E. ADMINISTRATION OF INSTRUMENT

E.1 Organizational / Management Plan

The proposed instrumentation upgrade will replace the existing obsolete 3 Tesla MRI scanner—which has been part of the Technology Core at the Martinos Center for over a decade and has been a central part of the overall biomedical research effort at the Massachusetts General Hospital—with the next-generation MAGNETOM Vida 3 Tesla MRI scanner. Directly administered by the Athinoula A. Martinos Center for Biomedical Imaging, and located at the MGH Research Campus in Charlestown, the 3 Tesla MRI laboratory is a unique core resource for the large community of investigators in the Boston area who rely on the Martinos Center facilities for cutting-edge MR imaging technologies to help advance their research studies. The organizational team responsible for administering the grant will include key faculty and personnel at the Martinos Center, supported by the local Advisory Committee and internal Facilities Management and Operations Committees as detailed in sections *E.1.a–E.1.c*. Susie Y. Huang, M.D., Ph.D., is Director of Translational MR Imaging at the Martinos Center and within the Department of Radiology and will serve as the Shared Instrument Director for the proposed instrument. Bruce Rosen, M.D., Ph.D., Director of the Martinos Center, oversees and ensures access to all imaging facilities, support labs, and computational and educational resources of the Martinos Center, making sure that the facility is used in accordance with all Martinos Center, MGH and federal guidelines. He has assumed the overall administrative and scientific oversight responsibilities for the facility and is responsible for all compliance and reporting requirements of the Martinos Center. Lawrence Wald, Ph.D., is Director of the Martinos Center Imaging Core and oversees the support laboratories including the RF Laboratory that are particularly pertinent to the effective operation of the instrument. John Kirsch, Ph.D., as the Human MR Imaging Core Director, manages instrument operation, maintenance and upgrade, and safety, under the guidelines set forth by the Operations Committee. The Martinos Center operations management, under the oversight of Grae Arabasz and Jacob Calkins, R.T., provides supplies and management of the routine service needed for the operation of the magnets.

The proposed next-generation 3T system will be utilized by the broad set of clinical, translational, and basic science researchers at Mass General Brigham and other Harvard-affiliated hospitals and academic institutions in the greater Boston area. Requests for scan time on the next-generation 3T scanner will be made on a quarterly basis through an established web-based scheduling system that is described in detail below in section *E.1.d: Policy for Allocation of Instrument Time and Resources*. The allocation of scan time will be made based on the total amount of funding budgeted for use of 3T MRI at the Martinos Center in each user's grant. As such, Major Users will be allocated a greater amount of scan time in aggregate than Minor Users, proportionate to the budgeted scan time in their respective projects. Other users and new users will be actively enlisted through quarterly review of funded grants by the Shared Instrument Director in collaboration with the Advisory Committee. Users will be trained in the experimental design, operation of the instrument, and data analysis through formal training sessions scheduled with the core MR physicists, technologists and members of the Operations Committee, as detailed in section *E.1.e: User Training in Experimental Design, Instrument Operation and Data Analysis.*

E.1.a: Facilities Management Committee

The role of the Facilities Management Committee for this High-End Instrumentation Grant will be served by the senior core faculty and staff members of the Martinos Center. *The committee meets bi-weekly to discuss scientific, academic, financial, safety, instrument management and policy matters involving <u>all facilities</u> operated by the Martinos Center.* The members of this committee include the Martinos leadership, directors of all core facilities, and leaders of the staff teams as well as senior faculty at the Center. As Director of Translational MR Imaging, Dr. Susie Huang, the PI of this grant, serves as a key member. Members of the committee in 2021-2022 included:

Bruce R. Rosen, MD, PhD	Director, Martinos Center for Biomedical Imaging
David Boas, PhD	Director, Neurophotonics Center, Boston University
Randy Buckner, PhD	Director, Harvard University Neuroimaging Core
Josh Roffman, MD	Director, MGH Psychiatric Neuroimaging Program
Jacob Hooker, PhD	Director, Martinos Center PET Chemistry Core
Susie Huang, MD, PhD	Director, Translational MR Imaging & Connectomics, MGH Radiology
Monica Langone	Senior Administrative Manager, Martinos Center
David Sosnovik, MD	Co-Director, Cardiovascular Research Center, Cardiology
Peter Caravan, PhD	Director, Institute for Innovation in Imaging, MGH

