

CIBM/CHUV Research Scanner Use Policy & Agreement

Revised: Wednesday, September 18, 2013

This is an agreement between the Department of Diagnostic and Interventional Radiology at the CHUV, represented by the CIBM/CHUV core director Professor Matthias Stuber and the Department of _____, represented by (PI) _____ for the project entitled:

Studies in Human Subjects:

No human study can be performed without a current, valid, FBM Ethics Committee Approval (pilot studies are exempt, see below). It is the principal investigators responsibility to ensure that a valid Ethics Committee Approval is in place, and that all aspects of the human study shall be performed consistent with that approval.

- Approval to conduct human MR studies must be obtained via the steps 'Phase A' and 'Phase B' outlined above.
- Studies in human subjects must be performed by an MR technician or by an investigator who has written approval by the Director to scan independently.
- Prior to entering the scan room, the study subject must have read, understood, signed and dated the consent form.
- The consent form must be signed and dated by the PI.
- The safety checklist must be completed, signed and dated by both the PI and the study subject.
- The operator is responsible for the safety of the study subject and individuals who meet exclusion criteria cannot be scanned.
- The scan has to be entered into the MR research logbook at the scanner.
- After 7pm and on weekends, a minimum of two investigators need to be present simultaneously at the scanner console and scanning of patients is not permitted.

Should the study participants (healthy volunteers) already be registered in the hospital database, a study number has to be obtained (ask for the document "Request to Generate an MR Study Number") for each participant. Clinical studies (patients) must have an official Study Number. At the Radiology front desk on the 7th floor, these study numbers will be provided in form of bar code strips and will have to be attached to the individual MR exam requests.

Pilot Studies in Human Subjects:

As a service to the users, the CIBM-CHUV MRI core provides access to its general FBM Ethics Committee Approval. Under this approval, pilot studies that include up to 5 healthy adult human subjects can be conducted if the following rules are adhered to:

- Approval to conduct pilot studies in human subjects must be obtained via the steps 'Phase A' and 'Phase B' outlined above.

- Pilot studies in human subjects must be performed by an MR technician or by an investigator who has written approval by the Director to scan independently.
- Prior to entering the scan room, the study subject must have read, understood, signed and dated the consent form.
- The consent form needs to be signed and dated by the PI.
- The safety checklist must be completed, signed and dated by both the PI and the study subject.
- The operator is responsible for the safety of the study subject and individuals who meet exclusion criteria cannot be scanned.
- The scan has to be entered into the MR research logbook at the scanner.
- After 7pm and on weekends, a minimum of two investigators need be present simultaneously at the scanner console.
- Scanning of patients, individuals younger than 18 years of age, paid volunteers and volunteers recruited by public announcements, is not permitted under this protocol.
- Studies that require blood samples, the administration of drugs or invasive procedures (including IV access) cannot be conducted under this protocol.

Animal Studies:

Animal studies are not permitted on the CIBM CHUV Trio MRI system at this point.

Phantom Studies:

Should there be a need to scan new and non-standard phantom equipment (self made phantoms; e.g. moving phantoms, phantoms with electronic components etc.), their use first has to be approved by the Chief Technologist (Chantal.Rohner@chuv.ch).

Safety Training:

All investigators who want to scan independently without technologist support must undergo annual safety training and test. This is currently in the form of a web-based module and scheduling can only be performed if the annual safety test has successfully been completed.

Time slots:

Users are allowed to book scanner time 30 days in advance. Exemptions to the 30-day notice may be considered upon application to the Director (Matthias.Stuber@chuv.ch) for extraordinary reasons, such as logistics peculiar to the specific research study. All scanner bookings including nights and weekends have to be registered in the online calendar. Investigators with calendar bookings are entitled to have access during their reserved time.

MONDAY TO FRIDAY:

- 8 slots are available: 1pm-2pm, 2pm-3pm, 3pm-4pm, 4pm-5pm, 5pm-6pm, 6pm-7pm, 7pm-8pm, 8pm-9pm
- A maximum of 5 hours/week is available for each PI/group.
- The first two slots (1-3pm) is dedicated to patient studies (MR technician mandatory) or to studies for which the support of an MR technician is required.

- In cases where this first slot has not been reserved between 5 and 2 working days prior to the actual date, it can be reserved for general scanning for which no technician support is needed.
- Should this 1st slot not be claimed 2 working days prior to the actual date, it may be used for clinical work.
- The slots after 3pm, which are not reserved for the next day, can be used as a supplement.

