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# Participant information sheet

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## We invite you to take part in a research study

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**You are being invited to take part in the Discover Me study.**

**Discover Me is a nationwide research study that aims to analyse health and genetic information on thousands of people. The research aims to improve our understanding of many different diseases, and to find ways to help GP practices improve patient care.**

**As part of the Discover Me study, along with providing information about yourself and a saliva or mouth swab sample, you will be able to receive and view information about your ancestry and some of your health information through a secure online participant portal. Access to this information could help you and your GP make better decisions about your healthcare.**

**Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please read the following information carefully and ask us if there is anything that is not clear or if you would like more information.**

**Omnigen Biodata, a research and development company based in Cambridge, is running this study with GP practices and online patient services.**

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### 1. What is this research study about?

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We aim to study the health of thousands of people from all around the UK in order to improve patient care.

By connecting genetic information to other health information, we hope to better understand:

- Why diseases affect some people more than others.
- Why diseases progress differently in different people.
- How to better prevent, manage and diagnose diseases.

This information may help us to monitor and understand disease epidemics and pandemics, such as the coronavirus (COVID-19) pandemic. This information may also

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help us improve existing treatments and find new treatments for conditions such as cancer and diabetes, and improve the health of this and future generations.

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## **2. Can I take part in Discover Me?**

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If you are 18 or over and able to consent for yourself, then you can take part in Discover Me.

We would like you to take part whether you are in good health or have health problems. It is important that all types of people join the study.

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## **3. What will happen if I decide to take part?**

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Taking part in Discover Me would involve you:

- Enrolling to be part of the study online.
- Providing a saliva or mouth swab sample using the sample collection kit sent to you once you have enrolled in the study.
- Allowing information from your health and care records (such as GP records, hospital records and disease registries) and other sources to be collected and used alongside your sample.
- Agreeing to be contacted in the future by the research team about this study and other new research studies.
- Choosing whether to receive information on your genetic ancestry from your sample and some of your health information from your health and care records.

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## **4. What happens during enrolment?**

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Enrolment will be conducted online, on an electronic device you use (such as a smartphone, laptop or tablet), and should take around 20 minutes.

Enrolment will include:

- Viewing a short video and reading this information sheet to learn more about the study. You can also contact the research team if you have any additional questions.
- Answering some questions about the study to check your understanding of what you are consenting to.

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- Filling in a consent form to show that you have agreed to join the study.
  - Giving some simple information about yourself including your date of birth and contact details.

Once you have completed these enrolment steps you will have enrolled in the Discover Me study.

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## **5. What happens next?**

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We will send you a confirmation of enrolment once you have completed all the enrolment steps and provide access to an electronic copy of your signed consent form. If you were invited to enrol into Discover Me by your GP practice, we will also inform your GP practice that you are taking part in the Discover Me study. Alternatively, if you were invited to enrol into Discover Me by an online patient service provider or by another research study you are already taking part in, we will inform the respective parties of your participation in the Discover Me study.

We will then:

- Check the information you provided about yourself to ensure you can take part. If we are unable to check your identity or eligibility against your health record we will ask you to review and update the details you provided to us. If after some time, it is still not possible to check your identity or you have been found to be ineligible you will not be able to continue participating in the study. In this case, any health or genetic data that may have been obtained will not be retained or shared, and your sample will be destroyed. We may retain some personal information for our administrative records in line with data protection regulations.
- Send you a straightforward sample collection kit so that you can provide a saliva or mouth swab sample and post these back to us. We may send you reminders to complete sample collection.

We will send you confirmation when we have received your sample. We will also notify you when your ancestry results and some of your health information are available to view on your secure online portal, if you have chosen to receive these. Please note, these will only be made available to you if we are able to verify your identity and you are found to be eligible.

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## **6. What happens to my sample?**

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The DNA (genetic material) will be extracted from your sample and placed into long-term secure storage. Using a range of scientific methods, we will read your DNA and use

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this information to see how genetic differences (inherited differences between families because of ancestry) may help explain how some diseases are caused and how they progress. In time, this might also help us find new treatments.

If you choose, we will provide you with information on your ancestry, based on your DNA. We will **not** provide you with any other genetic information from this study.

Your sample may be sent to service providers, commercial organisations and research centres in the UK and other countries, for storage, processing and analysis (including obtaining genetic information). Your sample will be labelled with a unique code rather than your name so that you cannot be directly identified.

If your sample cannot be processed for any reason, we may contact you to provide additional samples. You do not have to provide any additional samples if you do not wish to. For additional sample collection, you will be posted another sample collection kit to complete.

