PREDICT-TBI

(Prediction and Diagnosis using Imaging and Clinical biomarkers Trial in Traumatic Brain Injury)

Study Standard Operating Procedures:

Imaging

Version 10.0

4 May 2023

Contents

1 Overview

This PREDICT-TBI Study Operations Manual provides detailed information on the PREDICT-TBI Study procedures. It is an essential tool that facilitates consistency in study protocol implementation across study sites. This section will describe the SOPs for all MRI PREDICT-TBI imaging processes and procedures.

2 Contact Details

2.1 General Contacts

Name	Contact details	Responsibility
Fatima Nasrallah	f.nasrallah@uq.edu.au	Lead Investigator – all trial related enquiries- data acquisition, data archiving
Project Manager	Predict-tbi@uq.edu.au	Project Manager – all trial related enquiries

2.2 Neuroimaging Contacts

Name	Contact details	Responsibility
Fatima Nasrallah	f.nasrallah@uq.edu.au	Lead Neuroimaging Investigator – all trial related enquiries- data acquisition, data archiving
Aswin Narayanan	a.narayanan@uq.edu.au	Data management – all data transfer and archiving related enquiries
Katie McMahon	k21.mcmahon@qut.edu.a	Data Acquisition – sequence related enquiries

3 Site Qualification

Each site must be qualified for MRI. Qualifications will include QA phantom scans on ADNI (structural integrity), BIRN (temporal stability) and NIST (diffusion accuracy) phantoms along with a human volunteer. The human volunteer should be scanned with the same, complete protocol as PREDICT-TBI participants, described in Addendum A. The phantom and human data will be reviewed to assure protocol compliance and image quality.

4 Goals and Specific Aims

The overall goals of the neuroimaging group is to oversee all the imaging activities across all seven imaging sites included in the study which would include designing MRI protocols, quality control of all the imaging activities, archiving and storing of data and overseeing the data analysis. This group will aim to:

- Ensure that quality data is acquired from all sites in a consistent manner that is harmonised across all the different MRI systems.
- Conduct proper quality control of all the data that is acquired throughout the study.
- Assessment of data quality at each of the scanners and proper quality control throughout the period of the study.
- Determine quality control and stability of the scanners over time for all data.
- Analyse all data qualitatively and quantitatively.

Only 3T scanners will be included as part of the trial. All Siemens scanners have been assessed and qualified by Siemens for appropriate software and hardware availability and a dot engine has been created to ensure that all sequences are run with the least variation possible across all sites. The MRI scan protocol is 40 min in duration.

5 MRI Study Protocol

The PREDICT TBI MRI Study Protocol is Addendum A to this SOP.

6 MRI Procedure

6.1 MRI Timepoints

In this study, advanced MRIs will be performed up to three times for each patient at the following timepoints:

1.	Post ICU/HDU Discharge
2.	3 months post injury (± 14 days)
3.	6 months post injury (± 21 days)

For those participants who have stayed in intensive care for approximately two months, only two MRI scans will be done, at post ICU discharge (equivalent to the 3-month timepoint) and at 6 months post injury (Refer to Study Protocol: Section 15 - Schedule of Assessments). Study MRIs will be organised to coincide with follow up outpatients' appointments, when possible, to minimise the number of hospital visits for the participant.

6.2 MRI Contraindications

All participants will be medically assessed with regards to their suitability to undergo study MRI, both when the MRI is organised and on the day of the MRI scan.

The following are **contraindications** for MRI:

- Neurosurgery leading to the insertion of coils or clips
- Cardiac interventions with artificial heart valves, cardiac stents, pacemakers, defibrillator, loop recorders
- Ear implants (Stapes or Cochlear implants)
- Neuro-stimulators (spinal or deep brain)
- Implanted drug infusion pumps
- Shunts (programable valves, ventriculoperitoneal or spinal)
- Bullets or shrapnel injury
- Tissue expanders
- Claustrophobia
- Contrast allergy

- Renal failure: serum creatinine of estimated glomerular filtration rate (eGFR) must be recorded in the last 3 months as <30mL/min. Patients must not be on dialysis.
- Morbid obesity
- Non-removable items such as fixed dentures, medication patches on the skin or body piercings.

6.3 MRI Process

Participant safety is paramount. All site-specific approved MRI procedures will be followed. The Research Coordinator's (RC) role is to provide information, orientation, reassurance and ensure that the participants experience of this study procedure is as positive as possible.

Before the MRI	The RC will liaise with the participant and/or their carer to ascertain that the participant is willing to have an MRI scan. Please note that any accompanying the patient, such as a carer or next of kin, will also need to undergo the MRI checklist as per Appendix 2. The RC will discuss suitable days/times for the participant to attend with the participant and/or their carer and (if the participant is an inpatient) clinical staff The RC will arrange a date and time that is suitable for the participant to attend MRI - MRI sequence approximately 40 minutes The participant's MRI suitability to be assessed as per study site MRI protocol/guidelines – see Appendix B as an example Participant must have been discharged from ICU Participant must have cardiovascular and haemodynamic stability Participant must not be agitated and must be able to cooperate (the ability to lie still and remain flat for the procedure is essential for the examination). Participant must not require sedation Participant will be transported to the scanner Participant has (if any) only modest oxygen requirement (<50% inspired oxygen concentration) Participants must be re-screened for MRI contraindications immediately before the MRI scan. MRI appointment to be coincided with clinical outpatient appointments if possible For the 3-month post injury timepoint the RC is to arrange for study blood samples will be taken on the same day as the MRI, **BEFORE** the MRI procedure The RC will inform the participant and/or carer of the date and time of the procedure. Project Manager will make any necessary travel/accommodation/meal voucher arrangements.

