



IRB APPROVED
AS MODIFIED
Jun 26, 2019

BCM Patient Registry – www.BCMRegistry.org

Minor Participant Assent Form: 7-17 years of age

Effective Date: May 10th 2019

TITLE: Blue Cone Monochromacy International Patient Registry

PROTOCOL NO.: BCMRegistry-2019-V01
WIRB® Protocol #20191420

STUDY-RELATED

PHONE NUMBER(S): +393357109560

INSTRUCTIONS:

If you are registering a minor between the ages of 7 and 17 years (or if that person has not reached adult age based on local laws), have him read this document and answer any questions he may have about entering the BCM Registry. The information is written so that the average seven-year-old child can understand. If the child is not able to read, you may read the document to him. Please sign it at the end and send the signed assent to: Registry.Manager@BCMfamilies.org

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.

MINOR PARTICIPANT ASSENT:

Until you are 18 years old, your parents (or the adult who takes care of you) must give permission for most everything you do, especially things like doctors giving you medicine or doing tests. They must also give permission to share some kinds of information about you. Recently, your parents or the person who takes care of you have read about a project being done by the Blue Cone Monochromacy Families Foundation (BCMFF). This Foundation was started by parents of boys like you who have Blue Cone Monochromacy (BCM). BCMFF wants to help children and adults with BCM to be well. Your parents (or the adult who takes care of you) decided it will be safe for you to participate in this project and that it could be helpful for you and others to share

some information about you. Your parents (or the adult who takes care of you) have also given permission to your doctor to share some information about you.

The place where your information will be shared is called a patient registry. This note is to tell you what your parents (or the adult who takes care of you) and your doctor are going to share, what we do with it, and what we do to keep your information safe.

A patient registry is a place to collect information about you on a computer, like your name, age, what kind of doctors you go to, the kind of medical procedure or exams you may have had and their results, and other things about your health. A patient registry sometimes collects information about your relatives too. The same kind of information gets collected about a lot of other people, too, and all of it is saved on a special computer where scientists can look at it to see things that they are interested in, like how many people have the same disease and how they are.

The scientists are working to learn about diseases some people have and find ways to make the people better. When they find something they think will help, like a new medicine, they need people to try it out. To find the people they want to try out their new medicine, they look on the computer with the patient registry and find some people who they think the medicine will help and ask them (or their parents or the adults who take care of them, if they are children) if they want to try the new medicine.

But the scientists can't just call you up and ask if you want to try out their new medicine, because they are not allowed to see the part of the computer that has things like your name, your parents'/adults' who take care of you' names, the address of the place where you live, your email and phone number. Those things are secret. All of the secret stuff gets turned into a special number. Only a couple of people in charge of the patient registry get to know the special number that goes with your name, address, email, and phone number.

So, if the scientists want to ask your parents (or the adult who takes care of you) if you want to try their new medicine, they have to ask the people in charge of the registry to send your parents (or the adult who takes care of you) an email, e and tell your parents (or the adult who takes care of you) about the new medicine. Then your parents (or the adult who takes care of you) can call the scientists if you want to try the new medicine. You do not have to try the new medicine unless you want to and your parents (or the adult who takes care of you) say it's okay.

The people in charge of the registry sometimes share stuff in the registry that isn't secret so new scientists will get interested in learning about BCM. But your name, address, phone number, and email are always secret.

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.

Sometimes your parents (or the adult who takes care of you) and your doctor will be asked to update your registry information in the computer.

When you reach adult age (18 in most states), you will need to tell us if you want to keep being in the patient registry. If so, you will have to log into the registry and provide your consent.

However, you can change your mind and decide that you want to stop being in the registry. In this case, you will not have to give any explanation. All you have to do is to log into the registry and follow the instructions provided to remove all the information about you from the registry.

Would you like to be in the BCM Patient Registry?

- Yes, I will be in this Registry. No, I don't want to do this.

Assent instructions

For subjects under 18, consent is provided by the parent or guardian.

_____ Child's name	_____ Signature of the child	_____ Date
_____ Parent or Legal Guardian	_____ Signature	_____ Date
_____ Name of Person Obtaining Assent	_____ Signature	_____ Date

Please send the signed assent to: Registry.Manager@BCMfamilies.org