



Evaluation of novel imaging techniques for the detection of Glaucoma.

Dear

**Invitation to take part in a research study**

I am currently undertaking a national study to evaluate the performance of three new automated eye tests for the diagnosis of glaucoma in conjunction with The Health Services Research Unit, University of Aberdeen. As you are coming to the eye out patients department for an appointment I would like to invite you to take part.

I have enclosed an information sheet about the study which will help you decide whether or not you would like to participate and would be most grateful if you could take a few minutes to read through the information.

If you agree to take part then you will be given three automated eye tests during your appointment which should take no longer than one hour to complete before being seen by the ophthalmologist as per a normal clinic appointment.

Although your involvement is very important to us we would like to stress that you are under no obligation to participate. We will be happy to discuss any aspect of the study with you at the clinic when we see you and if you have any questions about the study we will be pleased to answer them then.

Yours sincerely,

Augusto Azuara-Blanco  
Consultant Ophthalmologist.

## **GATE study patient information leaflet**



Evaluation of novel imaging techniques for the detection of  
Glaucoma (GATE study).

### **Information leaflet.**

You are being invited 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 the time to read the following information carefully and discuss it with others if you wish. Ask us anything that is not clear or if you would like more information. Take time to decide whether you wish to take part. Thank you for reading this.

#### **What is the purpose of the Study?**

Glaucoma can reduce vision and quality of life but if diagnosed early it can be treated and reduction of vision prevented. The main risk factor for a reduction in vision due to glaucoma is being diagnosed late and damage to the eyesight has already begun. New promising diagnostic imaging tests are available and are easy to perform. They use a laser to explore and analyse the structure of the optic nerve head and surrounding tissues in the back of the eye. However, which test is the best to use is uncertain at present and this project will evaluate the performance of three new imaging tests. If one of the tests proves to be accurate and easy to perform, it could be implemented in the community to reduce the risk of reduced vision from glaucoma.

#### **Why have I been chosen?**

As you are attending the eye out-patient clinic for an eye examination from an ophthalmologist we would like to invite you to take part.

#### **Do I have to take part?**

No. It is up to you to decide whether you take part. 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 are still free to withdraw at any time and without giving a reason.

**What will happen if I take part?**

The study is carried out alongside your appointment in the local Eye Out-Patient Clinic. Depending on routine practice at your local clinic this may be one or two appointments. You will be given a visual fields test along with three imaging tests and finally a basic eye examination by an Ophthalmologist. The addition of the imaging tests may extend your appointment time by approximately one hour.

**What do the imaging tests involve?**

There will be three imaging tests carried out by a research technician. The imaging tests are non-invasive and do not usually require eye drops. During the test you will have to look at a fixation light for a short period whilst a series of images of the optic nerve head at the back of the eye are acquired. The imaging tests are rapid and take approximately 10 minutes to complete. In a small number of cases we may have to place some eye drops in your eyes to dilate your pupils. This can make it easier to take the image.

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

Most people will not need their pupils dilated. If we need to dilate your pupils it can sometimes cause some temporary blurring of vision and sensitivity to light. This is, however, a routine procedure which would normally be performed as part of your eye examination

**Are there any benefits to taking part in the study?**

There will be no direct benefit to yourself in taking part in the study, however if any of the tests prove to be accurate and easy to perform, they could be implemented in the community.

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

All information which is collected about you for the study will be kept strictly confidential. Information for all participants in the study will be kept for a minimum of ten years in line with current research governance arrangements and then destroyed. Only researchers involved with the study will have access to your information

**What happens to the results of the study?**

The results of the research will be published in relevant scientific journals and a report will be sent to the funder of the research, the NHS Health Technology Assessment programme. We would also be happy to send you a short report when the study when the research is complete. You will not be identifiable in any publications from this research.

**How do I Complain?**

If you wish to complain or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal NHS complaints mechanisms are available to you.

**Who has reviewed the study?**

This study has been reviewed and approved by the North of Scotland Research Ethics Committee.

Thank you very much for considering taking part in this research.

**Contact details for further information****Central office:**

GATE Study Office  
Health Services Research Unit  
University of Aberdeen  
Health Sciences Building  
Foresterhill  
Aberdeen AB25 2ZD  
Tel: 01224 438196  
Fax: 01224 438165  
Email: [gate@abdn.ac.uk](mailto:gate@abdn.ac.uk)

**Local contact details:**

[Contact details]  
[for local researchers]  
[Affix sticker here]

# GATE study consent form

*(Form to be on headed paper)*

Participant Study Number:

--	--	--	--	--

## CONSENT FORM

**Comparative study of new imaging technologies for the diagnosis of glaucoma: the GATE study**

**Please initial box**

- 1 I confirm that I have read and understand the information sheet dated .....  
(version .....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
  
- 2 I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
  
- 3 I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from the University of Aberdeen, from regulatory authorities or from the NHS Trust/Health Board, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
  
- 4 I understand that my personal details collected during the study will be held in a secure central database, and may be subject to audit and monitoring by University of Aberdeen or NHS Trust/Health Board staff, without breaching data confidentiality
  
- 5 I agree to take part in the above study.

\_\_\_\_\_  
Name of Patient

\_\_\_\_\_  
Date      Signature

I confirm that I have explained to the person named above the nature and purpose of the GATE study and the procedures involved

\_\_\_\_\_  
Name of Person taking consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

GATE study office, Health Services Research Unit, University of Aberdeen, Foresterhill, Aberdeen AB25 2ZD.

Tel: 01224 438196, Fax 01224 438165, Email: [gate@abdn.ac.uk](mailto:gate@abdn.ac.uk)

**Copies: Original to be returned to study office: 1 copy for patient; 1 copy to be filed with hospital notes**