

## PARTICIPANT INFORMATION STATEMENT

### ***Relationship between intellectual ability, anxiety and sleep problems in adults on the Autism Spectrum***

**You do not need to have sleep difficulties to participate in this project.**

#### ***Investigators:***

- Associate Professor Amanda Richdale (Supervisor, Olga Tennison Autism Research Centre, School of Psychology and Health Sciences, [a.richdale@latrobe.edu.au](mailto:a.richdale@latrobe.edu.au); ph 9479 1742)
- Ms Pura Ballester Navarro (PhD candidate, [P.BallesterNavarro@latrobe.edu.au](mailto:P.BallesterNavarro@latrobe.edu.au)), Universidad Miguel Hernandez, Spain

You are invited to participate in a research project being conducted by La Trobe University. This information sheet describes the project in straightforward language, or 'plain English'. Please read this sheet carefully and be confident that you understand its contents before deciding whether to participate. If you have any questions about the project, please ask one of the investigators.

#### ***Who is involved in this research project? Why is it being conducted?***

Ms Pura Ballester Navarro, PhD candidate and Associate Professor Amanda Richdale are conducting this research to investigate sleep patterns and circadian rhythms in adults on the autism spectrum who do not have an intellectual disability. Pura is a PhD student from Alacante, Spain who has been awarded an internship to study at Olga Tennison Autism Research Centre for 8 months.

Individuals diagnosed on the autism spectrum are vulnerable to the development of sleep problems, which can be associated with anxiety. However, much remains unknown about why people on the spectrum are vulnerable to poor sleep and anxiety. The sleep/wake rhythm is a circadian rhythm (24-hour rhythm). This research will examine sleep and temperature rhythms, anxiety, and the hormones melatonin, cortisol and alpha amylase, as well as the genes associated with melatonin and circadian rhythms in adults on the autism spectrum. Sleep, activity and temperature rhythms and genetic information will be compared with results already collected in Spain by Pura in adults on the autism spectrum with intellectual disability (ID). This will help us understand any additional impacts that ID may have on sleep in people on the spectrum.

This study has been approved by the La Trobe University Human Research Ethics Committee.

#### ***Why have you been approached?***

You have been approached because you are aged 18-45 years and are on the OTARC Participants' Registry, participating in an Autism CRC Longitudinal Study and have indicated a willingness to be contacted about other research.

You have responded to an advertisement about this research project.

#### ***What is the project about? What are the questions being addressed?***

The aim of this project is to investigate potential causes for the sleep disturbances that are commonly seen in individuals on the autism spectrum.

***If I agree to participate, what will I be required to do?***

After you provide consent online, you will be asked to complete an online screening questionnaire. If, you are then eligible for the study you will be asked to give your contact details. Pura will then contact you to arrange an appointment at the Olga Tennison Autism Research Centre at La Trobe University to commence your participation in the study. The study will be explained further to you and you will be able to ask questions about the study. You will also be given a Withdrawal of Consent Form should you then, or later decide you no longer want to participate.

If you decide to continue your participation, you will be asked to complete the Weschler Abbreviated Scale of Intelligence (WASI) and the Autism Diagnostic Observation Schedule-Second Edition (ADOS-2). This component of the study should take approximately 90 minutes. You will also be asked to provide a saliva sample for the analysis of circadian rhythm genes. Pura will then explain the other parts of the study in detail. With your permission we will request a copy of your diagnostic report, however this is not compulsory for your participation in the study. If you do provide us with a copy it will be kept confidential and stored within your participant file.

Your participation following your initial appointment will take place over a 7-day period and will be explained during your appointment. Below is a list of components you will complete over the 7-days:

- Online questionnaires about autism symptoms, sleep and anxiety
- 7-day sleep-wake diary (online)
- 7-day actigraphy assessment\*
- Saliva collection (1 at your appointment, 3 samples at home, 1 night and 2 morning)

You will be provided with the, actigraphy monitor, and a saliva collection kit. Pura will also send you a link via email to the online questionnaire and the 7-day sleep-wake diary.

The online questionnaire should take approximately 30 minutes to complete.

The sleep-wake diary should take approximately 10 minutes each day to complete.

