CAIR Program ACH 3T Handbook

The original 3T MRI scanner at the Alberta Children's Hospital (ACH) was installed in 2012. In 2024, it was upgraded to the Signa UHP 3T MRI.

Research use of the scanner is overseen by the **Child and Adolescent Imaging Research (CAIR)** program, supported by the **ACH Foundation** and the **University of Calgary Department of Radiology**.

Investigators interested in accessing the scanner for research studies should familiarize themselves with the policies outlined in this handbook.

Contents

CAIR Manager and Administrator

The CAIR Program employs a **Research Manager** (Perry Radau, perry.radau1@ucalgary.ca, 403-559-8269) to assist investigators with study planning, protocol setup, data acquisition, and basic data analysis. Perry also provides safety training for the 3T MRI scanner and the mock scanner.
The Program employs an **Administrator** (Kirandeep Bisla, kkbisla@ucalgary.ca) to assist with billing, MR scheduling and other administrative tasks.

Study Approval

All investigators must submit their study for approval to the **scientific review committee**.

The **Application for 3T Research Time** is available here under the section titled "Accessing the pediatric 3T scanner for a new study." The application should be submitted electronically.

When determining the appropriate scan time to request, consider the following:

- **Imaging protocol time** + **setup time** + **cleanup time** = **Total Scan Duration**.
- Use the **Scan Time Template** to calculate the total scan duration.

Special Requests:

- Carefully note any special requests on the 3T application form (e.g., equipment such as an fMRI projector, special acquisition sequences, or accommodation requirements like evening/weekend scanning).
- Direct any questions to the **CAIR Research Manager** or a **CAIR Imaging Scientist** (see contact information at the end of this document).

Ethics Submission:

- You are not required to have a signature from the **Diagnostic Imaging Director** (Ken Dunstall) on the **Operations Approval Form** prior to ethics submission.
- However, you must indicate in your ethics submission that you will utilize the ACH 3T Diagnostic Scanner.
- Our investigational scanner (GE Signa UHP 3T MRI) has been approved for research use (only) by Health Canada. There are specific rules for referencing the UHP in your ethics application and consent forms which are detailed in the Appendix with forms on Sharepoint.

- Diagnostic Imaging will assess and sign the form once your study has received scientific approval.

Study Kick-off Meeting

When you begin a new study, you will have a **kick-off meeting** with the **CAIR Research Manager**. This meeting is essential to:

- Ensure study staff are adequately trained.
- Gather study group information, including contact details.
- Discuss the UHP MRI dual consent process.
- Plan for the protocol development and first participant scan.
- Arrange networking configuration and storage.

Safety Training

The **Child and Adolescent Imaging Research (CAIR)** program offers training to investigators, trainees, and staff at the Alberta Children's Hospital to ensure safety for all involved in research projects. This includes training for activities involving the MR scanner (3 levels), related hardware/software, and the **Mock Scanner**.

Current information regarding the training process can be found here.

Creating a Study Protocol

When creating your study protocol, work closely with the **CAIR Research Manager**, who will assist in determining appropriate sequences, parameters, and conducting pilot scans. It is generally expected that study groups will have one or more sessions, that may include volunteer participant scans, as part of the protocol development. These **development** scans are complimentary (unbilled) and should not be used for publication. Pilot Scans are a separate category discussed later in this Handbook.

Booking Scans

Study scans can only be booked using the designated online booking calendar, **Calpendo**. Instructions for booking can be found here. Calpendo is updated in real time and includes the hours that technologists are available.

Regular Technologist Hours:

- **Monday**: 10 AM – 3 PM
- **Tuesday – Thursday**: 10 AM – 6 PM
- **Friday**: 10 AM – 3 PM

On rare occasion, a technologist is **not** available during these hours and these time slots will be marked as **NO TECH**.

Urgent Scanning Situations:

- For urgent scanning issues, the main contact is the chief technologist **Joanne Houghton** (Joanne.Houghton@albertahealthservices.ca). The **CAIR Manager and Admin** are also good contacts for most issues.
- In the event of same-day cancellations or unusual circumstances, call Diagnostic Imaging at the Siemens scanner (ext. 57572) or GE scanner (ext. 53161).

Additional Availability:

- AHS MRI Technologists may be available outside regular hours. Check the CAIR website for current availability.

Booking Guidelines:

- Each individual must be booked separately.
- Identify the **study name** (as documented in your scientific review committee approval) and the **subject identifier** in the booking form. The subject identifier should not include personally identifiable details such as initials or date of birth.
- Pre-screen participants to ensure eligibility (e.g., no contraindications to MRI) prior to booking. Review the **AHS Diagnostic Imaging Screening Form** (Appendix C) when discussing the study with subjects.

Time Allocation:

- The scanner can be booked in **15-minute increments**.

- Allow at least **10 additional minutes per participant** for setup, cleanup, and data transfer when booking your scan.
- The total booking time should include: **Setup + Scanning + Cleanup**.

Pilot Scans

A limited amount of funding is available to conduct pilot scans for grant submission. If you wish to apply for this funding, indicate it on the **Application for 3T Research Time** (available on the CAIR website).

Pilot Time Booking:

- If approved, pilot time should be booked through **Calpendo**.
- For human volunteers, proper **ethics approval** must be in place prior to scanning.

