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Neuroscience Research Australia

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Exploring the effectiveness of product information on child restraint use

The study is being carried out by the following researchers:		
Role	**Name**	**Organisation**
Chief Investigators	Dr Julie Brown	Neuroscience Research Australia
Co-Investigator/s	Prof Lynne Bilston [1] A/Prof Lisa Keay[2] Dr Kate Hunter[2] A/Prof Judith Charlton[3] Dr Sjaan Koppel[3] A/Prof Andrew Hayen[4] Dr Jane Elkington[1] Ms Catherine Ho[1] Ms Wennie Dai[2] Ms Ramanjot Sran[1]	[1] Neuroscience Research Australia [2] The George Institute [3] Monash Injury Research Institute [4] University of New South Wales
Research Funder	This research is funded by the National Health & Medical Research Council.	

If you would like to learn more about this study and what it would mean to be involved, please **visit our website www.neura.edu.au/car-seat-study or s**end a text **0488 824 611** with the message 'car seat study' and indicate your preferred language if other than English, and someone will call you.

An interpreter service and translated materials are available in 11 other languages: Arabic, Cantonese, Mandarin, Greek, Hindi, Indonesian, Italian, Korean, Tagalog, Turkish & Vietnamese

Invitation

You are invited to take part in a research study. The child car seat study is a research study looking at the factors that help or hinder proper child car seat use.

We are interested in the use of information sources about the correct use of child car seats. We are hoping that the study will help reduce the level of incorrect use of child seats and thereby reduce the risk of injury to children in the event of a crash.

We are not asking you to do anything differently than you would normally do. We are just interested in how effective the information that comes with the child restraint you have purchased is in guiding your use of the child seat.

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

1. What is the purpose of this study?

The purpose of the study is to establish whether supplementary product materials increase the correct use of child car seats among purchasers of new child car seats.

2. Who can take part in this study?

Parents or parents-to-be who are soon to purchase a new child car seat, being one of two models involved in the study: Britax MaxGuard Pro and Britax Compaq are eligible to participate in this study. It needs to be one of these two models as these are the models for which the study materials have been developed. Britax have agreed to these models being involved in the study but they are not directly involved in the study or benefitting financially as a result of the study.

Other criteria to be involved are, participants need to:

- Live within 2 hours of the Sydney CBD
- Be a primary carer of the child for whom the car seat will be purchased
- Be 18 years of age or older
- Hold a drivers' license
- Own their own motor vehicle

3. What if I don't want to take part in this study, or if I want to withdraw later?

Participation in this research study is voluntary. If you don't wish to take part, you don't have to. If you do withdraw, you will be asked to complete and sign the 'Withdrawal of Consent Form' which is provided at the end of this document. Alternatively, you can ring the research team and tell them you no longer want to participate. If you decide to leave the research study, the researchers will not collect additional information from you. Your decision will not affect your relationship with Neuroscience Research Australia (NeuRA), The University of New South Wales or Britax.

If you decide you want to take part in the research study, you will be asked to contact one of the staff listed under 'Research Team Contact' below. At that point you are free to ask any questions about the study, before deciding whether you want to participate.

If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason. However, it may not be possible to withdraw your data from the study results if these have already had your identifying details removed.

4. What does this study involve?

If you decide to take part, you will need to purchase the restraint through NeuRA at the current retail price at the time of purchase (around $440 for the MaxiGard Pro and $280 for the Compaq).

If you choose to participate, you will purchase the restraint online through a dedicated and secure website linked to a secure encrypted external commercial payment website (eWAY) to purchase the restraint. NeuRA will then send you the restraint and the study materials within 5 days of your payment. Your payment details will not be made available to NeuRA or any party other than the payment website.

You will be randomly assigned to one of two groups, each receiving different information about the use of child car seats. You do not need to do anything differently that you would otherwise do in the use of your child car seat. You are asked not to discuss the information you are given with others you know who are in the study or may enter the study so as to minimise the contamination between the two different groups. At the end of the study you will be able to access the information provided to the other group.

IN SIX MONTH'S TIME:

Arranging the visit:

After the five and a half months we will call you to arrange a home visit - which will be set up to be six months after your child started using the car seat. After the home visit your involvement with the study is complete.

A member of the research team will visit you and you will be asked to complete a questionnaire about your knowledge and practices of the child restraint product you have purchased. The questionnaire will be collected the next day. The researcher, qualified as a child restraint fitter, will record observations of the child restraint in your vehicle. The assessor will notify you of any safety errors they've observed in the child's car seat's installation and will demonstrate the correct approach to installing your child car seat correctly.

