Northern Ireland Clinical Research Facility
City Hospital
Belfast

CONSULTEE INFORMATION SHEET FOR PARENTS/GUARDIANS

Project title: The Eye in Down syndrome as a window to Alzheimer's Disease.

Your son/daughter (or person you care for) is invited to take part in a research study. This leaflet provides information outlining the study and what it involves. Please read it carefully before deciding to volunteer the person you care for and the researchers will be happy to address any concerns or questions you may have.

What is the purpose of this study?

There is a major need for early identification of those at risk of Alzheimer's Disease, a condition for which people with Down syndrome are at increased risk. Recent work has highlighted the potential for images of the inside of the eye to provide evidence of the onset of Alzheimer's Disease before other clinical signs are visible.

The main aim of this study is to profile features of the eye in those with Down syndrome.

We will also examine people who do not have Down syndrome (some of whom will have been diagnosed with mild cognitive impairment). We will also take spit (saliva) and tear samples, and from these we will measure proteins linked to inflammation in the body. We would also like to take a blood sample but this is not essential. We will compare our results to see whether there is a link between the changes in eye structure and inflammatory markers. If we find a connection, this will tell us that inflammation is an early part of Alzheimer's Disease development, and our insight into the structures of the eye could give us a way of monitoring this in the future. We will also undertake some memory tests, so we can profile how this relates to the spit, tear and blood samples, in addition to the eye assessments.

We will divide participants into three groups: younger people and adults with Down syndrome, older adults with mild cognitive impairment, older adults without mild cognitive impairment. We aim to recruit 50 participants for each group.

What will happen to the person I care for if he/she takes part?

You will receive copies of the signed assent form, consultee declaration form and this information leaflet for you to keep. The study itself will require you and the person you care for to attend the Northern Ireland Clinical Research Facility at the Belfast City Hospital on one occasion at a time convenient for you. The visit will last approximately three hours, including breaks for refreshments and for eye drops to take effect. **If the person you care for does wear glasses, please bring them with you. Due to the eye drops, we will give the person you care for a temporary pair of sunglasses at the end of the session.** You are welcome to be with them at all times during the visit.

At the study visit, the participant will be asked to:

1	Answer some straightforward general and eye health questions. It may be useful to have a list of medications to help prepare for these questions.
2	Measure vision and complete some straightforward memory and behavioural tests.
3	Have eye drops put into both eyes. This will dilate the pupils temporarily. This eye drop is routinely used in hospitals and optometry practices to widen the pupil; this improves the view inside the eye and will help us take the best photos we can.
	20 minute break for drops to take effect
4	Take a number of pictures of the inside of the eye (retina and lens). We will use several different cameras to try to get the best range of photographs we can. Most of the lights on the cameras are not bright. We will let the participant know when any brief flashes of lights will happen and they will not harm the eyes. These tests only requires the person to sit still for a couple of seconds at a time and will be paced according to the individual. We are experienced in putting participants at their ease, giving clear and concise instructions and responding to the participant's needs.
5	Take tear samples from the eye and spit (saliva) samples from the mouth. These will be collected on strips of paper and a small collection tube or sponge. Both of these are harmless and painless but may take a little time and may be a little irritating.
6	Take a small blood sample *(optional)*. We appreciate that not everyone may want to have this done. However, even if your child/the person you care for does not want to give a sample, we would still like them to participate in the rest of the study. We have a team of experienced clinical research nurses to take this blood sample.

There are no known side effects to having the photographs taken or doing these other tests. Eye drops may blur vision temporarily and can increase sensitivity to bright light. There may also be temporary stinging and a dry mouth after using the eye drops. The effects of the drops can last between two and four hours, but can be up to six hours. If the participant wears contact lenses, they will need to remove them for the study. Please bring contact lens storage container and their spectacles.

While we appreciate that this sounds like a significant number of tests, please note that most tests only require a couple of seconds of eye alignment and can be done with limited cooperation and brief periods of attention. These assessments are not painful or invasive.

Participants will have the opportunity for refreshment breaks during the study visit, and we have £20 to give for compensation of travel. You will be met and escorted to and from the building. For comfort, participants will be provided with single-use sunglasses to use on their journey home. During testing we may uncover an eye problem that would be useful to follow up. The research team are clinicians and we will refer the participant for further investigation if consent has been given to let us do so.

All tear, saliva and blood samples collected during the study will be stored within monitored locked freezers at the School of Biomedical Sciences at Ulster University. Part of the blood samples for all participants will be transferred to the lab of Henrik Zetterberg, UCL Queen Square Institute of Neurology for analysis.

