Parent/Guardian Information and Consent Form
Version 2 Dated July 2018
Site Monash Medical Centre

Full Project Title: **Validation of SmartSnugg Infant Sleeping Bags**

 Principal Researcher: Professor Rosemary SC Horne

1) YOUR CONSENT

This is an invitation for your baby to take part in a research project, titled: Validation of SmartSnugg Infant Sleeping Bags

This Parent/Guardian Information Sheet/Consent Form tells you about the research project. It explains the processes involved in taking part. Knowing what is involved will help you decide if you want your baby to take part in the research study.

Please read this Parent/Guardian Information carefully information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not your baby can take part, you might want to talk about it with a relative, friend or local health worker.

Participation in this research is voluntary. If you do not wish the baby in your care to take part, they do not have to.

If you decide you want the baby to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read

• Consent to your baby taking part in the research project

• Consent to your baby being involved in the research described

• Consent to the use of your baby’s personal and health information as described.

You will be given a copy of this Parent/Guardian Information and Consent Form to keep.

2 PURPOSE AND BACKGROUND

Keeping a baby’s head and face uncovered during sleep is an important part of safe sleeping for babies to prevent Sudden Unexpected Death in Infancy (SUDI). It is also important to not to let babies become overheated while they sleep. Increasingly infant sleep bags are being used to keep babies sleeping safely. Sleeping babies in a safe baby sleeping bag, one designed especially for baby, with fitted neck and armholes and no hood, has a number of features that help baby sleep safely. Research has shown that sleeping bag use reduces the risk of bedclothes covering the baby’s face, and delays the baby rolling onto the tummy during sleep until baby is past the age of peak risk of SUDI. Supine sleep is also promoted when the zipper is opened to the front.

In this study we will validate a new SmartSnugg infant sleeping bag which records and displays the temperature inside the sleeping bag so that parents can easily monitor this. Infants will be studied during sleep in two different thicknesses of SmartSnugg to assess if the SmartSnugg accurately records baby temperature. The company Smart Snugg are funding the Hudson Research Institute to conduct this study.

A total of 20 babies will be enrolled in this study.

You are invited to participate in this research project because:

* Your baby was born at term (between 38-42 weeks of gestation) and is healthy and aged either 3 or 6 months.

3 PROCEDURES

*When will your baby be studied?*

This research will be performed at either 3 or 6 months of age

*Infant Sleep Study*

During the sleep study we will perform a number of non-invasive assessments to record heart rate, and breathing patterns while your baby is sleeping. We will determine the sleeping patterns of your baby by carefully observing them and their breathing and heart rate patterns. We will also record heart rate, breathing pattern, and oxygen levels. We will add sensors to measure skin temperature on the trunk and limbs (4 sensors). Studies will take approximately 4-5 hours to complete.

These studies will be at the Melbourne Children’s Sleep Centre Level 4, Monash Children’s Hospital (Melways Map 79, C1). The studies will be conducted during the day and consist of a morning and afternoon nap between 9:00am and 4:00pm. The application of these sensors will not hurt your baby in any way. During your baby’s morning feed we will apply sensors as illustrated below.

There are no costs involved in participating in the sleep studies and we will pay your parking in the visitor’s car park (entrance from Clayton Road). Studies will be conducted during the day Monday to Friday on a date convenient to you. You will be able to stay and watch the study, have a sleep in a quiet bed room or leave your baby while you go shopping – we will happily babysit.

Baby set up for sleep study. Photograph used with permission

Parents will be asked to complete a demographics questionnaire that will take approximately 10 minutes to complete.

If you require any further information do not hesitate to call Prof Rosemary Horne (85722827) or visit our website <http://hudson.org.au/research-group/infant-and-child-health/>

4. POSSIBLE BENEFITS

We cannot guarantee or promise that you or your baby will receive any benefits from this research. This study will provide important information on safe sleeping for babies and may lead to the development of a new infant sleeping bag which accurately records infant temperature.

