

Consent

Title of Research Project:

The FFB/CIBC Children's Vision Research Registry

Investigator(s):

Principal Investigator (corresponding investigator): Dr. Elise Héon
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Purpose of the Research:

Foundation Fighting Blindness-Canada and CIBC have awarded Dr. Héon a grant to develop a National (Canada) Children's Vision Research Registry, which is a medical information database that will capture patients affected with retinal dystrophies.

The purpose of capturing these patients is to better understand the natural history of retinal dystrophies, standardize clinical assessment, and most importantly identify patients that could be eligible for clinical trials and/or other therapeutic opportunities that may become available in the near future.

This registry has the potential of expanding into a multi-centered project, but for now it will only involve patients at the Hospital for Sick Children (SickKids).

Description of the Research:

The FFB/CIBC Children's Vision Research Registry is an internet-based medical registry for retinal dystrophies. Retinal dystrophies are a group of genetic eye disorders that affect the retina of the eye. The retina is an important layer at the back of the eye, which picks up light and sends images to the brain. People who have a retinal dystrophy cannot see as well as other people because their retina is not working properly.

Patient information in the registry is not identifiable by name, but rather by a numeric code and not available to the public. Access to registry information is password protected and only available to researchers approved by Dr. Héon and the registry steering committee. All patient information is treated as confidential. The Hospital for Sick Children is the primary

administrative site where the registry is being developed. Once it is developed and validated, other centers will be invited to participate and use the registry to enter patient information from their site. Each center, except SickKids, can only view the information of their own center. However, under the direction of Dr. Elise Héon, health-care providers/researchers with an REB approved research question will be given access to restricted information from other sites.

The type of patient information obtained and entered into the registry will include a patient identifier/number (you will remain anonymous), diagnosis, medical and ocular history, genetic information (inheritance of disease and number of family members affected) and results (genes screened and details regarding DNA change identified), visual function and other eye tests (visual acuity, electroretinogram, OCT and visual fields etc...) as well as details of your retinal examination. This information will be stored indefinitely unless you withdraw from the study and request that your medical information be removed from the registry.

You are asked to be part of The FFB/CIBC Children's Vision Research Registry. This medical database will allow scientists/physicians access to large amount of medical information that will allow them to better understand the natural history of retinal eye disorders such as the one in your family. This project will ultimately provide you and other patients with retinal eye disorders the opportunity to be studied by other doctors, which will allow them to determine you eligibility for clinical trials and/or new treatments that may become available in the near future.

No immediate benefit from participating in this study is expected. However, when clinical trials and other therapies become available in the future, your eligibility for treatment will be determined and you will be managed following the standard of care protocols in place at SickKids. If we also find that you are eligible for any new Foundation Fighting Blindness and SickKids Research Ethics Board approved research projects that develop from the FFB/CIBC Children's Vision Research Registry you will be notified.

You will be informed of any changes made to the study or new information that might affect your willingness to continue to participate in the research.

Potential Harms:

There is no harm by taking part in this study.

Potential Discomforts or Inconvenience:

There are no potential discomforts or inconveniences by taking part in this study.

Potential Benefits:

To individual subjects:

You may not initially benefit directly from participating in this study. However, as the registry develops and physicians learn more about the natural history of retinal dystrophies, patients may find themselves having access to state of the art medical care and an opportunity to participate in clinical trials and/or new therapeutic opportunities that may become available in the near future.

To society:

The FFB/CIBC Children's Vision Research Registry will allow scientists/physicians to access a large domain of medical information that will improve their current understanding of retinal eye diseases, which will ultimately provide patients with evidenced based medical care, as well as help to identify those patients who are likely candidates for novel medical treatments.

Confidentiality:

Confidentiality will be respected and no information that discloses the identity of the subject will be released or published without consent unless required by law. This legal obligation includes a number of circumstances, such as suspected child abuse and infectious disease, expression of suicidal ideas where research documents are ordered to be produced by a court of law and where researchers are obliged to report to the appropriate authorities. For your information, the research consent form will be inserted in the main SickKids patient health record. Health records identifying the patient may be given to and inspected by the HSC Clinical Research Office Monitor.

By signing this consent form, you agree to let these people look at your records. We will put a copy of this research consent form in your patient health records.

The data produced from this study will be stored in a secure, locked location. Only members of the research team will have access to the data. Following completion of the research study the data will be kept as long as required by the SickKids "Records Retention and Destruction" policy. The data will then be destroyed according to this same policy.

Reimbursement:

You will not be paid to participate in this study.

Participation:

Participation in this research is voluntary. If you choose not to participate, you will continue to have access to the same quality of care at SickKids. You or your child can withdraw your child from the study at any time. You and your family will continue to have access to quality care at SickKids.

New information that we get while we are doing this study may affect your decision to take part in this study. If this happens, we will tell you about this new information and we will ask you again if you still want to be in the study.

You/Your child's participation may contribute to the creation of new diagnostic tests, new medicines or other events that may have commercial value. However, you/your child's participation in this study will not entitle you/your child to a share in any future economic benefits.

You will be given a copy of this consent form for your records.

In some situations, the study doctor or the company paying for the study may decide to stop the study. This could happen even if the medicine [or treatment] given during the study is helping you. If this happens, Dr. Héon will talk to you about what will happen next.

If you become ill or are harmed because you took part in this study, we will treat you for free. Your signing this consent form does not interfere with your legal rights in any way. The staff of the study, any people who gave money for the study, or the hospital are still responsible, legally and professionally, for what they do.

Sponsorship:

This research is sponsored by Foundation Fighting Blindness, Canada.

Conflict of Interest:

The investigators of this project have no competing or conflicting interests to declare.

CONSENT FORM (ADULT)

The FFB/CIBC Children's Vision Research Registry:

By signing this form, I agree that:

- 1) You have explained this study to me. You have answered all my questions.
- 2) You have explained the possible harms and benefits (if any) of this study.
- 3) I know what I could do instead of taking part in this study. I understand that I have the right not to take part in the study and the right to stop at any time. My decision about taking part in the study will not affect my health care at Sick Kids.
- 4) I am free now, and in the future, to ask questions about the study.
- 5) I have been told that my medical records will be kept private except as described to me.
- 6) I understand that no information about who I am will be given to anyone or be published without first asking my permission.
- 7) I agree, or consent, to take part in this study.

Printed Name of Subject & Age

X_____
Subject's signature & date

Printed Name of person who explained
consent & date

Signature of Person who explained
consent

Printed Witness' name (if the subject/
legal guardian does not read English)

Witness' signature & date

If you have any questions about this study, please call Ms.CatherineDeveault at 416-813-7654 x1511.

If you have questions about your rights as a subject in a study or injuries during a study, please call the Research Ethics Manager at (416) 813-5718.