PARTICIPANT INFORMATION SHEET

UNIVERSITY OF LINCOLN

Study Title	Building a longitudinal retinal imaging dataset from a diverse community: The University of Lincoln.
Principal Investigator	Dr Bashir Al-Diri baldiri@lincoln.ac.uk 01522 83 7111
Location	INB 0109

Chair of College Ethics Committee: Professor Oliver Burman

We would like to invite you to take part in our research study. Before you decide to participate, it is important that you understand the purpose of the research and what it will involve.

Please read the following information carefully as it details the purpose of the study and as a participant what will be asked of you and the benefits of getting involved

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1 Purpose and Benefits of this Study

The retina is a layer of predominately nervous tissue that covers the inside of the back two-thirds of the eyeball. It enables the conversion of incoming light into a neural signal, which is processed in the visual cortex of the brain. Various eye disorders affect the retina such as age related wear and tear (macular degeneration) and increase in eye pressure (glaucoma), as well as systemic diseases, such as diabetes and hypertension, which manifest themselves in the retina.

These systematic diseases cause complications such as diabetic retinopathy and hypertensive retinopathy, both of which can lead to blindness. Treating these diseases in their early stages has a huge impact on patients as most of these diseases cause irreversible damages to the eyes and have a huge impact on the treatment costs. The retina can be examined non-invasively through the pupil, and hence, the retinal vessels as well as the retinal structures can be reachable for imaging noninvasively. The ability to take images of the retina and to develop techniques for analysing retinal images is of great interest to a wide range of clinicians and researchers as these techniques could be utilised in detection, diagnosis and management of diseases.

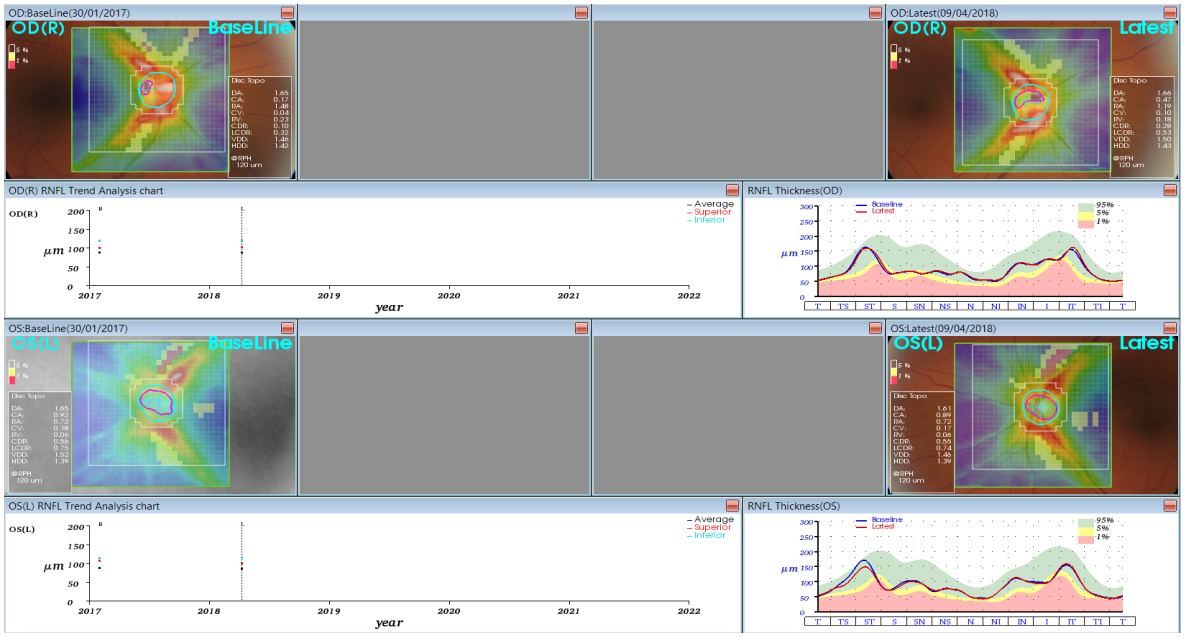
Our research aims to find and analyse new signs in the retinal vascular system photographed at the back of the eye that might be changing with disease. These signs can then be monitored and measured over time to detect and signify disease progression or change. Fundus photographs, as well as scans of

the back of the eye (Optical Coherence Tomography), are the most common techniques used for detecting eye diseases in routine clinical practice and for diagnosis and monitoring of a variety of eye conditions.

We believe that the longitudinal studies will be the best way to analyse progression of changes over time and to connect unlinked events over a period of time. Since longitudinal studies engage collecting vast amount of data over a long period of time, they are very rare in retinal image analysis.

