Introduction

This document serves as a supplement to established Rutgers University Environmental Health & Safety regulations and policies and is concerned only with safe operating policies unique to the Center for Advanced Human Brain Imaging Research (CAHBIR), principally due to its specialized facilities for studies using Magnetic Resonance Imaging (MRI) methods.

Magnetic Resonance (MR) systems in CAHBIR shall be operated in adherence to existing guidance for research activities for MRI devices.  These procedures were also guided by the recommendations of the “American College of Radiology White Paper on MR Safety,” combined papers of 2007, 2013, and subsequent updates, as well as The International Society for Magnetic Resonance in Medicine (ISMRM), and other similar organizations and entities.  All investigators using MR systems in CAHBIR are responsible for ensuring that their use of these systems will be in strict adherence to these policies and procedures.  Any categories not included in this document (e.g., the treatment of biohazards, laboratory safety for chemicals, etc.) are referenced to the relevant guidelines and policies governing other research facilities at Rutgers.  In the event of a conflict between this document and these guidelines/policies, the more restrictive guidelines and policies take precedence.

CAHBIR is a research facility, as opposed to a clinical facility as described in the American College of Radiology White Paper, and so our screening procedures are developed according to best practices for human subjects enrolled in a research study.  The MR examinations performed as part of research are generally not ordered by a physician (e.g., primary care or specialist physician), and so the risk-benefit evaluation is quite different than it is in a clinical setting. Our goal is to virtually eliminate substantial risk for research participants in our studies.

Organization of CAHBIR with respect to these Standard Operating Procedures is discussed in this document. At present, there is a Director and an Advisory Committee for the center.  The Technical Director serves as chief safety officer and reports all safety issues to the Director.

Users, Subjects, and Visitors

1. **MRI-trained Users and Staff.** These are individuals with ongoing IRB and CAHBIR approved research activities at CAHBIR. They will undergo extensive training in proper conduct of MRI-related research protocols and procedures at CAHBIR, with training certified by the CAHBIR staff (see Safety Training below). Note that scanner operation training is not part of the safety training curriculum and is run as a separate program. However, attaining at least Level 1 certification is a prerequisite to beginning the scanner operation training.
	1. Level 1 certified users are trained generally about safe operations in the vicinity of MRI systems. Level 1 training is the minimum requirement for unescorted access to the restricted areas of CAHBIR. All maintenance and custodial staff must have at least Level 1 certification.
	2. Level 2 certified users are individuals with extensive training on the safe use and operation of the MR system for specific forms of research at CAHBIR. A Level 2 certified user must be present to gain access to the magnet room and perform MRI experiments or procedures with human subjects.  All CAHBIR technical staff must be Level 2 certified.
2. **Subjects.** Subjects are individuals participating in research experiments at CAHBIR.  Subjects without other affiliation to CAHBIR will be escorted by researchers or CAHBIR staff.  Subjects can themselves be certified users, as described above, and enjoy the privileges their status provides.
3. **Visitors.** Visitors are individuals who are neither trained staff/user nor a research subject.  Such individuals will be escorted by Level 1 or 2 certified user or staff member. Note that in general visitors are expected to register with CAHBIR staff at least 24 hours before arrival, and such access always is dependent upon the suitability of that access in relation to the ongoing activities at the time of the planned visit (See Routine Access Policy below).

User Classes

1. **Research.** Principle Investigators (PIs) with a bona fide research program are eligible to apply to use the facilities at CAHBIR.  Projects need not be associated with Rutgers University or RWJ Health to qualify under this designation.  However, all new PI applications shall be evaluated by the Director.  Applications shall be evaluated by the Director for conformance to CAHBIR’s mission and the highest standards for scientific integrity and ethics and approved at their discretion.  The Director may solicit consultation from the Advisory Committee or other peers to aid in the evaluation.
2. **Education.**Projects associated with purely educational goals are eligible to apply to use the facilities at CAHBIR.  All the criteria for bona fide research listed above must be met, and the application process is identical.  However, emphasis will be placed on the project’s fulfillment of CAHBIR’s mission during the approval process.
3. **Commercial.** External businesses may contract to utilize CAHBIR for commercial purposes if specifically approved by the Director of CAHBIR. CAHBIR reserves the right to reevaluate this position in the future as the operational landscape develops. If, at any time, the use of CAHBIR facilities by a commercial interest is called into question for legal, safety, scientific, or ethical issues, the Director may revoke access privileges without notice and until such time they are satisfied that all outstanding issues have been resolved.

Study Registration

New projects must be registered at CAHBIR prior to their initiation. This includes submission of the IRB protocol and approval letter. Note: IRB protocols are not reviewed for scientific merit and are never shared with other users. They are only reviewed to ensure that the planned study conforms to CAHBIR standard operating procedures and that any deviations from those procedures are deemed as acceptable in relation to the safety of participants. The Director of CAHBIR may request changes to any study that deviates from these standard operating procedures to ensure that the study adheres to CAHBIR’s safety procedures. Investigators are encouraged to schedule a free consultation with the Director and/or Technical Director before initiating a study in order to facilitate the use of optimal scanning techniques and safety procedures.

Scheduling Policy

1. Scheduling of all CAHBIR resources shall be made using CAHBIR 's online scheduling system, iLab, which can be accessed at https://scheduling.cahbir.rutgers.edu.
2. Reservations must include all time necessary to set up experiments and clean up afterwards.
3. Users may not begin set-up procedures early, especially if there is another scheduled user engaged. Similarly, users must not take extra time to finish cleaning up after their scheduled time ends.
4. Users must keep to their reserved time limits even if unexpected hardware and/or experimental problems delay planned activities/scans that would have otherwise fit into the reserved time. Users must not overrun their scheduled time (see Overrun Policy below).
5. In general, no user or group of users shall have priority for scheduling of resources. Exceptional circumstances may require the temporary suspension of this policy point, and the need for such action will be evaluated on a case-by-case basis and approved at the discretion of the Director in consultation with the Advisory Committee.
6. Reservations are often a point of friction at imaging centers, especially when available slots become scarce. In order to provide a balance of needs between users, the following rules apply.
	* 1. Billable scans with confirmed subjects take precedence in scheduling. Reservations for scans made more than two weeks in advance are only allowed if the user or research group has a specific research subject booked for said scan.  Thus, for instance, reserving the scanner every Tuesday from 1:15-2:30pm for the next five weeks in *anticipation* of scheduling a subject or booking blocks of time ahead of conference submission deadlines, are both strictly forbidden.  In exceptional cases where a slot has to be coordinated with clinical procedures, a waiver to this policy may be granted with the explicit agreement of the Director, but the number of slots allowed to be reserved in advance will be highly restricted and will come with added stipulations regarding cancellations and fees.
		2. Users must request specific permission to book more than 4.5 hours on any given day or more than 15 peak hours in any given week. Granting of such permissions will be dependent upon a combination of justification and overall availability of the scanner. An example of an acceptable justification for exceeding daily limits would be that if a study requires school age children, permission might be granted for heavier booking on Saturdays if that is the only ongoing study that requires Saturday bookings.
		3. In order to provide flexible scheduling, beginning two weeks in advance of a potential session, researchers are allowed to book a “tentative” unconfirmed time slot in which a participant is not yet confirmed. However, these slots must be filled (changed to confirmed slots) within 48 hours, otherwise another group may over-ride the slot if they have a confirmed subject for that time. Any tentative slot may be over-ridden with a confirmed slot within 48 hours of the actual scan. It is thus critical for labs to change a tentative slot to a confirmed slot as soon as they have a confirmed subject. No lab is allowed to hold more than 2 tentative slots in a single day, or more than 3 tentative slots during a single week.

