Information sheet for the ePRO-Schools project

Electronic plarform for Health Promotion in Schools (ePRO-Schools project)

Study led by the Fundació Institut Universitari per a la recerca a l'Atenció Primària de Salut Jordi Gol i Gurina (IDIAP-Jordi Gol) and financed by the "Era4health Partnership" program of the European Commission (EC)

Principal researcher: Josep Vidal-Alaball

- Consent for the participation of the adolescent-

This information sheet provides details of a research project in which we propose that you take part. Please take the time to read this information carefully and ask any questions you may have.

- **Why are we conducting this study?**

There is little high-quality information on physical activity, sedentary behavior and dietary habits focused on adolescents. Therefore, there are a limited number of public health and education policies designed specifically for this population group. The ePro-Schools project aims to address these shortcomings by designing and implementing an electronic health platform (an application or app) to promote healthy habits among teenagers. The design of this application will be done with the active participation of students and teachers.

The study will be carried out in the area of Central Catalonia. In total, 1,000 teenagers from 6 secondary schools will participate. We will carry out a participatory process to design the app and a study to test the effectiveness and profitability of its implementation, with the aim of promoting physical activity and healthy dietary habits of adolescents, as well as reducing sedentary behavior.

The project has received funding from the Instituto de Salud Carlos III (ISC-III) under the umbrella of the Association for the promotion of a European research area for health (ERA4Health) (GA no. 101095426 of the Horizon of the EU). European Program for Research and Innovation).

- **What do I have to do to participate in the ePRO-Schools project?**

  First of all, you should know that your participation is voluntary. Therefore, it is you who decides to participate, together with your parents or legal guardians. To participate in the project you must:

  - Read and sign the informed consent, both you and your parents or legal guardians.
  - Actively participate, when asked, in the activities proposed to design and validate the app and promote it.
  - Answer three questionnaires about you, your health and lifestyle over the course of a year.
  - Allow the measurement of your height, weight and waist circumference also three times a year.

- **What happens if I decide to withdraw?**

Your participation in the study is completely voluntary. You have the right to withdraw from the study at any time. If you decide to leave the study, we will keep the data obtained until that time, unless you explicitly request that it be destroyed.

- **What advantages do I have for participating in this project?**

- You will learn how a research project works, and you will also be an active part of it.
- If you are chosen to participate in a smaller subgroup, you will also learn how to create guidance documents for making public health policy and recommendations.
- You will contribute to the development of a tool that, once validated, will be promoted for use, while contributing to the acquisition of healthy habits in the adolescent population.

- **What do I have to do to know the results of the project?**

Individually we will not be able to give results, since by themselves they have no informative value. Therefore, it is necessary to treat the information of all participants together in order for the results to have scientific meaning. The overall results of the project will be published in scientific journals and we will also disseminate them on the project website and social networks. We will also get back to all participants with the main conclusions of the study. No publication will identify individuals individually, and no individual results will be available.

- **Who is organizing this research?**

This research is organized by the Fundació Institut Universitari per a la recerca a l'Atenció Primària de Salut Jordi Gol i Gurina (IDIAP-Jordi Gol), in collaboration with other Catalan and European research centers, including the Centro de Investigación biomédica network (CIBER)-Mental Health (SAM).

- **How do we treat the information we collect and how do we guarantee the confidentiality and protection of your personal data?**

The data will be treated with absolute confidentiality and in accordance with Regulation (EU) 2016/679 of the European Parliament and of the Council, of April 27, 2016, relating to the protection of individuals with regard to the processing of data personal data and the free circulation of this data and Organic Law 3/2018, of December 5, on the protection of personal data and the guarantee of digital rights.

Health data will be kept separate from personal data. Data dissociation means that your health information cannot be associated as your personal data is replaced by a code. Dissociated information will be archived for use by project researchers and their research partners. All the results of the study will be presented in a database of the group of participants, data will never be presented individually.

