

Patient Terms and Conditions

Effective Date: May 10th 2019

These “Terms and Conditions” regulate the participation in the BCM Registry by patients who have BCM who have agreed to comply with BCMFF policies and protocols with respect to the use of the Registry, defined below (hereinafter, each of them, a “Patient”).

Understanding your participation

If you are a person who has been diagnosed with Blue Cone Monochromacy (BCM), we invite you to be a Patient in the BCM Registry.

However, before you enter personal information into the BCM Registry, please carefully read these Terms and Conditions which explain what is involved and what will be done with the information you provide. If you already have an account, you can [sign in](#).

What is a patient registry? And, what are its aims?

A registry is a collection of data about individuals with a specific disease or condition, who provide information about themselves to the registry on a voluntary basis. In general, disease registries are developed to increase understanding of the specific condition by providing health care professionals and researchers with first-hand information about the people with that condition, both individually and as a group. Registries can serve multiple aims such as: capturing the demographics of the disease, identifying patients for clinical trials, tracking clinical outcomes and more.

In this case, the BCM Registry is for individuals with Blue Cone Monochromacy. Its overall aim is to increase our knowledge about the clinical manifestations of the disease, including their prevailing clinical features and if and how they occur differently in the affected population, its natural history and long-term outcomes with or without treatments.

When you join the BCM Registry, you will insert your own personal medical record that, when combined with other people with BCM, creates the BCM Registry. For you to join, your diagnosis and medical data will have to be confirmed, validated and periodically updated by your clinician. Therefore, you

will need to indicate who your clinician is and ask him/her to register for the BCM Registry.

What is the BCM Registry?

The BCM Registry is an online patient registry dedicated to a rare genetic retinal disease, namely [Blue Cone Monochromacy \(“BCM”\) \(“Registry” or “BCM Registry”\)](#). The Registry has been created by [BCM Families Foundation \(“BCMFF”\)](#), the only non-profit patient-led organization worldwide with the mission to eradicate BCM.

BCM affects only 1 person out of 100,000 and, at present, has no cure. Because of the low number of patients and the fact that they are scattered around the world, knowledge of the disease is limited and so is the likelihood to develop innovative disease-modifying therapies soon. The BCM Registry was established to fill these gaps.

The Registry is a patient-powered registry where patients enroll themselves and input enter their own personal and medical data. However, the patients’ treating physicians are requested to check and validate all medical data.

What are the expected benefits of the BCM Registry?

The direct benefit of your participation in the Registry is having a secure place for you and your clinician to store information relevant to your disease. The information collected in the Registry is expected to advance our understanding of the disease and to foster research into the treatment of BCM.

The Registry will do this by:

1. providing Patients with the most up to date information about research that is being conducted on BCM;
2. informing Patients when they may be eligible to participate in clinical trials;
3. studying the spectrum of clinical manifestations in the Patient population;
4. helping medical staff to improve and standardize medical care and assistance;
and

5. providing researchers with accurate, firsthand information from as many people with BCM as possible.

Who is eligible for the BCM Registry?

Individuals (including minor children) with a confirmed genetic diagnosis of Blue Cone Monochromacy are eligible for participation in the BCM Registry. During the registration process, you will be requested to upload your medical records (i.e. genetic test) and to indicate who your clinician is. You will not be enrolled until your diagnosis has been confirmed by your clinician. If the clinician doesn't confirm your diagnosis, you will not be able to participate.

Consent to participate and who can give it.

To join the BCM Registry, we first need your consent. Consent is a process that informs you about the scope of the Registry and how your data can be used. It also explains how your participation in the Registry could affect you and what you need to consider before participating. Finally, it provides a record of what you have and have not agreed to.

You will find two (2) consent forms within the BCM Registry that you will need to carefully read and decide upon, with the first of those being necessary for your participation.

- [Consent A](#) to enroll in the BCM Registry – enables the registry manager and clinician to view, insert and modify your data and to contact you. With Consent A Patients accept to receive communications from the registry manager and from their selected clinician.
- [Consent B](#) to receive communications from researchers. For instance, if one researcher wants to reach you and announce a clinical trial, he/she may send short communications through the Registry. The length of communications is limited to 1000 characters. However, communications can contain urls of external webpages.
- **Further Declarations:** to acknowledge that you may revoke your / your child's Consent A and participation and have your / your child's information removed from the Registry at any time by accessing the web page 'Delete

my participation'. BCMFF will not use or disclosure Registry Data after you have revoked your participation. However, revoking your participation will not affect information that has already been shared with approved researchers, scientists, or other authorized third parties.

- If you provide Consent A it will expire after one year and if you I wish to disclose additional Registry Data to BCMFF, you must provide an additional consent.
- The expiration of Consent A to collect Registry Data will not affect Registry data already disclosed to BCMFF.

