Last updated: Nov. 14, 2022

CAIR Program ACH 3T Handbook

The 3T MRI scanner at the Alberta Children's Hospital (ACH) was installed in 2012, and is administered by Alberta Health Services, through Diagnostic Imaging at the ACH.

Research use of the scanner is overseen by the Child and Adolescent Imaging Research **(**CAIR) program, and is supported by the ACH Research Institute (ACHRI), 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 below.

Information regarding CAIR Relaunch and COVID-19 policies can be found here: https://cumming.ucalgary.ca/research/child-adolescent-imaging/relaunch-stage-2-information

Contents

CAIR Manager

The CAIR Program employs a Research Manager (Perry Radau, perry.radau1@ucalgary.ca, 403-955-5445) to assist investigators with study planning, protocol set-up, data acquisition, and basic data analysis. Perry also assists with safety training for the 3T MRI scanner and the mock scanner.

The Research Manager works on a cost-recovery basis. Please consult with Perry early in your study planning so you can assess what is needed and budget accordingly.

Study Approval

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

The Application for 3T Research Time is available here:

https://cumming.ucalgary.ca/research/child-adolescent-imaging/instructions-forms in the section title “Accessing the pediatric 3T scanner for a new study”. The application should be submitted electronically.

The scan session duration should take into consideration the time for set up and take down which varies based on study population and equipment (Imaging protocol time + Set up, clean up and data transfer = Total Scan duration). **Please use the Scan Time template when determining the appropriate scan time to request.**

Carefully note any special requests on the 3T application form (e.g., equipment such as an fMRI projector, special acquisition sequences, or accommodation requirements, such as evening/weekend scanning) to ensure they are available for your study. Any questions should be directed to the CAIR Research Manager or a CAIR Imaging Scientist (see contacts at end of this document).

You are **not** required to have a signature from Diagnostic Imaging Director (Ken Dunstall) on the Operations Approval Form **prior** to ethics submission. You do need to indicate that you will utilize the ACH 3T Diagnostic Scanner in your ethics submission. During the ethics approval process the Centre will be asked to approve the study. Diagnostic Imaging will assess and sign once your study has received scientific approval.

Submission of required documents

Once your study receives ethics approval, copies of ethics approval and budget details must be provided to the chair of the Joint Imaging Scientific Review Committee (currently Dr. Catherine Lebel, clebel@ucalgary.ca) to receive a booking identifier and study node.

Copies of ethics approval and consent forms must be provided to DI Director Ken Dunstall (kenneth.dunstall@albertahealthservices.ca) prior to booking any study subjects.

Safety training

The Child and Adolescent Imaging Research (CAIR) program offers training to investigators, trainees and staff at the Alberta Children's Hospital location to ensure safety for all involved in

research projects. This includes training for activities involving the MR (3 levels), related hardware/software and the Mock Scanner.

Current information regarding the training process can be found here: https://cumming.ucalgary.ca/research/child-adolescent-imaging/information-researchers/training

Creating a study protocol

Creation of your study protocol should be conducted in conjunction with the CAIR Research Manager who will assist in determining appropriate sequences, parameters, and conducting pilot scans. See section 7 for information about pilot and development time.

Booking scans

Study scans can only be booked by using the designated online booking calendar, Calpendo. Instructions can be found here https://cumming.ucalgary.ca/sites/default/files/teams/137/Booking%20on%20Calpendo.pdf. Calpendo is updated in real time and includes the hours that techs are available. Regular tech hours are listed below. Any time a tech is not available during these hours, will be marked as NO TECH.

Hours: Generally the AHS MRI Tech availability is as follows:

Monday	10 – 3pm
Tuesday - Thursday	10 – 6pm
Friday	10 – 3pm

For urgent bookings (<4 hours), please call the CAIR Research Manager or Martin Sherriff.

In the event of same day cancellations or other unusual circumstances requiring discussion with Martin Sherriff, please call Diagnostic Imaging at the Siemens scanner (ext. 57572) or GE scanner (ext. 53161).

AHS MRI Techs may be available outside of regular Tech hours. The CAIR website will be updated with the **current availability**: https://cumming.ucalgary.ca/research/child-adolescent-imaging/information-researchers/mri-scheduler.

Each individual must be booked separately - please identify 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.

