

# The Fenland Remote Assessment Feasibility Study

## Participant Information Sheet

### 1. What is the purpose of the study?

This Fenland research project is designed to investigate the interplay between environment and behavioural exposures in determining metabolic diseases. These conditions are a considerable public health concern, and investigating their causes and making personal exposure assessment more readily accessible is key to the development of personalised approaches to prevention. In this study we are investigating how we can conduct research remotely using wearables, smartphones, and web, without you needing to come to our clinical facilities.

This study includes a collaboration with Google who will provide Pixel 2 Watch for you to wear. As part of this collaboration, with your consent, we will share your Fenland data (past and present, after any identifiable information is removed) with Google.

### 2. Why have I been invited?

You were among the 12,500 people from across Cambridgeshire who took part in the first phase of the Fenland Study between 2005 and 2015. Phase 3 started in 2023 and is still in progress and we are inviting you to this remote assessment study because you have booked a visit to complete your Phase 3 assessments.

The information we collect from you will be used to inform the next phase of the Fenland Study which will examine how changes in behavioural and environmental factors over time relate to diabetes, obesity and other health conditions. We are testing how measurements that you can do yourself, for example using your phone or a smartwatch, compare to those we have done using more traditional research techniques in previous phases.

Before you decide to take part, we would like you to understand why the research is being undertaken and what it would involve for you. Please take the time to read the following information carefully and feel free to discuss it with friends, family or your GP.

### 3. Do I have to take part?

No, it is entirely up to you to decide whether or not to take part. If you decide not to take part, we will completely respect your decision and it will not affect the healthcare you receive in any way.

#### 4. What are the possible disadvantages and risks for taking part?

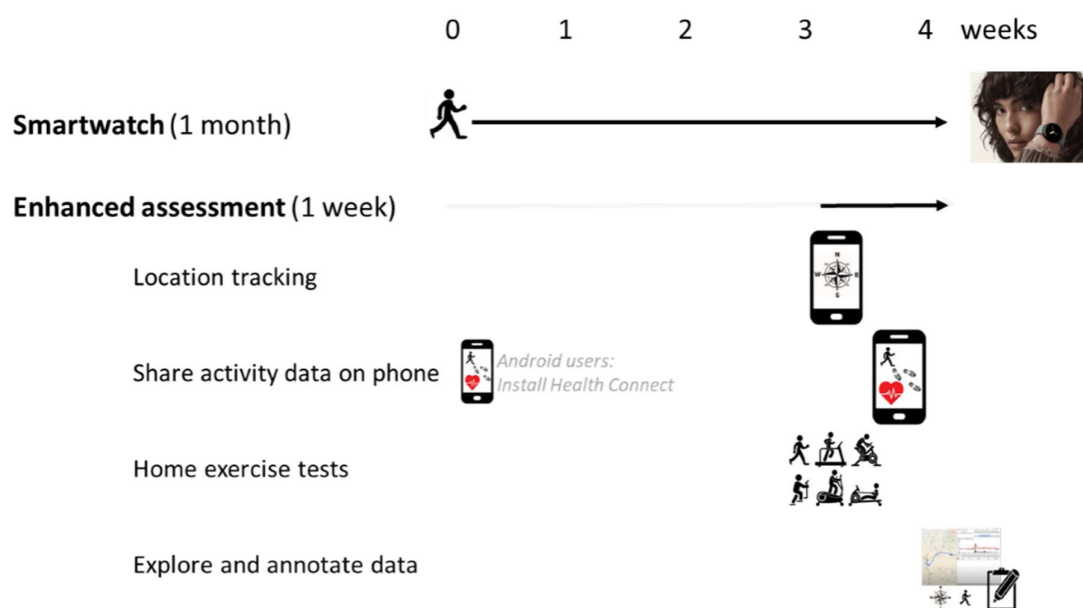
There are no significant risks involved in the assessments. However, to be eligible to take part in this study you are required to have your own personal email address and your own smartphone so the data captured are yours only and not data from someone else using your phone.

