Informed Consent Form

Title: Changing Developmental Trajectories through Early Treatment

Principal Investigator: Nathan Call, PhD

Sponsor: National Institutes of Health

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

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If you are the legal guardian of a child who is being asked to participate, the term "you" used in this consent refers to your child

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 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.** 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.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify you. At most the Web site will include a summary of the results. You may search this Web site at any time.

Study Overview
The purpose of this study is to evaluate two interventions. These interventions are for children between 12 and 15 months who show red flags for ASD. There is not a lot of research about treatment for children this young. We are comparing two intervention types, with each intervention lasting 9 months. Both interventions are designed to train parents how to support social communication skills for their child. We want to identify interventions that involve parents and build communication skills in toddlers with ASD. For this study, we are partnering with a research team at Florida State University. We share some of the information we collect about you with them. We do this to help us conduct this research study to the highest of standards.

Procedures
The study will involve teaching parents how to support social communication in everyday activities with their child using one of two different parent interventions: one that involves a parent education group, and another that involves home-based intervention sessions plus a parent education group. The type of parent intervention will be randomly assigned.

Before you can participate in the intervention, you and your child will be asked to do the following:

- Your child will be given several standardized tests of verbal and nonverbal skills and a standardized observation to assess his/her communication and social skills. ***Some of these measures will be videotaped*** so that the clinician and another person can verify the assessment of your child's skills. You will be present during all testing with your child.
- You also will complete questionnaires and interviews about your child's communication and social development.

Following these tests, it will be determined if your child meets the criteria to participate in this study. Then your child will be assigned to begin with either the parent education group or the home-based intervention + parent education group. Your treatment assignment will determine the intervention that is offered for 9 months. We are unable to change the treatment assignment once you are randomized. We will assign your child to a group randomly (e.g., by flipping a coin).

We will ask you to complete a set of questionnaires focusing on family resources as well as social emotional issues. We will ask you to complete these questionnaires 5 times. The first time will be before intervention begins. You will be asked to complete the same set of questionnaires every 6 months afterwards, with the last time two years after you begin treatment (e.g., 12, 18, 24, 30 and 36 months). You will also be asked to record the number of hours your child participated in other interventions every month. Completion of these questionnaires and the formal assessment are voluntary and does not impact your ability to participate in the study or limit the services available to you.

If your child is assigned to the **parent education group**, you will be asked to participate in group meetings every week and in monthly home observations.

- We will ask you and your child to attend parent education groups that meet for 75 minute sessions every week for 9 months. The parent education groups will be directed by one or two professionals who will provide information and resources about autism and how to support social communication development in your child. There will be up to 5 other families attending the parent education group, which will give you the chance to see your child interacting with other children and network with other families.
- We will ask you and your child to play during the parent education group and the professionals will give you feedback on how to support social communication skills with your child and will answer questions that you have.
- We will make video recordings of you and your child once a month at home for about an hour during everyday activities to see how you and your child are interacting.
- We will ask you to bring your child to our center every 6 months until 2 years after you begin participating to repeat the standardized observation to see if there were any changes over time. Some of these measures will be videotaped so that the clinician and another person can verify the assessment of your child's skills.

If your child is assigned to the **home-based intervention + parent education group**, you will be asked to participate in three (3) intervention sessions each week and in monthly home observations.

- We will ask you and your child to participate in intervention sessions for 9 months. These sessions will meet for 75 minutes three times a week. Two of these weekly sessions will be individual at your home. The other session will be conducted at our center in a group format. The intervention sessions will be directed by one professional who will teach you how to use specific supports to target specific intervention objectives for your child.
- During the individual intervention session, we will ask you and your child to play and interact during everyday activities and the professional will give you feedback on how to support social communication skills with your child and will answer questions that you have.

- During each week of the home-based intervention group, we are asking you to use the specific supports taught to you during everyday activities with your child for 5 hours a day 5 days a week. We will need you to keep a log or diary of these activities on a daily basis.
- In addition to the intervention sessions, we will make videotapes of you and your child once a month at home for an hour during everyday activities to see how you and your child are interacting.
- We will ask you to bring your child to our center every 6 months until 2 years after you begin participating to repeat the standardized observation to see if there were any changes over time. ***Some of these measures will be videotaped*** so that the clinician and another person can verify the assessment of your child's skills.

