AUSTRALIAN CATHOLIC UNIVERSITY

Cognition&Emotion Research Centre

PARTICIPANT INFORMATION LETTER

PROJECT TITLE: A brain study of oxytocin's effects on social cognition in ageing.
PRINCIPAL INVESTIGATOR: Dr Izelle Labuschagne
CO-INVESTIGATORS: Prof Peter Rendell
RESEARCH ASSISSTANT: Ms Sally Grace
ACU HREC REGISTER NUMBER: 2015-181H

Dear Participant,

You are invited to participate in the research project described below.

What is the project about?
The research project aims to assess whether performance in various social and cognitive skills affected by ageing may be improved by administration of oxytocin, and what brain responses might underlie these changes.

Who is undertaking the project?
This project is being supervised by Professor Peter Rendell and Dr. Izelle Labuschagne, researchers and lecturers in the School of Psychology at Australian Catholic University. The research team have extensive experience in conducting both clinical and neuroimaging research. Dr. Labuschagne and Miss Grace (a PhD student) have experience running both brain imaging studies involving MRI and clinical trials involving oxytocin and other pharmacological interventions. Prof. Peter Rendell has an extensive experience with research involving cognitive function in ageing populations.

What is the project about?
The research project investigates the biological processes, including brain and hormonal responses, underlying social and emotional processes in elderly populations. We will recruit healthy older adults (age 60 years and over) and 70 younger adults (aged 18 to 39 years). The research project will be a brain imaging study during which a MRI scan will be completed and we will also collect samples including blood and saliva samples from all participants.

Oxytocin and *vasopressin* are two hormones that are closely related and produced in the same area in the brain. Oxytocin is best known for its role in pregnancy, and it is commonly administered to pregnant women to induce labour. Our research is not interested in the pregnancy effects of these hormones, but instead how these hormones play a role in our everyday social and emotional behaviours.

This research is novel and will provide answers to questions such as whether hormonal levels and brain responses are implicated in social and emotional behaviours within different age groups.

What will I be asked to do?
Initially, participants will be screened over the phone to ensure that you are eligible to participate in the study. This screening involves some questions about your medical history. The study includes strict inclusion/exclusion criteria. The following forms part of the exclusion criteria: Left-handers; presence of metal or similar objects that are

attracted to magnetic fields; psychological or neurological medications; claustrophobia; history of significant head injury; presence of psychological or neurological disorder/disease, etc. If you meet any of the exclusion criteria, you will be informed by the researcher that you are unable to participate in the study. You will also be provided with details of why this is the case. However, if the exclusion criteria are not met, and you are deemed suitable to participate, you will be asked to meet one of the researchers to conduct the initial session. You will be asked to attend two 2 MRI sessions approximately a week apart.

Brain scan (MRI) assessment (approx. 2.5 hrs): The MRI scan session will be conducted at **The Brain and Psychological Sciences Research Centre (Swinburne University of Technology, Burwood Hwy, Hawthorn)**; see map at end of document.

i) Upon arrival – you will complete a MRI screening form. You will then be asked to complete a series of demographic questionnaires.

ii) You will be given one dose of a nasal spray of either oxytocin or the placebo and you will be asked to wait 45 minutes for it to take effect. After 45 minutes you will be asked to complete several tasks designed to measure aspects of social cognitive function.

iii) For the MRI scan, you will be screened again by a radiographer to ensure you are ready to enter the scanner. You will be asked to complete a Swinburne MRI safety questionnaire administered by our staff radiographer that largely entails questions regarding any metal you have on or in your body, such as that from any surgery involving metal plates and pace makers, though other questions are also asked. Due to the nature of MRI and the involvement of strong magnetic fields, no metal can be taken into the room. It is very important that you fill in this questionnaire correctly, as some conditions, i.e. having a pacemaker, can be dangerous. The scanner is also quite noisy so you will be provided with headphones and earplugs to reduce this noise. You will be in the scanner for approximately 1 hour during which we will talk to you throughout the session via a microphone. During the scan, you will be asked to complete three computerised tasks and you will be given a button box in your hands to make your responses – this will be similar to playing a computer game, only this time you will be doing this inside an MRI scanner. Both tasks involve viewing pictures of human faces with different emotional expressions. You will have a chance to practice these tasks prior to entering the scanner to make sure you are familiar with how it all works.

For more information, you can also visit the website for Swinburne's neuroimaging facility: http://www.swinburne.edu.au/lss/bpsyc/facilities.html

How much time will the project take?

