Department of Otolaryngology & Division of Graduate Medical Studies
Information Sheet & Consent Form (Parent/Guardian)
(for participants under 18 years of age)

Your child/ward is invited to participate in the following research study which will be conducted by a graduate student under the supervision of the staff members of the M.Sc. (Speech and Language Pathology) Programme in the Yong Loo Lin School of Medicine (NUS).

Please read the information provided below carefully and ask any questions you have before deciding whether to give consent for your child/ward to take part in the research study.

PARENT/GUARDIAN'S INFORMATION SHEET (FOR CHILD PARTICIPANTS)

1. **Research study title: Perspective-Taking Intervention Using Thought Bubbles with PiSCES Pictures for Children with ASD**

2. **Principal Investigator and co-investigator.**

Principal Investigator: Associate Professor Susan Rickard Liow	Co-Investigator: Wong Ci Xin (Graduate Student) Co-Investigators/Supervisors: Dr Mary Lee Lay Choo Ms Elizabeth Teh
Department : **Department of Otolaryngology & Division of Graduate Medical Studies** Email : entsrl@nus.edu.sg Telephone : 6516 8026	Department: **Department of Otolaryngology & Division of Graduate Medical Studies** Email : e0145763@u.nus.edu Telephone : 9760 1590

3. **What is the purpose of this research?**
   This intervention study aims to investigate the effects of a perspective-taking programme on increasing perspective taking in school age children with Autism Spectrum Disorder (ASD).

4. **Who can participate in the research? What is the expected duration of my participation? What is the duration of this research?**
   All physically healthy children from age 5 to 13 with an ASD diagnosis who are currently studying in a mainstream primary school or preschool and are proficient in the English language.

   Parents/Guardians of minor participants must complete the Consent Form and Participant Information Questionnaire for your child/ward to participate in this study. We understand that your child/ward may currently be seeing a speech-language therapist for treatment. As such, you are encouraged to discuss about your child/ward's participation in this research with your child's/ward's therapists *(if any)* before making any decision to enrol your child/ward in this research.

Please note that that the researchers will inform you if your child/ward is unresponsive during the programme or would like to discontinue from this research. If so, the researchers will cease all interactions with your child/ward who is not willing to participate in the research/wish to withdraw from the research even if you have given consent and where applicable, your child/ward have given their consent or assent to participate (whichever the case may be).

The whole research study is estimated to run from April 2018 to December 2018. Participants will be involved for a total of up to 20 sessions, possibly starting from April 2018.

5. What is the approximate number of participants involved?

A maximum of 10 children will be involved in the intervention study.

6. What will be done if my child/ward takes part in this research?

You will be asked to fill in a questionnaire about background information of your child/ward. This questionnaire takes about 10 minutes to complete.

During the pre-intervention session, your child/ward will be assessed using Raven's Progressive Matrices as an estimate of their Non-Verbal Intelligent Quotient (NVIQ) and Comprehensive Assessment of Spoken Language (CASL) as a gauge of their language abilities. They will also be assessed on the Autism Diagnostic Observation Schedule (ADOS) to confirm their ASD diagnosis. They will also be asked to describe some pictures in order to establish a baseline measure.

Consent will be obtained to contact your child/ward's current speech therapist, if any. As part of ethical and professional conduct, the speech therapist seeing the child/ward will be informed about the child/ward's participation in this study and any necessary details concerning the study (please refer to attached "Notification Letter to Therapists"), any other kind of information will not be exchanged.

Your child/ward will participate in up to 20 sessions of intervention study located at the home of the child, NUS or the school care centres. A caregiver will be required to be present with the child for all of the sessions conducted outside of the child's home. However, you may be invited to attend the first few sessions if your child/ward seemed anxious about the unfamiliar situation. This includes sessions to establish baselines and collect results. Each session will take up to a maximum of 2.5 hours, depending on the response of your child/ward.

English would be used as the main language of communication therefore, only minor subjects who are proficient in the English language would be considered for this research.

