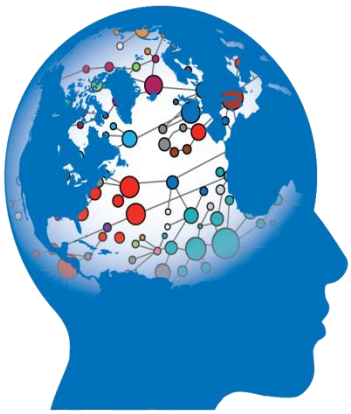
Transforming Research and Clinical Knowledge in Traumatic Brain Injury

TRACK-TBI 3T MRI Technical Procedures Manual



TRACK-TBI

Transforming Research and Clinical Knowledge in Traumatic Brain Injury

International Traumatic Brain Injury Research Initiative

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1. CONTACT INFORMATION

1.1 TRACK-TBI PRINCIPAL INVESTIGATORS (EXECUTIVE COMMITTEE)

Name	Role	Institution
Geoffrey Manley, MD, PhD	Contact PI + Administrative Core Leader + Study Site Leader	University of California, San Francisco
Ramon Diaz-Arrastia, MD	PI + Biospecimens Core Leader	Center for Neuroscience and Regenerative Medicine, USUHS
Nancy Temkin, PhD	PI + Biostatistical/CER Core Leader	University of Washington
Pratik Mukherjee, MD, PhD	PI + Neuroimaging Core Leader	University of California, San Francisco
Joseph Giacino, PhD	PI + Outcomes Core Leader	Harvard Medical School, Spaulding Rehab Hospital
David Okonkwo, MD, PhD	PI + Clinical Core Leader + Study Site Leader	University of Pittsburgh
Claudia Robertson, MD	PI + Clinical Core Leader + Study Site Leader	Baylor College of Medicine
Rotating Steering, Committee Member		

1.2 NEUROIMAGING CONTACT PERSONNEL

Question/Problem With:	Who to Contact:	Email:
Acquisition Aspects	Pratik Mukherjee, MD, PhD	pratik.mukherjee@ucf.edu
Site Qualification & QA	Alastair Martin, PhD	alastair.martin@ucsf.edu
Data Transfer	Karen Crawford (LONI)	kcrawford@loni.usc.edu
Individual Subjects	Site Study Coordinator or Research Associate	N/A

2. TRACK-TBI STUDY OVERIVEW

2.1 BACKGROUND AND GOALS OF TRACK-TBI

Effective treatment of traumatic brain injury (TBI) remains one of the greatest unmet needs in public health. Each year in the US, at least 1.7 million people suffer TBI; an estimated 3.2 to 5.3 million people live with the long-term physical, cognitive, and psychological health disabilities of TBI, with annual direct and indirect costs estimated at over $60 billion. The unique public-private partnership of investigators, philanthropy, and industry leaders brought together in the multicenter Transforming Research and Clinical Knowledge in Traumatic Brain Injury (TRACK-TBI) proposal share a mission to accelerate clinical research in TBI. The overall goal of TRACK-TBI is to create a large, high quality TBI database that integrates clinical, imaging, proteomic, genomic, and outcome biomarkers, and provides analytic tools and resources to establish more precise methods for TBI diagnosis and prognosis, improve outcome assessment, and compare the effectiveness and costs of tests, treatments, and services. Transforming Research and Clinical Knowledge in Traumatic Brain Injury (TRACK-TBI) will directly impact public health by creating an open-access Information Commons of integrated clinical, imaging, proteomic, genomic, and outcome biomarkers, which will permit more precise TBI diagnosis, prognosis, and treatment.

Please refer to sections 2 and 4 of the TRACK-TBI Clinical Protocol for an in-depth description of TRACK-TBI specific aims.

2.2 GOALS AND SPECIFIC AIMS OF NEUROIMAGING CORE (NC) FOR MRI

The NC, led by Dr. Pratik Mukherjee, has overall responsibility for all imaging activities including qualification and standardization of scanners (across vendors and platforms) at the 11 sites, designing MRI protocols, receiving all MRI and CT scans, and all imaging quality control activities. Multicenter imaging studies require quality control across imaging platforms and consistency throughout the enrollment period. Support for image quality assurance will be in conjunction with USC/LONI (Dr. Art Toga) where evaluations of image artifacts will be provided within 48 hours of each scan. The NC will provide coding and adjudication for all TRACK-TBI neuroimages according to the NIH-CDE criteria.

The specific objectives of the Neuroimaging Core for MRI include:

1) Obtaining high quality multi-site data that is consistent over time, and across different MRI systems.
2) Perform appropriate image quality control throughout the study.
3) Qualify (and re-qualify after upgrades) each scanner on the TRACK-TBI MRI protocol.
4) Correct specific classes of image artifacts in each image acquired; imaging intensity nonuniformity, image warping due to gradient nonlinearity, scaling changes over time, and diffusivity measurement changes over time.
5) Monitor each scanner longitudinally in the study using the ADNI, NIST and BIRN phantoms for structural, diffusion and BOLD fMRI imaging, respectively.
6) Perform quantitative measurements of all images.

The NC MRI protocol at 3T can be completed in one hour and consists of 6 sequences that are acquired on every MRI vendor system. These are:

1) 3D T1 MPRAGE/IR-SPGR – to detect focal lesions & for volumetrics/morphometry
2) 3D T2* GRE– to detect microbleeds
3) DTI or HDFT – to evaluate white matter microstructure and structural connectivity
4) Resting state BOLD fMRI – to evaluate functional connectivity
5) 3D T2-FLAIR CUBE/SPACE/VISTA – to detect focal lesions

6) 3D T2 CUBE/SPACE/VISTA – for volumetrics/morphometry

All subjects newly enrolled into TRACK-TBI who meet eligibility for MRI scanning will be scanned using the TRACK-TBI 3T MRI protocol.

Refer to Section 8.11 - Appendix 11 for specifics of the HDFT protocol.

2.3 MRI TIME POINTS

TRACK-TBI will have 2 mail cohorts: Comprehensive Assessment (CA) and Comprehensive Assessment + MRI (CA + MRI). The CA + MRI Cohort will receive a 3T MRI according to this protocol at the following time points:

2-Week/14 days (+/- 3 days) post-injury
Subsequent cognitive testing must be completed within 3 days of this MRI, but not to exceed 8-16 days post-injury (for example, if MRI was done on Day 15, outcomes still need to be completed by Day 16).

6-Month/180 days (+/- 14 days) post-injury
Subsequent cognitive testing must be completed within 7 days of this MRI, but must also fall between 173-187 days post-injury.

3. SITE QUALIFICATION

3.1 SITE QUALIFICATION OVERVIEW

Each site must be qualified for MRI. Qualification will include QA phantom scans on ADNI (structural integrity), BIRN (temporal stability) and NIST (diffusion accuracy) phantoms along with a human volunteer. Sections 7.1-7.3 contain detailed protocols for each of the phantom scans. The human volunteer should be scanned with the same, complete protocol as TRACK-TBI subjects, described in section 5.4. The phantom and human data will be reviewed to assure protocol compliance and image quality.

Please Note: The same MRI scanner must be used for site qualification and ALL subsequent subject scans during the TRACK-TBI study.

If the same MRI scanner is not used, the scan will not be reimbursed, and the subject will need to be re-scanned on the TRACK-TBI qualified scanner.

QA Phantom Scan Protocol Overview:

All phantom scanning should be performed with the same head coil used for TRACK-TBI participants.

ADNI Phantom (performed monthly):

1) Localizer
1a) Calibration/Reference Scan (if applicable)
2) QA ADNI Phantom MP-RAGE/IR-SPGR

BIRN Phantom (performed monthly):

1) Localizer
1a) Calibration/Reference Scan
2) QA BIRN Phantom fMRI

NIST Phantom (Schedule TBD; phantom available mid-2014):

1) Localizer
1a) Calibration/Reference Scan
2) QA NIST Phantom multiple-b-value

Please refer to **sections 7.1-7.3** of this protocol for detailed phantom scanning instructions.

Human Protocol Overview:

Volunteers must sign all appropriate informed consent and HIPAA documents before undergoing MRI procedures. Please follow the same pre-scanning and scanning procedures as TRACK-TBI subjects, outlined in sections 4 and 5, respectively.

(All scans are performed in straight orthogonal planes -- Sagittal or Axial)
(No manual adjustments should be made to this protocol)

1) Localizer
2) Sagittal 3D T1 MPRAGE/IR-SPGR
3) Sagittal 3D T2* GRE
4) Axial DTI or HDFT
5) Axial resting state BOLD fMRI
6) Sagittal 3D T2-FLAIR CUBE/SPACE/VISTA
7) Sagittal 3D T2 CUBE/SPACE/VISTA

Please refer to **section 5.4** of this protocol for detailed human scanning instructions.

3.2 SITE QUALIFICATION RESULTS:

The NC will examine the phantom and human data before TRACK-TBI enrollment begins to determine if the correct parameters have been met and assure that there are no other underlying problems with the scanning session. When finished, an email will be sent to your site notifying you of the results. After all site qualification requirements have been met, an additional email will be sent to the selected contact list for your site notifying them that your site has been approved and is ready to scan subjects.

Anticipation of Hardware Upgrades:

The Neuroimaging Core requires notification prior to any software and/or hardware upgrades for any scanner involved in the TRACK-TBI imaging study.

pratik.mukherjee@ucsf.edu

Depending on the impact of the upgrade the site may be required to scan a phantom and/or volunteer prior to resuming scanning.

4. MRI SUBJECT PRE-SCAN PROCEDURES

4.1 SUBJECT PRE-SCREENING

All subjects must be screened for MRI contraindications immediately before the MRI scan using your local standard protocol (please see Appendix 1 for example). Contraindications include, but are not limited to:

- The presence of non-removable ferrous metal objects
- Aneurysm clips
- Pacemakers
- Other contraindications such as defibrillators, etc.

Sedation during the MRI scan is not offered for this protocol. Subjects that are uncomfortable with MRI scans should not be included in this study. If you have a subject who is uncomfortable with MRI and refuses to complete the scan without sedation, please notify the study coordinator.

4.2 SUBJECT SAFETY AND MONITORING

All sites should follow the standard subject consent protocols as approved by your local IRB. Explain the scan procedure to the subject so that they know what to expect during the MRI. After appropriate consent documents and MRI screening documents have been signed and reviewed, please take the following steps to ensure subject safety:

1) Provide the subject with the opportunity to use the restroom before the scan begins.

2) Please use universal MRI safety precautions. Make sure that subject does not have any large ferrous metal on or inside of him/her such as shrapnel, a metal fragment in the eye, aneurysm clips, ear implants, spinal nerve stimulators, permanent makeup, or a pacemaker. Make sure that all loose metal objects are removed. If available, ask the subject to change into hospital robes or scrubs to ensure no ferrous objects or materials enter the scan room.

3) Please use standard local practice for monitoring the subject during the scan. These may include devices to monitor pulse and O_2 levels.

5. MRI SUBJECT SCAN PROTOCOL

After your site has received institutional IRB approval for the TRACK-TBI protocol, human volunteers may be consented and enrolled into TRACK-TBI by site's study coordinator or research associates.

MRI Subject Scan Protocol:
(All scans are performed in straight orthogonal planes -- Sagittal or Axial)
(No manual adjustments should be made to this protocol)
1) Localizer
1a) Calibration/Reference Scan
2) Sagittal 3D T1 MPRAGE/IR-SPGR
3) Sagittal 3D T2* GRE
4) Axial DTI or HDFT
5) Axial Resting State fMRI - Subjects should have eyes OPEN.
6) Sagittal 3D T2-FLAIR (CUBE/SPACE/VISTA)
7) Sagittal 3D T2 (CUBE/SPACE/VISTA)

Monthly QA scanning should be performed at a regular interval. See sections 7.1-7.3 for details.

5.1 MRI SCAN INFORMATION FORM

The MRI Scan Information Form (Appendix 2) should be completed at the time of acquisition for every TRACK-TBI subject.

Study Coordinator or Research Associate:
Please complete the top section of the MRI Scan Information Form (Appendix 2). After the entire form is filled out, please upload data into TRACK-TBI database. This form will be linked with the subjects' MRI data. Please keep a copy on site for your records.

