



“Development of a non-invasive baby sleep monitoring and intelligent control system for the prevention of unexpected death in previously healthy babies and early detection of risky situations.”

**D.9.2
Ethical clearance**

Grant Agreement No.: FP7-SME-2013-1-606088

Start Date of project: 01/11/2013

Duration: 24 months

Deliverable information:

| Dissemination Level | | | |
|---|---|---------------|------------|
| <i>(Tick the corresponding dissemination level of the deliverable according to Annex I)</i> | | | |
| PU | Public | | X |
| PP | Restricted to other Programme Participants (including the Commission Services) | | |
| RE | Restricted to a group specified by the consortium (including the Commission Services) | | |
| CO | Confidential, only for members of the consortium (including the Commission Services) | | |
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| Approvals: | | | |
| | Name | Organization | Date |
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1 Introduction

1.1 Objective

This deliverable is addressed to present the results from the following tasks:

Task 1.8. Secure ethical approvals

IBV is the task leader and have fulfilled and secured appropriate ethical applications for Spanish authorities to be able to conduct tasks relate with babies and users. IBV and Dr. Pin developed a draft with exclusion/inclusion criteria and protocols for its approval by the Ethical Committee of the Universitat Politècnica de València and clinic Hospital Peset respectively as independent third party.

IBV defined tests and protocols with the important collaboration of PIN. The protocols describe objectives, detailed steps, equipment, and newborn babies' profile (based on weight and age).

Ethical approvals for the experiments have been obtained at the beginning of the project before the ethical trials starts (month 3). Ethical approvals are the result of this task and are attached in annex 1 and 2 of this deliverable.

1.2 Scope

The document covers the following points:

- **Ethical Clearance:** description of the ethical approvals obtained.
- **Official Documents of the Ethical Clearance:**
 - Original Spanish document for the Ethical Clearance of Hospital Peset ethics committee.
 - Original document for the Ethical Clearance of Universitat Politècnica de València research ethics committee.

1.3 Integration within the project objectives

This deliverable belongs to the “**WP9. Management and Coordination**” because this clearance is needed for several WPs within the project. Nevertheless, the task to obtain the ethical clearance is on “**WP1. User characterization and system requirements**” which is part of the “**Research, Technological development and innovation activities**”. This deliverable is needed to start the trials with users and is an input for the following tasks where users and babies are involved.

Approval of ethics committee of Peset Hospital has been obtained for trials with babies and approval of Universitat Politècnica de València ethics committee for the other tasks where users are involved.

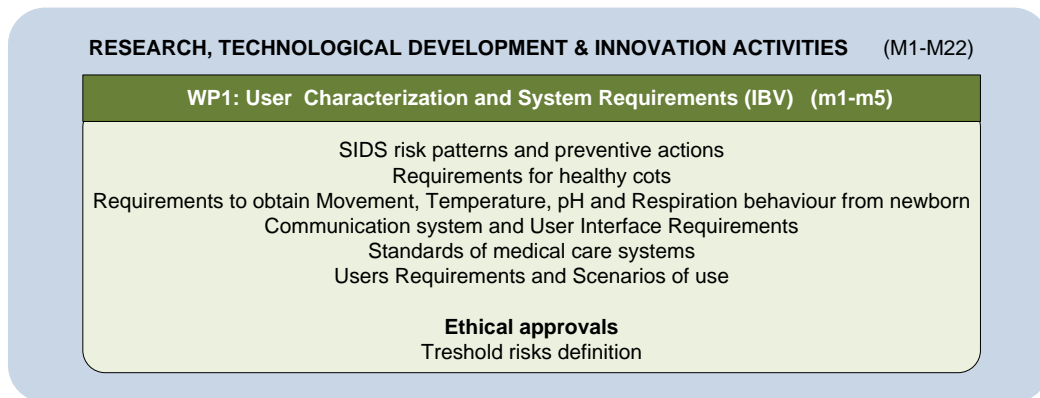


Figure 1. Block diagram.

2 Ethical clearance

Ethical approval of the Peset Hospital ethics committee for the experiments has been obtained in order to be able to start the ethical trials (Annex 1). A translation of the original document can be found in the next lines.

“D. Vicent Valentín Segura, president of the Research Ethical Committee of the Dr. Peset Hospital,

CERTIFIES

That this Committee has evaluated and check the clarifications required for the study named: «Development of a non-invasive baby sleep monitoring and intelligent control system for the prevention of unexpected death in previously healthy babies and early detection of risky situations».

Activity code: SME-2013-1.

CEIC code: 86/13.

Valencia, December 2nd 2013.

Signed: Vicent Valentín Segura

CEIC President of the Dr. Peset Hospital.”

Ethical approval of the research ethics committee of the Universitat Politècnica de València has also been received (Annex 2).

3 Annexes

Annex 1: Ethical clearance of Hospital Peset ethics committee



GENERALITAT VALENCIANA
CONSELLERIA DE SANITAT

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D. Vicent Valentín Segura, Presidente del Comité Ético de Investigación Clínica del Hospital Universitario Dr. Peset.

CERTIFICA:

Que este comité en su reunión celebrada el día 27 de noviembre de 2013 ha evaluado ha aprobado las aclaraciones solicitadas del estudio titulado: Desarrollo de sistema de control de monitorización inteligente no invasivo del sueño del bebe para la prevención de la muerte súbita a través de la detección de situaciones de riesgo previamente en la salud de los recién nacidos.
Código de protocolo: SME-2013-1
Código Ceic: 86/13

Valencia 2 de diciembre de 2013

Fdo.: Vicent Valentín Segura
Presidente CEIC Hospital Universitario Dr. Peset

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Annex 2: Ethical clearance of Universitat Politècnica de València research ethics committee



UNIVERSITAT
POLITÈCNICA
DE VALÈNCIA

JOSÉ ESTEBAN CAPILLA ROMÁ, PRESIDENT OF THE RESEARCH ETHICS COMMITTEE OF THE UNIVERSITAT POLITÈCNICA DE VALÈNCIA

I DECLARE: that the Research Ethics Committee of this university, in the meeting held on July 9, 2013, after evaluating the research project "**Development of a non-invasive baby sleep monitoring and intelligent control system for the prevention of unexpected death in previously healthy babies and early detection of risky situations. BabyCareSleep**" whose principal investigator is Dr. **Pedro Huertas Leyva**, has decided to report it FAVORABLY.

Valencia, on July 9, 2013


Fdo. José Esteban Capilla Romá