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## **7. What information is collected about me?**

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For many years, we will follow the health of everyone who has joined Discover Me. To do so, we will collect information about you for research from your existing health and care records (for example, from your GP records, hospital records and disease registries).

This information may be collected at multiple points after you consent to take part in the study, so we can update the information we hold on you over time. We may also add other information, such as from the census, or on the weather or pollution in your area, which may also affect health.

To obtain this information, the research team may send details about you to other organisations. These details may include your name and NHS number (or equivalent), or date of birth. To do this, we will use secure methods which are routinely used as part of your healthcare.

The research team may contact you or your GP practice directly to check and update our records if we think you may have changed practice.

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## **8. What happens to my information and how will it be used for this study?**

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We will keep all information about you safe and secure. Some of your information will be stored and processed by service providers, commercial organisations and research centres in the UK and other countries. They must follow our rules about keeping your information safe. Your information will only be shared for the purposes of running the study.

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We will use your health and genetic information to investigate why diseases affect some people more than others, and why disease progresses differently in different people. We will also use this information to find new or improved ways to prevent, diagnose and treat disease, and to help improve patient care and management.

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## **9. What results can I choose to receive from this study?**

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Once your information has been collected and your sample has been analysed, you will be able to see your ancestry results and some health information from your health and care records in a secure online participant portal. You can expect to see your health information within 12 weeks from enrolment. We aim to provide your ancestry information to you on the participant portal within 12 weeks from when we have received your sample; however, this may take up to 24 weeks. The return of your results cannot be guaranteed if there are problems with processing your sample or accessing information from your health and care records. If we are unable to verify your identity or you are found to be ineligible we will not be able to return your ancestry or health information.

You can choose on the consent form whether or not you would like to receive this information.

### **Information on ancestry**

The genetic information from your sample can be analysed to tell us things about your ancestry. This includes information on what populations your ancestors belonged to.

### **Information from your health and care records**

Some of the information from your health and care records will be available for you to view. This may include information on measurements taken at your GP practice, such as medications you have taken, vaccinations you have had and your conditions. The information we make available to you will be taken from the health and care records held at your GP practice and elsewhere. In the future, if you move GP practices we will still display this health information on your participant portal; however, we may not be able to continue to update your health information on your portal.

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## **10. What should I consider when choosing whether to have ancestry results or health information returned to me?**

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You may find viewing health information from your health and care records interesting, and it may help you keep track of, and manage, your health.

When deciding whether you wish to have ancestry results returned to you, you should consider that results may be unexpected and have ongoing effects.

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Genetic information can reveal things about your biological relationships to other members of your family. This may include you finding out that someone you thought you were related to is not your biological relative.

You can contact the research team, or complete a form in the secure online participant portal, if you change your mind about receiving your ancestry results or health information.

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## **11. Will I be contacted in the future about this study?**

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After you consent, we will contact you about activities relating to Discover Me. This will include notifying you that your ancestry and health information are available to view on your secure online participant portal, a short questionnaire about the information you have received, and general updates about the study or your ancestry and health information.

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## **12. Will my information and sample be shared?**

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Your information (including information that directly identifies you and your health and genetic information) and sample will be securely stored by Omnigen for many years, and possibly indefinitely.

To make sure that the information and samples collected from this study can provide the greatest benefit for society and medical research into human health and disease, we or trusted partner organisations will share your information with other institutions and organisations globally for analysis and further research. These may include research institutions, commercial organisations, universities, GP practices, hospitals, charities and service providers.

We may also share some of your DNA samples with other institutions and organisations globally for analysis and further research, including research institutions, commercial organisations, universities, GP practices, hospitals, charities and service providers.

Importantly, only information and samples which do **not** include your name or other information that directly identifies you will be shared for analysis. Where we share your information or samples, we will ensure there are safeguards to keep them secure and private.

Over the coming years, a wide range of research may be carried out using your samples and information. This research may be related to health or diseases, including research that may help with planning clinical services or developing new medicines, commercial technologies, products or services. Your information and samples may be analysed using new tests and techniques that don't exist yet, including new genetic tests. Importantly,

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sharing of your information and samples for these research activities will continue after your death, with the aim of benefitting research and healthcare in the future.

Where additional research is carried out on your samples, we will not provide the individual results of this research to you, as they are not suitable for making diagnoses.

You will not benefit financially if this research leads to the development of new treatments, medical tests or commercial technologies, products or services.

