DecodeME
The ME/CFS Study

PARTICIPANT INFORMATION DOCUMENT

CONTENTS

Inside this document you'll find:

OUR INVITATION TO YOU

We'd like to invite you to join DecodeME, a research study looking at the genetics of ME/CFS – also called myalgic encephalomyelitis, ME, or chronic fatigue syndrome.

ME/CFS affects around 250,000 people in the UK. We don't know why some people get ill with ME/CFS when others don't. At present, there aren't any diagnostic tests or effective treatments for it.

We'll use genetics to search for answers. Genetics looks at DNA, which carries the instructions in our cells that tell our bodies how to work.

We're looking for differences in DNA between people that make their risk of getting ME/CFS bigger or smaller. Those differences would help us understand the biological causes of ME/CFS. And that should help future researchers to create diagnostic tests and find treatments that work.

Also, the information that we'll collect about symptoms, whether someone's ME/CFS started with an infection, length of illness and so on, will enable us to build the world's biggest set of data on ME/CFS, helping further with research.

It's important that you understand why we're doing the research and what it will involve, so that you can make a proper decision about whether to take part. So please take the time to read the information in this document carefully before you make your mind up.

If anything isn't clear, or if you'd like further information, please contact us or take a look at our website at www.DecodeME.org.uk.

Who can take part?

You can take part if you're aged 16 or over, live in the UK, and a health professional has told you that you have ME, chronic fatigue syndrome, or ME/CFS.

Who are *we*?

DecodeME's sponsor, the University of Edinburgh.

Who is in DecodeME?

DecodeME is run by a partnership between the University of Edinburgh, the charity Action for M.E., other charities, and people with ME/CFS. DecodeME is funded by the Medical Research Council and the National Institute for Health Research.

How has the study been designed?

DecodeME has been designed by researchers consulting with patients at every stage. People with ME/CFS have helped choose how to recruit people to take part, how to decide who to ask to give their DNA, and how to help severely ill people take part. Patients also helped write this participant information document and the consent form.

How has the study been approved?

Research Ethics Committees independently check the designs of planned medical studies to make sure that your safety, rights, wellbeing and dignity will be protected. DecodeME has been reviewed and given a favourable opinion by the North West – Liverpool Central Research Ethics Committee.

WHAT YOU'LL NEED TO DO

There are three simple steps to taking part.

1. AGREE TO TAKE PART IN DECODEME

If you're happy to join the study once you've read this document, just complete the consent form to give us your agreement.
In the consent form, you can also choose to help research even more, if you'd like:

- by letting us receive data from the NHS from your medical records, *for DecodeME only;*
- by letting us share some of your questionnaire responses and DNA data with researchers doing other worthwhile studies;
- by letting us contact you in future about other studies approved by DecodeME that you could take part in that need new data and/or samples.

We tell you more about these options in the section called 'How you can help more with research'.

We'll give you a copy of your consent form showing what choices you made.

2. TAKE OUR QUESTIONNAIRE

If you consent to take part in DecodeME, we use a questionnaire to ask you about your symptoms.

- The questionnaire is online, but we can send you a paper copy if that's easier for you.
- You can start the online version straight after you've agreed to take part in the study, or do it later.
- You can also do it in stages, leaving and coming back to it later. You won't lose the answers you've already given.
- If you're too ill to do the questionnaire on your own, you can ask someone to help you.
- If you consent to take part but don't finish the questionnaire, we'll send you brief reminders by your preferred contact method.

Your answers will tell us if we also need to ask you to give us a DNA sample.

It may be that we don't ask you for a DNA sample. In all medical studies, researchers look at a narrower group than all the people who have a particular illness. This gives a clearer picture and helps the science to work.

So if we don’t invite you to go beyond the questionnaire stage, it certainly won’t mean that you don’t have ME/CFS.

Your questionnaire answers will have become part of the world’s biggest set of data on ME/CFS, and you’ll have made a very important contribution to research.

You may also have the chance to take more questionnaires, which will help researchers to understand ME/CFS better. But you won’t have to do them unless you want to.

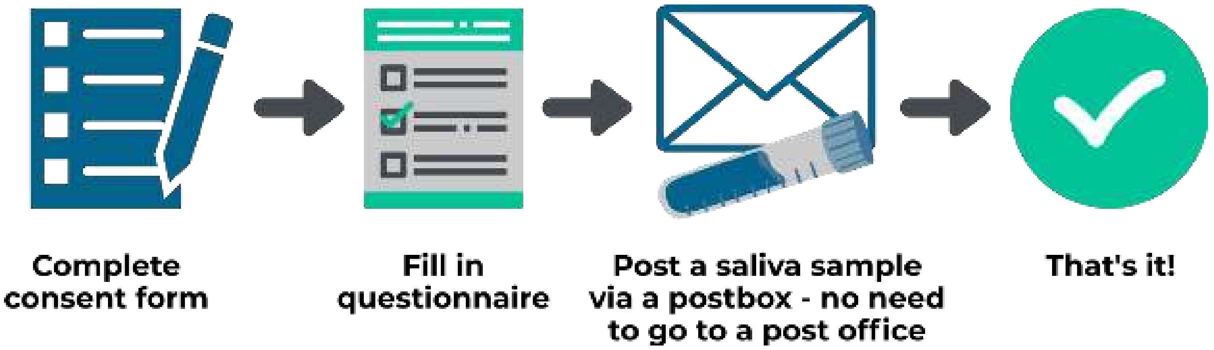
3. SPIT AND POST

If we ask you to send us your DNA, we’ll mail you a kit for you to give us a saliva sample. Your saliva contains your DNA.