If an individual is 18 or over and understands the consent form, he/she is eligible to join the BCM Registry on their own. Otherwise, the legal guardian, parent, or custodian of the Patient must provide the consent for the affected individual to join. When the eligible individual becomes 18, and if he is able, consent will be obtained directly from the affected individual for continued participation.

There is no cost for you in joining the BCM Registry. Participation is free and voluntary. If you change your mind and want to withdraw from the Registry, you can easily withdraw by following the instructions on this page [FAQ](#). You acknowledge and agree that BCM has the right to terminate your participation in the Registry and freely withdraw from these Terms and Conditions at any time, by sending you a withdrawal communication.

What are the steps to participate in the BCM Registry for a person with BCM or his authorized representative?

- If you choose to participate, you will need to create a username and a password and to provide an email address. Once your email address is confirmed, you will be guided through the registration process that requires you to:
 - Give your consent for participation in the Registry;
 - Provide your or your child's contact details;
 - Select your clinician (please, note that you will be able to choose from within a list of already registered clinicians or, if the name of your treating

physicians is not listed there, you will need to provide his/her contact details);

- Upload your or your child's BCM DNA test report.
- Once your account is complete with this information, you enter in a “waiting-list” until your clinician confirms that you have been diagnosed with BCM and validates your medical data. At that point you or your child become a Registry Patient.

As a Registry Patient, you can access yours or your child's record at any time if you want to change or update your data, by signing in with your username and password. You may also request that your clinician update your medical data following subsequent medical examinations.

If more than one member of your family has BCM, the first family member registering can create a family identification code in the Registry. That person can give the family identification code to his family members and they can use it during the registration process. However, every member of the family who registers will have their own separate account and registration code. Each individual family member must provide their own consent and enter their own data.

Who has access to my data? How is my privacy protected?

The BCM Registry is established by a patient organization that is committed to protecting the privacy of Patients. All the information you provide will be maintained in a safe, secure IT platform, and any information that could identify you and your family members (i.e. personal data) will not be seen by anyone, except the BCM Registry's staff and your selected clinician, without your approval. Your name and other personal information that can identify you and that might be displayed on your medical records uploaded to the registry, will be hidden. For the purposes of the BCM Registry, your medical information will be shared – pooled with that of other Patients - with clinicians and researchers only after any information that could identify you has been removed.

By becoming a Patient or otherwise using our site or Services, you accept our [Privacy Notice to Patients](#), subject to the terms of your applicable consent to participate.

Your personal information stored in the BCM Registry belong to you and you have the right to request that your information be removed at any time.

Am I expected to provide additional data/updates in the future?

It is essential that the information contained in the Registry be regularly updated to keep track of the course of disease and its outcomes over time.

Therefore, you and/or your clinician will be able to update your record in the Registry any time after a clinician's appointment; if new test results are available; 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.

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

There is no guarantee that that you or your child will be eligible for a trial. Patients in a clinical trial are selected based on strictly defined eligibility criteria. Therefore, even if you/your child might be initially selected for a trial, based upon your data collected in the Registry, but you/your child might not meet the eligibility criteria for that trial at a further examination.

I don't want to be involved in a clinical trial. Should I still register?

The availability to participate in clinical trials is not a condition for participating to the BCM Registry. You can register, or you can register for your child even if you or your child don't want to take part in a trial. Your information will still be useful to researchers who are studying BCM.

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

Your or your child's participation in the BCM Registry is entirely voluntary. Should you change your mind and wish to withdraw your or your child's data from

the Registry, you will be free to do so without having to provide any explanation. Simply follow the instructions that are provided to remove all your or your child's personal and medical information, including any medical records you have uploaded to the Registry.

Are there costs or compensations associated with my participation?

Participation in the BCM Registry is at no cost.

There is no financial compensation for participants.

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 manager at:

registry.manager@bcmfamilies.org.

General Provisions

By participating in the Registry, you agree not to attempt to re-identify participants through the aggregate and anonymized data provided by BCMFF.

To the maximum extent permitted by the applicable law, BCMFF does not assume and shall not be deemed to assume any liability with regard to your participation in the Registry and the performance of these Terms and Conditions.

Subject to the “Disputes with BCMFF and Agreement to Arbitrate” section below, (A) these Terms and Conditions and the respective rights and liabilities of the parties, shall be governed, construed, and enforced in accordance with the substantive laws of the State of Delaware without giving effect to its rules regarding conflicts of laws; and (B) with respect to any suit, action, or proceeding relating to these Terms and Conditions, you irrevocably (i) submits to the exclusive personal jurisdiction of the state and federal courts in Palm Beach County, Florida; and (ii) waives any objection which you may have to personal jurisdiction over you and the venue of any suit, action, or proceeding brought in any such court.

Limited License to Use Site

We only grant you a limited revocable license to access and use the public facing features of the BCM Registry for non-commercial purposes for purposes consistent with these Terms and Conditions and in a manner that does not cause harm to BCM Registry, our site, or services or any other users. You are not permitted to otherwise access or use our site or services, or any content thereon. We may suspend or terminate this limited license in our sole discretion and such license shall automatically terminate upon your breach of these Terms and Conditions.