d. Unless cleared in advance with the CAHBIR staff, reservations for unpaid development time must not be made more than 24 hours in advance.

e. Reservations work on an honor system. The system breaks down if users falsely indicate that they have confirmed subjects when scheduling, or book so many slots in a day or a week that other users are unable to schedule scan time. Complaints that a PI’s group is violating scheduling policies will be reviewed by the Director and in consultation with the Advisory Committee may result in restrictions of scheduling privileges.

Overrun Policy

1. Users who have a valid reservation on the scheduling system for a particular resource have the authority to assume control at the reserved starting time.  Anyone using the resource at that time must immediately vacate upon request of CAHBIR staff or the rightful user. It is not appropriate to ask the next user to encroach upon their reserved time.
2. If an overrun occurs when a study is started late due to a request from CAHBIR staff, the overrun will only be billed if it is longer than the amount of the requested delay.
3. CAHIR staff will conduct routine spot audits of the scanner usage logs to ensure compliance with allotted scan times.  Any scans that overrun the reserved time will be retroactively charged for the extra time, and repetitive violations and/or abuse will be subject to additional action under the provisions of CAHBIR policies.
4. If it becomes apparent that a particular scan session is running long, and will not finish at the scheduled time, the user(s) must extend their reservation on the scheduling system as soon as possible. If there is insufficient time available to complete the scan and clean and/or sanitize the resources before the next reservation, then the scan must sacrifice whatever experiments necessary in order to vacate the scanner on time.

Cancellation Policy

1. Reserved scan time during normal CAHBIR operational hours that is not canceled at least 24 hours before it starts will be billed even if the time is unused.
2. Any female subject past the age of menarche should be asked whether they are pregnant prior to scheduling. Scan time during peak hours that has to be cancelled because the participant is found to be pregnant at the time of scanning is still billable. All labs may request up to one waiver per calendar year based on pregnancy. Labs that scan more than 250 female subjects per year may request up to two waivers per year. More cases than this year per year suggest that the lab is not properly discussing nonpregnancy requirements with their subjects and will not be granted additional waivers.
3. Unfortunately, subjects sometimes fail to show for scans. No-shows are costly. During peak hours, no-shows are still billable. Waivers may be requested for no-shows. The first no show will automatically be granted. Additional waivers may be requested from labs that scan many subjects per year but will not typically be granted for more than one waiver per 100 billable scan subjects.
4. For “off hour” studies that do not require the presence of a CAHBIR staff member, reservations may be canceled without notice in the event of a subject “no-show” or pregnancy by e-mailing the Operations Administrator and following up with the submission of a scan fee waiver request.  No other reason for cancellation shall be accepted.  Excessive cancellations and/or abuse of this provision may lead to revocation of the privilege as determined by the Director. The start of off-hours timing during the week may vary anywhere from 6 to 9 PM depending upon scanner demand. Saturdays and Sundays after 6 PM are always considered off hours, and Sunday before noon is always considered off hours. However, the rest of the day on Saturday and Sunday will be determined based on scanner demand. If a user discovers they cannot use scheduled time within the allotted cancellation limit, and the same time can be transferred to another*paying* study, then the project PI will not be billed for the time.
5. From time to time, hardware problems related to the stimulus presentation system, response recording, and even the scanner itself will corrupt the integrity of data acquired. This is to be expected given the nature of the state-of-the-art equipment used in CAHBIR. When this happens, CAHBIR will not charge for the timeslot booked, provided that the researchers agree not to use any of the data acquired for purposes of publication, presentation, or acquisition of funding.  If the problem is discovered after the reservation has been billed, the fee will be recorded as a credit to the account of the PI.  This provision will not apply for problems stemming from the use of non-product (i.e., not provided as a standard option by the hardware and/or software manufacturer) grade equipment or software.  Examples of non-product grade configurations include, but are not limited to research pulse sequences, researcher-written interfaces to CAHBIR equipment (e.g., MATLAB API script to record eyetracker data), and stimulus presentation scheme faults.  CAHBIR will provide, to the extent it is capable and reasonable, support for research applications, but scanner fees will not be waived, regardless of the level of the CAHBIR’s involvement in the project when specific scan sessions are lost as a result of an unexpected failure.  Note that if a problem that renders a scanning session worthless is rooted in hardware and/or software provided by the researcher, the CAHBIR is unable to waive the associated usage fees, regardless of the equipment or software used.
6. The Director of CAHBIR has sole authority to interpret the clauses in this section, and any waiver of fees shall be at their discretion.

Violations Policy

1. Frequent, habitual, or abusive violators of the policies in this document shall be subject to penalties ranging from the incursion of additional fees billed to the PI (for staff time to resolve problems), to revocation of access privileges.
2. The director of the CAHBIR has the authority to evaluate the severity of policy infractions, and to determine which, if any, penalties will be issued.
3. Requests for reinstatement of revoked privileges require approval of both the Director and the Advisory Committee.

## **Routine Access to Facilities**

Access to CAHBIR facilities is restricted to trained staff and users. Research subjects and their accompanying family/acquaintances must be escorted by trained staff or users.  Visitors must also be escorted by trained staff or users.

CAHBIR is split into zones that correspond to the level of access control necessary to maintain appropriate levels of safety. These zones are labeled progressively I-IV, with IV being the most restrictive.

Entry into Zones III and IV is highly restricted, and the presence of a Level 2 user is required before anyone else may enter.  There are three purposes for controlling access to these areas:

1) to control the entry of ferromagnetic items and other materials which might cause injury to research subjects, personnel, or equipment;

2) to preclude persons with medical conditions or implants that may be aggravated by the static magnetic field of the MR system from entering the field, and;

3) to prevent untrained individuals from disturbing or tampering with the equipment.