Ciprian Catana, PhD	Director, PET Core, Martinos Center
Bruce Fischl, PhD	Director, Computational Core, Martinos Center
Samson Mehl	Manager, IT Support Services, Martinos Center
Grae Arabasz	Technical Research Manager
Jacob Calkins, RT	MRI Research Specialist
Steven Stufflebeam, MD	Medical Director, Martinos Center
Lawrence L. Wald, PhD	Director, Martinos Center Imaging Core, Martinos Center
John Kirsch, PhD	Director, Human MR Imaging Core, Martinos Center

E.1.b: Advisory Committee

The Advisory Committee for this High-End Instrumentation Grant will consist of senior core and affiliated faculty of the Martinos Center who will be responsible for overseeing the administration of the grant and usage of the instrument. The local Advisory Committee will apply their scientific expertise and experience in leading other imaging centers in the Boston area to set guidelines for the maximum utilization of the instrument and allocation of instrument time to current and future users. Working together with Dr. Huang, the PD/PI of the shared instrumentation grant, the Advisory Committee will develop the guidelines and detailed plan for day-to-day management and safe operation of the instrument and ensure that the next-generation 3T system is used only by those users whose projects have received formal approval from the Institutional Review Board. The Advisory Committee will also help establish a financial plan for long-term operation and maintenance of the instrument once awarded, including a systematic review process for considering future upgrades and extensions of the use of the new 3 Tesla system to meet the needs that arise throughout the lifetime of the instrument, thereby ensuring that the new system will benefit users for years to come. Furthermore, the Advisory Committee will provide oversight on any programmatic needs that may arise, including relocation of the instrument within or outside the institution and even potential change of ownership and/or leadership in recommending a new PD/PI, should the need arise. Dr. Huang and the Advisory Committee will convene quarterly meetings and issue annual reports on the instrument status to the broad user base at MGH/Martinos and within the greater Boston area, including recommendations for instrument operations, thereby ensuring that the instrument is maintained and optimally supported for greatest benefit to the users as their needs evolve.

The Advisory Committee will be chaired by the Director of the Martinos Center Imaging Core, Dr. Lawrence Wald, and include the following members: Martinos Center Director and Vice Chair for Research in the Department of Radiology, Dr. Bruce Rosen, who will serve as the senior institutional official representing the financial commitment of the institution; Founding Director of the Laboratory of Mathematics in Imaging at Brigham and Women's Hospital, Dr. Carl-Fredrik Westin; Director of the Cognitive Neuroimaging Center at Boston University, Dr. Chantal Stern; and Director of the Northeastern University Biomedical Imaging Center, Dr. Susan Whitfield-Gabrieli. Drs. Westin, Stern and Whitfield-Gabrieli are external advisors who will not be direct users of the next-generation 3 Tesla scanner and will thus be able to help resolve disputes if they arise. The Advisory Committee will also include as an advisor Professor Elfar Adalsteinsson, a senior faculty member at MIT who has extensive experience with the 3 Tesla MRI system for neuroscience, body and technical development studies.

Lawrence L. Wald, PhD	*Chair*
Bruce R. Rosen, MD, PhD	Vice Chair for Research in Radiology and senior institutional official
Carl-Fredrik Westin, PhD	Scientific lead, liaison to BWH Radiology
Elfar Adalsteinsson, PhD	Technology lead, liaison to Research Laboratory of Electronics, MIT
Chantal Stern, PhD	Liaison to the Cognitive Neuroimaging Center, Boston University
Susan Whitfield-Gabrieli, PhD	Liaison to the Northeastern University Biomedical Imaging Center

E.1.c: Operations Committee

The Operations Committee for this High-End Instrumentation Grant will consist of faculty and staff members of the Martinos Center who play a direct role in the operation of the 3 Tesla MRI laboratory and who represent the diverse set of investigators using the new 3 Tesla system. The committee will be chaired by the Principal Investigator for this High-End Instrumentation Grant and Director of Translational MR Imaging at the Martinos Center, Dr. Susie Huang, and include the following members: Director of the Martinos Center Imaging Core, Dr. Lawrence Wald; Director of the Human MR Imaging Core at the Martinos Center, Dr. John Kirsch; High Field Imaging Director, Dr. Jonathan Polimeni; Drs. Andre van der Kouwe and Berkin Bilgic, who have extensive experience in image acquisition and reconstruction across a range of 3 Tesla MRI systems. Dr. Huang and Dr.

Wald will serve as key liaisons between the Operations Committee, which is charged with the day-to-day operations of the scanner, and the Advisory Committee, who will receive quarterly updates on the instrument from the Operations Committee on the projected and actual usage of the instrument. The committee will oversee the installation and initial training period and help Martinos Center investigators migrate their studies to the new system. Dr. Shivraman Giri of Siemens Healthineers, who leads the Siemens MR R&D Collaborations team at the Martinos Center, will play a key role in training users in the new software interface, in alerting users to new applications that may help their investigations, and in coordinating between the Martinos Center and the Siemens MR unit in Erlangen, Germany, during both the installation process and during the routine operation and maintenance of the system.