#### 5. What are the possible benefits of taking part?

If you decide to take part, you will be contributing to knowledge about the interplay between our environment and behaviours in relation to obesity, diabetes and related metabolic conditions. In conjunction with Google (as part of this collaboration), you will help improve our (and Google's) measurement tools and pioneer a new approach to population health research which utilises recent advances in technology that will provide more personalised support for people to optimise their own health. It is also possible that this approach may make it easier for people to take part in health research which means we can also study and help those who find it difficult to attend a clinical assessment.

#### 6. What will happen if I take part in the study?

If you agree to help us with this research, we will ask you to wear a smartwatch over a 1-month period and perform various additional measurements for a week towards the end of this period. We refer to this week as the enhanced monitoring week. We will send you reminders when it is time to perform a new measurement. You will also be asked to wear a chest-mounted ECG monitor for 48 hours. Below is a graphical overview of the study, and the following sections explain the details of each measurement component.



#### 6a. Smartwatch:

Google is providing each participant in this study with a Google Pixel 2 smartwatch<sup>1</sup>. We will provide the watch at the end of your phase 3 assessment and ask you to wear it on your wrist and recharge it when required for a period of 1 month. This device measures your heart rate and movement to provide an estimate of physical activity, fitness and other health indicators. The watch is identical to what you would buy in a store but runs a special version of software for the study. We will set the watch up for you with an anonymous ID. Only the University research team knows the link between this and your identity.

We will ask you to read and accept the Google Terms and Conditions which can be found here: <https://policies.google.com/terms?hl=en-GB#toc-about> during the consent process so the watch can be used for the purposes of the study.

When you leave our clinic, you will need to connect the watch to Wi-Fi at the location where you are most likely to charge the watch. The amount of data being transferred over Wi-Fi (only during charging) is about 70Mb per day. This de-identified data first flows to a Google server and then to a University of Cambridge server. The Google server also monitors the technical functionality of the watch and can push out software updates via Wi-Fi if required. You do not need a smartphone app for the watch to work in this study. Full instructions on how to use the watch will be provided.

At the end of the 1-month period, you can keep the watch and we will not collect any more data from you. We will provide instructions on how to restore the watch to its factory settings.

If you already have a smartwatch, you can continue to wear that as well as the Pixel watch if you are happy to wear both. You can also share that data with us (see below)

#### **6b. ECG-based 48-hour heart rate monitoring:**

You will be asked to also wear an Actiheart monitor on your chest for 48 hours whilst wearing the Pixel watch on your wrist. You may remember the Actiheart monitor from your participation in Fenland Phase 1 and 2, when you wore this for 6 days. We will fit the monitor to your chest using ECG electrodes, once you have completed your Fenland Phase 3 measurements. The purpose of this is to allow us to compare the heart rate measures from the light-based wristwatch to the electricity-based chest monitor. We only need a few days' worth of data for this, and you can then take the ECG pads off. This short monitoring protocol should not cause much, if any, skin irritation.

#### **6c. Location tracking:**

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<sup>1</sup> The devices may be older models no longer sold by Google. They are provided "as is," without any guarantees, warranties, or support from Google. Google is not responsible for repairs or replacements, and the devices do not come with a manufacturer's warranty.

For the enhanced monitoring week, we will measure how you move through your environment over 7 days.

This is similar to the measurement we carried out in Fenland Phase 2, except we will not ask you to wear a separate GPS device. Instead, we will ask you to download a smartphone app called “BreathNow” which is available on the App Store for iOS and on the Play Store for Android devices. You do not have to subscribe to the app for using in this study. The app has “in-app purchases”, which you are not expected to buy, as well as advertisements. This app provides a convenient way to measure geolocation over one week via its “My Environment” (iOS) or “Nature Time Assessment” (Android) module. You will need to enter your study participant code and your weight and start the measurement. You will need to keep the app running in the background and set its location permission to “Always”. Your phone will then track your location for the next 7 days and then automatically stop. The location data is stored in a file on your phone which is sent to our secure web server when the tracking has finished. You can then delete the app from your phone if you wish.

