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The Health4Life app Pilot Study PARENTAL INFORMATION STATEMENT

(1) What is this study about?

Your child is invited to take part in a new research project examining the acceptability and impact of a healthy lifestyles app called the Health4Life app and the acceptability and impact of different types of text messages, sent at different times of the day to prompt adolescents to use the Health4Life app.

The Health4Life app is designed to help prevent and modify key risk factors for chronic disease, such as cardiovascular disease, type 2 diabetes and cancers. The Health4Life app addresses six key health habits (“the Big 6”): eating healthily, being physically active, sleeping well, limiting screen time, and avoiding alcohol use and smoking.

This Participant Information Statement tells you about the research study. Knowing what is involved will help you decide if you want to let your child take part in the research. Please read this sheet carefully and ask questions about anything that you don’t understand or want to know more about.

Participation in this research study is voluntary.

By giving your consent you are telling us that you:

- ✓ Understand what you have read.
- ✓ Agree for your child to take part in the research study as outlined below.
- ✓ Agree to the use of your child’s personal information as described.

You can download a copy of this Parental Information Statement to keep here [*insert link to downloadable copy*].

(2) Who is running the study?

The study is being carried out by the following researchers: Dr Louise Thornton, Professor Maree Teesson, Dr Katrina Champion, Prof Angela Webster, Associate Professor Nicola Newton, Associate Professor Cath Chapman, Dr Louise Thornton, Associate Professor Tim Slade, Associate Professor Katherine Mills, Dr Matthew Sunderland and Dr Lauren Gardner from the University of Sydney, and Professor Frances Kay-Lambkin and Dr Hannah Brown from the University of Newcastle.

This research is being funded by the Paul Ramsay Foundation and the National Health and Medical Research Council’s Clinical Trials Centre.

(3) What will the study involve?

If you consent for your child to take part in this research study, they will be asked to complete a confidential online questionnaire which will ask about their socio-demographic information (e.g. gender, age) and their current health behaviours and beliefs. The survey should take no longer than 20 minutes.

Following this, your child will be asked to download the Health4Life app to their smartphone and use it for 30 days. During this time, they will receive text message prompts to engage with the app – the timing and content of these messages will vary day to day. Each day, for the 30-days, your child will, at random, receive a message before school, after school or both before and after school.

At the end of the 30 days, your child will be asked to complete a brief online follow-up assessment and will receive a request via email/text message. At this time your child will also be asked to indicate their interest in participating in a telephone or zoom interview regarding their opinions and experiences with the Health4Life app. Interviews will be approximately 20 minutes long and will be conducted with a member of the research team over the phone or via zoom (depending on your child's preference).

(4) How much time will the study take?

The baseline online survey and follow-up online survey will take no longer than 20-30 minutes each to complete. Your child can then choose to use the Health4Life as much or as little as they would like. The app encourages users to record their health behaviours each day which takes less than 5 minutes. The app also contains seven detailed modules your child can choose to work through to learn tips and strategies for improving their health behaviours which take approximately 20 minutes each to work through. Additionally, if your child chooses to participate in a telephone or zoom interview, they will be approximately 20 minutes long.

(5) Who can take part in the study?

Young people aged 13-17 years who are living in Australia, have access to a smartphone and are willing to download the Health4Life app.

(6) Does my child have to be in the study? Can they withdraw from the study once they've started?

Being in this study is completely voluntary and your child does not have to take part. Your decision whether to let them participate will not affect your/their relationship with the researchers or anyone else at the University of Sydney or the University of Newcastle, now or in the future.

If you decide to let your child take part in the study and then change your mind later (or they no longer wish to take part), they are free to withdraw from the study at any time. You can do so by completing the 'Withdrawal of Participation Form' which is provided at the end of this document. If you are receiving this form via email, you can also click the withdrawal link at the end of the email. Alternatively, you can ring the research team and tell them you no longer want your child to participate

Your child's questionnaire responses can be withdrawn after submission and will not be included in publications, up to the point that we have analysed and published the results.

(7) Are there any risks or costs associated with being in the study?

We don't expect the study to cause any harm or discomfort, but if your child experiences feelings of distress because of their participation in this study they can contact a member of the research team

(their details are listed below). Alternatively, contact details for services are provided in the Health4Life app and at the end of each survey.

(8) Are there any benefits associated with being in the study?