Susie Y. Huang, MD, PhD	*committee chair*
Jacob Calkins, RT	operations lead
John Kirsch, PhD	technical lead
Lawrence Wald, PhD	hardware lead
Jonathan R. Polimeni, PhD	scientific lead
Andre van der Kouwe, PhD	acquisition lead
Berkin Bilgic, PhD	applications lead
Shivraman Giri, PhD	Siemens collaborative lead

E.1.d: Policy for Allocation of Instrument Time and Resources

Scan time on the 3T MRI system is awarded to funded studies under the fee-for-service policy outlined in the financial plan below. Due to the high technical complexity of the 3T MRI system, approximately 10% of the instrument time will be reserved for routine instrument quality assurance, maintenance, and repair procedures. This comparatively high level of maintenance serves to significantly reduce the loss of study time due to image quality issues and therefore effectively reduces the cost of studies on this system.

Time on the new instrument will be allocated to Major and Minor Users based on the number of hours of scan time budgeted in their grants for scanning at the Martinos Center core imaging facility, with users having the most number of hours allocated in their grants given priority over the scheduling of standing slots on a quarterly basis. New users will be enlisted through an established pilot funding procedure, in which investigators at MGH and in the local Boston community may apply for the Martinos Center pilot grant, which encompasses a small amount of scan time (~25-30 hours for one year). If their proposal is funded, they may use the awarded funds to purchase scan time on any of the Martinos Center instruments, including the new 3 Tesla MRI. New users will also be actively sought out through word-of-mouth as well as during regular bi-weekly Center-wide faculty meetings encouraging collaborators of current Martinos Center faculty and users to request scan time. The facilities and capabilities of the new 3T Vida scanner will also be broadly advertised through regular postings in the weekly MGH Research newsletter and MGH Research Institute's list of featured resources.

Under the standard scheduling scheme, users may request up to five scheduled imaging slots in a one-month period; slots cannot be requested more than 31 days in advance. New requests for imaging time are solicited and new schedules are posted every 3 to 4 months. These activities are carried out through the Martinos Center's web-based scheduling system. The system electronically records the time that a researcher spends using a particular facility, and that time is automatically charged to the appropriate account, project, and grant. The Technology Core Administrator, Karen Dervin, oversees all aspects of instrument scheduling, and billing, under the supervision of Martinos Imaging Core Director, Dr. Lawrence Wald.

All users of the Martinos Center MR facilities are required to complete the MR System Operation and Safety Training course and provide documentation certifying completion of institutional training on human subject research (e.g., CITI, HIPAA) prior to receiving a login account for a project. Prior to gaining access to the instrument, all human and animal studies must be approved by the Partners Human Research Committee and/or the Subcommittee on Research Animal Care, respectively, which evaluate the proposals for scientific, experimental, and ethical considerations. Projects are also screened by the Advisory Committee for scientific content, appropriateness of instrument use, and adequacy of user training and animal studies institutional approval.

As the Shared Instrument Director, Dr. Huang will be responsible for ensuring that the instrument is made available to all qualified users. She will be supported in the decision-making by members of the Operations Committee, who are knowledgeable about the users' needs and level of training. She will communicate regularly with members of the Facilities Management Committee, Martinos Center Director (Dr. Rosen), and Directors of the Martinos Center Imaging Core (Dr. Wald) and Human Imaging Core (Dr. Kirsch) to ensure that any questions

regarding usage of the instrument are addressed. Potential challenges and conflicts include technical obstacles, issues related to the recruitment of subjects that may lead to unexpected cancellations, as well as personnel changes. When a problem is identified, Dr. Huang will seek the advice and input of the Advisory Committee, particularly members who are not users of the shared instrument, and work with this committee to establish a plan of action to resolve any difficulties. In the unlikely event that consensus cannot be reached amongst the Advisory Committee members, a majority vote will be taken.

