 

**Title of Study: Improving parent awareness of normal health and development in infants and children.**

***Principal Investigator:*** *Ms Sandra Staffieri\**

***Associate Investigators:*** *Dr Gwyneth Rees, Dr Paul Sanfilippo, Dr Stephen Cole, Assoc. Prof. Alex Hewitt & Prof. David Mackey*

***Research Assistants:*** *Ms Linda Clarke and Ms Lisa Kearns*

*\*Sandra Staffieri is conducting this study as part of her qualification of Doctor of Philosophy at the University of Melbourne, under the supervision of the Associate Investigators*

**PARTICIPANT INFORMATION SHEET and CONSENT FORM:**

There are 6 pages in this Patient Information and Consent Form. Reading this document will help you decide if you would like to participate in this study.

**What is this study about?**

You are invited to take part in a voluntary research study looking at ways to improve parents’ knowledge about children’s health and development.

This Participant Information and Consent form tells you about this research study. Knowing what is involved will help you decide if you want to take part in this study. Please read this information carefully and ask questions about anything that you don’t understand or want to know more about.

By giving your consent to take part in this study, you are telling us that you:

1. Understand what you have read
2. Agree to take part in the research study as outlined below

**Who can take part in this study?**

This study is open to pregnant women attending the Ante-natal Clinic at the Royal Women’s Hospital, Victoria. You are welcome to participate whether you are expecting your first child, or whether you already have children.

**Why have I been asked to take part?**

You have been asked to take part in this study so we can decide whether an information pamphlet that has been developed to improve information for parents about children’s health problems would be useful.

**Do I have to participate?**

Participation in this study is voluntary. You do not have to take part if you do not want to. If you choose not to take part, it will have no effect on your care by any health service provider. If you agree to participate in this study, you will be asked to sign and complete this consent form.

If any questions make you feel uncomfortable, you do not have to answer them. You may cease participation at any time for any reason.

**What will I have to do?**

After you have had the opportunity to ask any questions of the study staff and have signed the consent form, you will be asked to complete a short survey that will determine what you already know about children’s health. You will complete this survey whilst you wait for your regular ante-natal appointment. This will take no more than 10 minutes of your time. There are no ‘right’ or ‘wrong’ answers, but it is important that we can measure what you already know.

You will then be ‘randomised’ into one of two study groups described below. “Randomised” means that you are put into a group by chance, like flipping a coin. You will have an equal chance of being placed in either group. Neither you nor the researchers will know which group you are in until the study is completed.

Group 1: Control Group – you will receive information about children’s health already provided and available to new parents

Group 2: Intervention Group – you will receive extra information about children’s health and development.

You will be asked to take your research envelope home and read the contents.

Two weeks later, you will be asked to complete a second, short survey to measure the effect of having received any or no additional information. You will be sent a link via email to complete the second survey on-line from the comfort of your home. This survey will only take 10 minutes of your time.

To provide all participants with the benefit of useful and potentially important information, if you are randomised to the control group, you will receive the information given to the intervention group at the completion of the study.

To ensure the success of this study, completing both surveys is very important.

If you do not complete the second survey, you will be reminded ONCE by email and ONCE by telephone. You can still decide at any time to no longer participate in the study and withdraw by contacting the researchers on 9929 8713 or sandra.staffieri@unimelb.edu.au

If you do not complete the second, follow-up survey, this will not have any effect on the care you or your baby will receive at the RWH.

**Are there any risks associated with participating in this study?**

We do not think there are any risks involved with participating in this study. You may find some images in the survey mildly confronting [eg. Naked woman’s breast; eye with conjunctivitis] however these are all situations a parent may encounter in day-to-day living.

**Will I benefit from participating in the study?**

By participating in this study, you might learn more about children’s health problems that you do not already know. This could be of benefit to your child or children you know in the future. Your participation will help us develop valuable resources for parents about their child’s health. Parents being better informed and more confident in seeking health advice for their child may lead to children having health problems diagnosed sooner with the potential for better outcomes.

**Will I be reimbursed for my time?**

No costs will be incurred by you as a result of your participation in this study. You will not be reimbursed for your time.