MRI Technologist:
Please complete the remainder of the form during the scan. If the top section is incomplete, please contact the study coordinator or research associate for the information. Please be sure to indicate if each sequence has been completed and note any problems or modifications to the protocol in the appropriate sections. Also, note if data transfer, archive, and local copy for clinical reads have been completed. Once the form is completed in full, please transfer the form to the study coordinator or research associate to upload into TRACK-TBI database. This form will be linked with the subjects' MRI data.

To report an incident regarding the MRI sequences please email: pratik.mukherjee@ucsf.edu

To report an incident about a specific subject, please contact your study coordinator.

5.2 ENTERING SUBJECT INFORMATION

Please enter the subject's information into the scanner following your standard local practice. This will assure the scan is formatted for your local archival system. When data are uploaded to LONI, the scan header will be de-identified and rendered HIPAA compliant. Data will be identified at the LONI site by subject code only. The subject code will be entered manually at the time of data transmission to LONI.

5.3 SUBJECT POSITIONING

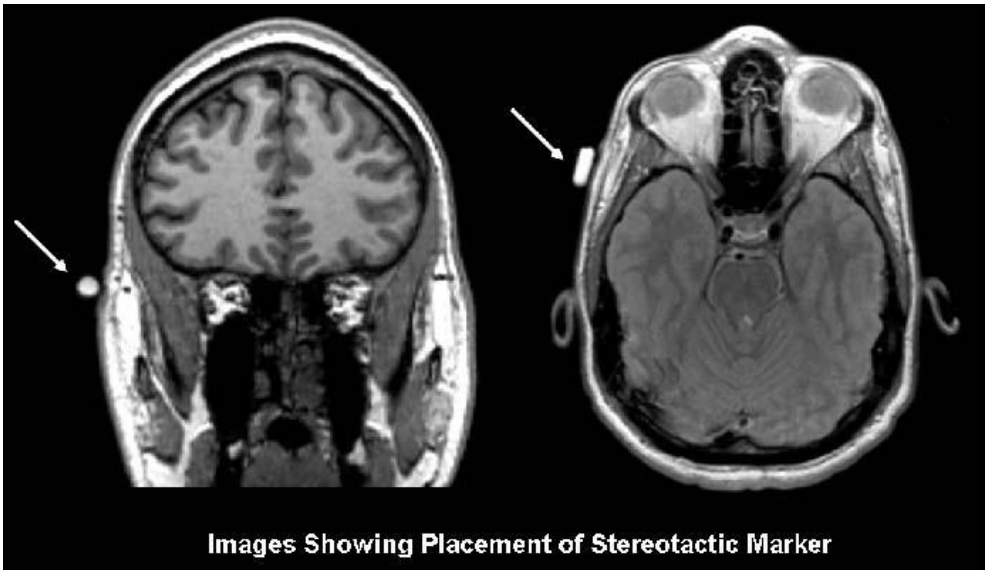
Proper subject positioning is crucial for successful reproduction of serial MRI exams. Therefore, it is important that each subject is positioned in the same manner for each and every MRI exam. Please follow the procedures below for positioning the subject in the head coil:

- Place clean sheet on scanner table and coil cradle.

- Besides standard room exclusions ensure the subject has removed their dentures as well as any hair clips, combs, earrings, necklaces, etc.

- Remove all upper body clothing with metallic trim, such as zippers, buttons or embroideries that may cause artifacts in the MRI images.

- **Tape stereotactic marker (vitamin E or fish oil capsule) on the subjects' right temple (RT).**



Images Showing Placement of Stereotactic Marker

- Provide each subject with ear protection. This may include ear plugs and ear pads.

- Position the subject so their head and neck are relaxed, but without rotation in either plane. Proper placement in the head coil is crucial because scans are acquired straight, not in an oblique orientation. The subject should also be well supported in the head coil to minimize movement. Motion artifacts may result in data rejection and request for a re-scan in many cases.

- Support under the back and/or legs can help to decrease strain on the knees and back as well as assisting in the stabilization of motion in the lower body.

- Once subject has been positioned, place sponges along the sides of head and a Velcro strap across forehead (if available) for stabilizing support and reduction of motion.

- **Align the centering crosshairs on the subject's nasion *(directly between the eyebrows)* at every scanning session.**

Please Note:

- It is extremely important that the subject is positioned in the same manner, at the nasion, for the Screening MRI exam and for all the subsequent MRI visits.
- It is imperative that the subject positioning procedures are followed exactly for all follow-up exams for a particular subject to ensure consistent imaging of the brain.
- If a deviation from these instructions is required to accommodate a subject, the MRI technologist must note this on the MRI Scan Form and refer to these notes during the follow-up exam.

- Center the head coil over the subject's head, making sure the subject is high enough in the coil to prevent signal loss at the inferior aspect of the brain.

- Offer each subject a panic button in case of emergencies or claustrophobia if common local practice at your facility (for example, a squeeze ball alarm.)

- Remind subject to hold as still as possible and advance subject to the iso- center of the scanning bore.

5.4 SCANNING SEQUENCES

MRI Subject Scan Protocol:
(All scans are performed in straight orthogonal planes -- Sagittal or Axial) (No manual adjustments should be made to this protocol)
1) Localizer
1a) Calibration/Reference Scan
2) Sagittal 3D T1 MPRAGE/IR-SPGR
3) Sagittal 3D T2* GRE
4) Axial DTI or HDFT
5) Axial Resting State fMRI - Subjects should have eyes OPEN.
6) Sagittal 3D T2-FLAIR (CUBE/SPACE/VISTA)
7) Sagittal 3D T2 (CUBE/SPACE/VISTA)

A QA scanning session should be scheduled on a monthly basis. QA should include ADNI, BIRN, and NIST (when available) phantom scanning.
Please see **section 7** for detailed instructions on phantom scanning.

The QA team will check all imaging parameters to assure the correct sequence was used. If the TRACK TBI protocol is not used to scan a subject, the scan will be excluded and the subject must be re-scanned with the correct sequences.

1) 3 PLANE LOCALIZER

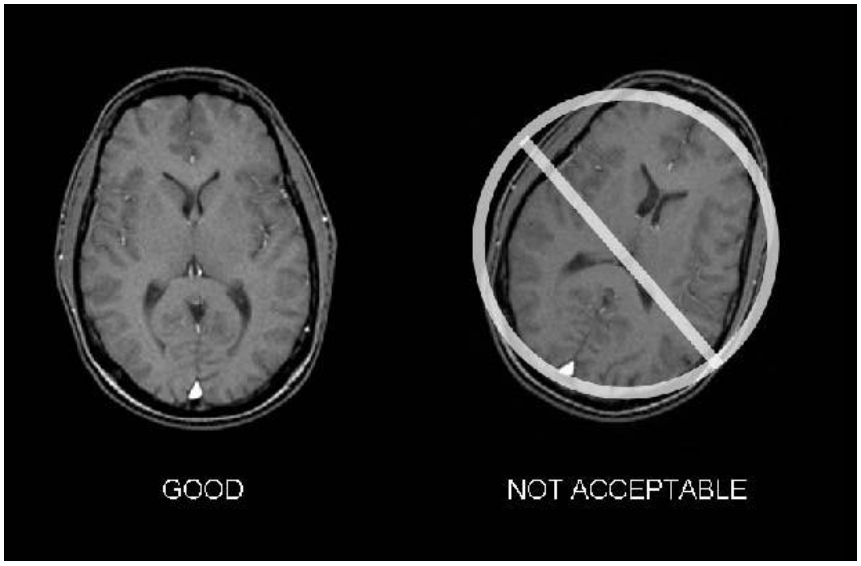
This sequence is a quick acquisition in 3 orthogonal planes for anatomical orientation. Multiple slices acquired in the middle of each plane (sagittal, coronal, transverse). The head should be centered laterally along the inter-hemispheric fissure and centered on the thalamus for the anterior/posterior and superior/inferior planes. Please use the images below as reference when determining if the subject is positioned properly.

Proper placement in the head coil is crucial because scans are acquired in straight orthogonal planes. (Oblique scans are not allowed).

If the subject is not positioned properly please adjust the subject in the head coil and re-scout. Continue repositioning and scouting until the subject is correctly centered in the head coil.

Box A – Axial image. FOV placed in center to avoid side-to-side wrap. Box B – Sagittal image. FOV placed anterior to avoid nose wrap. Box C – Coronal image. FOV placed to assure top of the brain is covered.

Make sure subject is aligned correctly in the head coil and is not rotated. Their head should be as straight as possible in the coil. Please adjust the subject if necessary.



Please Note:

- It is mandatory that the TRACK-TBI acquisition protocols be used for all sequences at the baseline MRI exam and for all the subsequent MRI visits unless otherwise directed by the coordinating center.
- Failure to use the same sequence at the time of baseline and all subsequent visits will result in the request for a rescan of the subject.
- It is mandatory that the TRACK-TBI qualified scanner be used for all **subjects**. Failure to use the TRACK-TBI qualified scanner will result in the request for a rescan of the subject.

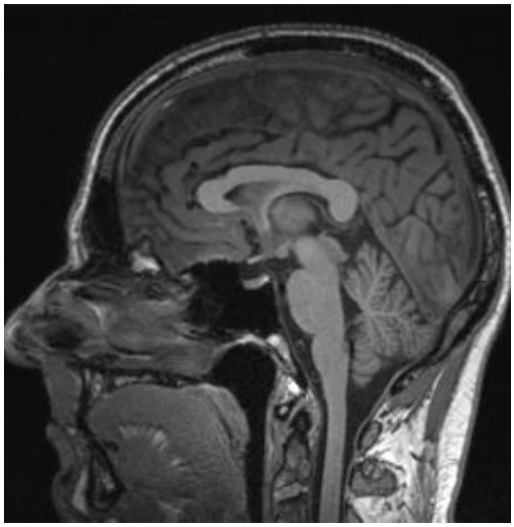
1a) CALIBRATION/REFERENCE SCAN

MRI scanners provide automated adjustment procedures, Calibration/RF coil tuning, and frequency adjustments after the subject is positioned in the magnet. Follow the adjustment procedures provided by your manufacturer.

2) 3D T1 MP-RAGE/IR-SPGR

MP-RAGE = Siemens/Philips – IR-SPGR=GE

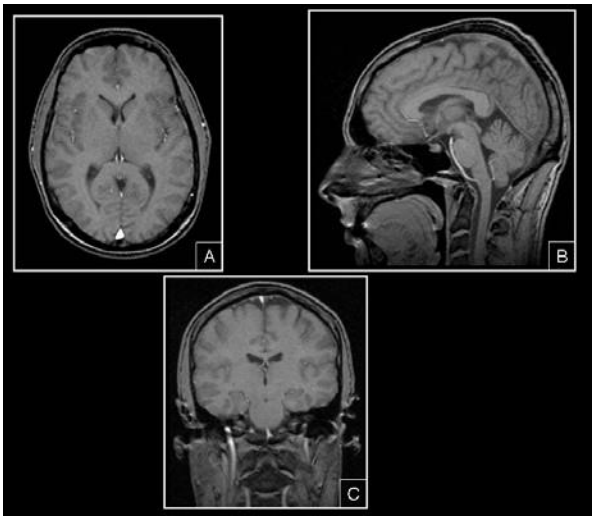
Example:



1. Orientation: **<u>Straight</u>** sagittal. Slices will be prescribed from left to right. ***<u>DO</u>*** ***<u>NOT</u>*** oblique the scanning FOV to compensate for subject held tilt.

2. Positioning: Use the tri-planar scout to position the acquisition box. Make sure to get full head coverage**. Studies that do not contain the whole brain and skull cannot be processed.** The skull must be fully included superiorly and laterally. The entire cerebellum should be included inferiorly. **In the anterior/posterior plane the nose should also be included otherwise image folding into the back of the brain will result and the exam may not be usable for the study**. Please see the images below and use as a guide to correctly position the acquisition box.