	The RC will explain the procedure (what to expect and timing) address concerns and provide reassurance. See Appendix C as an example of information provided to people undergoing MRI The RC will show the participant and carer where the toilets are located and provide the participant with the opportunity to use the toilet before the scan begins If the participant has a nasogastric feeding tube in situ it should be in free drainage to minimize risk of gastric reflux and aspiration whilst lying flat on the magnet If possible, if infusions are running and cannot be paused during the MRI, MRI compatible pumps are required. Alternatively, long intravenous (IV) extensions are used to allow non-MRI compatible pumps to be used located outside the MRI room
During the MRI	The RC to be available to the participant/carer throughout their attendance for the MRI procedure Participants will be provided with a way of communicating during the scan (buzzer or similar) Participants can ask for the scan to be paused or stopped completely at any time during the scan Noise cancelling and/or audio distraction equipment will be provided An intravenous cannula for contrast administration will be inserted by a member of the medical team MRI sequences will be hierarchised in order of priority Participants will be instructed to close their eyes during the fMRI sequence Standard hospital response systems are available throughout the procedure Use standard local practice for monitoring the participant during the scan will be used - these may include devices to monitor pulse and O2 levels
Following the MRI	Any questions or concerns that the participant and carer have will be addressed The RC will accompany the participant and carer to their ward or to their transport For sites that provide a clinical MRI report, the report will be uploaded to the hospital medical record. If a participant requests a copy of this report, it is to be sent to the participant's GP, with a completed MRI Report Letter to GP (Appendix D). Any incidental findings will be reported by the radiology team and reviewed by the participants treating team

6.4 Inpatient MRI Process

The following information is specific to study participants undergoing study MRI during their INPATIENT stay:

- The RC will liaise with the medical team according to local hospital policy for the participant to attend a study MRI scan
- The MRI will be booked by the RC once medical approval granted
- The scheduled study-MRI will be documented in participant's medical chart. The treating medical team and ward nurse manager will be notified by the RC of the date and time of the scan.
- The RC will arrange for study bloods to be drawn on the morning of the scan
- The participant (and carer if applicable) will be escorted by the RC and a ward nurse to the imaging department
- The participant's identity will be checked by the RC and ward nurse
- Identity check will also be performed prior to the MRI by imaging staff.
- At conclusion of the MRI, the radiology staff and RC will notify ward staff that the participant is ready to return to the ward.
- The participant will be escorted back to the ward according to local hospital policy.

6.5 Outpatient MRI Process

The following information is specific for study participants undergoing MRI as OUTPATIENTS.

The participant will be escorted by the RC from the time they arrive at the hospital/imaging facility until the conclusion of all study procedures, including escorting them back to their transport. If the participant is traveling to have the MRI from their usual place of residence, arrangements may include:

- Liaison with the participant and/or carer about their needs
- Liaison with a residential rehabilitation facility staff about the participant's needs
- Liaison with imaging staff about the participant's needs
- Calling the participant/carer/residential facility the week before, the day before and possibly the day of the MRI as a reminder of the procedure

Project Manager will be responsible for organising:

- transport
- accommodation
- reimbursement of costs e.g., petrol, parking, meals

6.6 Safety checklist for suitable patients

1. Suitable transport arranged
2. In-hospital preparation for MRI examination
3. Informed consent from participant or Person Responsible
4. Participant will need to be settled, cooperative to minimize movement artefact
5. A nasogastric feeding tube in free drainage is recommended, to minimize risk of gastric reflux and aspiration whilst lying flat on the magnet
6. In line suction catheters are not compatible and need to be removed
7. Core temperature probes are not compatible and need to be removed
8. ECG leads that are not compatible and need to be removed.

6.7 Patient suitability to undergo study MRI:

1. Participant is already discharged from ICU
2. Participant is cardiovascular and haemodynamic stable
3. Participant is not agitated and is able to cooperate (the ability to lie still and remain flat for the procedure is essential for the examination).
4. Participant does not require sedation
5. Participant is able to be transported to the scanner on a wheelchair
6. Participant only modest oxygen requirement (<50% Inspired Oxygen concentration)

6.8 MRI Data Labelling

On the Scanner, each patient will be given a specific ID with the following nomenclature:

Study	Site	Subject ID
PR-TBI	01	001-299

For example: PR-TBI-01-001

Where Sites are coded based on the following:

- 01 = The Royal Brisbane and Women's Hospital (RBWH)
- 02 = The Princess Alexandra Hospital (PAH)
- 03 = Royal Darwin Hospital (RDH)
- 04 = Liverpool Hospital (LH)
- 05 = Gold Coast University Hospital (GCUH)
- 06 = Townsville University Hospital (TUH)
- 07 = The Alfred Hospital (AH)

6.9 Instructions for the RC

The PREDICT TBI MRI Record Form (Appendix A) should be completed at the time of MRI acquisition for every participant. Both the form and the MRI data will be transferred by the radiographer and stored in non-identifiable format.

6.10 Instructions for the Radiographer

The radiographer must complete the MRI form during the scan. It must be indicated if each sequence was completed and any problems or modifications to the protocol noted in the appropriate sections. Once the form is completed in full, the form and the MRI data is uploaded either via a Cloud system or via a disc to the PREDICT TBI Research Data Manager (RDM) system at UQ. This form will be linked with the participants' MRI data. To report an incident regarding the MRI sequences please email: fatima.nasrallah@uq.edu.au To report an incident about a specific participant, please contact the RC.

7 Participant Positioning

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

- Place clean sheet on scanner table and coil cradle.
- Provide the participant with ear protection. This may include ear plugs and ear pads.
- Position the participant 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 participant should also be well supported in the head coil to minimize movement. Motion artefacts may result in data rejection and request for a re-scan.
- 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 the participant 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.
- Ensure the participant has removed any dentures, hair clips, combs, earrings and necklaces etc.
- Remove all upper body clothing with metallic trim, such as zippers, buttons or embroideries that may cause artefacts in the MRI images.
- Centre the head coil over the participant's head, making sure the participant is high enough in the coil to prevent signal loss at the inferior aspect of the brain.
- Offer the participant a panic button in case of emergencies or claustrophobia if common local practice at your facility (for example, a squeeze ball alarm)
- Remind participant to hold as still as possible and advance participant to the iso- centre of the scanning bore

8 Scan Discontinuation

If the participant 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 participant still does not want to complete the scan, then the MRI should be abandoned and noted as incomplete on the PREDICT-TBI MRI Record Form. The general notes section should include the reason the participant was unable to complete the MRI.

9 Data Transfer and Storage

Non-identified MRI images labelled with the participants' study ID will be securely transferred and stored at QBI, which houses Asia-Pacific's first and largest deployment of the nVidia Volta V100 GPU based supercomputer.
All the MRI data will be deidentified from each site (hospital sites or QBI) and will be uploaded into UQ's RDM. RDM can support mediated collaboration with internal and external parties via the use of AAF (Australian Access Federation) credentials, which facilitates local, state, national and international secure collaboration via the use of this data sharing fabric. Data is also backed up within RDM at UQ. MRI data will also be backed up on tape media, remotely, for digital preservation, as is usual practice for data stored on the supercomputer.
A comprehensive guide to accessing the data entry forms on the website and entering all follow-up data will be provided in the Data Completion Manual and Operations Manual. After collection, all data will be stored in an XNAT multi-repository managed at UQ. XNAT (xnat.org) is considered the open source standard for MRI and side band meta-data (that is, clinical data, textual annotation, survey data, spreadsheets, etc.) in the one structured repository, to achieve a shared and collaborative, but structured and secure approach.