All information about all participants will be kept confidential, no one outside of the research team will know who they are; and they will only be identified by a study number.

Why has the person I care for been chosen?

The person you care for has been chosen as they have Down syndrome and have not had cataract surgery. It is the decision of you and the person you care for whether they decide to take part in the study or not. If you and the person you care for decide to participate in the study you will be given this information sheet to keep. We would like to see the person you care for whether they wear glasses or not**.**

What are the possible risks/side effects to the person you care for by their taking part in this study?

All methods used in this study are quick to perform.

The blood sample that will be collected may cause some discomfort but this will be minimised by a trained phlebotomist collecting the sample.

The tests require the instillation of eye drops to temporarily increase the size of the pupil, allowing high-quality images of the eyes to be captured. These drops are routinely used in clinical eye care to improve the view of inside the eyes. The research team comprises GOC-registered optometrists and an ophthalmologist. We have experience using these eye drops and undertaking these eye assessments in people with and without cognitive impairment. For comfort, participants will be provided with single-use sunglasses to use on their journey home.

Tropicamide 1% is commonly used in optometric practice to dilate pupils however, it can cause mild discomfort (stinging) lasting a few seconds following instillation. Near vision may be a little blurred after the drops, and bright lights can be a little uncomfortable for up to 6 hours afterwards. **There is a small risk of increased eye pressure; this is extremely rare and will be minimized by conducting all necessary preliminary tests and monitoring eye pressure.**

What if something goes wrong?

It is unlikely that something will go wrong during this study however, procedures are in place should any adverse event occur. **An information sheet outlining the symptoms of increased eye pressure and what to do if the person you care for experiences them will be given to you at the end of the research session; Emergency contact details will also be on this sheet.** The University has insurance cover for staff and students who carry out research involving people. This research project has received a favourable opinion from Health and Social Care Research Ethics Committee A (HSC REC A). The study has also been reviewed and approved by the School of Biomedical Sciences Research Ethics Filter Committee within Ulster University.

Any complaint should be made, in the first instance, to the lead researchers; contact details are provided at the end of this document. Any complaint you make will be treated seriously and reported to the appropriate authority. The University complaints policy is available here:

https://www.ulster.ac.uk/__data/assets/pdf_file/0011/75638/Complaints.pdf

Will the person you care for's participation in this study be kept confidential?

All personal data will be stored electronically and password protected. The data will be anonymized for confidentiality and any written material will be kept in a locked filing cabinet. Data will only be used for the purposes of evaluating the aims of the study. Any details of the personal data collected in this study will not be disclosed to anyone other than the research team.

Data will be held securely under the requirements of Data protection legislation. Ulster University is the sponsor or managing organisation for this study and we will use information gathered from you and/or your records in order to carry it out. We will act as the data controller, which means that we are responsible for looking after your information and using it properly, as stipulated in GDPR and the Data Protection Act 2018. You can find out more about how we look after your information at: https://www.ulster.ac.uk/about/governance/compliance/gdpr

Should participants incidentally disclose inappropriate or illegal behaviour or poor practice to any member of the research team, they are obliged to report this to the relevant authorities.

How will we use information about you?

We will need to use information from you for this research project.

This information will include your:

- Name
- Contact details

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from **www.hra.nhs.uk/patientdataandresearch**

- by asking one of the research team
- by sending an email to e.coyle2@ulster.ac.uk, or
- by ringing us on +44 28 7167 5525.

What will happen to the results of the study?

This work will help us better understand how the early stages of Alzheimer's Disease affect the eye, which may lead to new, patient-friendly ways of identifying the condition earlier and investigating and monitoring the disease. If we find that inflammatory markers and ocular changes are related to the development of Alzheimer's Disease, we could then investigate this over time in individuals to see how these physical signs are related to cognitive decline. The results and information gained from this study may contribute to scientific knowledge and also be valuable in further studies of vision and disease in Down syndrome.

Who is organising and funding the research?

The research is funded by Alzheimer's Society, and both Prof. Julie-Anne Little and Dr Imre Lengyel lead the project, along with a research team including those with expertise in cognitive assessments and genomic testing in Down syndrome and Alzheimer's Disease from Kings College London, University of Gothenburg and Ulster University.

What do I do now?

If you and the person you care for would like to take part, please contact Dr Aoife Hunter to arrange an appointment to attend the Northern Ireland Clinical Research Facility. You or the person you care for are free to withdraw from the study at any time without reason, as participation in this study is voluntary.

Contact details

Further information can be obtained from:

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Thank you for your time and consideration.