Understanding Your Participation

We invite you to participate in My Retina Tracker®, the FFB Registry. Taking part in the Registry is voluntary. To participate in the Registry you must read and sign the FFB Registry Consent Form that follows this document. The consent form includes important information about what it means to be involved with this Registry. If you have questions that are not answered here, or in the consent form, please contact the Registry coordinator at: 800-683-5555 or Coordinator@MyRetinaTracker.org.

Definitions:

Affected individual - refers to a person who has been diagnosed with an inherited retinal degenerative disease.

Consent - is a process that informs you how your participation in the Registry could affect you, explains things that you need to consider carefully before participating and provides a written record of what you have and have not agreed to.

Inherited Retinal Degenerative Disease - is a disease of the retina that you inherited from one or both of your parents, that leads to a loss of vision. The most common examples of these diseases are retinitis pigmentosa, Stargardt disease and Usher syndrome.

You - refers to the person entering the information into the Registry. This may be the affected individual, a friend, family member or guardian of the affected individual (the person legally responsible for the care and maintenance of the affected individual) acting on the affected individual's behalf.

We are asking you to enter personal and other medically relevant information into the FFB Registry, which we refer to here as the Registry. It is important that we explain what is involved and what will be done with the information you provide. This section contains answers to questions about:

- the information we want you or your doctor to contribute,
- why we want the information,
- how it might benefit you, and
- possible risks of giving us this information.

After you have read this, the affected individual will be asked to read and complete the FFB Patient Registry Consent Form. The Consent Form asks a series of questions that determine who can use the information you provide and how it can be used. If the affected individual answers yes to any of these questions, they will have consented.
What is a registry?

A registry is a place to store detailed information about affected individuals, and their families, with a specific disease or syndrome, or group of diseases. In this case, the FFB Registry is for affected individuals with inherited retinal degenerative diseases and their families. When you join the Registry you will create your own personal retinal health record. Your personal retinal health record, combined with those of many other people with inherited retinal degenerative diseases, creates a Registry that meets several critical needs.

1. It is a place where you can collect and store information about your inherited retinal degenerative disease including medical history and information about other affected family members. You can track information that helps you work with your doctor, and other retinal healthcare providers, to better manage your personal retinal health.

2. It is a place where you can ask your doctor to record important information about your inherited retinal disease including diagnosis, test results (including genetic testing), and information on the progress of your disease, so you always have access to the most accurate and up to date information.

3. It will enable the Foundation Fighting Blindness Registry to provide you with the most up to date information about research that may be of specific interest to you, and other people with inherited retinal degenerative diseases, including clinical trials to evaluate possible new treatments.

4. Scientists studying inherited retinal degenerative diseases need accurate, firsthand information from many people to understand how each inherited retinal degenerative disease affects people, information only you and your doctor can provide.

5. Scientists, who are ready to start research studies or clinical trials, can use information in the Registry to help identify people that may be eligible to participate in studies. If an affected individual looks like a good match for a scientist's research or a clinical trial, the scientist or clinical trial coordinator will contact the FFB Registry. Then a member of the FFB Registry staff, or someone working with the Registry such as genetic counselor, will then contact you, and other individuals identified by the investigator. Scientists will not contact you directly unless you give the FFB permission for them to do so.
What are the benefits of collecting affected individual’s information in the Registry?

The only direct benefit of your participation in the Registry is having a secure place for you and your doctor to store information relevant to your inherited retinal degenerative disease. We do not expect there will be any other direct benefits of participation but information in the Registry is expected to help researchers, and the FFB, in their mission to find preventions and cures for retinal degenerative diseases. The Registry does this by:

1. letting affected individuals or their designated family member know when they may be eligible for clinical research studies or clinical trials.

2. studying why different people have different symptoms.

3. learning about how certain treatments work and don't work.

4. helping medical professionals improve how they treat affected individuals with inherited retinal degenerative diseases.

5. speeding up research in inherited retinal degenerative diseases by collecting information that scientists can use.