The collection of saliva samples will take place on one weeknight during the **last two days** of the 7-day data collection period. One of the samples will be taken the 6th day night, one hour before going to bed and after you have answered the anxiety questionnaire, this sample should be stored at the fridge. The following morning you will be required to provide a sample 30 minutes after waking and other after 1hour waking (2 samples). Every time you take the saliva sample, you must press the events button at the watch. You will not be able to eat or drink 15 minutes before taking each saliva sample. You will be required refrigerate the samples and post them, together with your actigraphy monitor, the next day in the pre-addressed post bag provided.

**\*Actigraphy** monitors are small watch-like devices worn on the wrist which sense physical motion and store the resulting information. From this information wakefulness and sleep can be distinguished. You will be required to wear this on your non-dominant wrist for the duration of the 7-day data collection period. You are required to remove the device only when it may get wet (showering, swimming, etc.)

***What are the risks or disadvantages associated with participation?***

It is not anticipated that participation in this study will expose you to risk above the everyday norm. However, if you have any questions or concerns during your participation in the study please contact Pura or Amanda to discuss these concerns. Pura and Amanda will discuss your concerns and if necessary, suggest you contact your family doctor, or refer you to the La Trobe University Psychology Clinic.

***What are the benefits associated with participation?***

Participation will allow you to reflect upon and gain insight into your lifestyle and sleeping habits. At the end of the study, participants will receive a summary of the study's outcomes. Your participation will assist us to better understand the causes of sleep disturbance in adults on the autism spectrum. This information can be used to inform the development of intervention and treatment strategies.

As an appreciation for your time, participation and interest you can have an opportunity to enter in our prize draw for a chance to win one of our 3, 30\$ Gift Cards in Coles/Myers group shops.

***What will happen to the information I provide?***

The information that you provide will remain confidential. Your questionnaires will be stored in a locked filing cabinet in the Olga Tennison Autism Research Centre at La Trobe University, Bundoora Campus. Your individual questionnaires will only be available to Amanda and Pura. Coded data will be entered into computer files for later analysis; this data file will not contain participants' personal information such as names or addresses, but will contain age and gender. The coded data file may also be available to Pura's supervisors in Spain, Prof Ana Peiro and Prof Eduardo Fernandez.

A brief report on the results from the assessments and questionnaires you complete will be provided. Any information that you provide can only be disclosed if (1) it is to protect you or others from harm, (2) a court order is produced, or (3) you provide the researchers with written permission.

Your data will be reported on in the format of a PhD research thesis. This research may also be published in scientific journals or presented at conferences. This research may also be used as the basis for funding applications for future research regarding sleep in autism spectrum disorders and as such the coded computer data file may be made available to future students at La Trobe University, or to researchers at La Trobe or other research institutions. Any information that will identify you will not be published so your privacy will be protected. Your original questionnaires will remain in a locked cabinet in the Olga Tennison Autism Research Centre for 7 years. After this, data will be destroyed.

***What are my rights as a participant?***

You have the right to withdraw from active participation at any time, without prejudice, provided that this right is exercised within *four weeks* of the completion of your participation in the project. You have the right to have any unprocessed data withdrawn and destroyed, provided it can be reliably identified and provided that so doing does not increase any risk to you. You also have the right to have any questions answered by the research team at any time. **You are asked to complete the "Withdrawal of Consent Form" or to notify the investigator by e-mail or telephone that you wish to withdraw your consent for your data to be used in this research project.**

***Whom should I contact if I have any questions?***

Any questions regarding this project may be directed to the Investigator(s), Ms. Pura Ballester Navarro or A. Prof Amanda Richdale. Contact information is provided on page 1 of this document.

***Funding Sources***

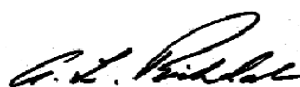
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If you have any complaints or concerns that the investigator has not been able to answer to your satisfaction, you may contact the Secretary, Human Ethics Committee, Research Services, La Trobe University, Victoria, 3086, (ph: 03 9479 1443, e-mail: [humanethics@latrobe.edu.au](mailto:humanethics@latrobe.edu.au)). Please quote UHEC application reference number HEC 17-072

Yours sincerely,



Pura Ballester Navarro  
PhD Candidate



Amanda Richdale,  
PhD, MAPS  
Associate Professor/ Principal Research Fellow