To: Partners IRB

From: Jacob Nazarian

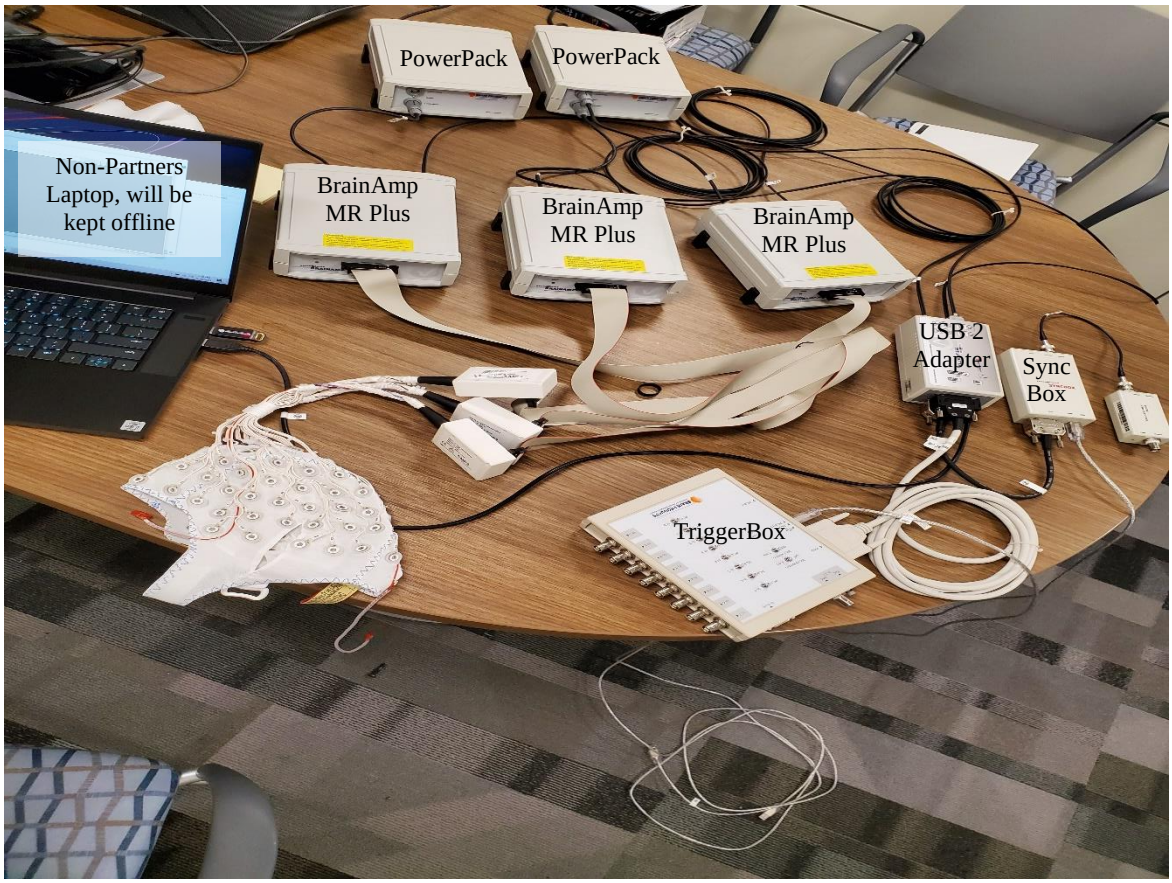
cc: Regal, Patricia Anglin

Subject: Human Studies Protocol Number 2013p001639 AME 109

Title:	Cerebrovascular Contributions to Brain Aging and Dementia
Principle Investigator(s):	David H Salat, PhD
Biomedical Engineering Reviewer(s):	Jacob Nazarian
Last Updated:	July 13, 2021
Biomed Work Order Number:	1388468

Protocol Short Summary:

This protocol evaluates study participants using an EEG and an MRI simultaneously to investigate cerebrovascular contributions to brain aging and dementia.



Biomed Findings and Recommendations:

Device 1: Electrical Geodesics Inc 400MR

General Device Information

Manufacturer: Electrical Geodesics Inc
Model: 400MR
Biomed Asset #: 40106423 (assigned prior to this review)

Device Description

This FDA-Approved device has already been added to the Biomed inventory and labeled accordingly. There is no preventative maintenance required by the manufacturer. The RF-interference guidelines listed in the user manual should be followed.