Figure 1:

   

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| **Zone Designation** | **Description** |
| **Zone IV** | Magnet and Equipment Rooms |
| **Zone III** | Control rooms  |
| **Zone II** | Scan prep areas |
| **Zone I** | Waiting area |

**Zone IV:**  Access to Zone IV (magnet room) will be restricted to Level 1 and 2 users, and those individuals who have been briefed and screened by a Level 2 user. Metallic items, wallets/purses, hearing aids and other items that could become projectiles and/or be damaged by the static magnetic field will be secured in personal storage lockers before entering the control room. The Level 2 certified user on duty has the responsibility to restrict access to Zone IV only to individuals who have been properly screened, and to require individuals acting in an unsafe manner to leave the room.  The Level 2 certified user must be in the magnet or control room when the magnet room is occupied by a research subject or visitor.

Only cleaning equipment specifically designed for use in the magnet room or approved by CAHBIR staff will be allowed into the magnet room.

Ferromagnetic and other metal objects will not be allowed into Zone IV unless prior arrangements have been made with CAHBIR staff and specific safety precautions have been taken. During use of the magnet room, its door is to be kept closed as much as possible to reduce the possibility of inadvertent entry.

When a research subject is being inserted into the magnet or being removed from the magnet, two people are required to be present in the control or magnet room; one of whom must be the Level 2 certified user on duty. While the subject is in the magnet, at least one Level 2 user must be present, and that user shall not be left alone for more than five minutes at a time, and only when absolutely necessary.

 **Zone III:**
Access to Zone III (control room and MR equipment room) is limited to Level 2 users and Level 1 users when a Level 2 user is present. Only Level 2 certified users and senior staff members will have direct access to the MR equipment room. The Level 2 user assumes full responsibility for the safety of research subjects and visitors as well as the actions of any Level 1 users working with them. Under no circumstances will non-certified users (subjects or visitors) occupy the control room without a Level 2 certified user physically in the control or magnet room.

**Zone II:**
Access to Zone II (scan preparation areas) is limited by a locked door.  All research subjects and visitors must be escorted into the zone and accompanied at all times by a trained user or staff member.

**Zone I:**
Access to Zone I can be granted by any trained user or staff.  Since the risks associated with this zone are no higher than any public access building, there are no special requirements for those that enter.  However, the person granting access should make sure that those that are granted access understand that that they may only occupy Zone I until escorted into other zones.

## **Emergency Access to Facilities**

1. **Immediate access to magnet room.**  In general, emergency procedures will be performed and managed by a Level 2 certified user. The Level 2 user must always be present when anyone is inside the magnet room.  In the event of an emergency that requires immediate access to the magnet room in such a fashion that screening and appropriate cautionary measures cannot be performed, the magnet must first be quenched. (see Magnet Quench below)
2. **Security emergencies.** RUPD will have access to Zone IV. RUPD officers have been trained to operate in an MRI environment. However, the Level 2 user should firmly and confidently remind responding officers of the presence of the magnet before they enter. RUPD officers expect this reminder, and it will not come as a surprise or considered disrespectful or uncooperative. If necessary, certified staff members will direct the officers in safe methods to access the magnet room and safe procedures to follow once the magnet room is entered.
3. **Fire and medical emergencies.** Fire and emergency medical personnel are restricted from the magnet room. These personnel are typically equipped with ferromagnetic tools and implements, and when responding to an emergency, it is not practical to screen them. In the event that medical or firefighting personnel must enter the magnet room without being screened, the magnet must first be quenched (see Magnet Quench below). In the event of a medical emergency, unconscious or non-ambulatory persons must be removed from the magnet room and then treated.  The Level 2 user will perform or oversee evacuation of victims from the magnet room before medical personnel arrive.

An MR-trained user or staff member must stand in front of the closed magnet room door during the entire emergent procedure to prevent emergency medical personnel from accidentally walking into the magnet room. In the case of a medical emergency, the Level 2 certified user may provide to the medical responders the information on the subject’s screening form to aid with treatment.

## **Magnet Quench**

The quench button is covered and protected by a plastic guard to ensure that it is not engaged by accident. The magnet is to be quenched only if a person cannot safely leave or be extracted from the magnet room with the magnet energized. Examples of such a situation are pinning by a ferromagnetic item, and a penetrating wound by a ferromagnetic item still lodged in the body.

## **Training Procedures**

All individuals who access CAHBIR will either be MR-trained personnel or escorted by someone who is. Categories of individuals are defined as follows: visitors, subjects, and MR-trained personnel.

**1. Visitors.**  Visitors include individuals who are not being scanned but potentially may need to enter the control room or magnet room to act as a supportive family member or friend, non-routine maintenance personnel, ancillary medical staff, non-routine cleaning service, etc. Visitors will always be escorted or visually supervised by a Level 2 user or staff member, except when they are in zones I or II.  Normally, visitors will not be allowed inside the magnet room unless their presence is needed for the performance of a scan (for example: In ADHD or autism studies, parents, once properly screened, may be allowed into the room with their children to reassure the child during preparation for the scanning and, if absolutely necessary, help keep them still during a scan).  Visitors who have need to enter the magnet room will be subject to a modified screening procedure similar to the one given to research participants.  The screening forms and procedures used for visitors are provided CAHBIR’s website.

**2. Subjects.**  Subjects are individuals who participate in human research directly. They may enter the CAHBIR for purposes of training for, preparation for, or participation in an experiment.  Except when in zones I and II, subjects will always be escorted or personally supervised (visually and verbally) by a Level 2 user or staff member. Before participation as a subject, the individual must be briefed by a researcher and must provide informed consent using methods approved by an associated IRB-approved protocol.  These briefings may take place in zones I or II, but are discouraged in zone II, and prohibited in zone IV.  After screening, subjects will then make use of adjacent changing rooms to store all non-MR safe personal belongings, and don scrubs if needed.  Next, they will be escorted into the control room where final metal checks are performed, last-minute instructions are given, and hearing protection is applied. Finally, the subject will be escorted into the magnet room, and prepared for the scan following standard safety protocols as specified by the associated IRB-approved protocol.  Subjects will be visually monitored by the operator throughout the scanning session.  Subjects will always be given a signaling device (e.g. “squeeze ball” or similar device) so that they can request that scanning be halted at any time.  The operator will halt the scanner upon any unsolicited use of the squeeze ball by the subject.  The operator must always permit audio contact with the subject between scans and should periodically communicate verbally with the subject to assess their status and comfort.

