

## **Consent Information Sheet for the adults and for child's parents/guardian**

Effective Date: May 10th, 2019

**TITLE:** Blue Cone Monochromacy International Patient Registry

**PROTOCOL NO.:** BCMRegistry-2019-V01  
WIRB<sup>®</sup> Protocol #20191420

**SPONSOR:** BCM Families Foundation

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### **STUDY-RELATED**

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About Inclusion in the Blue Cone Monochromacy (BCM) International Registry (also simply called the "Registry"), and Choices of Levels of Consent. This study involves research and your participation is voluntary. You may refuse to participate or may discontinue at any time without penalty or loss of benefits to which you are otherwise entitled.

On this page, you may choose and may check a box to give your consent. Just mark the check box you choose. Click the "*Save Changes*" button at the end of the page. Please carefully read the [online Registry Privacy Notice](#) before giving or revoking any consent.

You may change your consents at any time.

Only Consent A is needed to participate in the Registry. Consent B is an additional and optional consent that allows researchers to communicate with you.

## **Opening disclosure about Purpose of the Registry**

The purpose of the Registry is to collect and compile certain demographic, health, genetic, and other relevant information about patients with BCM. The data contained in the Registry will be used for the following purposes:

- developing a centralized database for information to be used for statistical analysis purposes;
- creating a repository of contact information for individuals with BCM to allow researchers to anonymously contact such individuals to solicit their participation in studies or clinical trials;
- compiling a pool of relevant data about the pathology and effects of BCM, to be used for the advancement of scientific understanding of BCM;
- linking data of individuals with BCM to their family members who have also joined the Registry and provided their consent to the linkage.

Information that is submitted for inclusion in the Registry may be retained indefinitely unless and until the patient, or a parent or guardian acting on behalf of a minor patient, requests the removal or deletion of such data from the Registry. Registry information will not be redisclosed to persons not identified on this form nor used for purposes not described in this consent.

## **Who will have access to my data?**

We may permit our consultants, and other service providers, including IT services providers, acting as data processors, to access information we collect about you/your child through the Registry to carry out work on our behalf. These third-party consultants/service providers are prohibited from using such personal information for any purpose(s) other than to provide their services we have engaged them to perform.

With your consent (see paragraph “How we use your information” above), we will allow access to your / your child’s Registry data by: (1) your / your child’s treating Clinician(s), who may view, insert, update and/or validate your data; (2) Registry administrators who will be responsible for the management of the Registry; (3) Registry Steering Committee members who will be responsible for the governance of the Registry.

Further, with your consent, we may share anonymized Registry information with researchers and other third parties who have agreed to comply with BCM Families Foundation (BCMFF)'s policies and protocols with respect to the handling and future use of that data. Here anonymized data means data that cannot identify you / your child; here third parties may include researchers, universities, scientists, research institutions, patients' organizations and patients, biotechnological and pharmaceutical companies interested in working on BCM. Reports containing Registry statistical data resulting by the aggregation of anonymized data may be published on BCMFF's websites and Newsletter.

We also may share your/your child's information: (1) if we are required to do so by law, regulation, or legal process (such as in response to a court order or subpoena); (2) to fulfill requests by government agencies, such as law enforcement authorities; (3) when we believe disclosure is necessary for the establishment, exercise or defense of legal claims; (4) in the event of a joint venture, partnership, merger, or other collaboration with another organization, to the extent permitted by the law; or (5) in the context of a business negotiation or transaction relating to BCMFF or any affiliated entity (e.g., further to a merger, reorganization, liquidation, or any other business transaction), including negotiations of such transactions, to the extent permitted by the law.

## **Risks**

There may be a breach in confidentiality.

## **Alternatives**

This is not a treatment study and your alternative is not to participate.

## **Confidentiality**

If the results of the trial are published, your identity will remain confidential.

## **Who can I contact for more information about this registry?**

You may request BCMFF's support by contacting BCMFF at [Registry.Manager@BCMfamilies.org](mailto:Registry.Manager@BCMfamilies.org)

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by an Institutional Review Board (“IRB”). An IRB is a group of people who perform independent review of research studies. You may talk to them at (800) 562-4789, [help@wirb.com](mailto:help@wirb.com) if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

## **Your current consents**

### **A - Minimum consent**

Note: This consent is needed to participate in the Registry.

