**

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 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.

**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 I HAVE TO DO?

You will be asked to do two things:

1. Complete an MR screening form (see attached) (5 – 10 minutes).
2. Undergo a brain imaging scan (1 – 2 hours).
   1. For the scan you must lie still.
   2. You may be asked to view and/or respond to stimuli (e.g. pictures), or complete tasks (e.g. 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.

The use of MRI helps us understand how the brain works in people. You will lie on a table that will move you into the scanner. You will be asked to lie still during the scan. The scanner makes loud clicking and buzzing sounds but you will be wearing protective earplugs. You will be able to talk to and hear the replies of the technician and researcher who are performing the scan. Because you must lie with your head and neck inside the scanner, you may become anxious in the enclosed space. Some participants may experience claustrophobic feelings (a fear of enclosed spaces) while in the scanner. Should you feel claustrophobic or as though you cannot tolerate remaining in the scanner for any reason, you can interrupt the study and rest outside the scanner. You are always free to terminate the procedure if you choose.

## WHAT ARE THE RISKS?

* The risks associated with having an MRI brain scan are minimal. There are no known risks from exposure to the magnetic field used for these tests.
* If you have metallic objects in your body, we will not allow you 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.
* You will be asked to change from street clothes into pyjamas or scrubs to eliminate sources of metal.
* The MRI machine is loud when turned on, and may cause some discomfort. Therefore, you will be given, and must wear, ear protection.
* The space inside the MRI machine is fairly limited, so some people may feel claustrophobic. Should you find the small space to be a problem during the procedures, you can inform us, and the scan will be stopped.
* There is an intercom system that allows communication with the researcher even during the scan. You will also be given a squeeze-ball so that you may stop the testing if you become uncomfortable or anxious at any time.
* The results of your research MRI scan will not become part of your 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 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.

If YES please provide the name of your Family Physician who will contact you OR leave blank if you prefer the neuroradiologist to contact you directly:

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

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

❑ YES

❑ NO

**ARE THERE ANY REPRODUCTIVE RISKS?**

No one knows if there is any risk from the magnet to a fetus, therefore, we will not allow you to take part in the study if you are pregnant or think you might be pregnant.

**WILL I BENEFIT IF I TAKE PART?**

If you agree to participate in this study there will not be a direct benefit to you. The information we get from this study may help us to develop better imaging research studies in the future for patients with various diseases and developmental disorders.

**ADDITIONAL RISKS PRESENTED BY COVID-19**

The COVID-19 pandemic presents additional risks to study participation, related to risk of virus transmission to you. 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.

## DO I HAVE TO PARTICIPATE?

Alternatives

The only alternative is to not participate in the study.

Voluntariness and Withdrawal of consent

Participation in this study is voluntary and you may withdraw from the study at any time without jeopardizing your health care. If you decide to withdraw from the study, please notify Dr. Bray, C. Lebel, M. Lebel, or MacMaster as appropriate. Researchers or research staff involved in this study can withdraw you 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.

**WHAT ELSE DOES MY PARTICIPATION INVOLVE?**

Nothing.

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

We will compensate you for parking or transportation costs incurred during your participation.

**WILL MY RECORDS BE KEPT PRIVATE?**

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

A master list connecting your name to your Study ID number will be kept in a separate, secure location. University policy requires that we keep your research records for a period of at least five years after final publication of the study results. Access to your identifying information will be limited to the researchers listed on the first page of this form. You will not be identified by name in any publication of the research results.

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

All information about you will be identified only by a code number. Data obtained from this study may be stored for future analysis. However, any new research arising from this study will be submitted to the Research Ethics Board for approval.

If you decide to revoke this consent at anytime, your research data will be destroyed, wherever possible. To revoke your consent, notify Dr. Bray, C. Lebel, M. Lebel, or Frank MacMaster - as appropriate - in writing.

**IF I SUFFER A RESEARCH-RELATED INJURY, WILL I BE COMPENSATED?**

In the event that you suffer injury as a result of participating in this research, no compensation will be provided to you by the University of Calgary, Alberta Health Services or the Researchers.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 participation in the research project and agree to participate as a participant. 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 from the study at any time without jeopardizing your health care. If you have further questions concerning matters related to this research, please contact:

# 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

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.

|  |  |  |
| --- | --- | --- |
| Participant’s Name |  | Signature and Date |
|  |  |  |
| Investigator/Delegate’s Name |  | Signature and Date |
|  |  |  |
| Witness’ Name |  | Signature and Date |
|  |  |  |

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.