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**PATIENT INFORMATION SHEET**

**Project title: Northern Ireland Sensory Ageing Study: NiSA Study**

You are being invited to take part in a research study. Before you decide to participate or not, 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 and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. *Thank you for reading this.*

**What does this study involve?**

This study aims to investigate how and why our vision and hearing change as we age. It is known that declines in vision and hearing with age can have a significant impact on quality of life and independence therefore it is important that we understand more about why it happens and if it can be prevented.

If you agree to take part in this study you will be asked to attend for an appointment at the Clinical Research Facility at Belfast City Hospital and complete a series of vision tests, hearing tests and a questionnaire.

This study does not involve the giving of any treatment and the tests that we will perform are harmless and though time consuming will cause no pain and minimal discomfort.

It is important that you know the following:

1. Your participation in this research study is entirely voluntary, and you may decide to withdraw from this research study even after signing the consent form.

2. You may choose not to take part in the research study and this will not affect your future care.

3. Your involvement in the NICOLA study will not be affected by your decision to take part, or not take part, in this separate study.

4. You may receive no benefit from taking part in this research study.

**Why have I been asked to take part?**

We are inviting a random proportion of NICOLA participants who have undertaken the health assessment to take part in this separate study which involves attending an appointment at which their vision and hearing will be assessed more carefully. This will help us to relate what we can see from the images of the back of the eye at the NICOLA appointment with how well you can see on a day to day basis.

**Do I have to take part?**

It is up to you to decide whether or not to take part in this separate study. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you can withdraw at any time and without giving a reason. Participation is entirely voluntary and if you choose to decline this will have no impact on your further participation in the NICOLA study and it will have no effect on how you are treated within the NICOLA study.

**How long will my participation last?**

If you wish to take part in this separate study you are required to attend for a 2-hour appointment at the Wellcome Trust Clinical Research Facility at the City Hospital, Belfast.

During the appointment we will ask to dilate your pupils. If you agree it is recommended that you not drive for 6 hours therefore we recommend that you bring a relative or friend with you to the appointment.

There are no other restrictions or requirements as part of this study. You can omit any questions on the questionnaire that you do not wish to answer.

**What does my participation entail?**

You will have your eyesight measured and take part in a variety of vision tests. None of these tests require any physical contact with your eyes. Some of these tests will be very familiar and will be similar to tests you would undergo at your high street optometrist appointment. Other will be more novel, with various shapes and targets presented on computer monitors and you will be required to press a button when you see the target. The tests will be used to assess different aspects of your visual system; such as your peripheral vision or how your eye adapts to bright light. While all tests are painless, some are time consuming so frequent breaks will be given as required.

A simple hearing test will also be completed.

During your visit one pupil of your eyes will be dilated (made bigger in size) using special drops. These may sting for a few seconds after administration.

You will also be asked for a blood sample; this will be taken by a staff member trained in taking blood (phlebotomist). It is a low risk procedure although it may be associated with minor bruising, bleeding, pain and infection at the site. The latter two risks will be reduced by the use of the sterile insertion technique. Approximately 20 millilitres of blood, equal to around 3 tablespoons, will be taken from a suitable vein in your forearm or hand. We will process the blood sample to test for fats such as cholesterol in the blood, diabetes indicators, and a range of other tests relating to ageing and for DNA extraction.

Finally, we will give you a questionnaire which will ask you some questions about your vision and your hearing.

**What is the drug or procedure that is being tested?**

No drugs are being tested in this study.

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

Pupil dilation:

Dilation of your pupils may cause some temporary glare and blurring of sight. The pupils will return to their normal size usually within 4 to 6 hours.

It is recommended that you not drive for 6 hours after dilation of your pupils and therefore we recommend that you bring a relative or friend with you.

The dilating drops may cause a sudden increase in pressure (acute glaucoma). This only happens in the eyes of persons who have a susceptibility to this condition (of the order of 1 in 3000 persons). Therefore the risk of this is extremely low. If it does occur, the study team are trained to deal with it and will institute appropriate treatment.

All the eye tests are non-invasive (meaning that only light is used to illuminate the eye through the pupil and nothing touches your eye). The same equipment is also used clinically on patients with various retinal diseases and therefore we know that the levels of light that are used in these tests are safe. The time taken for these tests is relatively short and for the vast majority of people the tests cause little or no discomfort.

Blood sample:

You will feel a slight pinch when the needle enters the skin. Insertion of the needle into your skin may cause some pain, discomfort, and slight bruising. This may cause you to feel faint. It is unlikely that you will develop an infection at the site.

You may participate in this study even if you do not want to provide a blood sample. If you agree to have your blood drawn for this study, researchers may be interested in using your blood cells and DNA for future research projects. Your blood cells and DNA may be stored for several years. We would like to emphasize that no one will be able to identify which sample is yours as all identifying information will have been removed.

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

This study will allow us to collect a significant amount of valuable data regarding the ageing process and visual and hearing function. It will generate information to allow further studies and research to be carried out which may have benefits to future eyecare and eye health policies.

**What do I do if I feel I have been harmed?**

It is very unlikely you will have any problem during this study but if you have any concerns please contact the supervisors whose contact details are listed below.

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

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

**What will happen to the results of the research study?**

In any publications/reports that arise from this study, volunteers will be acknowledged for their participation. Names of volunteers, however, will not be published in any of these releases.

**Who is organising and funding the research?**

This study is being funded by the College of Optometrists, Pocklington Trust, SENSE and RNIB. The study is being organized by Miss Katie Graham (PhD student) under the supervision of Dr Ruth Hogg, Professor Usha Chakravarthy, Professor Roger Anderson and Professor Jayne Woodside.

**Has the study got ethical approval?**

This study has been reviewed by the Research Ethics Committee of the School of Medicine, Dentistry and Biomedical Sciences, Queen’s University Belfast.

**Contact for Further Information**

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**The researchers would like to thank you for taking part in this study.**

**All volunteers will be provided with their own copy of this Patient Information Sheet along with a copy of the consent form which you sign.**