FOUNDATION FIGHTING BLINDNESS

My Retina Tracker® Registry

CONSENT

TITLE: Foundation Fighting Blindness Registry

PROTOCOL NO.: FFB-Registry-01
WIRB® Protocol #20121635

SPONSOR: Foundation Fighting Blindness

INVESTIGATOR: Brian Mansfield, Ph.D.
Foundation Fighting Blindness
7168 Columbia Gateway Drive
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United States

STUDY-RELATED PHONE NUMBER(S): 800-683-5555
Phone Number

Please review the following information before agreeing to the informed consent for the My Retina Tracker Registry.

How will my information be stored in the Registry?

Your information will be stored in a secure, electronic database permanently unless you ask to be removed from the Registry. All individuals who manage the registry are trained in the protection of personal data. Only these individuals will be allowed access to your full profile which contains identifying information. In addition, trained clinical workers, such as clinicians, clinical coordinators and genetic counselors may request access from the Registry staff to determine if you have a My Retina Tracker Registry account when offering to assist you in entering data into your profile. This is done to ensure you have a profile before they spend time entering data. Registry staff will review the request and only approve requests they believe to be necessary and appropriate. Registry staff will then allow the clinical worker access to query your full name, date of birth, gender, address and email only, to confirm you do or do not have a profile. The data in your profile will not be shared with the clinical worker.

To protect your data, Registry staff are trained in the protection of personal data and we comply with HIPAA (Health Insurance Portability and Accountability Act of 1996) a

United States legislation that provides data privacy and security provisions for safeguarding medical information as well as the European standard GDPR (General Data Protection Regulation).

Who will my information in the Registry be shared with?

Your de-identified information may be shared with researchers studying inherited retinal degenerative diseases. De-identified data is data that has been rendered anonymous by stripping out any information that would allow people to determine who you are or how to contact you.

The Foundation Fighting Blindness is the sponsor of the My Retina Tracker Registry. The Foundation's Registry staff will share only de-identified data from this Registry with academic and industry partners seeking information about the inherited retinal diseases, which may include research studies, focus groups, clinical studies, surveys and clinical trials. In addition, Federal and State regulatory agencies such as the US Food and Drug Administration and the Institutional Review Board may request Registry information to ensure the Registry is properly conducted and monitored. While Registry staff will do their best to ensure your privacy is protected, it is possible that the Federal and State regulatory agencies receiving this information may not be required to protect it and your information may be re-disclosed without your permission. If you do not provide permission to use your information in the manner described above, you cannot be in the Registry. Authorization to use members' de-identified information does not expire. It will not end unless you cancel it. To stop the sharing of your de-identified information in the Registry, you must cancel your membership. You may cancel it by sending written notice to the Registry Coordinator at Coordinator@MyRetinaTracker.org or by postal mail to Registry Coordinator, Foundation Fighting Blindness, 7168 Columbia Gateway Drive, Suite 100, Columbia, MD, 21046. Any de-identified information distributed to an investigator before you withdraw your permission may still be used.

Researchers must get permission from the Foundation Fighting Blindness to see your de-identified data. When provided access, only the de-identified data stored within the FFB Registry will be seen. Researchers will not be able to identify you personally.

If the member is a child under the age of 18, please print the assent form. If possible, review it with the child being registered. The person entering the information on behalf of the child will be asked to provide parental/legal guardian permission and affirm the child is willing to participate by checking a box at the end of the consent form. If the parent or legal guardian has any questions, they should call the Coordinator of the My Retina Tracker Registry at 800-683-5555 or by email Coordinator@MyRetinaTracker.org.

The FFB Registry Consent Form

We invite you to join the Foundation Fighting Blindness, My Retina Tracker Registry®. Taking part in this Registry is voluntary. You may decide not to participate or you may

leave the registry at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled. Your alternative is not to participate in the Registry.

This consent form provides important information about what it means to be involved in this Registry. People who want to take part in this Registry must read this consent form and agree to participate by checking an "I agree" box below.

If you have any questions about this consent form, please contact the Registry coordinator by phone at: 800-683-5555 or by e-mail at Coordinator@MyRetinaTracker.org.

You may withdraw your consent at any time by contacting the Registry coordinator at: 800-683-5555 or by e-mail at Coordinator@MyRetinaTracker.org. If you withdraw your consent, we will delete your data from the registry.

Terms Used in this Consent Form:

"the Registry" will refer to the My Retina Tracker Registry®, which is the patient registry of the Foundation Fighting Blindness.