- We’ll need 2ml of saliva, which is about half a teaspoon and should take you less than five minutes to produce.
- We’ll include a Freepost pack to send the sample back to us.
- You or a helper can post it in an ordinary postbox – you won’t have to go to a post office.
- Sometimes a sample won’t give us usable DNA. If that happens, we’ll send you a new kit and ask for another sample.

But once we’ve got one usable sample from you, and you’ve completed all the optional questionnaires that you want, that’s it – you’ve done everything you have to do for the study.

If we send you a saliva kit but don’t get a sample back, we’ll again send you brief reminders by your preferred contact method.



WHAT WILL HAPPEN TO YOUR SAMPLE AND DATA

What will happen to your saliva sample?

You'll post your sample to the UK National Biosample Centre at Milton Keynes and they'll extract your DNA from it.

DNA is a very long molecule and you can think of it as being written in three billion chemical letters that make up a book. The book is your genome – basically, your body's entire instruction manual.

We'll look at the roughly one million DNA letters in the places in the genome book where we know they differ most between people. We'll compare the letters at those places for people who have ME/CFS and healthy people, to look for differences.
The Biosample Centre will send part of your DNA sample to a company called Thermo Fisher Scientific in the US. Once they've identified your DNA letters, none of this sample will be left over.

We'll keep the other half of your DNA sample at the Biosample Centre. We hope in future to get funding to look in even greater detail at this sample by reading the full sequence of letters in your DNA book. For now, we need to store your sample until this 'sequencing' gets cheaper. Once we've finished recruitment to DecodeME, we'll apply for permission to store all the samples in a research tissue bank.

How will we keep your data safe and protect your privacy?

We take sample and data security, and your privacy, very seriously.

- All the organisations taking part in DecodeME will follow the UK's or international highest standards.
- DecodeME will use third-parties to process your data.
- Your information will only be used to do scientific research.
- Everyone working on this project has a legal duty to keep your personal information confidential.
- We'll follow the Human Tissue Act 2004 and all other relevant regulations and laws. These laws include the General Data Protection Regulation (GDPR).

- The scientific organisation running DecodeME is the University of Edinburgh. It will keep all information about you safe in its secure data vaults.
- The University of Edinburgh is the data controller for DecodeME and protects your information and controls who can access it.

Your information that we hold will include:

- your name and contact details;
- your answers to the questionnaire;
- your DNA data;
- (if you have agreed) your NHS or hospital number or (in Scotland) Community Health Index (CHI) number.

The DecodeME team will use this information to do the research or to check your records to make sure that the research is being done properly.

You can read the privacy notice for the University of Edinburgh's research projects at www.ed.ac.uk/data-protection/privacy-notice-research, and DecodeME's privacy notice at www.DecodeME.org.uk/Privacy-Notice/.

How we protect your identity

We'll store your personal data (such as your name, contact details and questionnaire answers) separately from your DNA data and any health record data. Your DNA and health record data will have a code number instead.

This means that scientists analysing the data won't be able to see your name or contact details or identify you.

Your saliva sample and the DNA extracted from it will also only be identified by your code so you can't be identified. Thermo Fisher Scientific and the Biosample Centre must follow our rules about keeping your barcode information safe.

We'll keep your data for at least 20 years, so that we can check the results and continue to learn from it as we learn more about ME/CFS. We'll write our reports in such a way that no-one can work out that you took part in the study.

Your genetic data can't be accessed by insurers or the police and will only be used for scientific research. We won't provide your DNA sample to security services or lawyers, unless required to do so by court order.

If you want to stay in touch

If you give consent to take part in DecodeME, your email address will also be held by the charity Action for M.E., which is a partner in DecodeME. Action for M.E. will use your email address to contact you with progress updates about the study and its findings.

Our privacy policy (www.DecodeME.org.uk/Privacy-Policy/) explains how Action for M.E. handles your data for that purpose.

Would you get information about your own genetics?

If you take part in DecodeME, we won’t give you any information about your own individual genetic findings. This is because there are many practical and ethical issues that make it difficult to give personal DNA results to people who take part in research studies.

Would you see the research results?

As well as sending you updates about the research, and putting them on our website, www.DecodeME.org.uk, we’ll also send our results to scientific publications where you’ll be able to read them in full detail.

What if your data or sample creates an invention?

