

Insert Header with institution's name or institution's letterhead

Participant Information Sheet/Consent Form

Interventional Study - Adult providing own consent

[Insert site name]

Title	<i>Does repetitive transcranial magnetic stimulation (rTMS), compared to sham rTMS, improve social communication in adolescents and young adults with autism spectrum disorder (ASD)?</i>
Short Title	<i>MRFF TBS-ASD</i>
Protocol Number	<i>v2, 11/09/2020</i>
Project Sponsor	<i>Deakin University</i>
Coordinating Principal Investigator	<i>Prof. Peter Enticott</i>
Associate Investigator(s)	<i>Prof. Paul Fitzgerald, A/Prof. Karen Barlow, Prof. Ian Hickie, Dr Melissa Licari, Dr Nigel Rogasch, Prof. Christel Middeldorp, Dr Scott Clark, Dr Ann-Maree Vallence, Dr Kelsie Boulton, Prof. Adam Guastella, Prof. Andrew Whitehouse, Prof. Cherrie Galletly, Dr Gail Alvares, Dr Hakuei Fujiyama, A/Prof. Helen Heussler, A/Prof. Jeffrey Craig, Dr Melissa Kirkovski, Dr Natalie Mills, Prof. Nicole Rinehart, Dr Peter Donaldson, Dr Talitha Ford, Prof. Karen Caeyenberghs</i>
Location	<i>[Insert site-specific location]</i>

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. This is because you have been diagnosed with autism spectrum disorder (ASD). The research project is testing a new treatment for ASD. The new treatment is called repetitive transcranial magnetic stimulation (rTMS).

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project

- Consent to have the tests and treatments that are described
- Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

Many individuals with ASD experience difficulty with social functioning; for example, in understanding what other people are thinking or feeling. This may cause significant distress and lead to difficulties and anxiety in social situations. There are very few treatment options for improving abilities related to social functioning in ASD.

The aim of this project is to determine whether rTMS can be used to improve social function. rTMS is a safe and non-invasive means of stimulating nerve cells in a particular part of the brain via the administration of brief magnetic pulses. rTMS has been developed as a treatment for major depressive disorder, and we have previously found that rTMS can benefit social aspects of ASD.

In this study we will stimulate a region of the brain that is involved in social understanding and social communication. This region is called the right temporoparietal junction, or rTPJ.

Some participants will receive the real form of rTMS, while others will receive a sham or placebo form. The sham or placebo form mimics the feeling of rTMS, but no brain stimulation is delivered. You will not know which one you receive until the end of your involvement in the study. Those who received the sham or placebo form will be given the opportunity to undergo the real rTMS treatment at the end of their involvement in the study.

150 people (aged 14-40 years) will take part in this study, which is being conducted throughout Australia. There are sites in Brisbane, Sydney, Melbourne, Adelaide, and Perth. Participants will be recruited from around Australia, but primarily the greater metropolitan regions within these five cities.

rTMS is an experimental treatment. This means that it is not an approved treatment for ASD in Australia or elsewhere.

This research has been initiated by the study investigator, Prof. Peter Enticott (Deakin University, Melbourne). This research has been funded by the National Health and Medical Research Council (NHMRC) of Australia through a Medical Research Future Fund grant (MRFF RCRDUN Neurological Disorders 2020; Application APP1199298).

3 What does participation in this research involve?

You will be participating in a randomised controlled research project. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. We put people into groups and give each group a different treatment (in this case, real rTMS vs. sham/placebo rTMS). The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random).

This is a double-blind study. This means that neither you nor your study doctor will know which treatment you are receiving (in this case, real rTMS or sham/placebo rTMS). However, in certain circumstances your study doctor can find out which treatment you are receiving. Participants will be randomly allocated to either the real rTMS or sham/placebo rTMS condition. As mentioned, those allocated to the sham or placebo form will be given the opportunity to undergo the real rTMS treatment at the end of their involvement in the study.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

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If you decide to take part in this project, you will be asked to take part in a number of interviews and procedures over the course of approximately eight months. These are outlined below.