Participants should be pre-screened to ensure eligibility (i.e. no contraindications to MRI) prior to booking time. We recommend that the study team review the AHS Diagnostic Imaging Screening Form when discussing the study with subjects (Appendix C).

The appropriate amount of time must be booked for each study. The scanner can be booked in 15-minute increments. The CAIR Research Manager can help you determine how much time to book for each study; in addition to the imaging protocol time please allow at least 10 additional minutes per participant for set-up, clean-up and data transfer when booking your scan. The amount of time depends on the population, considering age and any other relevant factors such as mobility.

Set up, scanning and clean up times = Total Calpendo booking time

Pilot and Development time

When you book a test participant for development of a new study protocol for a study that does not yet have ethics approval, you need to use **High Field Program Development** as the study name. You will have to use the consent form High Field Program Development, and have it signed by one of the following CAIR staff: Dr. Signe Bray, Dr. Catherine Lebel, Dr. Ashley Harris, Dr. Marc Lebel or Dr. Perry Radau. If your study has ethical approval you may choose to use your own consent form for this purpose. Scans that are conducted to test new protocols are pushed to the 'Development' node on the PACS and are NOT billed.

If you are scanning a volunteer who is familiar with the MR, you are still required to get consent and complete a screening form, for each scan.

Pilot Scans

A limited amount of funding is available to conduct **pilot scans** for grant submission; please indicate if you wish to apply for this on the Application for 3T Research Time (see CAIR website). Pilot time, if/when approved, should be booked through Calpendo. In the case of human volunteers, proper ethics approval must be in place prior to scanning. The application for a Pilot Study (unfunded) is available as a link in the Application for 3T Research Time webform, and should be attached there after completion.

Provide the appropriate research ethics board approvals as part of your application and after approval, send a copy to the DI Director**.**

Study Initiation

When you begin a new study, you will have a kick-off meeting with the CAIR Research Manager. It is important to plan and test the MR protocol carefully prior to the first date of participant scanning. In addition, networking configuration and storage must be arranged. Investigators who are not already familiar with the ACH 3T should contact the CAIR Research Manager to prepare adequately for the first real scan.

Study Scans

Please arrive 15 minutes prior to your booked time with your participant and bring a copy of the signed consent form. If you are late for your scan, it may be cancelled. An MR technologist or Level 2 Operator will screen study subjects and a parent/guardian if they will enter the MR room with their child, prior to the study.

Your study must be completed (scan suite ready for the next study) by the end of your booked time slot so that the next study can begin on time. If your study is not complete but your booked time has elapsed, your study may be ended prior to completion.

Only one parent/guardian may accompany children into the scanner area. Other children may be booked into Emily's Backyard for childcare if necessary; other family members must wait in the Diagnostic Imaging waiting room or another area of the hospital. For young children, a parent/guardian may remain in the scanning room with their child during the scan. Everyone entering the scanning room must undergo screening.

Consent of Mature Minors

Scanning participants who are unable to consent, such as those under 14 or lacking sufficient mental capacity, **must have a parent/guardian present during the scan** (in the hospital). In this case, 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.
In accordance with the TCSP2 policy, youths in the 14-18 age range may be treated as adults, and do not require a guardian to be present during their scans. Each study group makes a determination that the youth has the capacity to make their own decisions, and permit the minor to participate in studies without guardian consent.

A youth deemed qualified to give consent is treated as an adult. For example, the scan information of these mature minors should be kept confidential by research staff, even with respect to parents and guardians, and there is no requirement for their parents or guardians to be present in the hospital during the scan. If there are incidental findings, these will be first discussed with the family physician indicated on the consent form who will determine the appropriate follow-up procedures.

The guidelines developed by the Conjoint Health Research Ethics Board aim to assist researchers in determining appropriate policy for consent and assent. See these documents for details:

"CHREB Guidelines - Assent, Consent & Decision Making Capacity in Minors", and

"CIHR Best Practice for Health Research Involving Children and Adolescents,"

These documents can be found at the CHREB website:

https://www.ucalgary.ca/research/researchers/ethics-compliance/chreb#quickset-field_collection_quicktabs_1

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.

What is the policy?

