**

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.

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 permit your child to undergo MRI scanning following the general procedures outlined below 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 this study.

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

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

The main purpose of the MRI scans is to take pictures of 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 MY CHILD HAVE TO DO?

You will be asked to do two things.

1. You (the parent/guardian) will complete an MR screening form on behalf of your child, see attached. (5 – 10 minutes)
2. Your child will undergo an 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 and body works.

Your child will lie on a table that will move them into the scanner. Your child will be asked to lie still during the scan. The scanner makes loud clicking and buzzing sounds, but your child will be wearing protective earplugs. Your child 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, your child 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 your child cannot tolerate remaining in the scanner for any reason, then your child can interrupt the study and rest outside the scanner. You or your child are always free to terminate the procedure at any time. There are no consequences to ending the study early.

## WHAT ARE THE RISKS?

* There are no known risks associated with exposure to the magnetic field used for MRI.
* If your child has metal objects in their body, your child 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 your child.
* Your child will be asked to change from street clothes into pajamas 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 medical experts as needed to evaluate it as soon as possible after the scan. If the medical expert feels there is cause to have a follow-up, they will contact your family physician who will contact you to arrange appropriate follow-up and care.

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

**ARE THERE ANY REPRODUCTIVE RISKS?**

There is no known risk from the MRI scan to a pregnant woman or her child. However, as a precaution, we will not allow any participant to undergo the MRI scan if they are pregnant or suspect they might be pregnant.

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

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.

**DOES MY CHILD HAVE TO PARTICIPATE?**

Your child’s participation in this study is voluntary. As their parent/guardian, 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. The 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?**

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

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

Your child’s imaging data will be archived on a secure server without identifying the child’s 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.

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

If your child suffers injury because of participating in this research, no compensation will be provided to you by the researchers, the University of Calgary, or Alberta Health Services.You and your child still have all your legal rights. Nothing said in this consent form alters your right to seek damages on behalf of your child.

## 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.

**ASSESSMENT OF CAPACITY TO CONSENT FOR 14-17 YEAR OLDS**

For participants ages 14-17, we will assess their capacity to provide direct informed consent. This involves explaining the study and checking their comprehension.

If the minor demonstrates adequate understanding, they can consent without parental permission. If not, parental consent is required.

Please discuss any concerns with the research team.

## SIGNATURES

Your signature on this form indicates that you have understood to your satisfaction the information regarding your child’s participation in the MRI aspect of the research project and agree for the child 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 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 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.

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