Example of 3 Plane Localizer for MP-RAGE FOV Placements



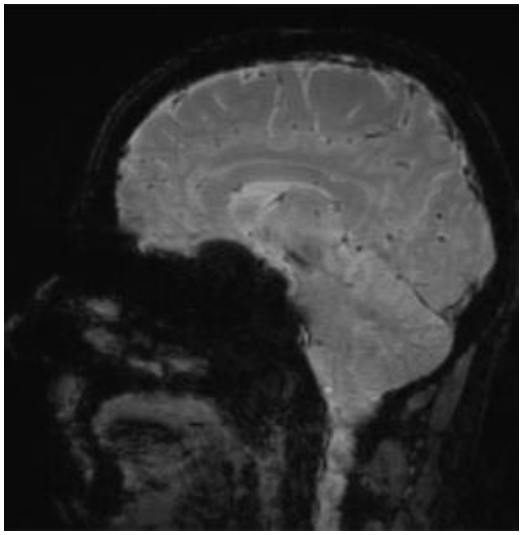
A *– Axial image. FOV placed in center to avoid side-to-side wrap.*

B *– Sagittal image. FOV placed anterior to avoid nose wrap.*

C *– Coronal image. FOV placed to assure top of the brain is covered.*

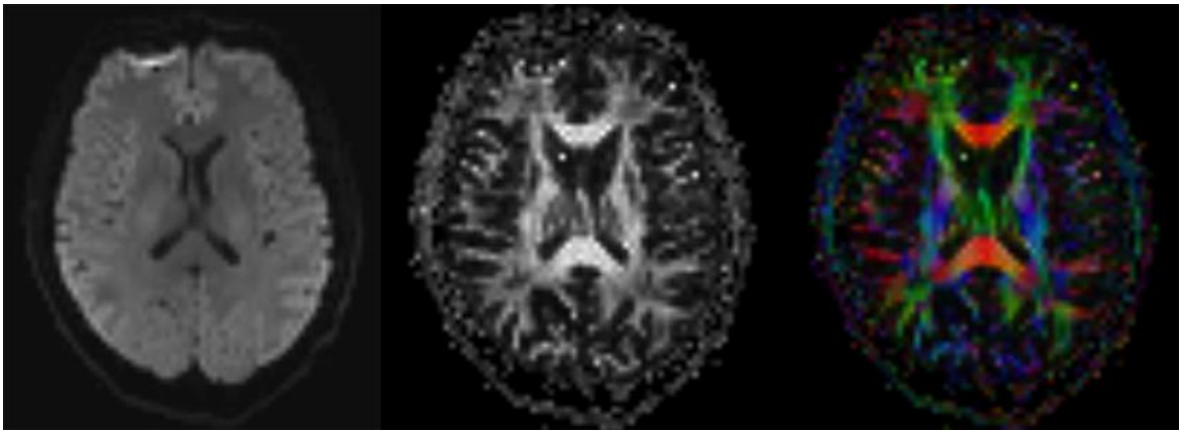
3) Sagittal 3D T2* GRE

Prescribe as shown above for sequence #2 (3D T1 MPRAGE/IR-SPGR)

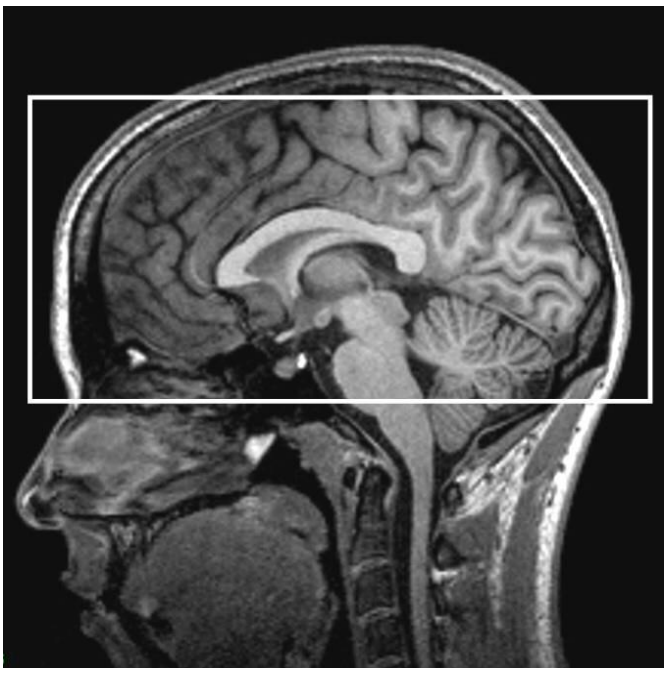


1. Orientation: **Straight** sagittal. Slices will be prescribed from left to right. ***DO NOT*** oblique the scanning FOV to compensate for subject held tilt. Where possible copy offsets and angulations or utilize the same "Geo" to assure consistent positioning.

4) Axial DTI (Diffusion Tensor Imaging)



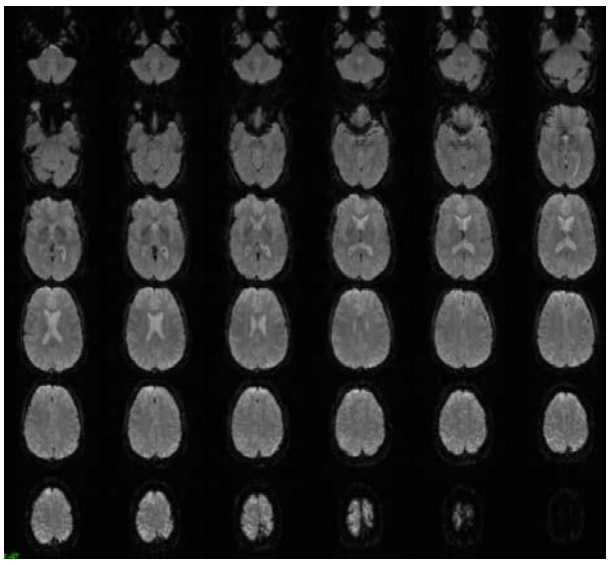
1. Orientation: **Straight** Axial. Prescribe the 3D Slab inferior to superior. ***DO NOT*** oblique the slab to compensate for subject held tilt. Scan as straight axial.



5) Axial Resting State fMRI

Subject should have his/her eyes OPEN

Example: Raw fMRI Images

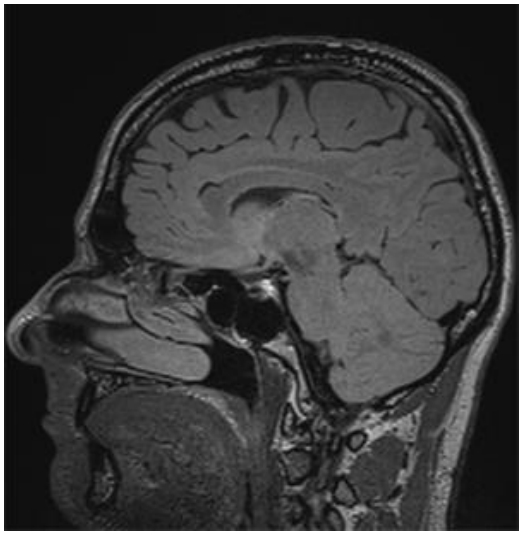


1. Orientation: **Straight** Axial **-- DO NOT** Oblique Scans.

2. Subject Instruction: **Please instruct the subject to keep their eyes open during the entire scan.** You can instruct them to focus on a point on the mirror or scanner. Also remind the subjects of the importance of holding their head still for the entire scan.

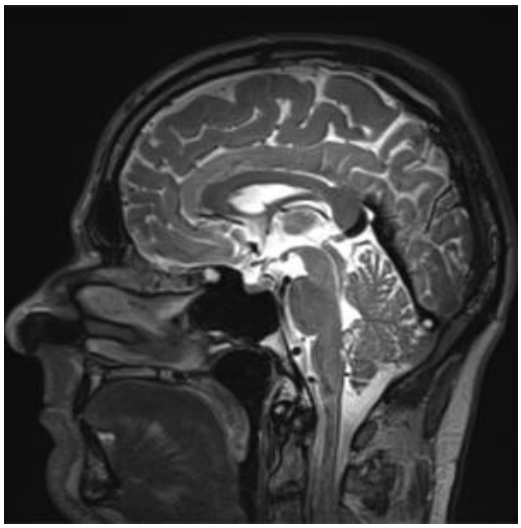
3. Positioning: Position on mid-sagittal slice from tri-planar scout. **The acquisition stack should be placed just above the most superior point in the brain and should cover the cerebellum if possible.**

6) Sagittal 3D T2-FLAIR CUBE/SPACE/VISTA –
Prescribe as shown above for #2 (3D T1 MPRAGE/IR-SPGR)



1. Orientation: **Straight** sagittal. Slices will be prescribed from left to right. ***DO NOT*** oblique the scanning FOV to compensate for subject held tilt. Where possible copy offsets and angulations or utilize the same "Geo" to assure consistent positioning.

7) Sagittal 3D T2 CUBE/SPACE/VISTA –
Prescribe as shown above for #2 (3D T1 MPRAGE/IR-SPGR)



1. Orientation: **Straight** sagittal. Slices will be prescribed from left to right. ***DO NOT*** oblique the scanning FOV to compensate for subject held tilt. Where possible copy offsets and angulations or utilize the same "Geo" to assure consistent positioning.

6. MRI SUBJECT POST-SCAN PROCEDURES

6.1 DATA TRANSFER

Please upload all the sequences acquired to the LONI website as detailed in Appendix 8.

Subject Naming:

TRACK-TBI MRIs of human subjects should follow the naming convention (entered during LONI upload):

XX_NNNN
X=Site#/N=Subject ID#

Site Codes:		
BCM-TIRR	–	01
MGH-Spaulding	–	02
UCSF	–	03
Univ. of Cincinnati	–	04
Univ. of Maryland	–	05
Univ. of Miami	–	06
Univ. of Pittsburgh	–	07
UT Austin	–	08
UT Southwestern	–	09
Univ. of Washington	–	10
VCU	–	11

For example, a 2-week MRI from UCSF should look like:
03_1001

Please see section 7.1 for more detailed instructions on phantom naming

De-identification:

As part of the upload process to LONI, all the identifying information entered into the scanner will be removed and replaced with the information entered during the LONI upload procedure. For this reason, you are encouraged to enter the subject's scan information into the scanner following standard local practice.

6.2 SCAN DISCONTINUATION

If the subject elects to discontinue the MRI because of discomfort, every effort should be made to adjust the table, head coil, etc. and finish acquiring the scan. However, if the subject still does not want to complete the scan, then the MRI should be abandoned and noted as incomplete on the TRACK-TBI MRI Scan Information Form. The comments sections should include the reason the subject was unable to complete the MRI.

6.3 CLINICAL READS

Every subject in the TRACK-TBI Study will receive a clinical read by a board-certified neuroradiologist affiliated with the Neuroimaging Core within 48 hours. The clinical dictation of the read will be transferred to the study coordinator at the referral site.

6.4 ARCHIVE PROCEDURES

Every MRI (both human and phantom) for the TRACK-TBI Study must be archived at the MRI facility following standard local practice in addition to the data transfer to LONI immediately after the MRI scan. Additional data transfers or copies will be requested by the coordinating center in the event that a data transfer is interrupted or incomplete. Possible MRI archive mediums include:

- Optical Disk
- PACS
- CD or DVD

6.5 REQUESTS FOR REPEAT MRI SCANS

Reasons Repeat MRI May Be Requested:

A request for a repeat MRI may be required in the event that the scans are found to be unacceptable due to subject motion or an incomplete MRI acquisition. Your site will be asked to schedule a repeat study.

QA will check all TRACK-TBI scans for protocol compliance. Repeat exams may also be required if the incorrect scan sequence, orientation, or angulations are used. It is imperative to use the TRACK-TBI approved acquisition sequence with every TRACK TBI subject. Scans with image degradation due to the incorrect scan sequence, orientation, or angulations will **NOT** be reimbursed. Re- scans will be reimbursed if the correct scan sequence, orientation, and angulations were used.

Procedures for MRI Repeats:

Repeat MRI scans should be performed as quickly as possible. The coordinating center for the TRACK-TBI Study will contact the referral site as well as the MRI facility requesting a repeat MRI. Detailed information regarding the reason for the repeat as well as suggestions for improvement will be communicated to both sites.