- Research participants (those undergoing a scan) should remove street clothes and shoes and change into the provided hospital pajamas or scrubs/gowns.
- All guardians of participants who wish to accompany the participant into the scan room must agree to metal detector wand screening in addition to visual screening, if deemed necessary by the Operator.
- The researcher may suggest that the participant bring in their own cotton pajamas, scrubs, or loose sweatpants and t-shirt combination. Yoga pants and other form-fitting clothing is explicitly excluded due to potential risks of fibers in some athletic wear. It is still **mandatory** that the participant **change from their street clothes** when using such an alternative "gown". The Operator will check the clothing and may use the wand for secondary screening.

All Level 2 Operators and ACH Techs are responsible for ensuring that this policy is followed

Where are the pajamas, gowns and scrubs?

- Our gowns are located in "Change Room 1" which is located to the right of the washroom that is beside the CT/MRI waiting room. This is the same room that has our weigh scale and tape measure.
- All pajamas (child-size) and gowns (adult-size) in this room are available for our use.
- In the event that gowns are not stocked, check for gowns in the cart near the recovery area or in another change room.

What should be done with the street clothing?

- The participant and guardian will be given a plastic bag that is stored in the control room.
- Alternatively, a locker across from the Change Room 1 may be used to store clothing and possessions.

Where is the wand (metal detector) and how is it used?

- The wand is located in the control room.
- The switch is a rocker, where one side is "vibration" mode and the other "beep" mode, with Off in the center. Either mode will be acceptable for detection of small objects if within a few centimeters. The wand should be used as an aid to the visual inspection and where an item material is unknown.
- **Please ensure the wand is turned off after use to preserve the battery.**

Policy on billing

Scans are billed at a rate of $550 / hour, pro-rated in 15 minute increments.

Sometimes a patient is not compliant, and scans need to be terminated early. If images are acquired they will be pushed to the research PACS and you will normally be billed for that session, even if it ends early or the data are not usable.

If no images are collected, you will not be billed for the time.

If you have a concern about billing, do **not** argue with the Operator / technician. Instead send the details of your concern including the date and time of the scan to the CAIR Research Manager and Scientific Director. For example, in case of equipment failure during your scan the Investigator should not be billed even though images were scanned and pushed to the research PACS.

Important note: Researchers pay for the duration of their scan time once data collection has started, so they have full discretion about how the time is used. It is up to study personnel present at the scan to 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 is able to tolerate the exam, even if the data is believed to be suboptimal.

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 a DICOM client. Alternatively, if the researcher is in need of the data immediately the data may be downloaded onto a USB stick or burned on a DVD after scanning is complete. (Please allow time to do this within your booking window.)

Study modifications

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

Confidentiality

As per the AHS confidentiality agreement and ethics protocols, you are responsible for protecting the confidentiality of your study data at all times. You are expected to access only data that is relevant to your study, and to maintain the strictest confidentiality in handling clinical or identifying information.

Investigators' meetings

Investigators' meetings are held periodically to communicate centre policies and address any new issues. Please ensure that the principal investigator or a delegate attends these meetings.

Incidental findings

Occasionally a researcher may observe in research images that they are acquiring or processing a suspected abnormality or otherwise troubling finding. These are considered incidental findings and represent a unique challenge to handle appropriately. We need to balance the general principle of informing research subjects of any incidental findings, with a number of ethical, privacy, legal and regulatory issues. Below we detail our process and guidance for appropriately reporting on incidental findings.

Please note, these guidelines do not pertain to studies that have both Clinical and Research components as Clinical/Research studies will all undergo review by a radiologist. Research-only studies do not undergo review by a radiologist.

1. Studies initiated in 2020 or later must include a question in the consent form for the participant to give consent to the researcher to share incidental findings with the participant and appropriate clinicians. This question should not be used as a qualification for inclusion in the study. This consent form change does not apply to ongoing studies initiated earlier than 2020. The High Field Program Development Program consent forms provide standardized language acceptable to the CHREB.

2. An investigator, research staff member or trainee who identifies a suspicious finding in a research scan should report this finding to the study PI immediately.

3. The study PI or his/her designate must report (by **AHS email only**) this suspicious finding in a form found here: https://cumming.ucalgary.ca/research/child-adolescent-imaging/instructions-forms

   The completed form must be sent to ACH DI Research Medical Director, Dr. Xing-Chang Wei (xingchang.wei@albertahealthservices.ca) or the pediatric neuroradiologist on duty for MRI (hereinafter referred to as the “Radiologist”) if the Director is away or on vacation, with a copy to the DI Director. Using the subject: “Incidental Finding”.

