FACULTY OF MEDICINE | UNIVERSITY OF CALGARY

TITLE: ACH SIGNA UHP MRI Program

SPONSOR: University of Calgary

INVESTIGATORS:

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Purpose of this Consent Form

This form explains the basics of taking part in research studies that use a specialized research magnetic resonance imaging (MRI) scanner at Alberta Children's Hospital. This main form covers the common safety rules, procedures, benefits, and risks for all the research studies using the research scanner. Many studies will use this research MRI scanner (called the GE SIGNA UHP) to take detailed pictures of the brain and body. Each study needs a separate consent form with more specific details. Some studies may also collect images for specific clinical assessments when that is part of the study objectives. This scanner is not used for initial or differential diagnosis, and any such diagnosis will have been done elsewhere before the study.

Please read this form carefully and ask if you need more detail about anything mentioned here or need additional information. Signing this form indicates your willingness to undergo MRI scanning following the general procedures outlined below for any studies using this research MRI machine. You will receive a copy of this form.

BACKGROUND

Magnetic resonance imaging (MRI) is a safe method to take detailed pictures of the inside of our bodies. The MRI scans in this research study will be performed using an

investigational MRI system that is still undergoing optimization and is not currently licensed for routine clinical use. This MRI system meets all applicable safety standards. There are no additional risks anticipated with use of this investigational 3T MRI system compared to a standard 3T MRI scanner. The research team and ethics board have reviewed the device information and approved the use of this investigational 3T UHP MRI system in the study. When a study includes clinical assessment as an objective, such imaging is conducted under the oversight of a radiologist.

WHAT IS THE PURPOSE OF THE STUDY?

The main purpose of the MRI scans is to take pictures of the brain and/or body, which will help researchers better understand health, development, and disease.

Different research studies will scan people using the Alberta Children's Hospital research 3T MRI scanner. By doing multiple research studies with this scanner, researchers hope to answer many questions about the structure and function of the brain and body, and how they develop normally and in illnesses. Researchers also will use scanning to improve their methods and get clearer MRI pictures in the future.

The separate consent form for each study will explain its specific goals in more detail. This main consent form covers how we ensure safe and ethical scanning across all studies.

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 an imaging scan (1 – 2 hours).
    a. For the scan you must lie still.
    b. 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 and body works.

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 scan are minimal. There are no known risks from exposure to the magnetic field used for these tests.
- If you have metal objects in your body, you cannot participate in the study because the strong magnetic field in the scanner could cause these objects to change position and may cause injuries to you.
- You will be asked to change from street clothes into pajamas 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 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.
- When a study includes clinical assessment, your images may be reviewed by a radiologist and may be shared with your care team or Alberta Health Services (AHS) for clinical follow-up, as described in the Incidental Findings section below.

INCIDENTAL FINDINGS

During the MRI scan, the researchers could learn something about you that they didn't expect. For example, the researchers may find out that you have an abnormality in your scan. The researchers will consult with medical experts as needed to evaluate it and will then share these results with you. You will be helped with arranging appropriate follow up and care.

When clinical assessment is part of the study, a radiologist will review any incidental findings. You may be referred to licensed clinical MRI for confirmatory assessment, and any clinical management will be based on those results. Where appropriate, images may be transferred to AHS clinical servers for care coordination.

I consent for the researchers to share findings with me:

- ❑ YES
- ❑ NO

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

Name of Family Physician: _____
Name of Physician's Clinic: _____

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?

There are no direct benefits from the MRI scan itself. The scans are being conducted for research purposes to help scientists better understand the brain and/or body, development, and diseases. Details about the specific goals and potential benefits of each study will be provided in the separate consent form for that study.

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 a member of the study team. Researchers involved in this study can withdraw you from the study for scientific, safety, or other reasons.

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?

Each study requiring MRI scans may involve additional procedures beyond the scanning described here. These will be outlined in the consent form for that specific study.

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

Details are provided in the consent form for the specific study.

WILL MY RECORDS BE KEPT PRIVATE?

Your imaging data will be archived on a secure server without identifying your name or confidential Personal Health Identifiers. This original consent form and a copy of the

study-specific consent form will be retained by this study team. No data will be stored on individual computers. Electronic records, including databases and participant identifiers, will be stored on password-protected devices behind university firewalls.
Personal identifying data will be encrypted for security. Paper documents will be stored in locked cabinets with restricted access. The principal investigator will securely archive all study data and records in cooperation with the University of Calgary. Further details are provided in the consent form for the specific study. When clinical assessment is part of the study, your images may be transferred to AHS clinical servers for care coordination, in accordance with provincial health information and privacy requirements.

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

If you suffer injury because of participating in this research, no compensation will be provided to you by the University of Calgary, AHS, 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. R. Marc Lebel is employed by GE Healthcare, the manufacturer of the Signa UHP MRI scanner used in this study. However, he does not receive any commission, bonus, or other financial incentive related to the use or promotion of GE Healthcare products within the scope of this research. Dr. Lebel has confirmed his compliance with the University of Calgary's Code of Conduct.

SIGNATURES

Your signature on this form indicates that you have understood to your satisfaction the information regarding your participation in the MRI aspect of the research project and agree to be scanned 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 the research study team.

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.