



**“Effectiveness of Multimodal imaging for the Evaluation of Retinal Oedema And new vessels in Diabetic Retinopathy (EMERALD)”**

**PATIENT INFORMATION LEAFLET**

You are being invited to take part in this research study called:  
“Effectiveness of Multimodal imaging for the Evaluation of Retinal Oedema And new vessels in Diabetic Retinopathy (**EMERALD**)”

Before you decide to take part, 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. Do not hesitate to ask us questions if there is anything that is not clear or if you would like more information.

**1. What is the purpose of this study?**

The purpose of EMERALD is to determine whether people with the complications of diabetes in the eye who had been previously treated and appear to be stable now could be safely reviewed in clinic by health care professionals other than eye doctors. If at any point the disease were to come back, then patients would be seen immediately again by the eye doctor.

**2. Why have I been chosen?**

You are being invited to take part in this study because you have had treatment for the complications of diabetes in your eyes.

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

No, taking part is voluntary. If you decide to take part you will be given this information leaflet to keep and will be asked to sign a study consent form. If you decide not to take part in this study that will be alright and your care will not be affected. You are free to withdraw from the study at any time without giving a reason.

### **4. What will happen if I decide to take part?**

- You will be given further information about the study and you will have a chance to ask questions.
- You will be asked to sign a consent form in which you are agreeing to take part in the study.
- Some information about you will be recorded (for example information about your age, gender, type of diabetes, etc – this will be obtained from your medical notes).
- The scans of your eyes which have been obtained already will be saved and used for the study once they have been anonymised (your name will not be attached to the photographs so nobody will be able to recognise you when seeing them).
- For the purpose of this study we will obtain some extra photographs of the back of your eyes (these will be also anonymised).
- You will be asked to fill in some questionnaires which will provide us with information about how your sight affects your quality of life.
- You will also be asked to participate in small group discussions to give your views on health professions, other than doctors reviewing your condition. You do not have to take part in the group discussions and can still participate in the EMERALD study even if you decide you do not want to be involved in the discussions. Participation in such groups is voluntary and patient's views will be kept confidential. There is a separate information sheet for the group discussions which you will be asked to read. If you agree to take part in the group discussions you will be asked to sign a separate consent form.

- It is possible that the photographs of the back of your eyes may be used not just for this study but for other research studies in the future; nobody will be able to recognise you from the photographs. The anonymised photographs of the back of your eyes will be sent to Queen's University Belfast who will then redistribute the photographs to the other centres participating in the study so that the photographs can be graded.

## **5. What are the possible inconveniences for me if I decide to take part on this study?**

There are no risks associated with this study, the only inconvenience is that you will have some extra photographs taken of the back of your eyes and you will need to fill in some questionnaires.

## **6. What are the possible benefits to my taking part?**

- You will be helping us to determine whether other health professionals besides doctors could look after people that have been treated for the complications of diabetes in the eye once they are considered to be stable.
- If we find that this is the case, this will relieve doctor's time in the NHS and doctors could then see patients with active disease and who require treatment more promptly.
- This may help you in the long term as this would potentially help with waiting times in the NHS.
- If the study shows that having other health professionals seeing patients once they are stable is not as good as having eye doctors evaluating them, then this strategy will not be implemented in the NHS.

## **7. Will my participation be kept confidential?**

Any information collected about you during the course of the study will be kept strictly confidential. During the course of the study data will be monitored by sponsor representatives. This will involve staff reviewing your medical notes to ensure that all results have been recorded

accurately. Anonymised data will be transferred to the Northern Ireland Clinical Trials Unit (NICTU), Queen's University Belfast, Oxford University and Warwick University. This information will only be seen by staff involved in the study. All the staff will have a duty of confidentiality to you as a research participant. Once the study ends your data will be kept for 5 years, after which time it will be destroyed.

### **8. What will happen to the results of the research study?**

Data from this research study will be published. Nobody will be able to identify you from any of the data/photographs published. The published data will contain no personal information and will be anonymised.

### **9. Who is organising and funding this study?**

EMERALD is organised and led by Professor Noemi Lois, who is a consultant at the Belfast Health & Social Care Trust, Northern Ireland and a Clinical Professor in Ophthalmology at Queen's University Belfast. It is funded by a grant from the National Institute of Health Research (NIHR). The Clinical Trials Unit coordinating the study is the Northern Ireland Clinical Trials Unit (NICTU), Belfast Health & Social Care Trust. Patients from many locations in UK are participating in this trial as several Hospitals in UK are taking part on this study.

### **10. Who has reviewed the study?**

This research has been reviewed by an independent group of people called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. Having reviewed the study, the Research Ethics Committee has given permission for the study to take place. The research office at your hospital has also reviewed and approved this study too.

### **11. What if I have any questions, concerns or complaints about the study?**

If you have any questions about participation in this study or concerns about the way it has been carried out you should ask to speak to the

researchers who will do their best to answer your questions. If you are based in Northern Ireland or Scotland please contact the research nurse or doctor who enrolled you in the trial. If you are based in England you can also contact your local Patient Advice and Liaison Service (PALS) at: [insert local PALS contact details here].

## **12. What if something goes wrong?**

There are no side effects of taking photographs of the back of your eyes.

Every effort will be made to ensure that no patient taking part in this study is put at risk or harmed in any way. It is very unlikely that anything will go wrong as a result of taking part in this study. If something does go wrong and you are harmed due to someone's negligence, then you may have grounds for legal action against your hospital, but you may have to pay your legal costs. If you remain unhappy and wish to complain formally, you can do this through the local health service Complaints Procedure by contacting

[Insert local complaints department details]

## **13. What are the costs and payments for taking part in this study?**

You will not be compensated for taking part in this study as this study does not involve any extra visits. The extra photographs will be taken at your normal clinic appointment.

The additional tests that will be performed for this study will be provided to you at no cost.

**Thank you for taking the time to read this  
Patient Information Leaflet.**

**Who to contact for further information:**

**Chief Investigator:**

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**Local Research Nurse:**

*Contact details to be inserted here*

**Local Principal Investigator**

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