**3. MR-trained Personnel.** Individuals who have been certified as Level 1 or Level 2 users by CAHBIR are considered MR-trained personnel.  All users performing any type of work using the MRI scanner are required to undergo Level 1 certification.  Level 1 certification is required for unescorted access to the CAHBIR.  All Level 1 users must be supervised by a Level 2 user or staff member in order to access zones III and IV.  Level 2 users undergo additional training and periodic refreshers that ensure their ability to perform and oversee MRI research procedures, as well as to handle emergency situations.  Level 2 certification designates users who have the capability to independently perform research safely and efficiently.  Like subjects, users will not be permitted access into zone III or IV until they have been briefed on and screened for MR-safety issues.  Training materials are available on the CAHBIR wiki. In addition, videos for current safety procedures are regularly updated from qualified safety experts and professional websites including [www.imrser.org](http://www.imrser.org/)

a. **Level 1 training*.*** Training for Level 1 researchers includes the following: 1) viewing of the video on MR safety provided on the CAHBIR wiki; 2) briefing by CAHBIR staff on MR-related hazards and protocols; 3) briefing on and demonstrated understanding of procedures to screen subjects for MRI procedures; 4) briefing on and demonstrated understanding of emergency procedures, such as fire and handling medical emergencies; and 5) completing a quiz over the information provided in the briefings and demonstrations.  Steps 2, 3, 4, and 5 must be renewed annually to maintain Level 1 certification unless the user graduates to Level 2 certification.  However, Level 2 certification becomes idle after more than six months without use of the facility pending Level 1 recertification.

b. **Level 2 training*.***  In order to qualify for Level 2 certification, a researcher must meet the following criteria: 1) They must be a current Level 1 certified user; 2) They must attend the CAHBIR Level 2 safety; 3) They must complete the CAHBIR apprenticeship program; 4) They must pass the CAHBIR Level 2 written safety exam; and, 5) They must pass the CAHBIR practical exam. A Level 2 user who goes more than 6 months without scanning will be required to attend the Level 1 safety briefings.  The programs described in steps 3, 4, 5, and 6 are detailed in Appendix A.

c. **Accelerated Level 2 certification.** From time to time, highly MR experienced researchers will visit the area for a short period of time, which would make completion of the full Level 2 training curriculum unviable. In such a situation, the visiting researcher’s PI may vouch for their safety qualifications, and they may be approved for their short time at the discretion of the Director after having completed the Level 1 training, which provides the necessary site-specific information needed to operate safely. Whenever possible though, users are strongly encouraged take advantage of the full training program if at all possible. Even the most seasoned researchers can benefit from it.

## **Phantom Studies**

Individuals with access to the magnet room and proper training in the use of the scanner (i.e. Level 2 users) may conduct research experiments or operations that utilize MR phantoms. When no human subject is being scanned, a single individual may carry out these experiments alone.

## **Human Studies**

**1. General guidelines for human research.**  Some general guidelines for human research studies in experimental protocols conducted at CAHBIR are:

● All subjects will be evaluated by an attending physician, principal investigator, or a Level 2 user, with regard to their physical and mental status before entering the control or magnet room.  Subjects deemed to have an unsatisfactory status will not be permitted to participate at that time.

● All subjects and visitors will undergo screening for metallic objects before entering the control room, and those with implanted metallic objects (i.e., ferromagnetic aneurysm clips, pacemakers etc.) will not be allowed in zone IV.

● All subjects are required to change into a surgical scrub shirt (provided by CAHBIR) for brain studies, and full surgical scrub garb (again, provided by CAHBIR) for all other studies. Scrubs not provided by CAHBIR are not acceptable substitutes. This policy is in place because some clothing contains ferrous microfibers that are not always clearly listed on clothing labels.

● Studies involving human subjects require prior approval of the IRB that has jurisdiction.  This includes pilot studies.  It is the responsibility of the Principal Investigator to ensure that IRB approval for all studies is current.

● New studies must be registered via a redcap form and approved prior to being allowed to schedule for a scan slot. An approved IRB protocol # is required at the time of study registration~~.~~

● The PI or their designee will ensure that all human subjects (and guardian, when appropriate) sign an IRB-approved informed consent form before entering zone III.

● All subjects will complete the standard MRI Subject Screening Form provided by CAHBIR. The Level 2 certified user will review the screening form and make final determination on the subject’s fitness to participate in the MRI study.  The signed screening forms will be maintained by CAHBIR. It is always best practice to determine whether a research subject meets inclusion requirements prior to the day of scanning in order to avoid costly last-minute exclusions. Researchers should contact the MRI technologist in advance if there are safety related questions about a specific participant

● Female subjects past the onset of menarche must complete a pregnancy test or complete a pregnancy waiver prior to scanning. Any woman who is found to be pregnant or does not complete the waiver is excluded from scanning.

● In the event of an incident or medical emergency requiring medical attention for the subject or other persons, the Level 2 certified user on duty shall first call 9-911 (or instruct an alternate individual to call) and remove the person from the magnet room so that the emergency response team will not need to enter the magnet room.  If this is not possible, the magnet must first be quenched to enable access by emergency medical staff and their equipment.  The latter situation is to be avoided whenever possible, but examples of situations requiring a quench include pinning of a subject to the scanner by a ferromagnetic object, or a traumatic back or neck injury where a person is severely injured and cannot be mechanically stabilized sufficiently to move them outside of the 50G line for treatment.  To assist operators in the event of an emergency, task lists for emergency procedures are kept in a **red binder** in the control room.

● In the event of an obvious pathological or structural anomaly in an MRI scan, the investigator will follow the step-by-step procedures detailed in Appendix D.

● Whenever minors are to be enrolled in imaging studies conducted using CAHBIR facilities, the investigators must follow the procedures and policies provided in Appendix E.

**2. Responsibilities of Level 2 user.**  At least two people, including one Level 2 certified user, must be present whenever the MR system is being used to scan a human. Before any scanning procedure, the Level 2 user will:

● Inform the subject that peripheral nerve stimulation may occur and describe the nature of the sensation as well as what to do if experienced during the scan.

● Instruct subjects not to clasp their hands, cross their legs, or otherwise configure their body parts in such a fashion as to create a conductive loop that can increase the possibility of stimulation and RF burns.

● Ensure that all cables from equipment are not to directly touch the human subject’s skin. Ensure that cables do not form a loop, either large or small within the bore of the magnet at any time.

● Ensure that all human subject anatomy is shielded from bore walls and that all cables and devices are spatially buffered from the human by a sponge pad or blanket thickness of at least ¼ inch that can be easily maintained throughout the entire MR examination.

