

# PROTECT

## Participant Information Sheet

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## **PROTECT Study: Platform for Research Online to investigate Genetics and Cognition in Ageing**

### **Invitation to take part in a research study**

We would like to invite you to take part in our research study. Before you decide, we would like you to understand why the research is being done and what it would involve for you.

Please take time to read the following information carefully and discuss it with family or friends if you wish. We recognise that there is a lot of information contained within this document. If you have any further questions, please contact a member of the study team (details are on the last page of this information sheet).

It is important that you understand that you do not have to take part in the study and that if you do take part you are free to withdraw at any time. If you decide to take part we will ask you to read and sign the declaration on the next page of the website.

### **What is the purpose of the study?**

This study aims to understand how the functioning of the brain, and our health and wellbeing, changes as we age. In particular the study will look at how certain genes and lifestyle factors (such as exercise or education) affect the way our brain ages and influence our health as we get older. This will provide valuable information

about the brain and could inform future research to prevent conditions such as dementia. The study is being led by the University of Exeter and run in partnership with King's College London and the South London and Maudsley NHS Foundation Trust.

### **Why have I been invited?**

We are inviting adults over 50 from across the UK to take part in this study. We are looking for 50,000 people to join the study for the next 25 years.

In order to participate, you will also need to

- Have a good working understanding of the English language
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- Have the ability to use a computer or touchscreen device with internet access.

If you have an established diagnosis of dementia from your doctor then unfortunately you will not be eligible for this study.

### **Do I have to take part?**

It is up to you whether or not to join the study. The purpose of this information sheet is to describe the study in detail to help you make your decision. If you agree to take part, you will then need to read and sign a consent form on the website. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive through your own General Practitioner or local NHS services. This study does not replace those services and if you feel less well during the time you are part of this study it is important that you seek help from your doctor or local health professionals in the usual way.

### **Why are we doing the study?**

As we get older our brains also begin to age, resulting in a 'slowing down' of abilities such as memory or reasoning. However, we do not fully understand how or why these changes occur. Studies have indicated that certain genes might govern these mental

processes, collectively known as ‘cognition’, and how it changes throughout our lives. To date there have been no large studies examining how these genes affect cognition in older adults over the long term. Furthermore, there is some evidence to show that lifestyle factors such as exercise and smoking status could also affect cognition but these links are still unclear and we need to understand more about how genes and lifestyle interact.

It is important to understand what affects our cognition as we age and why it affects people differently. This information could also provide vital knowledge about who is most at risk of dementia, which currently affects 850,000 people in the UK. In order to develop better prevention and treatment for this devastating condition, it is essential to understand cognitive decline and the factors that govern it.

This study will address these important issues by measuring cognition in 50,000 adults over 50 over 25 years through an online study. Participants will complete a series of tests each year and we will compare their performance with their genes to see how they affect their performance. By combining this work with information about each individual's lifestyle and medical status this study will provide valuable new knowledge about how genetics influence cognition in older adults. This information will also allow us to explore how overall health and wellbeing change with age, and what factors are involved.

### **What will happen if I take part?**

If you decide to take part the following steps will happen:

1. During registration you will be asked to provide some basic personal details including your name, address, email address, NHS number and GP details. These details allow us to contact you for research purposes and to send you important information.

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2. You will be asked to sign the online study consent form on the website.

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3. Once you have registered and signed the consent form you will be asked to provide some basic

demographic information including age, gender, marital status, ethnicity and education.

