Guidelines and Policies for Weizmann MR Center (WIC)

A. Facilities

The MRI center houses two scanners: a 3 Tesla (Prisma, Siemens) whole body magnet located in the Arison Laboratory for Human Brain Imaging building, and a 7 Tesla (Terra, Siemens) whole body magnet that is located in Lubin building.

B. Personnel

Edna Haran, Head of the fMRI facility. Tel: 6098, Mob: 0545-499-815

Amir Seginer, MR Physicist. Tel: 6212

Eiska Tegareh, MRI technician. Tel: 6214, Mob: 052-6397188 Natalie Oshri, MRI technician. Tel: 6214, Mob: 054-7287175

Sagit Shushan, Medical Advisor. Tel: 6273

C. Safety

C1. Safety committee

WIC representative: Edna Haran Safety Officer: Noam Sobel Engineer: Aharon Weissbrod

C2. Safety training

WIC will have an MR safety training. The training should be given by WIC personnel, and made available once every months or so. Any person who intends to be in the MR center on any regular basis (even if they won't run the machine), including all the coresearchers in the different Helsinki approved protocols that want to attend the control room during the experiment, must participate in the training. It is recommended that all graduate students in a lab that use the scanner will take the safety course, even those students who are not planning to do scanning in their own projects. The course has a course-booklet (http://www.weizmann.ac.il/LS_CoreFacilities/mri/safety).

C3. User course

WIC personnel will train users upon demand on how to run the scanner/s and become a certified operator. The training will be available only to Weizmann students and employees. An operator will be certified as such only after he/she has satisfactory completed training on MR safety, training on MRI including hands-on training. The formal training may be waived if adequate experience can be demonstrated.

A user will conduct his/her first independent scans under full supervision of WIC personnel. Then the user must undergo an apprenticeship period in which they may use the scanner/s only when one of the WIC personnel is present, and only after this after the user has exhibited that they are capable of scanning on their own, will WIC personnel activate the user status (or deny it). To remain a user, a person must scan at least 10 times per year (subjects or phantoms). If the person ran less than 10 scans in a given

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year, or if the time interval from the last scan was more than 3 months, they will have to be re-supervised in order to regain "user" privileges.

Training will also include emergency procedures, safe machine shutdown, maintaining records of system usage and performance as well as usage of the peripheral equipment, providing a safe working environment. In addition approved users must read the MR system operator manual, paying special attention to the safety chapter and sign that they read and understood all policies and procedures related to their research.

C4. Registry

WIC personnel will be responsible for maintaining a data base of status as to people with current safety and user privileges.

C5. Permissions

C5.1. Designation:

The typical danger point in any multi-user facility is uncertainty as to responsibilities. For example, a lab may be running an experiment, and a third party may enter the scanning room. The WIC personnel may assume that the lab is "in control" and that they know who the third party is. In turn, the lab people may think that the WIC personnel know who the third party is. This gray zone is a dangerous situation. Thus, on the door of the scanner control room we have installed a small white-board with an erasable marker. It will designate the "currently responsible person" (CRP). That person is then responsible for all scanner events. A lab member user will write in their name when they start working, and write the exact time when they leave. When the board is empty, the default is that WIC personnel are the CRP.

A CRP understands that safe operation within the MRI facility and the administration of this safety policy is his/her responsibility while he/she is present in the facility. Any incident or adverse event associated with the scanning should be reported immediately to the WIC personnel.

Users and CRPs should schedule a time slot in advance for their study via the web based scheduling system and inform the WIC staff regarding the protocol and type of experiment to be conducted.

C5.2. Entry:

<u>Control room</u>: The CRP can admit any person into the control room (zone 3). It is the responsibility of the CRP to assure that such people are without pacemakers or implants of any kind.

<u>Scanner room:</u> No one may enter the scan room without authorization from the CRP. Only the CRP can admit to the scanner room.