Prior to completing the study, we will need to determine your eligibility to take part in the study. We will do this by asking you questions (either over the phone or via email) about your health. We will also ask you to provide a letter or report confirming your diagnosis of ASD; if you are not able to provide this, we will seek permission (via the consent form) to contact your doctor or psychologist directly to confirm your diagnosis.

Assessment Session One: The first assessment will take place at [site-specific location]. It will take approximately three hours, but you will be given regular breaks throughout the session.

We will begin by asking you some questions about your health, which will help to confirm your eligibility to take part in the study. We will then ask some questions about yourself that are relevant to ASD. This will include, for example, what you enjoy doing and how much you like being with other people. We will also ask you to have someone who knows you well (e.g., a parent, sibling, spouse, or close friend) complete a series of questionnaires. You can nominate this person and we will ask that they agree to complete these questionnaires now and another four times during the study.

You will then complete a short cognitive assessment, which involves solving puzzles and describing what different words mean.

Finally, you will undergo electroencephalography (EEG), which involves wearing an “electrode cap” to measure the electrical activity of your brain, or your “brainwaves.” The electrode cap feels similar to a swimming cap. It will also feel a little damp, as we need to put a small amount of gel or saline into the cap to ensure that we get accurate recordings. For most of the EEG you will simply rest while sitting in a chair, but you will also complete a short task on a computer that involves looking at different objects (e.g., faces, household furniture, butterflies).

Assessment Session Two: Around one-week after “Assessment Session One” you will then undergo a magnetic resonance imaging (MRI) brain scan at [site-specific location]. The MRI brain scan takes around 45-60 minutes, during which you will be asked to lie still in an MRI scanner. (Please note that with preparation time you attend the MRI facility for up to two hours.) MRI is a routinely performed, painless ways of examining brain structure and activity. We will use the MRI to accurately place the rTMS device, and ensure that we are stimulating the correct brain region. The MRI procedure may also help us better understand how the treatment works and to determine who is likely to respond to treatment and why.

Assessment Session Three: During the same week of “Assessment Session Two,” you will attend a two-hour assessment session at [site-specific location]. Here we will ask you questions about yourself, some of which are relevant to ASD, while others relate to your mood, concentration, stress, and your satisfaction with life. We will also ask you to complete some cognitive tasks on a computer/tablet. These tasks measure your memory, attention, and understanding of other people’s emotions. We will also ask you to provide a sample for genetic analysis; this will involve having a cotton swab rubbed against the inside of your cheek. These genetic analyses are conducted to investigate whether people with certain genetic profiles respond better to the intervention. You will not receive any health information from these genetic analyses, and they are not considered to be clinically informative.

rTMS Intervention (4 weeks): The week after “Assessment Session Three” you will begin the rTMS intervention, which involves attending [site-specific location] and receiving rTMS for 3 minutes, 20 seconds each consecutive weekday for a four-week period (20 rTMS sessions in total).

You will have your first rTMS session on the Monday after “Assessment Session Three.” At the beginning of the first session we will administer transcranial magnetic stimulation (TMS) to the

area of the brain that controls the muscles in your hand. This will measure how excitable your brain is and is used to help us determine the personalised settings that will be used for your rTMS treatments. This takes approximately 10 minutes and is not uncomfortable, although you may feel some twitches in the muscle of your hand while the TMS is occurring.

During each rTMS session you will be awake, alert, and aware of what is happening at all times. During rTMS a coil will be placed against the head, through which rTMS is administered. This is connected to a machine that sends an electrical current through the coil. The current produces a magnetic field that is very focused and is able to stimulate electrical activity in nerves below the coil. These are usually nerve cells in the outer layers of the brain. The sensations associated with rTMS are mild, and most people describe it as a “tapping” sensation on their head. During a rTMS procedure you will hear clicking sounds as the current passes through the coil. You will wear earplugs so that this noise doesn’t disturb you.

