SYNEXUS HEALTHYMINDS REGISTRY

# Participant Information Sheet & Consent Form

**Version 1 Date: 25th February 2019**

# Synexus HealthyMinds Registry (Synexus HMR)

### Invitation to take part in a research study

Synexus Clinical Research Limited (Synexus) would like to invite you to take part in our research study (registry study) to help researchers understand how healthy brains age in order to identify ways to prevent cognitive decline, Alzheimer's Disease and other forms of dementia. 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 recognize 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 your consent at any time. If you decide to take part we will ask you to thoroughly read this information and consent to participate in the study using the online form on the next page.

### What is the purpose of the study?

This study aims to understand how the functioning of the brain 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. 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 research team at the University of Exeter in the United Kingdom and Synexus Clinical Research Limited and its Group Companies (i.e. entities/companies associated with Synexus) based in the United States. This includes Synexus Clinical Research US, Inc. (a company that conducts clinical trials) and Acurian, Inc. (a company that recruits patients for clinical trials).

This study is sponsored by Synexus Clinical Research Inc, who have responsibility for the design, management and oversight of the work.

**Why have I been invited?**

We are inviting adults aged 50 and over from across the United States of America to take part in this study. We are looking for 30,000 people to join the study and participate for the next five (5) years.

In order to participate, you will also need to:

- Have a good working understanding of the English language
- Have the ability to use a computer or touch-screen 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 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 need to read and consent to participate using the online form on the next page of the Synexus HMR website (synexushmr.com). You are free to withdraw at any time, without giving a reason. This study will not

affect the standard of care you receive through your primary care physician and does not replace those services. 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. There is some evidence to show that lifestyle factors such as exercise and smoking status could affect your cognition, but these links are still unclear and we need to understand more about them.

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. 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 30,000 adults over 50 years of age over five (5) years through an online study. Participants will complete a series of tests each year and we will analyze their performance to see how it changes as they age. By combining, this work with information about each individual's lifestyle and medical status this study will provide valuable new knowledge about how cognition changes as adults age. Additionally, this study will identify participants that are interested in receiving notifications about future clinical studies. If you choose to receive information about future clinical studies there is no obligation to participate in them.

**What will happen if I take part and what data will Synexus HMR collect?**

## 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 and email address. These details, will be transferred to the Synexus HMR database, allow us and the Synexus Group Companies to contact you for research purposes and to send you important information including how we collect and use your personal data. A full copy of this information can be found on our website in our Privacy Policy.

2. You will be asked to consent to participate in this study using the online form on the next page of the Synexus HMR website (synexushmr.com).

3. Once you have registered and consented to participate in this study using the online form on the next page of the Synexus HMR website (synexushmr.com) you will be asked to provide some basic demographic information including age, gender, marital status, ethnicity and education.

4. You will then be asked to complete a series of questionnaires on the website. One of these (the mental health questionnaire) is optional to complete. The questionnaires are:

    a. A medical history questionnaire, including your height and weight, 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.

    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).

5. You will then 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 allows 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.

6. 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 medical, lifestyle and mental health information. We will also keep you up to date with the study through a newsletter and the website.

7. There is a very small chance that people taking part in this study may develop cognitive impairment or dementia over the five-year period. In the unlikely event we detect a clinically significant drop in your performance in the study tests we will contact you by email to let you know our concerns and give you the opportunity to discuss them with one of our study doctors. We will also recommend that you

contact your physician to arrange an appointment with you to carry out further tests. This does not mean you would automatically be withdrawn from the study, but it ensures that you receive medical testing if needed. If you do receive a diagnosis from a medical professional we ask that you let us know through the website or by emailing the study team at hmrsupport@exeter.ac.uk. The website will provide information, links and useful contacts that may be helpful to you if this situation arises. However, the study team cannot provide medical support and/or advice.

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8. At the end of the five (5)-year study we will contact you to let you know the findings of the research.

**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. The outcome of this Registry study means we only wish to observe how you progress over time.

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.

**Internal and External Disclosures of Personal Information**

Study data, including coded medical information, may be used and shared for legitimate study and scientific purposes, including for future use in medical or pharmaceutical research, and these purposes represent the basis for processing such personal data.

Personal information will be held by Synexus and its Group Companies, and by the University of Exeter in the United Kingdom. Personal information will be shared within Synexus and its Group Companies on a “need to know” basis to meet stated legitimate business purposes. Access to databases and folders containing personal information is restricted to appropriate staff. Synexus does not trade or sell personal information. Under some circumstances, Synexus may be required by law enforcement or judicial authorities to disclose certain personal information as part of investigations or for litigation purposes.