"Affected person" will refer to the person with an inherited retinal degenerative disease.

"You" and "Your" refers to the person joining the Registry who is affected by an inherited retinal degenerative disease, or the friend, family member, parent, or the person legally responsible for the care and maintenance of the affected person (guardian) providing the information on behalf of the affected person.

What is a registry?

A registry is an organized system for the collection, storage, and sharing of information about people affected with a specific disease or syndrome or group of diseases. In this case, the My Retina Tracker Registry will focus on information about people affected with inherited retinal degenerative diseases and their families.

What is the purpose of the Registry?

There are five main purposes of the Registry.

- Provide a place where you can collect and store information about your inherited retinal disease that will help you keep track of this information over time and share it with your doctor and other healthcare providers if you wish.
- Provide a place where you can ask your doctor to record important information about your inherited retinal disease such as the results of specific tests, including any genetic diagnosis.

- Enable the collection and sharing of information about inherited retinal diseases from a large number of patients, with the research and medical community, so that researchers and healthcare providers can better understand these diseases and how to treat them.
- Enable the Foundation Fighting Blindness to provide you with the most up to date information about research of interest to people with your inherited retinal disease, including clinical trials to evaluate new treatments.
- Connect scientists studying inherited retinal diseases with people in the Registry who may qualify for their research studies or clinical trials. Researchers often use the Registry to announce clinical trials or other research studies, but they are not required to do so. Therefore, your participation in the Registry is not a guarantee that you will be notified of relevant research opportunities.

Who can take part in the Registry?

Any adult or child with an inherited retinal degenerative disease can take part in the Registry. In addition, family members who might be genetic carriers of these diseases can take part in the Registry. People under the age of 18 at the time of consent must agree to have a form filled in on their behalf and then complete this consent form when they reach the age of 18 to continue to take part in the Registry. When a child, who is a member of the Registry reaches the age of 18 they will receive a notification that they need to consent and will not be able to update their profile or add information to the Registry until they have completed the form.

What information will be collected in the Registry?

The Registry will collect the following:

- Personal information including, but not limited to, your name, date of birth, city of birth, country of birth, address, phone, and email address. This information will not be visible to other users of the registry. Only you and the trained My Retina Tracker Registry staff can see this information. These staff will not share your personal information with anyone.
- Information about your inherited retinal degenerative disease including, but not limited to, your specific diagnosis, your vision test and exam results, and your genetic test results and,
- Information about your personal and family health history as it relates to inherited retinal degenerative disease.

How will the information be collected for the Registry?

You will enter information into the Registry through a secure, password protected website or by submitting a completed printed form of the consent and questionnaire. In the future, the Registry may offer you the ability to upload data you choose to share, from an electronic device such as a mobile application or a wearable electronic device. You will always have control over determining the data you choose to share.

If you participate in a program the Foundation offers, such as a genetic testing program, in which you wish to share your genetic test result, the testing laboratory, the genetic counselor explaining the result to you, or a clinical coordinator associated with the study may enter your data on your behalf.

Using the Clinical Data Input Request form, you may ask your doctor and other retinal healthcare providers to enter information about your retinal degenerative disease on your behalf, into the My Retina Tracker Registry, using the same secure website. This could include results of recent standardized testing or genetic testing results. If you see more than one doctor, or retinal healthcare provider, you can give permission to as many of them as you choose, to enter information into your personal retinal health record in the Registry, but you are not required to do so. You are not required to give your doctor or other retinal healthcare providers permission to enter medical information into the Registry. You can participate in the Registry without giving this permission to your retinal healthcare provider. Responding to such requests is voluntary on the part of the healthcare provider. Your healthcare provider will not be able to see the data in your profile, they will only be able to provide information that is added to your profile.

Will my information be combined with other databases?

Your de-identified information may be shared with other databases in order to develop global knowledge of rare diseases to facilitate new research studies, clinical trials, and clinical treatments. If your de-identified information is shared with other registries or databases, the people who work for the other registries or databases will not be able to identify you personally or contact you directly.

How will my information be used to match me with relevant research studies?

Some researchers and therapy developers studying inherited retinal degenerative diseases may be looking for people with specific diseases or genetic mutations to participate in their research studies. If a researcher has an ethics committee-approved study protocol and they request assistance with identifying potential study participants, Registry staff, or one of your healthcare providers, will contact you to let you know about studies you may qualify for based on the de-identified information you provided in the Registry. If you receive a request to contact a researcher or therapy developer, it does not mean the Foundation Fighting Blindness recommends you participate. You are not required to participate and there is no consequence to you for declining to participate.

