

INFORMED CONSENT FOR MINORS

Project Title

“PainScan CP”: Mobile Application Based on Artificial Intelligence to Identify Pain in Non-Communicative People with Cerebral Palsy

(Funding organization or purpose; e.g., National Plan PSI2017-82550-R, master’s thesis, etc.)

Participant Data:

Minor’s Name: _____ Age: _____

I, _____, with ID: _____ (as the mother).

I, _____, with ID: _____ (as the father).

I, _____, with ID: _____ (as the legal representative/guardian).

(Note 1: Only in cases of separation or divorce with shared parental authority, both parents must fill out and sign this consent form.)

(Note 2: Only if necessary to achieve the study’s objectives, additional information such as ID, postal address, phone number, or email may be included.)

Study Objective

Our project focuses on developing a facial recognition mobile application using artificial intelligence (AI). The methodology combines data collection through videos of facial expressions of pain and the training of deep neural networks to accurately identify pain in people with cerebral palsy. This system will ultimately be integrated into the mobile application.

Objectives:

- Define a robust new methodology to retrain the already developed automated facial recognition system, improving accuracy in identifying pain in people with cerebral palsy and an inability to communicate it—creating version V 2.0.
- Collect images and videos of pain expressions to expand international databases, thereby facilitating decision-making for caregivers and healthcare professionals.
- Define new facial recognition patterns of pain to reduce the emotional impact on caregivers and healthcare professionals caused by uncertainty regarding the suffering of the individuals they care for.

- Develop a mobile app that meets published health app design criteria, accessibility criteria, and universal design principles to improve the quality of life and social participation of individuals with cerebral palsy who have severe communication impairments.

Responsible Researcher and Contact Email

Álvaro Sabater Gárriz

Email: alvaro.sabater@uib.es

Participation in the Study

Your participation in the study will involve providing us with videos of the minor's face under your guardianship, lasting at least 5 seconds, when you believe they might be experiencing any type of pain, at any intensity level. You will need to send the videos via WhatsApp to the number 659751371, selecting the High Definition ("HD") option before sending the video.

The videos will be received on a mobile phone specifically designated for this purpose, with access restricted to the project's principal investigator, Álvaro Sabater Gárriz. Once received, the videos will be pseudonymized, without any personal data. A record will be kept to correlate personal data with anonymized data, stored on an encrypted external hard drive used exclusively for this purpose and belonging to the Neurodynamics and Clinical Psychology Laboratory of the University of the Balearic Islands (UIB), with access restricted to Álvaro Sabater Gárriz. The pseudonymized videos will then be transferred to a second encrypted external hard drive exclusively for this purpose, managed by the Graphics and Computer Vision & Artificial Intelligence Laboratory of the UIB, with access restricted to researchers José María Buades Rubio, Francesc Xavier Gayá Morey, and Cristina Manresa Yee.

These videos will be used exclusively to train neural networks, and their viewing will be limited to the researchers participating in the project. The training of neural networks involves teaching a computer to recognize patterns and make predictions based on examples. In this case, we will use the videos you provide to teach the computer to identify signs of pain in people with cerebral palsy. The computer will analyze these videos multiple times, adjusting its 'knowledge' until it can accurately recognize pain, similar to how a child learns to identify emotions by observing many different faces.

For this purpose, the videos will be stored for a maximum of 6 months, after which they will be deleted.

Only if you expressly consent in this document, images extracted from the videos may be retained in a restricted-access institutional repository of the University of the Balearic Islands as part of a database of pain expressions in people with cerebral palsy. You may revoke this specific consent at any time by notifying Álvaro Sabater Gárriz

(alvaro.sabater@uib.es). In such a case, the images will be immediately removed from the database.

Risks and Benefits of the Project

The minor under your guardianship may not receive any direct health benefits from participating in this study. However, it is expected that a better understanding of facial expressions in cerebral palsy will contribute to improving pain identification in this population, potentially influencing future treatments and management strategies.

The final results of this research project will be disseminated to contribute to future studies on human pain recognition and its potential application in expanding and enhancing existing treatment approaches.

This study does not involve any clinical intervention, and there are no associated risks for participating in it.

I UNDERSTAND THAT:

1. My child's/ward's/represented person's participation is voluntary from the beginning and throughout the duration of the study, meaning they can withdraw at any time without needing to provide explanations.

2. The confidentiality of the obtained data is guaranteed under these terms:

- Data will be treated confidentially and in accordance with current data protection regulations.
- I have all legal rights regarding this data, as detailed at the bottom of this consent form.
- The research team will use this data exclusively for scientific purposes and will never share it with third parties, except where legally required.
- The data will be retained for two years from the date of this consent.
- Data collection is based on informed consent (Article 6.1(a) of the GDPR), and processing is essential to achieving the research objectives (Article 6.1(e) of the GDPR).

I declare that I have read the study's informational section and have been sufficiently informed. I have had the opportunity to ask questions about the project's objectives and methodology.

☐ Yes, I authorize / ☐ No, I do not authorize the use of images extracted from the videos as part of a database of pain facial expressions in people with cerebral palsy.