CONSENT FOR RESEARCH

The Pennsylvania State University

Title of Project: The Effect of Smart Ambient Bright Light for Nursing Home Residents with Alzheimer's Disease and Related Dementias (Smart Lighting Study)

Principal Investigator: Ying-Ling Jao (Contact PI)

Address: Dr. Ying-Ling Jao: 307B Nursing Sciences Building, University Park, PA 16802

Telephone Numbers: Weekdays: 8:00 a.m. to 5:00 p.m. (814) 865-5634

Subject's Printed Name: _____

We are asking you to be in a research study.

Whether or not you take part is up to you. You can choose not to take part. You can agree to take part and later change your mind. Your decision will not be held against you, and there will be no penalty or loss of benefits to which you are entitled.

This form gives you information about the research. Please ask questions about anything that is unclear to you and take your time to make your choice.

Some of the people who are eligible to take part in this research study may not be able to give consent to take part because of their medical condition. Instead we will ask the person's legally authorized representative to give consent. Throughout the consent form, "you" always refers to the person who takes part in the research study.

1. Why is this research study being done?

This research study is being done to find out whether the investigational smart light system we developed can efficiently and consistently deliver the light intervention in nursing homes and help improve mood, sleep, and behaviors in residents with memory problem. We plan to enroll about 40 residents from different facilities.

2. What will happen in this research study?

1) We will screen your eligibility to participate in the study by reviewing your medical record on age, memory problems, behavioral symptoms , and nursing home residency of more than 3 months. We will also interview your primary staff caregivers on your behavioral symptoms and will ask you questions about your memory problems and cognitive function, and behaviors. If you are eligible to participate in the study, we will complete the following research procedures.

2) We will install a smart lighting system by adding lighting sensors and replacing light bulbs/tubes as needed in your bedroom and areas in the facility where you commonly go during the day. In some weeks, you will receive your regular lighting, and in some weeks, you will receive bright light provided by our smart lighting system. You may not notice the difference between the two lighting conditions.

3) We will place a small lighting monitor (Figure 1), typically clipped on your shirt collar or shoulder, to collect information about the amount of light you receive, your sleep, and your activity patterns. You will wear the device 7 days a week, at the beginning of the study and every other week, for 7 weeks in total.

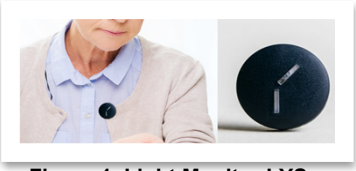

Figure 1. Light Monitor LYS

4) We will manually measure the lighting level on site twice a week.
5) We will review your medical record and collect information related to your demographics, current characteristics, and medical conditions at the beginning of the study.
6) We will also collect information from your staff caregivers about your mood, behaviors, sleep, and any potential side effects of the lighting at the beginning of the study and once every other week during the 13 weeks of the study.

What are my responsibilities if I take part in this study?

If you take part in this research, your major responsibility is to tell the study doctor or nurse about any discomforts during the process of the research.

3. What are the risks and possible discomforts from being in this research study?

There is a risk of loss of confidentiality if your information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening. The confidentiality of your electronic data created by the researchers will be maintained as required by applicable law and to the degree permitted by the technology used. Absolute confidentiality cannot be guaranteed.

Another potential risk is that you may feel uncomfortable with the lighting and lighting monitor, but we anticipate this will rarely happen. If you express any discomfort during the study, we will make all attempts to resolve that, up to and including discontinuing the procedures and reassessing the appropriateness of your study participation.

Finally, other individuals such as staff members, other residents, and visitors may know that you are participating in this study because you are wearing a sensor and may be asked to sit with other participants during certain activities.

4. What are the possible benefits from being in this research study?

4a. What are the possible benefits to me?

There is no guarantee that you will benefit from this research study. The possible benefits you may experience include improvement with your mood, behaviors, and sleep due to the exposure to the therapeutic lighting.