Below is the information on the protection of personal data, please read it carefully and consult us if you have any questions:

- ***Who is responsible for the processing of your personal data?***

Fundació Institut Universitari per a la recerca a l'Atenció Primària de Salut Jordi Gol i Gurina (IDIAP-JGol), CIF: G60954104, Adreça postal: Gran Via Corts Catalanes, 587, àtic, 08007, Barcelona. Delegat de Protecció de Dades, contacte: Josué Sallent Ribes, at dpd@ticsalutsocial.cat).

- ***For what purpose do we process your personal data?***

In accordance with your participation in the "ePRO-Schools: Electronic Platform for the Promotion of Health in Schools" research project, the Data Controller informs you that, in compliance with the provisions of the General Regulation on the Protection of data (hereinafter RGPD) and Organic Law 3/2018, your personal data will be used to carry out the research in which you have consented to participate. Likewise, it is important to inform you that personal data, if you give your consent, may also be used for other projects/research within the area of this project.

- ***What is the legitimacy for the processing of your personal data?***

The legal basis for data processing is the consent you have provided by accepting the data processing clause. Obtaining your data is necessary to carry out the research project without which it could not be carried out, without prejudice to the fact that at any time you have the right to withdraw the consents given, without this affecting the lawfulness of the treatment carried out prior to withdrawal.

- ***How long will we keep your personal data?***

The data provided will be kept as long as the research project is active or the successive research projects within the same area or line of research where your personal data is processed, in accordance with the criteria established by current legislation . The data will be kept for five years in pseudo-anonymized format, and then will be transferred in an anonymized format to a repository (this means that no one will ever be able to link your data to your person).

- ***To which recipients will your personal data be communicated?***

This information will be used by the Research Group in charge of the investigation/s (in particular, the study researcher and his collaborators, health authorities, and the promoter's monitors and auditors) who will be subject to the duty of secrecy inherent in his profession, to verify the data and procedures of the study, but always maintaining confidentiality in accordance with current legislation. The information will also be transmitted to public or private official bodies that, due to legal obligation or material need, must access the data for the purposes of the correct development of the research project, in accordance with good scientific practices.

For transfers to third countries, only encoded data will be transferred, which will in no case contain information that can directly identify you (for example, first and last name, initials, address, social security number, etc.). Should this transfer occur, it would be for the same purposes described in this document and guaranteeing confidentiality. If a transfer of coded data is made outside the European Economic Area, either to entities related to the center where you participate, to service providers to researchers who collaborate with us, your data will be protected by safeguards such as contracts or other mechanisms established by data protection authorities.

The data obtained can be published in scientific repositories intended to share information between researchers to speed up research. In case the data is shared through repositories, a minimization criterion will be followed, that is to say, the information shared will be limited and its anonymity will be guaranteed by avoiding the publication of data that can identify it.

- ***What are your rights when you provide us with your personal data?***

You are responsible for the veracity and correctness of the data you provide us and you have the right to exercise the rights of access, rectification, deletion, limitation of treatment, portability and opposition of your data in accordance with the that the regulations on data protection provide. To exercise them, you must write to the Data Protection Officer, Josué Sallent Ribes, at dpd@ticsalutsocial.cat. In any case, a photocopy of your national identification document or equivalent must be attached. Finally, in addition to the possibility of exercising your rights, if you

do not agree with the treatment carried out by the Entity or if you consider that your rights have been infringed, you can submit a claim at any time to the Spanish Data Protection Agency (http://apdcat.gencat.cat).