Maintenance

The system does not actually have any user-serviceable components other than the net. Please see the Manuals/Geodesic Sensor Nets/caring for you nets section:

https://www.egi.com/knowledge-center

Device 2: BrainAmp MR Plus

General Device Information

Manufacturer:	BRAIN PRODUCTS GmBH
Model:	BrainAmp MR Plus
Ownership:	Interdisciplinary Brain Center (IBC) at MGH
FDA Approved?	No - The components of the BrainAmp family are not medical devices. Use for diagnosis, therapy monitoring of vital physiological processes (such as cardiovascular functions) or other medical purposes is expressly forbidden
Contact:	Howard, Casey Michelle CHOWARD7@mgh.harvard.edu

Device Description

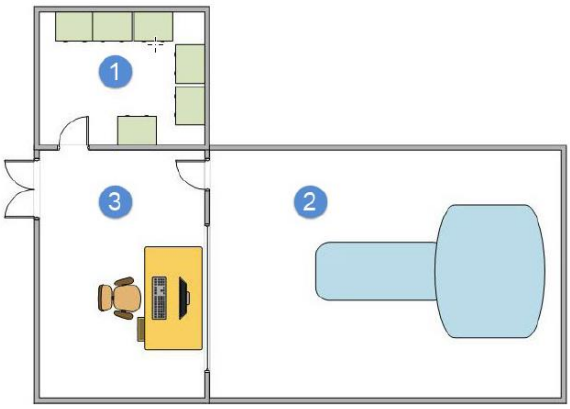
The components of the BrainAmp family are intended to be used for acquiring neuro/electrophysiological signals (e.g. EEG, EMG, ECG, EOG or signals from other approved sensors) in the context of non-medical applications in order to carry out fundamental or applied research on the basis of neurophysiological methodology and data. The acquisition of invasive EEG signals is permitted only if

- the acquisition is performed outside of the MR environment,
- the BrainAmp components are powered by the PowerPack (rechargeable battery),
- no other product is electrically connected with the test subject at the same time, and
- no simultaneous electrical stimulation is used.

Invasive electrodes must not be used for recording ECG signals and polygraphic signals with the BrainAmp components. The components of the BrainAmp family are not medical devices. Use for diagnosis, therapy, monitoring of vital physiological processes (such as cardiovascular functions) or other medical purposes is expressly forbidden.

2.1 MR facilities

The image shows an example of a scanner facility layout. The details below provide a recommendation for where to place the various components of the Brain Products EEG system.



1	**Technical room** (cabinets): SyncBox scanner interface
2	**MR scanner room:** BrainCap MR, BrainAmp MR, PowerPack
3	**Control room** (operator): EEG Recording PC, PC-Interface (BUA), SyncBox main unit, TriggerBox

Approved human whole body MR scanners:

Static gradient field

Siemens:	1.5 - 7 T*
Philips:	1.5 - 7 T*
General Electric:	1.5 - 7 T*
Bruker:	up to 4 T*

- If you have a scanner from a manufacturer not listed, please contact the Brain Products Technical Support team.

*** Over 3 Tesla:** Only possible after dedicated setup customization and site specific training by the Brain Products Technical Support team.

Power/Data requirements

- Device is only to be powered by the Brain Products PowerPack

Maintenance

- MFG recommendation is to apply test signal approximately once per month to ensure proper functioning, to be conducted by the end user
- Device has no other maintenance to be conducted by MGH Biomedical Engineering

Safety/ Risk Assessment

- Performing simultaneous EEG-fMRI measurements is subject to strict safety guidelines. The essential conditions for the safe use of the BrainAmp MR amplifiers and accessories in the MR environment are provided as standalone document, *Performing simultaneous EEG-fMRI measurements - Conditions for the safe use of BrainAmp MR amplifiers and accessories in the MR environment*

Device 3: PowerPack

General Device Information

Manufacturer:	BRAIN PRODUCTS GmBH
Model:	PowerPack BP-02620
Ownership:	Interdisciplinary Brain Center (IBC) at MGH
FDA Approved?	No - The components of the BrainAmp family are not medical devices. Use for diagnosis, therapy monitoring of vital physiological processes (such as cardiovascular functions) or other medical purposes is expressly forbidden
Contact:	Howard, Casey Michelle <CHOWARD7@mgh.harvard.edu>

Device Description

This device supplies power to the BrainAmp MR Plus device.