Disputes with BCMFF and Agreement to Arbitrate

The laws of the State of Delaware, without regard to conflict of laws provisions that would apply other law, shall govern the BCM Registry, these Terms and Conditions and any disputes arising related thereto between us, without prejudice to any provision of the laws of your country protecting patients or consumers, that, in the absence of choice, would have been applicable and cannot be derogated from by agreement by virtue of such laws. To the extent permitted by the applicable law, you and we each agree that any dispute, claim, or controversy arising from or relating to the BCM Registry or these Terms and Conditions shall be resolved by individual binding arbitration, and not through litigation, unless the claim is properly filed in a small claims court on an individual basis. The arbitrator's authority to resolve claims and make awards is limited to claims between you and us alone. Furthermore, claims brought by you against us, or by us against you, may not be joined or consolidated in arbitration with claims brought by or against someone other than you, unless agreed to in writing by all parties. No arbitration award or decision will have any preclusive effect as to issues or claims in any dispute with anyone who is not a named party to the arbitration. **THIS MEANS THAT NEITHER OF US WILL HAVE THE RIGHT TO FILE OR PARTICIPATE IN ANY CLASS ACTION OR REPRESENTATIVE ACTION RELATING TO THE BCM REGISTRY AND THESE TERMS AND CONDITIONS, AND THAT ANY ARBITRATION PROCEEDINGS WILL BE LIMITED TO THE CLAIMS BETWEEN YOU AND US. BOTH YOU AND WE ARE GIVING UP ANY RIGHT YOU AND WE MAY HAVE HAD TO A JURY TRIAL, AND ALL OTHER RIGHTS THAT YOU OR WE WOULD HAVE IN COURT THAT ARE NOT AVAILABLE IN ARBITRATION.**

This arbitration provision is intended to apply as broadly as possible, and to include all parties and claims that would be included in a case brought in court. Thus, this arbitration provision also requires arbitration as to any other corporate or natural persons who are parties to the claim, such as our corporate affiliates and vendors, and members of your family. This arbitration provision also applies to

claims of every kind and nature, including but not limited to counterclaims, crossclaims and third-party claims, and claims based upon torts, statutes, regulations, common law and equity; provided, however, that notwithstanding anything to the contrary in this arbitration provision any dispute over the validity, enforceability or scope of this arbitration provision shall be decided by a court, not an arbitrator and BCMFF may seek injunctive relief from a court to prevent or stop a misuse of its intellectual property or confidential information.

You or we may commence an arbitration proceeding by following the rules then in effect for either JAMS or the American Arbitration Association (“AAA”), as selected by the party commencing an arbitration. For a copy of the rules, to file a claim or for other information, contact either JAMS (jamsadr.com) or AAA (adr.org). In addition to JAMS and AAA, claims may be referred to any other arbitration organization that is mutually agreed upon in writing by you and us, or to an arbitration organization or arbitrator(s) appointed pursuant to § 5 of the Federal Arbitration Act as it may be amended (“FAA”), provided that any such organization and arbitrator(s) will enforce the terms of this arbitration provision. This arbitration provision is made concerning transactions involving interstate commerce and shall be governed by the FAA. If there is a conflict between the applicable arbitration rules and these Terms and Conditions, these Terms and Conditions shall govern. The arbitrator shall apply applicable substantive law consistent with the FAA and applicable statutes of limitations, shall honor claims of privilege recognized at law, and, at the timely request of either party, shall provide a brief written explanation of the basis for the decision. The arbitration proceeding shall not be governed by any federal or state rules of civil procedure or rules of evidence. The arbitrator shall take reasonable steps to preserve privacy and confidentiality.

You will be responsible for paying your share, if any, of arbitration fees, but only up to the amount of filing fees you would have paid to file a claim in the state or federal court closest to your residence. We will be responsible for any additional arbitration fees, even if we win the arbitration. In a dispute involving \$10,000 or less, you may choose to have the arbitration conducted by telephone, based on written submissions from the parties, or in person according to the JAMS or AAA rules. If there is an in-person arbitration hearing, it shall take place in the federal judicial district that is closest to your residence.

This arbitration provision shall survive termination of these Terms and Conditions or your use of the BCM Registry and any bankruptcy by you or us. If any portion of this arbitration provision is deemed invalid or unenforceable, it shall not invalidate the remaining portions of this arbitration provision; provided, however;

that the entire arbitration provision shall be invalidated if the requirement of arbitration solely on an individual basis is deemed invalid or unenforceable. If a court decides that the entirety of this arbitration provision is invalid or unenforceable, the remainder of the Terms and Conditions shall still apply.

Thanks!

Thank you very much for your interest in joining the BCM Registry!

The Registry collects data and information that are instrumental to scientific research into the treatments of BCM.

It is your commitment that will make the cure possible.