos will only be used by the research team and not shared for any reason without your permission. Video recording is required for your participation. If you do not wish to allow the research team to record your child, you will be unable to participate. These recordings are confidential.

With your permission, the study team would like to use these images, video or audio segments for purposes other than research. These include training, education and presentation purposes. You may choose to allow this or not. Your child's participation in the study is not affected by this decision.

- ❑ I **decline** to allow my child's image, video or audio to be used for educational and training purposes
  _____ Initial

- ❑ I **consent** to allow my child's image, video or audio to be used for educational and training purposes
  _____Initial

Data Sharing

The study staff of this study will have access to the test results and other research information obtained as part of this study. The study staff of this study will also have access to other tests and procedures done for standard of care, as needed for the conduct of this study.

By initialing below, you agree to share the information obtained as part of this study with the study staff of other studies you may be part of. Such studies should also have a statement like this one, and your consent, to be able to obtain or release your information to use in this study.

_____Initial

What are the possible risks and discomforts?

There are risks and discomforts associated with this study. The risks include:

- There is a chance for a breach of confidentiality. This means that someone who is not supposed to get your information does. We take many steps to prevent this from happening.
- Possible distress in your child. Since your child will be asked to give a response that they may grow frustrated. If your child gets too frustrated, we will take a break to calm the child or end the visit.

- Possible distress for the parent. Your child's frustration can be stressful for a parent. If you get too uncomfortable, we can take a break or end the visit

You may withdraw your child from the study at any time.

Costs
There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

Compensation
You will receive compensation for participation in the proposed study. After completing the diagnostic evaluation and attention assessment, you will receive $25. For children with autism who come back for a second assessment, you will receive an additional $25. For children with autism who receive the treatment, you will receive $25 for each week you participate in treatment.

All payments are made using a personal payment card. We issue this to you for free. The payment card is a prepaid debit card. It can be used exactly like a Mastercard. We load money onto your card electronically every time you need to be paid. The card system is run by Greenphire, an independent company specializing in payments for research studies and clinical trials. To issue your card, we need to give Greenphire some of your personal information. Banks and other financial institutions can access this information if they need to verify your identity when you use your card. Emory University is required by law to report any payments we make to the IRS. To do this, Emory University Department of Finance needs to keep your Social Security Number on file. We are asking you to allow us to communicate your name, address, date of birth, research study name and Social Security Number to Greenphire and Emory University Department of Finance. If you want to receive e-mail or text alerts when payments are made to you, we will ask you to provide your e-mail or phone number as well. All of this information will be stored on computers owned by Greenphire. Greenphire will not have access to any other information collected during this study. Full instructions about using your card are included when we issue it. Please ask if you have any questions or concerns about the card system or the use of your personal information.

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.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the study.

PHI that Will be Used/Disclosed:
The PHI that we may use or disclose (share) for this research study includes your child's diagnosis of autism.

Purposes for Which Your PHI Will be Used/Disclosed:

We will use and share your PHI for the conduct and oversight of the research study. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information.

Use and Disclosure of Your Information That is Required by Law:
We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study or receive research-related treatment. You may still receive non-research related treatment.

People Who will Use/Disclose Your PHI:
Different people and groups will use and disclose your PHI. They will do this only in connection with the research study. The following persons or groups may use and/or disclose your PHI:

- The Principal Investigator and the research staff.
- The Principal Investigator may use other people and groups to help conduct the study. These people and groups will use your PHI to do this work.
- The following groups may also use and disclose your PHI. They will do this to make sure the research is done correctly and safely. The groups are:
    - the Emory University Institutional Review Board
    - The Office of Human Research Protections (OHRP)
    - the Children's Healthcare of Atlanta Institutional Review Board
    - the Emory University Office of Research Compliance
    - research monitors and reviewers
    - data and safety monitoring boards
    - public health agencies
- Emory Department of Finance and Greenphire.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact [redacted], study coordinator, at [redacted].

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy

Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

Contact [redacted], study coordinator, at [redacted]:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury or a bad reaction to the study drug, or
- if you have questions, concerns or complaints about the research

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.

If you are a patient receiving care at Children's Healthcare of Atlanta and have a question about your rights, please contact Kristine Rogers, Director of Clinical Research at 404-785-1215.

Consent and Authorization

Please print your name and sign below if you agree to be in this study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed consent to keep at your request.

_____
Name of Subject

_____ _____
Signature of Caregiver Date

_____
Name of Person Conducting Informed Consent Discussion

_____ _____
Signature of Person Conducting Informed Consent Discussion Date