CONSENT FOR RESEARCH - Intervention
The Pennsylvania State University

Title of Project: *Using Serious Game Technology to Improve Sensitivity to Eye Gaze in Autism*

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Subject's Printed Name: _____

We are asking you to be in a research study. This form gives you information about the research.

Whether or not you take part is up to you. You can choose not to take part. You can agree to take part and later change your mind. Your decision will not be held against you.

Please ask questions about anything that is unclear to you and take your time to make your choice.

Some of the people who are eligible to take part in this research study may not be able to give consent because they are less than 18 years of age (a minor). Instead we will ask their parent(s)/guardian(s) to give permission for their participation in the study, and we may ask them to agree (give assent) to take part. Throughout the consent form, "you" always refers to the person who takes part in the research study.

1. **Why is this research study being done?** We are asking adolescents to be in this research because you may learn social skills from playing a computer game. This research is being done to find out find out how adolescents with autism learn social skills from a computer game. Adolescents may be asked to play the game or you may be asked to be part of a control group who does not play the game. We hope that the information we obtain from the way adolescents perform on these tests and respond to the computer-based training will lead to better understanding about the nature of face-to-face social skills in people with autism. Approximately 150 people will take part in this research study at Penn State.

2. What will happen in this research study? Dyads (adolescents ages 10 to 17 and their parents) have been invited to participate in two behavioral sessions over the course of three months. Adolescents will also be randomly assigned to either the intervention (playing a social skills video game) or control condition (not assigned to play a video game).

Parents will complete the following: The parent of each adolescent will complete several paper and pencil questionnaires asking about their child's behavior and health history at each of the two sessions. If your family is randomly assigned to participate in the intervention, you will help administer your child's computer-based intervention at home.

Adolescents (age 10 to 17) will complete the following:
Pre-test Session: The pre-test session completed by adolescents consists of two parts.

- *PART 1:* During the first portion of the pre-test session, adolescents will complete standardized testing as part of confirming the eligibility criteria. This consists of completing a reading test, an intelligence test, and a standardized observational measure of autistic symptoms (the ADOS). You will be video recorded while you complete the ADOS testing. *Based on your responses on these measures, you will*

be further assessed for eligibility in the behavioral intervention trial. A summary report of the ADOS and IQ results is available to parents upon request.

- *PART 2 for adolescents*: If you qualify for the study based on your standardized testing scores, adolescents will complete the second portion of the pre-test session, you will complete several computer-based eye-tracking tasks. You will be given a break before the second portion of the pre-test session. The eye tracker records your eyes and measures your eye movements while looking at pictures or videos. You will be asked to make decisions about what you see on the screen. The pictures and videos include scenes of people looking at objects. The videos will include scenes of people interacting, like from age-appropriate entertainment movies. Adolescents will also complete questionnaires about your behavior and social skills.

Group Assignment (Randomization): Because we want to understand whether the computer-based intervention has an impact on social behavior, we need to compare the intervention group to a control group who does not complete the intervention. To do this, we will assign adolescents taking part in this research into two groups. The two groups are selected by chance, as if by tossing a coin. This randomization happens at the end of the first session, so you won't know your group assignment until the end of your pre-test session. One group will be assigned to complete the computer game intervention. The other group will be the control group and will **not** be assigned to play our computer game. If you are assigned to the control group, you will be scheduled to return in 2 months for the post-test session and will not be assigned to any particular intervention procedures between sessions.

Intervention Group Procedures:

- If you are an adolescent assigned to the intervention group, you and your parents will be given the option to install the software directly on your home computer. Your family may also be provided a laptop if needed. A research assistant will teach families how to use the computer software programs for this testing at the end of the pre-test session. Families will be given a unique login account name and password at the lab, along with instructional materials. As the data will be submitted electronically to Penn State over the Internet, the game will require Internet connectivity to play.
- A parent will help adolescents complete the training sessions in a quiet room in your own home. The research assistant will also maintain daily contact with a parent, via text messaging, telephone, or e-mail, during the intervention to monitor your progress and address any questions or concerns. If you have technical difficulties with the program at home, adolescents can ask your parent to contact the researchers and our staff will assist in identifying and fixing the problem.
- This computer-based social skills intervention involves social interactions with animated characters in a adventure-themed game. Adolescents are be asked to recognize nonverbal social cues, such as pointing, head turns, or eye gaze cues. This training will take approximately 20 total hours over 2 months. Adolescents will play the game for 3 days per week (approximately 60 minutes per session), every week, for 2 months.