- Regardless of which assignment your child receives, your participation will continue through your child's 36 month birthday. You will be invited to monthly parent education booster sessions following your completion of the 9 month intervention. In addition to the parent education booster sessions, we will make videotapes of you and your child once every 3 months at home for an hour during everyday activities to see how you and your child are interacting.

If you choose to participate, information obtained from you as part of this study will be shared with the National Institutes of Health **National Database for Autism Resear**ch (NIH NDAR). The information will be available for researchers to use in research about autism and other social-communication disorders to answer questions about the causes of autism, diagnosis, development, and response to treatment. All personal details identifying you or your child will be removed before information becomes a part of this database. No video records will be provided to NDAR. If you agree to be in this study that means that your child's research information will be used in this way. If you change your mind later, we can ask to remove your child's data from NDAR. However, NDAR cannot get back information that was shared before you changed your mind.

Risks and Discomforts

Since the initial assessment portion of this study takes about 5 hours, there is a risk that your child may become bored or tired. This amount of time is typical for an assessment with children, so we minimize this risk by allowing breaks and snacks as needed. We will take breaks and can reschedule as necessary. Additionally, about half of the assessment is play-based involving toys and/or fun activities that are not test-like or school-related. You will be with your child during all testing and can let the professional know if your child needs a break or you want to end the session.
Since this study involves personal information, there is always the risk of breach of confidentiality. To minimize this risk, all clinical and videotaped records will be kept by project staff in a locked room. We will use identification codes on all research records; no names or other personal identifying information about you or your child will be included. Because this project is being completed as a partnership between Emory University and Florida State University, we will need to share research information with staff at the other site. All personal details identifying you or your child will be removed before information is shared with the other site. If you do not want you or your child's research information to be used in this way, you should not participate in this study.

As with any research study, there may be additional risks that are unknown or unexpected. The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even when the researchers are careful to avoid them. If you believe that you have been harmed, notify the researchers listed in the "Contact Information" section of this form below. If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

New Information

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Benefits

You or your child might not receive any personal benefits from being in this study. However, you and your child may benefit from involvement in this project in a few ways. First, you will be provided with a written summary of test results before and after each intervention. This information may be of benefit in planning future school and treatment choices. Second, the parent intervention may improve your ability to support your child's development of social communication. We also hope findings from this research will contribute to better and more effective services for other young children with autism spectrum disorders and their families.

Compensation

Compensation is as follows:
Group- $10 for each Group session. You may have up to 51 visits for up to $510.00 in compensation.
Home Observation- $10 for each Home Observation session. You may have up to 16 sessions for up to $160.00 in compensation.

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 scheme 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 scheme or the use of your personal information.

Please note that Emory University is required to complete form 1099 for any participant payments over $600. To comply with this federal mandate the researchers are required to obtain your social security number to complete the form.

Other Treatment Outside this Study

Your access to services at the Marcus Autism Center for yourself and/or your child will not be affected if you do not participate in this study. If you choose not to participate we provide you with referrals to intervention programs available in your community upon request.

Confidentiality

Emory and Children's Healthcare will keep any research records that it creates private to the extent that this is required to do so by law. Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

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

Medical Record

If you are or have been an Emory or Children's Healthcare patient, you have an Emory or Children's Healthcare medical record. If you are not and have never been an Emory or Children's Healthcare patient, you do not have one. An Emory or Children's Healthcare medical record will not be made for you if an Emory or Children's provider or facility gives you

any services or procedures for this study. Copies of the consent form/HIPAA authorization that you sign will not be put in your Emory or Children's Healthcare medical record.

Emory or Children's Healthcare may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results will not be put in your Emory or Children's Healthcare medical record.

We will take reasonable steps to keep a copy of the consent and HIPAA authorization forms you sign out of Emory or Children's Healthcare's medical records system. If we aren't successful in keeping these forms out, despite our efforts, we will take steps to remove them. If they cannot be removed, we will take steps to limit access to them.

Emory and Children's Healthcare do not control results from tests and procedures done at other places, so these results will not be placed in your Emory or Children's Healthcare medical record. They will likely not be available to Emory or Children's Healthcare to help take care of you. Emory and Children's do not have control over any other medical records that you may have with other healthcare providers. Emory and Children's Healthcare will not send any test or procedure results from the study to these providers. If you decide to be in this study, it is up to you to let your health providers know.

