PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM

Project Title	**Tipping Point Project**
Principal Investigator	**Professor Greg Murray –** Swinburne University, Australia
Associate Investigators	**Professor Richard Porter** – University of Otago, New Zealand **Dr Sandipan Ray** – Institute of Technology Hyderabad, India **Professor Jan Scott** – Newcastle University, UK **Professor Denny Meyer** – Swinburne University, Australia **Dr Fatemeh Hadaeghi** – University Medical Center Hamburg-Eppendorf (UKE), Germany **Dr Hailey Tremain** – Swinburne University, Australia **Ms Ly Nguyen** – Swinburne University, Australia **Ms Amber Weller** – Swinburne University, Australia **Ms Claire Sidlow** – Swinburne University, Australia **Mr Joe Bertoia**– Swinburne University, Australia
Lived Experience Researchers and Collaborators	**Ms Maree Choi-** Swinburne University, Australia **Dr Sara Lapsley**- Carleton University, Canada

Project and researcher interests

We are a group of mental health researchers with a long-standing interest in the role of sleep and daily activity rhythms in bipolar disorder. We would like you to consider taking part in a study funded by the UK Wellcome Trust philanthropic organisation. The study is being conducted through Swinburne University of Technology in Melbourne, but we will be recruiting people from across Australia and New Zealand.

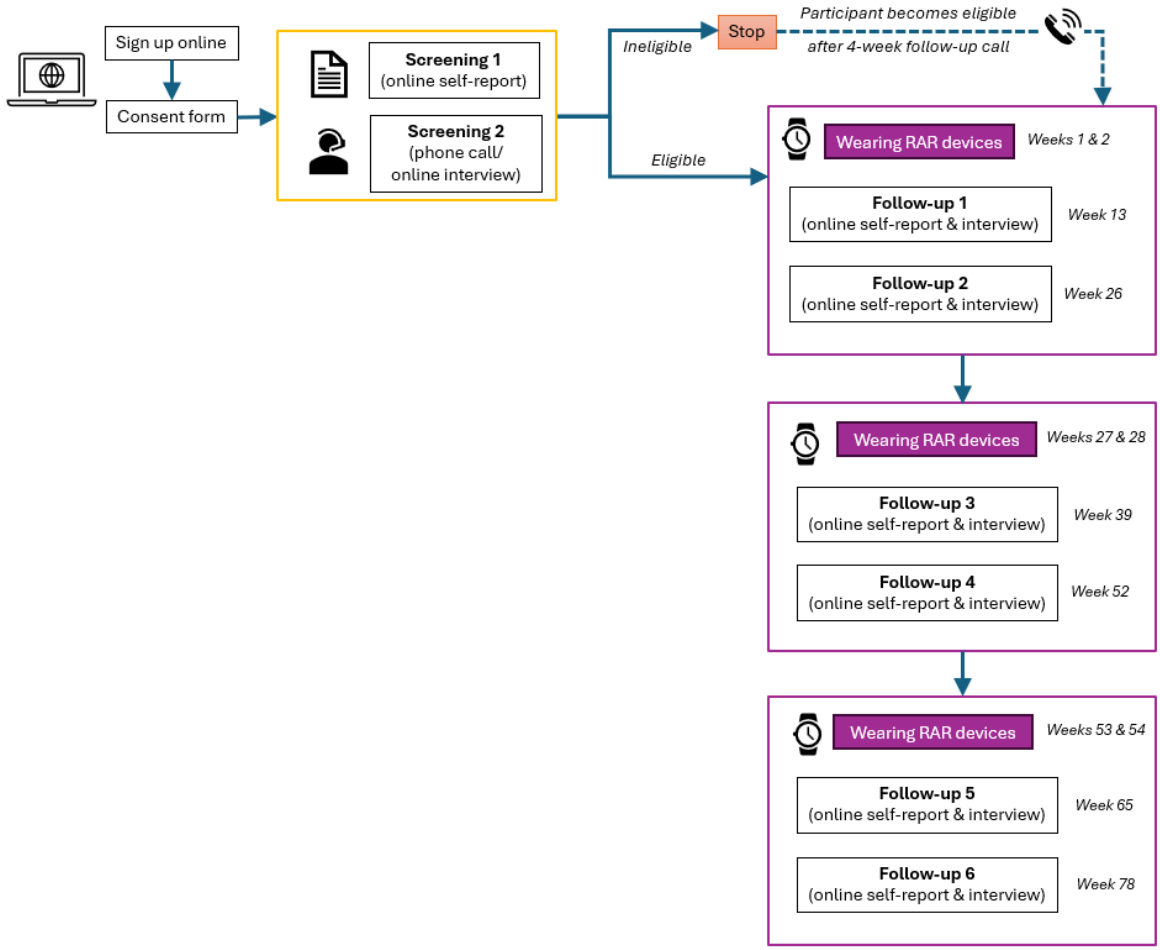
Changes in sleep and daily activity rhythms can impact the moods of people living with bipolar disorder. The aim of this study is to **investigate whether we can improve prediction of mood changes in bipolar disorder by measuring sleep and daily activity**. Our main measure of sleep and daily activity will be an actigraph – a small wrist-worn accelerometer that looks like a watch (see picture). We are also interested in how light exposure is involved and will measure light exposure using a sensor pin you wear like a brooch (see picture).