Coordinate data are sensitive and we have extra security measures in place for handling this information, for example by limiting linkage to other data and processing it in what is known as a Trusted Research Environment; an access-controlled computer that only allows non-identifiable results to be exported. For the avoidance of any doubt, we will not share any individual-level coordinate data with Google as part of this collaboration.

#### **6d. Sharing physical activity data from your smartphone:**

When you set up your location tracking session in your smartphone via the BreathNow app, there is an option to also provide access to your phone’s platform-level health apps. On iPhones, this is the Apple Health app (which is already pre-installed). For Android, this is the Health Connect app which, if you haven’t already, will need to be installed from the Play store in order to provide this information. These platform apps include steps data from the phone itself plus data from any connected wearable that you may use which you have given permission to write data to the platform apps. We provide guidance on our website to show you how this can be done. If you agree to sharing these data with us, the BreathNow app will ask for your consent and then extract up to 12 months of historical steps and heart rate data stored in the platform apps and send that data to our secure web server.

#### **6e. Visual feedback and annotation of context (web):**

At the end of the enhanced monitoring week, your location and physical activity data will be available for you to view via our web tool called “Location Activity Visualisation and Annotation” or LAVA. We will invite you to log in to the LAVA tool where you can explore your own data. You can also tell us a bit more about the activities you might have been doing on the days of monitoring – we would like you to do this annotation for at least one day. You log into LAVA with a username and password that we will provide you with, plus a time-sensitive token generated by any smartphone authenticator app, e.g. Microsoft Authenticator. This level of security is

necessary to protect your information. There are full instructions on how to set this up and how to use the LAVA tool on our website. The LAVA tool works best on a larger screen such as laptop, PC or tablet.

#### **6f. Measure your fitness:**

For the enhanced monitoring week, we will ask you to perform a step test and an exercise test of your own choosing. This can be a self-paced walk test, stepping, treadmill, bike ergometer, or anything you like – there are suggestions on our website if you would like some inspiration. We can estimate your fitness from your heart rate response to these tests and the first minute of recovery after the test. A dedicated heart rate monitor like a smartwatch is the best way to measure that.

For the step test, you can download and play a sound file from our web site that will provide an “up-up-down-down” voice guide of step frequency that slowly ramps up over 5 minutes. The test is also available via the iOS version of the “BreathNow” app (“Cambridge cardio test” module) which will play the step audio prompt, ask you to measure your heart rate recovery using the phone camera on your finger and transmit the data to our secure web server. If you are not using the BreathNow app for the step test, you can use other time stamp apps to help you remember or just note the time and step height on a piece of paper and enter this information later on when you log in to the LAVA tool. There is a video guide on the study web site to show you how.

For the self-selected exercise test, this could be any test or bout of exercise you like as long as you are able to describe how hard it is in terms of the exercise load. For example, if it is a self-paced walk test, just tell us how far and how fast you were walking. If it is a treadmill test, tell us speed and inclination, and if it is a bike ergometer test, tell us the resistance power in Watts. We recommend choosing an exercise that you think you can manage for at least 4 minutes – this is how long your heart takes to stabilise to a new load. Aim for a moderate intensity – as a rule of thumb, that corresponds to an intensity where you can speak short sentences but not sing. You can choose a test with a single exercise load or one with multiple loads – it is entirely up to you. Again, note down this information and the time of the test and use the LAVA tool to get that information to us.

Submaximal exercise tests are safe if you are able to walk unaided. If you do have a condition that may be aggravated by certain types of exercise, or your doctor has advised you to avoid certain types of exercise, try and find an alternative form of exercise that you think you can manage and try to have another person with you when you do the test. If you do experience any acute pain or discomfort during these tests, just stop and note the time you finished – the data is still very useful to us.