Including setup time, each subsequent treatment session should only take approximately 10 minutes. At the end of each treatment week (i.e., on the Friday session) we will ask you a number of questions about your experience of rTMS, and whether you feel you have experienced any side effects.

Assessment Session Four: The week after your last rTMS session, you will attend another two-hour assessment session at [site-specific location]. Here we will again ask you questions about yourself, some of which are relevant to ASD, while others relate to your mood, concentration, stress, and satisfaction with life. We will also again ask you to complete some cognitive tasks on a computer/tablet and to provide another sample (cheek swab) for genetic analysis.

Assessment Session Five: One-month after your last rTMS session, you will attend another two-hour assessment session at [site-specific location]. This session will be identical to Assessment Session Four.

Assessment Session Six: Three-months after your last rTMS session, you will attend a one-hour assessment session at [site-specific location]. This session will be identical to Assessment Session Five except that you will not complete the computerised cognitive tasks.

Assessment Session Seven: Six-months after your last rTMS session, you will attend a final two-hour assessment session at [site-specific location]. This session will be identical to Assessment Session Five. Following the assessment, you will be unblinded; that is, a member of the research team will tell you which treatment condition you received (i.e., real or sham/placebo). If you received the real treatment, your involvement in the study will conclude. If you received the sham/placebo condition, you will be given the opportunity to receive the real treatment and can liaise with research staff to determine when you would like to undergo this four-week treatment.

There are no costs associated with participating in this research project. All treatments, tests, and medical care required as part of the research project will be provided to you free of charge.

You will not be paid for your participation in this research, but you will be reimbursed \$200 to contribute towards costs that you incur as a result of participating in this research project (e.g., travel). If you complete only part of the study and then decide to withdraw, you will be reimbursed a proportion of this amount based on the proportion of the study completed.

Please note that no study procedures will be performed until consent has been obtained.

It is desirable that your local doctor be advised of your decision to participate in this research project. If you have a local doctor, we strongly recommend that you inform them of your participation in this research project.

The research will be monitored by an independent Data Safety Monitoring Board, who will meet twice per year and review the conduct of the trial, monitor study data, and review any serious adverse events that might arise throughout the trial.

4 What do I have to do?

You will be able to continue taking your usual medication if you participate in this study, but you will need to inform us of any changes to this medication that occur during your participation in the study.

There are several reasons why you may not be able to take part in this study. These include:

- The presence of metal anywhere in the head (except the mouth)
- A history of seizure or epilepsy, or evidence of significant seizure activity as assessed by EEG
- A history of serious head injury
- The presence of certain implanted medical devices (e.g., cardiac pacemaker, medication pumps)
- Serious heart disease (as there is an increased risk of serious injury in the event of a seizure)
- Being deemed unsuitable to undergo MRI (e.g., due to presence of metal in the body)
- Unstable medical condition
- Unstable medication regime
- Certain medications
- Substance use disorder
- Undergoing another current treatment for social communication
- Employment as a professional driver or machine operator (as the event of a seizure may affect employment)
- Pregnancy (female participants for whom child-bearing is a possibility will be required to undergo a urine screen)
- Certain neurological or psychiatric diagnoses (i.e., those not commonly associated with ASD, such as psychosis)
- A measured verbal intelligence quotient (IQ) of less than 55

5 Other relevant information about the research project

This study is only taking place in Australia. There will be 150 participants in this study, with 30 taking part in each of the five cities involved: Brisbane, Sydney, Melbourne, Adelaide, and Perth. There are a total of 14 organisations involved, including Universities, hospitals, and medical centres. This study is a follow-on study from our previous trials of rTMS in ASD, which have taken place at Monash University, Deakin University, The Alfred hospital, and the Epworth Camberwell.

6 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you, or your relationship with *[site-specific Institution/s]*.

7 What are the possible benefits of taking part?

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We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits include an improvement in social understanding and functioning, including an increased ability to accurately infer what other people are thinking or feeling.