Companies working as vendors of Synexus and its Group Companies are required to sign “processor” and/or confidentiality

agreements whereby they will commit to only process personal information consistent with contracted purposes and apply appropriate organisational and technical security safeguards.

The University of Exeter manages the Registry website and will hold a copy of your personal details. The University will access these details if there are concerns about your cognitive function (as described in the section ‘What will happen if I don’t want to carry on with the study?’) or if you contact us with an enquiry. Only authorised staff will have access to these details. The University of Exeter will also store and analyze your demographic information (psuedonymised data) alongside your results data (i.e. your cognitive test data and all other answers to questionnaires) for research purposes.

By registering with us you indicate your consent for Synexus Clinical Research Limited and its Group Companies to store your Personal Information in their database and contact you about clinical trials for which you may be eligible by various means, including telephone, email, and US mail address. If you receive a text message from us and would like to discontinue such messages, you may reply with the word “STOP”. Providing a telephone number constitutes your consent for us to contact you at that number for the purposes outlined in this information sheet. Participation in clinical trials is optional and you are not obligated to take part in any future studies if you do not wish. By registering with us you are only agreeing to receive information about future studies and you are under no obligation to take part. If you only want to take part to the HMR, you may remove your information from Synexus’ database and contact list by sending an email entitled “Unsubscribe” to optout@synexus.com . Please note that we may retain and use your information as necessary to comply with our legal obligations, when we believe that disclosure is necessary to protect our rights and/or comply with a judicial

proceeding, court order or similar legal process, resolve disputes, and enforce our agreements. You have a number of rights in relation to the personal data that is collected and held by an organisation about you. For further information on how your personal data is handled and on your various data protection rights please review our Privacy Policy at the following address https://www.synexushmr.com/Home/PrivacyPolicy

**Inquiries, Complaints and Requests to Exercise Rights**

General communications and queries should be addressed to hmrsupport@exeter.ac.uk where responses are aimed to be returned within three working days.

You may have the right to lodge a complaint with a supervisory authority. You may have the right to request from Synexus or University of Exeter access to and rectification or erasure of personal data or restriction of processing concerning your data or to object to processing as well as the right to data portability.

Any requests to exercise informational rights (e.g., access to data) or complaints can be addressed to the attention of The University of Exeter's Data Protection Officer who is responsible for monitoring compliance with relevant legislation in relation to personal data processed by University of Exeter, may be contacted by emailing dataprotection@exeter.ac.uk.

The Data Protection Officer of Synexus Clinical Research Limited and its Group Company who is responsible for monitoring compliance with relevant legislation in relation to personal data processed by Synexus Clinical Research Limited, may be contacted by emailing compliancecontact@synexus.com.

**Expenses**

You will not have to pay any money to participate in this Registry study.

**Payments**

You will not be paid for participating in this Registry study.

**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 from the study' link on the website or by contacting us on the study email address at hmrsupport@exeter.ac.uk. Your withdrawal of consent does not affect the lawfulness of the processing before the withdrawal.

If you receive a diagnosis of dementia or lose the capacity to make decisions independently about your involvement in the study, you would then be withdrawn from the study.

Your withdrawal from the study does not affect your eligibility to continue receiving communication about clinical trials from Synexus and its Group Companies. If you would like to opt out from receiving such communication please send an email entitled "Unsubscribe" to optout@synexus.com

Will my taking part in this study be kept confidential and how long will you keep my data?

Research data will be collected online through the study website over the five (5) year period. All data will be stored securely according to the applicable data protection and regulation laws.

All of the information we collect will be kept confidential. The University of Exeter will keep all personal details data for 10 years after the study has finished, then they will destroy it. The University will retain your anonymised results data indefinitely to allow the research questions to be answered and to support future research. Synexus and its Group Companies will retain your data for as long as needed to contact you about future clinical trials and to ensure we have your consent to process your data. You may withdraw

your consent at any time.

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

At the end of the five (5) 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 summary of our findings in the form of a newsletter. The findings will also be available on the study website. The information collected is very confidential and no individuals will be identified in any publications.

**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 by emailing us at hmrsupport@exeter.ac.uk.

**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 www.synexushmr.com. If you would like more information about the study before you decide whether to take part, you can contact a member of the study team at the Synexus HMR by emailing us at hmrsupport@exeter.ac.uk.

Please note that this email address 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 tell you 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.

When you take part in a research study like this Registry, you have rights. If you have questions about your rights as a research

subject or if you have questions, concerns, input or complaints about the research, you may contact:

Integ Review Institutional Review Board (“IRB”)

Address: 3815 S. Capital of Texas Highway, Suite 320

Austin, Texas 78704

Telephone: 512-326-3001

E-mail: integreview@integreview.com

The IRB will not be able to answer study-specific questions. However, you may contact the IRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.