Parent/Guardian Information Sheet

Introduction

You are invited to participate in this research project, which is called the ‘Australian ASD and ADHD Study’. We are seeking parents or caregivers of children under 18 who have been diagnosed with or treated for Autism Spectrum Disorder (ASD) and/or Attention Deficit Hyperactivity Disorder (ADHD).

This Information Sheet/Consent Form tells you about the research project. It explains what is involved in the study to help you decide if you want to take part.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your doctor.

If you decide you want to take part in the research project, you will be asked to provide your consent online. You will be able to save an electronic copy of this Information Sheet and Consent Form to keep.

If you do not wish to take part in this study, you do not have to. The project investigators do not have your name or contact details unless you provide them, so if you do not wish to take part you do not have to do anything further.

2. Why are we studying ASD and ADHD in the same research project?

In 2013 the criteria used to diagnose ASD and ADHD were updated. Autism spectrum disorder replaced the diagnoses of autistic disorder, Asperger’s disorder and pervasive developmental disorder and changes were made to the age criteria for ADHD. The new criteria also make it possible for a person to be diagnosed...
with both ASD and ADHD.

We’re interested in the way these changes might have influenced the support, impacts and treatment experiences of individuals who are living with ASD and/or ADHD and their families. We’re also interested in finding out if the updates to the diagnostic criteria might help us find new genetic factors that influence these traits. To look at this we plan to compare the data provided by individuals diagnosed before and after these changes were made.

3. What is the purpose of this study?

The purpose of the study is to try and improve our understanding of the financial, emotional and educational impacts on individuals and their families who are living with ASD and ADHD and the genetic factors that influence these traits.

The aim of the study is to collect information to help improve treatment as well as access to and delivery of health and education services for Australian families.

To do this we are interested in finding out what your experiences are with accessing health care and education. What has worked for you and what hasn’t?

An aim of this research project is to identify environmental and genetic factors that may influence the response to treatment. We hope that this research will help us learn more about ASD and ADHD and the factors influencing why some treatments are successful for some people and not for others.

For this study we hope to recruit at least 5,000 individuals who have been diagnosed with or treated for ASD and/or ADHD. This research has been funded by the National Health and Medical Research Council (NHMRC). There is no drug company funding involved in this study.

Your participation is voluntary

Your participation in this study is completely voluntary and there will be no cost to you. If you do not want to take part in this study you do not have to. You should feel under no obligation to participate in this study. Choosing not to take part in this study will not affect your current and future medical care in any way.

4. What does participation in this research involve?

There are 3 parts to this study:

(i) Before providing any of your personal information, you will be asked to complete an online consent form. We ask that you discuss your decision to participate in this study with your child.
After giving your consent, you will be asked to complete a 30 minute online questionnaire. There are no questions for your child to answer in the questionnaire.

(ii) Depending on your responses to the online questionnaire, your child may be asked to donate a saliva sample.

To collect the saliva sample, we will send you a specialised collection container. The collection kit is easy to use and the sample can be collected in your own home.
You will be asked to return this sample via Australia Post to our laboratory, at no cost to you.
Some details of your child’s medical history that would be helpful to the project investigators (like how many prescriptions they may have had for various medications) would be hard for many people to remember.

So we will ask for your permission to access your child’s Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) claims information from the last five (5) years.

Medicare collects information on medical visits and procedures, and the associated costs, while the PBS collects information on the prescriptions that have been filled at pharmacies. Once you complete the online questionnaire we will post you a consent form authorising the study access to your child’s Medicare and PBS data as outlined in this information sheet. If your child is aged 14 and over they will provide their own consent. Once you return this consent form to us, it will be sent securely to Services Australia which holds Medicare and PBS information confidentially.

Consent to access your child’s Medicare and/or PBS claims information is completely separate from consent for the rest of the study (online questionnaire and biological sample). You can participate in the other parts of this study without consenting to the Medicare and PBS component.