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### **13. Will I be contacted in the future about other studies?**

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At some points in the future, the research team may contact you directly, to see if you would like to join new research studies. These new research studies will also be available to view in the secure online participant portal and may include surveys or trials of new therapies. The new research studies may or may not be related to this study. You may be invited to take part based on your health and/or genetic information collected as part of this study. Taking part in these new research studies would be entirely optional; you will be able to decide at the time.

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### **14. How will information about me be kept private?**

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All information which directly identifies you will be held securely, with access restricted to the research team. The research team will use this information to contact you about this study, manage the running of the study, carry out and audit the information collection process or invite you to join new research studies.

The people who analyse the information will not be able to identify you, and will not be able to find out your name or contact details. Any information or sample shared for analysis with other organisations will **not** include your name or other information that directly identifies you. Where we share your information or samples, we will ensure there are safeguards to keep them secure and private. Researchers who analyse your samples and information will sign a contract to say that they will not try to find out who you are. You will not be identified personally in any publication or report.

We will not allow access to your information or samples to the police, security services, relatives or lawyers, unless required to do so by the UK legal courts.

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### **15. What are the possible risks and benefits of taking part?**

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You may find knowing about your ancestry and health information useful or interesting and you might benefit in terms of your health and care personally. Also, patients in the future may benefit from the knowledge generated by this study.

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We do not expect that you will get sick or unwell from taking part in this research study. There will be minimal risk of you being identified by those analysing your samples and information.

When deciding whether to learn about your ancestry and receive information from your health and care records, you should carefully consider what this means for you personally.

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## 16. Who is organising the study?

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Omnigen Biodata is the sponsor of the Discover Me study based in the United Kingdom. The sponsor of the study has overall responsibility for the conduct of the study, including being responsible for ensuring the study is carried out ethically and in the best interests of the people taking part in the study. Omnigen Biodata is a Research and Development company registered in the UK (company number 10565653).

The risk of participants in the study suffering harm as a result of taking part is minimal, and Omnigen Biodata has full insurance to undertake the study.

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. The study has been reviewed and approved by <insert REC> (study reference <insert>).

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## 17. How does this study comply with data protection law?

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As a result of the General Data Protection Regulation and the Data Protection Act 2018, we are required to inform you about how we use your personal information if you decide to take part in this study.

Omnigen Biodata will be using information about you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly.

Because we are using your personal information for research, under data protection law, your rights to access or change your personal information are limited. This is because 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. You can contact us directly if you have any concerns about how we handle your personal information, or you can contact the UK government's Information Commissioner's Office.

You can find out more about how we use your personal information at <insert website> or by contacting the research team (see section 22 for contact details).



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## **18. Is it my choice to take part in the study?**

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Yes, it is completely your choice to join the study. You do not have to take part in this study. Your decision will not affect your routine medical care in any way.

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## **19. What if I no longer want to take part in the study?**

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If you consent to take part in the study but later decide you would like to leave, you are free to do so at any time. You do not have to give a reason, and your decision to leave the study will not affect your routine medical care in any way.

If you decide to leave the study, you can tell us by completing a form available on the secure online participant portal.

On telling us that you wish to leave the study, you will be able to choose options for further collection and sharing of information and your samples, future contact and access to the secure online participant portal. If you choose to withdraw from the study, we will not erase or destroy any information and samples already collected (including your identifiable information), and we will be unable to recall any information and samples that have already been shared for research.

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## **20. What if I no longer have the capacity to consent to the study?**

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If you consent to take part in the study, your doctor or relative may later inform the research team if they feel you have lost the capacity to consent to the study; or, we may check your health records for this information. If we pick up this information from your health records, we may check this information with your GP practice. "Loss of capacity to consent" means when a person has lost the ability to make or communicate a decision. This may be the result of conditions such as dementia, mental illness, learning disabilities or other conditions causing confusion or loss of consciousness (e.g. stroke).

On being made aware of this, we will suspend further information and sample collection, future contact, and access to the secure online participant portal. Information and samples already collected will continue to be stored (including your identifiable information) and shared for research (including for further research after this study).

If you later regain capacity to consent, you can ask to participate in the study again if you wish.

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## **21. What should I do if I want to take part?**

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If you would like to be part of the Discover Me study, please continue through the enrolment form.

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## **22. How do I contact the Discover Me research team?**

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After enrolment, if you have any questions, concerns or complaints about anything to do with this study, you can contact the research team by:

Telephone: <insert telephone number>

Email: <insert email address>

Post: <insert postal address>

You can also access further information at <insert website>.