Participant Information Sheet

What is the psychosocial impact of deteriorating vision in people with sporadic and familial cases of aniridia?

You are being invited to take part in a research project. Before you decide whether or not to take part, it is important for you to understand why the research is being undertaken and what it will involve. Please take time to read the following information carefully and discuss it with others, if you wish.

Thank you for reading this.

1. What is the purpose of this research project?

The purpose of this student research project is to investigate two areas of the experience of those with aniridia. Firstly, how deteriorating vision affects people with aniridia from a psychosocial perspective. Secondly, to explore the experiences of adults with sporadic versus familial aniridia to identify any similarities and differences.

The purpose of this study is to provide insights that will help to inform support needs of different groups of people with aniridia, and perhaps other genetic eye conditions, in order to improve support and other services provided by patient support organisations and clinical genetics services.

2. Why have I been invited to take part?

You have been invited because you are affected by aniridia, you are aged 18 or over, and are able to communicate in spoken English.

3. Do I have to take part?

No, your participation in this research project is entirely voluntary and it is up to you to decide whether or not to take part. If you decide to take part, we will discuss the research project with you and ask you to provide your verbal consent which will be recorded in a consent form and audio recorded. If you decide not to take part, you do not have to explain your reasons and it will not affect your legal rights. Your decision to take part or not to take part will not affect any support relationship you may have with Aniridia Network.

You are free to withdraw your consent to participate in the research project at any time, without giving a reason, even after signing the consent form.

4. What will taking part involve?

Participation will involve an interview with a researcher for approximately one hour via a secure video conferencing software (Zoom) or by telephone, at a time to suit you.

The topics under discussion in the interview will be about your experiences of aniridia and specifically with deteriorating vision. You will be asked about whether you have familial or sporadic aniridia, and how you think this may have affected your experience with aniridia more broadly.

If you are unable to participate in an online interview, the interview can be conducted over the phone, depending on distance and student researcher availability.

5. Will I be paid for taking part?

No. You should understand that any data you give will be as a gift and you will not benefit financially in the future should this research project lead to the development of a new treatment/test/assessment.

6. What are the possible benefits of taking part?

There will be no direct advantages or benefits to you from taking part, but your contribution will help to develop a greater understanding of the experiences of those with aniridia, and especially areas where those with sporadic and familial aniridia may be similar or different. This will contribute to understanding different support needs and help patient support groups to identify areas of future service development.

7. What are the possible risks of taking part?

You may find it emotionally difficult to discuss certain topics around how you feel about your vision and living with aniridia. If this happens, you will be free to take a break, or stop the interview altogether at any time. You would also be provided with a list of contact details for organisations you could seek support from.

8. Will my taking part in this research project be kept confidential?

All information collected from (or about) you during the research project will be kept confidential and any personal information you provide will be managed in accordance with data protection legislation. Please see ‘What will happen to my Personal Data?’ (below) for further information.

In exceptional cases, the research team may be legally and/or professionally required to over-ride confidentiality and to disclose information obtained from (or about) you to statutory bodies or relevant agencies. For example, this might arise where the research team has reason to believe that there is a risk to your safety, or the safety of others. Where appropriate, the research team will aim to notify you of the need to break confidentiality (but this may not be appropriate in all cases).

9. What will happen to my Personal Data?

Audio recordings of the interviews will be securely stored by Cardiff University within the Panopto (LearnPlus) system for the required data retention period. This is a minimum of five years after completion of the research study, or after publication of any findings based upon the data (whichever is later). Audio recordings will be transcribed and anonymised as soon as possible. Only the student researcher and her academic supervisor will have access to listen to audio recordings for the purpose of transcription. Once transcribed, anonymised transcripts will be stored on a password-protected computer and on completion of data analysis will be sent to the academic supervisor for storage on the secure Cardiff University shared drive for the data retention period and deleted from all other devices. No identifiable participant information will be published, and pseudonyms will be used in transcripts. Anonymised information may be published in support of the research project and retained in accordance with the Cardiff University retention period mentioned above.

Cardiff University is the Data Controller and is committed to respecting and protecting your personal data in accordance with your expectations and Data Protection legislation. Further information about Data Protection, including:

- your rights
- the legal basis under which Cardiff University processes your personal data for research
- Cardiff University's Data Protection Policy
- how to contact the Cardiff University Data Protection Officer
- how to contact the Information Commissioner's Office

may be found at https://www.cardiff.ac.uk/public-information/policies-and-procedures/data-protection.

If you are unable to access the above link, printed copies of the documents and privacy notices can be made available on request.

Although participants will be recruited through Aniridia Network, Cardiff University will not need to share your personal data with Aniridia Network for the purposes of this research project. Aniridia Network will not be privy to the content of the interviews, other than via the anonymised outputs.

All personal data collected from or about you will be anonymised by the student researcher as soon as possible after the interview takes place, with the exception of your consent form. Your consent form will be sent to the academic supervisor overseeing the project immediately following completion of each interview to be stored on the secure Cardiff University shared drive and retained for the data retention period in accordance with the Cardiff University Records Retention Schedules (see above). Consent forms may be accessed by members of the research team and, where necessary, by members of the University's governance and audit teams or by regulatory authorities. Anonymised information will be kept for a minimum of five years but may be published in support of the research project and/or retained indefinitely, where it is likely to have continuing value for research purposes.

You can withdraw from this study at any time, but we may need to retain the information you provide for audit purposes. If you withdraw from this study, any data collected may still be used in line with the relevant legal provisions. We will always try to respond to concerns or queries you may have and comply with your wishes as far as possible, but it will not be possible to withdraw any anonymised data that has already been published or in some cases, where any personal identifiers are already removed during the course of a research project, from the point at which it has been anonymised.

10. What happens to the data at the end of the research project?

At the end of the research project, any data will be disposed of in accordance with University guidelines and relevant GDPR legislation.

11. What will happen to the results of the research project?

The results of the research project will be written up and submitted as an MSc Dissertation to Cardiff University in the summer of 2024. A copy of the final dissertation may be obtained either through the Cardiff University library or by contacting the student researcher or a member of the research team. A summary of the research will also be written for the Aniridia Network's members.

It is our intention to publish the results of this research project in academic journals and present findings at conferences. Participants will not be identified in any report, publication or presentation, but verbatim quotes from participants may be used where appropriate.

12. What if there is a problem?

If you wish to complain, or have grounds for concerns about any aspect of the manner in which you have been approached or treated during the course of this research, please contact Helen Campbell (Student Researcher) via campbellhl@cardiff.ac.uk or Professor Marion McAllister (Project Academic Supervisor) via McAllisterMF@cardiff.ac.uk. If your complaint is not managed to your satisfaction, please contact the Chair of the School of Medicine Research Ethics Committee, Dr Ned Powell via powellng@cardiff.ac.uk.

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, you may have grounds for legal action, but you may have to pay for it.

13. Who is organising and funding this research project?

The research is organised by Helen Campbell (MSc student) and Professor Marion McAllister (Academic Supervisor) as part of the MSc in Genetic and Genomic Counselling at Cardiff University Centre for Medical Education. The research is not funded.

14. Who has reviewed this research project?

This research project has been reviewed and given a favourable opinion by the School of Medicine Research Ethics Committee, Cardiff University.

15. Further information and contact details

Should you have any questions relating to this research project, you may contact me during normal working hours:

Helen Campbell
campbellhl@cardiff.ac.uk
07443 466 952

Thank you for considering to take part in this research project. If you decide to participate, you will be given a copy of the Participant Information Sheet and a copy of your completed consent form to keep for your records.