

Information statement and consent form

HREC Project Number: 34046G

Research Project Title: Standardization of PEERS (Pediatric Evaluation of Emotions, Relationships and Socialization)

Principal Researcher: Professor Vicki Anderson
Theme Director, Clinical Sciences Research, MCRI

Version Number: 8.0 **Version Date:** 29/07/2016

Dear Parents/guardians,

Thank you for taking the time to read this **Parent/Guardian Information Statement and Consent Form**. We would like to invite your child to participate in a research project that is explained below. This document is 6 pages long. Please make sure you have all the pages.

What is an Information Statement?

These pages tell you about the research project. It explains to you clearly and openly all the steps and procedures of the project. The information is to help you decide whether or not you would like your child to take part in the research. Please read this information statement carefully.

Before you decide if you want your child to take part or not, you can ask us any questions you have about the project. You may want to talk about the project with your family, friends or a health care worker.

If you would like your child to take part in the research project, please sign the consent form at the end of this information statement. By signing the consent form you are telling us that you:

- understand what you have read
- had a chance to ask questions and received satisfactory answers
- consent to your child taking part in the project.

We will give you a copy of this information statement and consent form to keep.



1. What is the research project about?

Humans are social by nature and a large part of daily life involves social contact – talking, meeting, phone calls, texting, Skype, Facebook, play, sports, etc. Appropriate social skills are important for developing satisfying and lasting relationships, which in turn are essential to well-being throughout life. Failure to develop social skills can have significant consequences for developing these important relationships with others.

Failure to develop social skills is a key symptom of certain childhood disorders, such as attention deficit/hyperactivity disorder (ADHD), autism spectrum disorder, conduct disorders, a brain injury and other chronic illnesses. Currently, doctors and psychologists do not have a reliable way to assess social skills in children, making diagnosing these disorders and developing treatment plans difficult.

The *Pediatric Evaluation of Emotions, Relationships and Socialization* (PEERS) is a way to assess, describe and diagnose social impairment in children and young people. In this research study we want to find out if the PEERS iPad application is a useful way to identify children who need help in developing social skills. We plan to assess social skills in two groups of children. In the first group, we hope 1500 children aged 4-18 years old who attend mainstream public or private Victorian schools will take part. In the second group, we hope 125 children who have a known diagnosis where social impairment is a core symptom (autistic spectrum disorder, ADHD, conduct disorders, acquired brain injury and chronic illnesses) will also take part.

2. Who is funding this research project?

This research project is funded by the NHMRC Development Scheme.

3. Why are we being asked to be in this research project?

We are asking you and your child because your child attends a Victorian public or private mainstream school.

4. What do we need to do to be in this research project?

Participating in this study involves your child completing one assessment (the PEERS iPad application and some questionnaires). A member of the research team will visit your child at school during regular hours to conduct the assessment. The study also involves you and your child’s teacher completing some questionnaires about your child. The questionnaires can be completed online or can be posted to you.

	Child	Parent	Teacher
PEERS iPad app.	✓		
IQ assessment	✓		
PEERS-Q (questionnaire)	✓	✓	✓
Questionnaires		✓	✓
Estimated time	60-75 minutes	30 minutes	30 minutes

PEERS iPad app

A member of the research team will administer PEERS, a computerised iPad application, with your child. PEERS assesses your child in a number of social skills areas such as attention, decision-making and communication in social settings. PEERS is an entertaining, interactive app and feedback indicates children enjoy completing the assessment. PEERS takes approximately 45 minutes to complete.

PEERS-Q Questionnaire

For children aged 12 years and older, we will ask them to complete the PEERS questionnaire (PEERS-Q), which asks questions about their own social skills, for example “I have the opportunity to engage in a hobby or interest” or “I have a very close relationship with my friends”. This questionnaire usually takes less than 15 minutes to complete. This questionnaire is on an iPad and will be completed once. A member of the research team will provide your child with the questionnaire during the school visit and be available to help your child work through the questions if required.

IQ assessment

A member of the research team will conduct a brief intelligence assessment with your child. It involves pencil and paper tasks (such as copying shapes and remembering numbers). Most children enjoy doing them. This test will take about 15 minutes to complete.

Parent/guardian questionnaires

We will ask you to complete some questionnaires about your child’s social skills and behaviour. These questionnaires usually take 30 minutes or less to complete and can be completed online or in paper and pencil format. For example: “Does your child frequently lose important information (e.g., notes to and from school)?” or “is your child helpful if someone is hurt, upset or feeling ill?”.

Teacher questionnaires

We will ask your child’s main teacher (the teacher who spends the most classroom time with your child) to complete a questionnaire about your child’s social skills and behaviour at school. This questionnaire usually takes less than 30 minutes to complete and can be completed online or in paper and pencil format. Your child’s teacher will be invited by the research team after you and your child have consented to participate in the study, and teacher consent is required. All information provided by the teacher is strictly confidential and will not be shared with you or your child.

5. What are our alternatives to taking part in this project?

Participation in a research project is voluntary. It is your choice to let your child take part in this research. You do not have to agree if you do not want to.

If you give your consent and change your mind, you and your child can withdraw from the project. You do not need to tell us the reason why you or your child want to stop being in the project. If you leave the project, any information that we have already collected will be kept unless you or your child ask that it be destroyed.

Your decision will not affect any treatment or care your child gets, or your family’s relationship with The Royal Children’s Hospital.