I am an adult or I’m the parent or guardian of a minor whose information I am submitting for inclusion in the Registry. I authorize BCMFF to store and process my personal data / my and the minor’s personal data (including health and genetic data, collectively “Registry Data”) for the purpose of allowing me / the minor to participate in the Registry, in accordance with the online [Registry Privacy Notice](#). I authorize BCMFF to allow access to my / my child’s Registry Data by the Registry Managers who will be responsible for the management of the Registry and by the Registry Steering Committee who will be responsible for the governance of the Registry.

I consent to link my Registry Data to the ones of my / my child’s family members who have also joined or will join the Registry and received or furnished me a Family ID.

I authorize BCMFF to anonymize and aggregate my / my child’s Registry Data and to share the resulting anonymized and aggregated data with researchers and other approved third parties who have agreed to comply with BCMFF’s policies and protocols with respect to the handling and future use of that anonymized data. Here anonymized data means data that cannot identify you / your child; here third parties may include researchers, scientists, universities, health and research institutions or associations, biotechnology and pharmaceutical companies, patients’ organizations and patients, interested in working on BCM Reports containing Registry statistical data resulting by the aggregation of anonymized data may be published on BCMFF’ websites and Newsletter.

I consent that my/my child's Registry Data will be stored and transferred to the United States, where BCMFF has its registered office and may have its servers, having being informed that the United States is a country which does not offer the same level of protection of the privacy which is offered by the European Law and for which adequacy decisions issued by the European Commission do not exist.

I consent that BCMFF can include my / my child's personal profile in the Registry the ophthalmic clinical examination reports and genetic test results as entered, modified and/or cancelled by my / my child's Clinician, including the reports uploaded by my / my child ERG tests, color tests, and any other tests the Clinician may deem appropriate to upload.

I consent to receiving communications from the Registry Manager by email, postal mail, and/or telephone regarding my / my child's participation in the Registry, as well as communications by email, postal mail, and/or telephone regarding me / my child's participation in the Registry, that may be sent by my / my child's selected Clinician.

- By checking this box, I authorize BCMFF to collect and process my / my child's Registry Data as explained above.
- By checking this box, I do NOT authorize BCMFF to collect and process my / my child's Registry Data as explained above.

**B - Adult consent / Adult consenting for minor to receive communications sent on behalf of researchers, scientists, universities, health and research institutions or associations, biotechnology and pharmaceutical companies:**

- By checking this box, I authorize BCMFF to send me communications on behalf of researchers, scientists, universities, health and research institutions or associations, biotechnology and pharmaceutical companies regarding potential clinical trials or research projects. The researchers, scientists, universities, health and research institutions or associations, biotechnology and pharmaceutical companies pursuant to a specific request approved by the [Registry Steering Committee](#), will be enabled to send communications but will not be provided with identifying information about who is receiving the communications. I may

respond to these communications and provide identifying information about my / my child if I so choose.

- By checking this box, I do NOT authorize BCMFF to send me communications on behalf of researchers, scientists, universities, health and research institutions or associations, biotechnology and pharmaceutical companies regarding potential clinical trials or research projects.

I understand that providing my consent to receive communications is not required for my / my child's participation in the Registry.

## **C – Further declarations**

- By checking this box,
  - I understand that my consent to the collection of Registry Data will expire after one year and that if I wish to disclose additional Registry Data to BCMFF, I must provide an additional consent;
  - I understand that the expiration of my consent to collect Registry Data will not affect Registry Data already disclosed to BCMFF. If I want BCMFF to delete my / my child's Registry Data, I can do so by visiting the Delete my participation webpage;
  - I understand that I may revoke my / my child's Minimum Consent and participation, and have my / my child's Registry Data removed the Registry at any time by accessing the web page 'Delete my participation'. BCMFF will not use or disclosure Registry Data after I have revoked my participation. However, revoking my participation will not affect information that has already been shared with approved researchers, scientists, or other authorized third parties as described above; and
  - I understand that I have a right to receive a copy of this authorization and consent.