E.1.e: User Training in Experimental Design, Instrument Operation and Data Analysis

Prior to the initiation of a new study on the proposed instrument, all users will meet with the Technical Director, Dr. Kirsch, to set-up an appropriate protocol on the scanner. Dr. Kirsch will ensure that the experimental design for each study is tailored for the users' technical and scientific needs, drawing upon the expertise of the Shared Instrumentation Director, Dr. Huang, as well as the acquisition and applications expertise of Operations Committee members Dr. van der Kouwe and Dr. Bilgic, and other members of the Martinos Center user community as needed. New users will be trained in the proper operation of the instrument through bi-weekly MR system operation training sessions to ensure that all study staff carrying out experiments on the new scanner are familiar with the nuts and bolts of operating the new system and are aware of the enhanced capabilities of the next-generation 3T Vida while operating within the safety standards as specified by the manufacturer. Users will be trained in the use of data analysis tools available on the Martinos Center compute cluster. Depending on the body part and types of sequences/contrasts acquired, users will be directed to the appropriate in-house scripts for the preprocessing of different data types such as diffusion and functional MRI. All users are trained in the appropriate use of anatomical segmentation and parcellation tools that have been installed on the Martinos Center computing system, including tools such as FreeSurfer, FSL, SPM, DSI Studio, and other Matlab-based tools that have been custom-written by individual labs and can be tailored for different data types.

The day-to-day management of the new scanner will involve standard QA scans performed before the first scan of the day, to ensure stability and proper operation of the most-utilized coils, software and hardware components. Prior to a scheduled slot, users are required to login to the scanner schedule to ensure that other users and Center personnel are aware that the scanner is in active use. A ticket system has been established for users to note any technical difficulties or issues encountered during their scans. The ticket system is actively monitored by the MR Operations managers, Grae Arabasz and Jacob Calkins, who respond promptly to ticket notifications and directs the questions to the Technical Director, Dr. Kirsch, and/or the on-site Siemens service engineer as appropriate. At the end of each scan, users are required to thoroughly sanitize and clean the scanner and console rooms and must logout of the scanner schedule system to alert other users to the availability of the scanner. At the end of the day, users are required to leave a standard water bottle phantom in the scanner with the 32-channel head coil plugged in, thereby ensuring that the scanner is left in a pristine state and facilitating the prompt initiation of stability scans the next morning.

E.1.f: Documentation of Use and Acknowledging the S10 Award in Publications

A log of all users with funded scan accounts is kept throughout the year and updated weekly by the Technology Core Administrator, Ms. Dervin. The Shared Instrumentation Director, Dr. Huang, will meet with Ms. Dervin on a quarterly basis to assess usage of the instrument by funded users. Dr. Huang will be responsible for instructing new users to cite the S10 award and will send quarterly reminders to the entire user base of the new instrument to cite the S10 award in their publications. Dr. Huang will work with Ms. Dervin to ensure that NIH-funded users at the Martinos Center and MGH requesting time on the new scanner are regularly citing the S10 award in their publications by inserting instructions for citing the S10 grant up-front in the scan time request form. A Center-wide policy has been established based on previously funded shared instrumentation grants that all funded users actively cite the S10 award in their publications. Users who do not cite the S10 award in their publications will be given lower priority for the next funding period. At the end of the year, a report of all NIH-funded Major and Minor Users utilizing the shared instrumentation will be published as part of the annual report.

E.2 Financial Plan

E.2.a: Long-term costs of proposed upgrade

The cost of the scanner upgrade involves replacing an existing Siemens 3-Tesla scanner with a newer, state-of-the-art model and will not change the projected long-term costs in practice compared to the existing scanner. The new scanner will have the same support personnel staffing and service contract pricing and terms as the scanner that is being removed, keeping the operational expenses constant. Also, the existing space for the

instrument is suitable to be reused for the new instrument—minor upgrades to the electrical wiring will be funded by MGH ECOR, see ***Sec. F.1***. In the following section, we lay out the long-term financial plan for the upgraded instrument.

E.2.b: Long-term financial plan of upgraded instrument

As a shared instrument, housed in the Martinos Center Technology Core and made broadly available to a diverse user community, the proposed instrument upgrade will enhance the lifetime of an existing system supported under a long-term financial plan that includes contributions from its users in a fee-for-service format. Based on the current usage of other 3T systems at the Martinos Center, the expected lifetime of the proposed instrument is projected to be at least 10-15 years, and likely longer given the central role it will play in Center activities and development. The Martinos Center will continue to provide the necessary services to oversee and execute general operations and maintenance procedures, while the Center's broad portfolio of research projects funded by NIH and other Federal and non-Federal sources will support operation costs on an ongoing basis. Funded investigators will be charged for the time spent on the instrument at an hourly rate calculated to equitably distribute the costs associated with providing the aforementioned operating and maintenance services as well as related expenses of the proposed instrument. The institution will commit to provide backup of the financial plan for five years from installation of the instrument.