Post-test Session: The post-test session will be scheduled for approximately 2 months after your first session, for both groups. Adolescents will complete the same self-report questionnaires as done at pre-test. Adolescents will also complete the same eye tracking tasks that were completed at pre-test. Adolescents from the intervention group will also be asked to rate your enjoyment of the intervention game.

3. Who can be in this study? You are an adolescent diagnosed with autism who passed the initial pre-screening for the study, and:

- are between the ages of 10 and 17 at the time of enrollment

- are capable of cooperating with testing, and are able to use a computer keyboard and mouse
- have normal vision and hearing (with correction)
- have no history of seizures within the last 2 years

Adolescents will complete background testing today, to confirm your eligibility to participate in the intervention. Completion of the background measures will allows researchers to confirm that you:

- have a full scale and verbal intelligence (IQ) greater than 70 (as confirmed on the KBIT-2)
- are able to speak in full sentences and can read at or above a 2nd grade reading level (as confirmed on the OWLS-2 reading comprehension scale)
- have current symptoms reflecting a diagnosis of autism (as confirmed in the ADOS interview).

If you meet these criteria, you will complete the remaining study measures. If you do NOT meet these criteria, you will not be enrolled in the remainder of the study. In such an event, you will not suffer any penalty or loss of benefits or rights, which you or might otherwise be entitled.

4. What are the risks and possible discomforts from being in this research study?

The risks and discomfort associated with participation in this study are no greater than those ordinarily encountered in daily life. The risk to you is minimal for the eye tracking and computer-based tasks. At most, participants may find the testing too simple and become bored or too difficult and become frustrated. Previous experience with these sorts of tests suggests that participants can perform them reasonably well with minimal impact on them. Sometimes people worry about how well they do on tests or become tired. To reduce these problems, testing will not begin until you are comfortable with the laboratory, procedures and research personnel. There are no consequences for poor performance on any of the tests. You can take breaks at any time.

The eye-tracking device uses near-infrared light to create reflections off the eyes. This type of light can be commonly found in the environment. The infrared light is emitted from the eye tracker at very low amperage and causes no damage to the eye. This kind of infrared eye tracking has been used for many years at many universities and no negative consequences have been reported.

There is a risk of loss of confidentiality if your information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening. The confidentiality of your electronic data created by you or by the researchers will be maintained to the degree permitted by the technology used. Absolute confidentiality cannot be guaranteed.

Incidental findings: The investigators for this project are not trained to perform medical diagnosis, and the testing procedures are not optimized to diagnose disorders. However, on occasion, scores on the self-report measures by adolescents may indicate that they are at risk for suicide or other serious self-injury. If an adolescent displays suicidal behavior or ideation, a member of the research staff will inform the principle investigator and will ask a staff member in the clinical psychology department at Penn State to conduct a suicide risk assessment. Based on levels of risk, the clinical staff at Penn State may suggest various options for your family. In rare cases, this may involve suggesting the seeking of emergency services or providing information to help parents arrange for future follow-up monitoring and/or medical attention with your primary care providers. Costs for clinical follow-up are not covered in the cost of research.

Video Recording: Adolescents will be videotaped when you complete the ADOS. This video recording is required so that the researchers can review this video for scoring the observational assessment. During eye

tracking, a video may be recorded of your eye-movements, in order to determine where your eye movements fall on the screen, and will not be associated with your personal information. Any video collected during this research study is kept confidential and is not shared with other researchers.

5. What are the possible benefits from being in this research study?

5a. What are the possible benefits to you?

If you participate in the intervention, adolescents may experience improved social skills or face-processing abilities as a direct result of participating in the intervention training. In addition, you may experience a sense of satisfaction from contributing to research about autism.

5b. What are the possible benefits to others?

We hope that the information we obtain from the way participants perform on these tests and respond to the computer-based training will lead to better understanding about the nature of face-to-face social skills in people with autism. Findings from this study will be used to improve future computer-based interventions for people with autism.

6. What other options are available instead of being in this research study?

You may decide not to participate in this research at any time.

Because it is investigational, the therapy offered in this research is only available to you if you take part in the research study.