We appreciate the time and effort you and your child will give in this study. In return we will provide your family with an e-gift card to the value of $25 at the end of participation in the study. You will still be reimbursed for your time in participating if you do not provide consent to access your Medicare and PBS information. Please note that we can only reimburse participants up to 31st January 2024; we are unable to reimburse those who participate after this date.

5. Do I have to take part in this research project?

Participation in this research project is voluntary. If you or your child do not wish to take part, you do not have to. The project investigators do not have your name or contact details unless you provide them, so if you do not wish to take part you do not have to do anything. If you or your child decide to take part and later change your mind, you are free to withdraw from the project at any stage.

You are under no obligation for your child to continue with the research study. People withdraw from studies for various reasons and you do not need to provide a reason. You can withdraw your child from the study at any time by contacting the research team and requesting a withdrawal of consent form for you to complete and sign.

If you withdraw your child from the study, you will be able to choose whether the study will destroy or retain the information it has collected about your child. You should only choose one of these options. Where both boxes are ticked in error or neither box is ticked, the study will destroy all information it has collected about your child. If you withdraw from the study, any information that has already been analysed and/or included in a publication may not be able to be withdrawn or destroyed. In such circumstances, all personal information will continue to form part of the project/research study records and results. Your privacy will continue to be protected at all times.

6. What are the possible benefits of taking part?

This study is unlikely to be of any immediate and specific benefit to you or your child. Extensive research is required to find answers to the questions we are studying. However, future medical or scientific discoveries may come from the research in which you participate. These may help improve the available treatments and outcomes for people living with ASD and/or ADHD.
7. What are the possible risks and disadvantages of taking part?

Risks are minimal for involvement in this study. You may feel that some of the questions we ask in the questionnaire are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately. If you find that you are becoming uncomfortable or distressed and wish to speak to someone about this, you can also contact:

- the researchers (The researchers can be contacted using our free call number 1800-257-179, email aaaStudy@qimrberghofer.edu.au)
- Parentline (who provide free confidential psychological and parenting support, ACT: (02) 6287 3833, NSW: 1300 1300 52, QLD & NT: 1300 30 1300, SA: 1300 364 100, TAS: 1300 808 178, VIC: 13 22 89, WA: 1800 654 432)
- Lifeline (who provide free confidential psychological support, 13 11 14), or
- Beyond Blue (who provide free confidential psychological support, 1300 22 4636).

8. What will happen to information about you and your child?

All personal, questionnaire and genetic information collected for the study remains confidential in accordance with the National Health and Medical Research Council (NHMRC) ethical guidelines and the Privacy Act. Personal details, questionnaire data and genetic data will all be stored separately. The only link between personal details and other data is a participant identification number. Linking personal details and other data using this number is restricted to selected members of the QIMR Berghofer research team. All information provided by you will be stored securely, with access restricted to members of the research team.

Any Medicare and PBS data you consent to provide (including the consent form itself) will be used for the purposes of this study only. It cannot be shared with anyone outside the research team for this project without specific Commonwealth Government approval. The original records supplied to the research team, and any copies, will be deleted from our computer systems 5 years from the publication of the final project report, or after 10 years from the date of supply (whichever is sooner). However, any research findings associated with your child’s Medicare or PBS data will not be able to be destroyed or recalled.

The researchers will store personal, questionnaire and genetic information indefinitely (but not Medicare or PBS data) at QIMR Berghofer Medical Research Institute. This information may continue to be valuable to researchers many years into the future, and may be considered for use in future, related projects. Before any future work proceeds it will be subject to approval by the relevant ethics committees. Your child’s genetic information and some of the questionnaire information (but no names, other personal details, Medicare or PBS data) may eventually be contributed to an international genetics data repository. Information in the database would only be available to researchers who are approved to study how genes influence health conditions. These scientists will never know your or your child’s names or any other personal information.

Results of this research project may be presented in scientific papers in medical literature, or in public talks, but you and your child’s identity will not be revealed. The data collected as part of this study will be combined at analysis with the data from many other people, and as such there will be no way of identifying individual participants.