In this project we aim to collect 2D fundus images and 3D OCT images from participants using a fully automated user-friendly retinal-imaging camera (3D OCT-1 Maestro). Participants will be recruited from our University of Lincoln community. The University community fairly represents the Lincolnshire community, which represents the national community. Individuals in our community might have various conditions. We hope to collect images over 5 years in order to have 10 images per eye for each participant.

We will carry on longitudinal studies in the near future, using the collected dataset to discover patterns and to learn cause-and-effect relationships. We hope to develop a set of integrated techniques that are expected to influence routine clinical patient care in the years to come.



2 Participant Involvement

To ensure you are suitable for this research you are required to complete a Medical History and Health Questionnaire. The information you provide will allow us to understand your health status and previous experiences when having medical examinations. This form needs to be filled out to the best

of your ability to provide the research team with the most accurate information possible. This form will also ask you to provide consent.

You will be invited to visit the automated retinal image analysis lab (ARIAL) every six months to provide images of your eyes and to provide clinical data. Each visit is expected to be 15 minutes long. A short version of Life Style and Health Questionnaire will be completed for each visit. We are going to capture two image modalities at the same time (3D-OCT images and fundus images).

You will sit in front of the fundus camera with your chin in the designated rest and your forehead against a padded bar. A photographer (i.e. Principal Investigator or one of his team) focuses and aligns the fundus camera. A flash appears as the photographer presses the shutter release, creating a fundus image. For each visit, two image sets will be captured from your eyes to cover the nasal and temporal sides of your eyes.

3 Risks and Discomforts

Every effort will be made to minimise the risks by evaluation of each participant's health information. As the procedure of capturing retinal images is well established with no reports of side effects, no adverse effects are expected during this procedure. There is no risk when capturing retinal images, however, capturing retinal images requires a flash, which may cause discomfort for a few seconds. Due to this flash, you are not allowed to participate if you have:

1. Epilepsy or migraine as it can induce attacks with the bright flickering light,
2. Recently undergone photodynamic therapy (PDT),
3. Taking medication that causes photosensitivity.

Mr Maged Habib is a consultant ophthalmologist at the Sunderland Eye Infirmary and will assess your participation eligibility based on your completed documents.
Mr Maged Habib will review all captured images. All images will be stratified to normal or abnormal and provisional diagnosis would be made based on any abnormality noted in the images. The participants will be notified with the outcome of their images review and any abnormality will be reported directly to the candidate and their registered GP with clear advice on further action if needed.

4 Data Collection

Recent research has utilized contextual information together with image analysis, to assign risk profiles to patients in a screening environment. In this project, we want to integrate clinical data that can be captured by individuals or those that are known by participants in addition to the imaging data. A set of clinical data will be captured using the following forms

1. Medical History and Health Questionnaire will record medical and lifestyle data on the first visit and a shorter version to record any changes to the lifestyle data every visit.
2. Personal Detailed Form will record ethnicity, date of birth, gender and medical surgery details.
3. Collection Body Metrics & Images Form will record, for each visit, heart rate, blood pressure, height, weight and visual acuity.
    a. Blood pressure will be measured using a wireless device (OMRON EVOLV All-In-One, Wireless, Upper Arm Blood Pressure Monitor). It wraps around the upper arm over clothes and the user press a button to get a reliable and accurate result that has been rigorously tested by major health organizations.
    b. The heart rate and blood oxygen saturation will be measured using a digital pulse oximeter (MeasuPro OX200 Instant Read Digital Pulse Oximeter with Carry Case and Lanyard CE, FDA Approved).

These devices and equipment will be cleaned with anti-bacterial cleaning wipes after every use.

Participants will have the option to request a copy of their data results to be sent to them via mail or secure email address or to be sent directly to their GP if needed for further assessment.

5 Data Storage

A database will be created to store data attributes and images for each participant. Each participant will have an anomalous unique participant's code, which will be associated with his or her data records. The database will be stored in a local secured machine connected to the retinal-imaging camera. A regular backup will be taken and the back up will be stored in a secured cabinet in the project coordinator office. All of the external hard disks will be encrypted.

6 Enquiries

If you have any doubts or queries about the procedures used in our lab, please request further information (Bashir Al-Diri; 01522837111; baldiri@lincoln.ac.uk).

7 Freedom of Consent and Confidentiality

Your involvement in this project is voluntary and confidential and our procedures for handling, processing, storing and destroying data are compliant with the GDPR. Identifying details will be removed from any final report or publication. Consent forms and results sheets will be kept by the University for 5 years in a secure location and then destroyed.

8 Publication and Presentation of Research Results

Our aim is to present our findings in national and international conferences and also to publish them in scientific journals. An overall summary report will be sent to participants for their information if requested, but it will not be possible to produce individualised reports.

Please ask any questions you may have here.

Feedback provided in response to the above questions.