**

TITLE: ACH High Field Program Development

SPONSOR: None

# INVESTIGATORS:

# Signe Bray, PhD, 403-955-7389

# Catherine Lebel, PhD, 403-955-7241

# Marc Lebel, PhD, 403-955-5042

# Frank P. MacMaster, PhD, 403-955-2784

Ashley Harris, PhD, 403-955-2771

Perry Radau, PhD, 403-955-5445

This consent form is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your child’s participation will involve. If you would like more detail about something mentioned here, or information not included here, please ask. Take the time to read this carefully and to understand any accompanying information. You will receive a copy of this form.

**BACKGROUND**

Magnetic resonance imaging (MRI) is a safe method to make pictures of our bodies. In order to develop new ways to use the MRI, and to ensure feasibility of particular parameters (such as resolution and scan time) for research studies, there is a need to test such protocols on people.

As part of this study, your child will be asked to participate in at least one brain imaging (MRI) scan at the Alberta Children’s Hospital.

**WHAT IS THE PURPOSE OF THE STUDY?**

The purpose of this study is to test imaging acquisition protocols at the Alberta Children’s Hospital on their 3T MRI Scanner.

## WHAT WOULD MY CHILD HAVE TO DO?

You will be asked to do two things.

1. You will complete an MR screening form on behalf of your child (see attached) (5 – 10 minutes)
2. Your child will undergo a brain imaging scan (1 – 2 hours)
   1. For the scan your child must lie still
   2. Your child may be asked to view and/or respond to stimuli (i.e., pictures), or complete tasks (i.e. finger tapping, press a button in response to stimuli).

**Information about the MRI**

MRI is a safe and non-invasive procedure. An MRI scanner uses a magnetic field to see structures inside the body. Unlike an X-ray, there is no radiation involved. We use MRI to help improve our understanding of the way the brain works.

Your child will lie on a table that will move them into the scanner. They will be asked to lie still during the scan. The scanner makes loud clicking and buzzing sounds but you will be wearing protective earplugs. They will be able to talk to and hear the replies of the technician and researcher who are performing the scan.

Because your child must lie with head and neck inside the scanner, they may become anxious in the enclosed space. Some participants may experience claustrophobic feelings (a fear of enclosed spaces) while in the scanner. Should your child feel claustrophobic or as though they cannot tolerate remaining in the scanner for any reason, you or your child can interrupt the study and rest outside the scanner. You are always free to terminate the procedure at any time if you choose. There are no consequences to ending the study early.

## WHAT ARE THE RISKS?

Brain Imaging Scan

* There are no known risks associated with exposure to the magnetic field used for MRI.
* If your child has metallic objects in their body, we will not allow them to take part in the study because the strong magnetic field in the scanner could cause these objects to change position, and may cause injuries.
* Your child will be asked to change from street clothes into pyjamas or scrubs to eliminate sources of metal.
* The MRI scanner will produce loud noises while in operation. Therefore, your child must wear the provided ear plugs.
* Some people may feel claustrophobic while in the MRI scanner. If this is a problem for your child, they may stop the scan at any time.
* An intercom system allows communication between your child and the researcher throughout the scan. Your child will also be given an emergency squeeze-ball to stop the testing at any time.
* The results of your child’s research MRI scan will not become part of their hospital record.

## INCIDENTAL FINDINGS

The MRI scans in this study are intended to answer research questions and are not the type that would usually reveal medical conditions. In the unlikely event that we detect an abnormality in your child's scan, the researchers will share the MRI scan with a neuroradiologist at the ACH to evaluate the findings as soon as possible after the scan. If the neuroradiologist feels there is cause to have a follow-up, they will contact your family physician who will contact you to take the next steps.

**Name of Family Physician: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

I consent for the researchers to share my child's MRI with the neuroradiologist and for the neuroradiologist to share any material incidental findings with my family doctor:

❑ YES

❑ NO

**ARE THERE ANY BENEFITS FOR MY CHILD?**

There are no direct benefits to you or your child for participating. The information we get from this study may help us to develop better imaging research studies, which will ultimately lead to research providing better treatments for children with various diseases and developmental disorders. You may request a printed picture of your child’s brain to take home.

***﻿* ADDITIONAL RISKS PRESENTED BY COVID-19**

The COVID-19 pandemic presents additional risks to study participation, related to risk of virus transmission to you and/or your child. These additional risks are incurred:

* During transit to the ACH
* Possible exposure at the ACH
* Time spent in close contact with study staff

We have established several mitigation strategies to reduce the risk of transmission:

*COVID screening*

* Researcher will call each participant 2 days before scan to confirm process of entering the hospital with participant as well as complete screening protocol for symptoms or exposure to COVID-19. Another screening will occur on the day of scan before the participant enters research areas.
* No COVID-19 positive patients permitted on research scanner.
* Research staff must also use the [COVID-19 self-assessment tool](https://myhealth.alberta.ca/journey/covid-19/Pages/COVID-Self-Assessment.aspx) on the day of the session.