DecodeME’s samples and data might lead to somebody creating a new medicine, treatment or test for ME/CFS. We hope it will. But your taking part in DecodeME wouldn’t give you the right to any payment for it.

What if you change your mind about being in the study?

You can stop being part of the study at any time, without giving a reason, by contacting us by phone, email or letter and asking for ***no further use*** of your data and sample.

We’d stop using your data and sample, as far as possible.

- We’d remove your study data from DecodeME if the study analysis hadn’t already started.
- We’d also stop your DNA sample from being sequenced, if that hadn’t already happened.
- And you can tell us if you want your biobank sample destroyed.

We need to manage your records in specific ways for the research to be reliable. This means that we won’t be able to let you see or change the data we hold about you.

Even if you want your data and sample to continue to be used in DecodeME, you can ask us at any time to stop sending you study updates by contacting us and asking for ***no further contact***.

HOW YOU CAN HELP EVEN MORE WITH RESEARCH

Sharing your health data with DecodeME

Your health data – past, present, and future– would make your DNA even more useful for our research. We’d be interested in your data from birth, and not just health data obviously related to your ME/CFS.

This is because we know that factors other than genes can play a role in ME/CFS. For instance, infections, injuries, operations or medicines you had before you got ill might be important. And genes and health factors might work together to cause ME/CFS.

Having data about your health would allow us to study possible links like these.

So we’d like to receive data that the NHS would provide from your health records so we can do more research – but it’s your choice.

The NHS would give us your health data only identified by your NHS number. The data would be linked to your DNA and other information by your code number, but wouldn’t be stored with your personal data.

Researchers analysing the data would not know your identity.

If you agree to us receiving your data, that would continue for 20 years after the end of the study to see how your health changes over time.

If you’d contacted us to say you wanted *no further use* of your sample and data, we’d stop using your NHS data as far as possible and would stop receiving data from the NHS about your health records. We’d remove it from DecodeME if the study analysis hadn’t already started.

Sharing your data to help other researchers make discoveries

Your genetic and/or other data could also help researchers in projects other than DecodeME make discoveries about both ME/CFS and other diseases.

Having data on up to 25,000 people means these scientists could find out very quickly what would take them years to discover if they had to start from scratch.

You can choose to share your data to help speed up research in this way.

A DecodeME committee of a scientist, a patient and a charity representative will strictly control access to the data. The committee will make sure that we only share DecodeME’s data with studies that meet our high standards and are ethical and worthwhile.

- We won’t share any personal details that could identify you, or any of your NHS health data.
- The researchers must agree to treat your data with respect and to keep it secure.
- They might work for universities or medical companies, and might be in other countries.

The consent form will ask you if you’re happy to share your data.

If you agree to taking part in future studies but later tell us that you want *no further use* of your sample and data in DecodeME, we'd no longer make your data and sample available for new studies. And even if you wanted your data and sample to continue to be used in DecodeME, you can ask us at any time to stop asking you to join future studies.

Your chance to take part in new research studies

New, future studies might need different data or samples from people with ME/CFS, such as blood samples or information about family history.

These studies could be very valuable in helping people with ME/CFS or other diseases, and you can choose to have us contact you about them. You can then decide whether to take part or not in each study.

A DecodeME committee of a scientist, a patient and a charity representative will make sure that we only contact you about ethical, worthwhile studies that meet our high standards.

The consent form will ask you whether you'd like to hear from us about these studies.

HOW TO GIVE YOUR CONSENT TO TAKE PART

Before you consent to take part in DecodeME, please check that you're happy that you understand the information in this document. If you don't, please contact us, using the details below.

Once you feel that you understand everything, you can then carry on to the consent form.

CONTACT INFORMATION

How to contact us

You can contact us with any questions, including about how we use your information, in the following ways.

Phone: 0808 196 8664 Mon–Fri, 9am–5pm (answerphone outside working hours)

Email: info@DecodeME.org.uk

Social Media: @DecodeMEstudy (Twitter, Facebook, Instagram)

Post:
DecodeME Study
MRC Human Genetics Unit
Institute of Genetics and Cancer
University of Edinburgh
Western General Hospital
Crewe Road South
Edinburgh
EH4 2XU

You can contact DecodeME's sponsor via www.accord.scot/contact-us.

How to contact an independent person to discuss the study

If you'd like to discuss the study with someone who isn't part of the research team, please contact Dr Nina Muirhead on 0770 431 3397 or via nina.muirhead@btinternet.com.

How to contact the Data Protection Officer

You can reach the Data Protection Officer for DecodeME at DPO@ed.ac.uk.

Post:
Data Protection Officer
Old College
University of Edinburgh
South Bridge
Edinburgh EH8 9YL

How to make a complaint

If you have any concerns about the study, we want to hear from you! Please get in touch with us right away so we can try to fix any problems. But if we can’t, and you’d like to make a formal complaint about the study, please email the University of Edinburgh’s Research Governance team at researchgovernance@ed.ac.uk.

Thank you for taking the time to consider taking part in DecodeME.