THE NEWCASTLE

STUDY: Stage 3

With your support we hope to help people stay healthy and active in older age

Please take the time to read this information booklet for consultees. It contains all you need to know about stage three of the study.

We are inviting …….to participate in stage three of The Newcastle 85+ Study.

We understand that they may find it difficult to make decisions about participation because of memory problems. However it is important that we find out about the needs of all older people and we believe they can make a valuable contribution.

What role and responsibility would I have in making this decision?

We would be grateful for your opinion as to whether you think they would wish to continue to take part in this research. We are not asking you to provide a personal view on the research topic or consent on behalf of the person, we are asking you to consider, to the best of your knowledge, if they would not object to taking part in this study and would not be caused any undue distress by participation.

Before you decide whether they should take part, we feel it is important to go over the reasons why we are asking you to do this, why they were chosen, why this research is being carried out and what stage three of the study involves. Please take time to read this information booklet carefully. If there is anything that is not clear, or you need more information, please ask. You will find our contact details at the back of the booklet. This leaflet is yours to keep.

Please understand you are under no obligation to act as a consultee and you may feel that someone else is better placed to take this role. If this is the case then let us know.

Why are we asking your opinion?

The research team have a lot of experience of working with people in the older age group. We understand that some individuals may have problems making it difficult for them to fully understand what taking part in a research study will involve. In other cases a person who consented to take part in an earlier stage of the study is now having memory problems and unable to fully understand the implications of

continuing in the study. In all cases such as these we have a legal duty to seek approval from another individual known as a consultee, who will act in the person's best interest.

Why was I chosen to take part in the research as a consultee?

A consultee may be 'personal' or 'nominated'. A personal consultee is usually a spouse, partner, close relative or friend and may have been nominated by the person taking part in the research at a time when they were able to make such a decision. A nominated consultee is usually an individual who is a paid carer or healthcare professional, who has knowledge of the person but no connection with the research study. An individual would be approached to be a nominated consultee in situations where:

- Where there are no relatives or close friends willing and able to act as consultee
- Where family or friends live a long distance away and are not in frequent contact with the person

What is the purpose of this study?

It is becoming more common for people to live to age 85 and beyond. Previously little attention has been paid to the health and needs of individuals in this age group. We are a team of doctors, nurses and scientists from the Institute for Ageing and Health at Newcastle University who are interested in the health and needs of older people. We want to find out what health, or other problems, older people have in their lives and what helps some individuals stay healthy and independent whilst others are not doing so well. We are also interested in finding out more about the scientific processes that happen with ageing. We hope to use the information from this research to find ways to help people stay healthy, independent and active in old age and to improve medical and social services for older people.

Why have we chosen certain people to take part in this study?

People who have survived beyond 85 years of age are very important, and we would like to find out more about the secret of their success.

Three years ago, we invited all people who were born in 1921 and who were living in Newcastle or North Tyneside to take part in The

Newcastle 85+ Study. We are very grateful to those who agreed to take part and who are helping to make the study a great success.
About 18 months ago, we visited these people again in stage two of the study and now we are inviting them to take part in stage three.

Do people who took part in stages one and two of the study have to take part in stage three?

It is up to you to decide whether or not to give approval to continue to take part in this study. You do not have to do so; however any information is extremely valuable to us. If you do decide to give approval, you will be asked to sign a consultee approval form, a copy of which you will be given to keep. You can still change your mind and withdraw your approval at any time without having to give a reason. Deciding not to participate, or withdrawal from the study, will not affect the current or future medical care of individuals in any way. If you decide not to approve the taking part in stage three of the study we will ask your permission if we can keep and use the information gained up to this point.

What will happen if I give approval to take part in stage three of the study?

As consultee you have the opportunity to be present for the duration of all visits. If you do agree, a nurse will come and talk to you and the person taking part in the study in their home at a time convenient to you both. They will explain about this stage of the study in more detail and answer any questions.

They will arrange three nurse visits over a period of a few weeks. Two of the visits will last about one hour and twenty minutes each and involve answering questions about the health of the person taking part together with some medical tests e.g. blood pressure, lung function. The third visit will be a shorter visit to take blood samples and complete the tests.

There is a full list and explanation of each of these tests at the end of this booklet. You may decline to allow some or all of these tests if you wish.

We can adapt the interview to suit individual needs e.g. with shorter visits and/or another family member or carer can be present at the interview to help or to answer questions.

The nurse will also request your approval for the research team to review the medical records of the person taking part (general practice, community health services, dental and hospital records). She will also ask for approval to review the records held by social services about use of their services. It should be acknowledged that some individuals will die during the course of the study and that permission is asked to review records in the event of death.

What about usual medical care?

Taking part in this study will not affect usual medical care. If treatment is currently received from a doctor or hospital, this will continue unchanged. This study does not involve taking any extra treatments (tablets/medication).

We would like to keep people's own doctor informed about their involvement in this study. The nurse will ask your permission to contact their doctor with the results of those medical tests that are particularly important for their health.

What are the possible benefits of taking part?

While there are no immediate personal benefits to individuals taking part in this study, we believe the information gained will improve what is known of the health and needs of individuals in older age group. We also hope that people enjoy taking part.

What are the possible disadvantages of taking part?

It is very unlikely that people will experience any harm by taking part in this study. If you do find that taking part causes distress or concern, you are free to withdraw your approval at any time.

What will happen after stage three of the study?

We hope that this study will continue for many years, providing more funding is secured. We would very much like to keep in touch with people in the future and to visit them again every year or two to find out how they are getting on and to repeat some of the medical tests. Each time, we will contact you again to see if you still approve the involvement in the study and to let you know in more detail about the questions and tests we would like to do. With your permission, we will use the information held by the NHS and records maintained by the General Register Office to follow up health status.

