Participant Information Sheet and Consent Form

Title	Accurate measurement of core body temperature and shivering occurrence in emergency caesarean sections compared to elective caesarean sections
Short Title	Body temperature and shivering during caesarean sections
Project Sponsor	South Metropolitan Health Service
Coordinating Principal Investigator/ Principal Investigator	Dr Yayoi Ohashi, Dr Jana Lau
Associate Investigator(s)	Dr Gargeswari Sunanda, Dr Preethi Nagubandi, Dr Warren Pavey, Mr Glenn Boardman, Mr Chris Reed
Location	Department of Anaesthesia, Pain and Peri-operative Medicine, Fiona Stanley Hospital

PARTICIPANT INFORMATION SHEET

You are being invited to participate in a research study because you are scheduled to have an elective caesarean section, **or** you are not planning on having a caesarean section but there is a small possibility you may need to have an urgent caesarean section for a medical reason (e.g. failure to progress)... This information sheet explains the study introduced above and describes what will be involved should you decide to participate. Please read the information carefully and ask any questions you might have. You may also wish to discuss the study with a relative or friend or your GP.

What is the background and aims and of this study?

Hypothermia (a low body temperature) is a common problem during elective caesarean section. By contrast, hyperthermia (a high body temperature) is a side effect of epidural pain relief during labour and therefore it is possible that hyperthermia is the dominant problem during emergency caesarean section.

Temperature changes during caesarean sections are not fully understood. Hypothermia and hyperthermia are associated with some undesirable outcomes for the mother and the baby (e.g. delayed wound healing, increase in blood loss, increase in antibiotics use, neonatal neurological dysfunction).

Shivering during both elective and emergency caesarean sections is a common phenomenon.

Although it has not been associated with any serious health effects to mother or baby, it is often severe and impairs the patient's birth experience due to it being uncomfortable, preventing patients holding their newborn baby, interfering with skin-to-skin contact, and decreasing accuracy of vital monitoring equipment. When a mother shivers, we warm her up, however we don't really know why shivering happens. What we know so far is shivering during elective caesarean section is caused by hypothermia and is effectively treated with active warming. During emergency caesarean section, however, shivering may occur at normal or increased body temperatures and therefore active warming is likely inappropriate.

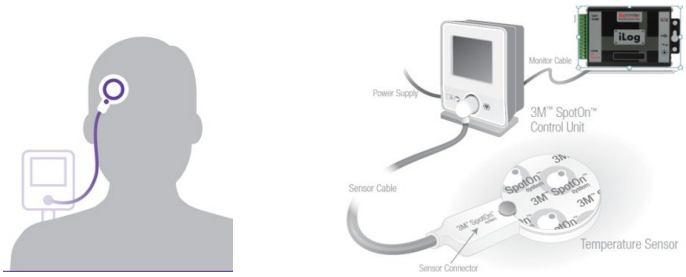
At present, body temperature is not routinely checked during caesarean section and therefore it is not possible to tailor temperature regulation strategies to individuals' needs.

The aim of this study is to identify core body temperature changes during emergency and elective caesarean sections and link these changes to the presence or timing of shivering. In this way the study might be able to identify the causes of shivering during caesarean sections and create strategies to decrease shivering and improve patient's birth experiences

What does participation in the study involve?

If you agree to participate in this study, we will ask you to sign the consent form on the last page of this document. This information sheet is yours to keep.

While you are waiting for your surgery or once you enter the operating theatre (in the case of an emergency caesarean section), your anaesthetic team will attach normal monitoring (blood pressure cuff, oxygen finger probe, heart rate monitoring), alongside a small temperature probe that sticks to the forehead, allowing continuous body temperature measurement throughout the caesarean section and recovery, shown on a small screen attached to the probe. See picture below.



Infographic from 3M™ Bair Hugger™ Temperature Monitoring system

There will be no change to the care you are given during your procedure, other that continuous monitoring of temperature throughout the duration of your caesarean section and in the recovery room. The temperature sensor will be disconnected when you leave the recovery room to go to the postnatal ward.

