

11 July 2018

Prof Rosemary Horne  
The Ritchie Centre  
Department of Paediatrics  
Level 5 Monash Children's Hospital  
246 Clayton Road Clayton 3168

Dear Researcher,

**Study title: Validation Of Temperature Recording For SmartSnugg Infant Sleeping Bag**

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**NMA Reference: HREC/18/MonH/485**  
**Monash Health Ref: RES-18-0000-359A**

We advise that the above project was reviewed by the Monash Health Human Research Ethics Committee at its meeting on 05 July 2018 has been approved subject to the following conditions:

The responses are to be reviewed outside of the Committee by the Medical Administrator and Research Support Services staff.

**1. Submission of a response to the following Ethical Issues:**

- a. This is a trial of the Smart Snugg Sleeping bag, which is an infant sleeping bag. Infant Sleeping Bags are commonly available but this one is fitted with device to record the baby's temperature, so that if it is too hot, the parent/caregiver may be alerted and the baby doesn't overheat, which is risk factor for SIDs. What is not clear in the application is whether this is commercially available or not and a search on the Internet does not show the product. Therefore, the feedback provided is on the basis that this is an unapproved and not yet commercially available product. Please advise of the status of the sleeping bag device;
- b. Submission of the clinical trial registration details;
- c. Submission of a HREC Review Form of Indemnity for the Monash Health HREC by Smart Snugg who are sponsoring the study through the Hudson Research Institute;
- d. Submission of a completed Victorian Specific Module;
- e. Submission of a revised advertisement with the version number and date included. Please also state that the research has been reviewed and approved by the Monash Health Human Research Ethics Committee;
- f. Clarification of the funding arrangement with the sponsor and how the funding will be allocated and used;

- g. Submission of a response to the biostatistician's comments:
- Application seeks to enroll n=20 infants for the study. This choice of sample size has not been justified, and the applicant should be asked to provide justification;
- h. Submission of a revised Parent/Guardian Information and Consent Form with the following amendments:
- a. It should state clearly that the company Smart Snugg are funding the Hudson Research Institute to conduct this study;
  - b. Under section 6, please amend the wording to state 'your baby';
  - c. Under section 13, amend 'Southern Health' to 'Monash Health';
- i. Submission of the following Site Specific Assessment items:
- a. Submission of a Standard Form of Indemnity for the study to be conducted at Monash Health;
  - b. Submission of a Certificate of Insurance for Smart Snugg;
  - c. Submission of a copy of the agreement between Smart Snugg and the Hudson Research Institute;
  - d. Submission of a research collaboration agreement including the budget.

**2. Submission of the following Site Specific Assessment Items:**

N/A

It is requested that any responses be submitted as follows:

- Inclusion of covering letter identifying the project number and title of the application;
- The covering letter must clearly refer to the individual items mentioned in this letter together with a response to that item listed beneath;
- All documents should detail the changes made, including all additions and changes to the text and ~~strike through~~ any deleted original text and highlight in **bold** or by underline any new text;
- A new version number and date is required in the footer of each page of any revised Patient Information Sheet. Please ensure that any Consent Forms are correspondingly updated.

The project cannot commence until all the conditions outlined have been complied with and a final HREC Review Approval and Site Specific Authorisation have been issued. If the conditions are not fulfilled **within three months**, conditional approval may be withdrawn and a new application may need to be submitted if the project is to proceed.

Should you have any queries, please contact me on 9594 4605 or via email [deborah.dell@monashhealth.org](mailto:deborah.dell@monashhealth.org)

Yours sincerely

A handwritten signature in black ink, appearing to read "Michael Kios". The signature is fluid and cursive, with a large initial "M" and a stylized "K" at the end.

**Mr Michael Kios**  
**Research Governance Manager**

Cc: MUHREC

***Please Note: It is requested that correspondence be forwarded electronically to [research@monashhealth.org](mailto:research@monashhealth.org) with the local Monash Health reference number inserted.***