



**INFORMATION SHEET for the University of Alberta Research Project:**  
***Communicating the Risks and Benefits of Ocular Gene Therapy***

**Purpose:** This research project is done to understand how to best communicate genetic information about eye conditions and the risks and benefits of gene therapy. Gene therapy is now in early stages of clinical trials for some eye conditions.

**Background:** At this time there are many advances in genetic technologies and research, but most patients with genetic diseases still don't receive treatment. Up to now, clinical genetics has focused on prevention, diagnosis and management. Now, there is some potential for gene therapy to treat genetic eye conditions. We are interested in helping clinicians and the media communicate the risks and benefits of gene therapy to patients, their families, and the general public.

**What will you be asked to do?**

A project researcher will interview you. This interview will take approximately three-quarters to one hour of your time. We will give you the option to review our notes on your comments, and you may request to receive the final report by providing your contact information on the last page.

**What type of personal information will be collected?**

Should you agree to participate in this study you will be asked to express your point of view and tell us about your experiences with choroideremia. We will ask your permission to audio record our conversation. You may request the audio recording device to be shut off at any time.

**Are there risks or benefits for participating?**

You may find some of the questions upsetting. If you feel uncomfortable answering any question you don't have to answer it. We are not aware of any long-term risks posed by participating in an interview. There are no costs for you to participate in this study, other than the investment of your time. The benefits include the opportunity to provide feedback on your experiences with choroideremia and to help us understand how to improve clinical care for patients with genetic diseases.

**Participation:**

Participation in this research is voluntary. If you choose not to participate or if you choose to withdraw from the study, you will continue to have access to the same quality of clinical care. Participation in this research will not promote access to therapeutic interventions that are not standard-of-care.

**Withdrawal from the study:**

Even after you have agreed to participate in the interview you can decide at any point that you do not wish to continue. You may decide that you do not want what you said to be used up until the time the results of this study are put together for publication. The researchers then cannot use this information and it will be destroyed.

**Confidentiality:**

The information you provide will be de-identified by being assigned a number rather than your name. The de-identified data will be made available to the study researchers working on this project. The audio recordings will be used for research reference only. The data collected, including tapes, transcripts of tapes, and any notes, will be stored in a secure manner by the principal investigators and kept for 5 years after which the data will be destroyed.

**Use of the Information:**

From the results of this research, the researchers will make recommendations to clinicians and the media on the communication of genetic information about eye conditions and the risks and benefits of gene therapy. The results may also be used in academic presentations and be published in academic journals.

**Contacts:**

This study is run by Shelly Benjamy (Department of Public Health Sciences) and co-supervised by Drs Tania Bubela (Department of Public Health Sciences) and Ian MacDonald (Department of Ophthalmology).

If you have any further questions or want to clarification regarding this research and/or your participation, please contact:

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**Additional Contacts:**

The plan for this study has been reviewed for its adherence to ethical guidelines and approved by the University of Alberta Research Ethics Office. For questions regarding participant rights and ethical conduct of research, contact the University of Alberta Research Ethics Office at 492-2615.



CONSENT FORM

To Participate in the University of Alberta Research Project:

Genetic Risk Communication: Case Study Gene Therapy for Genetic Retinal Dystrophies

Investigator:
Shelly Benjamy
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- Do you understand that you have been asked to be in a research study? Yes No
Have you read and received a copy of the attached Information Sheet? Yes No
Do you understand the benefits and risks involved in taking part in this research study? Yes No
Have you had an opportunity to ask questions and discuss this study? Yes No
Do you understand that you can quit taking part in this study at any time without giving a reason? Yes No
Has the issue of confidentiality been explained to you? Yes No
Do you consent to being audio recorded? Yes No
Do you understand who will have access to the records from this interview? Yes No
Do you understand that the information you provide will be used to make recommendations for communicating genetic risk in health settings? Yes No
Can we use this information in the future for presentations and publications? Yes No

This study was explained to me by: \_\_\_\_\_

I agree to take part in this study.

Signature of Research Participant Date Printed Name

I would like to receive a copy of research results (check one): [ ] No [ ] Yes

If you would like to receive a copy of the research results please provide us with your address:

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

Signature of Investigator

Date