Participant information leaflet

Study title: Attitudes to genetic testing for inherited retinal disease

1. An invitation
We would like to invite you to take part in a research project. Before you decide, we’ll explain why the research is being done and what it will involve for you. Please feel free to talk to others about the study or ask us if anything is unclear or if you would like more information.

2. What is the purpose of the study?
The main purpose of this study is to record what adults with inherited retinal disease feel about genetic testing. The study also wants to find out what they know about genetic testing, what they believe to be the benefits and disadvantages of testing, when they feel that genetic testing should be made available and what they feel their reaction would be to a genetic test result.

The responses from the study participants will be used to develop an information resource for both patients and doctors. This resource will fill gaps in current knowledge about genetic testing for inherited retinal disease, identify people’s hopes and fears and review the possible outcomes of testing in order to improve the quality of care offered to patients in NHS eye clinics.

3. Why have I been invited to take part?
You have been invited to take part because you have been diagnosed to have an inherited retinal disease. This study aims to record the attitudes to genetic testing from 200 people with different inherited retinal diseases.

4. Do I have to take part?
It is up to you to decide whether to take part or not. You will be given time to go through this information leaflet and the opportunity to ask questions. If you decide to take part, you are free to withdraw at any time without giving a reason. This will not affect the standard of care you receive in your future eye clinic appointments.
5. What will happen to me if I decide to take part?

Most study participants will be invited to take part by staff working in NHS eye clinics. During a clinic visit, they may be asked for permission for their contact details to be passed to the researchers from Leeds University who are helping to conduct this study. Others may be sent a letter inviting them to contact the researchers directly. Some may have heard about the research from friends or a charity newsletter.

The researchers will make initial contact with you by telephone, provide more details about the research and then send additional information to you either as a leaflet, by email, on CD or in Braille format. (The information will be available in English and Urdu.) You will be asked to contact the researchers by phone or email and let them know if you would like to take part in the research or not. If you do not reply within a month, the researchers will try to contact you again by telephone, offer to answer any outstanding questions and ask if you are willing to take part in the study.

Everyone who decides to take part will be allocated a study number. All answers or responses that you give will be saved onto a computer and matched to your study number only, not to your name or any other identifying information. Every participant will be asked to complete an initial, telephone questionnaire. This will take approximately 30 minutes and can be done at a time that is convenient to you. You will be asked for your verbal consent to complete the questionnaire and for your answers to be saved. The initial questionnaire will collect baseline information about all participants. This will include your age, sex, marital status, ethnicity etc. You will also be asked about your knowledge of genetic testing, what you feel to be the risks and benefits of testing, how you feel genetic testing should be available and what you think you might do with the results of a genetic test.

Once all the initial questionnaires have been completed, about a quarter of all those taking part will be invited for a more detailed, face-to-face interview at a later date. Before this interview, participants will be asked to sign a consent form to confirm that they understand what the interview involves. The interviews are expected to take place at a location that is convenient for you, such as at home, work or at Leeds University. This interview is expected to last, on average, for 60 minutes. Reasonable travel expenses will be paid. The interval between the questionnaire and the subsequent interviews may be up to a year. During the interviews, the topics covered in the initial questionnaire will be explored in greater detail.
6. What are the possible disadvantages or risks of taking part?

For this research study, the main disadvantages are that you will be asked to give up some of your time and you will be asked questions to find out the extent of your eyesight problems, how much you know about genetic testing and what you feel about genetic testing. Some people may find these questions upsetting or difficult to answer. The researchers from Leeds University are experienced interviewers who know how to deal with such situations appropriately. You do not need to answer any question if you do not want to.

7. What are the possible benefits of taking part?

You may find that your discussions with the researchers provide both support and some new, useful information. This research was prompted by comments made by patients with inherited eye disease. The topics to be covered in the initial questionnaire and the subsequent interview have been developed after focus group work done with groups of patients. The aim of the research is to provide an up-to-date source of information. This information resource will help to address gaps in the knowledge of both patients and doctors in order to improve the quality of NHS eye clinic visits for patients with inherited eye disease. You may find this information helpful. The research findings may also influence access to genetic testing for inherited retinal disease within the NHS, making it more readily available for those who want testing.

8. Will my part in this study be kept confidential?

If you consent to take part in this study, your personal details and your responses to the questionnaire and the interview will remain strictly confidential at all times. You will be allocated a study number, which will be used as a code to identify you on all electronic documents. Your personal details and responses will be held separately on password protected computers at Leeds University, in accordance with the 1998 Data Protection Act. Your name and contact details will not be passed to anyone other than members of the research team or the Research Sponsor. (The Research Sponsor is the organisation responsible for ensuring that research is carried out correctly. For this study, Leeds Teaching Hospitals NHS Trust is the Sponsor.) After the research ends, the folder containing all personal and contact details will be deleted.

Although the interviews will be recorded, this is only done so that the questions and your answers can be entered onto a computer and analysed. Once this has been done, the recordings themselves will be deleted. Direct
quotations from the face-to-face interviews may be used in the published material or the information resource but care will be taken to ensure that none of the study participants will be identifiable.