Rates are periodically reviewed, dually by the Martinos Center Operations Committee and MGH Research Administration, and adjusted to reflect actual costs for system operation and usage. As noted, we anticipate that the new instrument with its upgraded features will increase its usability for a broader range of projects and further increase the quality of the data, attracting more users and research projects to utilize it. It will also foster the development and ultimate funding of new projects, and as such will serve as an important mechanism for growing and evolving research at Mass General Brigham on a broader scale.

E.2.c: Accessible User Time (AUT) of the instrument

The instrument is available with support from all necessary support staff and medical coverage for six days a week with 10-hour days, from 8AM to 6PM, for 50 weeks a year. During this time, two trained operators must attend to the scan session. All operators must have cleared safety training with one of the Center's MRI technologists. Of the 60 hours allotted during the week, 10% will be used to perform the necessary safety measurements and adjustments for smooth scanner operation. These procedures will include daily quality control checks of the scanner system to assess its stability. These assessments will be performed before any subject scanning is allowed; all scanning will follow a daily verified system check of the scanner. Subtracting an additional 10% of the available time used for system stability checks, as well as hardware and software updates, QA/QI, and RF coil maintenance, yields 2400 hours per year available to users for research.

Accessibility to the instrument during normal working hours accounts for building access hours and safety regulations in place at the Martinos Center for human scanning. During this time, two operators must attend to the scan session, one of whom must be a qualified "green badge" scanner who has been cleared for safe scanning of humans by the Center's MRI technologists. All other operators must have cleared their initial safety training with one of the Center's MRI technologists. After-hours accessibility is allowed on a case-by-case basis with special approval from the Martinos Center Operations Committee for essential use that does not entail human scanning, in compliance with Center regulations for demonstration of adequate safety training, expertise and site access to ensure the safe operation of the instrument off hours. As such, after-hours use of the instrument should not be considered routine and is not included in the current estimate of Accessible User Time.

E.2.d: Projected Annual Instrument Costs and User Fees

Based on the billable hours on the existing 3T system in past years and the improved usability of the new, advanced system, we estimate at least 1800 billable hours per year for this system, accounting for at least 75% of AUT being utilized by our Major and Minor Users. The proposed instrument will be administered on a fee-for-service basis, as are all other existing imaging resources at the Martinos Center. Hourly imaging fees are calculated to cover the bulk of operating and maintenance costs of the proposed instrument and related expenses. The rate is calculated on a per-hour basis, based on the total costs of operation (including the salaries of relevant support staff, equipment/cleaning services, and supplies) divided by the total estimated billable hours.

Our annualized cost estimates for operating the device are provided in Table 1 for Year 1 and are expected to be maintained at a similar level in Years 2-5, allowing for cost of living adjustments to personnel salaries in the subsequent four years. Similarly, the anticipated income that is generated through the annualized paid usage of the instrument fees as supported by federal and institutional grants is expected to be maintained at a similar

rate in Years 1-5. The expected amount of income in Year 1 calculated from a conservative estimate of 1800 hours billable hours per year with an hourly usage fee of $665/hour – the typical rate set for all our human MRI scanners – totals $1,197,000 and will comfortably cover the cost of keeping the system functioning and available to the users for immediate and long-term use. The hourly usage fee may be adjusted upward slightly to keep up with the operating costs in the subsequent four years.

Table 1. Estimated Annual Instrument Operating Costs in Year 1

	% effort	Base salary	Salary	Benefits	Cost
PERSONNEL					
MR Technologist 1	100	100,000	100,000	35,000	135,000
MR Technologist 2	100	100,000	100,000	35,000	135,000
MR Physicist	60	200,000	120,000	42,000	162,000
Nurse Practitioner	60	200,000	120,000	42,000	162,000
Software Engineer	50	95,000	47,500	16,625	64,125
RF Engineer	50	90,000	45,000	15,750	60,750
Core Administrator	50	80,000	40,000	14,000	54,000
					$772,875
OPERATING COSTS					
Service contract					120,000
Cleaning services					60,000
Supplies (laboratory, patient)					60,000
					$240,000
TOTAL EXPENDITURES					**$1,012,875**

E.2.e: Timeframe for Instrument Delivery

Siemens estimates delivery approximately 12 months from the date on which the purchase order is placed. Once it is installed, the commissioning of the upgraded system (to make it available for our users to use routinely) can take up to 1 month. The current plan is to decommission the existing 3T system a short period before the new system arrives, therefore minimizing the interruption to investigators. Though the system is operating on a newer platform, the system user interface is similar enough that current users can easily transition to the new system without a prolonged trial phase.