This research project will require a phone screening session of approximately 15-20 minutes during a convenient time. If you are suitable for the MRI scan, the MRI session at The Brain and Psychological Sciences Research Centre will take approximately 2.5 hours which includes the 1 hour long MRI scan. You will be given several breaks when needed during the duration of the testing sessions to minimise any fatigue or discomfort.

Are there any risks associated with participating in this project?
During the two sessions you will be asked to take part in a several tests that will measure your social cognitive function. These tests will take no longer than one hour to complete and will pose no major stress to participants taking part. Some tests may be conducted in pen and pencil, whilst others may be conducted orally with a researcher. Although the testing session is 1-2 hours long, each task is relatively short and participants will be encouraged to take breaks between tasks when needed.

Brain scan (MRI): The MRI procedure does not involve any exposure to any ionizing radiation, and there is no known health risks associated with the MRI procedure. It is possible, however, that some discomfort will be felt during scanning due to the small cavity of the MRI scanner which could restrict your body movements, and also due to the noise from the MRI scanner. To minimise and manage any risks posed by the study, a number of steps will be put in place. Firstly, you will be thoroughly screened for MRI clearance prior to participating by both the research staff and the MRI radiographer. This will involve questioning you and/or your parents/guardians about metal implants or accidents whereby metal may have become lodged in the body, and about potential pregnancies. Secondly, physical discomfort inside the scanner will be reduced by cushioning and earplugs (standard procedure for MRI facilities). Thirdly, you will be able to communicate with the MRI radiographer and the researcher at all times during scanning; they will also provide you with a 'panic' button which you may press at any stage to stop the scanner if you are not comfortable to continue. Fourthly, you will also be made aware prior to participation of your rights to stop the scanning and/or cease participation at any stage.

What are the benefits of the research project?
Participants will be financially reimbursed to cover any costs they may incur as a result of participating in this research by the psychology department at ACU. There are no immediate benefits to participants. However, the study will provide the researchers with a better understanding of age-related social and emotional changes and will assist researchers in exploring the role of oxytocin related changes.

Will anyone else know the results of the project?
All participants will be given a code and names will not be retained with the data. The students will be reporting the findings in a thesis and we plan to also report the findings at a conference and/or in a scientific journal. It is emphasized that individual participants will not be able to be identified in any report of the study, as only aggregate data will be reported.

Can I withdraw from the study?
Participation in this study is completely voluntary. You are not under any obligation to participate. If you agree to participate, you can withdraw from the study at any time

without adverse consequences. If you are an ACU student withdrawal from this study will in no way affect your ACU studies. Confidentiality will be maintained during the study and in any report. In the event that you decide to withdraw from the study, any data collected prior to withdrawal will be kept in a non-identifiable format by assigning a participant ID code. If you would like for your study data to be removed, please inform the researcher when you inform them of your withdrawal. Your data will then be deleted. Otherwise, the data will be retained for analysis. There are no consequences involved in withdrawing your data.

Will I be able to find out the results of the project?
Findings of the study will be made available to participants upon request.

Who do I contact if I have questions about the project?
Any questions regarding this project can be directed to the Principal Investigator: Professor Peter Rendell in the School of Psychology, St. Patrick's Campus (Australian Catholic University, Level 5, The Daniel Mannix Building, Young Street, Fitzroy 3065, phone 03 9953 3126).

What if I have a complaint or any concerns?
The study has been reviewed by the Human Research Ethics Committee at Australian Catholic University (review number 2014 145V). If you have any complaints or concerns about the conduct of the project, you may write to the Manager of the Human Research Ethics Committee care of the Office of the Deputy Vice Chancellor (Research).

Manager, Ethics
c/o Office of the Deputy Vice Chancellor (Research)
Australian Catholic University
North Sydney Campus
PO Box 968
NORTH SYDNEY, NSW 2059
Ph.: 02 9739 2519
Fax: 02 9739 2870
Email: res.ethics@acu.edu.au

Any complaint or concern will be treated in confidence and fully investigated. You will be informed of the outcome.

I want to participate! How do I sign up?
If you are willing to participate please sign the attached informed consent forms. You should sign both copies of the consent form and keep one copy for your records and return the other copy to the staff supervisor. Your support for the research project will be most appreciated.

Yours sincerely,

Dr Izelle Labuschagne
Principal Investigator

Professor Peter Rendell
Principal Investigator

Ms Sally Grace
Research Assistant

Professor Peter Rendell
Tel: 03 9953 3126 **Fax:** 03 9953 3205
Email:peter.rendell@acu.edu.au **Web:**www.acu.edu.au

MAP
The Brain and Psychological Sciences Research Centre Swinburne University of Technology
Burwood Hwy, Hawthorn

The MRI facility is at the bottom/basement level of the ATC building.