



National Ophthalmic Disease Genotyping Network

eyeGENE®

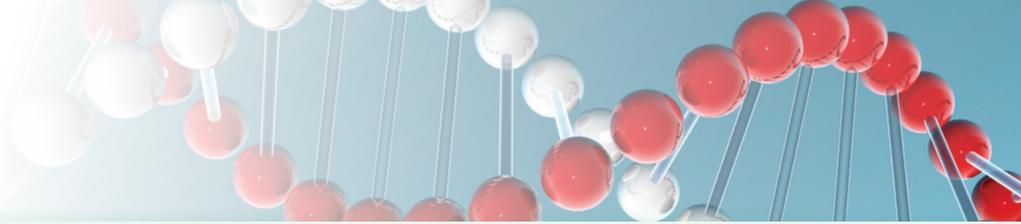


What You Should Know

INFORMATION FOR PARTICIPANTS

Preserving vision through genetics





What is eyeGENE®?

The National Ophthalmic Disease Genotyping and Phenotyping Network (eyeGENE®) is a research project created by the National Eye Institute (NEI), part of the National Institutes of Health (NIH), to help build on promising research findings in the field of genetics. Over the past 30 to 40 years, more than 400 genes have been found that cause inherited eye diseases. eyeGENE® wants to aid researchers who study eye diseases and their genetic causes by allowing them to request access to DNA samples, clinical information, and patients interested in research studies and clinical trials.

The eyeGENE® Network is made up of a group of vision research and clinical labs located across the United States and Canada; a Coordinating Center located at NEI in Bethesda, MD; a bank of blood/DNA samples; and a secure online database. The eyeGENE® Network gives patients a chance to get genetic testing for their eye diseases and a chance to be contacted for future studies.

Preserving vision

Are you eligible to participate in eyeGENE®?



- You may only participate in eyeGENE® by first seeing a healthcare provider, who must register with eyeGENE® and can provide information about your eye condition (i.e., ophthalmologist, optometrist, geneticist, genetic counselor, neurologist, etc.).
- You must have an eye condition that eyeGENE® is studying. Please ask your eye healthcare provider, or check eyeGENE®'s list of diseases and genes at <http://www.nei.nih.gov/eyeGENE>.
- People of any age may participate in eyeGENE®.
- Family members who do not have an eye disease may also participate. Please ask your eye healthcare provider for more details.
- Genetic testing is not offered for unborn children.

through genetics

What are the steps necessary for you to participate in eyeGENE®?

STEP 1

You should talk to your eye healthcare provider about your interest in participating in eyeGENE®. If your eye healthcare provider does not know about eyeGENE®, please ask him/her to contact eyeGENE®. (See information at the back of the brochure.)

STEP 2

Your eye healthcare provider (or a member of his/her staff) will register you with eyeGENE® and enter your personal information (such as your name, address, and date of birth) and information about your eye condition (such as how old you were when you first noticed your symptoms) into the secure eyeGENE® database. **Please note that the cost of the eye exam is not covered by eyeGENE®.**

Your eye healthcare provider will arrange genetic counseling for you. Your genetic counselor will tell you what a genetic test is, what the test will or will not tell you, and what a positive result (i.e., finding the gene[s] causing your eye condition) may mean to other family members. **Please note that the cost of genetic counseling is not covered by eyeGENE®.**

Preserving vision



STEP 3

You will complete a consent form to participate in the eyeGENE® research study. Minors need permission from their parent or guardian to participate. Consenting means you agree to have your DNA/blood stored and later used for eye research by approved researchers in the vision community. You can decide if—

- You want your test results back.
- You want to be contacted by the eyeGENE® Coordinating Center if a researcher would like to include you in a research study or clinical trial.

STEP 4

You will need to get your blood drawn (about 6 tablespoons of blood for adults, and 3 tablespoons for children) and have it shipped to the eyeGENE® Coordinating Center. Your eye healthcare provider can help you with this process. **Please note that eyeGENE® cannot pay for the blood draw or shipping costs.** Your blood sample will be processed into DNA. Your DNA will be coded when it goes into the eyeGENE® storage bank. A sample of your coded DNA will be shipped to a genetic testing laboratory. Personally identifying information, like your name and address, will be removed from your clinical information and samples, which will be assigned a code number. Approved researchers who are granted access to the secure database will see only the code number.

through genetics



STEP 5

Your test results will be returned to you through your eye healthcare provider, which may take several months to over a year. Your eye healthcare provider will explain the test results to you and/or arrange for genetic counseling. Please keep in mind that testing does not always give a positive or clear result, and some tests are harder to complete and explain. **There is no charge to participants for genetic testing through eyeGENE®.**

STEP 6

Keep the eyeGENE® Coordinating Center updated as to any change in contact information (for example, your address and telephone number), so that the eyeGENE® Coordinating Center may contact you for future research studies or trials (if you have chosen to be contacted).

Preserving vision

What are the benefits and risks?



Benefits

The vision community has learned a lot about inherited eye diseases over the past several decades. By increasing the number of people who can get genetic testing, and by allowing eye researchers to study a large number of DNA samples, the vision community will be able to increase its knowledge and be better able to develop treatments for inherited eye diseases. By participating in this study, you will help us reach these goals. You may also learn more about the genetics of your own inherited eye disease. In addition, as an eyeGENE[®] participant, you may elect to become part of a registry that will allow eyeGENE[®] to contact you about other research trials and studies.

Risks

Genetic testing may provide information about how an eye condition is passed on within your family, which may cause you or your relatives stress or anxiety. It might also affect your relationship with your relatives. Insurance or work discrimination might occur if you disclose this information. Please know that we will not release this information to anyone except you without your written permission. Risks are further described in the consent form and you are encouraged to ask questions.

through genetics



Contact Information

eyeGENE® Coordinating Center
National Eye Institute
National Institutes of Health

Telephone 301-435-3032
E-mail eyeGENEinfo@nei.nih.gov
Website <http://www.nei.nih.gov/eyegene>

For information on clinical trials or about eyeGENE®
(NCT00378742), visit <http://www.clinicaltrials.gov>.
Study #06-EI-0236

