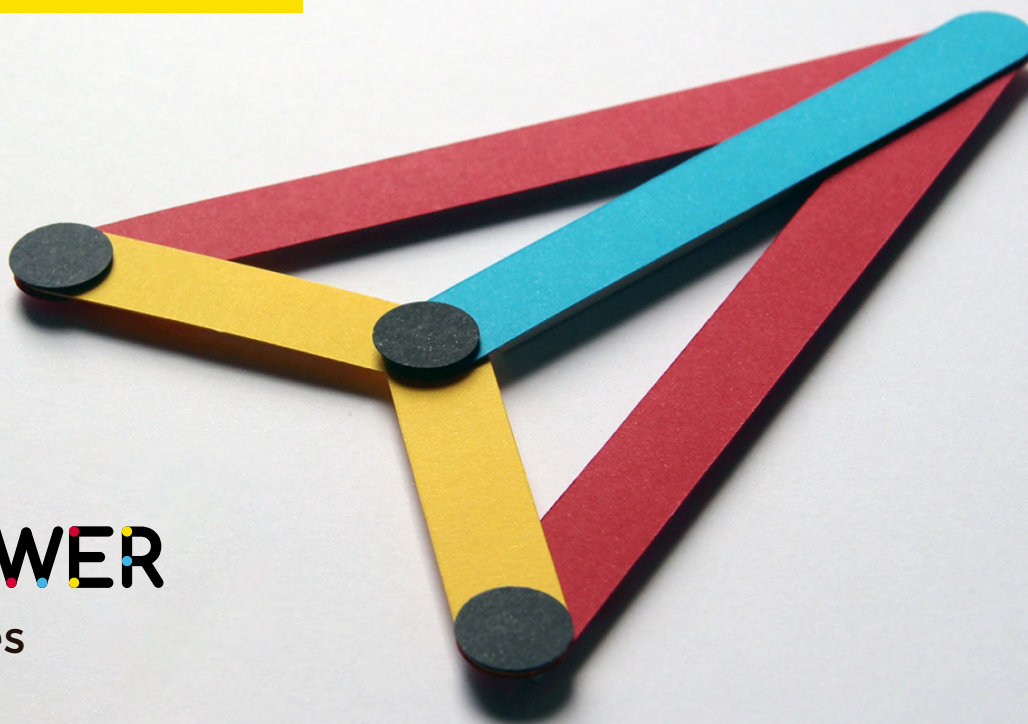


D1.5

# EMPOWER

deliverables



Deliverable name

Appointment of the Ethics Board

Type

R — Document, report

Dissemination level

PU - Public



1

This deliverable is to appoint an Ethics Board that will oversee the activities in the project, and be involved, in particular, in tasks T5.1-5.5

Description

WP.1

Work Package No.

Lead beneficiary - UVEG



## Table of contents

<b>1. Context: Ethics Self-Assessment.....</b>	<b>2</b>
<b>1.1 Ethical dimension of the objectives, methodology and likely impact .....</b>	<b>2</b>
Methodology .....	2
<b>1.2 Compliance with ethical principles and relevant legislations .....</b>	<b>3</b>
The need for an Ethics Board .....	3
<b>2. Appointment of the Ethics Board.....</b>	<b>4</b>
<b>2.1 Maria Spante (Sweden) .....</b>	<b>4</b>
Full name .....	4
Position.....	4
Short Bio .....	4
Why is she appropriate for that work in EMPOWER? .....	4
Contact information .....	4
<b>2.2 Cristian Buică-Belciu (Romania) .....</b>	<b>5</b>
Full name .....	5
Position.....	5
Short Bio .....	5
Why is she appropriate for that work in EMPOWER? .....	5
Contact information .....	5
<b>2.3 Arturo López Fernández.....</b>	<b>5</b>
Full name .....	5
Position.....	5
Short Bio .....	5
Why is he appropriate for that work in EMPOWER? .....	5
Contact information .....	6
<b>3. Disclaimer.....</b>	<b>6</b>

# 1. Context: Ethics Self-Assessment

## 1.1 Ethical dimension of the objectives, methodology and likely impact

The EMPOWER project involves studies on children with a diagnosis of neurodevelopmental disorders (NDDs), specifically by the universities in Romania and Portugal. We will acquire the Ethics Approval of the ethical committees of the involved universities. We will provide understandable information sheets regarding the procedure of the study, the data analysis, confidentiality, possible risks and the forms to acquire free informed consent. The free informed consent will be obtained from legally authorized representatives of the child, and we will make sure that they receive sufficient and understandable information to enable them to consent on behalf and in the best interests of the participants.