10 Clinical Reporting

If applicable, participants' study MRIs will be clinically reported by a radiologist. Concerning or incidental findings will be discussed with the participant's treating physician. The RC will upload the clinical report in non-identifiable format, to the research database.

11 Requests for Repeat MRI Scans

A request for a repeat MRI may be required in the event that the scans are found to be unacceptable due to participant motion or an incomplete MRI acquisition. After consultation with the Coordinating Chief Investigator of the study and the site PI, the RC may schedule a repeat study if the participant (and/or carer) is willing to undergo this. Repeat scans may also be required if the incorrect scan sequence, orientation, or angulations are used. It is imperative to use the PREDICT-TBI approved acquisition sequence with every PREDICT TBI participant.

12 MRIs Ordered for Clinical Indications

Some participants may have CT scans and/or MRIs ordered for standard clinical indications. In these situations, the RC will organise for these images and reports to be uploaded into the study database and RDM.

13 Safety Reporting

In this study, adverse events are likely to be rare as there is no medical intervention beyond blood sample collection and MRI scans, which will include the use of Contrast. However, it is possible for adverse events to arise from the interactions required for participation in the study (for example, a reaction to the Contrast solution) and these will be reportable to the Central Coordinating Centre (UQ) and local ethics committee where applicable. Clinically significant procedural related adverse events will be reported and submitted to the Central Coordinating Centre within 72 hours. These will be reviewed by the coordinating centre staff and recorded in a safety database. Only those reactions that are thought to have a direct causal relationship with the study procedures should be reported as an Adverse Event (AE).

14 Image Acquisition Parameters

	3D T1w pre-contrast	T2w dark fluid	SWI-QSM	DWI[1]	rs-fMRI[2]	T1 mapping[3]	DCE[3]	3D T1w post-contrast
Sequence	MPRAGE	TSE-FLAIR	GRE	EPI	EPI		T1w VIBE	MPRAGE
Orientation	Sagittal	Traversal	Traversal	Traversal	Traversal	Traversal	Traversal	Sagittal
2D/3D	3D	2D	3D	2D	2D	3D	3D	3D
TR (ms)	1900 ms	9000 ms	30 ms	4700 ms	820 ms	3.37 ms	3.21 ms	1900 ms
TE (ms)	2.26 ms	81 ms	multi-TE	84 ms	33 ms	1.18 ms	0.87 ms	2.26 ms
TI (ms)	900 ms	2500 ms						900 ms
Flip Angle (deg)	9	150	15		53	multi-FA	9	9
FOV read (mm)	256 mm	220 mm	224 mm	244 mm	206 mm	256 mm	256	256 mm
Base resolution	256	320	224	122	86	192	192	256
Phase enc. Dir	A >> P	R >> L	R >> L	P >> A	P >> A	R >> L	R >> L	A >> P
Slices number	192	35	144	74	60	128	128	192
Slice thickness (mm)	1	3	1	2 mm	2.4 mm	1.5 mm	1.5	1
Slice gap (% of thickness)	50%	10%	20%	0%	0%	20%	20%	50%
Effective res.	1 x 1 x 1 mm	0.7 x 0.7 x 3 mm	1 x 1 x 1 mm	2 x 2 x 2 mm	2.4 x 2.4 x 2.4 mm	1.33 x 1.33 x 1.5 mm	1.33 x 1.33 x 1.5 mm	1 x 1 x 1 mm
NEX	1	1	1	1	1	1	1	1
Bandwidth	200 Hz/Px	289 Hz/Px	310 Hz/Px	2276 Hz/Px	2154 Hz/Px	500 Hz/Px	500 Hz/Px	200 Hz/Px
Multi-slice mode	Single shot	Interleaved	Interleaved	Interleaved	Interleaved	Sequential	Sequential	Single shot
Series	Ascending	Interleaved	Interleaved	Interleaved	Interleaved	Ascending		Ascending
Concatenation	1	2	1	1	1	1		1
Suppression	None	Strong Fat Sat.	None	Strong Fat. Sat	Fat. Sat.	None	Q-fat sat	None

Parallel Imaging	GRAPPA Phase dir: 2x	None	GRAPPA Phase dir: 3x	Slice accel. Phase dir: 2x Slice dir: 2x	None	GRAPPA Phase dir: 3x 3D accel.: 2x	CAIPIRINHA Phase dir: 3x 3D accel.: 2x	GRAPPA Phase dir: 2x
Notes			Monopolar readout Multi-TE: 5.84 ms, 10.63 ms 15.42 ms, 20.21 ms 25.00 ms	Phase Partial Fourier: 6/8 8 dirs x b = 0 20 dirs x b = 1000 60 dirs x b = 3000			Multiple measures 38 meas: 16 seconds temporal resolution	
Scan time	4 minutes 26 secs	4 minutes 32 secs	5 minutes 12 secs	8 minutes 52 secs	6 minutes 51 secs	49 seconds	10 minutes 6 secs	4 minutes 26 secs

The sequences above are to be acquired with parameters similar to the specifications below:

[1]DWI EPI main sequence are to contain at least 8 b = 0 s/mm^2 scans, 20 diffusion-weighted direction scans at b = 1000 s/mm^2, and 60 diffusion-weighted scans at b = 3000 s/mm^2 and this can be accomplished in different ways, depending on the capability of each scanner.

If it is possible to have multi b-value shell acquisition within the same sequence (i.e. Siemens Magnetom Prisma scheme, where within the same sequence, one can acquire b = 0, b = 1000, and b = 3000 scans) multiple blocks of alternating A >> P then P >> A phase encoding directions can be used to acquire the required number of diffusion-weighted volumes for each b-value. The opposite phase-encoding acquisitions allow for EPI distortion correction in post-processing stage.