In accordance with relevant Australian privacy and other relevant laws, you and your child have the right to request access to the information that is collected about you and stored by the research team. You or your child also have the right to request that any information with which you disagree be corrected. Please inform the research team member named at the end of this document if you or your child would like access to the information you provided.
By confirming your consent online you consent to the research team collecting and using personal, questionnaire and genetic information about you and your child as described for the research project.

9. What will happen to my child’s biological sample?

We will use your child’s biological sample to extract DNA. The research team will then look for differences and similarities between participants’ DNA samples. This information can help us understand, for example, why some people respond to a treatment while others do not.

Your child’s biological sample and samples of DNA will be stored securely at QIMR Berghofer Medical Research Institute along with samples from many other people. They will be re-identifiable, which means that they will be stored with a barcode label, and can be identified as your child’s even though their personal details will be stored separately. Linking your child’s personal details with their biological sample or DNA using the barcode is restricted to specific members of the QIMR Berghofer research team.

We may wish to send part of your child’s saliva sample or DNA to another laboratory (which may be overseas) for processing or analysis. If this occurs, that sample would only be labelled with a number, and would be transported along with samples from many other people. No information about you or your child will be sent to or accessible by the other laboratory. Any sample remaining after processing or analysis by another laboratory would be destroyed.

We would like to store your child’s biological and/or DNA samples for use in any future research studies that may or may not be related to the original research project. There is no direct benefit to you or your child from the storage of your child’s biological and/or DNA samples. In the future, other doctors and scientists at this and other medical and research centres may use your child’s samples to learn about many different diseases and conditions. Their goal is to improve health outcomes and develop new treatments. The purpose of storing these types of samples is to answer questions in the future, so we expect to keep your child’s samples indefinitely.

10. Will I or my child be given the results of the research project?

No. Your information will be used for research purposes and you and your child will not be given any clinical results from this study.

This research is not intended for the purpose of treating any health problems your child may have. Participation in this research study does not take the place of visits to a doctor or other health professionals.

Please note that genotype results are for research purposes only. They are not intended and validated for clinical purposes and will not be returned to participants.

11. Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of the QIMR Berghofer Medical Research Institute (QIMRB-HREC).

This project will be carried out according to the “National Statement on Ethical Conduct in Human Research (2007)”. This statement has been developed to protect the interests of people who agree to participate in human research studies.
12. What if we don’t want to participate or what if we change our minds later and want to withdraw from the study?

Participation is voluntary and you or your child can choose not to participate. If you do choose to participate you or your child can withdraw from the study at any time, at any stage, or for any reason for some, part, or all of the research. You or your child can withdraw your consent by contacting the Project Coordinator by phone 1800 257 179 (freecall) or email aaaStudy@qimrberghofer.edu.au. These contact details will be listed on your correspondence with the project team.

13. Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you or your child want any further information concerning this project, you can contact the project coordinator:

<table>
<thead>
<tr>
<th>Name</th>
<th>Richard Parker</th>
</tr>
</thead>
<tbody>
<tr>
<td>Position</td>
<td>Project Coordinator</td>
</tr>
<tr>
<td>Telephone</td>
<td>07 3362 0297 or Freecall 1800 257 179</td>
</tr>
<tr>
<td>Email</td>
<td><a href="mailto:richard.parker@qimrberghofer.edu.au">richard.parker@qimrberghofer.edu.au</a></td>
</tr>
</tbody>
</table>

If you or your child have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

<table>
<thead>
<tr>
<th>Reviewing HREC name</th>
<th>QIMR Berghofer Medical Research Institute Ethics Committee</th>
</tr>
</thead>
<tbody>
<tr>
<td>HREC Executive Officer</td>
<td>Secretary to the Chairperson of the Ethics Committee</td>
</tr>
<tr>
<td>Telephone</td>
<td>07 3362 0117</td>
</tr>
<tr>
<td>Email</td>
<td><a href="mailto:HREC.Secretariat@qimrberghofer.edu.au">HREC.Secretariat@qimrberghofer.edu.au</a></td>
</tr>
</tbody>
</table>

If you have a privacy complaint in relation to the use of your MBS/PBS data you should contact the Office of the Australian Information Commissioner. You will be able to lodge a complaint with them.