Unfunded Pilot Studies:

- The application for an unfunded pilot study is available as a link in the **Application for 3T Research Time** webform. Attach the completed application to the webform.
- Provide the appropriate **research ethics board approvals** as part of your application.

Study Scans

Arrival:

- Arrive **15 minutes before** your scheduled time with your participant and a **signed consent form**.
- Late arrivals may result in cancellation.

Screening:

- An MR technologist or **Level 2 Operator** will screen study subjects and any accompanying parent/guardian before entry into the MR room.

Time Management:

- Your study must conclude by the end of your allotted time slot to ensure punctuality for subsequent MR scans.

- Incomplete studies may be terminated at the end of the booked period.

Accompanying Guardians:

- For child participants, **one parent/guardian** may enter the scanner area.
- Childcare for siblings is available at **Emily's Backyard** if needed.
- Other family members should remain in the **Diagnostic Imaging waiting room** or elsewhere in the hospital.

Pregnant Guardians:

- Pregnant or potentially pregnant guardians who will enter the MR room must have this noted on their screening form, along with verbal advice on potential effects on the fetus (e.g., loud noise without hearing protection).
- Pregnant guardians do not require special handling compared to other guardians entering the MR room, but they should be made aware that **MR sounds will penetrate the uterine wall**.
- The risk is considered very low, and no additional precautions are required.

Consent of Mature Minors

Participants Unable to Consent:

- For participants under 14 or lacking sufficient mental capacity, a **parent/guardian** must be present during the scan (in the hospital).
- The guardian must sign the **consent and screening forms** on behalf of the participant.
- Depending on the study's ethics approval requirements, the participant may also be required to sign an **assent form**.

Mature Minors (14-18 Years Old):

- In accordance with the **TCSP2 policy**, youths aged 14-18 may be treated as adults and do not require a guardian to be present during their scans.
- Each study group must determine that the youth has the capacity to make their own decisions and permit the minor to participate in studies without guardian consent.

Confidentiality:

- The scan information of mature minors should be kept confidential by research staff, even with respect to parents and guardians.

- If there are incidental findings, the neuroradiologist will determine the appropriate follow-up procedures and the study team should not directly release the information to the participant. Incidental findings are discussed in greater detail below.

Guidelines:

- Refer to the following documents for details on consent and assent:
- CHREB Guidelines - Assent, Consent & Decision Making Capacity in Minors
- CIHR Best Practice for Health Research Involving Children and Adolescents

Gowning (Clothing) Policy for MRI Room

The **Operations Committee for the ACH 3T (Research)** has adopted the practice of “gowning” for participants and screening for guardians joining the participant in the MRI room.

- **Research participants** (those undergoing a scan) should remove street clothes and shoes and change into provided hospital pajamas, scrubs, or gowns.
- Participants may bring their own **cotton pajamas, scrubs, or loose sweatpants and t-shirts**. Yoga pants and other form-fitting clothing are **explicitly excluded** due to potential risks of fibers in some athletic wear. The Operator will check the clothing before it is worn into the MR room.
- **Guardians** accompanying participants into the scan room must agree to **visual screening,** and sometimes metal detector wand screening, as deemed necessary by the Operator. Guardians are not required to be gowned.

Gown Location:

- Gowns, pajamas, and scrubs are located in **Change Room 1**, to the right of the washroom beside the CT/MRI waiting room.
- If gowns are not stocked, check the cart near the recovery area or another change room.

Street Clothing Storage:

- Participants and guardians will be given a **plastic bag** to store clothing and possessions.
- The plastic bag is stored in the control room during screening, or if necessary, it is placed in a locker across from Change Room 1.

Metal Detector Wand:

- The wand is located in the control room.

- It has two modes: **vibration** and **beep**, with **Off** in the center. Either mode is acceptable for detecting small objects within a few centimeters.
- Ensure the wand is turned off after use to preserve the battery.

Policy on Billing

Billing Rate:

- Scans are billed at a rate of **$550/hour**, pro-rated in **15-minute increments**.
- Studies are approved for a fixed duration (e.g. 1 hour) per scan, though this may be modified after experience with CAIR approval.
- Scans may be cancelled without penalty after booking, provided that no images have been acquired. Please contact the CAIR manager and/or tech staff if this cancellation is on the same day as the booked date.

Early Termination:

If during the session the study team determines that the scan should be terminated early (e.g. participant is non-compliant):

- If **images are acquired**, they will be pushed to the research PACS, and the Investigator **will be billed** for the scan, despite early termination or poor data quality.
- If no images are collected, the Investigator will **not** be billed.

Billing Concerns:

- If you have a concern about billing, do not argue with the Operator or technologist. Instead, send the details of your concern (including the date and time of the scan) to the **CAIR Research Manager** and **Scientific Director**.
- In cases of **equipment failure** during the scan, the Investigator should **not** be billed, even if images were scanned and pushed to the research PACS.

Researcher Discretion:

- Researchers pay for the duration of their scan time once data collection has started, giving them full discretion over how the time is used.
- Study personnel present at the scan make the final decision about whether specific imaging data is acceptable, when to re-acquire or move on to another sequence, and how to pace the exam.