6. What are the possible benefits for my child and other people in the future?

There may be no direct benefits to you or your child as a result of participating in this study. The tasks completed by your child may show your child has academic concerns that are significant enough for referral to healthcare professionals, for example difficulties with vocabulary. If you give your consent, we will provide feedback about your child’s results from the assessment. If we identify anything significant we will contact you to discuss it and organise appropriate referrals for further assessment.

7. What are the possible risks, side-effects, discomforts and/or inconveniences?

We have been careful to make sure the questionnaires do not cause any distress. However, if you or your child feels anxious about any of the questions you do not need to answer them. If you or your child feels upset by any of the questions, we can arrange for you to speak to someone who is not part of the research team.

If we identify issues with your child, you should consider it may be upsetting for you and your child. The potential financial and emotional burden of identifying clinically significant social skill issues should be taken into consideration. For example, if a behavioural issue is identified, you may be required to seek and pay for further medical/psychological intervention beyond services provided in the public system.

The main inconvenience is the time to complete the project questionnaires.

8. What will be done to make sure my child's information is confidential?

Any information we collect for this research project that can identify you and your child will be treated as confidential and used only in this project unless otherwise specified. We can disclose the information only with your permission, except as required by law.

All information will be stored securely in Murdoch Childrens Research Institute at The Royal Children's Hospital.

The following people may access information collected as part of this research project:

- The research team involved with this project
- The Royal Children's Hospital Human Research Ethics Committee

The information will be re-identifiable. This means that we will remove your names and give the information a special code number. Only the research team can match your names to the code number, if it is necessary to do so.

We are required to keep information collected as part of a research project for a certain length of time. Because the participants in this project are under 18 years old, we must keep information until all participants turns 25 years old. The research information may be destroyed or kept indefinitely in secure storage after this time.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access and correct the information we collect and store about your child. Please contact us if you would like to access this information. When we write or talk about the results of this project, information will be provided in such a way that your child cannot be identified.

9. Will we be informed of the results when the research project is finished?

At the end of the project we will send you a summary of the results for the whole group of participants. We expect that the project will be completed within one year.

If you would like more information about the project or if you need to speak to a member of the research team in an emergency please contact:

Name: Professor Vicki Anderson **Contact telephone:** 03 9345 5524

If you have any concerns and/or complaints about the project, the way it is being conducted or your child's rights as a research participant, and would like to speak to someone independent of the project, please contact: Director, Research Ethics & Governance, The Royal Children's Hospital Melbourne on telephone: (03) 9345 5044.

Office Use Only:

CONSENT FORM
Your copy to keep

HREC Project Number: 34046G

Research Project Title: Standardization of PEERS (Pediatric Evaluation of Emotions, Relationships and Socialization)

Version Number: 8.0 **Version Date:** 29/07/2016

- I have read, or had read to me in my first language, the information statement version listed above and I understand its contents.
- I believe I understand the purpose, extent and possible risks of my child's involvement in this project.
- I voluntarily consent to take part in this research project.
- I voluntarily consent for my child to take part in this research project.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I understand that this project has been approved by The Royal Children's Hospital Melbourne Human Research Ethics Committee and will be carried out in line with the National Statement on Ethical Conduct in Human Research (2007).
- I understand I will receive a copy of this Information Statement and Consent Form.

OPTIONAL CONSENT

<input type="checkbox"/> I do	<input type="checkbox"/> I do not	Consent to being contacted about future projects that are related to this project
-------------------------------	-----------------------------------	---

<input type="checkbox"/> I do	<input type="checkbox"/> I do not	Consent to being contacted about my child's results from the assessment
-------------------------------	-----------------------------------	---

Child's Name

Parent/Guardian Name

Parent/Guardian Signature

Date

Declaration by researcher: I have explained the project to the parent/guardian who has signed above, and believe that they understand the purpose, extent and possible risks of their child's involvement in this project.

Research Team Member Name

Research Team Member Signature

Date

Note: All parties signing the Consent Form must date their own signature.

Office Use Only:

CONSENT FORM

Research Team Copy – Please return

HREC Project Number: 34046G

Research Project Title: Standardization of PEERS (Pediatric Evaluation of Emotions, Relationships and Socialization)

Version Number: 8.0 **Version Date:** 29/07/2016

- I have read, or had read to me in my first language, the information statement version listed above and I understand its contents.
- I believe I understand the purpose, extent and possible risks of my child’s involvement in this project.
- I voluntarily consent to take part in this research project.
- I voluntarily consent for my child to take part in this research project.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I understand that this project has been approved by The Royal Children’s Hospital Melbourne Human Research Ethics Committee and will be carried out in line with the National Statement on Ethical Conduct in Human Research (2007).
- I understand I will receive a copy of this Information Statement and Consent Form.

OPTIONAL CONSENT

<input type="checkbox"/> I do	<input type="checkbox"/> I do not	Consent to being contacted about future projects that are related to this project
-------------------------------	-----------------------------------	---

<input type="checkbox"/> I do	<input type="checkbox"/> I do not	Consent to being contacted about my child’s results from the assessment
-------------------------------	-----------------------------------	---

Child’s Name

Parent/Guardian Name

Parent/Guardian Signature

Date

Declaration by researcher: I have explained the project to the parent/guardian who has signed above, and believe that they understand the purpose, extent and possible risks of their child’s involvement in this project.

Research Team Member Name

Research Team Member Signature

Date

Note: All parties signing the Consent Form must date their own signature.