The people who can be admitted are only: A) experimental subjects (participants) who have completed the current "MR compatibility safety form" (http://wpre.weizmann.ac.il/LS_CoreFacilities/sites/LS_CoreFacilities/files/uploads/quest

ionary_heb.pdf), and informed relevant consent forms, and B) lab members and WIC personnel who have current safety course designation. In other words, other than experimental subjects (participants), **anybody** who enters the scanner room has participated in the safety course and has been currently tested for safety regulations. All users must fill out the MR safety screening form to ensure that it is safe for them to enter the magnetic scan room.

It is the investigator's responsibility to ensure that scanning of Human subjects is conducted **only** as part of a protocol approved by the Helsinki committee.

It is the CRP's responsibility to ensure anonymizations of the participants personal details on the MR console, and to archive the acquired data when he/she completes the study session.

It is recommended to fill the screening form, <u>prior to arriving</u> to the MRI center, in order to ensure that the participants can enter the magnet. Additionally, investigators must ensure that their volunteers read and understood all the items in the screening form. It is the policy of the WIC center to defer scanning if there is any possibility of causing injury to the subject or staff.

Before entering the scanner room instruct your subject to remove all metal containing objects from your body and pockets (watch, jewelry, hairpins, keys, wallet, magnetic cards, coins, etc..) and store them in a personal locker located near the dressing room.

Researchers are instructed to arrive to the facility before their subjects arrive or with their subjects. To keep the privacy of volunteers from other research groups, users should stay in room 5 (3T facility, Arison fMRI Lab) or in room 8 (7T facility, Lubin building) while preparing their volunteers for the MRI scanning and wait for their queue, as well as while filling post scanning questioners.

Visits at the MRI center must be coordinated with the WIC staff.

C5.3. Use:

All those who have passed both the user and safety courses, the MR training, and have also been approved in writing by their PI, can use the scanner at all times. For research involving scanning volunteers without the presence of an MR technologist, users must also participate in a two-days safety and usage course given every three months by the Medical Technology Directorate of the Ministry of Health (WIC personnel will register the users upon request to that course). This is of course subject to individual Helsinki documents and agreements. That is, there may be cases where a particular Helsinki calls for the presence of an MR technician or an MD. In those cases, the users are obviously bound by the letter of the Helsinki form.

When scanning human subjects two people (MR technician and a co-researcher of the particular Helsinki who passed the safety course or, but only at the 3T system, two co-

researchers that are certified as CRPs) must be present at the control room during the scan. Additionally, in any experiment that involves a human subject who is currently a patient and defined as a member of a non-healthy subject population in the Helsinki-approved research, a physician from the medical center that is partner to the Helsinki must be present and an MR technician.

Any new proposed Helsinki protocol should first be sent to Edna (to the safety committee) to review before or in parallel to submission to the Helsinki committee to ensure adherence to all WIC safety policies. Additionally, every approved protocol should be sent to Edna, who takes care of activating an insurance policy for that particular Helsinki.

Users should be familiar with the details of the Helsinki approved protocol that they are applying to their subjects. It is the users and PIs responsibility to follow in their experimental protocol the exact details of the original approved protocol.

Additional rules:

- Failures of the system should be documented and reported immediately to the WIC personnel.
- ➤ All broken equipment and equipment failures should be immediately reported to the WIC personnel
- ➤ It is not allowed to install any software on the MR PCs (both not on the scanner's console and the workstation) or change any definition of the MR console.
- > Installations of WIPs or new pulse sequences should be coordinated with Edna.
- Any researcher who uses the facility is required to return all equipment to its place and clean up properly. If the equipment was not returned to it's place or if the rooms are not tidy when he/she arrives please notify the WIC personnel.
- > Used clothing should be placed in the laundry basket.
- > Drinks and Food are not allowed in the magnet room.
- ➤ Do not throw food/drinks wrappers in the scanner room trash basket.
- > Drinks and Food are allowed in the control room, but must never be at the consoles tables or near the equipment.

C6. Supplies

All supplies, such as earplugs, etc., will be made available by the WIC. Any additional supplies must be approved by WIC personnel before they are used in the MR environment.