What if I change my mind and want to withdraw my approval?

If you feel that the person who you have given approval to participate in the study should now be withdrawn due to distress, or any change in circumstance, or where you feel it is no longer appropriate to continue with the research then you are free to withdraw your approval and them from the whole or any part of the study at anytime without having to give a reason. You are also free to request that all information and or samples donated are destroyed by the study team (although it may not be possible to trace all distributed sample remnants). Such a withdrawal would prevent information about people from contributing to further analyses, but it would not be possible to remove data from analyses that have already been done.

Will the identity of people taking part in this study be kept confidential?

All the information provided during the course of this research will be securely stored in either locked files or a secure computer database and kept strictly confidential. The answers to interview questions and medical tests will be kept separate from personal information (such as name or address) and will only be identified by a special code number. No individual will be identified or identifiable in any publication arising from the research.

Who is organising and funding the research?

The research study is organised by the doctors, nurses and scientists listed at the end of this information booklet. The study has the agreement of the appropriate authorities in the NHS and in Newcastle

University. The study is funded by the Medical Research Council, Unilever Corporate Research, the British Heart Foundation, Newcastle University Dental School and the Department of Health through the Newcastle Biomedical Research Centre funding.

Who has reviewed the study?

The study has been reviewed by the Newcastle and North Tyneside Medical Research Ethics Committee.

Whom can I contact for further information?

We will be happy to answer any questions you, your family or your carers may have about any aspect of this research study. Please call the number at the end of this booklet and ask to speak to our Research Nurse Manager: Karen Davies or one of the 85+ Research Nurse Team. If no-one is available, please leave your details on the answer machine and we will return your call. Alternatively you can write to us at the address at the end of the booklet.

Your help is very important to us; we very much hope you will agree to take part.

Thank you for reading this.

Now please read the **'Information about Tests'** section of this booklet.

INFORMATION ABOUT TESTS

All tests will be carried out within the individual's own home. They will involve minimal inconvenience and, apart from some mild discomfort when taking a blood test, are quite painless. The research team are very experienced in collecting this type of information and realise that not everyone has the same level of ability. All of the following tests will only be carried out with your permission and the consent to the level of ability of the individual taking part in the study.

- **Weight and body composition**

The research nurse will weigh the person taking part in the study in their own clothes (with bare feet) using specialised electric scales. These scales will also calculate the amount of fat and water in their body.

- **Blood pressure**

The research nurse will measure blood pressure, whilst the person taking part in the study is sitting, using an automatic blood pressure machine by placing an inflatable cuff on the top of their arm.

- **Hand-grip strength**

The research nurse will measure how strong hand grip is by asking the person taking part in the study to squeeze a lever as tightly as possible on a special machine which measures the force of their grip.

- **Memory and concentration tests**

The research nurse will do some tests of memory and concentration using a computer.

- **Spirometry**

The research nurse will ask the person taking part in the study to blow into a special machine to measure how strong their lungs are.

- **Oximetry**

The research nurse will measure the oxygen level in the blood stream by attaching a monitor to their finger tip of the person taking part in the study.

- **Seven day Activity Monitor**

The research nurse will measure the normal daily activity of the person taking part in the study for one week. This involves asking them to wear a small, light-weight monitor, like a wrist watch, for seven days whilst they carry on with their routine as normal. The monitor is fully waterproof so they can bathe as normal.
The monitor will tell us how active you are during the 7 day period together with information on patterns of movement such as walking, brushing your teeth, pouring a drink. It is not able to tell us *where* you are.

- **Up and go test**

Whilst they are wearing an activity monitor the research nurse will time how long it takes them to get up from a chair and walk a short distance within their home.

- **Chair stand test**

Whilst they are wearing an activity monitor, the research nurse will time how long it takes them to stand up and sit back down in a chair. They will be asked to do this five times in a row.

- **Tooth count**

The research nurse will count the teeth of the person taking part in the study. They will also ask for their dentist's contact details so we can arrange to review their dental records.

- **ECG**

The research nurse will perform a heart tracing. This test involves attaching stickers to the chest and limbs which are then connected to a monitor to record their heart trace by picking up the electrical pulses their heart makes when it beats.

- **Blood tests**

The research nurse will take samples of blood.
If possible, they will call first thing in the morning before the person taking part in the study has had anything to eat or drink. If this would be a problem for them, please let the nurse know and they will call at another time.
The samples will be used for the following tests:

- blood count
- liver, kidney, heart, bone and cartilage function
- sugar level
- insulin level
- cortisol level
- lipid level (e.g. cholesterol)
- thyroid function
- markers of inflammation
- markers of immune function (how the body tackles infection)
- markers of ageing
- mitochondrial function (mitochondria are small organelles found in cells of the body)

Some of their blood samples will also be used to investigate whether there are certain genetic or other factors which help some people live longer and more healthily than others.

We would like to store these samples for a long time; this is because new and important tests may become available over the coming years. We would then ask an ethics committee for permission to use these samples.

At any time you have the option to request withdrawal of their blood samples and they will be destroyed (although it may not be possible to trace all distributed sample remnants). Such a withdrawal would prevent information about them from contributing to further analyses, but it would not be possible to remove their data from analyses that have already been done.

THE NEWCASTLE 85+ STUDY TEAM

Research Nurse Manager: Karen Davies

Research Nurse Team

Sally Barker
June Edwards
Judith Hunt
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Lead researchers

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(If no-one is available please leave your details on the answer machine and we will return your call)

RESEARCH NURSE TEAM:

Karen Davies – Research Nurse Manager

Sally Barker ***June Edwards***

Joan Hughes ***Judith Hunt***