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 this study.

PHI that will be Used/Disclosed:
We will not use any of your personal information outside of this study. If you wish to share the findings of this study with other healthcare professionals, you must sign a separate consent to release information.

Purposes for which your PHI will be Used/Disclosed:
We will use and disclose your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. 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 (Florida State University). 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 use to report child abuse or abuse of elder 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 authorize the use and disclosure of your PHI for the study, then you may not participate in the research study or receive research-related treatment. You may still receive non-research related treatment.

People that will Use and/or Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- Emory and Children's Healthcare may use and disclose your PHI to get payment for study related treatment and to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- National Institutes of Health is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection Program and those that involved in study administration and billing. These include the Emory IRB, Western IRB, and other IRBs or privacy boards involved in this study; the Emory Research and Healthcare Compliance Offices; and the Emory Office for Clinical Research.
    - Children's Healthcare offices involved in the study administration and billing.
    - Government agencies that regulate the research including: [Office for Human Research Protections; Food and Drug Administration; Veterans Administration].
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
    - Emory Department of Finance and Greenphire for study payment purposes.

Expiration of Your Authorization
This authorization will not expire because it is a research study.

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 write to: Nathan Call, PhD. Marcus Autism Center 1920 Briarcliff Road, Atlanta, GA 30329

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. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers or 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 and/or for other purposes besides this study.

In Case of Injury

If you or your child get ill or injured from being in the study, Emory and Children's Healthcare would help you to get medical treatment. Emory, Children's Healthcare, and the sponsor have not, however, set aside any money to pay you or to pay for this medical treatment. The only exception is if it is proved that your injury or illness is directly caused by the negligence of an Emory, Children's Healthcare, or sponsor employee. "Negligence" is the failure to follow a standard duty of care.

If you or your child becomes ill or injured from being in this trial, your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurer does not pay, then you will have to pay these costs.

If you believe you or your child have become ill or injured from this research, you should contact Dr. Nathan Call at telephone number 404-785-9400. You should also let any health care provider who treats you know that you are in a research study.

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.

Withdrawal from the Study

You have the right to leave a study at any time without penalty. If you leave the study before the final planned study visit, the researchers may ask you to have some of the final steps done.

The researchers and sponsor also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interest;
- You were to object to any future changes that may be made in the study plan;
- or for any other reason.

Contact Information

Contact Ashley Trumbull at 404-785-9323:

- 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

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

_____
Name of Subject

_____ _____
Signature of Person Conducting Informed Consent Discussion Date

_____
Name of Person Conducting Informed Consent Discussion

_____ _____
Signature of Legally Authorized Representative Date

_____
Authority of Legally Authorized Representative or Relationship to Subject

PHOTOGRAPHY/VIDEOGRAPHY and AUDIO RECORDING
PERMISSION FORM

Title: Changing Developmental Trajectories through Early Treatment

Principal Investigator: Nathan Call, PhD.
Funding Source: NIH

Name of Child_____ DOB___/___/_____
Name of Parent_____
I understand that audio/video recordings of my child are made at no cost to me for research purposes and that I may watch them. This and the nature of the taping procedure have been explained to me. I understand that the recording is confidential material and will not be used without my specific consent. I understand that I may request the recordings be erased after the study is completed and that my consent for any use of them may be withdrawn by requesting so in writing.

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In addition, I give my consent to the faculty at the Marcus Autism Center Social Neuroscience Laboratory to use these photographic images, video or audio segments for reasons other than research purposes:

- ❑ For educational and training purposes within Emory, Children's Healthcare of Atlanta and Marcus Autism Center ____(initial)
- ❑ For use at national and international conferences ____(initial)

- ❑ I decline to give my consent for any use of my child's image or voice for educational or training purposes.___(initial)
- ❑ I decline to give my consent for any use of my child's image or voice for use at national or international conferences. __(initial)

Your ability to participate in this study is not affected in any way by your willingness to consent to your child's image being used for educational or training purposes as described above.

_____ _____
Signature Date

_____ _____
Signature of Person Obtaining Consent Date

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator, Nathan Call, Ph.D., at 404-785-9400. If you have any questions concerning your rights as a research subject, you may contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797.