Washington University in St. Louis

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INFORMED CONSENT DOCUMENT

Project Title: Video-based analysis of behavior in autism spectrum disorder

Principal Investigator: Dr. Shuo Wang, PhD

Research Team Contact: Dr. Shuo Wang, PhD (314) 362-7338

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant.

KEY INFORMATION

The first section of this document contains some key points that the research team thought you would find important. The research study is described in more detail after this section.

This is a research study conducted by Dr. Shuo Wang, PhD to understand social behavior in autism spectrum disorder (ASD). You should carefully consider the information in this consent document and discuss it with the research team. Be sure you understand why you might want to participate, or why you might not want to participate. You may choose to participate or not.

If you agree and sign this consent, you will be volunteering to participate in the research study. All of the information below will be explained and is listed in more detail in the consent document below. The research team must give you a copy of this signed consent document.

How will this study affect me?

- The purpose of the study is to collect videos when you play with your child following our specific task instructions. We will then employ computer vision approaches to analyze these videos.
- As a voluntary participant, you will be asked to spend about an hour to complete questionnaires, take videos and upload videos at your home.
- You were selected because your child has been diagnosed with autism spectrum disorder or your child does not have autism.
- You will be in this study for social interaction with your child with videotaping at your home.
- The main risks to you are physical fatigue or psychological stress. More details about risks are provided below.
- You will not benefit from being in this study. However, we hope that, in the future, other people might benefit from this study because the knowledge that we gain insight into the ways which humans behave in social interactions.
- You will be paid for participating in this study (the details are provided below). You will not have costs for participating in this study.
- If you withdraw from the study, the research team may continue to use information already collected about you in this study.

The rest of this document provides more details about the study.

WHAT WILL HAPPEN DURING THIS STUDY?

This study involves taking videos of the study participant. Videos will be taken at home by the parent or caregiver while they are speaking to the child or observing them. Only the study participant and perhaps one parent/caregiver will appear in the home videos; however, another parent/caregiver may be heard speaking to them on these home videos. The home videos will be short (usually less than a minute long) and the total time to take all of the videos is about 15-20 minutes including reading the instructions, setting the camera settings on the phone, capturing the video, and uploading the videos.

If your child is being referred for an autism evaluation, the administration of the Autism Diagnostic Observation Schedule (ADOS-2) by a trained professional will be recorded at the Washington University Autism Clinic. Depending upon the age of the child, the parent may be in the room during the administration of the ADOS and may be heard on that video as well. Autism evaluations using the ADOS-2 are done by a trained clinician and will take about one hour (including videotaping). If you choose not to participate in this study and are seeking a clinical autism evaluation for your child, s/he will receive the same evaluation at the WU Autism Clinic even if you choose not to participate in this study. The only difference would be that the ADOS-2 evaluation will be videotaped for later analysis if you do choose to have your child participate in this research.

Additionally, you may be asked to fill out questionnaires including the Social Responsiveness Scale (SRS), Modified Checklist for Autism in Toddlers (MCHAT-R), and the Autism-Spectrum Quotient (AQ) survey. These questionnaires will take approximately 30 minutes to complete. The AQ can be used to help in the diagnosis of autism, although it is not a definitive test. You do not have to answer all the questions. You will have the opportunity to see the questionnaires before signing this consent form. These forms will have a unique participant identifier in the Name section; please do not add your name or the child's name or other information to these forms. The unique identifiers are used to help keep participant information confidential.

Will you save my research information to use in future research studies?

We would like to use the data we are obtaining in this study for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding autism, or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use your data you give up any property rights you may have in the data.

We will share your data with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at Washington University, at other research centers and institutions, or industry sponsors of research. We may also share your research data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual research data is placed in one of these repositories only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.

Your data will be stored without your name or any other kind of link that would enable us to identify which sample(s) or data are yours. Therefore, it will be available indefinitely for use in future research studies without your additional consent and cannot be removed.

Audio Recording/Video Recording/Photographs

The main aspect of this study involves making video recordings of your child. In addition to our computational vision analysis of your home videos, our psychiatrist will evaluate your child's videos to determine your autism severity based on the Autism Diagnostic Observation Schedule (ADOS) research criteria. This is the routine procedure for a rigorous autism research.

While all video recordings are stored in a confidential manner, please be aware that the recording will likely contain information that would identify you / your child. We will analyze your videos for biometric data through the use of web-based software provided by Argus Cognitive. Videos will only be stored temporarily on their servers and will automatically be deleted once analysis is complete.