8 What are the possible risks and disadvantages of taking part?

Repetitive Transcranial Magnetic Stimulation (rTMS)

Medical treatments often cause side effects. You may have none, some, or all of the effects listed below, and they may be mild, moderate, or severe. If you have any of these side effects, or are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects.

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your study doctor immediately about any new or unusual symptoms that you get.

Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting, or permanent. If a severe side effect or reaction occurs, your study doctor may need to stop your treatment. Your study doctor will discuss the best way of managing any side effects with you.

Noise: The clicking noise made by the coil may be uncomfortable. You will wear earplugs during treatment to minimise any discomfort.

Headache: A headache can occur during rTMS and is thought to affect approximately 3% or 3 in 100 participants. It is thought to be caused by stimulation of nerves in the scalp. If you were to experience such a headache, it will respond quickly to simple pain medication such as aspirin, ibuprofen, or paracetamol.

Scalp Sensation: During the treatment itself, you might feel a tapping or twitching sensation on your scalp as the magnetic pulse stimulates muscles in your scalp as it passes into the brain. This sensation varies between people from very soft to quite strong. If you find it uncomfortable, we will use a lower stimulation intensity and only increase it as you find it tolerable.

Seizure: The main concern associated with rTMS is its potential to induce a fit or seizure. This risk is extremely low, but is increased for those with a history of seizure activity (where a seizure resulting from rTMS affects about 2% or 2 in 100 such individuals). If you have ever experienced a seizure, or if your EEG shows evidence of epileptiform activity, you will not be able to take part in this study. Investigators using rTMS have developed safety guidelines to minimise the risk of seizure. The rTMS we provide is well within what is considered to be safe. It is important to note that experiencing a seizure induced by rTMS has never led to the development of epilepsy or increased the probability of having subsequent unprovoked seizures. There will always be medically trained staff available when you have rTMS. Staff will monitor you and know how to treat a seizure should one occur.

The effects of rTMS on the unborn child and on the newborn baby are not known. Because of this, it is important that research project participants are not pregnant or breast-feeding and do not become pregnant during the course of the research project. You must not participate in the research if you are pregnant or trying to become pregnant, or breast-feeding. If you are female and child-bearing is a possibility, you will be required to undergo a urinal pregnancy test prior to commencing rTMS. This test will be processed by a female member of the research staff.

If you do become pregnant whilst participating in the research project, you should advise research staff immediately. The researchers will withdraw you from the research project and

advise on further medical attention should this be necessary. You must not continue in the research if you become pregnant.

Your ability to drive or use public transport will not be impaired following rTMS.

It is also possible that there are unknown risks of rTMS.

Magnetic Resonance Imaging (MRI)

MRI stands for magnetic resonance imaging. An MRI scanner is a machine that uses electromagnetic radiation (radio waves) in a strong magnetic field to take clear pictures of the inside of the body. Electromagnetic radiation is not the same as ionising radiation used, for example, in X-rays. The pictures taken by the machine are called MRI scans.

There are no proven long-term risks related to MRI scans as used in this research project. MRI is considered to be safe when performed at a centre with appropriate procedures. However, the magnetic attraction for some metal objects can pose a safety risk, so it is important that metal objects are not taken into the scanner room.

We will thoroughly examine you to make sure there is no reason for you not to have the scan. You must tell us if you have metal implanted in your body, such as a pacemaker or metal pins.

The MRI scanner is shaped like a narrow tunnel. Foam cushioning and Velcro straps are used to keep your head relatively still during scanning. While the mask, cushions, and straps are restraining, they should not be uncomfortable. Some people may experience claustrophobia while having an MRI scan. Please let us know if you have experienced claustrophobia in the past. The MRI scanner is noisy, so you will wear ear plugs and headphones to reduce the noise. We will be able to see you and communicate with you during the scanning, and you will be able to stop the machine at any time by pushing a button. If you become uncomfortable during the session, we can pause or stop the scanning.