Power/Data requirements

- No data, no wireless connectivity

Input voltage range	100 to 240 V AC, 50/60 Hz
Rated power consumption	Max. 145 mA

Maintenance

This device has no scheduled maintenance. The manufacturer recommendation is simply to use it and charge it, as described in the "How to keep battery/ PowerPack fit" article

Device 4: Non-Partners Issued Laptop

General Device Information

FDA-Approved?	No, not a medical device
Ownership:	Interdisciplinary Brain Center (IBC) at MGH
Contact:	Howard, Casey Michelle <CHOWARD7@mgh.harvard.edu>

Device Description

This non-Partners issued laptop will be kept offline at all times. It is not to be located in the MR scanner room, per Brain Products requirements, and it must fulfill EM 62368-1. This laptop is not considered a medical device and will not be added to the MGH Biomedical Engineering Inventory.

Device 5: Polaris Krios Handheld Camera System

General Device Information

FDA-Approved?	No, not a medical device
Ownership:	Interdisciplinary Brain Center (IBC) at MGH
Contact:	Howard, Casey Michelle <CHOWARD7@mgh.harvard.edu>

Device Description

This device scans the subject's EEG cap localize each marker's position and create a digital point cloud (3D model) of marker coordinates.

Maintenance

This device has no preventative maintenance per the manufacturer recommendations, as stated in the user manual

Safety/ Risk Assessment

All EMC Compatibility and Separation Distances recommended by the manufacturer in the User Manual should be followed (included in but not limited to section 8 of the user manual).

Biomed Approval

Biomed approves the devices listed in the table below for use in **IRB 2013p001639 AME 109** under the following conditions:

- All individuals who will operate the devices must be trained on the use of all devices, read through the instruction for use manuals for all devices/accessories, and aware of patient privacy/safety precautions.
- At all times PI ensures all devices are functioning correctly per manufacturer's recommendation and in good condition (no frayed or worn cables, casing is not damaged, etc).
- The PI must send any maintenance service reports from the manufacturer during time of study to the following e-mail address: MGHBMEVendorServiceReports@partners.org.
- The research team should ensure that all devices/accessory cables are cleaned and maintained according to manufacturer's recommendations and MGH Infection Control policies
- **In the event any approved device leaves campus, an inspection is required when the device returns on site, prior to being used on a patient. Contact Biomedical Engineering at 617.724.1333 to schedule device inspection.**
- In event of malfunction and the devices cannot be fixed, it is the PI's responsibility to work with the device vendor to secure a replacement device. At this time, Biomedical engineering should be informed to schedule incoming inspection on the new device and retire the old one.
- Please note that Biomed approval is restricted to the consent of the devices listed in this document. In the event that any components or protocols are exchanged or altered, an additional review is required by Biomedical Engineering. Contact Biomedical Engineering at 617.724.1333 to inquire about review of modification to the device/system.
- It is the responsibility of the PI to ensure appropriate Partners Information Security and HIPPA policies are being followed in using these devices.

Biomed Approved Devices

Device Type	MANUFACTURER	MODEL	MGH Biomed Control Number	Serial Number
AMPLIFIER, EEG	Electrical Geodesics Inc	400MR	40106423	A14400210

Devices Not Added to Biomedical Engineering Inventory

MANUFACTURER	MODEL	MGH Biomed Control Number	Serial Number
BRAIN PRODUCTS GmBH	BrainAmp MR Plus	Not a Medical Device	MRP32M130119-100701
BRAIN PRODUCTS GmBH	BrainAmp MR Plus	Not a Medical Device	MRP32M130119-100120
BRAIN PRODUCTS GmBH	BrainAmp MR Plus	Not a Medical Device	MRP32M130119-100118
BRAIN PRODUCTS GmBH	BrainAmp MR Plus	Not a Medical Device	MRP32M130119-100117
BRAIN PRODUCTS GmBH	BrainAmp USB2 Adapter Box	Not a Medical Device	BUA128070050-100010
BRAIN PRODUCTS GmBH	BrainAmp USB2 Adapter Box	Not a Medical Device	BUA64070099-100007
BRAIN PRODUCTS GmBH	BrainVision PowerPack	Not a Medical Device	PPBM071079-100701
BRAIN PRODUCTS GmBH	BrainVision PowerPack	Not a Medical Device	PPBM071071-100701
Polaris	Krios Handeld Camera System	Not a Medical Device	PA-00122