

The SMART-phone and Wearable Data for Health Research Database

(SMART-Health)

PARTICIPANT INFORMATION SHEET

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My name is Professor Tim Chico. I am an NHS heart specialist (cardiologist) and researcher at the University of Sheffield.

My team and I invite you to take part in a study called SMART-Health (Smartphone and Wearable Data for Health Research Database).

This aims to understand how data from smartphones and wearables could predict, prevent, diagnose and monitor disease.

Taking part involves:

- Reading this information (should take less than 15 minutes) You can see and hear a video with voice and transcript here (INSERT URL WHEN TEXT APPROVED BY ETHICS)
- Reading and signing a consent (permission) form
- Completing a questionnaire at the start (takes less than 15 minutes)
- Completing questionnaires every 3 months after joining (takes less than 10 minutes each time)
- Allowing us to see your smartphone data showing your physical activity (steps)
- If you use a smartwatch or other wearable device allowing us to see data on your physical activity, sleep, and heart rate. We may offer to loan you a wearable if you need one.

You can contact us any time on smarthealth@sheffield.ac.uk

THIS PARTICIPANT INFORMATION SHEET AND CONSENT FORM WILL BE PRESENTED ELECTRONICALLY BUT AVAILABLE TO DOWNLOAD AND PRINT

- Giving permission to access your health-related records (such as NHS or administrative records)
- We will also ask for permission to see your location (GPS) data from your smartphone or wearable. **You can take part without allowing access to your GPS.**

It is entirely up to you whether or not to take part.

This leaflet explains what taking part involves. Please talk to family and friends if you wish.

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Why is SMART-Health needed?

Over 9 in 10 UK adults use a smartphone or wearable (like a smartwatch). These generate lots of data on the user's health like their sleep, physical activity, and heart rate. Location (GPS) data can help understand a person's mobility (such as how far they travel) and environment (such as exposure to air pollution).

Data from smartphones and wearables is very valuable for research. However, researchers have little access to such data at the moment. This prevents important medical discoveries.

- **SMART-Health will collect smartphone and wearable data from up to 10,000 volunteers.**
- **We will remove anything that identifies these people and securely store their smartphone and wearable data alongside their health-related information (such as their medical record).**
- **SMART-Health will help researchers understand how smartphone and/or wearable data could be used to predict, prevent, treat or monitor diseases in future.**

Why am I being invited to join SMART-Health?

We want to recruit 10,000 people over 18 of different ages, sex, backgrounds and lifestyles who use a smartphone or wearable device, can use email, and can give permission to join. We need people **from all groups and communities**, living with any health conditions, or in good health, to take part.

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Do I have to join?

No. It is entirely up to you. Your decision will not affect your medical care. If you join but change your mind, **you can leave at any point.**

What does SMART-Health involve?

If you join, we will ask you to:

- **Read and sign an electronic consent form** giving your permission to take part.
- **Give your permission for us to obtain, store, and use your identifiable data** such as your name, date of birth and address. **This will never be shared with researchers or made public**
- **Use the SMART-Health smartphone app.** You will be shown how to download and use this. Most people will use their own smartphone, and their own wearable if they have one. However, some people may be loaned devices to help them take part.
- Give your permission to **access, store and analyse the following types of data from your smartphone** (and wearable device if you use one, or if we provide one) **including data from the past.**

Measures of Physical Activity: to calculate things like steps per hour or per day, minutes of exercise and other movements when carrying or using your device.

Measures of Sleep: the patterns of movement of your smartphone or wearable allow us to estimate your sleep and night-time behaviour patterns

Heart Rate: some wearables allow measurement of heart rate which changes with many health conditions

Questionnaire Data: that help understand your quality of life and any medical or health issues you experience

Environment and Mobility: Your GPS location (whereabouts) allows us to calculate information such as your mobility (how far you travel), what types of travel you use (car, train, walking), and your environment (weather, air pollution, closeness to traffic, green spaces etc).

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Sharing your GPS location is optional. You can take part without sharing your GPS location data.

- **Give permission for us to access, store and analyse health-related records about you.** These may be held by NHS or other organisations (such as disease registers, GP practices, dentists, occupational health records, or blood donor centres) within the UK.
- **Complete questionnaires** about your lifestyle and health. The first should take less than 15 minutes. Every three months we will ask another that should take less than 10 minutes. **You cannot be identified from your answers** and can choose not to answer.
- **Give us permission to contact you by email, phone, app notifications or text.** This will let us update you on our progress, ask if you would like to take part in future studies or invite you to events like webinars or events. These are all optional.

Because long-term data is important, we would like to keep collecting smartphone and/or wearable data as long as possible (up to life-long).

You will not usually need to meet a researcher as the study can be performed remotely through the internet or smartphone. We may offer to meet face to face to help you complete the questionnaires or provide you with a wearable.

We would like to keep collecting information about you from health-related records over the course of your lifetime or until you withdraw.

Collection of smartphone and wearable data will initially last for two years but we aim to obtain funding to allow us to extend this (life-long or until you withdraw).

Researchers (from universities, government and companies) will apply to access the de-identified smartphone/wearable data and health-related data on certain types of people.

Applications to use the de-identified research data will be judged by a data access committee of researchers, medical professionals, and patients. This will only approve uses of your data that are in the public benefit and might help predict, prevent, diagnose or monitor disease.

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Research findings will be published, but will never reveal your identity.

We will send you research summaries so you see how you are contributing to new discoveries.