4. The Radiologist will not initiate an image review until receiving an email from the study PI. Having received an email request, the Medical Director will review the concern and decide if the finding is medically significant. They will decide on the appropriate course of action.
   Typically this will consist of:

   a. Contacting the subject’s family physician if indicated on the consent form, or the participant directly. The family physician or Radiologist will discuss the significance of the incidental finding with the participant.

   b. If appropriate, placing a clinical requisition, conducting a clinical MR examination, and issuing a formal radiology report.

5. Commonly, a suspicious finding is first made by a MR technologist who is scanning the research subject but is not a research staff member. The MR technologist should notify the research team immediately so that they can initiate the above-described process. The MR technologist may also notify the Radiologist about the suspicious findings.

Then the Radiologist can review the research images, but will not initiate any actions of contacting a primary care physician or placing a clinical MRI requisition until receiving an email request from the study PI or his/her designate.

It is important to remember that all research data, including the possible significance of an incidental finding are covered by various statements of confidentiality. Once the Medical Director (or the delegate) is contacted, the incidental finding becomes a healthcare matter and is subject to various provincial and AHS healthcare privacy policies. These policies may prevent that final determination on significance and related healthcare management decision from becoming available to researchers, unless provision of such information is covered in the research ethics consent form.

It is recognized that some studies, particularly multi-centre studies, may require a modified incidental finding policy. Please 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; please contact the CAIR Research Manager for details. After you have completed 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). For more information contact the CAIR Research Manager.

Introduction of new devices to MRI room

To ensure safety of staff and participants and avoid damage to the MRI, investigators who would like to bring new devices into the MR room should adhere to the following procedure. A “new” device is defined as any equipment that has not been in use in the ACH 3T research MRI, regardless if it has been used in other MRI suites.

1. Martin Sherriff (MRI Supervisor) must inspect the device and give his approval for the device to be brought into the MR room.
2. Signe Bray (CAIR Director) and Research Manager Perry Radau (CAIR Research Manager) must be notified, and provided with documentation describing the device specs and associated MRI safety status (e.g. MR-safe, MR-conditional).
3. If the device is:

a. MR-safe: the Research Manager may opt to inspect and test the device directly with a metal detector.
b. MR-conditional: the Research Manager (or Director) and Martin Sherriff must be present and oversee the positioning in the MR room for the first scan. Ideally the device company educates the users at the ACH site on the proper use.

c. "active" (meaning it delivers energy to the patient in any form): additional safety steps should be taken:
   - Ideally a representative of the device company illustrates the proper use at the first scan.
   - The Research Manager is present for the first scan.
   - The first MR series delivers energy to a phantom and the effects are reviewed before proceeding to tests with a human.
   - If there is a significant concern regarding heating and SAR, the device should be tested with MR thermometry at our site or SFMRC prior to human testing.
   - The initial tests with a human are arranged to deliver energy to a limb prior to the head.

4. If the device requires connection via the penetration panel, the Research Manager must guide the users to available connections.
5. Introducing new cables through the wave guide requires notification similar to other devices.

Photo Policy

Staff and/or researchers who would like to take a photo in the non-public areas of the ACH GE 3T MRI should respect the following policy:

- a signed consent form must be obtained from every adult in the photos. This includes technologists, students, staff, participants and guardians. Guardians should sign on behalf of the child participants. Consent forms are described in the Appendix.
- photos should only be taken in the reception, waiting area or through the MR console window/door into the MR room.
- no photos should be taken of the ACH GE 3T MR console room, even when empty of people, due to the confidential information often present.
- if additional photos are required for training or other purpose, please speak to the CAIR Research Manager.

A participant and/or guardian who would like to take photos of their scan procedure are permitted under close supervision of staff/researchers. The rules listed above apply except that signed forms are not required. In most circumstances, staff or researchers should take the photos on behalf of the participants and guardians.