The detail of the sessions are as follows: -

Type of Phase	**Duration**	**Number of sessions**	**What will be done**
Pre-Intervention Phase	2.5 hours	2	Your child/ward will be assessed using Raven's Progressive Matrices as an estimate of their Non-Verbal Intelligent Quotient (NVIQ) and Comprehensive Assessment of Spoken

			Language (CASL) as a gauge of their language abilities. These assessments will be conducted by Ms Wong Ci Xin, a graduate speech and language pathology student. They will also be assessed on the Autism Diagnostic Observation Schedule (ADOS) to confirm ASD diagnosis. The ADOS will be conducted by Co-PIs, Dr Mary Lee Lay Choo and/or Ms Elizabeth Teh, a psychologist and a speech therapist trained to conduct the ADOS. The results of these assessments will be used as descriptive data. A picture will be introduced to your child/ward and he/she will be asked: "What do you think is happening in this picture?, "What do you think each person is thinking?" and "why do you think he/she is thinking that?" Your child/ward will be given some time to respond. Responses will be voice recorded and transcribed to obtain a baseline measure of the dependent variables.
Intervention Phase I	1-1.5 hour	Up to 8	A picture will first be introduced by asking the child: "What do you think is happening in the picture?" The researcher and child will then discuss the picture's social context, the people and their actions and feelings. Following which, thought bubbles would be drawn by the researcher and the child would be asked: "What do you think (Person A) is thinking?". The child's answer would be written down in the thought bubble regardless of accuracy. This process would be repeated for all the people in the picture. The child would be asked "Why do you think he/she is thinking this?" The researcher will provide the child with positive feedback on appropriate responses and guide the child to correct any inappropriate responses. Finally, the researcher repeats the question to check the child's learning.
Post-Intervention Phase I	2 hour	1	Your child/ward will be introduced the same set of pictures as used in the Pre-Intervention Phase/baseline measure and will be asked the same questions. Your child/ward's responses will be voice recorded and transcribed.
Intervention Phase II	1-1.5 hour	Up to 8	The Intervention Phase as described above will be repeated. However, Phase II is entirely

(OPTIONAL)			optional and is subjected to agreement of both parents and child participants.
Post Intervention Phase II **(OPTIONAL)**	2 hour	1	This phase will only be conducted upon completion of both Intervention Phase I & Phase II. Your child/ward will be introduced a different set of pictures and will be asked the same questions. Your child's/ward's responses will be voice recorded and transcribed.

As stated above, during the 4 baseline and post-intervention sessions, your child/ward's verbal responses will be recorded on a digital voice recorder (please refer to the Consent Form). **Please note that your child/ward will be excluded from this study if you do not agree to the audio recording.**

Also stated above, Intervention Phase II and Post Intervention Phase II are entirely optional and dependent upon both the consent of parents/guardians and the verbal assent/consent from the minor participant.

The first phase of the study targeting lower social engagement pictures is hypothesized to be sufficient in bringing about changes in perspective-taking in majority of children with ASD due to the relatively easier parameters. The researchers will nonetheless prepare all the necessary materials and would be carrying out Phase II of the study should both the parents and child participants decide that they would like to continue with the study. Please indicate whether you consent to your child/ward's participation in Intervention Phase II and Post Intervention Phase II of the study in the Consent Form.

If you would like to view some examples of the pictures your child/ward will see before you sign the consent form, I would be glad to show them to you.

A report summarising the implications of this study and further recommendations your child/ward would be given to you at the end of the study. The recommendations would be made in consultation with Ms Elizabeth Teh who is a qualified speech and language specialist registered with the Allied Health Profession Council, Singapore.

7. How will my child/ward's privacy and the confidentiality of my child/ward's research records be protected?

Data will be kept strictly confidential and no personal data will be used in publication/presentation. To protect your confidentiality, your child/ward's data will be coded by a participant number at the earliest possible stage. All identifiable information (e.g. names, contact details, nationality, parent's/guardian's education levels and child's/ward's date of birth) will not be destroyed but kept separately from the data to ensure privacy. Only the Principal Investigator and co-investigators have access to identifiable information, which will not be released to any unauthorized person.

If your child/ward is unable to attend one or more sessions, he/she will be excluded from this study and his/her data will be destroyed and discarded immediately. Similarly, should you or your child/ward choose to withdraw from this study, the data you have provided

and that of your child/ward will be destroyed and discarded immediately upon withdrawal from the study.

Upon completion of the research study, all data will be transferred for secure storage to the Department of Otolaryngology & Division of Graduate Medical Studies, Yong Loo Lin School of Medicine, National University of Singapore (NUS). Data not used for any publication/presentation and re-contacting purposes will be discarded upon completion of study. "Re-contacting purpose" refers to re-contacting you and/or your child/ward for follow-up studies from this project in the future provided you and/or your child/ward consent to the same. Research data used in publication will be kept for a minimum of 10 years before being discarded.