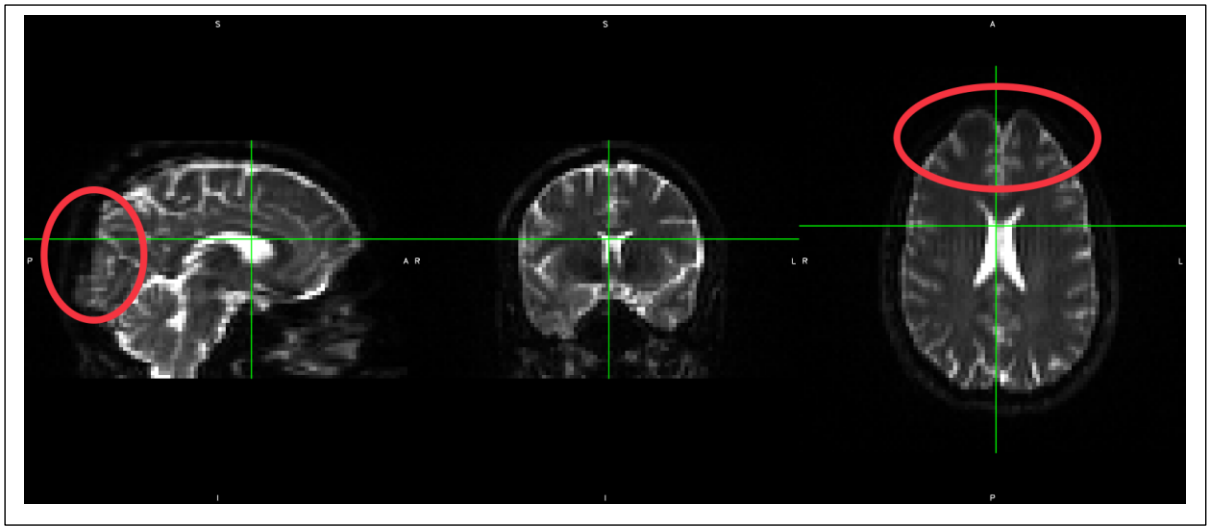
If the scanner does not for multi b-value shell acquisition within the same sequence, the required number of diffusion-weighted volumes main sequence can be acquired as multiple blocks, with each block having a different b value. If DWI data is to be acquired this way, a separate EPI sequence with the exact geometry and parameter as the main DWI sequence, except with **A >> P** phase encoding direction and containing only 3 volumes of b = 0 s/mm^2 should be acquired before the main DWI data sequence. The main DWI data should then be acquired in **P >> A** phase encoding direction and the main DWI sequence. **Please refer to the figure below for details on how the images should look like with different phase encoding directions.**

If a scanner does not allow for over 30 diffusion-weighted directions, a diffusion scheme of 15 diffusion-weighted direction scans at b = 1000 s/mm^2, and 30 diffusion-weighted scans at b = 3000 s/mm^2 is also acceptable.

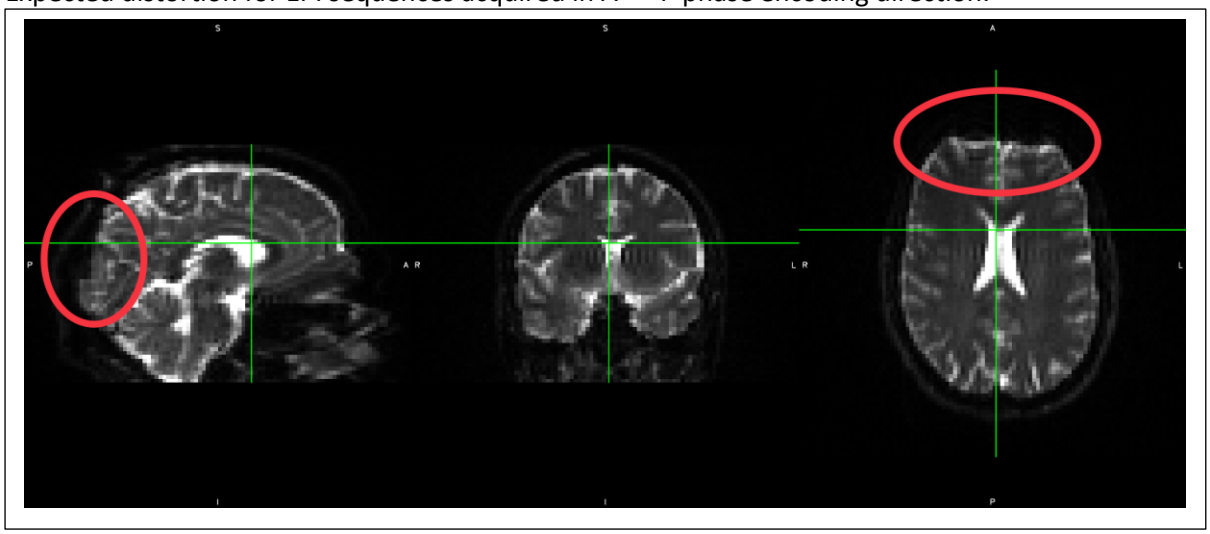
[2]The main sequence of resting-state fMRI is to be acquired in the P >> A phase encoding direction.
This main sequence is to be preceded by a pair of identical EPI scans to the main resting-state fMRI, one in P >> A and one in A >> P phase encoding directions. This EPI pair is to be acquire immediately prior to resting-state fMRI scan and this pair should have opposite EPI distortions. **Please refer to the figure below for details on how the images should look like with different phase encoding directions.**

[3]The T1 mapping and Dynamic Contrast Enhancement scan should have identical geometry.
For DCE scan, contrast agent injection (0.1 mmol/kg) should be started approximately 48 seconds after the start of the scan (3 measurements of 16 seconds temporal resolution). Intravenous contrast agent injection is required.