Eligibility - Whose information is being collected in the Registry?

Two groups of individuals are eligible for participation in the Registry:

1. People who have been diagnosed with inherited retinal degenerative diseases are eligible, including minor children. The diagnosis should have been made by a qualified medical professional, and whenever possible, confirmed by genetic testing.

2. Both affected and unaffected family members who might be genetic carriers of any inherited retinal degenerative diseases are also eligible.

Who can sign the consent form?

Eligible individuals, age 18 and over, who understand the consent form, and thus do not have a legal custodian, are eligible to join the Registry on their own. Otherwise, the legal guardian, parent, or custodian of the participant must sign the consent for the affected individual to join. When the eligible individual becomes 18, and if they are able, consent will be obtained directly from the affected individual for continued participation.
What are the steps to filling out the Registry with eligible individual's information?

1. You, or your authorized representative, should finish reading this document, *Understanding Your Participation*, and then decide if you want to participate in the Registry.

2. If you choose to participate, you, or your authorized representative, will need to complete and sign the consent form.

3. The next step is to provide basic information about you to create an account with a user name and password.

4. Complete the enrollment survey.

The questions in the survey will include your personal information. Once you send your completed enrollment survey to the Registry, your answers will be entered into your personal retinal health record in the Registry database. You can access your personal retinal health record at MyRetinaTracker.org any time, using the user name and password you created in step 3, if you want to change or update your answers.

If more than one member of your family has an inherited retinal degenerative disease, the first family member registering can create a family group number in the Registry. That person can invite other family members with inherited retinal degenerative diseases to join the Registry under that group number. However, every member of the family that registers will have their own separate account and registration number. Each individual family member must provide their own consent, and enter their own data. The value of the family group number is to link records from multiple family members to help retinal healthcare providers with diagnosis and help researchers identify the best candidates for research studies.

Where will the information I provide go?

All of the information you provide will be maintained in a safe, secure computer, and any information that could identify you and your family members will not be seen by anyone, except the FFB Registry staff.
Will I be expected to provide the Registry with additional information in the future?

Yes. The Registry is most valuable to you, your doctor and for scientific research, when it is kept up to date. You will be asked to update your profile and information once a year. We will send out notifications annually to remind you. We also ask you to authorize your doctor, or other retinal healthcare providers, to enter medical information relevant to your inherited retinal degenerative disease, including your genetic diagnosis if any, into your personal retinal health record in the Registry. You, or your authorized healthcare provider, can also update your record in the Registry whenever you wish, after a doctor's appointment, anytime there are new test results, whenever there is a change in your retinal health, a change in medication, or any new symptoms. Failing to update your record in the Registry does not lead to removal from the Registry. All your data will remain in the Registry unless you ask for it to be removed.

Who will have access to the medical and other records in the Registry?

The FFB is committed to protecting the privacy of participants in the Registry. However one of the main reasons for creating the Registry is to share detailed medical and other relevant information from many participants with scientists and other researchers. This is done by hiding your name, address and other identifying information from the researchers. We call this de-identified or coded data, information from which all personal identification has been removed. What registered scientists, researchers, clinicians, and pharmaceutical companies will be allowed to see is only this de-identified data, not your personal information. They will not know who you are. During the consent process you will be asked to decide if you want to share your data with researchers.

The de-identified data collected and compiled by the Registry belongs to you and you may request that it be removed at any time. The FFB Registry is the guardian of the information contained within the Registry.

During the consent process, you may agree to share a subset of de-identified information collected from your profile with the National Institutes of Health Global Rare Disease Registry, and certain other databases. We will combine our coded data with similar information from other databases in order to develop global knowledge of rare diseases that may lead to new research studies, clinical trials, and clinical treatments.

The Registry has to follow rules to protect personal information about you. Federal and State laws also protect your privacy. The consent form describes what information about you may be collected in this study. It also tells you who might see or use your information.
Generally, only members of the FFB Registry staff, who have a need to, will know that you have registered, answered the enrollment questionnaire and will see your personal information. However, there are a few exceptions that are listed in the consent form.