NIGHTS AND WEEKENDS:

- Investigator must have written approval of the director of the CIBM CHUV module (Matthias.Stuber@chuv.ch) for scanning during the night (7PM-7AM) or at weekends/holidays.
- Investigators need to be in possession of a personal CHUV identification badge
- Scanning of patients is not permitted.
- Scanning of human subjects is permitted only if 2 investigators are present at the scanner console.
- Scanning of phantoms and technical developments are strongly encouraged during nights and weekends.

Technologist Support, Charges & Billing:

Since both healthy subjects and patients are often participants in MR research studies, the Department of Diagnostic and Interventional Radiology may offer fully qualified and professional research technologist (RT) support between 1pm and 5pm. If RT coverage is needed, it should be clearly stated in the formal protocol application. An hourly fee of CHF 100.00 will be charged, should RT support be needed. While RT staff employed by the CIBM will endeavor to do everything they can to ensure a successful outcome for the study, it is understood that research by its nature, involves uncertainty, and the CIBM is not responsible for the failure of the research study to deliver the desired results or indeed any results, and provides no warranties as to the expertise of its RT staff in performing or attempting to perform a particular research protocol or study.

Since 2013, it has been mandated that the use of magnet time be subject to an hourly rate without exception (Convention CIBM n°17). See rates in the table below. These rates depend on the type of your study, the time slots you are booking, and whether this research is conducted in collaboration with the CIBM or not. A PI is considered “internal” if s/he is a member of an academic partner institution of the CIBM. For external PIs who conduct research as part of a scientific collaboration with the CIBM, special rates apply as detailed below. For all other external collaborators, for industry and for development of MR methodology, rates remain to be defined on a case-by-case basis. The services of an RT, extra equipment, and the use of contrast agents or other drugs are not included in the hourly rates and will be charged separately.

	• PI internal	• PI external & scientific collaboration	• PI external without scientific collaboration • Industry • Development
1 pm – 6 pm	CHF 200.00	CHF 200.00	TBD
After 6 pm and on weekends	CHF 100.00	CHF 200.00	TBD

Please provide the CGRA – CGRB numbers below if you are an internal CHUV applicant. External applicants, please provide billing information. By signing this document, the applicant further acknowledges that s/he is responsible to cover the costs for scanning as detailed above.

CHUV Internal Applicants:

CGRA: [_____]

CGRB: [_____]

External Applicants:

Name: [_____]

First Name: [_____]

Department: [_____]

Street Address: [_____]

City: [_____]

Billing:

Billing will occur twice annually (end of January and end of June) by CHUV/Radiology and the hours reserved on the on-line calendar will be billed. Should a study subject not be able to participate, cancellations are accepted until 48 hours prior to the study at no charge. Should payment for the prior cycle be outstanding, the CIBM may revoke your permission for scheduling.

Scanning without the Need for Technologist Support:

Should technologist support not be required, permission for independent scanning can be granted by the Chief Technologist Chantal Rohner (Chantal.Rohner@chuv.ch), should the operator be sufficiently experienced with scanning.

Grant Submissions:

Should grant submissions be planned that include MR as part of the study protocol, the feasibility of the MR study and the allocation of resources needs to be discussed with the CIBM core directors and associated staff. For grants that are submitted without prior discussion, access to the scanner and adequate support may not be guaranteed.

Scanner Upgrades:

Scanner software and or hardware upgrades may occur occasionally. Such upgrades lead to improved scanner performance and the CIBM CHUV module can therefore continuously provide the users with the latest MR technology and methodology. While most of the scanner protocols can easily be transferred from one software release to the next, there may be exceptions. For those users who program their own software, who use WIP products from the vendor, or who benefit from C2P arrangements, such upgrades may necessitate additional steps. For these reasons, notifications will be sent via e-mail to all the PIs 6-8 weeks prior to the planned upgrade. You can request to be added to the list of recipients of that e-mail by contacting Eleonora.Fornari@chuv.ch.

Non-Standard Use of Equipment:

The CIBM CHUV module provides MRI machine time and is not responsible for the success or failure of an MRI study, or for failures due to non-standard, non-clinical MRI pulse sequences, study protocols, detector coils, interface electronics or ancillary equipment owned in full or in part by the investigator or by other 3rd parties. Research involving installation of a research software or hardware modifications requires the prior approval of the Director (Matthias.Stuber@chuv.ch). At the end of the study: (a) unload such software and/or safely remove the hardware, (b) reinstall the commercial software or hardware where applicable, and (c) run a phantom scan to ensure proper operation.