Website: www.oaic.gov.au
Telephone: **1300 363 992**
Email: enquiries@oaic.gov.au
Mail: GPO Box 5218, Sydney NSW 2001

If you or your child do not want to participate, thank you for your time. You are not required to respond in any way. You may close the browser window to exit.

☐ I have read this information sheet and have understood it.

**Save and Continue**
Consent Form – Participant Providing Saliva Sample

If you'd like your child to participate in this study, we need you to tell us below that you've understood what is involved in participating and that you are giving us permission to collect and store the information that you provided us about yourself and your child.

**Declaration by Participant**

Clicking on the "Yes - I choose to participate" button below indicates that:

- I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

- I understand the purposes, procedures and risks of the research described in the project.

- I have had an opportunity to ask questions and I am satisfied with the answers I have received.

- I understand my involvement is strictly confidential and no information about me or my child will be used in any way that reveals my child’s or my own identity.

- I understand the information I provide will be stored in a data file using an ID code number and that my name and contact details will not be stored in this file.

- I understand reports and publications from the study will be based on de-identified information and will not identify any individual person taking part.

- I understand my decision on whether or not to take part in the Australian ASD and ADHD study will not disadvantage me or my child, or affect my future health care in any way.

- I understand there will be no cost, nor any financial benefit to me or my child for participating in the study.

- I understand I may be approached again to participate in future studies but I am under no obligation to do so.

- I understand that I will be able to save an electronic copy of this document to keep.

- I consent to my data and my child’s health data collected in this study being used in a de-identified format for future research and made available to other scientists for approved research studies.

- I understand that analyses of data collected during this study may include analysis of subgroups of participants based on characteristics such as Gender, Age, Ethnicity, Urban vs Rural locations but that these subgroups analyses will not identify any individual person taking part.

- I understand all information gathered during this research project will be treated in a strictly confidential manner in accordance with the National Health and Medical Research Council (NHMRC) Guidelines and the Commonwealth Privacy Act.

- I have discussed my participation in the Australian ASD and ADHD study with my child.
If you or your child do not want to participate, thank you for your time. You are not required to respond in any way. You may close the browser window to exit.

This research is being conducted under the supervision of Professor Sarah Medland at the Psychiatric Genetics Unit, QIMR Berghofer Medical Research Institute, and has been approved by the QIMR Berghofer Human Research Ethics Committee (QIMRB-HREC approval P3476).

☐ Agree and continue to survey [Date and time automatically recorded]

Save and Continue
Participant Details

We will store these details and use them if we need to contact you in future about the project.

* indicates a mandatory field

Please enter your details:

Title <text box>
First name * <text box>
Middle name <text box>
Last name * <text box>
Date of birth * <dropdown boxes for Day, Month and Year. Redirect to Terminal Page 2 if less than 18 years of age>
Sex * <dropdown box Male/Female>
Email * <text box>
Confirm Email * <textbox>
Mobile number * <textbox>
Phone number <text box>

Please enter your child’s details:

First name child’s details * <text box>
Middle name <text box>
Last name * <text box>
Date of birth * <dropdown boxes for Day, Month and Year. Redirect to Terminal Page 2 if less than 18 years of age>
Sex * <dropdown box Male/Female>

Residential address

Country * <drop down box, pre-select Australia>
Residential Unit/Apt No <text box>
Residential Street No. * <text box>
Residential Street Name * <text box>
City / Suburb * <text box>
Postcode * <text box>
State / Territory * <dropdown box>

☐ Postal address same as Residential <Default to selected. Display Postal address section if unselected>
Postal address

Country *<drop down box, pre-select Australia>*
Postal Unit/Apt No *<text box>*
Postal Street No. *<text box>*
Postal Street Name *<text box>*
City / Suburb *<text box>*
Postcode *<text box>*
State / Territory *<dropdown box>*

Save and Continue