● Be responsible for instructing the subject regarding the use of earplugs to prevent acoustic noise issues and ensure that the subjects are properly wearing the hearing protection.

● Maintain continuous visual, verbal, or electronic (e.g., squeeze ball or intercom) contact with the subject.

● Instruct subjects to inform the operator if they experience discomfort.

● Terminate the scan if the subject complains of discomfort, pain, or fear.

● Complete a report of any incidents involving severe discomfort or pain, including a description of the associated circumstances (imaging parameters, dB/dt value, level of pain, etc.), and submit this report immediately to the Technical Director. The individual investigator and the PI are both individually responsible for reporting any incidents to the IRB as well as to the Technical Director.

**3. Administration of exogenous agents.**  All MR examinations that include the administration of contrast agent or other pharmaceuticals require the presence of a physician, registered nurse, physician’s assistant, or paramedic licensed to provide health care in the state of New Jersey.  All examinations that include the administration of contrast agent must follow the relevant CAHBIR policies and procedures, and the risk of NSF (kidney problems, past and present) must be included on screening and consent forms for all subjects.  Investigators using contrast agent are responsible for maintaining a stock of pharmaceuticals and delivery equipment suggested by the agent’s manufacturer to manage potential life-threatening hypersensitivity and/or anaphylaxis.  Before administering a contrast agent to a subject with any renal insufficiency, the subject’s effective Glomerular Filtration Rate (eGFR) must be measured to be within acceptable limits within 72 hours of the injection.

## **Safety Policy Infractions and Incidents**

**1. Statement of intent.** CAHBIR takes MRI safety very seriously.  However, it generally must be understood that operating procedures in a research facility are fundamentally different from those established for clinical or clinical research facilities. Specifically, the continual infusion of new and experimental hardware and software can require continual modification of operating procedures and safety guidelines.  It is recognized that unexpected undesirable consequences can occur in such an environment.  While the present procedures attempt to minimize the possibility of such consequences, it is recognized that MRI-trained operators and staff may encounter such situations despite their best intentions.

**2. Definition of infraction and incident.**  An infraction is any action that violates CAHBIR or IRB policy, or applicable laws and/or regulations.  An incident is any occurrence or condition that results in an unsafe environment (regardless of outcome), damage to equipment, or injury to any human.  “Close calls” and “near misses” qualify as incidents and are to be treated accordingly. Incidents may or may not be a direct result of an infraction, nevertheless, all incidents should be treated the same.

**3. Responsibility to report.**  In order to foster a safer and more effective research environment, CAHBIR requires all staff members and users who encounter unsafe conditions to report these to the Technical Director, Medical Director, or Director (preferably in writing when not unsafe to do so) so that remediation can be implemented.

**4. Required action.**  When infractions or incidents are observed or otherwise noted, it is the duty of all users to immediately stop experiments or procedures in order to take all necessary corrective action.  Such events must be reported to the Technical Director, Medical Director, or Director as soon as possible using the CAHBIR incident report form.

**5.  Reporting and corrective action.** The Technical Director will immediately report all communicated incidents and infractions to the Director. Safety incidents will be evaluated by one or more members of the senior staff. Generally, the response to infractions and incidents will be remedial – some action that reduces the likelihood of a recurrence.  However, if a safety violation is found to have occurred through willful action or negligence, punitive actions may be taken (e.g., the withdrawal of scanning privileges for a period of time).  Particularly egregious or multiple violations may lead to permanent loss of scanning privileges.  Safety incidents will be reported to the MR scanner manufacturer and FDA within the time window(s) required by any applicable statutory and contractual requirements.

# **Appendix A: Level 2 User Training and Certification**

**1. Overview.**  Level 2 users are certified to perform and oversee research.  Therefore, all scans involving human subjects require the presence of at least one Level 2 certified user or staff member.  Level 2 certified users must complete all basic Level 1 training, maintain that certification, and then meet six additional requirements: 1) apprenticeship-style training by an expert offering hands-on experience in all aspects of research; 2) attendance at a Level 2 training lecture; 3) completion of a written safety exam; and, 4) completion of a practical exam in which the applicant demonstrates proficiency in all stages of MRI research operations.

**3. Apprenticeship period*.*** This is a fundamental element of the training plan. It is believed that researchers best learn to perform safe and effective research by working with experts who perform similar work. This allows for the development of expertise that often goes beyond general, handbook-level instruction.  Complemented by written documentation and the other certification steps, this hands-on training provides repeated and expert training in exactly the methods that the experimenter will employ.  It also provides an opportunity for existing Level 2 users to further develop their teaching skills and to refine their own lab-specific operating procedures, while providing an independent assessment of expertise and competence.

Each Level 2 candidate and a Level 2 mentor must document and describe at least 5 apprenticeship sessions on the CAHBIR Level 2 certification form.  The trainee must attend the entire session for it to qualify as an apprenticeship session for the purposes of this Level 2 user requirement.  The trainee must observe everything from screening and consent through the scanning and until the point at which the subject is escorted from the control room at the conclusion of the study.  The Level 2 mentor need not be the same person for all 5 sessions.  On the contrary, candidates are encouraged to seek mentorship from multiple Level 2 users as it provides broader exposure to skills and techniques.  While simple attendance and observation of 5 scanning sessions does fulfill this requirement, it may be helpful to the candidate to operate the scanner when the mentor feels s/he is ready.  However, it should be clear that the apprenticeship program is specifically designed to train candidates in safety procedures.  Scanner operation training is a separate program unrelated to Level 1 or Level 2 certification.  Therefore, a candidate shall not be required to operate the scanner during the apprenticeship sessions unless the mentor feels that it is necessary or helpful.  The mentor will not be held responsible for the performance level of trainees and should not feel required to involve trainees in their study in any way in order to train.  These sessions are primarily for observation.  If circumstances permit question and answer interaction, then that is encouraged.

**4. Attendance at a Level 2 training lecture*.***  This lecture briefly reviews the basic tenets of Level 1 safety – basic emergency procedures, facility layout, terminology, and subject screening.  Additional discussion of subject (and experimenter) MRI screening is performed, given that effective screening is a critical part of ensuring safety.  In particular, it is emphasized that being conservative with subject screening (i.e., declining to scan a subject based on an ambiguous screening response) is appropriate, and that if any doubt regarding the screening answers remains, the subject should not be scanned until it is confidently determined that the participant can be safely scanned.  Techniques for disambiguating questions and answers are discussed, and specific anecdotes and scenarios are used to generate discussion.  Other concepts that are emphasized include the benefits of maintaining an open line of communication with CAHBIR staff about safety that are foreseen or arise, however minor.  The notion of continually adapted and improving safety procedures is stressed.