- Researchers may choose to make multiple attempts to scan a difficult subject, provided the subject can tolerate the exam, even if the data is believed to be suboptimal.
- The Operator has the authority to terminate a scan if he or she determines that the participant cannot tolerate further scanning.

Accessing Data

Images from your research study can be accessed after scanning through **Research PACS**. The **CAIR Research Manager** can help provide access to PACS to download data, either directly from our server or by means of WebPACS. Contact the **SFMRRC IT team** (help@sfmrrc.on.spiceworks.com) for further details or other options.

Study Modifications

Minor Modifications:

- Minor modifications to the scanning protocol may be made by the CAIR Research Manager or Level 2 personnel.

Major Modifications:

- Major modifications, including adding sequences or changes that significantly alter the length of the protocol, should be sent for additional **scientific and administrative review**.
- The CAIR Research Manager can assist with this procedure.

Confidentiality

As per the AHS confidentiality agreement and CHREB ethics protocols, you are responsible for protecting the confidentiality of your study data at all times. You are expected to:

- Access only data relevant to your study.
- Maintain the strictest confidentiality in handling participant identifying information.

Investigator Communications

Investigators are periodically contacted by email to communicate centre policies and address any new issues. Please ensure that the **principal investigator** or a delegate (e.g. senior staff) reads these communications and responds as required.

Incidental Findings

Occasionally, a researcher may observe a suspected abnormality or troubling finding in research images. These are considered **incidental findings** and represent a unique challenge to handle appropriately. Below is the process and guidance for reporting incidental findings:

Note: These guidelines do not pertain to studies with both **Clinical and Research components**, as these studies undergo review by a radiologist. Research-only studies do not undergo review by a radiologist.

1. **Consent Form**:

- Studies must include a question in the consent form for the participant to give consent to share incidental findings with the participant and appropriate clinicians.
- This question should not be used as a qualification for inclusion in the study.
- The **UHP MRI Program** consent forms provide standardized language acceptable to **CHREB** for incidental findings.

2. **Reporting Findings**:

- An investigator, research staff member, or trainee who identifies a suspicious during a scan should report it to the **chief technologist** to determine if the matter should be followed-up.
- If deemed important by the chief technologist, the finding should be reported to the **Investigator** immediately.
- The Investigator must report the finding via AHS email using the form found here.
- The completed form must be sent to the **ACH DI Research Medical Director**, Dr. Xing-Chang Wei (xingchang.wei@albertahealthservices.ca), or the pediatric neuroradiologist on duty for MRI, with a copy to the **DI Director**. Use the subject line: **“Incidental Finding”**.

3. **Radiologist Review**:

- The Radiologist will not initiate an image review until receiving an email from the Investigator.

- The Medical Director will review the concern and decide if the finding is medically significant. Typical actions include:
- Contacting the subject's family physician (if indicated on the consent form) or the participant directly.
- If appropriate, the Medical Director will consider placing a clinical requisition, conducting a clinical MR examination, and issuing a formal radiology report.

4. **MR Technologist Role**:

- If a suspicious finding is first made by an MR technologist (who is not a research staff member), they should notify the research team immediately.
- The MR technologist may also notify the Radiologist about the suspicious findings, but no further action will be taken until the Investigator initiates the process.

5. **Confidentiality**:

- All research data, including incidental findings, are covered by confidentiality agreements.
- Once the Medical Director (or delegate) is contacted, the incidental finding becomes a healthcare matter and is subject to provincial and AHS healthcare privacy policies.

6. **Multi-Centre Studies**:

- Some studies, particularly multi-centre studies, may require a modified incidental finding policy. Indicate this on the **Application for Research Time** submitted for scientific review. These cases will be reviewed on a study-by-study basis by the Medical Director and other centre staff.

Resources

Mock MRI Scanner

A **mock scanner** is available for preparing subjects before scans. Prior to accessing the mock scanner, you must complete a training session. Contact the **CAIR Research Manager** for details. After training, you will be given access to **Calpendo** for booking the mock scanner.

EEG

The CAIR program has a **64-channel, MRI-compatible EEG system** (EGI - Electrical Geodesics). This may be booked for either separate studies or combined with MRI. For more information, contact the **CAIR Research Manager**.

Introduction of New Devices to MRI Room

To ensure the safety of staff and participants and avoid damage to the MRI, investigators who wish to bring new devices into the MR room must follow this procedure. A “new” device is defined as any equipment that has not been used in the ACH 3T research MRI, even if it has been used in other MRI facilities.

1. **Inspection**:

- **Perry Radau** (CAIR Research Manager) must inspect the device and approve it for use in the MR room.
- Provide documentation describing the device specifications and MRI safety status (e.g., MR-safe, MR-conditional).
- Where deemed necessary by the Manager, the device may require Operations Committee approval.

2. **Device Categories**:

- **MR-safe**: The Research Manager may inspect and test the device directly with a metal detector.
- **MR-conditional**: The Research Manager (or Chief Technologist) must oversee the positioning in the MR room for the first scan. Ideally, the device company educates users on proper use at the ACH site.
- **Active devices** (those that deliver energy to the patient):
- A representative of the device company should illustrate proper use at the first scan.
- The Research Manager must be present for the first scan.
- The first MR series should deliver energy to a phantom, and the effects should be reviewed before proceeding to human tests.
- If there are concerns about heating and SAR, the device should be tested with MR thermometry at either ACH or SFMRRC before human testing.
- Initial tests with a human should deliver energy to a limb prior to the head.

