## SAFE WORK PROCEDURE

Use this form to document Safe Work Procedures for hazardous activities and processes. The information in your Safe Work Procedure (SWP) should be supported by a risk assessment.

<table>
<thead>
<tr>
<th>Faculty/School:</th>
<th>Science / Psychology</th>
<th>Initial Issue Date: 11 June 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>SWP Reference Number:</td>
<td></td>
<td>Version: 2 Version Issue Date: 28/07/2017</td>
</tr>
<tr>
<td>SWP Title:</td>
<td>Transcranial Magnetic Stimulation</td>
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<tr>
<td>Prepared by:</td>
<td>Justin Harris</td>
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<tr>
<td>Responsible supervisor/s:</td>
<td>Justin Harris and Irina Harris</td>
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### List the Hazards and risk controls as per risk assessment

<table>
<thead>
<tr>
<th>Associated risk assessment reference:</th>
<th>Hazards</th>
<th>Risk controls</th>
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<tbody>
<tr>
<td>Low</td>
<td>Participant fainting</td>
<td>Participants will be asked about their history of fainting spells, and encouraged to discontinue if the circumstances of the experiment are likely to provoke a spell. Participants that continue will be monitored for signs of an impending spell. Participants are instructed to have had a meal recently and something to drink.</td>
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<tr>
<td>Low</td>
<td>Participant seizure</td>
<td>Participants are screened with a full questionnaire to exclude participants with a history of seizures or family history of epilepsy.</td>
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<tr>
<td>Low</td>
<td>Malfunction of implanted medical device</td>
<td>Participants are screened specifically for any intracranial implant or metallic plates, or other medical devices. Participants with such implanted devices are excluded.</td>
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</table>

### List resources required including personal protective clothing, chemicals and equipment needed

N/A

### List step by step instructions or order for undertaking the task

- When a participant signs up, they are sent the screening questionnaire by email and told to let the experimenter know immediately if they would answer yes to any of the questions. They are also told to make sure they have had breakfast (if they have signed up for a morning session) or lunch (if an afternoon session) before coming, and to have drunk something shortly before coming. (Low blood sugar and dehydration are risk factors for fainting.)

- Once the participant has read the Participant Information sheet and has signed the consent form, they should be taken through the safety screening questionnaire. If the participant answers yes to any of the first 10 questions, they should be excluded from the study.

- If the participant answers yes to Q11 (about fainting), this should initiate a discussion between the experimenter and participant about what sort of events provoke fainting spells. Check if the participant has eaten recently. If it seems likely that the participant could faint in response to the experimental procedures, then they should be encouraged to discontinue. Otherwise, the participant should be encouraged to monitor how they feel during the experiment and report any signs that they might be going to faint. The experimenter should also “check in” with the participant frequently to make sure they are feeling comfortable and OK to proceed.
The participant should be seated in the apparatus and EMG electrodes attached if MEPs are being performed.

To alleviate anxiety in the participant, the following steps can be taken:

1. An initial demonstration can be made with the TMS machine is set at a low output (30% or lower); the coil is triggered while held by the experimenter away from the participant (holding the coil against the experimenter’s own hand will demonstrate that the pulses are not painful).

2. While still using a low intensity, the coil is placed against the participant’s hand and triggered, so they can experience the sensation of the magnetic pulse.

3. The participant is moved into position and the coil is placed against his/her head, in the approximate location for the experiment, while still set at 30%. From this point until the start of the actual experiment, the participant is asked to trigger each pulse using the space bar on the computer keyboard.

4. The coil intensity can be increased in steps of 10%, while triggering pulses with the coil in place against the participant’s head, up to a maximum of 70%, each time checking with the participant how they feel about the stimulation and if they are happy to proceed with a stronger pulse. If a clear muscle contraction occurs, the TMS intensity should be reduced and the experimenter starts the hunt for the “hotspot”, with the participant triggering each pulse. If a hotspot is not found relatively quickly, the intensity is increased to the previous value and the hotspot again is searched for.

5. If no muscle contraction or MEP is elicited with intensities up to 70%, the intensity can be increased in steps of 5%, but always checking with the subject that they are willing to receive the stronger stimulation.

6. If the pulses produce clear muscle contraction in the face and/or neck, then lower intensities should be used.

7. Once the desired location and intensity is reached, the coil can be locked into position and the subject can commence the experiment. The experimenter should explain to the participant that from this point the pulses will be triggered automatically from the computer running the experiment and will not be triggered by the participant.

The participant can ask to stop the experiment at any stage.