7. How long will you take part in this research study?

If you agree to take part, it will take about 2 months to complete this research study. During this time, we will ask adolescents and your parents to make 2 visits to the lab. Adolescents may also be invited complete an intervention at home lasting up to 20 hours (3 times per day for 2 months). For adolescents, the first visit will consist of background standardized tests (approximately 2.5 hours) and a testing session consisting of computer-based eye tracking tasks and paper-and-pencil surveys (approximately 2.5 hours). The post-test session involves computer-based eye tracking tasks and paper-and-pencil surveys (approximately 2 hours). During each lab visit, parents will complete questionnaires, lasting 60 minutes.

8. How will your privacy and confidentiality be protected if you decide to take part in this research study?

Your participation in this research is confidential. All possible steps have been taken to assure your privacy. You will be assigned a code number that will be used throughout the study. Only this code (and never your name) will be used when analyzing or reporting the data. Any identifying information will be kept in a locked location and password protected electronic files.

All personally identifiable records pertaining to your involvement in this research will be stored in a locked file cabinet and room in our office and your computerized data will be password protected. This information will only be accessible to the investigators listed on the cover page, and their research staff. All research records will be kept indefinitely with identifiers removed.

In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared. The results of the research may be published and presented at lectures and professional meetings, but neither you or your parents will be identified in any such publication or presentation. Your data and consent form will be kept separate. Your consent form will be stored in a locked location on Penn State property and will not be disclosed to third parties.

Some of these records could contain information that personally identifies you. Reasonable efforts will be made to keep the personal information in your research record private. However, absolute confidentiality cannot be guaranteed.

We will do our best to keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people may find out about your participation in this research study. For example, the following people/groups may check and copy records about this research.

- The Office for Human Research Protections in the U. S. Department of Health and Human Services
- The Institutional Review Board (a committee that reviews and approves research studies) and
- The Office for Research Protections.

To help us protect your privacy, we have obtained a Certificate of Confidentiality (CoS) from the study sponsor, the National Institutes of Health. We can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. We will use the Certificate to resist any demands for information that would identify you, except as in the following circumstances.

The Certificate cannot be used to resist a demand for information

- from personnel of the United States federal or state government agency sponsoring the project (NIH)
- that will be used for auditing or program evaluation of agency funded projects
- for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA)
- to prevent disclosure to state or local authorities such as child abuse and neglect, or harm to self or others

A CoS does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then we will not use the Certificate to withhold that information.

9. What are the costs of taking part in this research study?

9a. What will you have to pay for if you take part in this research study?

For costs of tests and procedures that are only being done for the research study:

- The Game Intervention will be provided by The Laboratory of Developmental Neuroscience and The NIH at no cost to you while you take part in this study.
- You and/or your insurance company will not be charged for the cost of any tests or procedures that are required as part of the research and are outside the standard of care (what is normally done) for your condition.
- The research-related tests and procedures that will be provided at no cost to you include: ADOS-2 Evaluation.

If you have any questions about costs and insurance, ask the research study doctor or a member of the research team.

10. Will you be paid or receive credit to take part in this research study?

If you decide to participate in this research, you will receive $20/hour for each of the two sessions in the lab (approximately $80 for the first session and $50 for the second session). If you participate in the training intervention, you will also receive $5 per 30 min session, up to $200 for the training. If applicable, parents will also be reimbursed for transportation fees (e.g. mileage, flight, hotel, parking). Meal expenses will not be reimbursed.

Total payments within one calendar year that exceed $600 will require the University to report these payments to the IRS annually. This may require you to claim the compensation that you receive for participation in this study as taxable income.

11. Who is paying for this research study? This study is funded by the National Institutes of Health.

12. What are your rights if you take part in this research study?

Taking part in this research study is voluntary.

- You do not have to be in this research.
- If you choose to be in this research, you have the right to stop at any time.
- If you decide not to be in this research or if you decide to stop at a later date, there will be no penalty or loss of benefits to which you are entitled.

Refusal to take part in or withdrawing from this study will involve no penalty or loss of benefits you would otherwise receive. If you decide to leave the research, contact the investigator so that the investigator can cancel future lab visits and/or intervention sessions and can ask you questions about why you chose to leave the study.