Your participation in the research could help us understand the role of sleep and daily rhythms in mood changes, which could improve the management of bipolar disorder. This project aims to find the risk algorithm that could be built into a 'smart' actigraph. The 'smart' actigraph would help people manage their bipolar disorder by providing an early warning of mood changes.

What does the research involve?

We are conducting an 'observational study'. This means that **we are not providing any treatment, and we do not want to change anything about how you live your everyday life**.

We will recruit 100 participants with bipolar disorder from across Australia. We will follow these people for a total of 18 months. As shown in the flow chart below, on three occasions we will measure sleep and activity by actigraph for 14 days (for 7 of these 14 days we will measure light exposure with the light pin). In between the three sleep and activity measurements, we will catch up with participants six times (Follow-up 1 through 6) to assess their sleep and mood.



Participation will involve the use of wearable devices (actigraph and light sensor) as shown in the flow chart above. We will send you those in the mail and organise a telehealth call to make sure you're confident with how to wear the two devices. You will also complete an online sleep diary, and answer questions online and at telehealth interviews about your quality of life, recent life events and mood symptoms.

You will be asked to undertake these activities at specific times over a total period of 78 weeks. The actigraph will be worn for three 14-day periods: Weeks 1 & 2, 27 & 28, and 53 & 54. During each of these three periods, you will also be asked to complete an online sleep diary, and to also wear the light sensor for 7 days during each 14-day actigraphy period.

You will be asked to complete an online questionnaire and interview with a clinical rater every 3 months. You will receive information and support from the research team throughout the 78-week period of the study. These study procedures are described in the flow chart above.

We will be recruiting participants 'remotely'. **This means that you can participate no matter where you are in Australia or New Zealand**. We will be sending the actigraph and light sensor through the mail (with a reply paid envelope), we will be conducting interviews by telehealth (on the Microsoft Teams platform, or similar), and you will be completing some surveys on our website.

Overview of the study

If you agree to be in this study, you will be asked to:

1) Complete an online sign-up form and screening questions. This will include providing your name, email, residential address, phone number, and the name and phone number of the primary doctor who is treating your bipolar disorder (General Practitioner or Psychiatrist). This will take less than 30 minutes.
2) Complete an eligibility interview via Microsoft Teams (secure video telehealth software) in which you will be asked questions about your mental health. It will take up to 3 hours.
    a. At this online interview, both the interviewer and the participant will show photo ID as proof of identity.
    b. If eligible, you will be asked to start your participation as described above.
    c. If you are ineligible but later become eligible during a follow-up, call after 4 weeks and agree to proceed with the study, you will also start your participation as above.
3) We ask you to contact the research team if you have any questions or difficulties related to your participation in the study.

Am I eligible to participate?

To be eligible to participate in this research you:

- Are aged 18 to 65 years;
- Currently reside in Australia or New Zealand;
- Can understand written and spoken English;
- Have been given a diagnosis of bipolar disorder by a health professional (e.g., a general practitioner);
- Will provide us with the name and contact details of the medical practitioner treating your bipolar disorder;
- Are not currently experiencing a manic, hypomanic, or depressive episode; and
- Have provided your full contact information and shown us photo ID.

You will be unable to participate if you:

- Do not meet the diagnostic criteria for bipolar disorder type I or II;
- Are currently experiencing psychotic symptoms;
- Are currently experiencing active suicidal ideation;
- Have a lifestyle that might interfere with the measurement of daily activities (e.g., working shiftwork, time zone travel);

- Have a physical problem that might interfere with the measurement of daily activities (e.g., a condition impacting mobility);
- Might be negatively impacted by participating (e.g., participation would distract from intensive monitoring of medication or side-effects; you are currently an inpatient).

If you join the study and then meet criteria for a current a mood episode, we will discuss with you whether you would like to continue in the study as planned or take the option of pausing your participation in the study for a 4-week period. You will be able to discuss this with the Tipping Point Study clinician to support your decision making. At all times your clinical care will be with your medical practitioner, regardless of whether you are paused in the study or not. If you do decide to pause your participation we will offer you the option of being recontacted in 4 weeks to see if you would like to be un-paused and continue in the study as planned.

If you are unsure about whether you might be eligible to participate, complete the sign-up process and a member of the research team will be in contact to assist with determining eligibility.

What are the possible risks of participating in this research?

We think that any risks of participating in the study are minimal. Nonetheless, it is useful to be aware of negative experiences that could occur.