**5. Written exam*.***  The written exam provides an opportunity not just to document basic understanding of safety and procedural functions, but also offers an arena for disambiguation and discussion of terminology and details.  Often these post-exam discussions provide feedback for the further refinement of the training and testing materials, as well as for internal practices (e.g., consistent labeling of a particular room).  A passing grade is 100%.  If fewer than four questions are answered incorrectly, the candidate must fill out an explanation form to document both weak training methods and follow up training.  If four or more questions are answered incorrectly, the user must repeat attendance at the Level 2 training lecture before retaking the test.  Under these circumstances, the candidate’s mentor is expected to provide remedial training as necessary to supplement the curriculum provided.  A second failure of the exam is evidence of an unsuitable candidate, and the Director must approve any further progress toward Level 2 certification. Depending on the circumstances, and at the Director’s discretion, this may include anything from additional training to a denial of certification.

**6.  Practical exam*.***  Level 2 users are required to demonstrate hands-on facility in screening and handling subjects as well as responding to emergency situations as well as screening and handling subjects.  The examination takes the form of scenario-based training, in which a non-research subject volunteer is used to mock the session. The candidate screens them, prepares them, and scans them using their own protocol.

**8. Optional, additional training*.***  The standard Level 2 training applies to researchers performing MRI and fMRI measurements in healthy adult subjects.  Research involving special populations (e.g., clinical patients, children), animals, and/or techniques may require additional training.  Such conditions will be evaluated by the Director and Advisory Committee on a case-by-case basis.

**Appendix B: Incidental Findings**

Occasionally, previously unknown abnormalities are noted in MRI scans of unsuspecting research subjects that are otherwise normal.  All investigators can expect the IRB to require a statement that is concordant with CAHBIRs minimal operating procedures for handling incidental findings. These procedures assume that there is an ethical obligation to have an observed, previously unknown, incidental finding read by a neuroradiologist, or an MD with appropriate experience to read and provide a recommendation regarding the MRI results. These incidental findings may be observed by the person conducting the scan or by an MRI technologist review of the scan. A contract is in place to have University Radiology Group (URG) read scans with potential incidental findings, and this is considered to be the standard approach of the center. A rationale for this approach has previously been reviewed by the IRB, and standard template language is available for inclusion of these procedures in IRB protocols. Note, that there is no charge to the user for reads of incidental findings, as CAHBIR will cover the costs of these occasional reads. If, a study is required to have every scan in a study read because the population being studied is at particular risk for neurological issues, and the investigator intends to use our arrangement with University Radiology Group to handle those reads, there will be a read fee (currently $50 per subject) added to the scan charges. If a study has permission to have someone else connected to their study perform reads, then no scans will be sent to URG, and it will be that study’s responsibility to ensure that scans are evaluated for incidental findings following the procedures defined in their IRB protocol.

When the possibility of an incidental finding arises, the Level 2 researcher on duty shall strictly follow these procedures:

1) In the extremely rare case of a severe emergent finding, the researcher will run a predefined pseudo-clinical imaging protocol on the scanner.  This protocol takes about seven minutes to run and is designed to simulate a clinical study for the identification of most abnormalities.  If there is insufficient time remaining in the reserved experiment time to complete the study and run the extra protocol, the study shall be immediately terminated, and the extra protocol will be run.  If the researcher cannot in good faith permit the subject to leave CAHBIR for fear of their safety or the safety of others due to the obvious severity of the abnormality, then emergency services should be contacted (unless a study-related, or CAHBIR affiliated MD indicates otherwise). Only in cases in which there is an immediate concern of safety of the patient should the person be shown, or informed of, the abnormality prior to the scan being read by a qualified professional.

2) In all other cases in which an incidental finding is observed, a study may continue as planned. If there is time at the end of the study, as a service to the individual, the pseudo-clinical protocol should be run. As these are research studies, there is no expectation to have these extra clinically oriented scans run, but they should be included whenever time permits.

3) At the conclusion of a study with a non-emergency incidental finding, the researchers should not indicate any suspicion of an adverse finding.  The study should end as usual, and the researcher should confirm the subject’s contact information before being permitted to leave.  If the subject specifically asks if the researcher observed anything out of the ordinary, the researcher should inform the subject that their images will be read by a qualified radiologist, and if anything is noted, they will be contacted.

4a) In cases where a protocol has a qualified study team member reading scans for incidental finding, the PI must be alerted of the incidental finding by the researcher performing the scan. The PI is responsible for any further actions. In all other cases, the below steps must be followed.

4b) As soon as possible after the subject leaves the control room, the scan operator should upload (or “push” in the PACS terminology) the relevant images to the URG, where the scans will be read by a board- certified and licensed neuroradiologist. Both the CAHBIR director and the study PI need should be alerted of the incidental finding by the researcher, so they know about the situation. In all written communications regarding any potential finding, extreme care should be taken to ensure that PHI is properly handled and excluded when appropriate.

5) The URG radiologist will provide a brief written report of their evaluation of the finding. In all cases, the radiologist will indicate the need for a follow-up on the findings. The CAHBIR director will ensure that the PI is given the information. If finding is deemed significant, it is the PIs responsibility to communicate the radiologist’s evaluation and recommendation with the participant, and to verify with the CAHBIR director that the information was communicated. It is the CAHBIR director’s responsibility to “close the loop” in confirming to URG that the radiologist’s recommendations were communicated to the participant. Because many researchers lack the clinical knowledge and credentials to appropriately advise subjects about a neuroradiological finding, it is possible to ask a CAHBIR affiliated MD be brought in to assist in communicating with the subject, but this must be done with the subject’s permission if the MD is not part of the study team. In all cases, if the radiologist indicates the need for a follow-up on the findings, the PI must indicate to the CAHBIR director that this recommendation was provided to the subject.

6) If the radiologist considers a finding to be clinically significant, their report with preliminary findings will be mailed with delivery confirmation (registered mail is preferred) to the subject as soon as possible after being notified on the phone. The participant should also be sent (via postal mail or email) a release of information if they wish to have a CD burned of their exam to be sent to a doctor of their choosing. CAHBIR’s MR technologist will be responsible for handling any requests for a CD of their exam. A copy of the request will be retained in the CAHBIR center files.