The scans we are taking are for research purposes. They are not intended to be used like scans taken for a full clinical examination. The scans will not be used to help diagnose, treat, or manage a particular condition. A specialist will look at your MRI scans for features relevant to the research project. On rare occasions, the specialist may find an unusual feature that could have a significant risk to your health. If this happens, we will contact you to talk about the findings. We cannot guarantee that we will find any/all unusual features. There may be wider implications from abnormal findings (e.g., for future applications for some kinds of insurance).

Other

We will ask you if you have used illegal drugs. That information will be stored in a re-identifiable (or coded) format. In the event that the researchers are required to disclose that information, it may be used against you in legal proceedings or otherwise.

If you become upset or distressed as a result of your participation in the research, the study doctor will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

9 What will happen to my test samples?

You will be asked to provide additional consent for the collection of your tissue (i.e., cheek swab) during the research project. As noted, these samples are collected to allow us to investigate whether certain genetic profiles are associated with a better response to the rTMS intervention. We will only conduct these analyses at a group level. You will not receive any health information (e.g., genetic disease predisposition) from these genetic analyses, and they are not considered to be clinically informative. Your genetic material and information, where

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identified or potentially identifiable, will not be released for other uses without your prior consent, unless required by law.

Samples of your tissue obtained for the purpose of this research project will be transferred to the Institute for Molecular Bioscience, University of Queensland, who will charge a fee to the research team to recover some of the costs of storing and administering the tissue samples. The University of Queensland will not transfer or sell your samples to any third party.

10 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, your study doctor will explain the reasons and arrange for your regular health care to continue.

11 Can I have other treatments during this research project?

Whilst you are participating in this research project, you can continue to take the medications or treatments you have been taking for your condition or for other reasons. It is important to tell the research staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture, or other alternative treatments. You should also tell the study staff about any changes to these during your participation in the research project.

Because this trial is assessing the effect of rTMS on social communication, you cannot participate if you are also undergoing any other treatment or intervention for social communication. This includes interventions delivered by psychologists.

12 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want the researchers to do this, you must tell them before you join the research project.

13 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

- Unacceptable side effects
- The drug/treatment/device being shown not to be effective
- The drug/treatment/device being shown to work and not need further testing
- Decisions made by local regulatory/health authorities.

14 What happens when the research project ends?

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You will be sent a summary of the main findings when the project has been completed. This is a 4-year study and it is expected that study results will be available by late 2024. Your data will then be securely archived at Deakin University.

Please note that rTMS will not be available from the research sites after completing the study. It may be approved for future use in ASD, but this will depend on the results from the current study.

Part 2 How is the research project being conducted?

15 What will happen to information about me?

By signing the consent form, you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Upon enrolment in the trial you will be allocated a unique study identification code. Your name will not appear with the research data that we collect from you and it will only be possible to re-identify your data using the study code. Only the research team will know which code identifies which participant. Your information will only be used for the purpose of this research project and future research projects, and it will only be disclosed with your permission, except as required by law.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form, you agree to the study team accessing health records if they are relevant to your participation in this research project.

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the Sponsor, Deakin University, the institution relevant to this Participant Information Sheet, *[Name of institution]*, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. We will only present group-level findings (e.g., average scores across the group) and no individual data will be reported.

In accordance with relevant Australian *and/or [Name of state/territory]* privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project and for future research that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

It is expected that deidentified data from this study will be made available to other researchers via online data repositories. You will not be able to be identified in these repositories. It is also possible that the research team will use your data from this research project for future studies, but again you will not be able to be identified.

16 Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical

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treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

If you have complaints about your treatment by members of staff working on this research project, you should contact the person nominated in Section 19 below. If you have complaints about any of the ethical aspects of this study, you can contact the local reviewing HREC Executive Officer nominated in Section 19 below. Complaints about clinical trials can also be directed to the Office of the Australian Information Commissioner.