These include:

- It is possible that you might feel self-conscious wearing the actigraph and/or the light meter in public, especially if someone were to ask you what they were for. We would encourage you to raise any queries or concerns with the research team if you thought this might be a problem for you. We have some suggestions on how to approach it.
- Assessments of psychological symptoms can be distressing. Please let the interviewer know if you are finding questions difficult – it might be useful to take a break. If any distress arises after the assessment is completed, we would encourage you to contact your health care provider, or one of the resources below.

Australian Participants:

- **Lifeline:** 13 11 14 Lifeline are a national charity providing all Australians experiencing emotional distress with access to 24/7 crisis support and suicide prevention services.
- **BeyondBlue:** This national organisation provides information and 24/7 qualified mental health support (via phone or text)
- **Black Dog Institute:** This organisation specialises in depression and bipolar disorder. They have information about bipolar disorder, including self-tests and suggested actions that you can take.
- **SANE Australia:** This national mental health organisation provides information and resources for bipolar disorder.
- **Health Direct:** This government health information service provides a general overview of bipolar disorder and links to additional services.

- **New Zealand participants:**

- **Lifeline Helpline NZ:** This is a national service for all people located in New Zealand providing 24/7 mental health support via phone or text
- **Health New Zealand:** Health New Zealand Te Whatu Ora provides 24/7 Mental Health Crisis Support and provides guidance on where to find support local to you in New Zealand.

Can I withdraw from participating in this research project?

You are free to stop taking part in the study at any stage. If you withdraw, data you have already contributed to the study cannot be withdrawn. Your decision to participate or not will have no impact upon your future or current relationships with Swinburne University of Technology. If you did decide to withdraw, we would like to invite you to an optional interview to help us understand people's experience of the study.

What will happen to information about me?

In this study we will be collecting the following types of information from you:

- Personal information: Your contact details and the contact details of your GP.
- Health information: Information about your mental health and rest-activity patterns, including, but not limited to, sleep data, activity counts, and light exposure.
- Clinical interviews: Interviews about the participant's mood symptoms at baseline and over the course of the study. These interviews will be recorded via the Teams online platform. Participants can opt out of their image being recorded and instead an audio file will be generated.
- Self-report data: You will complete a small number of common surveys instruments and other questions administered online

Your privacy and confidentiality will be maintained throughout. All the data we collect will be gathered and stored using a highly secure web-based research data collection system (*REDCap*). All information we collect will be stored on a password-protected secure drive at Swinburne University of Technology (*Microsoft OneDrive*).

We will allocate you a unique ID number so we can keep track of your data. During data collection, we will maintain a password-protected file that links your unique ID number to your personal information (name, address etc.). This file will also be held on a password-protected secure drive at Swinburne University of Technology and will be destroyed once data collection is complete. Only the investigators named above will have access to the study data during data collection.

After data collection is complete, de-identified data from this study (i.e., data that cannot be tracked back to any individual) will be securely stored for a period of 20 years before being destroyed. Within that 20 years, de-identified data from this study may be used for related research, including student projects supervised by a member of the research team.

We will share a copy of the study results with you by email, and we expect the findings to be published in recognised scientific outputs (journal articles and conferences). We will also ensure that the findings are shared through our networks of bipolar disorder support groups and other community agencies. In any form of publication/presentation emerging from this study, only group data will be used, and no individual's responses will be identifiable.

Limits to confidentiality

There are some limited circumstances under which your information may be disclosed to others outside of the research team. Specifically, if you informed us that you were at immediate risk of harm to yourself or others, we would discuss this information with you and potentially inform your designated medical practitioner or other appropriate services such as emergency services.

Reimbursement

In recognition of your time and contribution to the project, you will receive reimbursement for each completed component of the study across 18 months involvement. Reimbursements will be received by way of an e-voucher through the Giftpay platform. You will receive a link to your voucher after each completed interview and wearable period. You can select from multiple retailers for where you can use your voucher- you can read more about Gift Pay here.

The value amount you will receive as a Giftpay voucher for each interview or wearable period are outlined below

- Online screening and baseline interview: $112.50
- Follow-up online and interview assessments: $90 for each of the six interviews
- Two-week periods of wearing devices (actigraphy for 14 days, light pin for 7 days): $150 for each of three two-week periods
- Completion bonuses: If you complete all assessments across the 18 months, you will receive a bonus of an additional $100.00. You will also be invited to participate in a prize draw for one of ten $1000.00 prizes.
- The maximum payment for participation (if you do not win one of the $1000 prizes) is therefore $1202.50

If you would like to contact the researchers about any aspect of the study, please contact:

Professor Greg Murray: gwmurray@swin.edu.au or email the Tipping Point Study Email address at tippingpoint@swin.edu.au. Please note these email addresses are only monitored during business hours.

If you are in crisis, please contact the organisations listed on pg. 4 or **Lifeline on 13 11 14** for Australian participants and **0800 543 354 or the TAUTOKO Suicide Crisis Helpline on 0508 828 865 for New Zealand** participants.

If you have a complaint concerning the way this research is being conducted, please contact the Swinburne University of Technology Human Research Ethics Committee.

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