Resources/contact information

CAIR: https://cumming.ucalgary.ca/research/child-adolescent-imaging
Seaman Family MR Research Centre: http://www.mrcentre.ca

MRI4kids: http://www.mri4kids.ca

Research Manager: Perry Radau, perry.radau1@ucalgary.ca; 403-955-5445

Imaging Scientists:

Signe Bray (slbray@ucalgary.ca)

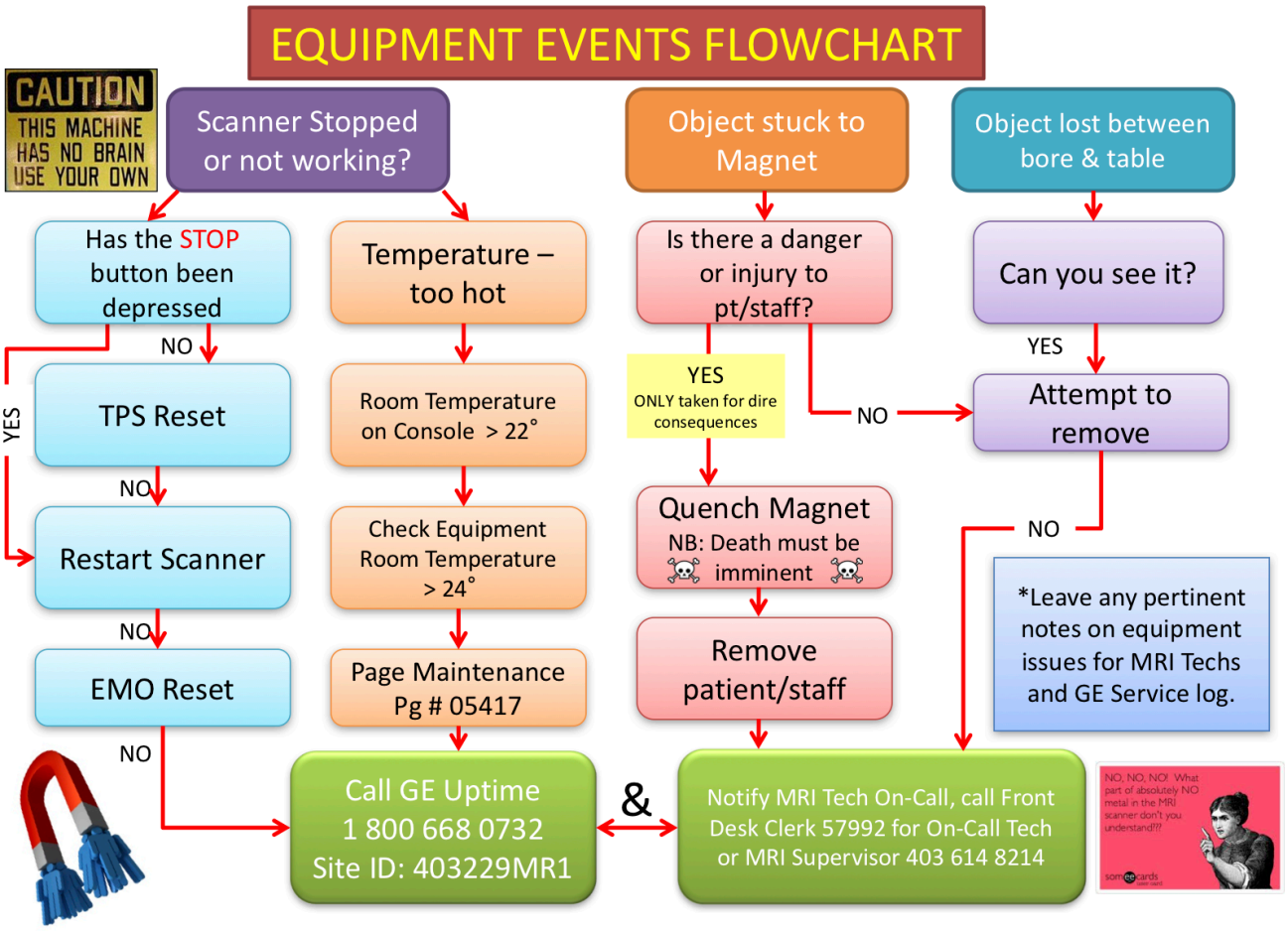
Catherine Lebel (clebel@ucalgary.ca)

