PARTICIPANT INFORMATION SHEET v1.1

Aberdeen Birth Cohort 1936 (ABC1936) Study: A longitudinal study of ageing: Wave 4

Dear Sir / Madam,

We would like to invite you to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to the investigators about the study if you wish.

- *Part 1 tells you the purpose of this study and what will happen to you if you take part.*
- *Part 2 gives you more detailed information about the conduct of the study.*

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

PART 1

What is the purpose of the study?

The study aims to discover the factors that influence how our brain ages. This includes normal brain ageing, but we are particularly interested in those factors associated with the development of Alzheimer's Disease.

Why have I been chosen?

We are asking you to participate because you are already part of the 1936 Aberdeen Birth Cohort. The cohort consists of volunteers who, at age 11, undertook the Scottish Mental Survey in 1947. Previous studies involving the cohort have already provided unique and very valuable insights into brain ageing. The present study is the fourth to be undertaken and will improve our understanding even further.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep and be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. Your clinical care will not be affected if you do not wish to take part.

What will happen to me if I take part?

As with the last study, you will be invited to the Health Sciences Building at the University's Foresterhill site. You will get the chance to discuss the study with our Research Nurse, Dale Sherriff (who has taken over from Dr. Helen Fox). The assessments are in two stages. You may agree to both or part of the assessments. You may withdraw your agreement at any stage.

Part A. The clinical interview and examination

This is virtually the same as the interviews you agreed to do in waves 1, 2 and 3. The research nurse will ask questions about how your health may have changed since you last attended. The research nurse will examine your current physical health. This examination will take about 30 minutes and will include checking your blood pressure and lung function. We can now also get a measure of artery stiffness by placing a probe, shaped like a pen, on the skin overlying an artery at the wrist. This is totally painless and only takes a few minutes. We will also need a small **blood sample** (one tablespoon), for markers of general health, nutrition, vascular disease and degree of damage to your DNA (the genetic material in every cell). This sample will have a code that is unique to you. We will ask for your permission to keep this sample in a freezer so that we can use it in the future if new research shows that there are other things we should be measuring.

After the physical examination you will be asked to do some memory tests similar to those that you did at your previous visits. These tests will take about 90 minutes.

Part B. MRI Brain Scan

This brain scan takes between 20 and 30 minutes and is accomplished without the use of X-ray. Before the scan you may eat and drink normally. You will be made comfortable on a sliding couch. You will be required

to stay as still as possible while the images are being made. You may move a little to adjust your level of comfort between each image taken. You will be able to listen and talk to the staff operating the scanner. You will not experience any discomfort or unusual feeling of any kind, nor should you experience any after effects from the scan. In the unlikely event of feeling unwell, you will be provided with an emergency button to alert staff. You will only be asked to have an MRI scan if you had one on a previous visit.

There are many factors that may influence brain ageing and we would like to take as many of them as possible into account. For this reason, it is unlikely that we will be able to collect all the required information from you in just one visit, and most volunteers will require two visits. These will be arranged at dates and times to suit you.

What do I have to do?

If you would like to participate, or if you are unsure and would like to discuss the study with a member of our team, please fill in the reply form and return it to us in the stamped addressed envelope. Alternatively you can ring us on 01244 558063. If you do not wish to participate you do not need to do anything, but we would appreciate it if you could send us your reply in the envelope so that we do not contact you again.

What are the possible disadvantages and risks of taking part?

We do not think there are any serious risks or disadvantages. The procedures we use are very safe. MRI brain scanning is not safe for certain people that have some types of metallic implant such as a pacemaker. Your health check (Part A) will ensure that only those in whom MRI scanning is safe proceed to Part B.
You may wish to consider that in a small minority of volunteers the tests we undertake may reveal an unexpected abnormality (e.g. that there are signs of dementia or other illness). We believe it is almost always a good thing to catch health conditions early, but you may disagree. Our policy is to inform our volunteers of any such abnormalities and arrange an appointment with Dr. Soiza, who will discuss the results and any further action (e.g. further tests or treatment options) with you. If you do not agree with this it may be best not to participate, but we are happy to discuss this with you. Please note that we also require your consent to inform your GP of these results.