7. ON GOING QUALITY CONTROL AND PHANTOM SCANNING INSTRUCTIONS

To ensure scanner stability and scan quality throughout the TRACK TBI Study, each site is **required** to perform *on going* quality control scans. A regular time should be reserved on a monthly basis for acquiring TRACK TBI QA data. The QA program utilizes the ADNI (SNR, structural), BIRN (temporal stability) and NIST (diffusion accuracy) phantoms. QA protocols are defined for each of the phantoms: ADNI = MP-RAGE/IR-SPGR; BIRN = fMRI scan used for subjects; and NIST = multiple b-value diffusion. The NIST phantom is presently only available as a prototype and its inclusion is anticipated to begin in the second half of 2014. QA must be performed every month whether or not a TRACK TBI patient was scanned on the magnet during that month.

IMPORTANT: If a site fails to maintain a monthly QA program, TRACK-TBI will not reimburse for subject scans until the QA program is brought up to date.

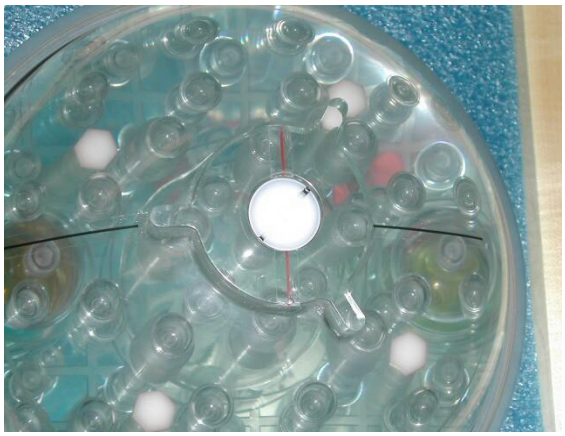
7.1 ADNI PHANTOM SCAN INSTRUCTIONS

ADNI Phantom Positioning:

The following image shows the ADNI phantom placed in the appropriate position within the coil to be used for TRACK TBI subjects. Achieving a reproducible position is a key element to the system performance analysis that will be conducted on a monthly basis. The phantom should be placed in the coil with the alignment markers facing upward and the serial number SN XXXX positioned out of the bore as shown, along with alignment guides, will facilitate the reproducible positioning of your phantom.

ADNI phantom shown positioned inside of an 8-channel head coil.

Please note that your phantom has a base and positioning markers (in black and red, see image below). The phantom should be placed inside the head coil with the indicated “top” facing upwards. This orientation is due to space constraints within some coils and we would like to maintain a consistent orientation for all scanners across the TRACK-TBI study. Please inspect the phantom and note the additional marks added to help you position your phantom. We have indicated the top of the phantom with red and black marks to aid with placement in the coil.



The top of the phantom and the alignment lines are indicated above. These markings should be used with the alignment lights on your scanner to position the phantom.

Please place the phantom in your head coil with the alignment marks facing up, with the phantom SN number (e.g. 9996) facing you, out of the bore (see the following picture). Furthermore, try to align the center of the phantom with the center of the coil. Use the alignment lights on your scanner to position the phantom into the center of the magnet.

The phantom is shown in the correct position, with the Serial Number (SN 9999) positioned forward and reading correctly from right to left. This will be the typical scanning position for your phantom.

ADNI Phantom QA Scan Protocol:

For on-going quality control and post processing image analysis, each site must scan the specially designed ADNI phantom using the electronically loaded TRACK-TBI QA protocols **on a monthly basis.** Always use the RF coil that you are using in patient studies.

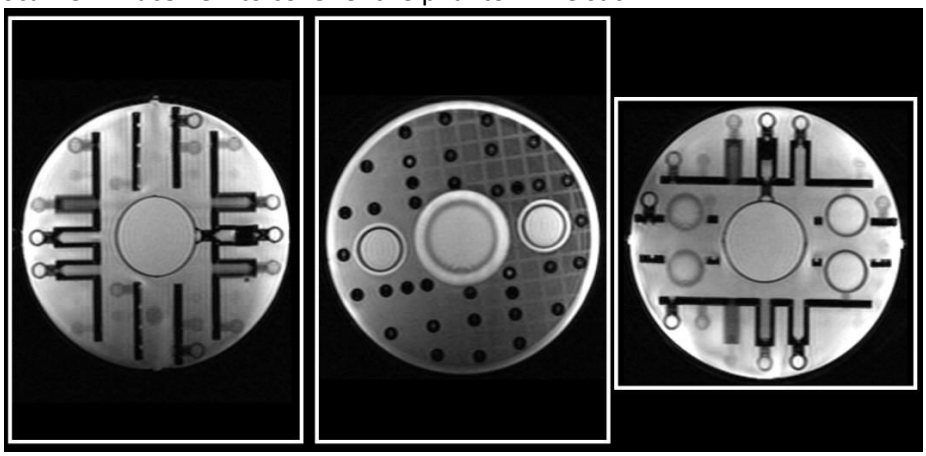
NAMING CONVENTION: Please use the following patient ID for all QA studies: XX_9999, where XX is your site ID.

ADNI Phantom Scan Protocol *(performed monthly)*:
1) Localizer
1a) Calibration/Reference Scan (if applicable)
2) QA Phantom MP-RAGE/IR-SPGR

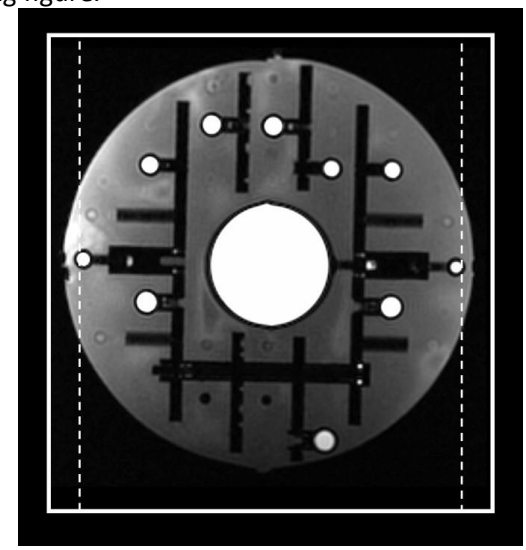
Transfer data to ImageOwl (see Appendix 6, LONI will not analyze this data)

ADNI Phantom Setup Procedure:
When performing the monthly QA procedure, register the phantom as a new exam with the naming convention indicated above.

1) Localizer
3 Plane Localizer. Place FOV to cover entire phantom like such:



2) QA Phantom MP-RAGE/IR-SPGR
The on-going quality control scans are identical to the subject 3D scans except the field of view and slice thickness have been increased to ensure that the phantom has been covered completely. Please refer to the following figure.



Note that the dotted line shows original slice thickness of 1.2 and solid line represents thickness of 1.3, which is adequate for covering entire phantom.

Please see **Appendix 6** for instructions on how to transfer ADNI Phantom data via ImageOwl.

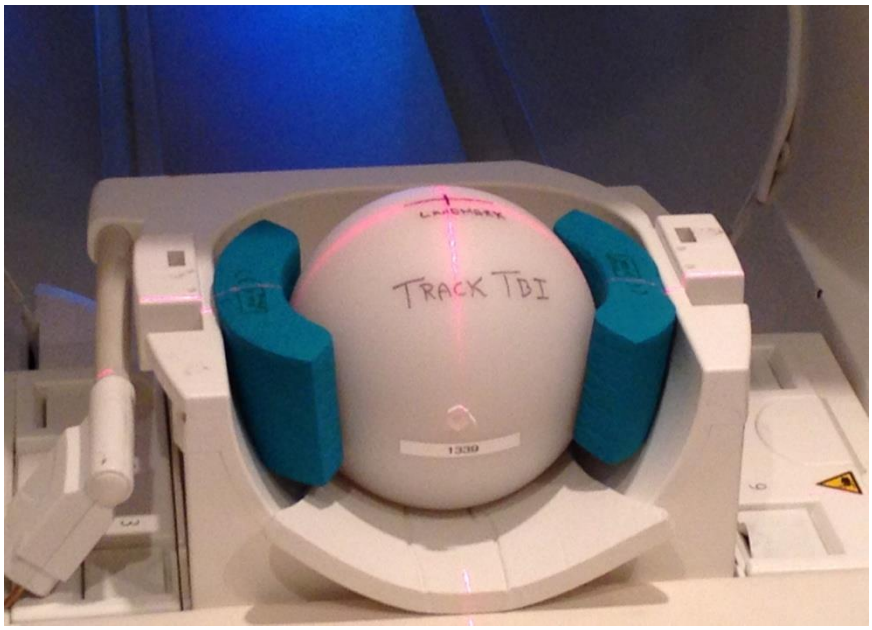
7.2 BIRN PHANTOM SCAN INSTRUCTIONS

BIRN Phantom Scan Protocol *(performed monthly OR following any system changes)*:
1) Localizer
1a) Calibration/Reference Scan (if applicable))
2) QA BIRN Phantom fMRI

Transfer data to LONI (Appendix 8, **do NOT** send to ImageOwl)

BIRN Phantom Setup Procedure:

Always use the RF coil that you are using in patient studies and run the resting state fMRI acquisition. It is important that you utilize the same set-up each time that you acquire quality control images of the phantom. Orient the phantom such that the plug is in the inferior position and make a crosshair mark to denote the point that will always be anterior in the images (see figure below). Place the BIRN phantom in center of the coil in a reproducible fashion. Landmark at the center of the phantom/coil and send to isocenter. When prescribing the sequence, make sure you prescribe no angulations and ideally always use the same Y (A-P) offset.



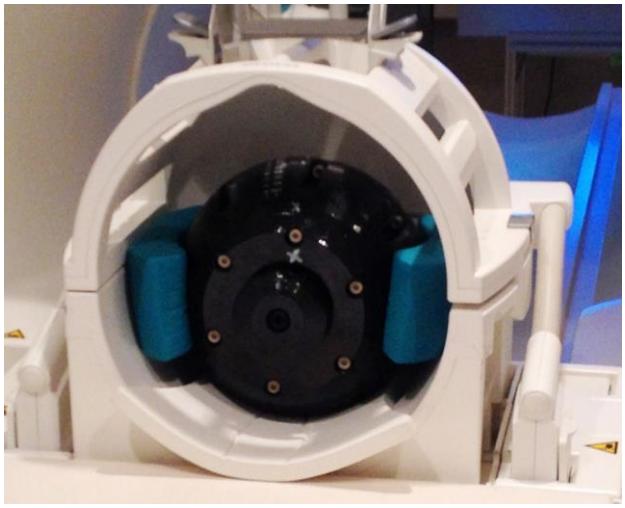
The BIRN phantom is shown with the plug oriented inferiorly and with a crosshair marked on the point that will be anterior for all QA studies.

7.3 NIST PHANTOM SCAN INSTRUCTIONS

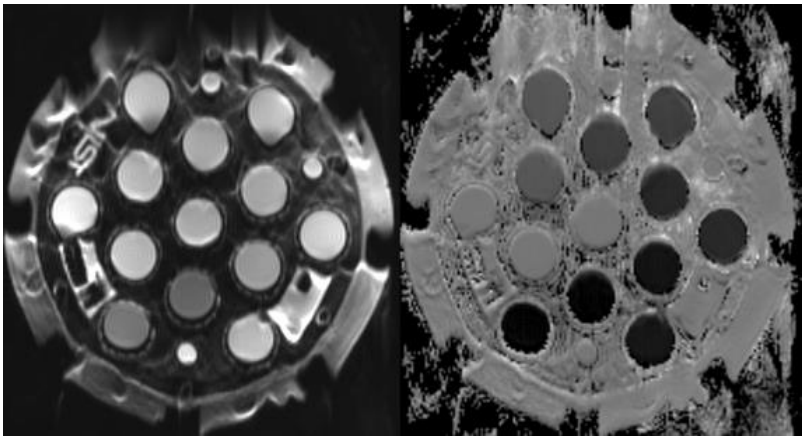
Diffusion Phantom Scan Protocol *(Schedule TBD, pending phantom availability)*:
1) Localizer
1a) Calibration/Reference Scan
2) QA Diffusion Phantom multiple b-value Scan

Transfer data to LONI (Appendix 8, **do NOT** send to ImageOwl)

Diffusion Phantom Setup Procedure:
It is important to prepare the ice water phantom prior to performing the QA scans (see **Appendix 7**). The phantom should be positioned such that its central plane is oriented axially and a mark should be placed on it to indicate the anterior side (to landmark to) and inferior sides (see X in photo).



