Appendix I Participant Information Sheet & Consent Form

Title: Understand the relationship between hot flushes and sunlight exposure by examining the symptom's seasonal variation in working women
Short title: Hot Flushes and Sunlight Exposure
HREC Reference: TBD
Project Sponsor: SafeWork SA, Augusta Zadow Award 2017
Principle Investigator: Dr Qunyan (Andie) Xu
Location: Calvary North Adelaide Hospital, Calvary Central District Hospital, Calvary Rehabilitation Hospital, Calvary Wakefield Hospital

1. Introduction

We are inviting working women who meet the following criteria to participate in the study.

1) Being a female
2) Currently employed at >=0.8 FTE (e.g. at the Central Adelaide Local Health Network)
3) Presence of hot flushes for ≥30 days prior to study entry
4) Currently experiencing **≥ 2 hot flushes daily** OR **14 hot flushes per week**
5) Working on fixed shift schedules (e.g. permanent dayshifts, permanent night shifts) and will continue to work on the current shift schedule for the next 10 months.

2. What is the purpose of the study?

The purpose of this research study is to find out the relationship between hot flushes (a cardinal menopausal symptom) and sunlight exposure by looking at the seasonality of this symptom. Bright light therapy has been used to treat depression due to its ability to increase brain serotonin, therefore it might also affect hot flushes, whose aetiology involves low brain serotonin.
If a significant relationship between hot flushes and sunlight exposure is found, light therapy (e.g. sunlight) then can be developed as a new alternative treatment for hot flushes. Inadequate sunlight exposure might also be managed as a modifiable risk for hot flushes.

3. Who is undertaking this research

The investigators of this research study are Dr Qunyan (Andie) Xu (PI), Dr Jane Warland (CI) from School of Nursing and Midwifery, and Dr Jill Dorrian (CI) from School of Psychology, Social Work and Social Policy. This research study is funded by SafeWork SA via the Augusta Zadow Award 2017.

4. Do I have to take part in this research project?

This is a research project and you do not have to be involved. If you do not wish to participate, your medical care/employment will not be affected in any way. Also, you may withdraw from the project at any time after you have commenced.

5. What does participation in this research involve?

Below outlines that you will do if you decide to participate in this research study.

- Complete a baseline questionnaire that contains questions on sociodemographic information, health history, medications you are on, lifestyle and reproductive health. It takes about 20 minutes to complete this questionnaire.

- This research study involves two 7-day study periods, with each study period occurring in winter (June, July & August) or summer (December, January & February). During each study

period, you will complete 1) a hot flush diary, 2) an indoor-outdoor light exposure diary, and 3) wear a light/temperature logger during all your waking hours for 7 days. It takes about 5 minutes/day to complete the two diaries. The light/temperature logger needs to be worn as a necklace, with the light sensor facing away from the body and uncovered all the time. Assistance will be provided to you to secure the logger in this position.

- Meet at a time and place that are convenient to you to return the completed diaries and the light/temperature light logger.

- You will be reimbursed $50 voucher for your time spent in each study period upon receiving the complete data.

6. What do I have to do?

To enable accurate identification of the relationship between hot flushes and sunlight exposure in working women, it is important that you

- Are not on leave during either of the study periods
- Notify us if you commence any antidepressants, antinauseants, antiparkinsonians, cardiac medications, antihistamines, antipsychotics, medication for urinary incontinence, muscle relaxants and gastrointestinal medications before the completion of the entire study. If this happens, you will be assessed for your eligibility to remain in the study and notified of the outcome, because these medications can potentially alter hot flushes.
- Notify us if you fall pregnant. Pregnancy means your participation in the study will need to be ceased.

7. What are the possible benefits of taking part?

You will get a free assessment of your light exposure pattern across different seasons, especially in relation to sunlight exposure. You will also get a clearer idea of the hot flushes you are experiencing. Depending on the results of the study, you can receive an individualised sunlight exposure chart in relation to hot flush severity if you wish. Your contribution to the study means light therapy might be developed as an alternative effective intervention for hot flushes for many women.

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

There is no foreseeable risks of taking part in this study other than inconvenience and time expenditure.

9. Can I have other treatment during this research project?

As explained earlier, you cannot commence the medications listed in the attachment (Appendix IX) during this study. If you commence any of these medications, please let us know immediately. This means your participation in the study will need to be ceased.

10. What will happen to information about me? Confidentiality and data security

All information will be kept private. During data collection, your name will be used to identify your data. You will be asked to construct a study code that will be able to remember. Once data collection is completed, your name will be replaced with a numeric code. The record linking your name and the numeric code will be destroyed after the completion of this project. Your identity will not be

disclosed in any publications or presentations from this project. Your information will remain confidential, except when required by law.

During the study, hard copy data (e.g. questionnaires & diaries) will be stored in a locked filing cabinet in Qunyan Xu's office (RM C5-34) at City East Campus, UniSA. QX will be the sole person possessing the key to the filing cabinet. Electronic data will be kept under a specific research folder on university's shared drive. This folder will be installed by UniSA IT service and password protected. Access to this research folder is granted to the research team only (QX, JW & JD). A backup research folder will also be created on QX's staff drive. The University automatically backs up these folders every 24hrs to prevent data loss.

After completion of the study, hard copy data will be stored in School of Nursing and Midwifery's data storage office (Room C6-30, UniSA City East Campus). Electronic data will remain in the researcher folder. QX will be the only person who can access the data after the completion of the study in case she receives inquiries about the published data. The school manager possesses the sole key to the room.

As per UniSA's data storage policy, data of this project will be retained for 5 years after the completion of the project, as it is considered general research. When the 5 year period transpires, QX will dispose of the data. Hard copy data will be placed in security bins. Electronic data will be emptied from the researcher folder, and the recycle bin on desktop will be emptied as well. If QX ceases to be employed at UniSA before the 5-year period transpires, school manager will be responsible for physical disposal of data after confirmation with QX.

11. What happens if I withdraw from the research?

You may withdraw from the project at any time after you have commenced. By signing the consent form, you agree for us to use the data collected prior to your withdrawal. However, if you wish to destroy the data collected prior to the withdrawal, please let us know.

Withdrawing from the study does not impact on your employment or care in any form.

12. What happens if I am injured from taking part in the study?

It is not anticipated that you will get injured as a result of participating in the study.

Your participation in this study shall not affect any other right to compensation you may have under common law.

13. Complaints and contacts (Investigators and Ethics Committee)

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

[The study has been approved by the Human Research Ethics Committee of the Calvary Hospital]. If you wish to speak to someone not directly involved in the study about your rights as a volunteer, or about the conduct of the study, you may also contact the Chairperson, Research Ethics Committee, Calvary Hospital on 08 8239 9175.

14. Dr Andie Xu, 08 83022531 or andie.xu@unisa.edu.au

Consent Form

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Short title: Hot Flushes and Sunlight Exposure
HREC Reference: TBD
Project Sponsor: SafeWork SA, Augusta Zadow Award 2017
Principle Investigator: Dr Qunyan (Andie) Xu
Location: CALHN sites including Royal Adelaide Hospital & The Queen Elizabeth Hospital

- I have read the Participant Information Sheet or someone has read it to me in a language that I understand.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- The nature, purpose and risks of the research project have been explained to me. I understand them and agree to take part.*
- I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.
- I understand that I will be given a signed copy of this document to keep.
- I understand the statement about reimbursement and costs contained in the Information Sheet.
- I understand that I must not be pregnant or become pregnant during the course of the study.
- I understand that if I do become pregnant I must notify the researchers immediately.

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

Name of Senior Researcher/
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