What are the possible benefits of taking part?

The study intends to improve our understanding of ageing and dementia, and is unlikely to help you directly.

What happens when the research study stops?

Once we finish the assessments in all our volunteers we will let you know of the results. There is likely to be a Wave 5 in 2010 or 2011. We will ask your permission to contact you for this study also.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

Will my taking part in the study be kept confidential?

Yes. All the information about your participation in this study will be kept confidential. The details are included in Part 2.

Contact Details:
Dale Sherriff, Research Nurse, Section of Population Health, University of Aberdeen, AB25 2ZD; Telephone No.: 01224 558063; E-mail: d.sherriff@abdn.ac.uk
Dr Roy L. Soiza, Consultant Geriatrician, Department of Medicine for the Elderly, Woodend Hospital, Aberdeen, AB15 6XS; Telephone No.: 01224 556319 ; E-mail: roy.soiza@nhs.net

This completes Part 1 of the Information Sheet.
If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

Part 2

What if relevant new information becomes available?

Should relevant new information become available that affects your participation in the study we will inform you, and discuss with you how best to proceed. This is unlikely to happen.

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

If you withdraw from the study, we will destroy all the identifiable information from you that we hold, but we may ask to use the data collected up to your withdrawal. Where possible we will also destroy the data collected up to your withdrawal if you wish.

What if there is a problem?

In the unlikely event that there is a problem or if you are unhappy at any point in time with regards to any matter during the study, please do not hesitate to contact any member of the study team.

Complaints:

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the University's Monitoring and Audit Group. The Group secretary is Mrs. Susan Caldwell, phone number 01224 554851 or e-mail s.caldwell@abdn.ac.uk.

Harm:

In the event that something does go wrong and you are harmed during the research study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Aberdeen, but you may have to pay your legal costs.

Will my taking part in this study be kept confidential?

You will be assigned with a study number and all data and blood samples for analysis will be coded such that they will be anonymous. However, your study number can be traced back to you by the researchers.

All information that is collected about you during the course of the research will be kept strictly confidential.

Involvement of the General Practitioner/Family doctor (GP)

Although your General Practitioner is not involved in the study, we feel that we should keep him or her informed of the study that you have taken part in. A simple information sheet will be forwarded to your GP for his or her records.

What will happen to any samples I give?

The routine blood samples collected for analysis will be stored in a secure freezer within the University of Aberdeen. We plan to keep the samples for 25 years. Only the research team will have access to your sample. We will only use the samples to measure substances that we think have a role to play in ageing of the brain or the development of dementia. Please note that we would like to retain your samples even if you lost the ability to give us your consent to use it in the future. If you are not in agreement with this, please let us know – you can still participate but we will ensure your samples are destroyed if you ever drop out of the study.

Will any genetic tests be done?

Genetic tests were performed in Wave 1. During the current wave we will be looking for degree of DNA methylation – a measure of damage to DNA, the chemical that makes up your genes.

What will happen to the results of the research study?

The results will be published in quality medical journals and presented at national and/or international meetings of specialists with an interest in brain ageing. We will also invite you to a reunion with other volunteers where we will present results directly to you.

Who is organising and funding the research?

The ABC Studies were developed by Professor Lawrence Whalley who has recently retired. The present study is headed by Dr. Roy Soiza, Consultant Geriatrician, who has taken over the Study since Prof Whalley's retirement. Funding for this part of the study is provided by the Alzheimer's Research Trust.

Who has reviewed the study?

This study has been reviewed by other experts in this field and is approved by the NHS North of Scotland Research Ethics Committee.

Can I obtain independent advice about participating in a research study?

Yes, Professor Gwyn Seymour is independent of the study group and has kindly agreed to be contacted if you want to discuss participation in a research study. His secretary can be contacted on 01224 556860.

We would like to thank you for participating in the study – should you have any further queries with regards to the study, please do not hesitate to contact us.