5. POSSIBLE RISKS

There are no known risks from any of the procedures performed. All techniques and measurements are routinely used clinically and all measurements are non-invasive. We have over 30 years of experience in performing research sleep studies in infants.

6. INJURY

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

7 PRIVACY, CONFIDENTIALITY AND DISCLOSURE OF INFORMATION

Any study information that can identify you or your baby will be confidential. It would only be disclosed with your permission or if required by law. In any publication, information will be provided in such a way that you and your baby cannot be identified.

All of the data collected will be stored on computer discs. All babies are given a coded number to ensure that their details are stored in a de-identified form and confidentiality is maintained. Numbered files will be stored in a locked filing cabinet in the hospital. Only members of the research team will have access to these files. Data will be retained for until the youngest baby recruited to the study reaches the age of 28 years. After this period of time data will be destroyed either by shredding or deletion of computer files.

8. NEW INFORMATION ARISING DURING THE PROJECT

During the research project, new information about the risks and benefits of the project may become known to the researchers. If this occurs, you will be told about this new information. This new information may mean that you can no longer participate in this research. If this occurs, the person(s) supervising the research will stop your participation. In all cases, you will be offered all available care to suit your needs and medical condition.

9. RESULTS OF PROJECT

Group results of the study will be published in scientific journals which are freely available to the public. You can also contact the researchers (see below) for the published results. A plain English summary of the results will be provided to families if they would like to receive it. Please provide your email address if you wish to receive a copy.

10. FURTHER INFORMATION OR ANY PROBLEMS

If you require further information or if you have any problems concerning this project (for example, any side effects), you can contact the researchers. The researchers responsible for this project are:

Professor Rosemary Horne on 85722827.

 11. OTHER ISSUES

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

Ms Deborah Dell

Manager, Human Research Ethics Committee

Research Support Services I Monash Health

Level 2, I Block, Monash Medical Centre, Clayton, 3168

telephone: (03) 9594 4605 email: deborah.dell@monashhealth.org

You will need to tell Ms Dell the name ofone of the researchers given in section 10 above.

12. PARTICIPATION IS VOLUNTARY

Participation in any research project is voluntary. If you decide to withdraw your baby during the study, you are free to discontinue from the project at any stage. This will not affect your baby’s medical treatment or your relationship with medical staff at Monash Medical Centre.

Before you make your decision, a member of the research team will be available to answer any questions you have about the research project. You can ask for any information you want. Sign the Consent Form only after you have had a chance to ask your questions and have received satisfactory answers.

If you decide to withdraw from this project, please notify a member of the research team before you withdraw.

13. ETHICAL GUIDELINES

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research* (NHMRC, 2007) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

The ethical aspects of this research project have been approved by the Monash Health Human Research Ethics Committees.

14. REIMBURSEMENT FOR YOUR COSTS

You will not be paid for your baby’s participation in this project, however we will cover the cost of parking.

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I have read, or have had read to me in my first language, and I understand the parent/Guardian/Participant Information Version 1dated June 2018.

I give my permission for \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_to participate in this project according to the conditions in the Parent/Guardian/Participant Information Sheet.

I will be given a copy of Parent/Guardian/Participant Information Sheet and Consent Form to keep.

The researcher has agreed not to reveal the participant’s identity and personal details if information about this project is published or presented in any public form.

Participant’s Name (printed) ……………………………………………………

Name of Person giving Consent (printed) ……………………………………………………

Relationship to Participant: ………………………………………………………

Email address if you wish to receive a summary of the study results……………………………

Signature Date

Name of Witness to Parent/Guardian Signature (printed) ……………………………

Signature Date

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

Signature Date

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

Revocation of Consent Form

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I hereby wish to WITHDRAW my consent to participate in the research proposal described above and understand that such withdrawal WILL NOT jeopardise any treatment or my relationship with Monash Medical Centre.

Participant’s Name (printed) …………………………………………………….

Signature Date