Thank you for reading this information sheet and considering participating in this study. If you want more information about the study, contact:

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Carrer de Soler i March, 6
08242 Manresa (Barcelona)
Telèfon : +34 93 874 81 78
Email: mgascon@idiapjgol.org

ePRO-Schools

Principal researcher: Josep Vidal-Alaball

ID

Consent form for participation in the ePRO-Schools project "Electronic Platform for the Promotion of Health in Schools"

- Consent of the adolescent and their parents or legal guardians -

(Example for participants)

- I have received and read the information sheet on the ePRO-Schools study.
- I had the opportunity to ask questions about the study.
- I have received sufficient information about the study.
- I spoke with _____, who clarified all my doubts
- I understand that my participation is voluntary.
- I understand that I have the freedom to withdraw from the study at any time and without the need for justification and without this affecting my legal rights.
- I understand that the study is designed to increase medical and scientific knowledge and promote health.
- I understand that the information I provide will be treated with strict confidentiality and in accordance with current legislation.
- I have been informed that the study has been approved by the Scientific Research Committee (CEI) of the Jordi Gol i Gurina University Institute for Research in Primary Health Care Foundation (IDIAPJGol).
- I understand that all results are confidential.
- I freely accept my consent to participate in the study.

Faced with this information that the Data Controller has given me, and having understood this, I offer my consent to the treatment of:

☐ My personal data (name and surname)_____ to carry out the research project

Signature of the participant (adolescent)	*Signature of the mother/legal guardian*	*Signature of the father/legal guardian*	*Signature of the researcher*

*Place and date:*_____

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Principal researcher: Josep Vidal-Alaball

ID

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- Consent for the participation of the teachers-

This information sheet provides details of a research project in which we propose that you take part. Please take the time to read this information carefully and ask any questions you may have.

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- **Què he de fer per participar al projecte ePRO-Schools?**

First of all, you should know that your participation is voluntary. Therefore, it is you who decides to participate. To participate in the project you must:

- Read and sign the informed consent.
- Give your contact details (e-mail and telephone) in order to be able to coordinate with the field workers of the project.
- Actively participate, when asked, in the activities proposed to design and validate the app and promote it.
- Help collect data of interest for the project.
- Answer questionnaires about your students.

- **What happens if I decide to withdraw?**

Your participation in the study is completely voluntary. You have the right to withdraw from the study at any time. If you decide to leave the study, we will keep the data obtained until that time, unless you explicitly request that it be destroyed.

- **What advantages do I have for participating in this project?**

  - You will learn how a research project works, and you will also be an active part of it.
  - If you are chosen to participate in a smaller subgroup, you will also learn how to create guidance documents for making public health policy and recommendations.
  - You will contribute to the development of a tool that, once validated, will be promoted for use, while contributing to the acquisition of healthy habits in the adolescent population.

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ePRO-Schools

Principal researcher: Josep Vidal-Alaball

ID

Consent form for participation in the ePRO-Schools project "Electronic Platform for the Promotion of Health in Schools"

- Consent of the teacher-

(Example for participants)

- I have received and read the information sheet on the ePRO-Schools study.
- I had the opportunity to ask questions about the study.
- I have received sufficient information about the study.
- I spoke with _____, who clarified all my doubts
- I understand that my participation is voluntary.
- I understand that I have the freedom to withdraw from the study at any time and without the need for justification and without this affecting my legal rights.
- I understand that the study is designed to increase medical and scientific knowledge and promote health.
- I understand that the information I provide will be treated with strict confidentiality and in accordance with current legislation.
- I have been informed that the study has been approved by the Scientific Research Committee (CEI) of the Jordi Gol i Gurina University Institute for Research in Primary Health Care Foundation (IDIAPJGol).
- I understand that all results are confidential.
- I freely accept my consent to participate in the study.

Faced with this information that the Data Controller has given me, and having understood this, I offer my consent to the treatment of:

☐ My personal data (name and surname)_____ to carry out the research project

Signature of the participant (teacher)	*Signature of the researcher*

Place and date: _____

ePRO-Schools

Principal researcher: Josep Vidal-Alaball

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Consent form for participation in the ePRO-Schools project "Electronic Platform for the Promotion of Health in Schools"

- Consent of the teacher-

(Example for participants)

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Signature of the participant (teacher)	*Signature of the researcher*

Place and date: _____