The Leeds University researchers will not have access to your hospital records. They will note the date that participants agreed to take part in the initial questionnaire and they will keep the signed consent forms for the face-to-face interviews. Copies of these forms may be made available to people authorised by the Research Sponsor, the UK Regulatory Authority and an Independent Ethics Committee. This is to ensure that the study is carried out to the highest possible scientific standards. All of these organisations have a duty of confidentiality to you as a research participant.

9. What happens after the study stops?

After the study stops, you will be sent a summary of the research findings and told how you can access the information resource, if requested. You will not be contacted again by the researchers. Your NHS eye clinic appointments will continue as normal.

10. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your question(s). If you remain unhappy and wish to complain formally, you can do this either through the NHS Complaints Procedure or through the Leeds University complaints office. The researchers, or any health care professional, will be able to give you more information about these procedures.

11. What will happen if I don’t want to carry on with the study?

You are free to withdraw at any time and without giving a reason. If you have already completed the initial questionnaire or the interview, you may be asked if your responses can be included in the final analysis. Whatever you decide, your medical care will not be affected in any way.

12. What will happen to the results of this research project?

The main results of this research will be sent to participants, if requested, after it finishes and will usually be published in a medical journal or be presented at a scientific conference. All the data will be anonymous and none
of the patients involved in the study will be identified in any report or publication.

13. Who is organising and funding this study?

This study is being organised by eye doctors from hospitals in Bradford, Dewsbury, Halifax, Harrogate, Hull and York and researchers from the Leeds Institute of Health Sciences. The project is being funded by the National Institute for Health Research.

14. Who has reviewed the study?

This study was given favourable ethical opinion for conduct in the NHS by Leeds (East) Research Ethics Committee.

15. Further information

You are encouraged to ask any questions you wish, before, during or after your participation. If you have any questions about the study, please speak to your study nurse or doctor, who will be able to provide you with up to date information. Additional information can also be obtained from INVOLVE, a national group set up to support and promote public involvement in NHS research.

Go to http://www.invo.org.uk Or telephone or write to INVOLVE at:
INVOLVE
Wessex House
Upper Market Street
Eastleigh
Hampshire SO50 9FD
Tel. 02380 651088
16. Contact Details

Your Doctor
Mr M McKibbin   Tel 0113 206 5335
martin.mckibbin@leedsth.nhs.uk

Your Research/Specialist Nurses
Mrs F Cassidy    Tel 0113 206 6429
frances.cassidy@leedsth.nhs.uk

Mrs A Van Lare   Tel 0113 206 6429
alice.vanlare@leedsth.nhs.uk

Your non-clinical Researchers
Dr B Potrata    Tel 0113 343 7356
b.potrata@leeds.ac.uk

Professor J Hewison Tel 0113 343 1814
j.hewison@leeds.ac.uk

Information in Urdu and Punjabi can also be obtained from a senior genetic counsellor

Dr M Ahmed Tel 0113 392 4408
mushtaq.ahmed@leedsth.nhs.uk
Verbal Consent for a telephone interview (to be read to the research participants and the response(s) recorded)

Attitudes to genetic testing for inherited retinal disease

• I confirm that I have read and understood the information leaflet dated 1 February 2011 (Version 3) for the above research project. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

• I understand that my participation is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected.

• I understand that even if I withdraw from the above study, the data already collected from me will still be used in the final analysis, unless I specifically withdraw consent for this.

• I understand that any information I provide, including both personal details and my responses, will be kept confidential, stored securely on password protected computers and only accessed by those carrying out the research. I understand that any information I give may be included in the study summary or other published documents but my identity will be protected.

• I understand that my medical records may be looked at by authorised individuals from the Sponsor for the study, the UK Regulatory Authority or the Independent Ethics Committee in order to check that the study is being carried out correctly. I give permission, provided that strict confidentiality is maintained, for these bodies to have access to my medical records for the above study. I also give permission for a copy of my consent form to be sent to the Sponsor for the study.
Patient Consent Form for a Face-to-face interview

Attitudes to genetic testing for inherited retinal disease
(Participant to initial each box)

• I confirm that I have read and understood the information leaflet dated 1 February 2011 (Version 3) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

• I understand that my participation is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected.

• I understand that even if I withdraw from the above study, the data already collected from me will still be used in the final analysis, unless I specifically withdraw consent for this.

• I give my permission for the interview to be taped and stored in a computer.

• I understand that any information I provide, including both personal details and my responses, will be kept confidential, stored securely on password protected computers and only accessed by those carrying out the research.

• I understand that any information I give may be included in the study summary or other published documents but my identity will be protected.

• I understand that my medical records may be looked at by authorised individuals from the Sponsor for the study, the UK Regulatory Authority or the Independent Ethics Committee in order to check that the study is being carried out correctly. I give permission, provided that strict confidentiality is maintained, for
these bodies to have access to my medical records for the above study. I also give permission for a copy of my consent form to be sent to the Sponsor for the study.

____________________________
Name of participant

________________________________________
Participant's signature and date*

____________________________
Name of the researcher taking written consent

________________________________________
Researcher's signature and date

* Researcher to initial box if participant has indicated his or her consent but is unable to initial boxes and/or sign and date the consent form

(Original to be retained and filed, 1 copy to participant, 1 copy for Sponsor if required.)