A research member and your anaesthetist will record the temperature changes during your surgery, as well as asking you about your experience of shivering, if it occurs. This includes information such as if you feel shivering, if you're uncomfortable, and if you feel cold or hot. Your treating team are there to ensure your comfort and safety, hence these questions help your anaesthetic team maximise your comfort during your surgery e.g. if you require warming or cooling this can be facilitated.

The researcher and your anaesthetist will also record other useful information for the study, such as the medication used in your spinal or epidural anaesthetic, other medication given intravenously, your vital signs, basic demographics, and your baby's temperature and vital signs at birth.

What are the possible side effects and risks?

We don't anticpate that there is any risk to you in participating in this research because we will only be measuring your body temperature during a caesarean section. We are not seeking to alter your care at all. Whether or not you participate in this study it will not affect the standard of your anaesthetic care in any way.

What are the possible benefits?

The use of the temperature probe may help alert your anaesthetic team to you being too hot or cold, and helping correct this.

The knowledge gained from this study may help to improve anaesthesia care after the study results are published in a medical journal in the future. Ideally, we would like to improve the patient birth experience of having an elective or emergency caesarean section, and decreasing shivering, improving patient's temperature control is an integral part of this. In addition, we could also identify other side effects of shivering with hypothermia or hyperthermia, such as effects on newborn babies, and impact to surgery, such as increased blood loss.

What about my privacy and confidentiality?

The information we collect about you and your baby will be held by the investigators in strict confidence – no individually identifiable information will be stored. This information is de-identified (name removed and replaced with a code) and will be stored securely in REDCap, which is an online platform. Some information we collect may form part of your medical records which is stored securely on-site at Fiona Stanley Hospital Anaesthetic Department inside a locked office. Only research team members will have access to this information.

The results of this research will be published in a medical journal, but you will not be identifiable in any way. We will store the data we collect about you and your baby securely at Fiona Stanley Hospital for a period of at least 7 years for you and 25 years for your baby, after publication.

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 South Metropolitan Health Service (project reference number RGS5199).

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.

Is there a cost for participation?

There will be no costs incurred as a result of participation in this study. You will not be paid for participation.

What if I decline to participate or withdrawal from the study if I change my mind?

Participation in this study is entirely voluntary. You do not have to participate if you do not want to. Whether you decide to participate or not will in no way affect your current or future care at Fiona Stanley Hospital. You are free to withdraw from the study at any time without reason or justification.

Further information and who to contact

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

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact Dr. Yayoi Ohashi or Dr Jana Lau on (08) 9224 1036.

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name	South Metropolitan Health Service Research Support and Development Unit
Position	Manager
Telephone	08 6152 3214
Email	SMHS.RGO@health.wa.gov.au

If you 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:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	South Metropolitan Health Service Human Research Ethics Committee
HREC Executive Officer	Ethics Coordinator
Telephone	08 6152 2064
Email	SMHS.HREC@health.wa.gov.au

CONSENT FORM

Patient's MRN sticker

Title: Accurate measurement of core body temperature and shivering occurrence in emergency caesarean sections compared to elective caesarean sections.

Investigators: Dr Yayoi Ohashi, Dr Jana Lau, Dr Warren Pavey, Dr Gargeswari Sunanda, Dr Preethi Nagubandi, Mr Glenn Boardman, Mr Chris Reed

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I, …….. agree to participate in the above study.

- I have been provided with a copy of the Participant Information Sheet explaining the study which I have read and understood.
- I have been given the opportunity to ask questions about the study by the researchers and any questions have been answered to my satisfaction.
- I understand that I may withdraw from the study at any time without affecting any future medical treatment, or the treatment of the condition which is the subject of the study.
- I am aware that all research data collected will only be used for the purpose of this study and will be kept confidential and that my participation will not be disclosed without my consent.

Signed (participant) ……. **Date ……..**

Signed (person obtaining consent) …… **Date ……..**

Name of person obtaining consent ……..

Withdrawal of CONSENT FORM

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I, …….. withdraw my consent to participate in the above study.

- I understand that this withdraw from the study will not affect any of my future medical treatment, or the treatment of the condition which is the subject of the study.

Signature (participant) ……. **Date** ……..

Print name (participant) …….

Please email the signed form to SMHS.HREC@health.wa.gov.au