The inclusion criteria will be based on the children's age and their prior diagnosis of NDDs. Also, the age will be limited to 6 to 9 because of the nature and level of difficulty of the tasks. Participation is voluntary, and anyone has the right to refuse to participate and to withdraw their participation or data at any time (before, during or after the studies) without any consequences. The objectives of our studies are to validate a technological platform that assesses the emotional and cognitive factors of children with NDDs and to test the effectiveness of a technology-based intervention which aims in reducing challenging behaviours, and emotional problems and increase school integration for children with NDDs. 10-12 children will be recruited for the pilot studies, one sample from Romania and one sample from Portugal and 84 children will be recruited for the validation study and randomized clinical trial (RCT) from Romania.

### Methodology

In our validation study and RCT, children will participate in an assessment by the platform, which will consist of several games which will measure executive functions and emotion regulation strategies. Physiological data (heart rate) will be collected through fitness bracelets, and behavioural observations will be acquired from parents and teachers who will have access to the application. The equipment used will be selected on its technical robustness and safety. For testing the effectiveness of the EMPOWER platform in reducing challenging behaviours and emotional problems, as well as in increasing executive functioning ASD we will implement 20 sessions of interventions and a post-test assessment of their behaviours and emotions.

Regarding the AI component, the project and studies will adhere rigorously to the 7 requirements of trustworthy AI as specified by the EU. All data collection and storage will take place under human control, by experts that guarantee human agency and oversight. The data will be pseudonymized and stored on privacy-secure project-hosted computers. Controlled access to qualified researchers will be enabled on request to the consortium. The platform's measurements and recommendations for the assessment of children and possible interventions will be monitored ('on loop') by human experts. All decisions will be made by human users and researchers. Platform operations will be made transparent by ensuring traceability and explainability according to the wishes of participants and stakeholders. The studies are currently small-scale, but within the participant groups diversity, non-discrimination and fairness in terms of access and evaluation will be ensured.



The potential impact of the activities is the increased support for learning of children diagnosed with NDD. The evaluation and psychological interventions proposed will be selected on their non-maleficence. All the data will be used only for scientific purposes and all the data will be confidential. Our activities do not contribute to the stigmatization of any groups and the participants will be able to stop the interventions whenever they want. We will make sure that ethical guidelines are respected concerning data protection and working with a vulnerable population (e.g., informed consent procedures, codes of conduct, data protection, and confidentiality, disclaimer, and referral options). Our activities within the project do not involve invasive techniques. Our results will benefit the participants by helping them to improve their executive functioning and emotion regulation strategies.

## 1.2 Compliance with ethical principles and relevant legislations

In order to adhere to the ethical principles, we will take regular, complete, and documented measurements of compliance with the International, EU, and national laws, regulations, and codes of conduct. We will respect national regulations and international codes of conduct: The Nuremberg Code (October 1946 April 1949), World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects, all relevant World Health Organisation resolutions, The UN Convention on the Rights of the Child, The Universal Declaration on the human genome and human rights adopted by UNESCO, Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Directive 2001/20/EC. We will organize an ethical audit, inviting external ethics consultants, of our procedures, applications, and interventions at the start of our main studies. Moreover, to implement our studies we will contact the Ethical Committee of Babes-Bolyai University and Instituto Universitario de Lisboa and ask for their Ethical approval and use Informed consents forms and Information sheets for the enrolment of the participants. Regarding data protection, we will consult the legislation of protection of individuals with regard to the processing of personal data and on the free movement of such data and we respect all the regulations regarding data protection. We will avoid the unnecessary data collection and use of personal data, and we will consider issues of informed consent for any data being used. We will ask for specific consent for the data that will be shared with other stakeholders or the scientific community.

### The need for an Ethics Board

In order to supervise the fulfilment of all these principles, an Ethics Board will be appointed by month 1 as part of 1.5 Task “Ethical compliance”. This ethics board will be created where the members will have specific experience in the ethical issues of research with children with NDD, data protection, safe AI and medical device regulatory requirements.

