

Implementing wearable devices into the 45 and Up Study

July 2024

This research project is in addition to the main 45 and Up Study. Participation is voluntary. Participation in this project does not change your involvement in the main 45 and Up Study. Information collected by this research project will become part of the 45 and Up Study in future.

What is this research project about?

This pilot study will test the feasibility of implementing wearable devices, worn for seven (7) consecutive days on the wrist and/or thigh, that track activity, sedentary behaviour, and sleep in the 45 and Up Study. Part of this study is to request participant feedback on their preferred wear placement for future implementation in the full 45 and Up Study.

Taking part in this research project is completely voluntary.

Please read this information carefully and ask questions about anything that you don't understand or want to know more about.

Who is running the research project?

The project is being carried out by researchers at the University of Sydney, including:

- Professor Emmanuel Stamatakis
- Dr. Matthew Ahmadi

This research project is being funded by National Health and Medical Research Council. This research project is affiliated with the Royal Prince Alfred Hospital (RPAH).

Who can take part in the research project?

You are invited to take part in this research project because you are a current participant in the 45 and Up Study.

How do I join this research project?

If you agree to participate in the research project, we ask you to read, complete and submit the consent form.

If you are not interested in participating, you do not need to do anything further, but if you wish to you can inform the 45 and Up team by emailing 45andUp@saxinstitute.org.au or calling the Infoline 1300 45 1145. Your details will not be shared unless you give consent to join this research project.

What will the research project involve for me?

You will be asked to wear an activity monitor over 7 consecutive days and nights and complete a questionnaire that will take approximately 3-5 minutes to complete providing your feedback about wearing the device, demographic information, and about your leisure time and household tasks in the last month. You will be asked to return the monitor and questionnaire in a pre-paid postal envelope that will be provided for you.

By signing the consent form, you consent to the research project investigators collecting and using personal/health information about you. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Any information obtained that can identify you (such as your name, address, phone numbers and email address) will be stored at the University of Sydney and kept completely confidential on a

secure password-protected data repository. Any identifiable information will not be shared with anyone outside of the research project site without your permission and we will make sure to keep this information separate to your health information.

Your identifiable information will only be visible to the research project site and delegated research staff at the University of Sydney, and will be login and password-protected. This information will be identified by a unique study number and your identifying details will be removed from the information you give to research study investigators at the completion of the project.

As part of this research project, the information collected will be linked to health information that you have already provided to the 45 and Up Study and to records that you have previously allowed the 45 and Up Study to access.

Can I withdraw once I've started?

Being in this research project is completely voluntary and you do not have to take part.

If you wish to withdraw, you can do so at any time without having to give a reason. Your decision will not affect your current or future relationship with the researchers or anyone else at the University of Sydney, your involvement in the main 45 and Up Study, or the Sax Institute. You can withdraw from the research project and remain in the 45 and Up Study.

If you decide to withdraw consent for participation in this research project or if you decide to take part in the project and then change your mind and want to withdraw, please contact the 45 and Up Study team on the Infoline 1300 45 11 45 or by email 45andUp@saxinstitute.org.au. The Study team will advise the research project team about the withdrawal.

If you choose to withdraw, we will not collect any more information from you. If participants choose to withdraw, personal information will be deleted and removed. Information already collected will be kept in our records and may be included in the project results in a de-identified manner, where any identifying details will be removed.

Are there any risks or costs?

Aside from giving up your time, we do not expect that there will be any risks or costs associated with taking part in this research project nor will you be paid. Taking part in this project is considered to be of a low risk.

Are there any benefits?

There will be no immediate personal benefit to you from your participation in the research project. This project aims to assess the feasibility of implementing wearables in the wider 45 and Up Study cohort.

What will happen to information that is collected?

By agreeing to be part of this research project, you agree to the Sax Institute providing the investigators with:

- Information relevant to this research project that you previously provided to the 45 and Up Study including information from questionnaires
- Data and/or information that you provide as part of this research project
- Information relevant to this research project that is collected via data linkage as part of the 45 and Up Study

After a period of 15 years, any information related to this project within the research project site will be permanently deleted from the computer system and any hard copies will be destroyed.