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4. You will then be asked to complete a series of questionnaires on the website. Some of these are optional so you can choose which you would like to complete. They are:
  - a. A medical history questionnaire, including your Body Mass Index, sleep quality, any pain, current diagnoses or prescriptions for any conditions you may have. We will only ask you about conditions that are relevant to this study.
  - b. Information on your current lifestyle habits, such as exercise, technology use and smoking.
  - c. A questionnaire about your diet and any dietary supplements you take. There is also an optional in-depth dietary questionnaire that asks about your dietary intake for a week. If you opt in to this questionnaire we will ask you to complete it every three months.
  - d. Information on any family history of dementia, including other brain conditions.
  - e. A questionnaire about how you feel you are performing day-to-day tasks.
  - f. A questionnaire about how you feel about your cognition.
  - g. A questionnaire about your behaviour and personality.
  - h. An in-depth questionnaire about your history of mental health, including depression, anxiety, stress and psychosis and information about your previous alcohol and drug use (Optional).
  - i. A questionnaire about early development (Optional).
  - j. If you are female, a questionnaire about menopause and female fertility (Optional).
  - k. A questionnaire about your views on ageing (Optional).
  - l. A questionnaire about your history of head injury (Optional).
5. You will also be asked to complete a series of online cognitive assessments, for example to test your memory, reasoning and attention. These will take around one hour to complete in total. There are some similarities in some of these tests, which allow us to detect subtle changes in your performance. If possible we would encourage you to complete the tests three times in one week to give us the best quality data. Prior to starting your cognitive assessments, we will ask some questions about your mood on that day.
6. If possible we will ask you to nominate an 'informant'. This should be someone who knows you well and spends time with you frequently, such as a spouse, child or close friend. If your nominated informant agrees to take on this role, they will be contacted with information on the study and asked to complete a consent form on the PROTECT website. Your informant will be asked to answer questions about you twice a year for the duration of your participation. For confidentiality purposes, we will not be able to share these answers with you. If you decide you would like to continue participating in the study without their support, we will contact them to let them know and thank them for their participation. Nominating an informant is optional.
7. We will send a saliva sample kit to the address you provided with clear instructions on how to use it. We will ask you to provide a saliva sample to allow us to have samples of your DNA for the study.

This is a very simple, quick and painless procedure. A pre-addressed envelope will be provided for you to post your sample back to us. If you are unable to provide a saliva sample you may be able to provide a blood sample instead. Unless you opt to take part in additional research studies this information will be for research purposes only and will not be made available to research participants. This is because the medical value of this information is not yet sufficiently understood to give people clear guidance. Your DNA samples will be stored anonymously in a secure biomedical facility collaborating directly with our team for the purposes of PROTECT. For further information on the King's College London NIHR BioResource for Mental Health please see below (page 6).

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8. With your permission we will contact your GP to request a confidential copy of your medical notes. These will only be used for information that is directly relevant to the PROTECT study. The medical notes help us to have a more accurate picture of your medical status.
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9. You will be asked if you would like to be contacted about taking part in future research into ageing and brain health including treatment studies. It is difficult to know exactly what new treatments will emerge and be assessed in clinical trials, but studies are likely to look at different ways of preventing cognitive decline in people in middle and later life. Studies may look at a variety of different treatment approaches such as lifestyle approaches (e.g. brain training or exercise) as well as drug therapies. This is entirely optional and you are not obliged to take part in any future studies if you do not wish to. By signing this part of the consent form you are only agreeing to receive information about future studies and you are under no obligation to take part. For any potential future study you would receive details about the study and it would be your choice whether to take part or not. In order to assess your suitability for future studies we, or our collaborators, may look at the anonymised data you have already provided in your assessments, including your scores on the cognitive, mental health and other tests. You can tell us if you would like us to check your suitability based on your anonymous DNA data, when you complete your consent form. You will only ever be contacted by a PROTECT study member regarding involvement in other studies. None of your personal details will be passed onto any other researcher, institution or company without your specific consent. You will be asked to complete a separate consent form for any additional study you are involved in. New studies are expected to be made available around three times each year.
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10. Each year we will contact you by email and ask you to repeat the cognitive assessments three times in one week, and to update your answers to the other questionnaires (with the exception of the early development and menopause/fertility and family history questionnaires). We will also keep you up to date with the study and its findings through a newsletter and the website.
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11. At the end of the 25-year study we will contact you to let you know the findings of the research.

### **What will happen to the data I provide?**

The University of Exeter 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 data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Exeter will keep identifiable information about you for ten years after the study has finished. Anonymised information, such as your assessment and DNA data, may be kept indefinitely and up until the study

objectives have been achieved.

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. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information at [www.exeter.ac.uk/dataprotection](http://www.exeter.ac.uk/dataprotection) or by emailing [dataprotection@exeter.ac.uk](mailto:dataprotection@exeter.ac.uk).