The Principal Investigator may at his/her discretion remove you from the study after you have been enrolled for any number of reasons including demonstration of an inability to complete the behavioral testing. In such an event, you will not suffer any penalty or loss of benefits or rights, which you or might otherwise be entitled.

During the course of the research you will be provided with any new information that may affect your health, welfare or your decision to continue participating in this research.

13. If you have questions or concerns about this research study, whom should you call?

Please call the head of the research study (principal investigator), Dr. Suzy Scherf at (814) 867-2921, if you:

- Have questions, complaints or concerns about the research.
- Believe you may have been harmed by being in the research study.

You may also contact the Office for Research Protections at (814) 865-1775, ORProtections@psu.edu if you:

- Have questions regarding your rights as a person in a research study.
- Have concerns or general questions about the research.
- You may also call this number if you cannot reach the research team or wish to offer input or to talk to someone else about any concerns related to the research.

INFORMED CONSENT TO TAKE PART IN RESEARCH

Signature of Person Obtaining Informed Consent

Your signature below means that you have explained the research to the subject or subject representative and have answered any questions he/she has about the research.

_____	_____	_____
Signature of person who explained this research	Date	Printed Name

(Only approved investigators for this research may explain the research and obtain informed consent.)

Signature of Person Giving Informed Consent (PARENT)

Before making the decision about being in this research you should have:

- Discussed this research study with an investigator,
- Read the information in this form, and
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

Signature of Subject - Parent

By signing this consent form, you indicate that *you voluntarily choose* to be in this research and agree to allow your information to be used and shared as described above.

_____	_____	_____
Signature of Subject	Date	Printed Name

Signature of Parent(s)/Guardian for Child

By signing this consent form, you indicate that you *permit your child* to be in this research and agree to allow his/her information to be used and shared as described above.

_____	_____	_____
Signature of Parent/Guardian	Date	Printed Name

Optional part(s) of the study
In addition to the main part of the research study, there is another part of the research. You can be in the main part of the research without agreeing to be in this optional part.

Data from this study may be submitted to the National Institute of Mental Health Data Archive (NDA). NDA is a data repository run by the National Institute of Mental Health (NIMH) that allows researchers studying mental illness to collect and share de-identified information with each other. A data repository is a large database where information from many studies is stored and managed. De-identified information means that all personal information about research participants such as name, address, and phone number is removed and replaced with a code number. With an easier way to share, researchers hope to learn new and important things about mental illnesses more quickly than before.

During and after the study, the researchers will send de-identified information about your health and behavior to NDA. Other researchers nationwide can then file an application with the NIMH to obtain access to your de-identified study data for research purposes. Experts at the NIMH who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

You may not benefit directly from allowing your information to be shared with NDA. The information provided to NDA may help researchers around the world treat future children and adults with mental illnesses so that they have better outcomes. NIMH will also report to Congress and on its web site about the different studies that researchers are conducting using NDA data. However, you will not be contacted directly about the data you contributed to NDA.

You may decide now or later that you do not want to share your information using NDA. If so, contact the researchers who conducted this study, and they will tell NDA, which can stop sharing the research information. However, NDA cannot take back information that was shared before you changed your mind. If you would like more information about NDA, this is available on-line at http://data-archive.nimh.gov.

PARENTS: Please let us know if you will allow us to share the data for you and your child with NDAR by checking one of the following choices:

_____ Provided that our identities stay private, my data and my child's data may be shared with NDAR.

_____ My data and my child's data MAY NOT be shared with NDAR.

Signature of Subject - Parent
By signing below, you indicate that you have read the information written above and have indicated your choices for the optional part(s) of the research study for your data.

_____	_____	_____
Signature of Subject -Parent	Date	Printed Name

Signature of Parent(s)/Guardian for Child
By signing this consent form, you indicate that you have read the information written above and have indicated your choices for the optional part(s) of the research study for your child's data.

_____	_____	_____

Signature of Parent/Guardian Date Printed Name

Signature of Person Obtaining Informed Consent

Your signature below means that you have explained the optional part(s) to the research to the subject or subject representative and have answered any questions he/she has about the research.

_____ _____ _____

Signature of person who explained this research Date Printed Name

Permission to Contact for Future Studies

I would like to be contacted about future opportunities to participate in research conducted by Dr. Scherf.

_____ _____ _____

Parent Participant Signature Printed Name Date

_____ _____

Email Phone number