Expected distortion for main EPI sequences (for DWI and resting-state fMRI) acquired in P >> A phase encoding direction:



Expected distortion for EPI sequences acquired in A >> P phase encoding direction:



14.1 Image Acquisition Notes

a. Quick localizing sequence in three planes

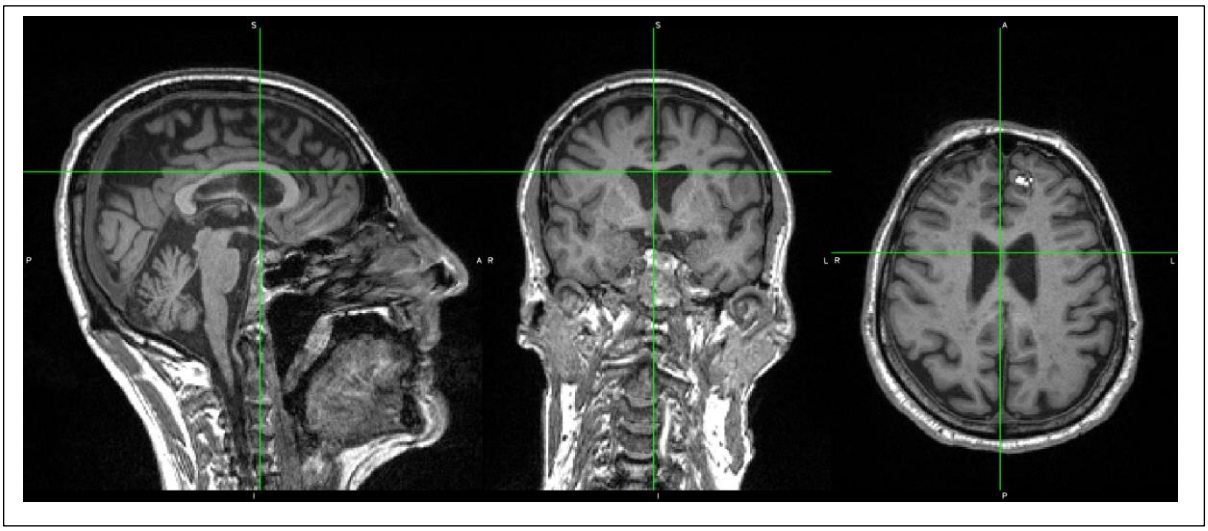
This sequence is a quick acquisition in three orthogonal planes for anatomical orientation. The head should be centred laterally along the inter-hemispheric fissures and cantered on the thalamus for anterior-posterior and superior-inferior directions.
It is important that the head placement is as straight as possible and subsequent scans can be acquired in straight orthogonal planes with without using rotated FOVs and oblique scans.
Adjustment of FOV position along the x, y, and z direction is allowed.
If the subject is not positioned properly, adjust the subject's head orientation, and re-acquire the localizer. Repeat the positioning and localizing process until the subject is correctly centred in the coil and magnet.

b. Routine calibration, reference, and shimming procedure

Automated procedures for adjustment, calibration, shimming, RF coil transmitting power and receiving gains, and frequency adjustment are to be performed according to manufacturers' instructions.
Frequency adjustment should be repeated after running a sequence longer than a few minutes.

1. 3D T1-weighted anatomical imaging sequence using magnetization-prepared rapid acquisition with gradient echo (MPRAGE)

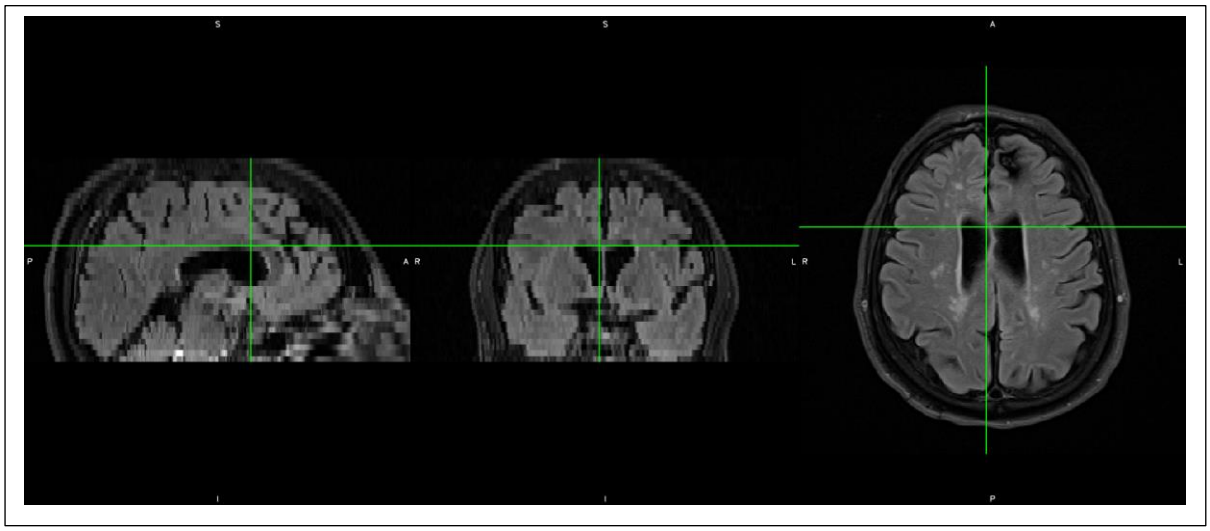
Example



Orientation: straight sagittal. Slice direction will be Left – Right. Phase encoding direction should be A >> P. FOV should cover the head and skull in all directions, especially the Anterior-Posterior direction: both the nose and back of the head need to be included in the FOV or wrap arounds will occur.

2. 3D T2-weighted anatomical imaging sequence using Fluid-attenuated inversion recovery (FLAIR)

Example:

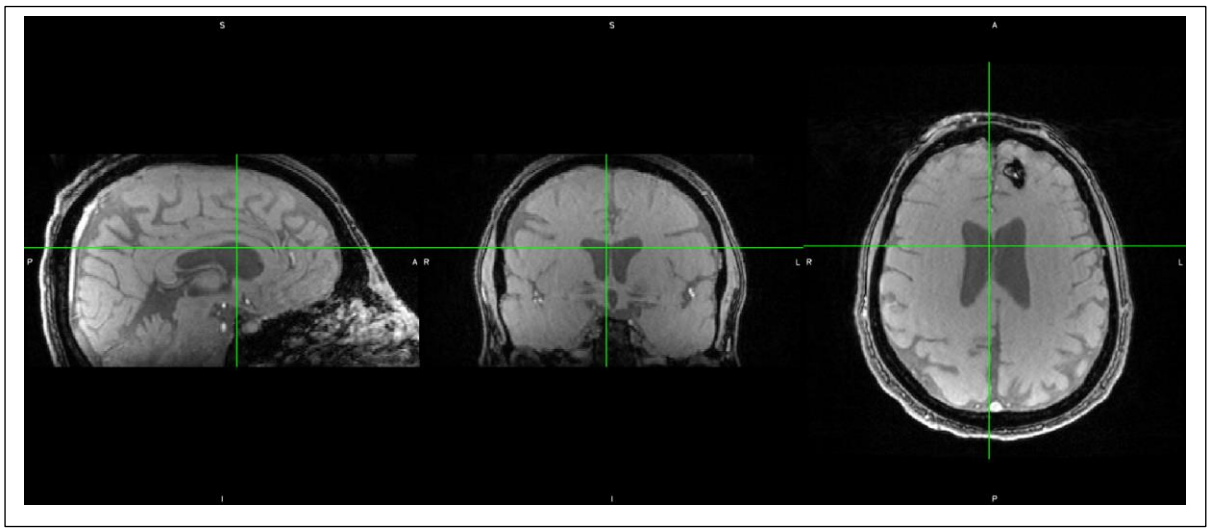


Perform frequency adjustment prior to scanning

Orientation: straight traversal. Slices will be in the Superior-Inferior direction and phase encoding direction should be R >> L. FOV should cover the brain in the Superior-Inferior direction and all of the head and skull in the Left-Right direction or wrap arounds will occur.