We cannot guarantee that your child will receive any direct benefits from being in the study. After your child has completed the baseline survey and downloaded the Health4Life app they will receive a \$25 e-gift voucher, and when they complete the follow-up survey 30 days later, they will receive a \$15 e-gift voucher. If your child participates in a telephone or zoom interview they will receive an additional \$15 e-gift voucher

(9) What will happen to information that is collected during the study?

By providing your consent, you are agreeing to us collecting personal information about your child for the purposes of this research study. Their personal information will only be used for the purposes outlined in this Participant Information Statement, unless you consent otherwise.

Your child's information will be collected via online questionnaires and their data will be stored securely and confidentially, housed on a secure server at the University of Sydney. Information entered into the Health4Life app is hosted by our web development company on an external server. The external server is based in Australia, and complies with Australian standards in security, ethics, and integrity. At the end of the study all data collected by Health4Life app will be transferred to a secure server at the University of Sydney and deleted from the external server. Study findings may be published, but your child will not be individually identifiable in these publications.

We will keep the information we collect for this study for a minimum of 20 years, after which time it will be securely disposed. We may use data collected in this study in future projects. By providing your consent you are allowing us to use your child's information in future projects. We don't know at this stage what these other projects will involve, however we will seek ethical approval before using the information in these future projects.

We may give the information from this project to other researchers so that they can use it in their projects. Before we do so, we will take out all the identifying information so that the people we give it to won't know whose information it is. The other researchers won't know that your child participated in the project, and they won't be able to link your child to any of their personal information.

(10) Can I or my child tell other people about the study?

You are free to tell other people about this study and we would be grateful for you to do so.

(11) What if we would like further information about the study?

If you or your child would like to know more at any stage during the study, please feel free to contact Dr Louise Thornton (Senior Research Fellow, louise.thornton@sydney.edu.au). Dr Thornton will happily discuss the study with you further and answer any questions you may have.

(12) Will we be told the results of the study?

You and your child have a right to receive feedback about the overall results of this study. This feedback will be in the form of a one or two-page summary document and will be provided after the study is finished.

(13) What if we have a complaint or any concerns about the study?

Research involving humans in Australia is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by the HREC of the University of Sydney [.....]. As part of this process, we have agreed to carry out the

study according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect people who agree to take part in research studies.

If you (or your child) are concerned about the way this study is being conducted or wish to make a complaint to someone independent from the study, please contact the university using the details outlined below. Please quote the study title and protocol number.

The Manager, Ethics Administration, University of Sydney:

- **Telephone:** +61 2 8627 8176
- **Email:** ro.humanethics@sydney.edu.au
- **Fax:** +61 2 8627 8177 (Facsimile)

PARENT/CARER CONSENT FORM

After reading the information sheet, if you wish for your child to participate in the study you can complete the form below online at [insert link to online form].

Research Study: The Health4Life app Pilot Study

Dr Louise Thornton (Responsible Researcher)

The Matilda Centre for Research in Mental Health and Substance Use

Phone: +61 403744089 | Email: Louise.Thornton@sydney.edu.au

In giving my consent I state that:

- ✓ I understand the purpose of the study, what my child will be asked to do, and any risks/benefits involved.
- ✓ I have read the Information Statement and have been able to discuss my child's involvement in the study with the researchers if I wished to do so.
- ✓ The researchers have answered any questions that I had about the study and I am happy with the answers.
- ✓ I understand that being in this study is completely voluntary and my child does not have to take part. My decision whether to let them take part in the study will not affect our relationship with the researchers or anyone else at the University of Sydney or University of Newcastle now or in the future.
- ✓ I understand that my child can withdraw from the study at any time.
- ✓ I understand that personal information about my child that is collected over the course of this project will be stored securely and will only be used for purposes that I have agreed to. I understand that information about my child will only be told to others with my permission, except as required by law.
- ✓ I understand that the results of this study may be published, and that publications will not contain my child's name or any identifiable information about my child.

I agree for my child may take part in this research study.

- Yes
- No

Parent/Carer's First Name

Parent/Carer's Surname

Child's First Name

Child's Surname

Date

FORM FOR WITHDRAWAL OF PARTICIPATION – PAPER AND PENCIL

You can return this page at any time to revoke consent and withdraw your child from this study.

I wish to **WITHDRAW** my consent for my child to participate in this research study described above and understand that such withdrawal **WILL NOT** affect my relationship with The University of Sydney.

Participant Signature

Name of Child Participant (please print)	
Name of Parent/Carer (Please print)	
Signature of Parent	
Date	

The section for Withdrawal of Participation should be returned to your child's school or forwarded to Dr Louise Thornton (Louise.Thornton@sydney.edu.au).