Prescribe axial slices and it is acceptable to oblique these slices to the central plane of the phantom. This assures that the vials within the phantom are cut cross-sectionally.



Diffusion weighted (left) and ADC (right) images of the NIST ice water diffusion phantom are shown. The scan plane should be obliqued to the plane of the vials within the phantom to assure a cross-sectional view of the phantom is achieved.

Phantom Storage:
Due to its small base, please store your ADNI phantom in the wooden box that it came in. This will ensure that the phantom does not roll of its base and fall when it is not being used.

The BIRN and (when available) NIST phantoms should be labeled as "TRACK TBI" and stored in a safe location that is not exposed to heat or direct sunlight.

De-identification:
As part of the upload process to LONI, all the information entered into the scanner will be removed and replaced with the information entered during the LONI upload procedure. Thus, it is not mandatory to follow the naming convention on the scanner. However, since some data is sent to ImageOwl it is advantageous for all data to have consistent naming. For this reason, we encourage you to use the same name for the acquisition as you will input when uploading to LONI.

7.4 DATA TRANSFER
Each site must send the phantom data (along with all subject data) to LONI (Appendix 8) **within 24 hours** after the completion of the scan. Additionally, the ADNI phantom MP-RAGE/IR-SPGR must be uploaded to ImageOwl (Appendix 6) also **within 24 hours**.

7.5 MEASUREMENTS
The Neuroimaging Core will perform the following on the phantom data: Gradient Linearity Measurements, Signal to Noise measurements, Image contrast, Inhomogeneity, and RF Power measurements.

7.6 PHANTOM RESULTS
The Neuroimaging Core will examine each phantom data set to ensure that there are no underlying problems with the scanning session, and that the scanner has not drifted out of specification. When finished, if there is an issue that needs to be addressed, an email will be sent to your site notifying you of the problem.

8. APPENDICES

8.1 APPENDIX 1—EXAMPLE OF MRI SCREENING FORM

UCSF Medical Center

UCSF Benioff Children's Hospital

UNIT NUMBER

PT. NAME

BIRTHDATE

LOCATION DATE

MRI SCREENING

You have been scheduled for an MRI exam. The MRI scanner uses extremely strong magnetic fields that can produce heating, movement, or electric currents in ANY metal in or on your body. WARNING: This can be hazardous to you, if you have certain metal objects in or on you. Please complete this accurately and carefully.
(Please circle **Yes/No** responses)

1. **Do you have any metal or possibly metal containing objects in or on your body?** Yes / No

If yes, check box and give details _____

☐ Aneurysm clip	☐ Shunt (programmable) ☐ non-programmable
☐ Cardiac pacemaker	☐ Feeding tube with mercury tip
☐ Implanted cardioverter defibrillator (ICD)	☐ Radiation seeds or implants
☐ Electronic implant or device	☐ Medication patch
☐ Magnetic stent, filter, or coil	☐ Any metallic fragment or foreign body
☐ Neurostimulator, deep brain stimulator	☐ Breast tissue expander
☐ Spinal cord stimulator	☐ Surgical staples, clips
☐ Internal electrodes or wires	☐ Bone/joint pin, screw, nail, wire, plate
☐ Bone growth/bone fusion stimulator	☐ IUD, diaphragm, or pessary
☐ Cochlear, otologic, or other ear implant	☐ Dentures, partial plates, or braces
☐ Insulin or other infusion pump	☐ Permanent makeup or eyeliner
☐ Implanted drug infusion device	☐ Body piercing jewelry
☐ Prosthesis of any kind(eye, penile, etc.)	☐ Eye lid spring or wire
☐ Heart valve prosthesis	☐ Temperature probe
☐ Artificial or prosthetic limb	☐ Hearing aid (remove prior to entry)

2. Have you had an injury to the eye involving a metallic object or fragment? Yes / No
3. Have you ever been injured by a metallic object or foreign body (e.g. BB, bullet, shrapnel)? Yes / No
4. List any past surgeries/Date: _____

Height_____ Weight_____

To be completed for patients who may receive MRI CONTRAST (GADOLINIUM)

5. Have you ever had a previous reaction with intravenous contrast ("x-ray dye")? Yes / No
   If yes, give details:_____
6. Have you ever had a life-threatening allergic reaction? Yes / No
   If yes, give details:_____
7. Are you 60 years of age or older? Yes / No
8. Do you take medication for diabetes? Yes / No
9. Do you take medication for high blood pressure? Yes / No
10. Do you suffer from kidney disease? Yes / No
11. Does anyone in your family suffer from kidney disease? Yes / No
12. Do you have only one kidney or a kidney transplant? Yes / No
13. Do you have any other organ transplant? Yes / No
14. Do you have multiple myeloma? Yes / No
15. Do you have end-stage liver disease/need a liver transplant? Yes / No

eGFR (To be completed by RN or technologist)

"Yes" answers to Q7-15, enter eGFR within 6 weeks.

"No" answers: if eGFR is available, enter it below.

Level: _____ (mL/min/173mL^2)

Date: ____ /____ /_____*

< 60

≥ 60 or not needed

16. **FOR WOMEN:** Is there any possibility that you may be pregnant? Yes / No

Yes

No

Please sign below to confirm that you have received, read, and understood the "Frequently Asked Questions about MRI exams". A physician is available to answer any further questions you may have.

STOP — Consult with Radiologist

GO — Proceed per protocol

Form completed by: _____

Signature of Patient/parent/guardian:_____

Signature of RN or Technologist:_____ Date: _____ Time: _____

500-0250 (Rev. 03/12) WorkflowOne MEDICAL RECORD COPY

MRI SCREENING

INSTRUCTIONS FOR RADIOLOGY RN OR RT

YES answers to questions 7-16 and no recent eGFR available:
Proceed with an immediate Cr/eGFR test at the direction of the protocoling physician.

STOP - If there are ANY circles in the STOP column, further consultation with a supervising radiologist is required before administration of contrast. Nursing and technical staff should consult with a supervising radiologist for further instructions. Proceed only when the order for this examination has been reviewed, and is updated by the supervising radiologist in ImageCast.

GO - If ALL the circled responses are in the GO column: PROCEED with contrast administration as per the contingent order in ImageCast. This order is now final, and the electronic signature of the protocoling physician in conjunction with this form attests that the administration of contrast material has been reconciled with the patient's current medication.

Before entering the MRI environment or MRI system room, you must remove *all* metallic objects including hearing aids, dentures, partial plates, keys, beeper, cell phone, eyeglasses, hair pins, barrettes, jewelry, body piercing jewelry, watch, safety pins, paper clips, money clip, credit cards, bank cards, magnetic strip cards, coins, pens, pocket knife, nail clipper, tools, clothing with metal fasteners and clothing with metallic threads.

Please consult the staff if you have any questions or concerns BEFORE you enter the MRI system room.

Filled out by staff:

1. Patient Screened for MRI contraindications? ☐ Yes ☐ No
2. Patient and Table Top Checked? ☐ Yes ☐ No
3. Staff Physicians Safety Trained? ☐ Yes ☐ No
4. Staff/Physicians Removed Metallic Objects? ☐ Yes ☐ No
5. Final verification/ "time-out" is performed by the team prior to entry into the magnet, including patient screening form, and all equipment checked for MRI safety or compatibility. ☐ Yes ☐ No

8.2 APPENDIX 2—MRI SCAN INFORMATION FORM

Please follow instructions listed in section 5.1

Subject ID: _____

TRACK-TBI

Transforming Research and Clinical Knowledge in Traumatic Brain Injury

International Traumatic Brain Injury Research Initiative

MRI Scan Information Log

To be completed by Study Coordinator (SC) or Research Associate (RA):

Site Name: _____
SC/RA Name: _____
SC/RA Phone: ( ) ____-_____
Anticipated Date of MRI: ___/___/_____

MRI Operator Initials: _____ Date of MRI: ___/___/_____

Please follow instructions in the TRACK-TBI 3T MRI Technical Procedures Manual

1. Localizer
Check participant positioning in the head coil. Re-position and re-scout, if necessary

Comments

Localizer Completed?

○ Yes
○ No

---

2. Sagittal 3D T1 MP-RAGE/IR-SPGR

Position the acquisition box to contain the whole brain and skull. Studies without full brain coverage cannot be processed.

Comments

Sagittal 3D T1 MP-RAGE/IR-SPGR Completed?

- ○ Yes
- ○ No

---

3. Sagittal 3D T2* GRE/SWAN/SWI

Orientation is Straight Axial. Prescribe slices inferior to superior. Do NOT oblique the scanning slices to compensate for subject held tilt. Scan as Straight Axial. If extra transverse slices are required to achieve this coverage please acquire those slices.

Comments

Sagitaal 3D T2* GRE/SWAN/SWI Completed?

- ○ Yes
- ○ No

---

4. Axial DTI

Orientation is Straight Axial. Prescribe the 3D Slab inferior to superior. Do NOT oblique the slab to compensate for subject held tilt. Scan as Straight Axial.

Comments

Axial DTI Completed?

- ○ Yes
- ○ No

---

5. Resting State fMRI

Orientation is Straight Axial. Do NOT oblique scans. Positioning: Position on mid-sagittal slice from tri-planar scout. The acquisition stack should be placed just above the most superior point in the brain and should cover the cerebellum if possible.

Subject Instruction: Please instruct the subject to keep their eyes open during the entire scan. You can instruct them to focus on a point on the mirror or scanner. Also remind the subjects of the importance of holding their head still for the entire scan.

Comments

Resting State fMRI Completed?

- ○ Yes
- ○ No

---

6. Sagittal 3D T2-FLAIR CUBE/ SPACE/VISTA

Orientation: Reproduce the positioning and coverage used for the MP-RAGE/IR-SPGR sequence obtained in item 2.

Comments

Sagittal 3D T2-FLAIR CUBE/SPACE/VISTA Completed?

- ○ Yes
- ○ No

---

7. Sagittal 3D T2-TSE

Orientation: Reproduce the positioning and coverage used for the MP-RAGE/IR-SPGR sequence obtained in item 2.

Comments

Sagittal 3D T2-TSE Completed?

○ Yes
○ No

---

8. QC ADNI Phantom Protocol (completed in a new exam)

First, run Localizer sequence to be sure the phantom is positioned correctly in the head coil.

Next, run QC Phantom Sagittal MP-RAGE/IR-SPGR. This is identical to the subject 3D scans except the slice thickness has been increased to ensure that the phantom has been covered completely.

Comments

QC ADNI Phantom Protocol Completed?

○ Yes
○ No

Date of MRI Transfer to LONI: ___/___/_____

Transfer to LONI completed within 24 hours of MRI scan?