4b. What are the possible benefits to others?

Results of the study may benefit other people in the future by helping us learn more about the use of lighting intervention and its effect in improving mood and behaviors for nursing home residents with dementia. The results may help further refine the lighting intervention to be more effective and practical to use in nursing homes and improved quality of life and health outcomes for individuals with dementia.

5. What other options are available instead of being in this research study?

You may choose not to be in this research study.

6. How long will I take part in this research study?

If you agree to take part, it will take you about 13 weeks to complete this research study. All research procedures will be primarily conducted at the nursing home facility and incorporated in your daily care routine.

7. How will you protect my privacy and confidentiality if I decide to take part in this research study?

7a. What happens to the information collected for the research?

Efforts will be made to limit the use and sharing of your personal research information to people who have a need to review this information. Reasonable efforts will be made to keep the personal information in your research record private. However, absolute confidentiality cannot be guaranteed, and there may be situations where disclosure is required by law.

- A list that matches your name with your code number will be kept in a locked file in Dr. Ying-Ling Jao's office.
- Your research records will be labeled with your code number and your name and initials will be stored electronically in a secured drive approved by Pennsylvania State University and the hard copies and a list that matches your name and initials with your code number will be kept in a locked file in Dr. Jao's office or in a safe area at Pennsylvania State University.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot disclose information that identifies you to anyone not connected with the research. This protection also prevents this information from being used or disclosed for legal proceedings, such as being accessed through a court order. The Certificate of Confidentiality however does not prevent disclosures required by law, such as information about child abuse or neglect and harm to yourself or others. Also, your information may be disclosed in accordance with any consent you provide, including for your medical treatment or use in other research. Additionally, the Certificate of Confidentiality does not prevent your information from being disclosed to National Institute of Health in order for it to evaluate or audit the research, or prevent disclosures required to meet FDA requirements. For additional information ask the principal investigator or a member of the study team or contact the Human Research Protection Program at (814) 865-1775.

In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

We will do our best to keep your participation in this research study confidential to the extent permitted by law. However, the following people/groups may check and copy records about this research.

- The Office for Human Research Protections in the U. S. Department of Health and Human Services
- U.S. Food and Drug Administration
- The research study sponsor, National Institute of Health
- The Penn State Institutional Review Board (a committee that reviews and approves human research studies) and the Penn State Human Research Protection Program
- The investigator, Penn State study staff, and other Penn State professionals who may be evaluating the study or need this information to do their jobs (such as for treatment, payment (billing), or health care operations)

Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your identifiable information and samples may be shared with that new institution and their oversight offices. Data will be shared securely and under a legal agreement, if applicable, to ensure it continues to be used under the terms of this consent and authorization.

7b. What will happen to my research information and/or samples after the study is completed?
We may use your research information in future studies or may share your information or biological samples with other investigators for future research without your additional informed consent. Before we use or share your information we will remove any information that shows your identity.

Researchers can do studies that are more powerful when they share with each other the data or information they get from research studies. They share this information with each other by putting it into scientific databases. Your research information may be put in one or more databases and used for future research. Your information stored in these databases will include the following identifiers: age. Your research data will only be available to researchers who have received approval from the scientific database and/or Institutional Review Boards. Some of these databases are maintained by Penn State, some are maintained by the federal government, and some are maintained by private companies and other institutions.

8. What are the costs of taking part in this research study?

8a. What will I have to pay for if I take part in this research study?
There is no cost to you for taking part in this study.

8b. What happens if I am injured as a result of taking part in this research study?
It is possible that you could develop complications or injuries as a result of being in this research study. If you experience a side effect or injury and emergency medical treatment is required, seek treatment immediately at any medical facility. If you experience a side effect or injury and you believe that emergency treatment is not necessary, you should contact the principal investigator listed on the first page of this consent form as soon as possible and the principal investigator will arrange for medical treatment. You should also let any health care provider who treats you know that you are in a research study.