3. 3D Susceptibility Weighted imaging (SWI) scan:

Example:



Perform frequency adjustment prior to scanning

Orientation: straight traversal. Slices will be in the Superior-Inferior direction and phase encoding direction should be R >> L. FOV should cover the brain in the Superior-Inferior direction and all of the head and skull in the Left-Right direction or wrap arounds will occur.

This sequence should output multiple volumes acquired from multiple echo times. The example shows the magnitude image of the first echo time

4. Diffusion Weighted Imaging

DWI data can be acquired in different ways (see the Notes under 5.3) though some common principles and requirements still apply. If acquisition is broken into multiple blocks, all blocks are to have the exact same geometry and their required phase encoding directions (for EPI distortion correction during post-processing); double-check the actual phase encoding direction prior to starting the scans. Perform frequency adjustment prior to acquisitions if the preceding acquisition last more than a couple of minutes.

Orientation: straight traversal. Slices will be in the Superior-Inferior direction and phase encoding direction should be **P >> A** or **A >> P** (depending on the schemes). FOV should cover the brain in the Superior-Inferior direction and all of the head and skull in the Anterior-Posterior direction or wrap arounds will occur.

5. Resting-state functional imaging

Resting-state functional imaging requires 3 scans: a pair of single volume EPI acquired in **P >> A** then **A >> P** phase encoding directions, respectively, and a main EPI-based resting-state functional MRI acquired in P >> A phase encoding direction. These three scans should have the exact same geometry and have their phase encoding directions double-checked prior to running.

Orientation: straight traversal. Slices will be in the Superior-Inferior direction and phase encoding direction should be **P >> A** or **A >> P** depending on the scan. FOV should cover the brain in the Superior-Inferior direction and all of the head and skull in the Anterior-Posterior direction or wrap arounds will occur

6. Dynamic Contrast Enhanced Imaging

Dynamic Contrast Enhanced (DCE) Imaging requires 2 scans: T1 mapping scan and the main DCE scan. T1 mapping **must** be acquired prior to the main DCE scan and contrast agent injection. Main DCE must be acquired after all other scabs and only prior to post-contrast agent injection T1w MPRAGEs. T1 mapping and main DCE scans must have the exact same geometry.

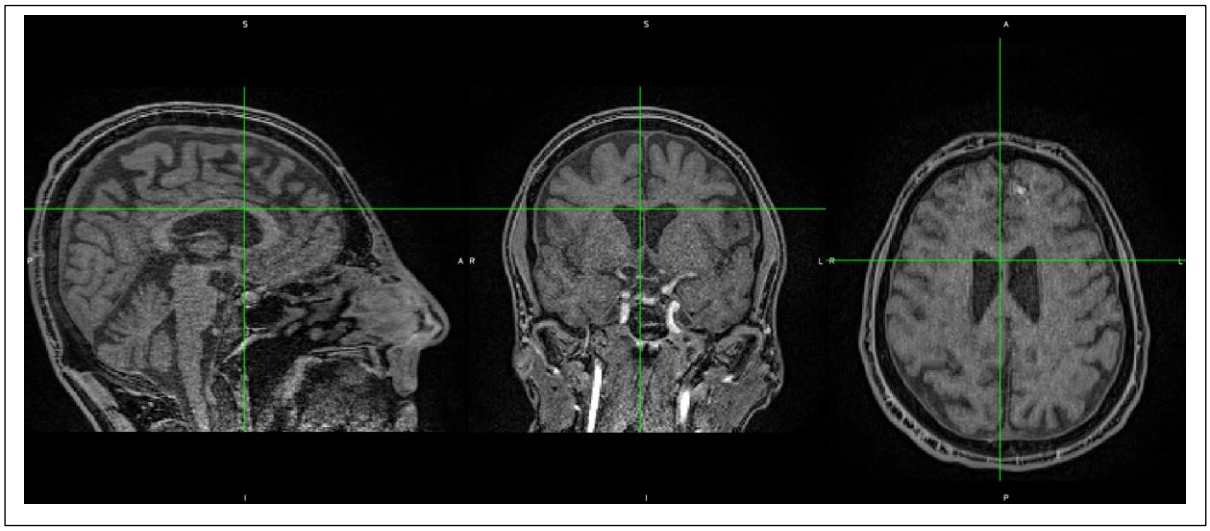
6-1. T1 mapping sequence using variable flip angles

Perform frequency adjustment prior to acquiring.

Orientation: straight traversal. Slice direction will be in Superior-Inferior direction. Phase encoding direction should be R >> L. FOV should cover the head and skull in all directions, especially the Left-Right direction: both the nose and back of the head need to be included in the FOV or wrap arounds will occur.

6-2. 10 minutes Dynamic Contrast Enhanced scan using a VIBE sequence

Example:



Orientation: slice group and FOV geometry should be copied fromT1 mapping scan exactly.

This scan involved Intravenous contrast agent injection. Contrast agent injection should start exactly 48 seconds (3 volumes) after slice acquisition start (not counting automatic adjustment, only count from the start of slice acquisition).

7. Post-contrast agent 3D T1-weighted anatomical imaging sequence using magnetization-prepared rapid acquisition with gradient echo (MPRAGE)

Orientation: slice group and FOV geometry should be copied from the first T1 MPRAGE scan exactly.

Perform frequency adjustment prior to acquiring.

