2022

# Participants consent

ENGLISH VERSION

ESTHER ESPUÑES MESTRES

**SUBJECT INFORMATION DOCUMENT FOR RESEARCH STUDY PARTICIPANTS**

Research protocol code: 2021/115-ENF-ASEPEYO act 21/2021
Protocol version:1
Date of protocol version: November 30, 2021
Date of protocol submission: November 30, 2021

Project title: Efficacy of perioperative hypothermia prevention measures in osteosynthesis. Clinical trial with control group and validation to Spanish of the "BEDSIDE SHIVERING ASSESSMENT SCALE".

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| Project Director: Albert Gallart Fernández-Puebla (PhD), Jordi Castillo García (PhD) |
| 1. Researcher: Esther Espuñes Mestres (PhD Student) |
| Department: Health Education |

We have asked you to participate in a research study. Before deciding whether you agree to participate, it is important that you understand the reasons why the research is being conducted: how your information will be used, what the study will consist of, and the possible benefits, risks and discomforts that may be involved.
In case they participate in any other study, they will have to inform the person in charge to evaluate if they can participate in this one.

**WHAT IS THE BACKGROUND AND OBJECTIVE OF THIS STUDY?**

The study is part of a doctoral thesis that aims to improve perioperative care of patients requiring trauma surgery. It focuses on activities to prevent perioperative hypothermia to reduce its occurrence, as well as to reduce the complications associated with it, for example, infection and thermal discomfort.

**AM I OBLIGATED TO PARTICIPATE?**
The decision whether to participate in the research is up to you. If you do not want to participate, or you want to drop out, the quality of the care you receive will not be affected. If you decide to participate, we will provide you with an informed consent form for you to sign.

**WHAT DOES MY PARTICIPATION CONSIST OF?**
If you agree to participate, you must consider that you can be in the group that will be treated with hot air blankets during the surgical process, or you can be in the group that will be treated with conventional textile blankets as it is routinely done in the hospital center.
The assignment to which group you will belong to will be done randomly by computer software; you have the same chances of being in one group as in the other.

At the end of the surgical process all participants, regardless of which group they have been assigned to, will have their needs covered and agree to answer three follow-up phone calls that will be made by nurse Esther Espuñes 30, 60 and 90 days after surgery to determine the evolution of their surgical wound.

**WHAT ARE THE POSSIBLE SIDE EFFECTS, RISKS AND DISCOMFORTS ASSOCIATED WITH PARTICIPATION?**

No side effects are expected from the study other than the sensation of heat that may be produced by the hot air blankets during the surgical process.

**WHAT ARE THE POTENTIAL BENEFITS OF PARTICIPATING?**

The benefits of participating in this study lie in the satisfaction of contributing to improve the knowledge of body temperature behavior during the perioperative process in traumatology to improve the health care provided to future patients through the contribution to scientific development to improve perioperative nursing care in this area. No financial or other compensation is contemplated.

In the long term (90 days) it is expected to be able to demonstrate a trend towards a decrease in the incidence of infection.

**HOW WILL MY DATA BE USED IN THE STUDY?**

The treatment, communication, and transfer of the personal data of the subjects participating in the study

in the trial are in accordance with the provisions of the Organic Law 3/2018, of December 5, 2018, on the Protection of Personal

of Personal Data and guarantee of digital rights and the European data protection regulation: Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons regarding the processing of personal data and on the free movement of data.

These data do not include neither your name nor your address but will be assigned a code number. Only the research team will have access to the code key that allows the study data to be associated with you. However, regulatory authorities, the independent ethics committee or other oversight bodies may review your personal data. The purpose of such reviews is to ensure the proper conduct of the study or the quality of the study data. If you withdraw your informed consent to use your data for the study, you may not continue to participate in the research. Please note that the results of the study may be published in the literature, but your identity will not be disclosed.

**HOW CAN I CONTACT YOU IF I NEED MORE INFORMATION OR HELP?**

By signing this form, you agree that you have been informed of the characteristics of the study, that you have understood the information and that all your doubts have been clarified.

In case of suffering an injury related to the study or to obtain answers to any questions that may arise during the research, please contact:

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**INFORMED CONSENT DOCUMENT OF INFORMATION TO THE SUBJECT RESEARCH STUDY PARTICIPANT**
**Study code: 2021/115-ENF-ASEPEYO act 21/2021**

I, Mr./Ms.: .....
- I have received verbal information about the study and have read the attached written information, a copy of which has been provided to me.
- I have understood what has been explained to me and the possible risks and benefits of participating in the study.
- I have been able to discuss the study and ask questions to the responsible professional.
- I give my consent to take part in the study and assume that my participation is completely voluntary.
- I understand that I may withdraw at any time.

By signing this informed consent form, I agree that my personal data may be used as described in this consent form, which is in accordance with the provisions of the Organic Law 3/2018 of 5 December on the Protection of Personal Data and Guarantee of Digital Rights and the European Data Protection Regulation: Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of data.

I understand that I will receive a copy of this informed consent form.

Participant's Signature and Name
ID Card.
Date of signature

Signature and Name of Researcher
Date of signature