7) Although responsibility for communication with the participant ends after they have been informed of the radiologist’s evaluation, researchers may consider including in their protocol a plan to recontact participants two weeks after disclosing the radiologist’s findings to the research subject to see if they need help obtaining an appointment with an appropriate physician if s/he has not already done so.  If the subject indicates that s/he does need help, CAHBIR staff can assist in providing the name of an appropriate physician as a courtesy to the participant.

**Appendix C: Minors Participating in Imaging Studies**

**1. Background.**  Special precautions must be taken when enrolling children in MRI studies. Some important considerations are listed below. Researchers may, on a study-by-study basis, choose to utilize other procedures. Those situations will require consultation with CAHBIR staff. The standard operating procedures outlined below represent study procedures that present no more than minimal risk to the research subjects – that is, the risk of participation will be no greater than that of everyday life or routine medical imaging procedures.

**2. Reports of Pregnancy.**  Any female research subject past the age of menarche and less than 18 years of age will be asked to self-report pregnancy and will be required to either take a pregnancy exam or to sign a pregnancy waiver form. As with adult subjects, these individuals should be prompted to report in written form (through the MRI Screening Form) and verbally. This process should take place in private, away from the parent or guardian. Under no circumstances should the researcher convey the response to the parent or guardian of the research subject. The fact that this information will not be shared should be conveyed clearly in the assent form and in the parental permission form. This information should also be clearly conveyed in the verbal component of the informed consent process.

If the subject indicates that she is or might be pregnant, researchers should not enroll the subject in the study.  In recording such an exclusion, an indication that a participant did not meet inclusion/exclusion criteria for a study is acceptable, but specific information about a self-report of possible pregnancy or a positive pregnancy test result should not be included in study data sets.

All research subjects that self-report possible pregnancy or have a positive pregnancy test should be provided with a resource list listed below. Researchers are strongly encouraged to use these resources when speaking with the research subject. For instance, researchers may use a speakerphone or conference phone to call the Texas Youth Hotline with the research subject in order to ensure the subject has the opportunity to speak with a trained professional about the options available to them.

**Resource List for Pregnant Adolescents.**  This list of resources shall be provided to adolescents who identify themselves as pregnant under the procedures described in the section above.

**Planned Parenthood:** 800-230-PLAN (7526)-National or 732-246-2411 local in New Brunswick.

<http://www.plannedparenthood.org/>

Planned Parenthood has information about options for teens who have discovered they are pregnant.  On their website, you can go to “Info for Teens” (menu on the right screen) - > “Pregnancy”  -> “I’m Pregnant. Now What?” for more information.  You can also call 800-230-PLAN (7526) or go to a Planned Parenthood clinic (there are three in Austin) for pregnancy testing and information.

**Central Jersey Family Health Consortium** (888) 551-6217

<https://www.nj211.org/resource-search/detail/63458815>

The Central Intake Hub provides pregnant women, families/parents, and providers with easy access to resource information and referrals to local community services that promote child and family wellness. The range of service referrals may include the following: - Prenatal care - Pediatric medical home - Infant/child health - Family planning - Nutrition/WIC - Home visiting programs and Healthy Families.

**3. Reporting Abuse.**  New Jersey law (NJSA 9:6-8.10) requires all persons who have reasonable cause to believe that a minor has been subject to abuse or neglect to report it to the New Jersey Division of Child Protection and Permanency (DCPP), formerly the Division of Youth and Family Services (DYFS) at 1-877-NJABUSE (1-877-652-2873). It is the explicit and individual responsibility of each researcher working with children to familiarize themselves with the relevant legal requirements involved.  For more information on legal responsibility for reporting, we direct researchers to the DCPP website: <https://www.nj.gov/dcf/about/divisions/dcpp/>. A useful concise review of definitions and expectations is also available at <https://apps.rainn.org/policy/policy-state-laws-export.cfm?state=New%20Jersey&group=4>.

Note that it is not the responsibility of the researcher to do **ANY** investigation into any allegations or suspicions of abuse, but if a minor spontaneously provides information about potential abuse or does so in response to standard research or screening questions, the researcher has an obligation to report this spontaneous outcry to the DCPP. This is a legal obligation for each individual who hears this information from the minor; it is that individual researcher’s responsibility to report to DCPP and this obligation cannot be satisfied by reporting to more senior research staff, CAHBIR staff, faculty mentors, or any other individual. While it is totally appropriate to consult with more senior staff in such cases, the consultation does not remove the researcher’s obligation to report if they believe there is reasonable cause to believe the minor has been abused.

Each individual who reports suspected child abuse should maintain a record of the time and method of their reporting, and any identifying information provided by DCPP. The record should comply with the data security provisions as outlined in the IRB approved proposal. If the research proposal approved by the IRB states that information will not be stored with the research subject’s name, then the individual reporter has an obligation not to create a record with the subject’s identifying information, even if that record is maintained for the researcher’s personal use as a record of their report.

**4.  Training in detecting and reporting abuse.**  Requesting information from adolescents about pregnancy status requires that researchers are aware of their legal and ethical obligations as mandatory reporters of child sexual abuse. As such, all researchers who enroll adolescent minor females will be required to have specific training regarding those obligations. Any researcher (faculty, staff, or student) that interacts with research participants in these studies is required to complete the [Recognizing and Reporting Child Sexual Abuse: A Training for Caregivers](https://www.dfps.state.tx.us/Training/Child_Sexual_Abuse_for_Caregivers/index.htm) online training.

Documentation of completion of the webinar training should be maintained by the senior faculty member on each research project that involves imaging minors at CAHBIR. That information should include:

1. Date of the training
2. Names and RUNETD’s of individuals who completed the training
3. Signatures for each individual who has completed training

**5. Motion Control.**  As with adults, it is important that minors remain still during the imaging process. For younger minors, this can be more difficult than for adolescents and adults. Researchers who use younger children in the research process must take special care to ensure that children are not distressed by the process of participation in a study that uses imaging tools and to ensure that children are provided with ample opportunity to withdraw from participation.

Required Procedures:

* 1. All minors should be given the opportunity to use the mock scanner located in the CAHBIR imaging suite. This may occur on either a preliminary visit or immediately prior to utilizing the actual scanner at the same visit. For subjects under the age of 10 years, CAHBIR very strongly encourages use of this resource. Researchers are encouraged to use this resource with older participants on a case-by-case situation as well.
	2. Research subjects under the age of 10 years must be scanned with a handheld metal detector specifically designed as a pre-screening detection tool for MRI scans and provided by the CAHBIR in order to ensure the child has not swallowed any metal/magnetic items. Researchers are strongly encouraged to use this resource with older participants as well.
	3. Minors who are unable to remain still to a degree that produces scans of acceptable image quality after two tries will be given the opportunity to take a break or to discuss the problem with the researcher. For example, the researcher may conduct a more detailed “check-in” with the child, inquiring whether they think they can hold still or not.
	4. If the child cannot continue after the check-in or break because of discomfort, the scan session should cease, with no negative comments or consequences towards the child at all. For example, the researcher may use phrases like, “We’re so glad you gave it a try! You were so brave and tried so hard!”
	5. If the child cannot remain still but expresses no discomfort or desire to cease participation, the scans may be continued at the discretion of the researcher, with prompts to remind the children to hold still. Some post-hoc analysis methods may allow for the development of usable data from these scans.