3. **Connection and Cables**:

- If the device requires connection via the penetration panel, the Research Manager must guide users to available connections.
- Introducing new cables through the waveguide (tube through RF shield) requires notification, similar to other devices. Leaving cables in the waveguide should first receive approval to ensure they will not interfere with other studies.

Photo Policy

Staff/Researchers:

- Staff and researchers who wish to take photos in non-public areas of the ACH GE 3T MRI must follow this policy:
- Obtain a **signed consent form** from every adult in the photos, including technologists, students, staff, participants, and guardians. Guardians should sign on behalf of child participants.
- Photos should only be taken through the MR console window/door into the MR room under supervision of a MR technologist or CAIR staff person.
- No photos should be taken of the **ACH GE 3T MR console room**, even when empty, due to the confidential information often present.
- For additional photos required for training or other purposes, contact the **CAIR Research Manager**.

Participants/Guardians:

- Participants and guardians who wish to take photos of their scan procedure are permitted under close supervision of staff/researchers. The rules above apply, except that signed forms are not required. In most cases, staff or researchers should take the photos on behalf of participants and guardians.

Resources/Contact Information

- **CAIR**: https://cumming.ucalgary.ca/research/child-adolescent-imaging or https://www.mri4kids.ca
- **Seaman Family MR Research Centre**: http://www.mrcentre.ca
- **Research Manager**: Dr. Perry Radau, perry.radau1@ucalgary.ca; 403-955-5445

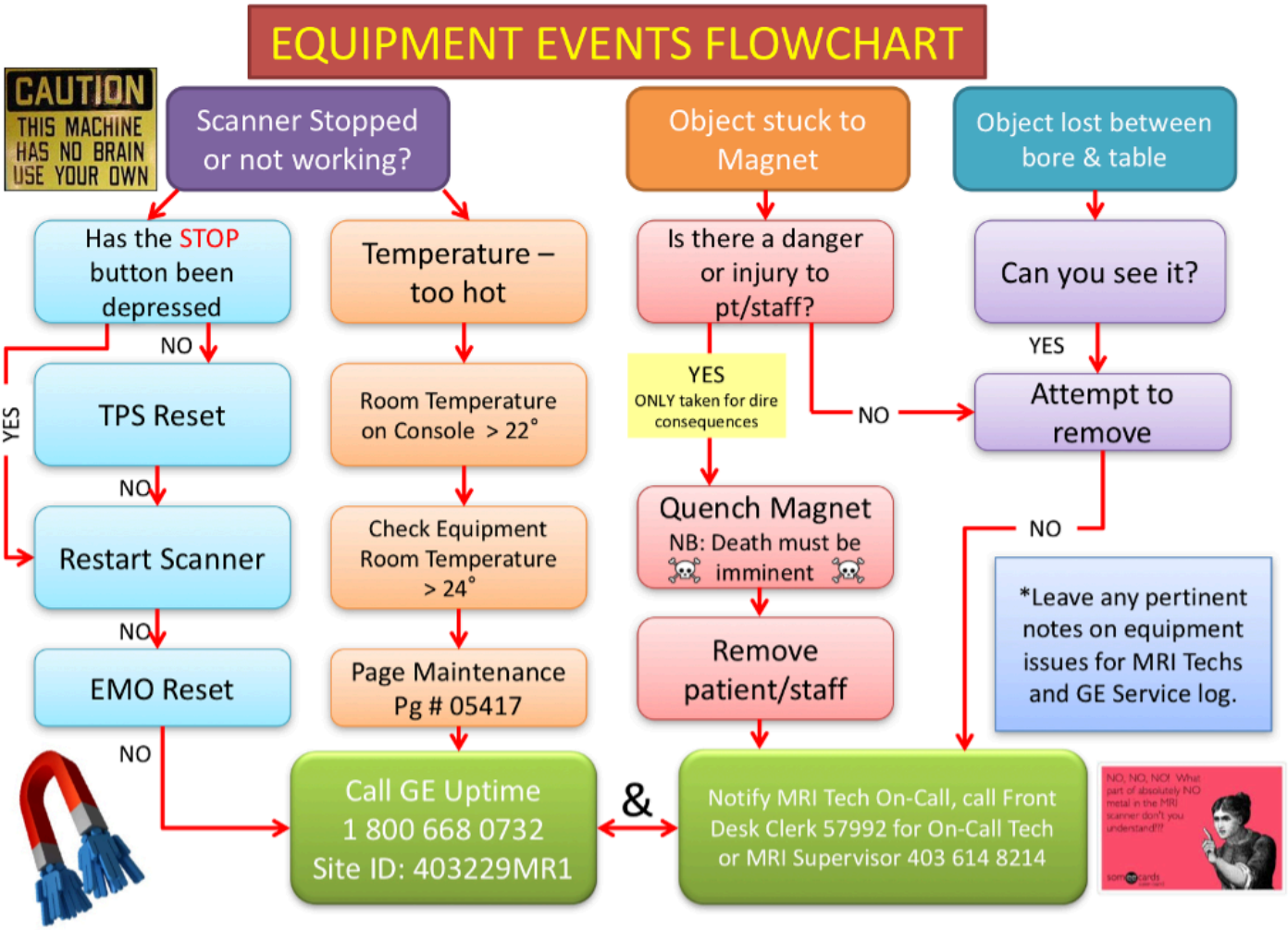
Imaging Scientists:

