INFORMED CONSENT FOR ADULTS

Project Title

Development of a Mobile Application Based on Artificial Intelligence to Identify Pain in Non-Communicative People with Cerebral Palsy

Participant's Full Name: _____

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.

Participation in the Study

Your participation in the study will involve providing us with videos of your face, lasting at least 5 seconds, while you are 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). Access to this data will be 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.

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.

Responsible Researcher and Contact Email

Álvaro Sabater Gárriz

Email: alvaro.sabater@uib.es

Risks and Benefits of the Project

You 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. These data will be handled confidentially and in accordance with current data protection regulations.

2. I have all legal rights regarding this data, as detailed at the bottom of this consent form.

3. This data will only be used for scientific purposes by the responsible research team and will never be shared with third parties, except where legally required. Data will be retained for 6 months from the date of this consent.

4. The project is legally authorized under Article 6.1(a) of the General Data Protection Regulation (GDPR) through informed consent, and data processing, as outlined, is the only way to achieve the research objectives (Article 6.1(e) of the GDPR).

I DECLARE THAT:

I have read the informational part of the study at the beginning of this document and have been fully informed. I have had the opportunity to ask questions about the project's objectives and methodology.

Therefore:

1. I voluntarily give my consent, knowing that I am free to withdraw from the study at any time, for any reason, without explanation, and without any negative consequences for me.

2. I agree to participate in the project and have received a copy of this consent form.

3. I give my consent for the submitted videos to be used for training deep neural networks in pain recognition.

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

Date (dd/mm/yyyy): _____

Participant Signature _____

Responsible Researcher _____