Ashley Harris (ashley.harris2@ucalgary.ca)

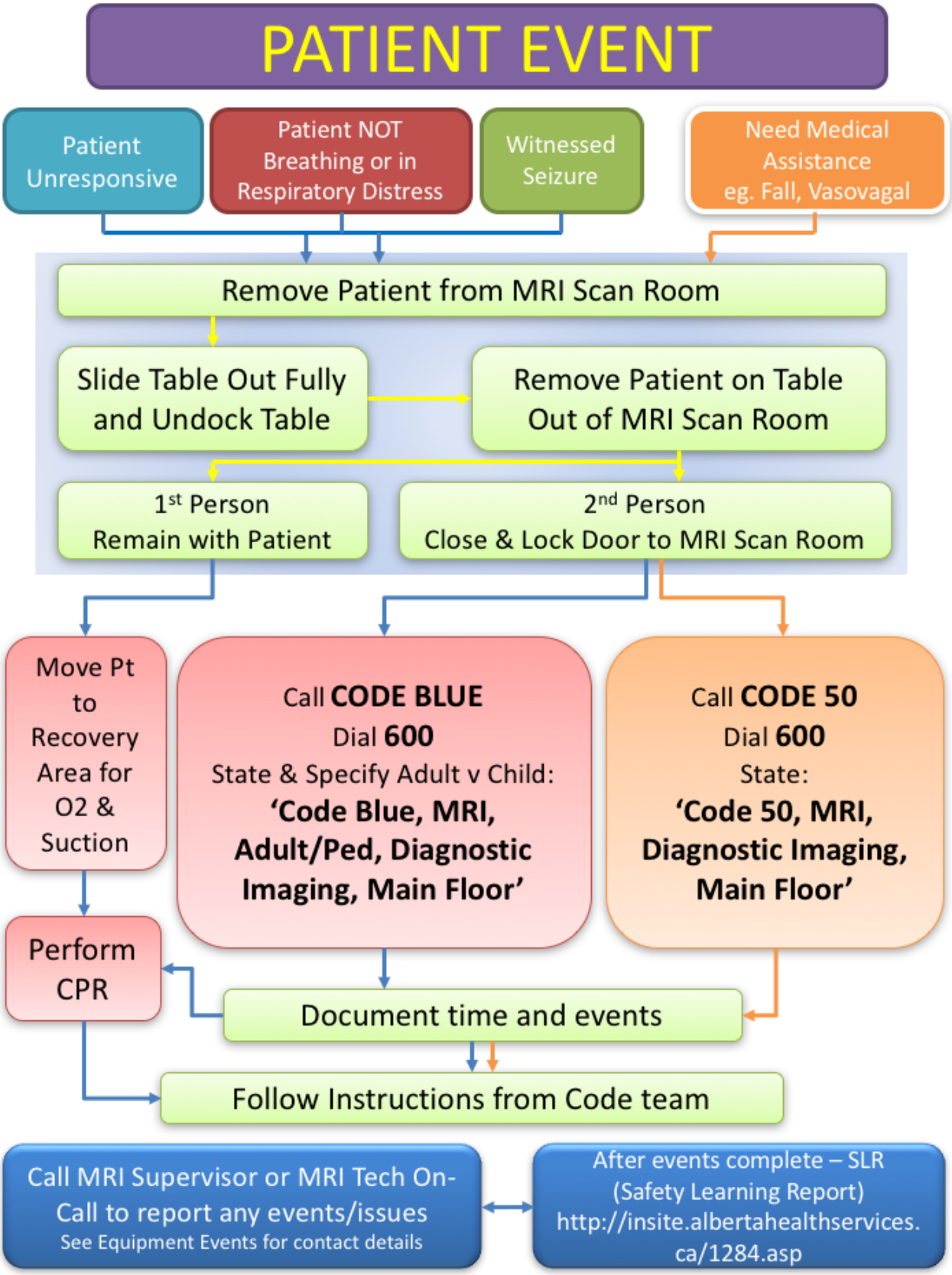
GE MR Physicist: Marc Lebel (marc.lebel@ge.com)