8. **What are the possible discomforts and risks for participants?**

No risks are anticipated. The sessions are conducted at a maximum of 2.5 hour each session to prevent fatigue. Rest/play breaks will be given when necessary.

Although no risks are anticipated, if your child/ward follows the directions of the PI/Co-PIs in charge of this research and he/she is physically injured, the NUS will pay the medical expenses for the treatment of that injury. By signing this consent form, you will not waive your child's/ward's legal rights or release the parties involved in this study from liability for negligence.

9. Will there be reimbursement for participation?

As participation in this research study is on a voluntary basis, no reimbursement (including any reimbursement of travelling costs) will be made.

10. What are the possible benefits to my child/ward and to others?

Benefits to your child/ward include increased awareness of social situations, as well as exposure to language, social interaction and teaching on perspective-taking.

The knowledge gained from this research study will go towards helping to develop a standardized and structured tool for local clinicians to help children with ASD address social goals through perspective-taking intervention.

11. Are there any alternative procedures or treatments available? If so, what are the potential benefits and risks of such alternatives?

While there are no alternatives for the procedures used in this research, you and/or your child/ward are free to explore other alternative procedures and treatments available and/or continue to work with your child's/ward's existing therapist *(if any)* as this research study will not bear any effects on the alternative treatments.

12. Can my child/ward refuse to participate in this research?

Participation is voluntary. **Please note that your child/ward will be excluded from this research if he/she does not agree to participate, regardless of your decisions**. You can withdraw your child/ward from the study at any time without giving any reasons by informing the Principal Investigator. The data you have provided and that of your child/ward will be discarded upon withdrawal from the study.

13. Whom should I call if I have any questions or problems?

Please contact the Co-Investigator (Wong Ci Xin: 9760 1590) for all research-related matters and in the event of research-related problems.

For an independent opinion regarding the research study and the rights of research participants, you may contact a staff member of the National University of Singapore Institutional Review Board (Attn: Dr Chan Tuck Wai, at telephone 6516 1234 or email at irb@nus.edu.sg).

PARENT/ GUARDIAN CONSENT FORM
(FOR PARTICIPANTS UNDER 18 YEARS OF AGE)

Research study title: Perspective-Taking Intervention Using Thought Bubbles with PiSCES Pictures for Children with ASD

Principal Investigator: A/Prof Susan Rickard Liow, Director, MSc (Speech & Language Pathology), Department of Otolaryngology & Division of Graduate Medical Studies

Contact details : 65168026

I hereby acknowledge that:

1. I have read the Parent/Guardian's Information Sheet, which explains the collection and use of data in the above mentioned research study.

2. I understand what the research study involves. I agree to let my *child/ward** _____ (name) participate in this research study.

3. I *agree/do not agree** to let my *child/ward** participate in Intervention Phase II and Post-Intervention Phase II of the study which are optional phases.

4. I know that my *child/ward** and/or myself can withdraw from the research at any time, without giving any reasons, by informing the Principal Investigator and all the data will be discarded.

5. Neither I nor my *child/ward** will have the right to any commercial benefits that may result from this research study.

6. I *agree/do not agree** to the audio recording of my *child's/ward's** verbal responses for the use of this research study.

7. I am willing to be contacted for follow-up studies from this project in future. Yes / No

8. I understand that I will be informed if my child/ward is unresponsive during the programme or would like to discontinue from this research.

9. I *allow/do not allow** the researcher to contact my *child/ward** directly for follow-up studies from this project in future via the following method: _____ (*please leave blank if not applicable*).

10. I consent to the researcher contacting my *child's/ward's* current speech-language therapist to provide them with information about this study. Yes / No

11. I understand that the assessments/tests proposed in this research may be conducted in the home and/or the after-school care centre of my *child/ward**, and/or the National University of Singapore.

12. I understand I will be receiving a report summarising the implications of this study and further recommendations for my child/ward at the end of the study.

* This research study has been explained to me in _____ (state language), which I understand, by _____ (name of translator) on _____ (date).

_____	_____
Name and Signature (Parent/ Guardian)	Date
_____	_____
Name and Signature (Consent Taker)	Date
_____	_____
Name and Signature (Witness)	Date
_____	_____
* Name and Signature (Translator)	Date