C7. Installing equipment

MR research facilities typically amass a huge array of experiment-related set-ups. Research facilities look nothing like clinical facilities in this respect. Here, on one side it is critical that we maintain flexibility. That is, if a scientist has an idea for a device in the scanner, he/she should definitely be encouraged to explore this. In turn, we don't want the center to turn into a jungle, and of course above all else, there is the issue of MR safety. With that in mind, we will implement the following:

C8. Equipment Safety Officer

There will be an equipment safety officer, who will head a safety committee to include the Officer, a member of the center's personnel, and an engineer. The rule will be that equipment can be installed or brought into the MR room only after it has been approved in writing by the safety committee. After approval in terms of safety, installation will be made only in coordination with the scanner personnel.

C9. Running modified pulse sequences

The center must be able to implement novel pulse sequences developed at other centers, as well as write our own. To this end, we have established a pulse-sequence committee that must approve sequences before use on human subjects. This committee must contain an MR physicist, as well as representative of the center and representative of the scientists. Guidelines for decisions will be clearly stated in a document to be written.

All new pulse sequences and modified pulse sequences can be installed on the scanner only in coordination with the WIC personnel and when the WIC personnel are present (this is to make sure that the protocol is indeed inserted to the correct directory and to avoid a situation where a customer new protocol is accidentally applied to a human subject).

All user's new sequences need to be tested adequately on a phantom before use on human subjects. The PI of the study remains ultimately responsible for problems associated with sequence development.

C10. CRPs should complete the MRI experiment equipment form and indicate the experimental setup that was used in their experiment.

D. Primate use

- **D1.** Animal use is regulated by the Institutional Animal Care and Use Committee (IACUC). Each principal investigator is responsible for securing approval for all procedures involving animals from IACUC. Investigators must specify the Imaging Center as the area of use on IACUC protocols.
- **D2.** Any new proposed IACUC protocols should first be sent to Edna to review before submission to IACUC to ensure adherence to all WIC policies.
- **D3**. All animal studies will use a separate magnet table top, trolley, coils, and pads that are all designated "animal only". There will be no shared equipment other than the magnet bore itself. The human equipment will be removed from the magnet room before the animal is entered into the facility, and will be returned to the magnet room only after it (the room) has been disinfected. Separate storage areas for the human equipment and animal equipment will be designated by WIC.
- **D4.** Animals with open wounds, canulas, any implanted devices, or any unhealed surgical scars (stitches in place), may not be scanned under any circumstances. In cases of animals with implanted electrodes, these must first be tested by the safety committee for MR compatibility.
- **D5**. The PI must provide the WIC with written assurance from the WIS veterinary services for each individual animal to be scanned, that the individual animal has been tested for any known transferable diseases that are considered risk-factors for that animal species (e.g., Cercopithecine herpesvirus 1 (B virus) in rhesus macaque)
- **D6.** Transport of animals into the magnet suites must be conducted without visual contact by human subjects or other researchers not involved with the animal model research study being conducted. Please check with Edna for approved routes of magnet access and transport through the WIC, as well as designated times. As a rule, animal studies will be conducted in the afternoon, ending at least 5 hours before the beginning of the next human session. In other words, the scanner room will have 5 hours to air-out between an animal study and a human study.
- **D7**. Each investigator is responsible for the cleanliness of the area following animal use. The animal table, animal coils and sponges must be wrapped and/or lined with protective underpads before an animal is positioned in the magnet. Ensure that all fluids, from the animal or contrast media, are contained and not allowed to run into the bore or cradle/table damage to hardware and body coil will result.
- **D8**. Following the completion of the experiment, all loose hairs and debris should be removed and the table should then be cleaned and disinfected with a hospital grade disinfectant. Ensure that all cleaning fluids are contained and not allowed to run into the bore or cradle/table damage to hardware and body coil will result.

D9. The **inside** of the bore is to be cleaned first with hospital grade disinfectant, and then with mild detergent (to remove the disinfectant), **before** the human designated equipment is brought back into the scanner room. Ensure that all cleaning fluids are contained and not allowed to run into the bore - damage to hardware and body coil will result. For cleaning use commercial disinfection materials.

> Do not use solutions with alcohol or acetone