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	Please indicate if you have the following	No	Yes
Cardiac pacemaker			Eye prosthesis		
Implanted cardiac defibrillator (ICD)			Eyelid spring or wire		
Brain Aneurysm clip(s)			Penile prosthesis		
Electronic/Magnetic implant or device			IV access port		
Implanted drug infusion device (e.g., insulin, baclofen, chemo, pain meds…)			Intrauterine device (IUD), diaphragm, pessary		
Endoscopy Clips (i.e. Resolution Clip)			Artificial joint/Limb		
Cardiac Pacing Leads / Wires			Bone/Joint pin, screw, nail, wire, plate, etc.		
Bone Growth/Neurostimulator			Wire mesh implant		
Coils, Filters, or Stents			Medication patch (hormone, nicotine etc.)		
Shunt (renal, brain, heart, spine)			Hearing aid		
Middle Ear Implants (cochlea, stapes)			Dentures or partial plates		
Swan-Ganz or thermodilution catheter			Tattoo or permanent makeup		
Heart valve prosthesis			Body piercing jewelry		
Tissue expanders			Have you ever had metal in your eyes?		
Surgical staples, clips, wire sutures			Was the metal removed by a doctor?		
Silver impregnated dressing			Are you pregnant?		
Shrapnel or bullet			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

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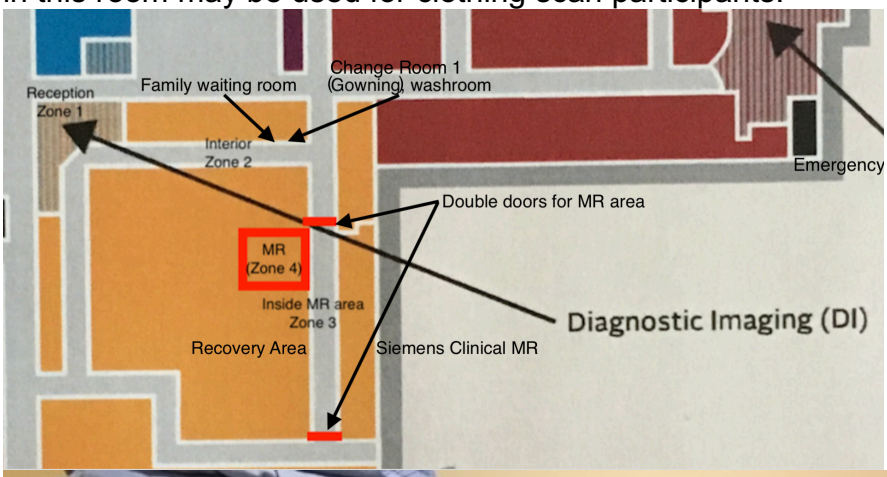
D) Checklist for Setup of a New MR Study

The scientist that plans to initiate a new MRI study with the ACH 3T MRI research scanner should follow these steps or delegate to their Research Coordinator.

1) Read the relevant CAIR Handbook sections. This provides detail for many of the following checklist points. https://cumming.ucalgary.ca/research/child-adolescent-imaging/instructions-forms
2) Submit the study online for approval to the scientific review committee by means of the CAIR website.
3) Submit study for ethics approval (https://www.ucalgary.ca/iriss/). After approval, send docs to chair of scientific review committee, with copies to Director of Diagnostic Imaging.
4) New: After scientific approval, schedule a kick-off meeting with the CAIR Research Manager (Dr. Perry Radau; perry.radau1@ucalgary.ca). This is needed to plan and test the protocol, and request Pilot or Development time.
5) Obtain a booking identifier (Calpendo) and study node by submitting your scientific review approval to the CAIR Research Manager with names of individuals given permission to book the study. Bookers must be at least Level 1 trained (https://cumming.ucalgary.ca/research/child-adolescent-imaging/training).
6) Create an MR study protocol, install on MR scanner console and insert a notes sheet in the protocol binder. Ask Research Manager for assistance developing protocol and notes at least 2 weeks in advance of the first subject's 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 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 the individual's health information using a recording device or camera that may not be obvious to the individual for a purpose authorized under the *Health Information Act* which may include: Clinical Care, Patient Safety, and Health Care Provider Education

2) 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 other similar purposes.

3) Consent to Collect, Use and Disclose Photos for University of Calgary media, promotions, publications, education, presentations and other similar purposes. See consent form on following page

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, public 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. We 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 favour 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: _____