- **Scientific Director**: Dr. Ashley Harris, (ashley.harris2@ucalgary.ca); 403-955-2771
- Dr. Signe Bray (slbray@ucalgary.ca); 403-955-7389
- Dr. Catherine Lebel (clebel@ucalgary.ca)
- Dr. Chathu Kumaragamage (chathura.kumaragamag@ucalgary.ca

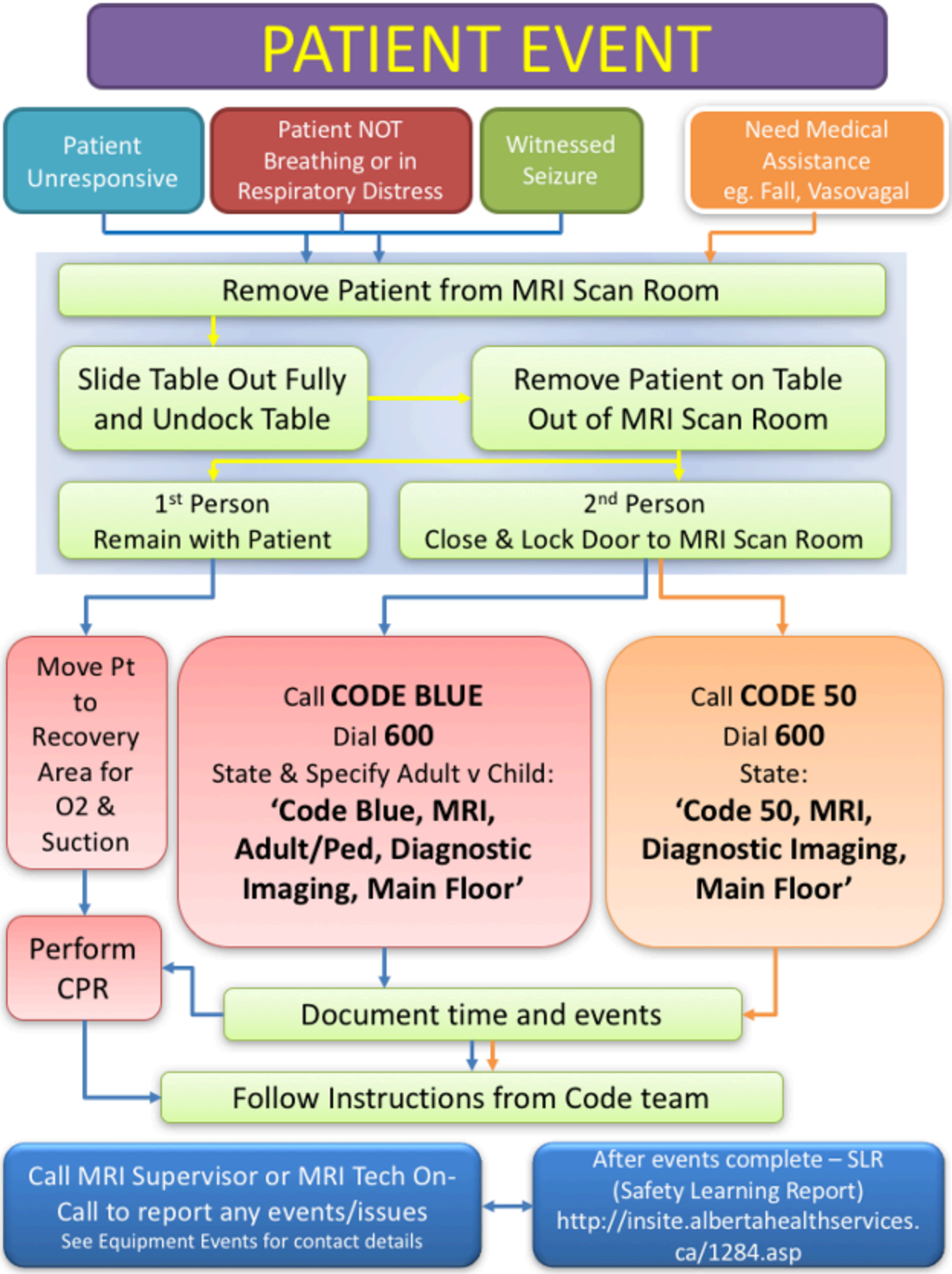
GE MR Physicist: Dr. Marc Lebel (marc.lebel@ge.com)

Appendix

A) Equipment Events Flowchart



B) Patient Events Flowchart



C) Screening Form

Alberta Health Services

Place Label Here

MRI Patient History and Screening

The following items may interfere with your Magnetic Resonance Imaging examination, and some can be potentially hazardous.

