

CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

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Project Title: CSAAT - Culturally Sensitive Autism Assessment Tool

INTRODUCTION

The investigator or the study staff to explain any words or information that you do not clearly understand.

Your child is being asked to participate in a research study. This research is being conducted to observe the behaviour of your child in order to develop an automated screening tool for Autistic children with similar conditions. When you are invited to participate in research, you have the right to be informed about the study procedures so that you can decide whether you want to consent to participation. This form may contain words that you do not know. Please ask the researcher to explain any words or information that you do not understand.

You have the right to know what you will be asked to do so that you can decide whether or not to be in the study. Your participation is voluntary. Your participation is not mandatory. You may refuse to be in the study, and it is your right. If you do not want to continue to be in the study, you may withdraw at any time without penalty or loss of benefits to which you are otherwise entitled.

This research is funded by Accelerating Higher Education Expansion and Development (AHEAD) which is a World Bank funded Sri Lankan government operation.

WHY IS THIS STUDY BEING DONE?

The purpose of this research is to observe the behaviour of children with the same condition as your child in order to help children who are not yet diagnosed in order to develop an automated screening tool for Autistic children. The child's behaviour will be monitored through gaze and emotion analysis, speech and language analysis and gait and motion analysis.

HOW MANY PEOPLE WILL BE IN THE STUDY?

The Doctor at LRH and a research assistant outside the consultation room will be at LRH for data collection during the child's sessions with the Doctor.

WHAT AM I BEING ASKED TO DO?

You will be asked to provide consent in order to collect a video recording of your child. The child will not be interfered at any stage where the Doctor is in session. This video recording will not interfere the Doctor's engagement with the child. Furthermore, recording will be confidential, and it will not be shared with anyone else and your child's identity will not be revealed at any cost.

HOW LONG WILL I BE IN THE STUDY?

This study will take the duration where the doctor/ speech therapist examines the child during your regular LRH visits. You can stop participating at any time without penalty. This will not affect the consultation time the doctor attends to your child.

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

Your participation will benefit the country since this is the first time a technology-based solution is proposed and developed in Sri Lanka for ASD. The child will be provided a learning toy to the child for early childhood development.

WHAT ARE THE RISKS OF BEING IN THE STUDY?

There are no risks involved to the child when participating to this research.

WHAT ARE THE COSTS OF BEING IN THE STUDY?

There is no cost to you.

WHAT OTHER OPTIONS ARE THERE?

Instead of being in this study, the mother may be able to record the child from her mobile phone and provide the video recording to the researchers via email to pradeepa.s@sliit.lk.

CONFIDENTIALITY

The data collected will be stored securely in a dedicated storage device at Sri Lanka Institute of Information Technology. Only the research team has the access to data. The researchers will ensure the confidentiality of the information collected where the child's identity will not be revealed at any instance and the data will be used only for research purposes and will be destroyed in a secure manner once the research is complete.

WILL I BE COMPENSATED FOR PARTICIPATING IN THE STUDY?

You will receive no payment for taking part in this study. However, your child will be provided with a learning toy which facilitates early childhood development.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Participation in this study is voluntary. Your participation is not mandatory. You will also be informed of any new information discovered during the course of this study that might influence your child's health, welfare, or willingness to be in this study.

WHO DO I CONTACT IF I HAVE QUESTIONS, CONCERNS, OR COMPLAINTS?

Please contact your Doctor or the research assistant if you have questions about the research. Additionally, you may ask questions, voice concerns or complaints to the research team.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have any questions regarding your rights as a participant in this research and/or concerns about the study, or if you feel under any pressure to enroll or to continue to participate in this study, you may contact the Dr Pradeepa Samarasinghe, Principle Investigator at Sri Lanka Institute of Information Technology at 0723537952 or pradeepa.s@slit.lk . A copy of this Informed Consent form will be given to you before you participate in the research.

SIGNATURES

I have read this consent form and my questions have been answered. My signature below means that I do want my child to be in the study. I know that I can withdraw my child from the study at any time without any problems.

Legal Guardian/Advocate/Witness (if required)*

Date

Additional Signature (if required) (identify relationship to subject)**

Date

**The presence and signature of an impartial witness is required during the entire informed consent discussion if the subject or subject's legally authorized representative is unable to read.*

***The "Additional Signature" line may be used for the second parent's signature, if required. This line may also be used for any other signature which is required as per federal, state, local, sponsor and/or any other entity requirements.*

Annexure

Data gathering form

1. Clinic no. -
2. Date of birth -
3. Sex -
4. Presenting complaint –
 - Poor eye contact
 - Speech delay
 - Regression of speech
 - Not responding to name when called
 - Repetitive behaviours
 - Gait abnormalities
 - Delay in motor skills
 - Hyperactivity
 - Other – please specify