○ Yes
○ No

Is the data archived locally? (if No, please explain in Comments section below)

○ Yes (archive medium) _____
○ No

Comments

8.3 APPENDIX 3—MRI ACQUISITION SUMMARY

Please Note: Your TRACK-TBI protocols will be loaded as part of the site certification process). This will ensure that you have the correct protocol for your MRI scanner. If you have any questions about this procedure please contact: **alastair.martin@ucsf.edu**

Use only the provided TRACK TBI sequences

TRACK-TBI QA Phantom Scan Protocol:

ADNI Phantom (Structural Integrity):

1) Localizer
1a) Calibration/Reference Scan (if applicable)
2) QA ADNI Phantom MP-RAGE/IR-SPGR

BIRN Phantom (Temporal Stability):

3) Localizer
3a) Calibration/Reference Scan
4) QA BIRN Phantom fMRI

Diffusion Phantom (Gradient Accuracy):

5) Localizer
5a) Calibration/Reference Scan
6) QA Diffusion Phantom multiple b-factor

TRACK-TBI 3T Human Protocol:

(All scans are performed in straight orthogonal planes -- Sagittal or Axial)
(No manual adjustments should be made to this protocol)

1) Localizer
1a) Calibration/Reference Scan
2) Sagittal 3D T1 MPRAGE/IR-SPGR
3) Sagittal 3D T2* GRE
4) Axial DTI or HDFT
5) Axial Resting State fMRI - Subjects should have eyes OPEN.
6) Sagittal 3D T2-FLAIR (CUBE/SPACE/VISTA)
7) Sagittal 3D T2 (CUBE/SPACE/VISTA)

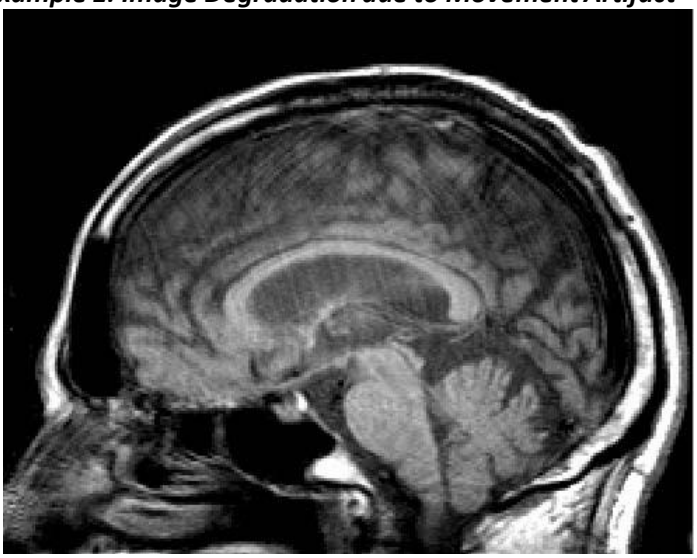
8.4 APPENDIX 4—TRACK-TBI ACQUISITION TROUBLESHOOTING GUIDE

Superior image quality is imperative to the success of the TRACK-TBI Study. Every effort should be made to acquire excellent scans on TRACK-TBI subjects at their first MRI appointment and at all subsequent visits. This prevents the clinical centers from rescheduling additional repeat MRI's for study subjects.

It should also be noted that the sequences are performed in their order of importance to the study. Please do not alter the order of the protocols.

Please use the following reference as a guide for identifying and remedying inferior image quality, image artifacts, and subject issues that may degrade image quality. Also, please contact **pratik.mukherjee@ucsf.edu** for specific questions or concerns outside the scope of this manual.

Example 1: Image Degradation due to Movement Artifact



Problem:

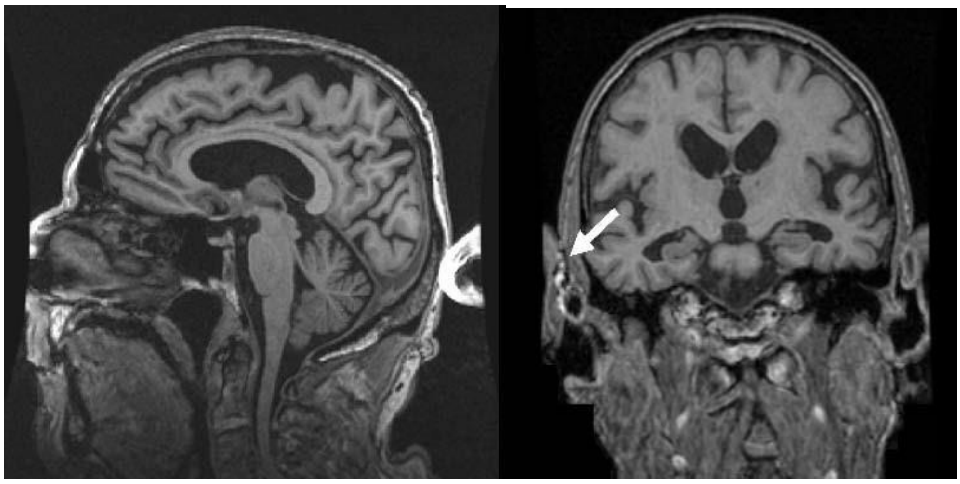
In this example movement has caused motion artifacts. Acquisitions with major motion artifacts will not be accepted and a repeat scan may be requested.

Possible Remedies:

If movement is due to the subject's head moving, reacquire MP-RAGE/IR-SPGR after tightly securing the subject's head with additional restraints and discussions with subject to hold their head still.

If the subject is not moving it is possible the artifact is the result of mechanical problems. Please discuss with your service engineer.

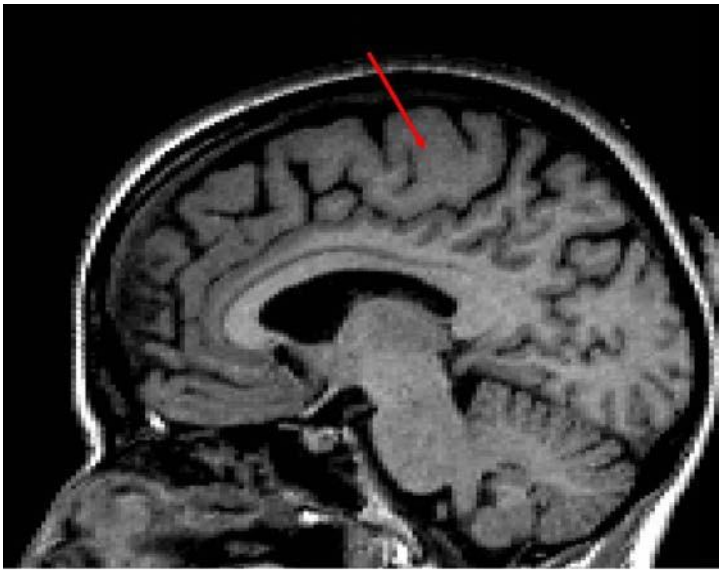
Example 2: Wrap Around



Problem:
In this example, wrap around occurs in the MP-RAGE/IR-SPGR image above. In the figure on the left, the nose folds into the back of the skull. In the figure on the right, the ear wraps into the side of the skull. Acquisitions with wrap around artifacts will not be accepted and a repeat scan will be requested.

Possible Remedy:
Wrap around generally occurs when the subject's head size is larger than the acquisition box. Please try to position the acquisition box so that the wrap can be avoided.

Example 3: Signal Loss at the Top of the Brain



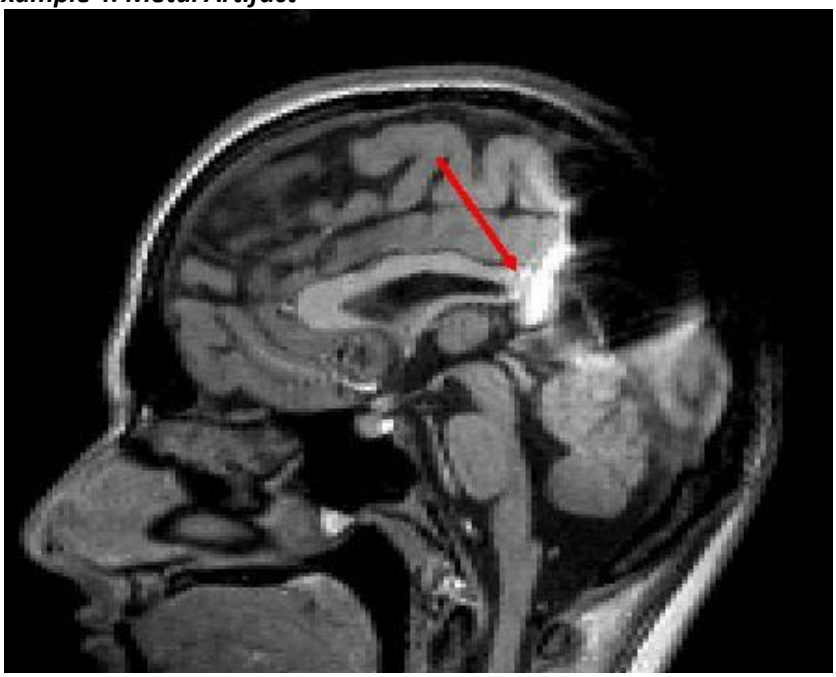
Problem:
In this example, the image has a loss of signal at the top of the brain due to incorrect positioning in the head coil. The subject was placed too high in the coil. Please note the lack of contrast between gray and white matter at the top of the brain only. Acquisitions with signal loss, especially due to incorrect positioning, will not be accepted and a repeat scan will be requested.

Possible Remedies:

1. Check to be sure subject is positioned correctly in the head coil. Please see "Subject Positioning" for information on positioning.

2. Make sure head coil is properly secured.

Example 4: Metal Artifact



Problem:

Magnetic field distortions: In this example there is a signal void due to the presence of metal near the subject's head. Acquisitions with metal artifact will not be accepted any circumstances and a repeat scan will be requested.

Possible Remedy:

Make sure the subject is not wearing any metal. Check for hair clips, metallic makeup (i.e. permanent eyeliner), necklace, safety pins, removable dentures, and facial jewelry. Remove metal and rescan.

8.5 APPENDIX 5—FREQUENTLY ASKED QUESTIONS

Q – My subjects head is tilted quite a bit. Can I oblique the scans then?
A – No, do not oblique the scans, we can deal with the subjects head being tilted more easily than we can with scans that were acquired obliquely.

Q – I forgot to put the marker on the subject. Do we need to rescan?
A – No, that will not be a reason for re-scan, please just try to remember next time.

Q – What is the ADNI phantom filled with?
A – Mostly distilled water and some anti mold ingredients. If you notice your water level is getting low, please top off with distilled water. Distilled water acts differently when imaged than tap water, so please make sure you are using distilled water.

Q – Can I scan the phantom in the same exam as the subject?
A – No please, start a new exam and name the phantom with the correct ID. The phantom scans are handled differently than the subject scans. Starting a new exam gives that study a different unique identifier (UID) thus much easier to upload separately and store separately.

Q – I noticed some wrap on my image. Should I increase the FOV to compensate?
A – No, unless the wrap is affecting brain tissue you do not need to re-scan. If the wrap is affecting brain tissue please try to place the FOV to avoid wrap if possible.

Q – Should I append this scan to the previous scan in the PACS system.
A – Please do not append the sessions, it causes the exams all to have the same UID.

Q – Do I need to have the subject remove their dentures?
A – Yes, please have all your subjects remove their dentures to avoid artifact.

Q – I am having trouble with upload data to LONI, who do I contact?
A - TBD

Q – The exam was already sent to LONI, do we need to keep a copy of it?
A – Yes, please keep a copy of all human AND QA phantom scans your site performs.

Q – Our scanner was upgraded, do I need to re-certify?
A – If it was a major upgrade (both software and hardware) the answer is yes. However, many minor upgrades do not need a full re-certification scan, just a phantom scan. In that case, we may just ask you run the QA phantom scans to make sure system performance has been maintained.

8.6 APPENDIX 6—DATA TRANSFER TO ImageOwl

The MP-RAGE/IR-SPGR images of the ADNI phantom should be uploaded to the ImageOwl web server. You may need to export the images in DICOM format to a computer with internet access to do this.

Instructions for the ImageOwl Service:
Go to: http://qcc.imageowl.com/home/

- Enter your login name and password (see below)
- Click the "Upload phantom images"
- Select the appropriate post ("TRACK-TBI -> YOURSITE -> YOURSITE QA") and hit "Select"

On the next page "Add files" and browse to locate the DICOM files; select ***ONLY*** the DICOM image files for the MP-RAGE scan and then hit "Open"; the files should now be listed in the "Upload Phantom Images" window; select "Start Upload" and the system will begin transferring images (this typically takes a few minutes). Once done hit "Continue" and, on the next page, hit "Finish Upload".

Once the data has been uploaded, the software will automatically analyze them. This will also take several minutes and the software will notify you of its progress (yellow dot eventually appears during processing). Once the analysis is complete a green dot will appear and you can navigate to the results by clicking on the "Study" link to the right of the green dot. This will show you the measured parameters and whether or not they are within our set specifications. You can view how these parameters change over time by selecting the "Show Plot" tab from this page, selecting a date range, select the parameters you want to track (there is a "Select All" box at the bottom) and then hitting the "Submit" button at the bottom of the page.

Institution:	ImageOwl Username:
University of California, San Francisco	UCSFTRACK
University of Pittsburgh	UPittTRACK
Baylor College of Medicine	BaylorTRACK
Harvard Medical School	HarvardTRACK
University of Cincinnati	UCincTRACK
University of Maryland	UMdTRACK
University of Washington	UWTRACK
University of Miami	MiamiTRACK
University of Texas Southwestern	UTSWTRACK
Seton Brain & Spinal Institute – Austin	SetonTRACK

The default password is ***tbi.*** Each site can choose to change this, as desired.