List emergency shutdown procedures

The following events should lead to immediate termination of the experiment, and removal of the TMS coil. If the participant:

- feels unwell (nauseous, dizzy, gut cramps etc)
- feels faint or “needs air”
- complains of disturbances to vision or hearing
- experiences changes in heart rhythm or palpitations
- experiences sensations of heat
- becomes unresponsive
- loses consciousness
- develops stiffening of muscles, jerking movements, vocalizations, or convulsions
- develops hallucinations
- becomes incontinent

The experimenter must protect the participant from injury if he/she is losing consciousness. The coil should be pulled away from the participant’s head and the TMS machine switched off. The participant should be removed from the chair and assisted into a reclining position on the floor. Airway breathing and circulation should be assessed. Unless tonic-clonic seizure activity occurs, the participant should be turned on one side to help clear the airway and avoid aspiration. If the participant is convulsing, he/she should be turned on one side as soon as movement ceases, and maintained in that position until recovery of awareness. The experimenter must remain with the participant. When possible, seek assistance from the local First Aid Officer (John Holden, Nenad Petkovski, Caleb Owens). The participant must not leave the laboratory while still disoriented and, if necessary, the experimenter should contact a friend or relative to come and take them home.

The most likely cause is syncope (fainting). This can be difficult to distinguish from some seizures. The cardinal characteristic that distinguishes fainting from seizure is rapid recovery of consciousness within seconds.
and not minutes. Fainting is often preceded by complaints from the sufferer that “I need to lie down”, or “I need air”. Narrowing and blacking out of the visual field, sensations of heat, slowed heart rate, and loss of peripheral pulses are also more consistent with fainting. Visceral distress, nausea, dizziness, pallor are frequent symptoms. Upward eye deviation is common with fainting, but rare in partial seizures unless they progress to generalized convulsions. A participant who has fainted should remain in a reclining position after regaining consciousness until they feel recovered. They should be assisted slowly to their feet. If a friend cannot be contacted who can accompany them home, they should remain in the laboratory for at least 20 min after recovering.

If the participant has a generalised seizure, follow these steps:

- Stay calm - remain with the person.
- Time the seizure.
- Protect the person from injury - remove any hard objects from the area.
- Protect their head - place something soft under their head and loosen any tight clothing.
- Gently roll the person on their side as soon as it is possible to do so and firmly push the angle of the jaw forward to assist with breathing. A person cannot 'swallow their tongue' but the tongue can move back to cause a serious block to breathing.
- Stay with the person until the seizure ends naturally and calmly talk to the person until the regain consciousness, usually within a few minutes.
- Reassure the person that they are safe and that you will stay with them while they recover.

**DO NOT**
- restrain the person's movements.
- force anything into the mouth.
- give the person water, pills or food until they are fully alert.

After the seizure, the person should be placed on their side. Keep in mind there is a small risk of post-seizure vomiting, before the person is fully alert. Therefore the person's head should be turned so that any vomit will drain out of the mouth without being inhaled. Stay with the person until he/she recovers (5 to 20 minutes).

If the following happens, call an ambulance (000):

- the seizure activity lasts 5 or more minutes or a second seizure quickly follows.
- the person remains non-responsive for more than 5 minutes after the seizure stops.
- the person is injured or goes blue in the face.

Delayed recovery of normal consciousness beyond 30 s following a seizure mandates further medical evaluation. The participant should see their GP.

**List Emergency procedures for how to deal with fires, spills or exposure to hazardous substances**

In the event of an emergency evacuation, the following steps should be followed.

- If the “prepare to evacuate” alarm sounds (BEEP… BEEP… BEEP…), the experiment should be stopped as soon as possible, the TMS machine should be switched off, and the participant should be assisted out of the chair. Both experimenter and participant should gather personal possessions and be prepared to leave.
- If the alarm progresses to the EVACUATE alarm (WHOOP… WHOOP… WHOOP, and a recorded voice advising to leave the building), both the experimenter and subjects must leave the building. The nearest fire exit is via the stairs directly opposite the lab door, and out through the back door of the building. The experimenter and participant should go to the congregation point on the lawn between the Education Building and Teachers College.

**List Clean up and waste disposal requirements**

N/A
List references used in the development of this SWP, e.g. codes of practice

http://www.epilepsyaustralia.net/

List competency required – qualifications, certificates, licensing, training - e.g. course or instruction:

Researchers must have completed the safety induction for working in the TMS laboratory.

Staff approved to assess competence for this SWP

Justin Harris; Irina Harris

SWP Sign off sheet

SWP name and version:

<table>
<thead>
<tr>
<th>Name</th>
<th>Signature</th>
<th>Date Competent</th>
<th>Name of Assessor/Authoriser</th>
<th>Assessor/Authoriser signature</th>
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