Conduct of Study & Citizenship:

It is the responsibility of the investigators to ensure on-time arrival of research subjects, their suitability for study, and the availability of any non-standard materials (hardware, coils, software, pulse sequences, ancillary equipment) required for the study.

As a courtesy to the others and for equal access, each investigator is responsible to finish his/her study on time. Time for setup, cleanup and data storage must not infringe on the time of the following investigator. Unforeseen events such as failure of the equipment, late arrival of volunteers etc. do occur and may shift or prolong the examination with a resultant infringement of the right of the subsequent investigator to start on time. While this should be a very rare exception and flexibility of all involved parties is expected, an overtime that exceeds 15min is not tolerated. The investigator on whose watch the overtime occurs is responsible to communicate the delay to all the investigators with reservations who follow. The same applies to standard clinical studies that infringe on research scanner time.

Incidental Findings:

Incidental findings are a rare but known risk to imaging studies performed in healthy subjects. The investigators are asked to inform the study subjects about this potential risk on the consent form (see language below).

Should an incidental finding indeed occur during one of your studies, the involvement of a physician trained in medical imaging will become necessary. For these reasons, the investigators are asked to obtain agreement of a trained professional to be the referent medical imaging specialist on their study. This should occur prior to the submission of the study protocol to the Ethics Committee. Please contact Prof. Philippe Maeder or Prof. Reto Meuli should you have further questions.

Language for Incidental Findings on Consent Form:

« Cette étude n'est pas conçue à des fins de diagnostic clinique et les investigateurs ne sont pas formés à un tel diagnostic. Par conséquent, nous ne sommes pas responsables de la non-détection d'une anomalie. Cependant, si une anomalie devait être remarquée, nous soumettrons vos images au Dr spécialiste en radiodiagnostic. S'il confirme cette anomalie, il vous en informera et vous prendra en charge médicalement en informant votre médecin traitant. Il vous expliquera la nature de l'anomalie découverte et vous fera la meilleure

recommandation médicale possible. Dans ce cas, toutes les procédures médicales qui en découleront seront à charge de votre assurance maladie ou de vous-même (en cas de franchise) ».

Data Storage, Handling and Transfer:

The capacity of the scanner for data storage is limited. To ensure successful operation of the scanner, the database on the scanner needs to be cleared periodically. For this reason, it is the investigators responsibility to store and backup their own data on CDs, external harddrives, PACS for research etc. It is further the PI's responsibility to anonymize the data prior to their storage on the research PACS system or on devices that are not exclusively stored within the CHUV premises. Data can currently not be stored on the PACS devoted to clinical applications.

Clean Up:

It is the responsibility of the users to clean up when finished: (a) trash is to be emptied; (b) linen is to be deposited in the linen hamper; (c) all coils and scanner equipment are to be cleaned and put away properly; (d) any scanner or equipment problem is to be reported immediately to CIBM staff.

Acknowledgments & Co-Authorship:

Acknowledgment:

Should part of the results obtained in collaboration with the CIBM be published, the undersigned agrees to include the following sentence in the 'Acknowledgments' section: *"This work was supported by the Centre d'Imagerie BioMédicale (CIBM) of the University of Lausanne (UNIL), the Swiss Federal Institute of Technology Lausanne (EPFL), the University of Geneva (UniGe), the Centre Hospitalier Universitaire Vaudois (CHUV), the Hôpitaux Universitaires de Genève (HUG) and the Leenaards and the Jeantet Foundations."*

Co-Authorship:

Co-authorships of an individual from the CIBM is warranted if:

1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data have been made; 2) drafting the article or revising it critically for important intellectual content is involved; and 3) final approval of the version to be published has been granted. Authors should meet conditions 1, 2, and 3. Guidelines for co-authorship can be found at *New England Journal of Medicine* (1991:324; 424-428) and under http://www.icmje.org/ethical_1author.html

Legal:

- The employer of the principal investigator bares the general responsibility for the study.
- The use of the machines and directly related rooms are covered by the institution where the MR systems are located.
- For the principal investigators who are not CIBM affiliates, a proof of insurance coverage for the study needs to be provided to the CIBM together with the study application.

The undersigned Applicant acknowledges that s/he has read and understood the 'CIBM/CHUV Research Scanner Use Policy & Agreement'.

CIBM/CHUV
Prof. Matthias Stuber
Directeur

[Applicant]

Date: _____

Date: _____

M. Stéphane Coendoz
Directeur administratif du
département de radiologie

Directeur administratif

Date: _____

Date: _____