Do you have drug allergies ☐ No ☐ Yes Please list them:	
Patient Height _____ in/cm	Patient Weight _____ lbs/kgs
Have you had MRI contrast before ☐ No ☐ Yes ▶ Did you have a reaction? ☐ No ☐ Yes	
Kidney Disease/Renal Failure? ☐ No ☐ Yes ▶ Are you on dialysis? ☐ No ☐ Yes	
Do you have Asthma? ☐ No ☐ Yes	Do you have Diabetes? ☐ No ☐ Yes
Do you have Sickle Cell Disease/Haemolytic Anemia? ☐ No ☐ Yes	

Please indicate if you have the following	No	Yes
Cardiac pacemaker		
Implanted cardiac defibrillator (ICD)		
Brain Aneurysm clip(s)		
Electronic/Magnetic implant or device		
Implanted drug infusion device (e.g., insulin, baclofen, chemo, pain meds…)		
Endoscopy Clips (i.e. Resolution Clip)		
Cardiac Pacing Leads / Wires		
Bone Growth/Neurostimulator		
Coils, Filters, or Stents		
Shunt (renal, brain, heart, spine)		
Middle Ear Implants (cochlea, stapes)		
Swan-Ganz or thermodilution catheter		
Heart valve prosthesis		
Tissue expanders		
Surgical staples, clips, wire sutures		
Silver impregnated dressing		
Shrapnel or bullet		

Please indicate if you have the following	No	Yes
Eye prosthesis		
Eyelid spring or wire		
Penile prosthesis		
IV access port		
Intrauterine device (IUD), diaphragm, pessary		
Artificial joint/Limb		
Bone/Joint pin, screw, nail, wire, plate, etc.		
Wire mesh implant		
Medication patch (hormone, nicotine etc.)		
Hearing aid		
Dentures or partial plates		
Tattoo or permanent makeup		
Body piercing jewelry		
Have you ever had metal in your eyes?		
Was the metal removed by a doctor?		
Are you pregnant?		
Date of Last Menstrual period?		

Have you ever had any surgical procedures or operations? List All ☐ No ☐ Yes ▼	
Type	Year
Type	Year
Type	Year
Type	Year
Type	Year

I have answered the above questions to the best of my ability. The MRI examination has been explained to me, and I have had my questions answered to my satisfaction.

Signature of Patient or Guardian	Date *(yyyy-Mon-dd)*
Witness/Technologist Name *(print)*	Witness/Technologist Signature

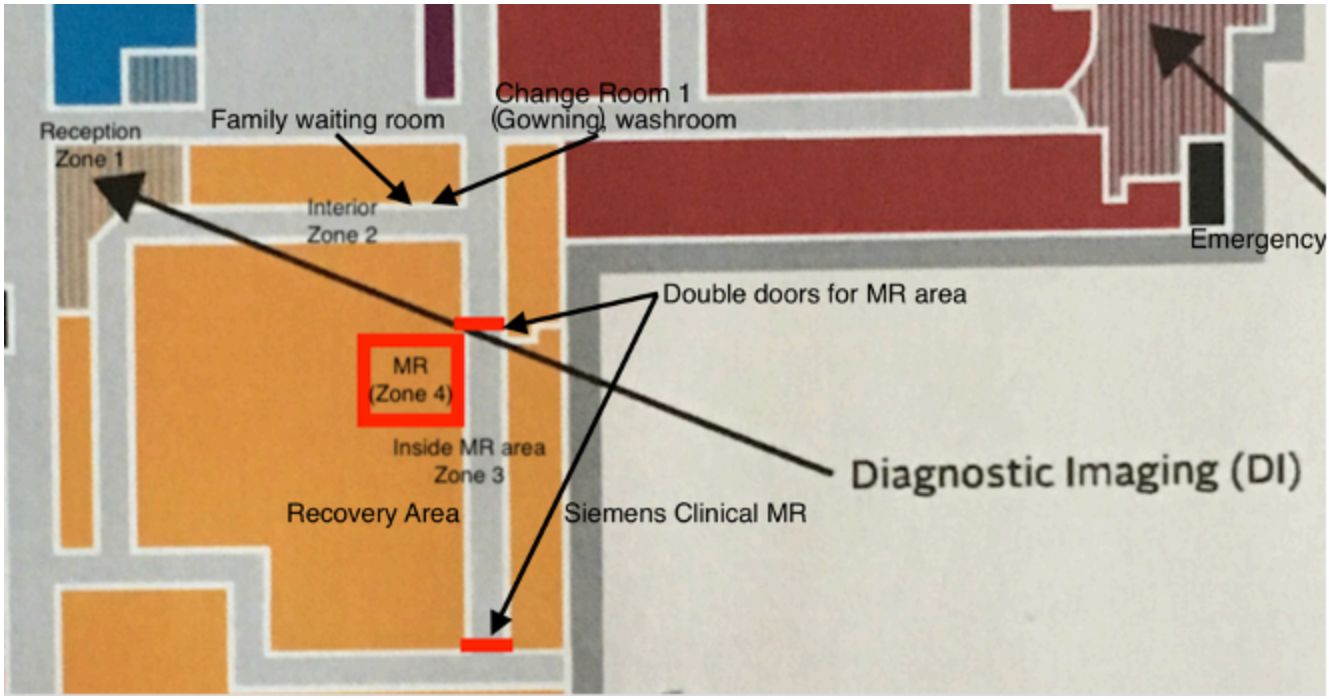
D) Checklist for Setup of a New MR Study