<u>Penn State compensation for injury</u>

- There are no plans for Penn State to provide financial compensation or free medical treatment for research-related injury.
- If an injury occurs, medical treatment is available at the usual charge.
- Costs will be charged to your insurance carrier or to you.
- Some insurance companies may not cover costs associated with research injuries.
- If these costs are not covered by your insurance, they will be your responsibility.

When you sign this form, you are not giving up any legal right to seek compensation for injury.

9. Will I be paid to take part in this research study?
You will not receive any payment or compensation for being in this research study.

10. Who is paying for this research study?

The institution and investigators are receiving a grant from the National Institute of Health to support this research.

11. What are my rights if I take part in this research study?

Taking part in this research study is voluntary.

- You do not have to be in this research.
- If you choose to be in this research, you have the right to stop at any time.
- If you decide not to be in this research or if you decide to stop at a later date, there will be no penalty or loss of benefits to which you are entitled.

If you decide to leave the research due to discomfort from the smart ambient lighting, contact the investigator so that the investigator can pause your participation in this study. If you stop being in the research, the data that have already been collected may not be removed from the study database. You will be asked whether the investigator can collect medical information from your routine medical care. If you agree, this data will be handled the same as research data. If you withdraw completely from the research study, no further information will be collected, and your participation will end. You may discontinue taking part at any time without penalty or loss of benefits to which you are otherwise entitled. If you choose to be in this research study but decide to stop your participation at a later date, all the data collected from you up to the point of withdrawal will be used for the study. The research team will confirm with you the aspects of research procedures you wish to withdraw and the procedures you will agree to continue. The research team may continue the study procedures that you agree continue but will discontinue all the study procedures that you wish to withdraw.

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include not being able to participate in the intervention or developing new medical conditions that make you no longer meet the inclusion or exclusion criteria for this study. During the course of the research, you will be provided with any new information that may affect your health, welfare or your decision to continue participating in this research.

12. If I have questions or concerns about this research study, whom should I call?

Please call the head of the research study, *Dr. Ying-Ling Jao* at *814-865-5634* if you:

- Have questions, complaints or concerns about the research.
- Believe you may have been harmed by being in the research study.

You may also contact the Penn State Human Research Protection Program (HRPP) at (814) 865-1775 or visit the HRPP website at https://www.research.psu.edu/irb/participants if you:

- Have questions or want information regarding your rights as a person in a research study.
- Have concerns, complaints or general questions about the research.
- Have questions about your privacy and the use of your personal health information.
- You may also call this number if you cannot reach the research team or wish to offer input or to talk to someone else about any concerns related to the research.

A description of this clinical trial will be available on https://www.ClinicalTrials.gov, as required by U.S. Law or policy. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

INFORMED CONSENT TO TAKE PART IN RESEARCH

Signature of Person Obtaining Informed Consent

Your signature below means that you have explained the research to the subject or subject representative, provided the subject or subject representative an opportunity to discuss and consider whether or not to participate in the research, and have answered any questions about the research.

_____	_____	_____	_____
Signature of person who explained this research	Date	Time	Printed Name

(Only approved investigators for this research may explain the research and obtain informed consent.)

Signature of Person Giving Informed Consent and Authorization

Before making the decision about being in this research you should have:

- Discussed this research study with an investigator,
- Read the information in this form, and
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

Signature of Subject

By signing this consent form, you indicate that you voluntarily choose to be in this research and authorize your information to be used and shared as described above.

_____	_____	_____	_____
Signature of Subject	Date	Time	Printed Name

Subject's Legally Authorized Representative

By signing below, you indicate that you give permission for the subject to be in this research and authorize the subject's information to be used and shared as described above.

_____
Printed name of subject

_____	_____	_____	_____
Signature of Legally Authorized Representative	Date	Time	Printed Name

Check the applicable box below indicating authority to act for subject:

☐ Court-appointed legal guardian
☐ Health Care Power of Attorney
☐ Health Care Representative: _____
Relationship to Subject