**What are the risks to registering?**

There is minimal risk in taking part in the Registry. The Registry includes questions that are very personal and you may feel uncomfortable answering. You do not have to share any information you do not want to.

Another unlikely risk is potential breaches in the computer system. In the event the there is a breach in the Registry's computer system all affected Registry participants will be notified.

If you chose to provide information about the results of your genetic testing, or ask your doctor to provide this information, and if those results were to be accidentally released, it might be possible that the information we will gather about you as part of the Registry could become available to an insurer, an employer, a relative, or someone else outside the Registry. Even though Federal Law and the law in many States protect you from discrimination based on your genetic test, 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 you genetic information. Be aware that 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 being tested.

**I want to be involved in a clinical trial. If I register, is this guaranteed?**

No. Although one of the main goals of the Registry is to make it easier for affected individuals to participate in research, there is no guarantee that that you or your affected family members will be eligible for a trial.

Please note that even if the investigators of a clinical trial believe that you might be eligible for the trial, based on the data about you stored in the Registry, it is still possible that you do not meet the trial selection criteria after all. Please also be aware that if we inform you about the existence of a trial, and you choose to participate in the trial, you will need to fill out a separate informed consent form for that specific trial.

**I don't want to be involved in a clinical trial. Should I still register?**
Yes. By joining the Registry you do not have to agree to be available for a clinical trial. We hope that you will still be willing to register, even if you don’t want to take part in a trial. Your information will still be useful to researchers who are trying to learn more about inherited retinal degenerative diseases.

Can I withdraw from the Registry if I change my mind?

Yes. Your participation in this project is entirely voluntary. Should you change your mind and wish to withdraw your information from the Registry, you will be free to do so without having to provide any explanation. Simply contact the Registry coordinator and all of your information will be removed from your personal retinal health record and the FFB research database and any documents you have sent to the FFB Registry will be destroyed.

Please note that any de-identified data provided to researchers prior to your request for removal cannot be retrieved from researchers that have already used it. Once your information has been removed from the Registry it cannot be recovered. If you wish to retain any information from your personal retinal health record you must download or print it from the Registry web site, or request a copy from the FFB Registry coordinator before your record is destroyed.

If I have given data or information to doctors, researchers, clinics or hospitals in the past, is it OK to give my data to the Registry now?

Yes. The data or information you have given to doctors, researchers, clinics or hospitals in the past cannot be shared with the Registry without your written authorization. If you wish to contribute this information to the Registry you can send a written request authorizing them to enter the information into your Registry record, or ask them to give you the information so you can send it to the Registry coordinator to be entered into your Registry record.

What are my options if I do not want to be in the Registry?

You do not have to join this Registry. Participation is voluntary. You do not need to participate in this Registry to be a member of the Foundation Fighting Blindness and to continue to receive their updates and newsletters. The Foundation Registry staff will not share with anyone else in FFB whether you accept or decline to join the Registry and there are no adverse impacts on the support you receive.

Will it cost me anything to be in this Registry?

No. Registration is free and there is no cost to you for participation in the FFB Registry.
Will I be compensated for my participation?

No. There is no financial compensation for participants in the FFB Registry.

Who should I contact if I have any questions?

If you have any questions about the registration process or about participation in The Registry, please contact The Registry Coordinator at Coordinator@MyRetinaTracker.org or at 800-683-5555 or +1-410-423-0600.

To report problems that result from your participation in The Registry, you may contact the Registry coordinator at: Coordinator@MyRetinaTracker.org or at 800-683-5555 or +1-410-423-0600.

To inquire about your rights as a participant in the Registry, you may also contact the Western Institutional Review Board the, IRB for this study at: help@wirb.com or 800-562-4789.

For additional information regarding the terms and conditions of the FFB Registry web site or the privacy policy please go to Terms and Conditions or Privacy Policy at www.MyRetinaTracker.org.