8.7 APPENDIX 7—NIST Phantom Preparation

Diffusion is a thermally-dependent process: as temperature increases, the apparent diffusion coefficients of the phantom solutions will also increase. While this increase is small for the most viscous solution of PVP (50 %), the increase is on the order of 1 % per degree Celsius for DI water. It is therefore critical that temperature be consistent when scanning the phantom, a goal best achieved by use of ice water. Please use the following procedure to equilibrate the phantom at 0 °C, and maintain temperature during the scan.

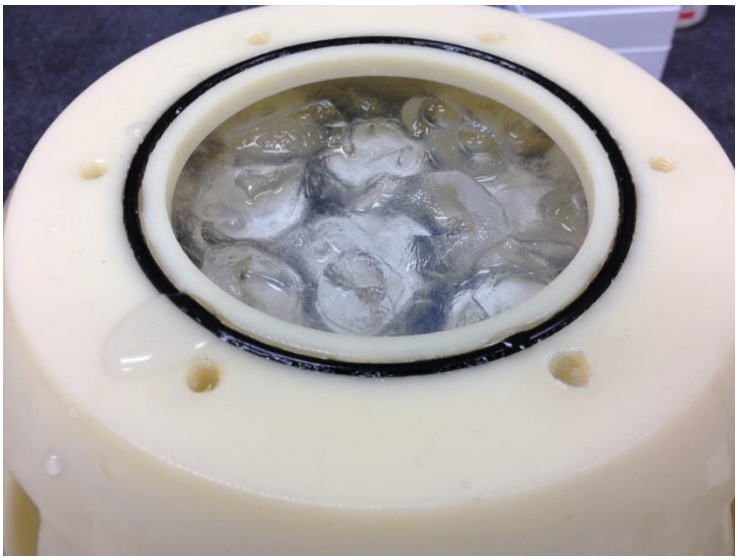
1. The evening before the day of the scan, begin by obtaining ice and crushing it as finely as possible. This may be done with a rubber mallet, or even a blender. To gauge how much ice is needed, the phantom has a free volume of just under 4 L.

2. Remove the bottom fill port cap. Pack ice in and around the vials as tightly as possible. Make sure to push ice underneath the lip of the bottom hemisphere to fill the bottom half of the phantom as much as possible. Close the bottom-fill port, *making sure to not over torque the PEEK screws*, using the included non-magnetic 4 mm Allen wrench.

3. Remove the top fill port cap, and repeat the ice filling procedure from above. Do not replace the cap yet.

4. When the top half of the phantom is as full of ice as is possible, add cold DI water to the phantom to the top of the upper hemisphere. **There should be more ice than water to ensure a proper ice water bath at 0 °C. The ice should not float; instead, water should fill the interstitial spaces formed by the ice.**

5. Replace the top fill port cap, and place the phantom into a 4 °C sample refrigerator. Take care to not over-tighten the PEEK screws, as the ABS material is soft, and damage may occur to the threads. Take special care with the two darker threaded inserts, as over-tightening may cause these inserts to pull away from the body of the phantom. Leave the phantom in the refrigerator overnight.



6. The next morning, remove the phantom from the refrigerator. Some of the ice will have melted, but there should be some still in the phantom (Figure 3). This does not mean that the phantom is at 0 °C. More ice will need to be added. Remove the bottom fill port cap.

Do not dump the water, but add more crushed ice in order, displacing the water. Add enough ice to have a proper bath, where the ice does not float and water fills the interstitial spaces.

7. Flip the phantom right-side up and repeat step 6 for the top half of the phantom.

8. In order to eliminate residual air bubbles in the phantom, one may add water to the phantom via the secondary fill ports. These ports are the M-8 black screws located in the handle of the top and bottom fill port caps (Figure 4). If a large enough Philips-head screwdriver is unavailable, utilize a large standard screwdriver: the M-8 screw is made of nylon, and the head can strip if over-tightened. Create an ice water bath (as described above) in a medium-sized beaker. Use the liquid water from this beaker to top off the phantom via the secondary fill ports.

Figure 2- Assembled phantom. The top secondary fill port is closed by the black screw in the middle of the handle of the top fill port cap.

9. Before closing off the phantom's secondary fill ports, check the temperature of the phantom using the provided thermocouple probe. It is a good idea to check both halves of the phantom, and to record these values.

8.8 APPENDIX 8—DATA TRANSFER TO LONI

INTRODUCTION

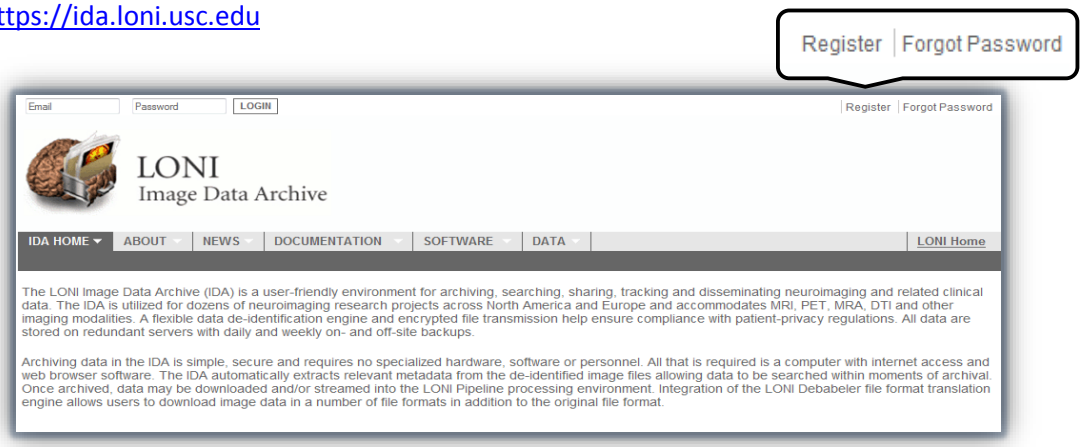
Neuroimaging data collected for the TRACK-TBI study will be sent to the Laboratory of Neuro Imaging's Image & Data Archive (IDA) which utilizes a data de-identification engine and encrypted file transmission to help ensure compliance with subject-privacy regulations.

SYSTEM REQUREMENTS

The IDA system requires a computer with Internet access, newer web browser software (IE, Netscape, Mozilla, Safari, Chrome), Sun/Oracle Java Plug-in version 1.5 or higher, and a valid user account.

USER REGISTRATION

1. If you do not have a user account, **CLICK** REGISTER on the Image & Data Archive Log-In page at https://ida.loni.usc.edu



2. Complete the New Account form and click the REGISTER button. A confirmation email will be sent to your email address with instructions for setting your password. NOTE: You will be unable to access and upload data until completion of step 3.
3. Email dba@loni.usc.edu to request upload access. Be sure to include the name of your TRACK-TBI site and the name of the site PI.

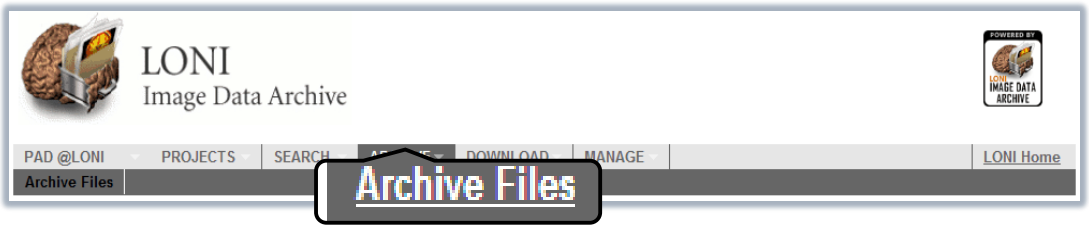
ARCHIVING (UPLOADING) MRI SCANS

PREREQUISITES

- Image files for each subject should be within a single directory (may contain subdirectories). The source directory must not contain multiple image formats.
- Create an empty directory where the de-identified files will be written (**target directory**). This directory may be removed after the data is successfully transferred.

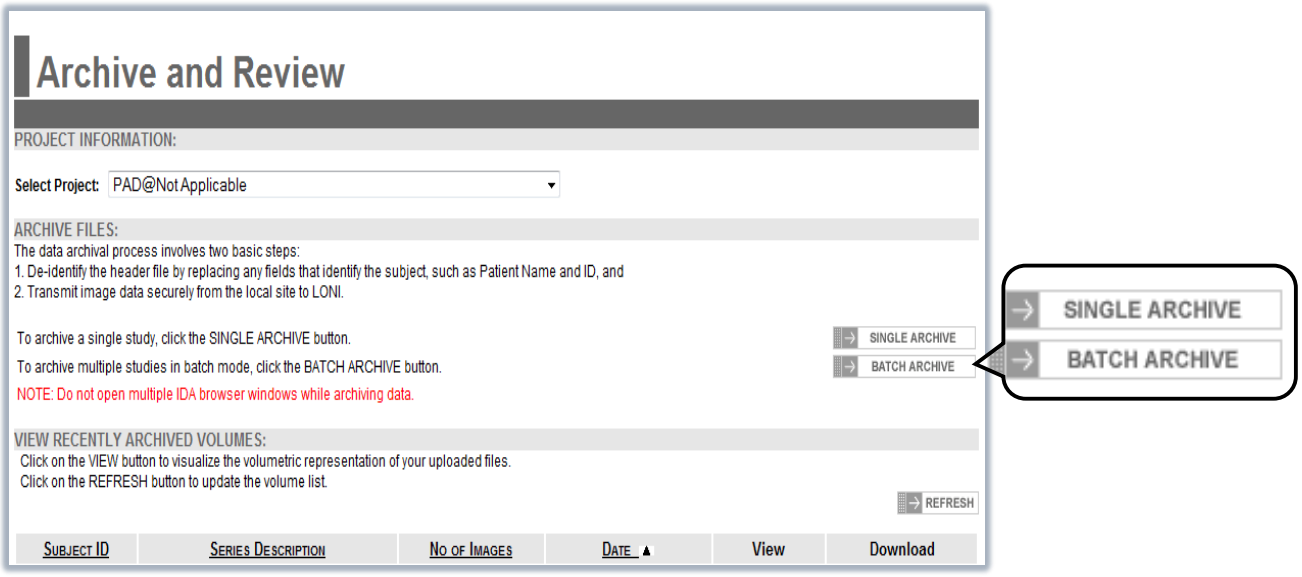
NOTE

- The browser window must remain open during the entire upload process. Closing the browser window cancels the upload. You may minimize the window.



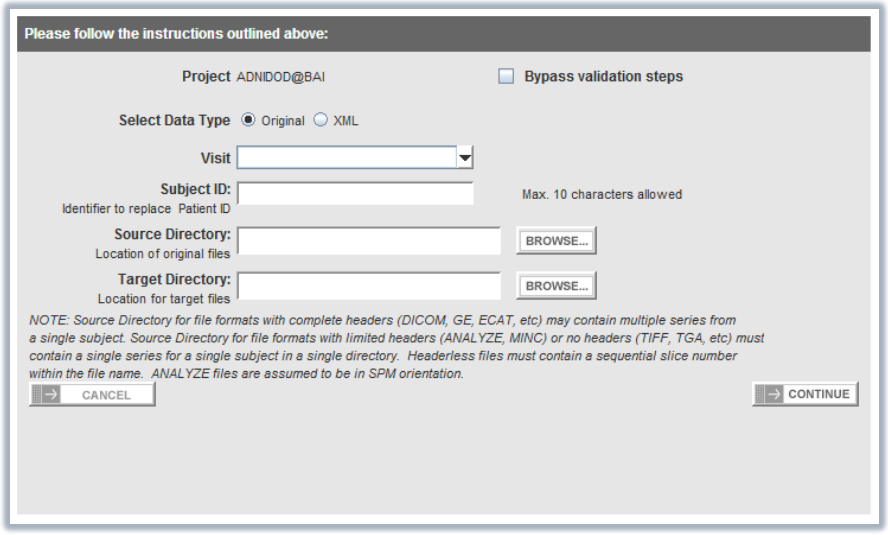
Choose ARCHIVE from the Menu

Select your Project/ Site from the drop down menu, and then click SINGLE ARCHIVE.



