Participant Information Sheet/Consent Form

Interventional Study – *Parent or Spouse completing questionnaires*

Monash Alfred Psychiatry Research Centre (MAPrc); School of Psychology, Deakin University; Monash Biomedical Imaging, Monash University

Title	*Theta burst stimulation (TBS) to improve social relating in autism spectrum disorder (ASD)*
Project Number	*432/16*
Short Title	*TBS-ASD*
Project Sponsor	*Deakin University*
Principal Investigators	*A/Prof. Peter Enticott, Prof. Paul Fitzgerald*
Associate Investigators	*Dr. Melissa Kirkovski, Dr. Bernadette Fitzgibbon, Dr. Natalia Albein-Urios, A/Prof. Kate Hoy, Ms. Susan McQueen, Dr. David Elliot, Ms. Lenore Wambeek*

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. This is because somebody close to you has been diagnosed with autism spectrum disorder (ASD), and is taking part in this study. They have identified you as somebody who knows them well, and who is able to complete some questionnaires about their ASD-related symptoms or behaviours.

The research project is testing a new treatment for ASD. The new treatment is called “theta burst stimulation” (TBS), which is a form of 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 complete the questionnaire described
- Consent to the use of your responses to the questionnaire 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?

This is a study testing whether TBS may be effective in improving social functioning in ASD.

20 people (aged 14-30 years) will take part in the study, which is being conducted at three places: Monash Alfred Psychiatry Research Centre (MAPrc, St Kilda Rd, Melbourne), Deakin University (Burwood Highway, Burwood), and Monash Biomedical Imaging (MBI, Blackburn Rd, Clayton). Participants will be recruited from around Australia, but primarily the greater Melbourne area.

Participants will also nominate somebody close to them (i.e., a parent or a spouse) who is able to complete a questionnaire about them on several occasions throughout the study. You have been identified as somebody who might be able to complete this questionnaire during their involvement.

TBS is an experimental treatment. This means that it is not an approved treatment for ASD in Australia or elsewhere. If you would like to receive more detailed information about the intervention and the research project, please contact the Primary Investigator (A/Prof. Peter Enticott, [03] 9244 5504 or peter.enticott@deakin.edu.au).

This research has been initiated by the study investigator, A/Prof. Peter Enticott. This research has been funded by the Brain and Behaviour Research Foundation (New York, USA).

3 What does participation in this research involve?

If you decide to take part, you will be asked to complete a questionnaire called the “Social Responsiveness Scale” (SRS) on 9 separate occasions over a 12-month period (average every 1-2 months). The SRS is a commonly-used measure of some of the features and symptoms of ASD. You will be asked to complete it in relation to the participant who is taking part in the intervention study and has nominated you as a potential person to complete the questionnaire. You will be posted this questionnaire, and can complete it at home and mail back to the researchers. Self-addressed, stamped envelopes will be provided.

You will not be paid for your participation in this research.

Please note that no questionnaires will be administered until consent has been obtained.

4 What do I have to do?

If you agree to take part, one of the researchers will contact you by phone or email to obtain your address. As noted, you will then be sent the SRS via post every 1-2 months over a 12-month period (9 times in total). Instructions for completing this questionnaire will be included. You will be asked to complete and return the SRS within a week of receipt. If you would prefer, we can instead administer the SRS to you over the phone. Please let one of the researchers know if you would prefer to complete the SRS via phone.

5 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 The Alfred, Monash University, or Deakin University.

6 What are the possible benefits of taking part?

There will be no clear benefit to you from your participation in this research; however, completing these questionnaires will help us to determine whether rTMS has a benefit for social aspects of ASD.

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

There are no risks to taking part in this research. You may find completion of the SRS a slight inconvenience, as it will take approximately 10-15 minutes each time.

Please note that your responses will not be shared with the study participant, but they do have the right to access this information if they wish.

8 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. If you do withdraw your consent during the research project, the study staff will not collect additional information from you, although 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 by the researchers up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

Part 2 How is the research project being conducted?

9 What will happen to information collected from me?

We will not collect any personal information about you other than that collected as part of the SRS. By signing the consent form you consent to the study doctor and relevant research staff collecting and using this information for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Your information will be used for the purpose of this research project or for another purpose by the researcher (for which ethical approval will be sought). Your information will only be disclosed with your permission, except as required by law. All personal information that can identify you will be stored at MAPrc in a locked area by the investigators and will be kept under safe storage indefinitely as per the hospital protocol. Electronic data will be kept on a secure server hosted by Deakin University. All questionnaires will be labelled with a numerical code and will not contain any information that can identify you as a participant. Only the researchers A/Prof. Enticott, Prof. Fitzgerald, and Dr. Kirkovski will have access to the data.

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.

In accordance with relevant Australian and Victorian 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 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.

10 Who is organising and funding the research?

This research project is being conducted by A/Prof. Peter Enticott and Prof. Paul Fitzgerald. It is funded through a NARSAD Independent Investigator Award to A/Prof. Peter Enticott from the Brain and Behaviour Research Foundation.

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

11 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 HRECs of The Alfred, Deakin University, and Monash University.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

12 Further information and who to contact

If you want any further information concerning this project please contact:

Name	A/Prof. Peter Enticott
Position	Associate Professor of Psychology (Cognitive Neuroscience)
Telephone	(03) 9244 5504
Email	peter.enticott@deakin.edu.au

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 name	Alfred Hospital Ethics Committee
Telephone	(03) 9076 3619
Email	research@alfred.org.au

Consent Form – *Parent or Spouse completing questionnaires*

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Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand. I understand the purposes, procedures and risks of the research described in the project.

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 consent for the data collected in this project to be used for another purpose by the researchers (for which ethical approval will be sought). (Please tick if you agree.)

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by 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.

Form for Withdrawal of Participation - *Parent or Spouse completing questionnaires*

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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 The Alfred, Monash University, or Deakin University.

Name of Participant (please print) _____

Signature _____ Date _____

Relevant Circumstances (to be completed by Senior Researcher):

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.