The University of Exeter will use your name, NHS number and contact details] to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from the University of Exeter and regulatory organisations may look at your medical and research records to check the accuracy of the research study. NHS sites involved in the research (South London & Maudsley, Guy's & St Thomas', Royal Devon & Exeter, Devon Partnership Trust) will pass these details to the University of Exeter along with the information collected from you and your medical records. The only people in the University of Exeter who will have access to information that identifies you will be people who need to contact you to discuss issues directly relating to the study or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details. The research sites will keep identifiable information about you from this study for 10 years after the study has finished.

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other

organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research. This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

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

This is not a clinical trial and there are no risks associated with any treatment or other intervention. This is an ‘observational’ study, meaning we only wish to observe how you progress over time.

All the information we collect will be stored securely, according to the law.

The main advantage of this research is that participants will be taking part in an important research study that could provide valuable new knowledge about how the brain works as we get older. Participants will also be part of the NIHR BioResource for Mental Health, which supports wide-ranging research into dementia and other conditions. If you agree to be contacted you will have the opportunity to take part in future important research into the brain, and how we can prevent conditions like dementia.

The London Bridge NHS Research Ethics Committee has approved this research (Ref: 13/LO/1578) and the research will be covered by normal insurance policies at the University of Exeter.

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

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

reason. You can do this through the 'I wish to withdraw' link on the website or by contacting us on the PROTECT helpdesk. If you withdraw from the PROTECT study you will be automatically withdrawn from the NIHR Bioresource for Mental Health, and any saliva sample you have provided will be destroyed. If you withdraw from the study you can tell us whether you want us to retain any personal information that could be used to identify you (email address, home address and full postcode, GP details, NHS number) or whether you would like us to destroy that information. Please note we will retain the full name, partial postcode and participant ID of any withdrawn participants to ensure we have a record of your consent when you registered. We will retain all anonymised data that we have collected up to the point you withdraw. This includes all anonymised data from assessments and questionnaires, anonymised genetic data and extracted DNA, which is also entirely anonymised.

There is a very small chance that people taking part in this study may develop cognitive impairment or dementia over the 25 year period. Based on the existing evidence this may occur in 5% of people over 60, although the risk of cognitive decline increases with age. In the unlikely event we detect a clinically significant drop in your performance in the study tests we will contact your GP to recommend they arrange an appointment with you to carry out further tests. If you do receive a diagnosis from a medical professional we ask that you let us know through the website or by contacting the study helpdesk. The website will provide information, links and useful contacts that may be helpful to you if this situation arises. However, the study helpline cannot provide detailed or medical support and advice.

If someone develops dementia and loses the capacity to make decisions independently about their involvement in the study, they would then be withdrawn from the study. If this happens all

anonymised information you have provided up until that date will be retained. If you would prefer identifiable data (email address, home address and full postcode, GP details, NHS number) collected up to this date to be removed from the study you can indicate this by following the withdrawal link on the website or by contacting the study helpdesk. Please note, we will retain your name, partial postcode and participant ID to ensure we have a record of your consent when you registered.

**Will my taking part in this study be kept confidential?**

Research data, such as your answers to the questionnaires, will be collected online through the study website over the 25 year period. The study database will not include your name, just a study number. These data may be used by other researchers in the future, however they will be completely anonymised and it will not be possible to identify you.

During the study we will collect minimum required personal information such as your full name, contact details and GP address. This information will be stored in a secure separate database and will only be available to a small number of researchers on the PROTECT study team at the University of Exeter and King's College London to support you should you contact the PROTECT helpdesk and to communicate study information such as alerting you to new assessments. A secure list linking your full name, study number and contact details will be made available to our collaborating biomedical facility, so that they can send and receive your DNA sample. We will never pass your personal information on to any third party without your written consent.

All study data will be stored securely according to Data Protection Laws\* and the security procedures in place at the University of Exeter, King's College London, South London and Maudsley NHS

Foundation Trust and the biomedical facility processing your saliva sample.

For further information on how your personal information will be processed please visit our privacy policy on the study website.

\*Data Protection Laws means (a) any law, statute, declaration, decree, directive, legislative enactment, order, ordinance, regulation, rule or other binding restriction (as amended, consolidated or re-enacted from time to time) which relates to the protection of individuals with regards to the Processing of Personal Data to which a Party is subject, including the Data Protection Act 1998 ("DPA") and EC Directive 95/46/EC (the "DP Directive") (up to and including 24 May 2018) and on and from 25 May 2018, the GDPR and all legislation enacted in the UK in respect of the protection of personal data; and (b) any code of practice or guidance published by the ICO (or equivalent regulatory body) from time to time.