The work of the Ethics board will consist on producing 5 reports/deliverables at:

- Month 6 (March 2023)
- Month 12 (September 2023)
- Month 18 (March 2024)
- Month 30 (March 2025)
- Month 36 (October 2025)

The members of the Ethics board will participate in the project meetings that will take place on the same months detailed above. For the first meeting (March 2023) and the last meeting (October 2025) they will attend physically. They will attend other three meetings online.

The ethics board will be provided with a template with all the relevant information fields that should be covered in each report. RU will lead this work with the support of UVEG which will carry out its coordination and the necessary administrative work to pay the members' expenses. A task for Ethics compliance has been added to WP1 (Project Management and Coordination).

## 2. Appointment of the Ethics Board

In their first (Kick-off) meeting, EMPOWER Consortium agreed to appoint the following members for the Ethics Board:

### 2.1 Maria Spante (Sweden)

#### Full name

Maria Spante

#### Position

Senior lecturer, Docent at University West, Sweden

#### Short Bio

PhD from Chalmers, Sweden, in Social Interaction in Virtual Environments. She works at the University West, Sweden as Associate professor, Senior Lecturer and is elected Head of quality board of PhD education in Work Integrated learning at University West. Furthermore, she is elected member of the national steering committee of Swedish Information Systems Academy (SISA), and elected member of the prize committee of Börje Langefors award for best national PhD in Information Systems annually. She is experienced with national and international projects with a focus on processes of digitalization and professional agency for organizational development of schools.

#### Why is she appropriate for that work in EMPOWER?

Spante will be able to advise the EMPOWER project on handling digitalization in schools in international settings with the focus on contacting children, teachers, and children's parents for data collection and data management, essential issues in the Ethics Summary Report. EMPOWER will collect sensitive data about children's health and well functioning, and with Maria Spante's experiences in projects focusing on digitalization in schools and data protection. Spante is well-placed to advise on the ethical issues of processing such data. Her expertise will be beneficial in evaluation and guidance on data management, consent/assent procedures, as well as ensuring compliance with relevant regulations such as GDPR, Helsinki Declaration in combination with national regulations from the Swedish Research Council.

#### Contact information

[maria.spante@hv.se](mailto:maria.spante@hv.se)

+46 520223524



## 2.2 Cristian Buică-Belciu (Romania)

### Full name

Cristian Buică-Belciu

### Position

Associate Professor, Head of Special Education Department, University of Bucharest

### Short Bio

Cristian Buică is a well-known professor and researcher in the domain of special education. He worked in several international projects developing digital tools for assessment and intervention for children with special needs. His previous work in the domain of intervention and assessment through technology for children with special educational needs and in European projects funded by the European Commission recommends him for being part of the Ethical Board of the EMPOWER Project.

### Why is she appropriate for that work in EMPOWER?

He will be able to analyse and give input in regard to the informed contents, implementation of the assessment and intervention protocol and the use of personal data. He will be able to advise in regard to teachers training and intervention procedures.

### Contact information

[cristian.buica-belciu@fpse.unibuc.ro](mailto:cristian.buica-belciu@fpse.unibuc.ro)

+40 0728 767 055

## 2.3 Arturo López Fernández

### Full name

Arturo López Fernández

### Position

Clinical neuro-psychologist in “Autismo Ávila association”. Lecturer in the “Department of Developmental Psychology and Education” at the “University of Salamanca”

### Short Bio

Arturo López Fernández is a clinical neuropsychologist who works in Autismo Ávila, with the aim of offering support and improving the quality of life of autistic people. He is part of the team of different European Erasmus+ projects. He also works as a lecturer and researcher at the University of Salamanca.

### Why is he appropriate for that work in EMPOWER?

Arturo López has specific training and experience in the field of neuropsychology, which involves specific knowledge related to executive function and emotion regulation. This experience combines theoretical and practical knowledge, so he will be able to work as a link between technical issues and the legal obligations derived from data processing. His experience working with children of different ages makes him a good resource to know if the activities that are being carried out threaten the individuality of each child, ensuring that their basic rights are respected.



Contact information

[psicologia@autismoavila.org](mailto:psicologia@autismoavila.org)

+34 639068219

### 3. Disclaimer

The sole responsibility of this publication lies with the author. The European Union is not responsible for any use that may be made of the information contained therein.