At the end of the study you will have the opportunity to access both sets of study materials.

5. What information will be collected?

When you choose to take part you will provide us with your contact details so that we can contact you for the home visit that will be held after six months. This information will be kept separately from other information we collected via the inspection of the child car seat in your car and the questionnaire about your use of the car seat, your understanding of what needs to be done and checked when using a child car seat, and a few demographic details. Only your study identification number will be linked with this information.

6. How will my confidentiality be protected?

Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission, or except as required by law. Only the researchers named above will have access to your details and results that will be held securely at NeuRA.

7. What happens with the results?

By signing the consent form you will consent to the research team collecting and using information about you for the research study. We will keep your data for 7 years. We will store information about you at Neuroscience Research Australia (NeuRA), Randwick. Your information will only be used for the purpose of this research study and it will only be disclosed with your permission.

It is anticipated that the results of this research study will be published and/or presented in a variety of forms. In any publication and/or presentation, information will be provided in such a way that you will not be individually identifiable. No participant's names or identifiable details will be listed in any reports or in any correspondence about the study.

You have the right to request access to the information about you that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. You can do this by contacting a member of the research team

8. **How is this study being paid for?**

The study is being funded by the National Health & Medical Research Council.

9. Are there risks to me in taking part in this study?

Aside from giving up your time and purchasing the restraint, we do not expect that there will be any risks or costs associated with taking part in this study.

10. Will I benefit from the study?

The researchers who will be trained child restraint fitters will inform all participants of any errors in the installation or use of the child car seat that they observe. They will correct any errors in how the child car seat is installed if you wish it to be corrected. This will allow you to either be reassured that all is fine or how to use the car seat more safely from that point onwards.

At a broader level, we hope to use the findings from this research study to improve future instructions that come with new child restraints. We hope that this will help increase the number of child car seats being used correctly and thus, making it safer for children travelling in motor vehicles.

11. Will taking part in this study cost me anything, and will I be paid?

Other than your initial purchase of the child restraint, participation in this study will not cost you anything.

12. What should I do if I want to discuss this study further before I decide?

When you have read this information, the researchers will contact you to see if you wish to participate, if you have not already discussed this with them. If you would like to know more at any stage, please do not hesitate to contact them on 9399 1234.

13. Who should I contact if I have concerns about the conduct of this study?

This study has been approved by the South Eastern Sydney Local Health District Human Research Ethics Committee. Any person with concerns or complaints about the conduct of this study should contact the Research Support Office which is nominated to receive complaints from research participants. You should contact them on 02 9382 3587, or email SESLHD-RSO@health.nsw.gov.au and quote [*18/162*]

Thank you for taking the time to consider this study.
If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.

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WITHDRAWAL OF CONSENT

I hereby wish to **WITHDRAW** my consent to participate in the study described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with Neuroscience Research Australia, Britax, The University of New South Wales, The George Institute and Monash Injury Research Institute.

Signature of participant [*or person responsible*]	**Please PRINT name**	**Date**
_____	_____	_____

The section for Revocation of Consent should be forwarded to A/Prof Julie Brown at Neuroscience Research Australia, Randwick 2031 (Ph: 02 9399 1632)

CONSENT FORM

[To be used in conjunction with a Participant Information Sheet]

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1. I,.....
of.....
agree to participate in the study described in the participant information statement set out above ***(or: attached to this form).***

2. I acknowledge that I have read the participant information statement, which explains why I have been selected, the aims of the study and the nature and the possible risks of the investigation, and the statement has been explained to me to my satisfaction.

3. Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers.

4. I understand that I can withdraw from the study at any time without prejudice to my relationship to Neuroscience Research Australia, Britax, and study partners including The University of New South Wales, The George Institute and Monash Injury Research Institute.

5. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.

6. I understand that if I have any questions relating to my participation in this research, I may contact A/Prof Julie Brown on telephone 02 9399 1632 who will be happy to answer them.

7. I acknowledge receipt of a copy of this Consent Form and the Participant Information Statement.

Complaints may be directed to the Research Ethics Secretariat, South Eastern Sydney Local Health District, Prince of Wales Hospital, Randwick NSW 2031 Australia (phone 02-9382 3587, fax 02-9382 2813, email SESLHD-RSO@health.nsw.gov.au .

Signature of participant [*or person responsible*]	**Please PRINT name**	**Date**
_____	_____	_____
Signature of witness	**Please PRINT name**	**Date**
_____	_____	_____
Signature of investigator	**Please PRINT name**	**Date**
_____	_____	_____