17 Who is organising and funding the research?

This research project is being conducted by a team of researchers led by Prof. Peter Enticott from Deakin University, Victoria. It is funded through a Medical Research Future Fund grant from the National Health and Medical Research Council to Prof. Enticott and the research team.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

18 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Monash Health and *[Name of institutions]*.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2018)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

19 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems that may be related to your involvement in the project (for example, any side effects), you can contact your site's principal study doctor on *[phone number]* or any of the following people:

Study contact person

Name	<i>[Name]</i>
Position	<i>[Position]</i>
Telephone	<i>[Phone number]</i>
Email	<i>[Email address]</i>

Clinical contact person

Name	<i>[Name]</i>
Position	<i>[Position]</i>
Telephone	<i>[Phone number]</i>
Email	<i>[Email address]</i>

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name	<i>[Name]</i>
Position	<i>[Position]</i>
Telephone	<i>[Phone number]</i>
Email	<i>[Email address]</i>

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	<i>Monash Health</i>
HREC Executive Officer	<i>Ms Deborah Dell</i>
Telephone	<i>(03) 9594 4605</i>
Email	<i>research@monashhealth.org</i>

Local HREC Office contact (Single Site - Research Governance Officer)

Name	<i>[Name]</i>
Position	<i>[Position]</i>
Telephone	<i>[Phone number]</i>
Email	<i>[Email address]</i>

Consent Form - Adult providing own consent

Title *Does repetitive transcranial magnetic stimulation (rTMS), compared to sham rTMS, improve social communication in adolescents and young adults with autism spectrum disorder (ASD)?*

Short Title *MRFF RTMS-ASD*

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Location *[Location where the research will be conducted]*

Consent Agreement

I have read the Participant Information Sheet.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to *[Name of Institution]* concerning my condition and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

I agree for my anonymous study data to be shared with other researchers, including those outside *[Name of Institution]* and outside Australia, for future studies.

I agree to my anonymised data being made available through online repositories and to the use of my data in any future research.

Declaration by Participant – for participants who have read the information

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____
Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

I consent to the storage and use of tissue samples (cheek swabs) taken from me for use, as described in the relevant section of the Participant Information Sheet, for:

- This specific research project
- Other research that is closely related to this research project
- Any future research.

By signing this consent section, I agree to the use of my tissue samples for genetic testing, as outlined in the relevant Section of the Participant Information Sheet.

Name of Participant (please print) _____
Signature _____ Date _____

Name of Study Doctor/
Senior Researcher† (please print) _____
Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning the research project.

Note: All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation - *Adult providing own consent*

Title *Does repetitive transcranial magnetic stimulation (rTMS), compared to sham rTMS, improve social communication in adolescents and young adults with autism spectrum disorder (ASD)?*

Short Title *MRFF RTMS-ASD*

Protocol Number *v2, 11/09/2020*

Project Sponsor *Deakin University*

Coordinating Principal Investigator *Prof. Peter Enticott*

Associate Investigator(s) *Prof. Paul Fitzgerald, A/Prof. Karen Barlow, Prof. Ian Hickie, Dr Melissa Licari, Dr Nigel Rogasch, Prof. Christel Middeldorp, Dr Scott Clark, Dr Ann-Maree Vallenge, Dr Kelsie Boulton, Prof. Adam Guastella, Prof. Andrew Whitehouse, Prof. Cherrie Galletly, Dr Gail Alvares, Dr Hakuei Fujiyama, A/Prof. Helen Heussler, A/Prof. Jeffrey Craig, Dr Melissa Kirkovski, Dr Natalie Mills, Prof. Nicole Rinehart, Dr Peter Donaldson, Dr Talitha Ford, Prof. Karen Caeyenberghs*

Location *[Location where the research will be conducted]*

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with *[Institution]*.

Name of Participant (please print) _____

Signature _____ Date _____

Description of circumstances where communicated verbally:

Declaration by Study Doctor/Senior Researcher[†]

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher[†] (please print) _____

Signature _____ Date _____

[†] A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.

Master Adult Participant Information Sheet/Consent Form 11/09/2020

Page 1 of 1

[Site Name] Site Master Participant Information Sheet/Consent Form *[Date]*

Local governance version *[Date]* (Site PI use only)