*Participant interaction and procedure*

* Only the minimum number of people required to safely complete the study will be on site.
* Personal Protective Equipment (face masks and appropriate hand hygiene) mandated for anyone entering the facility as per the AHS continuous masking policy.
* Participants being scanned can remove their masks when being positioned in the scanner and for the duration of the scan. A clean mask will be provided upon completion of the scan. Researchers will maintain continuous masking.
* For gowning, participants will be provided disposable bag to store their belongings.

*Cleaning*

* A 30-minute buffer will be mandated between bookings so that study groups do not overlap, and thorough cleaning can take place.
* Cleaning at end of every day of door handles, desks, workstations, control room, etc. in addition to routine cleaning procedures for MR scanner and facility. Appropriate cleaning of high contact areas between users (workstations, computers, etc.) also required. Any equipment that touches participants must follow strict cleaning procedures between participants.

**DOES MY CHILD HAVE TO PARTICIPATE?**

Participation in this study is voluntary and you may withdraw your child from the study at any time without jeopardizing their health care. If you decide to withdraw from the study, please notify the research staff. Researchers or research staff involved in this study can withdraw your child from the study for any reason. If any new information becomes available that might affect your willingness to participate in the study, you will be informed as soon as possible.

**WILL WE BE PAID FOR PARTICIPATING, OR DO WE HAVE TO PAY FOR ANYTHING?**

We will compensate you for parking costs that you incur on the days that you will be participating in the study.

**WILL MY CHILD’S RECORDS BE KEPT PRIVATE?**

Any information about your child obtained from or for this research study will be kept as confidential (private) as possible. All records pertaining to your child’s involvement in this research study will be stored in a locked file cabinet and data will be kept in secured computer databases. A Study identification (ID) number will be used on any research records (your child’s name will not be on these records).

A master list connecting your child’s name to their Study ID number will be kept in a separate, secure location. University policy requires that we keep your child’s research records for a period of at least five years after final publication of the study results. Access to your child’s identifying information will be limited to the researchers listed on the first page of this form. Research records may be released to other investigators for related research, and these records will not contain any personal identifiers. Your child will not be identified by name in any publication of the research results.

If you participate, your child’s reports related to this research will only be made available to the regulatory authorities including the University of Calgary Conjoint Health Research Ethics Board. This organization will treat such information with strict confidentially. This means that no records bearing your child’s name will be provided to anyone with exception of the regulatory authorities, where necessary, and investigators involved in this study.

If you decide to revoke this consent at anytime, your child’s research data will be destroyed, wherever possible. To revoke your consent, notify the researcher who conducted your scan in writing.

**IF MY CHILD SUFFERS A RESEARCH-RELATED INJURY, WILL WE BE COMPENSATED?**

In the event that your child suffers injury as a result of participating in this research, no compensation will be provided to you by the researchers, the University of Calgary, or Alberta Health Services.You still have all your legal rights. Nothing said in this consent form alters your right to seek damages.

## CONFLICT OF INTEREST STATEMENT

Dr. M Lebel is an employee of GE Healthcare.

## SIGNATURES

Your signature on this form indicates that you have understood to your satisfaction the information regarding your child’s participation in the research project and agree to their participation as a subject. In no way does this waive your legal rights nor release the investigators, or involved institutions from their legal and professional responsibilities. You are free to withdraw your child from the study at any time without jeopardizing their health care. If you have further questions concerning matters related to this research, please contact:

Dr. Catherine Lebel (403) 955-7241

Dr. Signe Bray (403) 955-7389

Dr. Marc Lebel (403) 955-5402

Dr. Frank MacMaster (403) 955-2784

If you have any questions concerning your rights as a possible participant in this research, please contact The Chair, Conjoint Health Research Ethics Board, University of Calgary, at 403-220-7990.

|  |  |  |
| --- | --- | --- |
| Parent/Guardian’s Name |  | Signature and Date |
|  |  |  |
| Child’s Name |  |  |
|  |  |  |
| Investigator/Delegate’s Name |  | Signature and Date |
|  |  |  |
| Witness’ Name |  | Signature and Date |
|  |  |  |

The investigator or a member of the research team will, as appropriate, explain to your child the research and his or her involvement. They will seek your child’s ongoing cooperation throughout the study.

The University of Calgary Conjoint Health Research Ethics Board has approved this research study.

A signed copy of this consent form has been given to you to keep for your records and reference.