**Can I tell other people about the study?**

Because this is a randomised controlled trial [not all participants will initially receive the information] it would be preferable for you not to discuss this study with other women in the waiting room.

**What if I would like further information about the study?**

When you have read this information, the research assistant will be available to discuss it with you further and answer any questions you may have. If you would like to think about participating on another day, we can arrange for you to participate at your next appointment if the study is still open.

If you would like to know more at any stage during the study you can contact Sandra Staffieri on 9929 8713 or sandra.staffieri@unimelb.edu.au

**What will happen to the results of this study?**

The results of this study will be: presented at relevant scientific conferences; published in an appropriate medical journal and will be included in the PhD thesis to be completed by the Principal Investigator.

**Will I be told the results of this study?**

At the conclusion of this study, all participants will be sent a letter of thanks. Participants in the ‘control group’ who did not initially receive the child health information will be provided with a copy so all participants in this study may benefit. An e-newsletter with the results of this study will be distributed to all participants once the results of the study have been analysed.

**What about my privacy?**

Maintaining your privacy is important to us and will be protected at all times.

Only the researchers named in this study will have access to your personal details.

You will be allocated a unique study identifier which will be recorded on your completed questionnaires.

General information will be collected about your: age, gender, number of children, contact details, country of birth, confidence with English and your level of formal education. Your email and postal address will be stored on a secure database on an access restricted computer at the Centre for Eye Research Australia, East Melbourne. The database with your personal information will be destroyed after 15 years as required by the *National Statement on Ethical Conduct in Human Research* (March 2007). Your contact details will not be provided to any third party. You will not be contacted about any other research studies unless you indicated you were happy to.

Your name will not be used in any report that is published.

Ethical Guidelines

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 study have been approved by the Human Research Ethics Committee of the Women’s Hospital [HREC # 17-38]

This study will be carried out according to the *National Statement on Ethical Conduct in Human Research* (March 2007) This statement has been developed to protect the interests of people who agree to participate in human research studies.

If you have any concerns and/or complaints about the study, the way it is being conducted or your rights as a research participant, and would like to speak to someone independent of the study, please contact:

Royal Women’s Hospital Consumer Advocate:

Telephone: (03) 8345 2290

Email: consumer.advocate@thewomens.org.au

**CONSENT TO PARTICIPATE IN A RANDOMISED CONTROLLED TRIAL**

**UNIQUE STUDY IDENTIFIER: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ agree to participate**

(please print your name)

**in a randomised controlled trial about children’s health.**

* I understand that no personal information about me will be recorded, other than my age, gender, number and date of birth of my children, my contact details, my country of birth, confidence with the English language and my level of education.
* I understand that I can withdraw from this study at any time.
* I understand that my privacy will be protected at all time
* I understand my name and contact details will kept confidential by the researchers
* I understand any paper record of my email or postal address will be kept in a locked filing cabinet in the access-restricted premises of the Centre for Eye Research Australia
* I understand any electronic record of my email or postal address will be kept on a password protected computer and server at the Centre for Eye Research Australia. This server is protected by multiple firewalls and user authentication.
* I understand my name or contact details will not be provided to any third party and will not be used to solicit further participation in future research unless I have indicated.
* Once my email or postal address has been used to send information I have requested, I understand it will be deleted from the server and a hard copy will be destroyed using commercial sensitive document destruction methods available at the Centre for Eye Research Australia.

**SIGNED: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ DATE:**

**Declaration by study researcher\***: I have given a verbal explanation of the research study, its procedures and risks and I believe that the participant has understood that explanation.

Researcher’s Name (printed) ……………………………………………………

Signature:…………………………………………………………………………..Date………………

\* A senior member of the research team must provide the explanation and provision of information concerning the research study.

**CONSENT TO PARTICIPATE IN FUTURE RESEARCH RELATED TO THIS STUDY**

It is possible that the results of this study may lead to further research.

Please indicate whether you are happy to be contacted about future research that may result from this study.

**I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

 (please print your name)

am happy to be contacted about future research relating to this study.

am NOT happy to be contacted about future research relating to this study.

**SIGNED: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_DATE:\_\_\_\_\_\_\_\_\_\_**