I give you permission to make video recordings of me during this study.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 600 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for an hour for home videos, and you may be invited to the Autism Clinic for ADOS. Our estimated time for each task is as follows:

- Questionnaires: 20 – 30 minutes
- Home videos: 20 – 30 minutes
- Video upload: 5 minutes
- ADOS evaluation with videotaping (around 1 hour)

You can complete all tasks within 1 session, or you can split them into multiple sessions. You may only need to participate in a subset of the tasks (the order of the tasks is determined by the experimenters), and you are not required to participate in all the above listed tasks.

We do not require a certain length of time in between each visit. For each visit, we will discuss with you about the duration of participation during scheduling.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Videotaping

Risks include physical fatigue and psychological stress, but these risks are minor.

Breach of Confidentiality

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will be asked to provide your social security number (SSN) in order for us to pay you. You may also need to provide your address if a check will be mailed to you.

You may choose to participate without being paid if you do not wish to provide your social security number (SSN) for this purpose. You may also need to provide your address if a check will be mailed to you. You should receive this check in approximately 3-4 weeks after completion of your imaging visit. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

- $30 for home videos
- $30 per hour ADOS

WHO IS FUNDING THIS STUDY?

The National Institutes of Health and National Science Foundation are funding this research study. This means that Washington University is receiving payments from the National Institutes of Health and National Science Foundation to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from the National Institutes of Health and National Science Foundation for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator Dr. Shuo Wang, PhD at 314-362-7338 and/or the Human Research Protection Office at 1-(800)-438-0445.

Decisions about whether payment for medical treatment for injuries relating to your participation in research will be made by Washington University. If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

- Other people such as those listed below may become aware of your participation in this study and

may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.
- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- National Institute of Health (NIH)
- National Science Foundation (NSF)
- Hospital or University representatives to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

To help protect your confidentiality, you will be assigned a unique patient identification number. The research team will make sure information cannot be linked to you. All hardcopies will be stored in a locked file cabinet in a locked office. Electronic records will be maintained on a HIPAA secure password protected database. Both your electronic and paper records will be labeled with your assigned unique patient identification number.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:
- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others*;*
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

This Certificate may not be effective for information held in foreign countries.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research,

you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
    - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
        - **If you revoke your authorization:**
            - The research team may only use and share information already collected for the study.
            - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
            - You will not be allowed to continue to participate in the study.

Can we contact you by email and/ or text?

We would like to contact you by email and/or text for the purposes listed below. Some of these messages may contain health information that identifies you.

- Appointment scheduling containing PHI and appointment reminders.

Only the research team will have access to your email and/or text communications. We will only communicate in this method to send you the information listed above. If you have any questions, wish us to stop sending these messages or need to contact us for an urgent or emergent situation, please contact the research team member identified at the top of this document.

You should be aware that there are risks associated with sending your health information via email and/or text.

- Text messaging is not a secure communication method.
- There is always a risk that the message could be intercepted or sent to the wrong email address and/or phone number. To avoid this, we will send a test message to ensure we have the correct email address and/or telephone number.
- For email when using any computer you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.
- If you share a home computer or cell phone with other family members, and do not want them to know you are participating in this study make sure you provide an email address that only you can access.
- Your employer will have access to any messages sent or received on any electronic devices used for work or through a work server.
- If you lose your phone, others may be able to access the messages that we send.

Do you agree to allow us to send your health information via email?

_____ Yes **_____ No**
Initials **Initials**

Do you agree to allow us to send your health information via text?

_____ Yes **_____ No**
Initials **Initials**

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ under Withdrawing from a Research

Study.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?

Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because the investigator considers it appropriate. If you appear in anyway uncomfortable participating in the study or you are not able to participate you will be withdrawn from participating.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Dr. Shuo Wang, PhD at (314) 362-7338. If you experience a research-related injury, please contact: Dr. Shuo Wang, PhD at (314) 362-7338.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

Parent/Guardian Name and Relationship to Participant:

Do not sign this form if today's date is after EXPIRATION DATE: N/A.

_____
(Child's name – printed)

_____ _____
(Signature of Parent/Guardian) (Date)

_____ _____
(Name of Parent/Guardian- printed) (Relationship to participant – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)

_____
(Name of Person who Obtained Consent - printed)