How will we use information about you?

We will need to use information from you, your smartphone, your wearable (if you use one) and from your medical and health-related records for this research. This information will include

Identifiable data. This includes your name, date of birth and address. People will use this information to check your records to make sure the research is done properly and to obtain data from organisations that hold your health-related records. **We will never use your identifiable data in research.**

People who do not need to know who you are will not be able to see your name, contact details or location (GPS) data. This includes researchers who use your data in their projects. **Your data will have a code number instead.**

Research data (smartphone, wearable, questionnaire and health-related data). Before using your data for research we will remove anything that reveals your identity. **This is called de-identification.** De-identification protects your privacy, so data can be used in research without revealing who provided it.

If you allow us access to your GPS location data, we will never share this or use it in research. Instead we will use it to **calculate things that do not reveal your identity** like your exposure to air pollution and how far you travel (but not where you travel to).

The University of Sheffield is the sponsor of this research, and is responsible for looking after your information. We will keep all information about you safe and secure by:

- Keeping it in secure, accredited computer systems called “Secure Data Environments”
- Training all team members and researchers in data security.
- Keeping anything that identifies you separately from other information (such as your smartphone or health record data).
- Not allowing researchers who use the data to see anything that reveals your identity.
- Not allowing researchers to remove or copy any of your data.

If we do not provide you with a wearable, none of your data will be shared outside the UK.

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If we provide you with a wearable (such as a Fitbit or Apple Watch), this may require some of your data to be shared outside the UK. Users of wearables usually give their name, date of birth and email address to the manufacturer to create an account. This data and the data collected by the wearable may be transferred outside of the UK. This applies to all users of these devices, not just our research.

The countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK

Even if we provide you with a wearable, your questionnaire and health-related data will remain in the UK.

We have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when we legally have to. For further details about UK breach reporting rules visit the [Information Commissioner's Office \(ICO\) website](#).

Researchers who we allow to analyse the data will only do so within the secure data environment. They will not be able to copy the data, transfer or share it. They **will not be able to work out the identity of the people who provided the data**.

We will keep your study data for a maximum of **10** years after the study ends. The study data will then be fully anonymized and securely archived or destroyed.

You can withdraw from the study at any time, without giving a reason.

What are your choices about how your information is used?

If you withdraw your consent we will keep your personal information to allow the authorities to check we are doing our research correctly, but will stop collecting new data as soon as is practically possible.

After you withdraw we will stop collecting new data as soon as is practically possible. We will not request further access to your healthcare records and where possible we will not perform new research using your information.

You have the right to ask us to remove, change or delete data we hold about you for the purposes of the research. We will try to do so but might not always be able to do this. For example, if we have already used

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your data in our research we cannot remove it from these results. If so, we will tell you why we cannot do this.

You can continue in the research but stop providing your smartphone data by deleting the app from your phone.

Where can you find out more about how your information is used?

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK.

- our leaflet (accessible www.hra.nhs.uk/patientdataandresearch)
- Emailing smarthealth@sheffield.ac.uk or
- Ringing us on 0114 226 6159 (ask for SMART-Health team)

Are there any benefits to taking part in the study?

If you join, you will contribute to helping find ways to improve health and medical care. **Joining does not give you any personal health or medical benefit** because we do not yet know how to use this data to predict or diagnose disease. Our research could lead to improvement in future medical care that you, your friends and family could benefit from.

We may offer to loan a wearable device to use (for free). If we do, you will need to accept the manufacturer's terms and conditions and return it if we ask.

Does taking part pose any risks?

This research does not ask you to take any new treatment or drug that might cause problems, so there is no health risk of taking part.

We have tried to minimise any inconvenience taking part.

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Using our smartphone app will use some phone battery and memory. The app aims to minimise this. If you share your location data it will use more battery and data. Completing questionnaires should take no more than 45 minutes a year.

Will my data tell me or my doctor if I have a health problem?

We cannot use your data to tell you if you have a health problem and cannot monitor your data for signs of health problems.

Your smartphone or wearable is not a medically approved device and we do not yet know if data from these devices is medically useful. Readings such as a low heart rate may be inaccurate, caused by a low battery or not wearing the device properly.

The healthcare data we will access from the NHS and other systems will be months or years old. This data will already be available to your doctor.

This means we will not provide any data to your doctor and cannot tell you if you have a health problem or are at risk of disease.

Taking part in SMART-Health does not replace or improve normal medical care.

You MUST seek medical attention as normal if you have any health problems.

Will you contact me in the future?

- We will ask for permission to contact you for reasons including:
- Sending you news and updates about the research.
- Asking about your experiences of taking part.
- Asking if you would agree to complete more questionnaires.
- Asking your permission to collect information about you from other sources.

You do not have to agree to take part in any other studies or provide any other information.

Who is leading and funding SMART-Health?

You can contact us any time on smarthealth@sheffield.ac.uk

This study is led by the University of Sheffield. It is supported by the EPSRC/UKRI South Yorkshire Digital Health Hub.

Who has reviewed SMART-Health's plans?

The patient and public groups of the South Yorkshire Digital Health Hub and the British Heart Foundation Data Science Centre helped design SMART-Health and write this information.

Research in the NHS is assessed by an independent group called a Research Ethics Committee.

SMART-Health has been reviewed and given a favourable opinion (reference 25/EE/0061) by this Committee.

Thank you for reading this. Please keep it to refer to in future if needed.

Further Information and Contact Details

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