PATIENT CONSENT TO PARTICIPATE IN A RESEARCH PROJECT

TITLE: Genetic Testing for Risk of Age-related Macular Degeneration

SPONSOR: National Human Genome Research Institute

PRINCIPAL INVESTIGATOR: Catherine McCarty, PhD, MPH

Essentia Institute of Rural Health

CO-INVESTIGATORS: Michael Fuchs, OD; Essentia Health Duluth Clinic

Patricia Conway, PhD; Essentia Institute of Rural Health

Why are you being asked to take part in this research study?

You have been asked to participate in this research because you are over the age of 50, you receive your vision care at Essentia Health and you don't have age-related macular degeneration. The goal is to enroll 100 people in this research project.

Why is this research being done?

This research is being done to better understand how genetic information can affect medical care of patients. Specifically, we are looking at how genetic information about risk of age-related macular degeneration affects health care and personal behavior.

What will happen if you agree to participate in the study?

If you agree to be part of this study, you will be asked to do the following things:

1. Meet with research staff to discuss the project in depth and sign the consent form.
2. Complete a short questionnaire about smoking history and family history of age-related macular degeneration.
3. Provide a sample of blood (about 2 tablespoons). DNA will be extracted from this blood sample. A sample of your DNA (labeled with a number, not your name) will be sent to an outside lab to test for genetic markers that predict risk of age-related macular degeneration.
4. Meet with Dr. Fuchs to discuss the genetic test results. The genetic test results will become a permanent part of your medical record.
5. Allow access to your medical record by research staff.
6. Participate in a brief telephone survey with research staff approximately one month after receiving your genetic test results. Staff will ask you questions about your reaction to the genetic testing.

What are the possible risks and discomforts from being in this study?

Genetic testing requires DNA from a blood sample. There is always a risk from having blood taken from a vein. This blood draw will not be different than for your normal clinical labs. Risks associated with blood draws include the potential for minor pain and slight bruising. There is a small chance of infection at the site where the blood was drawn. Some people might faint when their blood is drawn.

What are the possible benefits from being in this research study?

Your genetic test results may help you and your study doctor make more informed decisions about your health care.

How long will you be in this research study?

There is no specific end date for this study. This study will build resources at Essentia Health to incorporate genetic information into clinical care. This information will be placed in your medical records for your doctor to be able to use for your future medical care. You are agreeing to be part of ongoing research about genetics and macular degeneration at Essentia Health. Although there is no planned end date for the research, your time in this part of the study is planned to be done after a telephone interview about your experience with genetic testing.

Will there be a cost to take part in this research study?

Neither you nor your health insurance company will have to pay for any of the genetic testing.

Will you be paid for taking part in this research study?

You will be paid $25 for participation in this project. A check will be sent to you after the final follow-up phone call.

How will information about you and your participation be kept confidential?

Your medical information will be kept as confidential as possible within the limits of the law. Your medical information may be given out if required by law. The results of this study may be published in medical journals or presented at scientific meetings. You will not be identified by name, picture or any other personally identifying information.

The results of the genetic testing will be included in your medical record and protected in the same way that other information in your medical record is protected by Essentia Health policies.

The Genetic Information Non-Discrimination Act (GINA) is a Federal law that applies to health insurance companies, group health plans and employers with more than 15 employees. Under the terms of GINA, these groups may not: request genetic information collected as part of a research

project, use your genetic information when making decision about your insurance eligibility or premiums, or use genetic information from research when making employment decisions. GINA does not protect against discrimination by companies that sell life insurance, disability insurance or long-term care insurance.

What happens if you become ill or injured from this study?

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for the treatment of an injury. The study will not pay for any medical treatment.

What do you do if you want to withdraw from the study?

Taking part in research is voluntary. You have the right to withdraw your participation at any time. If you withdraw, your remaining DNA will be destroyed. If your sample and information have already been used in research, it would not be possible to remove the information that has learned prior to your request to withdraw. If you want to take back your consent, call Dr. McCarty at 218-786-2128.

Who can I contact for more information on this research?

For more information or to report injuries, you may contact Dr. Cathy McCarty, Essentia Institute of Rural Health, at 218-786-2128; or Dr. Michael Fuchs, Essentia Health, at 218-786-3937.

What are my rights if I take part in this research?

Being in this study is voluntary. If you choose not to sign this consent form, your relationship with your doctor and Essentia Health will not change. You are not giving up any legal rights by signing this consent form and participating in this research study.

Collection/banking of human biological material for future research:

Research staff would like to store some of the DNA from this research project for future research (DNA biobanking). Participation in this DNA biobanking is completely voluntary. You can participate in the genetic testing for age-related macular degeneration without participating in the DNA biobanking. You can change your mind at any time about storage and future use of your DNA. Please read the two statements below and check "yes" or "no" for each one.

1. My DNA may be stored for possible use in future research to learn about prevention, treatment and cures for age-related macular degeneration. I understand that the researcher will be required to obtain approval from an Institutional Review Board for future uses of my DNA.

   □ Yes □ No

2. My DNA may be stored for possible use in future research about other health problems related to genetics (such as heart disease, cancer, etc). I understand that the researcher will be required to obtain approval from an Institutional Review Board for future uses of my DNA.

   □ Yes □ No

What does signing the consent form mean?

By signing below I acknowledge that:

- I have read the consent form.
- I have been offered the opportunity to ask questions and discuss the benefits and limitations of the genetic test with the study doctor.
- I have discussed with the study doctor the level of certainly that a positive test result serves as a predictor for age-related macular degeneration.
- I consent to genetic testing for risk of age-related macular degeneration.

Printed Name of Participant

Signature of Participant Date

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent Date