If at any time during scanning the child expresses the wish to stop or take a break, this should be arranged immediately.  If the child expresses discomfort verbally or indicates discomfort with external cues, the researcher should respond immediately to create a more comfortable environment for the child and ensure that the child still wishes to participate.

Suggested Procedures/Practices:

Researchers working with children may try a variety of methods to overcome barriers to a child remaining still during scans. Some examples of best practices are listed below. These are not required by all researchers as each study, age-group, and individual child may benefit from different practices.

**6. Explanation of Procedures and Equipment*.***  All researchers should explain what an MRI is and what will be done in age-appropriate language.  For example, children can be introduced to the MRI environment by using an analogy with a camera.  In the same way that people moving when a picture is taken make the picture look blurry, people moving while the MRI machine takes pictures results in blurry brain pictures (like a cotton ball).  It will be explained that to help them hold still, researchers will do four things:

* 1. Have them lie down on a bed with pads and sheets to make them comfortable (Explain that staying still is easier lying down than holding really still standing on one foot or sitting in a chair with wheels.);
	2. Use headphones and pads to restrain their head movements (Explain that this is also how they will hear the researcher’s voice and hear the movie and/or game sounds);
	3. Give them games and movies to play and watch (Explain to the parent or child that it is easiest to hold still when distracted.); and
	4. Talk to them in-between each scan and ‘checking-in’ to make sure they are comfortable and doing ok (Explain that the researchers can hear them at all times and will stop whenever they need or want to do so).

The various components of an MRI scan may also be introduced progressively to prevent overwhelming the child. For example, they may first be shown the mock scanner and allowed to explore, then asked to lie down and be moved into the mock scanner bore. This can be followed by introducing the use of the pediatric coils necessary for the study outside the scanner, then using the coils inside the mock scanner. Researchers may also introduce each part of the study procedures by having the parent or stuffed animal go through them in the mock scanner first, then having the child undergo the same procedures.

**7. Addressing Issues.**  The following table is provided to summarize the techniques that may be used to address certain issues that are common when imaging children.

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| **Barriers to Stillness** | **Way to Mitigate Barriers** |
| Hyperactivity | a)     Administer screening questionnaires before visit to exclude any children who exhibit clear hyperactivity tendencies.b)     Use very engaging tasks, such as a stimulating age-appropriate video and a variety of different practice tests, which may help the child remain still.c)     Employ practice tests to see if the child can remain still for the necessary time before the actual MRI scan.d)     Use of stop video tests, where we stop the video at any time the child starts to move.e)     Use of a walking break between practice tests and the actual scan.f)     Allow the child to pick a toy from the toy bins after each successfully completed task; immediate reward tasks can help with short term focus.g)     Have the research team wear comical hats and/or masks to keep the child engaged. Or use a puppet to explain procedures and talk to the child, which also aids in making the task more engaging. |
| Claustrophobia  | a)     Administer screening questionnaires before the on campus visit to exclude any children who exhibit clear claustrophobia tendencies.b)     Practice tests in the mock scanner to see if the child can remain still in the machine for necessary time without distress.c)     Assess any and all anxiety cues, either verbal or non-verbal, during the entire testing session, and allow for the conclusion of testing at any time. |
| Stranger Anxiety | a)     Have parent model the behavior with their child in the first two practice tests.b)     Have parent stand near the child while in mock and real scanner.c)     Have research team wear comical hats and/or masks to make the child feel less nervous about working with the research team. Or use a puppet to explain procedures and talk to the children.d)     Have one research in the room with them; minimize the number of adults working with the children.e)     Consider using sex matched researchers, especially for younger female children. |
| Fear of Loud or Foreign Noises  | a)     Expose the child to the MRI sounds in a simulated and controlled environment such as while lying on the ground and in the mock scanner practice tests.b)     Use phrase that are familiar to describe the noise, such as “like a freight train”.c)     During the mock scan, fade the MRI noise in and out so that the child has a chance to acclimate to the noise gradually.d)     Have the video noise playing over the MRI noises to distract them and simulate the real MRI scan.e)     Provide the child a choice between headphones and ear plugs for noise protection. |

**Appendix D: Data Access and Security**

CAHBIR utilizes Flywheel implemented in Google Cloud Services to distribute and archive neuroimaging data. Data will be automatically “pushed” to Flywheel after each session and will be available for download to individual labs shortly after the session. Flywheel is HIPPA and DB Gap compliant. Data access is limited to the PI’s laboratory. MRI headers and other data on Flywheel should never include subject names, medical record numbers or social security numbers. These data should only include study and scan sessions IDs for identification, which allows proper data transfer and archiving to be audited without compromising data confidentiality. Flywheel uses Rutgers authentication to allow secure login. Individual PIs are responsible for giving members of their lab access to their data on Flywheel. Data are available on Flywheel indefinitely unless the investigator chooses to delete the data. Note, because these data are being placed on a server that is external to Rutgers, the use of Flywheel and Google Cloud Services needs to be listed on IRB applications under data security. Both Flywheel and Google Cloud have been reviewed and approved by Rutger’s IT risk assessment team. Rutgers PIs and their staff can additionally use Flywheel “gears” to perform data processing. Gear usage leads to processing costs on Google Cloud Services, which can be charged back to the PI’s lab. If a lab is planning on using Flywheel gears they should consult CAHBIR staff regarding costs. Depending upon the level of usage, these fees may be partially or entirely offset by discounts that are provided to academic researchers using Google Cloud Services.

Investigators can choose to participate in a CAHBIR image repository program that allows investigators to perform secondary analyses on stored imaging data on Flywheel. If a PI is interested in sharing data as part of this program, they must indicate in their IRB application that deidentified data can be utilized for secondary analyses by other researchers. Only PIs that share data to the CAHBIR image repository will be allowed to analyze data in the repository. Rules for data access will be determined by a committee composed of each PI that contributes data to the repository, but individual PIs retain the right to request that their data be excluded from a specific analysis, or that they be included as a co-author if the data from their lab represents a sizable contribution to the data that were analyzed in secondary analyses.