What are the risks of taking part in the Registry?

There is minimal risk in taking part in the Registry. The Registry includes questions that can be sensitive and you may feel uncomfortable answering. You do not have to share any information you do not want to share. Although every effort will be made to protect your identity, there is a small risk for loss of confidentiality.

If the results of any studies of your genetic make-up were to be accidentally released, the information could become available to an insurer, an employer, a relative, or someone else outside the registry. While there are discrimination protections in many State and Federal Laws, there is still a small chance that you could be harmed if a release occurred. A federal law called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long term care insurance. GINA also does not protect you against discrimination if you have already been diagnosed with the genetic disease.

What are the benefits of taking part in the Registry?

The direct benefit of your participation in the Registry is having a secure place to share information relevant to your inherited retinal degenerative disease. The information in the Registry will help researchers and therapy developers to learn more about the cause of inherited retinal degenerative diseases, how common each of the diseases are, the likely causes of those diseases, and how they impact the life of an affected person.

Will I receive results from research that uses my information?

Most research using your Registry information is not expected to return new information that would be helpful to share with you personally. However, if a researcher learns something that he or she thinks might be important to you, you may be re-contacted by the Foundation Fighting Blindness Registry Coordinator.

Will I be asked to give the Registry more information in the future?

Yes. The Registry is most valuable for scientific research when it is kept up-to-date. Occasionally, we will ask you to update your profile and information. You, or your retina healthcare provider, can also update your record in the Registry whenever there is a change in your information. Updating your record in the Registry is optional.

How long will information be stored in the Registry?

The information in the Registry is stored permanently. It will not be removed unless you specifically ask for it to be removed from the Registry (to do this see the question below).

Can I remove myself from the Registry?

Yes. Taking part in the Registry is voluntary. You can withdraw your information from the Registry at any time. If your information has been shared with researchers and

therapy developers before your request for removal, that information cannot be retrieved from the researchers and therapy developers that have already accessed it.

To withdraw your participation in the Registry, please contact the Registry Coordinator at Coordinator@MyRetinaTracker.org or call 1-800-683-5555. If you ask to withdraw from the Registry, your information in the database and any printed information you have sent to the Registry will be destroyed and cannot be recovered.

Are there any costs to take part in the Registry?

No, participation in the Registry is free to all members.

You will not be paid for being in this study.

Who should I contact if I have questions?

If you have questions, concerns or complaints about the Registry, please contact the Registry Coordinator at Coordinator@MyRetinaTracker.org or call 800-683-5555.

To report problems that result from your participation in the Registry, contact the Registry coordinator at: Coordinator@MyRetinaTracker.org or call 800-683-5555.

If you have questions about your rights as a member in the Registry or questions, concerns or complaints, contact the Institutional Review Board for this study at: help@wirb.com or call 800-562-4789.

For more information about the terms and conditions of the Foundation Fighting Blindness Registry or the privacy policy please go to Terms and Conditions | Privacy policy at www.MyRetinaTracker.org

Parental/Legal Guardian Permission and Child Assent for Member Under the Age of 18

☐ I have read and understand the terms and conditions and I/we agree to participate in the Registry as described above (Required):

I have discussed the Registry with my child and they agree to voluntarily participate. I understand that we may withdraw from the Registry at any time. Any questions we have about taking part in the Registry have been answered and we know how to contact the Registry Coordinator at Coordinator@MyRetinaTracker.org or at 800-683-5555 with any questions we have in the future. Lastly, we know how to access this document on the Registry web site, www.MyRetinaTracker.org, or by contacting the Registry Coordinator in the future if we want to review it.

****For Sites in California****

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits.

Who may use and give out information about you?
The study doctor and the study staff. They may also share the research information with an agent for the study doctor.

Who might get this information?
The sponsor of this research. "Sponsor" means any persons or companies that are:

- working for or with the sponsor, or
- owned by the sponsor.

Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries,
- The institution where the research is being done,
- Governmental agencies to whom certain diseases (reportable diseases) must be reported, and
- Institutional Review Board (IRB)

Why will this information be used and/or given to others?

- to do the research,
- to study the results, and
- to make sure that the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?
This permission will be good until December 31, 2070.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission.

Authorization:
I have been given the information about the use and disclosure of my health information for this research study. My questions have been answered.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.