15 Appendices

15.1 Appendix A – MRI Record Form

Study ID:	_____	**Date:**	_____
Session Start Time:	_____	**Session End Time:**	_____
MRI Start Time:	_____	**MRI End Time:**	_____
Radiographer:	_____	**Researcher:**	_____

Sequence	**Series #**	**Quality**	**Repeated?**	**Notes**
Scout/Localizer	1			
T1 MPRAGE 4:26min	2			
T2_tse_dark fluid 4:26min	3			
AP_BLOCK_1_22DIR 2:13min	4			
PA_BLOCK_1_22DIR 2:13min	5			
AP_BLOCK_2_22DIR 2:13min	6			
PA_BLOCK_2_22DIR 2:13min	7			
REST_PA_EP2D_BOLD 6:51min	8			
3D T2_STAR MEGRE 5:14min	10			
T1Map_p2_anatomical 0:57sec	11			
CONTRAST INJECTION				
T1 Dynamic VIBE 10min	12			
T1 MPRAGE POST 4:26min	14			

NOTES:

Quality options: good, fair, usable, poor

SWI: Only run if patient is compliant. The post contrast scans are more important.

To calculate AP angle from PA angle, use the following equation:

If -180 < AP < 0:	PA = 180 + AP	PA must be positive and < 180
If AP = 0:	PA = 180	
If 0 < AP < 180	PA = AP – 180	PA must be negative and > -180

AP angle: _____ PA Angle: _____

General notes:

Signature: _____

15.2 Appendix B – HIRF MRI Questionnaire

MRI Safety Questionnaire

Queensland Government

MRI uses very strong magnetic fields that are always on and some objects can pose a serious threat to your safety, or compromise the examination.

Therefore, this questionnaire is obligatory and all questions must be answered.

If you have any questions please contact MRI unit.

UR.....

Surname.....

Given names.....

DOB.....M/F.....

Height (cm) Weight (kg)

Do you have, or have you ever had, any of the following? (Please circle Yes or No)

Cardiac Pacemaker/Defibrillator/Pacing Wires/Loop Recorder.....Yes / No
Any operations on your heart.....Yes / No
- Artificial Heart Valves .....Yes / No
- Cardiac Stents.....Yes / No

Any operations on your brain.....Yes / No
- Aneurysm clip/coils/shunts.....Yes / No

Any implanted electronic device.....Yes / No
- Ear implant (e.g. Stapes or Cochlear implants).....Yes / No
- Neurostimulator (e.g. Spinal or Deep Brain stimulator).....Yes / No
- Implanted drug infusion pump.....Yes / No
- Shunt (Programmable, VP or Spinal shunt).....Yes / No

Any vascular implants (e.g. Stent, Coils, Filter, Graft).....Yes / No
Any other implanted prosthesis or foreign object.....Yes / No
- Joint replacement or artificial limb/s.....Yes / No
- Rods, plates, screws in your bones.....Yes / No
- Bullets or shrapnel injury.....Yes/ No
- Tissue expander .....Yes / No

Have you ever had metal fragments in your eye?..... Yes / No

Have you had any surgery? Please list

Do you have, or have you ever had, any of the following? (Please give details where appropriate)

Hearing Aid/Eye Implant.....Yes / No
Dentures or removable dental work.....Yes / No
Medication patches on skin.....Yes / No
Body piercing or tattoos.....Yes / No
Claustrophobia.....Yes / No
Require GP medication for MRI .....Yes / No

Are any of the following applicable to you?

Do you have a history of kidney disease? Yes / No
Do you have diabetes?.....Yes / No
Do you have any allergies?.....Yes / No
Have you ever had a reaction to contrast? Yes / No

For Female Patients

Are you, or could you be pregnant?.....Yes / No
Are you breast feeding?.....Yes / No

I confirm that I have read and understood these questions, and have answered them correctly.

Signature.....Date .....

Completed by: Patient Relative/Carer Doctor (Name & contact details) .....

MRI Safety Questionnaire

Warning: Please be aware that prior to entering the scan room **all** metallic objects must be removed including watches, jewellery, hearing aids, wallets, data cards, phones, hair pins and clips, piercings, clothing with metal such as bra or jeans etc. It may also be necessary to remove other items such as makeup.
Please note: You will be required to change into a hospital gown. Lockers are provided for your convenience.

Office use only:

1st Review by:..... 2nd Review by:.....

Action required:.....

Implant details:

_____
_____
_____
_____
_____
_____
_____
_____
_____

Outcome: _____

_____

DMI - Contrast

Oral Contrast/ Amount: .....

Skin Prep: ☐ 2% Chlorhexidine ☐ Alcohol Only

IV Inserted: ☐ Insitu ☐ Yes. No of Attempts: .....

IV Access Comment: .....

IV Cannula Gauge: ..... Site: .....

Inserted By: .....

Normal Saline Flush: ☐ 10mls ☐ 50mls Pressure Inj

Contrast Injection: ☐ IV Bolus ☐ Pressure Injector

IV Contrast Type, Volume: .....

Batch: .....

Administered By: .....

IV Removed: ☐ Yes ☐ No

Office use only:

eGFR.....ml/min Date Tested.....

Gynae/Breast Patient only

Date of LNMP.....

HIRF
HERSTON IMAGING RESEARCH FACILITY

Queensland Government

Version 1.0 Review date: July 2016

15.3 Appendix C – Queensland Health MRI Patient Information Form

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Queensland Government

Consent Information - Patient Copy
Magnetic Resonance Imaging

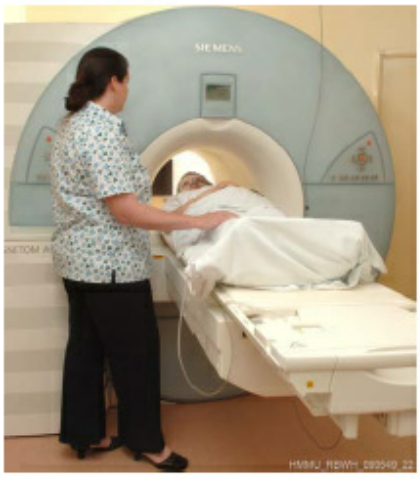
1. What is MRI?

Magnetic Resonance Imaging (MRI) is an advanced imaging method that uses a strong magnetic field, radio waves and a computer to produce pictures of the body. MRI does not use x-rays.

MRI pictures are very detailed. They can show both bones and soft tissues in the body.

MRI Safety

- *No one* is permitted into the scanning room until they have answered a series of safety questions and removed all metal objects from your body. (eg jewellery, eyeglasses and mobile phones).
- Because of the strong magnetic field there will be some patients who cannot undergo an MRI. These are patients who have metallic implants. These include but are not limited to: heart pacemakers, aneurysm clips in the brain, and foreign bodies such as metal shavings in the eyes.
- It is vital that you answer the safety questions as correctly as possible. You should discuss any internal implants (of any kind) that you may have with MRI staff to clarify any possible risks.