The Investigator planning to initiate a new MRI study with the ACH 3T MRI research scanner should follow these steps:

1. Read the relevant **CAIR Handbook sections** for detailed guidance: https://cumming.ucalgary.ca/research/child-adolescent-imaging/instructions-forms.
2. Submit the study online for approval to the **scientific review committee** via the CAIR website.
3. Submit the study for **ethics approval**: https://www.ucalgary.ca/iriss/. After approval, send the documents to the CAIR Research Manager.
4. After scientific approval, schedule a **kick-off meeting** with the **CAIR Research Manager**.
5. The study will be assigned a **booking identifier (Calpendo)** and **study node**. Staff assisting with the study should receive training for booking and/or MR safety: https://cumming.ucalgary.ca/research/child-adolescent-imaging/training.
6. Create an **MR study protocol**, install it on the MR scanner console, and insert a notes sheet in the protocol binder. Contact the Research Manager for assistance at least **2 weeks in advance** of the first participant scan.

E) Gown Shelving

The gowns are located in **Change Room 1**, as shown on the map below. Any gowns/pajamas in this room may be used for clothing scan participants.



F) Photo Policy Consent Forms

Researchers taking photos should have subjects sign the appropriate consent forms:

1. **Consent for Healthcare Purposes**:

- Consent to Collection and Use of a Recording Device or Camera for Photographs, Video, or Sound Recordings for Health Care Purposes
- https://insite.albertahealthservices.ca/main/assets/frm/frm-07998.pdf
- Use this form to record an individual's consent to the collection of their health information using a recording device or camera for purposes authorized under the **Health Information Act**.

2. **Consent for Media Purposes**:

- Consent to Collect, Use, and Disclose Stories, Photos, and/or Video and Sound Recordings.
- https://www.albertahealthservices.ca/frm-18273.pdf
- Complete this form when a photo, audio, video, or written recording is needed for AHS media, promotions, publications, education, presentations, and similar purposes.

3. **Consent for Education Purposes**:

- Consent to Collect, Use, and Disclose Photos for University of Calgary Media, Promotions, Publications, Education, Presentations, and Similar Purposes
- See the consent form below.

Waiver and Rights to the Photos

I, _____, hereby irrevocably grant and assign to the **"Institution" (University of Calgary)** the unlimited right and license, for the full term of copyright or any extension thereof, to copy, adapt, transmit, communicate, publicly display and perform, distribute, and create compilations and derivative works from photographic materials or images ("Photos"), and to publish, reproduce, and otherwise use and exploit the Photos in any manner and in any and all media, whether now known or hereafter devised, throughout the world, without further compensation. The Institution shall be entitled to edit the Photos. Nothing herein shall obligate the Institution to use or publish the Photos in any manner. The rights granted hereunder may be freely assigned or sub-licensed to any third party.

I irrevocably waive, in the Institution's favor, any and all moral rights in connection with my Photos. The Institution shall be entitled to use the Photos without compensation or obligation to me; and there is no relationship of any type created, including without limitation any agency or fiduciary relationship, as between me and the Institution, by virtue of the Photos.

Name (print): _____

Signature: _____

Date: _____

Witness (print): _____

Signature: _____

Date: _____

G) Procedures for UHP MRI

The approval of our investigational Ultra-High Performance (UHP) MRI by Health Canada and UCalgary REB required changes to our process as described below.

1. Ethics Approval and Modifications

- Modify your ethics application and informed consent forms in IRISS as per the later section (H) of this document.
- In brief, link your study's consent to the general MRI ethics protocol REB13-0898, which describes the UHP MRI, and remove redundant MRI information from your study's consent

forms.

2. Dual Consent Process

- Ensure participants sign two consent forms before MRI scans:
  i. The MRI consent form (REB13-0898) for the UHP MRI.
  ii. The consent form for your specific study.
- Obtain signed consent forms from participants before conducting MRI scans.
- The Centre will store original signed MRI consent forms, MRI screening forms, and copies of study consent forms.

3. MRI Logbook

- Maintain a logbook at the scanner, requiring entries **for every MRI scan of a human volunteer / participant**.
- Record any MRI malfunctions, health/safety incidents observed by staff or reported by participants (e.g., nerve stimulation, headaches, dizziness) in the logbook.
- Level 1 trained individuals will receive instructions on maintaining the logbook, and reporting serious events to the Centre in a timely manner.
- MRI technologists are encouraged to contribute to logbook entries, but researchers are **required** to maintain it.

4. Training

- Research assistants, students, and staff involved in consenting participants for MRI scans must complete Level 1 MRI training or an equivalent program.
- Level 1 training covers consenting procedures, logbook maintenance, and safety protocols for MRI operations.
- All current Level 1 or 2 personnel must watch the Level 1 UHP refresher video and send a confirmation email to CAIR. This qualifies them for addition to the MRI protocol (REB013-0898), authorizing them to consent participants and sign MRI consent forms. As before, only Level 2 personnel or technologists can perform MRI screening. The video is in the CAIR Sharepoint folder.