Step 1: De-identification

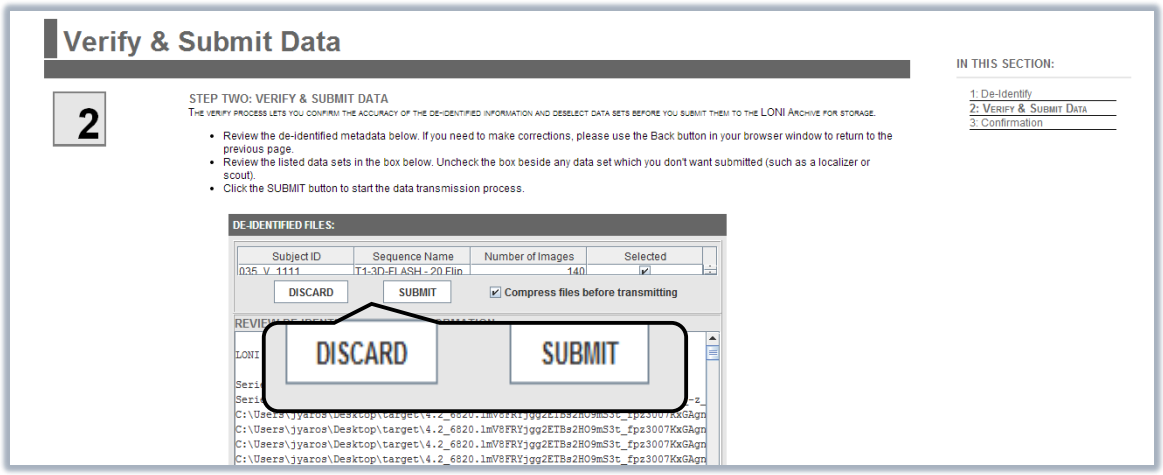
Complete the form entries:
Data Type = **Original**
The **Subject ID** you enter replaces the existing Patient ID in the image file(s). Be sure you are entering the research identifier provided by your site coordinator.
Source directory is the directory in which the original files are located (contains image files only).
Target directory is an empty directory which will contain the new, de-identified files.
Click the CONTINUE button to begin the de-identification process.



Step 2: Verify and Submit

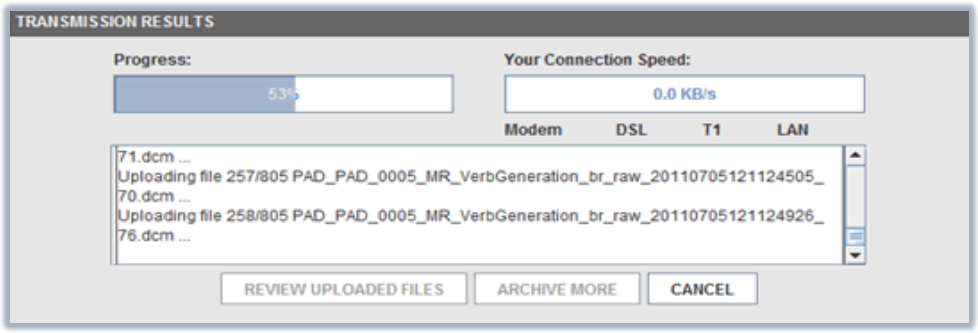
-To remove any images, uncheck the 'Selected' box beside the image.

Note: This feature is not an option with Batch Archive.
-Click SUBMIT to transmit the de-identified images. Choosing DISCARD cancels the upload.



The transmission process will begin. The progress bar will show the status of the upload.

Once the file transmission is complete, click REVIEW UPLOADED FILES to view a list of the archived images, or click ARCHIVE MORE to upload scans from another subject.



8.9 APPENDIX 9—QA QUICK REFERENCE GUIDE

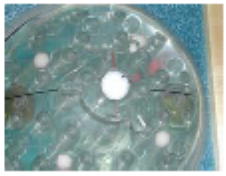
TRACK-TBI
Transforming Research and Clinical Knowledge in Traumatic Brain Injury
International Traumatic Brain Injury Research Initiative

QA QUICK REFERENCE GUIDE

QA scanning must be performed on a monthly basis. The QA protocol requires the TRACK-TBI ADNI and BIRN phantoms and the acquisition of the TRACK-TBI QA protocol. For more details see section 7 of the TRACK-TBI Manual.

Step 1: Start a study using the established naming convention (XX_9999; where XX=Site#)

Step 2: Place the ADNI phantom in the head coil used for TRACK TBI subjects



Make sure the phantom is upright and the serial number is facing out. Use the marks on the top of the phantom to center it in the coil and establish the landmark once this is achieved.

Step 3: Run the ADNI Phantom Scan Protocol

1) Localizer
   1a) Calibration/Reference Scan (if applicable)
2) QA Phantom MP-RAGE/IR-SPGR (center scan on the large central sphere of the phantom)

Step 4: Place the BIRN phantom in the head coil used for TRACK TBI subjects

Make sure the phantom is upright and the serial number is facing out. Use the marks on the top of the phantom to center it in the coil and establish the landmark once this is achieved.

Step 5: Run the BIRN Phantom Scan Protocol

3) Localizer
   3a) Calibration/Reference Scan (if applicable)
4) QA BIRN Phantom fMRI (center scan on the homogeneous sphere)

Step 6: Archive the imaging data and send to ImageOwl (ADNI) and LONI (BIRN)

- Store the data locally on a DVD, server, PACS etc per your sites standard practices
- Upload the MR-RAGE/IR-SPGR scan of the ADNI phantom to: http://qcc.imageowl.com/home/
  - Remember to select the post that specifies your site and, if applicable, specific scanner
- Upload the BIRN phantom fMRI scan to LONI at: https://ida.loni.usc.edu
  - Remember to re-enter the same naming convention you used when registering the study (XX_9999; where XX is site code)

Step 7: Store the phantoms in a safe location away from direct sunlight and heat sources

**The NIST ice water diffusion phantom is presently not part of regular QA, but may be added in the second half of 2014; additional details will be provided when appropriate*

8.10 APPENDIX 10—HUMAN SUBJECTS QUICK REFERENCE GUIDE

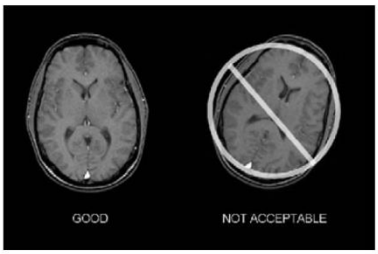
TRACK-TBI
Transforming Research and Clinical Knowledge in Traumatic Brain Injury
International Traumatic Brain Injury Research Initiative

HUMAN SUBJECTS QUICK REFERENCE GUIDE

Step 1: Ensure all subjects have completed and signed all appropriate informed consent documents and passed MRI safety and compatibility screening protocols.

Step 2: Begin a new study and enter subject information according to your standard local practice.

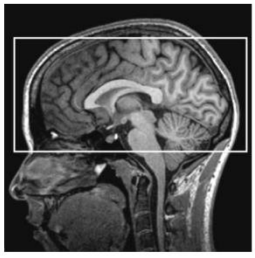
Ensure that the patient's head and neck are relaxed but without rotation in either plane. Affix a vitamin E capsule to the subject's right temple.



Align the centering crosshair on the subject's naison (directly between the eyebrows).

***Step 3: Run the TRACK-TBI protocol. (All scans are performed in straight orthogonal planes -- Sagittal or Axial) (No manual adjustments--<u>DO NOT</u>* oblique any scans)**

1) Localizer
1a) Calibration/Reference Scan
2) Sagittal 3D T1 MPRAGE/IR-SPGR
3) Sagittal 3D T2* GRE
4) Axial DTI
5) Axial Resting State fMRI - **Subjects should have eyes OPEN.**
6) Sagittal 3D T2-FLAIR (CUBE/SPACE/VISTA)
7) Sagittal 3D T2 (CUBE/SPACE/VISTA)



fMRI slab

Note: Earlier sequences in this protocol are more important and should be repeated if sub-standard data is initially acquired, even if this is at the expense of a sequence at the end of the protocol not being acquired.

Step 4: Archive data locally following your site's standard local practice (DVD, PACS, etc…)

***Step 5: Send imaging data to LONI within 24 hours of scan completion using naming convention* XX_NNNN where X=Site#/N=Subject ID#.**

- Upload to LONI at: https://ida.loni.usc.edu
- Scan types include: 2WK (2-week time point), 6MO (6-month time point), or CTL (healthy control)

8.11 APPENDIX 11—High Definition Fiber Tracking (HDFT)

Of the 2,700 TBI subjects enrolled into TRACK-TBI, 1,200 will undergo a 3T MRI at 2 weeks and 6 months following injury. In a companion study funded through the Naval Health Research Center (NHRC Contract Number: W911QY-14-C-0070, Dr. David Okonkwo, PI) 600 of these subjects from the six participating TRACK-TBI sites with Siemens MR platforms (Pittsburgh, Baylor, Harvard - MGH, Maryland, Miami, and Austin) will undergo the structural 3T MRI in accordance with the TRACK-TBI neuroimaging core protocol with the **High Definition Fiber Tracking (HDFT)** pulse sequence added in the place of the DTI scan sequence.

The steps outlined below must be completed in order to install the HDFT sequences onto the Siemens scanner and then to begin scanning human subjects.

1. **Execute a C2P research agreement**
   The HDFT sequence is distributed as a C2P agreement and each participating site will need to have a fully executed research agreement with MGH/Siemens. Please contact Walt Schneider, PhD at wws@pitt.edu for assistance.

2. **Local IRB and DON-HRPO approval**
   a. Each participating site will need to modify their IRB to include the HDFT scan and Department of the Navy (DON) DoD funding language .

   b. Each participating site will need to submit and receive DON HRPO approval.

      Because this research is sponsored by the Department of Defense it is subject to additional special requirements to enhance the protection of human subjects. Upon completion of your site's IRB review and approval, the Department of the Navy Human Research Protection Office (DON HRPO) must perform an administrative review of the research before activities with human subjects may begin. While the DON HRPO review is not an IRB review, the HRPO may require changes to the research prior to the start of the research.

   Please contact Ava Puccio, PhD at PuccAM@UPMC.EDU for sample language to use for both the IRB modification and the DON HRPO submission. She will help prepare the DON HRPO submission on behalf of each site.

3. Diffusion Spectrum Imaging (DSI) and HDFT analysis:

   DSI is a diffusion MRI q-space imaging method that acquires diffusion signals with multiple b-values to calculate average propagator and the diffusion ODF. MRI DSI data is followed by fiber tracking and tract-specific analysis along with region-of-interest (ROI) analysis.

   DSI data for the subject-specific approach will be acquired on 3T Siemens systems using a 32-channel head coil. This involves a 20-min, 257-direction scan using a twice-refocused spin-echo EPI sequence and multiple q values (TRe = 9,916 ms, TE = 157 ms, voxel size = 2.4 × 2.4 × 2.4 mm, FoV = 231 × 231 mm, b max = 7,000 s/mm2.

All scans are performed in straight orthogonal planes -- Sagittal or Axial.
No manual adjustments should be made to this protocol.

localizer_192x192 - Localizer
SAG-MPRAGE_256x240 - MPRAGE - Sagital MPRAGE
gre_field_mapping_96x96
ep2d_diff_SliceAcc_b3k_64_768x768 - HDFT 3k shell
ep2d_diff_SliceAcc_b5k_128_768x768 - HDFT 5k shell
ep2d_diff_SliceAcc_b1k_64_768x768 - HDFT 1k shell
pd_tse_tra_256x256 - PROTON DENSITY SCAN
SAG-SWI-3D_192x192 - SWI SCAN
Resting-State-fMRI-extended-ADNI_448x448.26 -fMRI
MoCoSeries_448x448
3D-T2-Turbo-FLAIR_512x480 - FLAIR

Please direct any questions regarding the HDFT scanning protocol to Walt Schneider wws@pitt.edu.

4. Completion of a TRACK MRI CRF to reflect performance of the HDFT sequences. This is an important step for payment verification on the NHRC contract.

5. Upload the MRI to LONI as described in previous sections of this MRI MOP, specifically, Section 6.1: Data Transfer and Section 8.8 – Appendix 8: Data Transfer to LONI.