2. Will there be any discomfort, is any anaesthetic needed?

An MRI Scan is a painless procedure, no anaesthetic is required.

Some people find that being inside the MRI machine makes them feel uncomfortable due to the confined space of the tunnel. This is known as 'claustrophobia'. If this occurs, let the staff know as there are many different ways they can help you.

Rarely, medication *may* be required to help you complete the scan. If you require medication for the scan please check the procedure with MRI staff.

3. Preparation for the procedure

The medical imaging department will give you instructions on how to prepare for your procedure.

- Please tell the staff if you are or suspect you might be pregnant or are breastfeeding.

4. During the procedure

You will not feel anything during the scan. The radio waves used to take your pictures are *very* noisy; you may hear thumping, and knocking sounds. You will be provided with headphones or earplugs to protect your ears from the noise.

MRI staff will not be in the room with you during the scan but they will be able to see you and talk to you between the scans via an intercom. You will be given a call button to use if you need help.

The MRI scan will take between 15 and 90 minutes. It is extremely important that you keep completely still during the scan. Any movement can blur the pictures.

Depending on the area being scanned, you may be given MRI Contrast.

A fine needle (IV cannula) will be put into a vein in your arm, to inject the MRI Contrast.

For more information on MRI Contrast and the risks involved in its use, please read the **MRI Contrast Patient Information Sheet** *(if you do not have this information sheet please ask for one).*

5. After the procedure

The IV cannula will be removed (if inserted).

There are no known side effects or after effects of having a MRI.

6. What are the risks of this specific procedure?

The risks and complications with this procedure can include but are not limited to the following.

Common risks and complications include:

- Minor pain, bruising and/or infection from the IV cannula. This may require treatment with antibiotics.

Less common risks and complications include:

- No known less common risks.

Rare risks and complications include:

- Death as a result of this procedure is *very* rare.

Notes to talk to my doctor/ Health practitioner about:

_____

_____

_____

03/2011 - v2.00

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Queensland Government

Consent Information - Patient Copy
MRI Contrast

1. What is a MRI contrast?

The medical imaging MRI procedure your doctor has asked you to have may use MRI Contrast. MRI Contrast is a colourless liquid that is injected into your blood stream. MRI Contrast is not a dye. It does not stain the inside of your body. It is used during MRI medical imaging procedures to allow your organs to be seen more clearly. Your doctor needs to use MRI Contrast to be able to get all the information needed to assist with your diagnosis.

This information sheet must be read together with the information sheet of the procedure you are booked for *(if you do not have this information sheet please ask for one)*.

2. During the procedure

When the MRI Contrast is injected you should not feel any different.

3. After the procedure

MRI Contrast does not affect your ability to carry out normal activities; you should be able to continue with your day as normal.

4. Precautions

MRI Contrast is not suitable for some people; you will be asked a series of questions before it is given to you. Your answers allow staff to identify any risk factors that you may have.

- Please tell the staff if you are or suspect you might be pregnant or are breastfeeding.

Kidney function:

- MRI Contrast is removed from your blood by your kidneys through your urine. It is easily removed from the body of people who have normal kidney function.
- People whose kidneys are poorly functioning (known as 'Renal Failure') cannot remove MRI Contrast from their body. This may lead to a very rare disorder called Nephrogenic Systemic Fibrosis (NSF).
- NSF is a condition that results in scarring or thickening of the skin and tissues throughout the body. This scarring can lead to a tightening of muscle, tendons, ligaments, or skin that prevents normal movement and function. This condition is severely disabling and may result in death.
- You may be asked to have a simple blood test to find out the level of their kidney function.

5. What are the risks of MRI Contrast?

The risks and complications with MRI Contrast can include but are not limited to the following.

Common risks and complications include:

- No know common risks.

Less common risks and complications include:

- Injected Contrast may leak outside of the blood vessel, under the skin and into the tissue. This may require treatment. In very rare cases, further surgery could be required if the skin breaks down.
- The injection may not be possible due to medical and/or technical reasons.

Rare risks and complications include:

- Allergic reactions occur within the first hour with most happening in the first 5 minutes.
- The reactions vary from:
- *Mild* – headache, brief nausea, dizziness, hives, rash and itching.
- *Moderate* – wide spread hives, headaches, facial swelling, vomiting, shortness of breath.
- *Severe* – Severe reactions are rare but include: life-threatening heart palpitations, very low blood pressure, throat swelling, fits and/or cardiac arrest.
- Nephrogenic Systemic Fibrosis (NSF) for severe renal impaired patients only.
- Death as a result of MRI contrast is very rare.

6. What are the safety issues when you leave the hospital?

Go to your nearest Emergency Department or GP if you become unwell.

Notes to talk to my doctor about:

03/2011 - v2.00

15.4 Appendix D – MRI Report Letter to GP

PREDICT-TBI

THE UNIVERSITY OF QUEENSLAND
AUSTRALIA
CREATE CHANGE

Date: March 23, 2022

Sender Name:
Address:
City:
State and postcode:

Recipient Name:
Address:
City:
State and postcode:

Subject: PREDICT-TBI MRI report

Dear Dr XXXXXXXXXX

Please find attached an MRI Report for one of your patients, Mr/Mrs/Ms XXXXX XXXXXX. This report was generated as part of Mr/Mrs/Ms XXXXXX's participation in the Prediction and Diagnosis using Imaging and Clinical Biomarkers Trial in Traumatic Brain Injury (PREDICT-TBI) research study. This study has been approved by the Royal Brisbane and Women's Hospital, Human Research Ethics Committee. The study involves patients with moderate to severe traumatic brain injury and collects clinical data, biomarkers and advanced MRI imaging with the aim of improving outcome prediction in TBI. The report enclosed is the report generated by a radiologist reporting the 'conventional' MRI sequences.

Mr/Mrs/Ms XXXXXX requested this report be sent to you as it may be useful for you in the continuing care of your patient. You agree, however, that the PREDICT study investigators do not accept any liability for any clinical decisions made as a result of this report.

If you have any questions or concerns regarding the report, please contact XXXXXXXXX on XXXXXXXX to discuss these findings.

Yours Sincerely

(Insert signature)

(Insert name)

PREDICT-TBI MRI Report Letter to GP_V1.0_24 March 2022