5. Authorization to Book Scans

- For studies that were previously approved, please send CAIR the CHREB modification approval letter, updated consent form(s), and email addresses of any Level 1 or 2 staff requiring refresher training. This is required for booking scans in Calpendo.

- For new studies, please send the CHREB approval letter, consent forms, and email addresses of those requiring Level 1 training to CAIR as part of your scan time application. We will discuss procedures at the kickoff meeting.

> Please direct any questions or send confirmation emails to Perry perry.radau1@ucalgary.ca and Kirandeep kkbisla@ucalgary.ca.

H) Modifications to Ethics Applications

The following provides specific guidance for modifying your ethics applications and consent forms to conform to the Health Canada and REB requirements for the dual consent process. The specific wording need not be followed. We recommend this wording only because a 'test' ethics application was deemed acceptable by the REB. Questions from the ethics application are quoted.

Study Staff, Funding, Location

Impact and Operational Approvals

"4.0 If this application is closely linked to research previously approved by an REB, provide the Ethics ID Number, REB name or other identifying information. Upload the approval letter in the Documentation Section ("Other Documents") at the end of the application."

Insert:

> The MRI procedures in this study are approved under the protocol REB13-0898, to which participants will provide consent.

Risks and Benefits Assessments

Risk Assessment

"3.0 Provide details of the risks and discomforts associated with the research, in addition to standard care:"

Insert a description of the MRI risks (in addition to other study risks). The exact wording **need not be precisely the same** as shown in this example:

> Risks of MRI and mitigation are approved under the protocol REB13-0898, to which participants will provide consent.

> Specifically,
>
> - The risks associated with having an MRI brain and/or body scan are minimal. There are no known risks from exposure to the magnetic fields used for these tests.
> - Participants with metallic objects in their body will not be allowed to take part. The strong magnetic field in the scanner could cause these objects to change position and may cause injuries.
> - Participants with suspected pregnancy will be excluded.
> - The MRI machine is loud when turned on and may cause some discomfort. Participants must wear hearing protection.
> - The space inside the MRI machine is limited, so some people may feel claustrophobic or anxious. Should the participant find the small space to be a problem during the procedures, they can inform us, and the scan will be stopped.
> - The MRI scans in this study are done 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 the scan, the technician will refer your scans (without their name) to a specialist for further examination as soon as possible after the scan. If the specialist feels there is cause to have a follow-up, they will contact the participant through the family physician, whose name is requested on the consent form.

"*4.0 Describe how you will manage and minimize risks and discomforts, as well as mitigate harm:*"

Insert a description of how you will manage MRI risks (in addition to other study risks). The exact wording **need not be precisely the same** as shown in this example:

> Risks of MRI and mitigation are approved under the protocol REB13-0898, to which participants will provide consent.

> Specifically,
>
> - MRI related risk mitigation
> - There is an intercom system that allows communication with the researcher even during the scan. Participants will be given an 'emergency' squeeze-ball so that they may stop the testing if they become uncomfortable or anxious at any time.
> - Participants will be informed of the procedure and its risks and will be given an opportunity to ask questions prior to commencing the tests.
> - Infection prevention and control guidelines from AHS will be followed. No participants with known infection will be permitted.
> - Participants will be provided with hearing protection, e.g. ear plugs.

Participant Info, Recruitment, and Informed Consent

Recruit Potential Participants

"*1.0 How will potential participants be identified and/or recruited? Describe how participants will be invited to take part in the study, if applicable:*"

Insert:

> Re: MRI Dual contact

> During recruitment conversations, families will be informed that the study involves MRI and that their participation would involve consenting to the study as well as the MRI.

Research Methods and Procedures

Radiation Safety Diagnostic Imaging

"*3.0 Does the research involve any of the following at screening, baseline, or follow-up? (Check all that apply)*"

Check the box for MRI.

Data Privacy and Confidentiality

Data Confidentiality and Privacy

3.0 External Data Access

"*3.1 Will identifiable data be transferred or made available to persons or agencies outside of the research team?*"

Yes

"*3.2 If Yes, describe in detail what identifiable information will be released, to whom, why they need access, and under what condition. What safeguards, including encryption, will be used to protect the identity of participants and the privacy of their data?*"

The PI's of REB13-0898 will keep the original signed consent form for the MRI portion of this study, along with a copy of the consent for this project and held using the procedures and safeguards outlined in that application.

Documentation

3.0 Informed Consent and 4.0 Assent forms

Consent form:

- Keep only **study-specific** details about the MRI (e.g. purpose of the scan, anatomical focus of the scan, duration). Cut very general comments about MRI procedure and risk and note the link by inserting in the risk section.

Insert:

> Risks associated with MRI are approved under the protocol REB13-0898, to which participants will provide consent.

Insert in the Introduction of your consent form:

> A separate consent form must be reviewed and signed for magnetic resonance imaging (MRI). The SIGNA UHP MRI system is not licensed in Canada but has been authorized by Health Canada as an investigational device only. This consent form only describes specific aspects of the research and what your participation will involve.

6.0 Other Non-Consent Participant Materials:

Attach the REB13-0898 approval letter.

Attach the MRI consent form(s) (clean, untracked) from REB13-0898 relevant for the participant age range.