TITLE OF PROJECT:
Genetic and environmental risk factors for susceptibility and severity of contact lens associated Acanthamoeba keratitis

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 time to read the following information carefully and discuss it with friends, relatives and your GP if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

1. What is the purpose of the study?

We hope to learn which factors cause the development of Acanthamoeba keratitis (an infection of the clear window of the eye) in contact lens wearers and why some have a more severe eye infection than others. We also hope to learn how this condition affects people’s quality of life.

2. Why have I been chosen?

You were selected as a possible participant in this study because you are one of up to 100 people who wear contact lenses, have or may have Acanthamoeba keratitis and you attend Moorfields Eye Hospital.

3. Do I have to take part?

No. Your participation is entirely voluntary. If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time without compromising your care.

4. What do I have to do if I take part?
If you decide to participate in this study, we will ask you to collect a DNA sample with a swab you will rub on the inside of your cheeks. The cheek swab will take a few minutes and is painless. Full instructions will be provided to you.

You will be asked to fill out some questionnaires. These are about how you use your contact lenses, whether you like to take risks, and your quality of life. We will ask you to complete the quality of life surveys at each visit; however the other surveys are only answered once, at the beginning of the study. You can answer these surveys on paper or on-line.

We will ask permission to collect some small samples of your tears and swabs from the front surface of your eye. The swabs will be done as part of the usual panel of swabs carried out for this condition when the eye has been anaesthetised. We plan to collect tears at each of your hospital visits.

We will also ask you to collect a small amount of water from your household taps and/or any water you have been in contact with around the time your infection started. We may ask you if we can collect a swab of, or your contact lens case. If we collect your contact lens case, we will replace it.

If you are willing to collect a cheek swab but do not want to answer the questionnaires or give tear, eye surface, water or contact lens case samples, you can still take part.

5. What will happen to my DNA sample?

The DNA from your cheek swab will be tested for genes associated with infection and inflammation in the eye. We hope this will allow us to better understand why and how Acanthamoeba keratitis occurs in contact lens wearers, which will ultimately contribute to reducing how often this disease occurs and how severe it is. The DNA sample will be retained and may be used in other studies looking at similar eye conditions in the future.

6. What are the possible disadvantages or risks of taking part?

The only disadvantage to you will be the time needed to take the samples and questionnaires. You may experience some slight discomfort while the cheek and tear samples are taken, but this will resolve on its own in a few minutes.

7. What are the possible benefits of taking part?

Whilst this study will not affect you directly, the results may be very useful in allowing us to better understand this rare but potentially severe condition.

8. What if something goes wrong?

We do not anticipate that anything will go wrong. The DNA collection kit will be sterile and there will be no risk of infection in using it to obtain a sample, which you will be doing yourself at your own convenience and following some simple instructions. The tear and eye surface samples will be collected by members of the study team specially trained in these procedures.

Nevertheless, in the unlikely event that taking part in this research project harms you, there are no special compensation arrangements. If you are harmed due to someone's
negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the usual NHS complaints mechanisms may be available to you.

9. Will my taking part in this study be kept confidential?

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission, except as required by law.

10. What will happen to the results of the research study?

The results of this study will be published in scientific journals and at conferences. In any publication, information will be provided in such a way that you cannot be identified. If you would like to receive a copy of the grouped (not individual) results of the study, please indicate this in the space provided in the consent form.

11. Who is organising and funding the research?

This study is being sponsored and funded by Moorfields Eye Hospital. No extra payments are being made to the researchers for including you in the study.

12. Who has reviewed the study?

The study has been reviewed by the London-Hampstead Research Ethics Committee.

13. Contacts for Further Information

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Research Optometrist
Moorfields Eye Hospital
City Road
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Tel: 020 7566 2285

Prof John Dart
Consultant Ophthalmic Surgeon
Moorfields Eye Hospital
City Road
London EC1V 2PD
Tel: 020 7566 2036

14. Contact for Complaints

Patient Advice and Liaison Service (PALS)
Moorfields Eye Hospital
162 City Road
London EC1V 2PD
Tel: 0207 5663620 or 0207 5663621
pals@moorfields.nhs.uk

Thank you for reading this and considering taking part in our study.
Please complete and return the attached reply slip

Prospective Patient Information Version 3, 27.02.13_ REC 13/LO/0032
Please detach this section and return it to the researcher.

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Name ........................................................................

Date of birth ............................................................

Telephone number .....................................................

Please tick one of the following boxes:

☐ I would like to take part in this study.

☐ I need more information. Please call me on my telephone number above. The best time to call is Day_______Time_______

☐ I do not wish to be contacted again for this study.