#### **6g. Tell us what you think:**

At the end of the study, we would like to know your feedback on the various components included in this study. We will send you a survey that would take a couple of minutes to complete.

## **7. What if there is a problem?**

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. They are contactable by email [fras@mrc-epid.cam.ac.uk](mailto:fras@mrc-epid.cam.ac.uk).

If you remain unhappy and wish to complain formally, you can do this by contacting the Assistant Director of the Research Office, University of Cambridge School of Clinical Medicine on 01223 333543.

## **8. What will happen if I don't want to carry on with the study?**

You are free to stop your participation in the study at any time and without giving any reason. You may choose for us to retain or destroy the information we have on you. However, if the data that you have provided have been analysed prior to you informing us of your wish to stop, then we will be unable to remove these data from the results. For further information on how we use your data, please see paragraph below.

Please note that by deleting any of the smartphone apps used in this study, you are not stopping your participation in the study and may still be contacted. It is important to inform the study team directly if you wish to stop your participation in the study.

## **9. Will the information collected on me in this study be kept confidential?**

All information that is collected about you during the course of this research will be kept strictly confidential. With your permission, the MRC Epidemiology Unit, University of Cambridge, will store information about you with your name and address removed so that you cannot be identified. It will not be used or made available to anyone for any purpose other than for research. Codes connecting your individual identity to the stored data records will be kept separately. Location data, which in coordinate form is potentially identifiable, will also be kept and analysed separately from other sensitive data in restricted access computing platforms.

We will only share de-identified data with our collaborators, including Google. This may include selected data from this and previous phases of the Fenland Study. It is not possible to identify you from the data that are shared.

The contact information you provide such as email address and phone number(s) will be used by the research team to keep you informed about your participation in the study. In the event it becomes necessary for the study team to use an external company to manage this process, for example an SMS service, the company will be GDPR compliant.

More information about how we use your data for the purposes of this study can be found in the study privacy notice, which is available here: <https://studies.mrc-epid.cam.ac.uk/fenland/privacy-notice>.

The University of Cambridge is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and



will act as the data controller for this study. The University of Cambridge will keep identifiable information about you for 20 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. To safeguard your rights, we will use the minimum personally-identifiable information possible.

We also work with other research groups and as part of these research collaborations, your pseudonymised information (i.e. your name is replaced with a code number on all data) may be made available to researchers who are working in other countries (including outside the EU) or in commercial companies.

You can find out more about how we use your information at <https://www.information-compliance.admin.cam.ac.uk/data-protection/medical-research-participant-data>

#### **10. What will happen to the study results?**

The study results will lead to better tools for assessing physical activity and fitness, and a better understanding of the causes of diabetes, obesity and related conditions and how to prevent them. It will help shape the future of health research using smartphones and wearables. You will not be identified personally in any report or publication.

#### **11. Who is organising and funding the study?**

The study is funded by the Medical Research Council (MRC) and is organised by the MRC Epidemiology Unit, University of Cambridge.

Google is providing the Google Pixel 2 Watches as part of the collaboration.

#### **12. Who has reviewed the study?**

To protect your interests, the Fenland Study has been reviewed by an independent group of people called a Research Ethics Committee. This study has been reviewed and given a favourable opinion by the Human Biology Research Ethics Committee of the University of Cambridge.

#### **13. Further information**

If you would like further information or have any queries about the study, e-mail us at [fras@mrc-epid.cam.ac.uk](mailto:fras@mrc-epid.cam.ac.uk). In addition, all the information about the study is available on our website at <https://studies.mrc-epid.cam.ac.uk/fenland/remote-assessment>.

#### **14. What should I do next?**

If you decide that you would like to take part, please complete the consent form. This will be made available for you to review at the end. A full copy of this information sheet can be found on our study website <https://studies.mrc-epid.cam.ac.uk/fenland/remote-assessment>.