Can Novel Telemedicine Tools Reduce Disparities Related to Early Identification of Autism

NCT03847337

Informed Consent Form

02/04/2019

VUMC Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Zachary Warren, Ph.D. **Revision Date:** 1/22/19
Study Title: Can novel telemedicine tools reduce disparities related to early identification of autism
Institution/Hospital: Vanderbilt University Medical Center

This consent form is for parents and caregiver(s) of children between the ages of 15 and 36 months

Name of participant: _____ Age: _____

The following information is provided to inform you about the research project and your participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. Also, you will be given a copy of this consent form.

What is the purpose of this study?

In this study, we are trying to find new ways to screen for autism spectrum disorder (ASD) in young children. We want to see if people like pediatricians can screen children for ASD while a psychologist watches on a monitor. We are testing out two screening tools and want to see if they are good at identifying children with ASD and children without ASD. We hope this research will make it easier for families to get answers when there are concerns for ASD.

We are asking you to participate because your child is between the ages of 15 months and 36 months. Your child also has a diagnosis of ASD or other developmental delay.

A psychologist on a screen will watch you and talk to you. The psychologist will ask you to play with your child in specific ways. The psychologist will also ask you some questions about your child. After you are done playing, we will ask you what you thought about the activities. We will also ask questions about other testing your child has had done.

There are no foreseeable risks of participating in this study. The risks are no greater than the risks young children face every day, such as falling or bumping their heads.

There are no direct benefits to participating in this study. This study may help us understand how to screen for ASD in new and better ways.

You do not have to be in this study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.

Procedures to be followed and approximate duration of the study:

You and your child will come to Vanderbilt for one visit. The visit will take approximately 1 hour.

We are testing two different screening tools. You and your child will be asked to complete one of them. This will be chosen at random. For either tool, a psychologist will talk to you through a computer monitor. The psychologist will ask you questions about your child's development and behavior. He/she

will also ask you to play with your child in specific ways. This will help the psychologist look for ASD symptoms.

We will also ask you for feedback. We want your input on the study activities. We will also ask about when your child received his/her diagnosis. Because we are testing out these new screening tools, you will not receive any test results at this visit.

Expected costs:

Expected costs for you include the cost of traveling to Vanderbilt and the time it takes for the visit.

Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:

We will watch your child for signs of being upset, such as crying. We will take a break if your child is upset. We can stop the session if your child does not calm. You will be with your child the whole time.

Unforeseeable risks:

This study is a minimal risk study. There are no unforeseeable risks associated with participating in this study.

Compensation in case of study-related injury:

If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided at Vanderbilt to treat the injury.

There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you money for your injury.

Good effects that might result from this study:

a) The benefits to science and humankind that <u>might</u> result from this study. The potential benefits to science and humankind that may result from this study include increased information about how to screen for ASD within primary care settings. Conducting ASD screenings within primary care settings will help to decrease travel and wait times for families.

b) The benefits you might get from being in this study. There is no direct benefit for your family.

Study Results:

This is a study of how a new tool works. This study will not provide you new information about your child. When the study is complete, results will be published.

Alternative treatments available:

This study does not involve treatments. Involvement in this study does not prevent you from accessing treatment for your child.

Compensation for participation:

Families will be compensated with a $50 gift card following completion of their research appointment.

Circumstances under which the Principal Investigator may withdraw you from study participation:

You will only be withdrawn from this study if you do not complete the study appointment.

What happens if you choose to withdraw from study participation?

There are no consequences for choosing to withdraw from the study.

Contact Information.

If you should have any questions about this research study or possibly injury, please feel free to contact the principal investigator, **Zachary Warren, Ph.D.** at **(615) 936-7159**.

For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Confidentiality:

All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. The information kept in your child's research record will be de-identified, meaning that your child's research documentation will be assigned a number and will not include your personal information. Any personal information we collect from you will be kept separate from your de-identified research data. Your personal information, including the log used to document your family's research number and results of the diagnostic evaluation, will be kept on a secure Vanderbilt server as well as in a filing cabinet behind two locked doors. Only research personnel involved in this research study will be given access to your personal information unless you provide written permission for us to share your information with anyone else, such as your child's pediatrician. Your research and personal data will be destroyed 3 years after the close of the study.

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible

harm to yourself or others, or if you need medical help. Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research.

Disclosures that you make yourself are also not protected.

Privacy:

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are

agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Vanderbilt University Medical Center may share the results of your study and/or non-study linked diagnostic evaluation, as well as parts of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the VUMC Institutional Review Board, and Vanderbilt University. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The sponsor and/or Vanderbilt may give or sell your health data, without identifiers, to others or use it for other research projects not listed in this form. The sponsor, Vanderbilt, Dr Warren and his staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

The study results will be kept in your research record for at least three years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will also be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Warren in writing and let him know that you withdraw your consent. His mailing address is [redacted]. At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

Principal Investigator: Zachary Warren, Ph.D. **Revision Date:** 1/22/19
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STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate.

Date _____ Signature of patient/volunteer _____

Consent obtained by:

Date _____ Signature _____

Printed Name and Title _____