### **What will happen at the end of the study?**

At the end of the 25 year study period you will complete your final annual assessments on the website. We will contact you to let you know the study has ended and to thank you for your contribution. The results of the study will be published in a scientific journal. We will provide you with a lay summary of our findings in the form of a newsletter. The findings will also be available on the study website. The information collected is totally confidential and no individuals will be identified in any reports/publications or presentations.

### **What is the BioResource Project?**

We will ask you to provide a sample of your DNA by completing a saliva sample kit at home.

DNA collection is managed by the NIHR BioResource for Mental Health based at King's College London, which is part of a national

NHS project to build up a central library of information (or “BioBank”) about people's health. It will be used in scientific/medical research to help us better understand why different mental illnesses happen and how we can develop better treatments for them. They aim to collect:

- Biological samples – blood and/or urine, hair, saliva for genetic and biochemical testing.
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- Clinical data - Examinations by doctors, family information, your response to treatment etc.
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- Neuroimaging data – X-rays and brain scans.

For your involvement in the PROTECT study we are only collecting saliva samples. In the unusual circumstance where someone is unable to give a saliva sample the BioResource will offer a cheek swab or blood sample (50 ml, or ten teaspoons) as an alternative option.

Your saliva sample and DNA material will be processed and stored at the NIHR Bioresource for Mental Health at King’s College London using a unique sample identification number allocated by the facility. Limited personal information (your full name and contact details) will be linked to a separate unique participant identification number. These data will be handled in a linked anonymised fashion, meaning that your personal details will not appear on the stored biological materials. Your name and contact details will be stored in a separate database to all genetic data, and only delegated staff members in the research team at the NIHR BioResource for Mental Health, will have access to both databases. All databases will be password protected and securely located behind an encrypted firewall at King’s College London. Any paper records that contain personal identifiers will be kept in key locked offices and fireproof lockable cabinets at King’s College London.

NIHR BioResource staff members at King’s College London will use your name and contact details to post a saliva sample kit to

your registered home address. Should your home address change and to ensure you receive your saliva sample kit without issues, you can update your home address at any time through your PROTECT account on the website. The NIHR BioResource may also contact you to invite you to take part in other research studies or to collect a minimum set of information, such as your demographic information and medical history, to ensure you are contacted about studies best suited to you. If you are contacted for any follow-up studies or extra information, it is up to you to decide whether you would like to participate in the study or provide this information.

Extracted DNA samples will be analysed either at the Bioresource for Mental Health or by a third party organisation in the UK or abroad that specialises in DNA analysis. This analysis process will not include any of your personal details and so will remain entirely anonymous. Some of this data will only be kept locally while some information and DNA samples from these facilities may also be made available to other scientists working in biomedical and healthcare research that may include the participation of commercial companies, subject to full ethical approval.

**What if there is a problem?**

If you have a concern about any aspect of this study, information and Frequently Asked Questions are available on the study website. If this does not answer your query you can contact the research team on 01392 72 5010 or email us on [support.protect@exeter.ac.uk](mailto:support.protect@exeter.ac.uk).

For independent advice and information you can contact the North Devon & Exeter Patient Advice and Liaison Service (PALS):

T: 01271 314090

W: <http://www.northdevonhealth.nhs.uk/contact/patient-advice->

liaison-service-pals

E: [ndht.PALS@nhs.net](mailto:ndht.PALS@nhs.net)

### **Further Information**

Thank you for taking the time to read the information about this study. If you would like to take part, please register for the study at [support.protect@exeter.ac.uk](mailto:support.protect@exeter.ac.uk). If you would like more information about the study before you decide whether or not to take part, you can contact a member of the study team by calling the study helpline on 01392 72 5010 or emailing your query to [support.protect@exeter.ac.uk](mailto:support.protect@exeter.ac.uk).

Please note that this helpdesk is for general information and support for the study. It will connect you to a member of the study team who will be able to talk about the study but will not be able to provide medical advice. Please also note that we are not able to give out information about your personal performance or progress in the study as your data are collected for research purposes only.