The information will also become part of the 45 and Up Study resource. It will be stored by the Sax Institute for the life of the 45 and Up Study plus 7 years and combined with other information from the 45 and Up Study. All future research projects using this information will require approval from a relevant human ethics committee and the Sax Institute.

By providing your consent, you are agreeing to us collecting information about you for the purposes of this research project and any future approved 45 and Up Study research. Any information you provide to us will be stored securely and we will only disclose it with your permission unless we are required by law to release information. There will be no identifiable information published from the research project or any other research.

It is anticipated that the results of any research will be published and/or presented in a variety of forums. All results will be published and/or presented in summarised formats and will be provided in such a way that you will not be individually identifiable in these publications and/or presentations.

The conduct of the 45 and Up Study is overseen by the University of NSW Human Research Ethics Committee and the conduct of the Implementing

wearable devices into the 45 and Up Study is overseen by the Sydney Local Health District Human Research Ethics Committee.

Will I be told the results of the research project?

No results from the research project will be provided directly to you, however updates on the progress and findings of this research may be included in the 45 and Up Study's regular participant newsletter and will be included on the Sax Institute website and Facebook page. You can also contact the Study team at any time if you have any questions about this research project. As it is not currently known how any future 45 and Up Study approved research project may use the information collected, it will not be possible to provide feedback for any other projects.

What if I would like further information?

For any questions or comments about this research project, or if you wish to withdraw

consent for participation, please contact the 45 and Up Study at the Sax Institute by email 45andUp@saxinstitute.org.au or call the Infoline 1300 45 11 45.

What if I have a complaint or any concerns?

The ethical aspects of this research project have been approved by the Human Research Ethics Committee (HREC) of The Sydney Local Health District (X24-0066) according to the National Statement on Ethical Conduct in Human Research (2007).

You can always contact the 45 and Up Study with any questions or issues. This study has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney Local Health District. Any person with concerns or complaints about the conduct of this study should contact the Executive Officer on 02 9515 6766 or SLHD-RPAEthics@health.nsw.gov.au and quote protocol number X24-0066.

About the 45 and Up Study

The 45 and Up Study is the largest general population program of health-related research ever conducted in Australia. More than 267,000 people aged 45 and over are participating in the Study, and they are being followed over time through routine follow-up questionnaires and linkage to health and other records.

The 45 and Up Study has been approved by the University of New South Wales Research Ethics Committee. Study participants have also given permission to be invited to participate in further research projects. Each of these research projects has been through a stringent review process prior to approval. Participation in these research projects is optional.

Study governance

The 45 and Up Study is owned and managed by the Sax Institute in collaboration with major partner Cancer Council NSW and partners the Heart Foundation and the NSW Ministry of Health.

About the Sax Institute

The Sax Institute is an independent, not-for-profit organisation that improves health and wellbeing by driving better use of evidence in policies, programs and services.

The Institute is a registered charity that works with governments, health organisations, research organisations and a network of experts nationwide to analyse policy problems and find the best evidence-based solutions.

Contact the Sax Institute about the 45 and Up Study

For any questions, comments, or complaints about the 45 and Up Study or this research project, to withdraw consent for participation or for further communication, please contact us:

Telephone: 1300 45 11 45 (toll-free Study Infoline)

Email: 45andUp@saxinstitute.org.au

In writing to:

Dr Martin McNamara, Chief Investigator,
45 and Up Study, GPO Box 5289, Sydney NSW
2001

Confidentiality

The 45 and Up Study, and any research projects associated with it, are bound by Commonwealth and State privacy legislation and guidelines: the Privacy Act 1988 (Cth), Health Records and Information Privacy Act 2002 (NSW); and the NSW Health Privacy Manual for Health Information. The 45 and Up Study has strict procedures and systems in place to safeguard participant confidentiality. The Study is also bound by strict scientific ethical accountability to the University of New South Wales:

Ethics Secretariat,

University of New South Wales,
Sydney NSW 2052

Telephone: (02) 9385 6222

Email: humanethics@unsw.edu.au

Thank you. We could not conduct the 45 and Up Study without the generosity of our participants. We are immensely grateful to all of you.

This information sheet is for you to keep.