PennState

HRP-592 - Protocol for Human Subject Research with Use of Test Article(s)

Protocol Title:

Provide the full title of the study as listed in item 1 on the "Basic Information" page in CATS IRB (http://irb.psu.edu).

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

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Version Date:

Provide version date for this document. This date must be updated each time this document is submitted to the IRB office with revisions. DO NOT revise the version date in the footer of this document.

04/21/2023

Clinicaltrials.gov Registration #:

Provide the registration number for this study, if applicable. See "HRP-103- Investigator Manual," under "ClinicalTrials.gov" for more information.

NCT05825404

Important Instructions for Using This Protocol Template:

This template is provided to help investigators prepare a protocol that includes the necessary information needed by the IRB to determine whether a study meets all applicable criteria for approval.

1. **GENERAL INSTRUCTIONS[1]:**
   - Prior to completing this protocol, ensure that you are using the most recent version by verifying the protocol template version date in the footer of this document with the current version provided in the CATS IRB Library.
   - Do not change the protocol template version date located in the footer of this document.
   - Some of the items may not be applicable to all types of research. If an item is not applicable, please indicate as such or skip question(s) if indicated in any of the instructional text.
   - **GRAY INSTRUCTIONAL BOXES:** Type your protocol responses below the gray instructional boxes of guidance language. If the section or item is not applicable, indicate not applicable.
     - **Do NOT delete the instructional boxes from the final version of the protocol.**
   - The protocol should be written in lay language. Do **NOT** copy and paste grant proposal information into the protocol.

[1] This template satisfies AAHRPP elements 1.7.B, I.8.B, I-9, II.2. A, II.2.I, II.3.A, II.3.B, II.3.C-II.3.C.1, II.3.D-F, II.4.A, III.1.C-F, II.2.D

- Add the completed protocol template to your study in CATS IRB (http://irb.psu.edu) on the "Basic Information" page.

2. **CATS IRB LIBRARY:**
   - Documents referenced in this protocol template (e.g. SOP's, Worksheets, Checklists, and Templates) can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

3. **PROTOCOL REVISIONS:**
   - When making revisions to this protocol as requested by the IRB, please follow the instructions outlined in the guides available in the Help Center in CATS IRB (http://irb.psu.edu) for using track changes.
   - Update the Version Date on page 1 each time this document is submitted to the IRB office with revisions.

If you need help…

All locations:
Human Research Protection Program
Office for Research Protections
101 Technology Center
University Park, PA 16802-7014
Phone: 814-865-1775
Fax: 814-863-8699
Email: irb-orp@psu.edu
https://www.research.psu.edu/irb

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1.0 Objectives

1.1 Study Objectives

Describe the purpose, specific aims or objectives. State the hypotheses to be tested.

Aim 1: Pilot test the effect of Smart Ambient Bright Light (SABL) in reducing agitation in persons with dementia. We will also examine the effect of SABL on other Behavioral and Psychological Symptoms of Dementia (BPSD), affect, and sleep and side effects. We hypothesize that participants will show less agitation and other BPSD and improve affect and sleep during and after SABL compared to baseline and control periods. We will also explore the intervention effect on residents' other behavioral and psychological symptoms and affect and monitor potential side effects.

Aim 2: Evaluate the fidelity of the SABL delivery. We will evaluate the fidelity of SABL delivery. We will measure lighting intensity (lux) and circadian stimulus (CS) levels via two methods: 1) on-site light measurements, and 2) a personal light monitor. We will compare the actual lighting dosage to our target lighting dosage.

Aim 3: Evaluate the feasibility of implementing the SABL. We will use convergent mixed methods to evaluate the acceptability, feasibility, and appropriateness of the interventions from perspectives of nursing home staff and administrators.

1.2 Primary Study Endpoints

State the primary endpoints to be measured in the study.

Research typically has a primary objective or endpoint. Additional objectives and endpoints are secondary. The endpoints (or outcomes), determined for each study subject, are the quantitative measurements required by the objectives. Measuring the selected endpoints is the goal of a trial (examples: response rate and survival).

The primary outcomes of this study are 1) the effect of SABL on residents' agitation, other BPSD, affect, sleep and any side effects, 2) fidelity of SABL (e.g., lighting level on site and at individual level), and 3) feasibility of implementing SABL (e.g., acceptability, feasibility, appropriateness, time, and cost of implementing and maintaining the lighting).

1.3 Secondary Study Endpoints

State the secondary endpoints to be measured in the study.

The secondary outcomes of this study include nursing home facility characteristics and resident characteristics.

2.0 Background

2.1 Scientific Background and Gaps

Describe the scientific background and gaps in current knowledge.

For clinical research studies being conducted at Penn State Health/Penn State College of Medicine, and for other non-PSH locations as applicable, describe the treatment/procedure that is considered standard of care (i.e., indicate how patients would be treated in non-investigational setting); and if applicable, indicate if the treatment, drug, or device is available to patient without taking part in the study.

Behavioral and psychological symptoms of dementia (BPSD) is significant in persons with dementia living in nursing homes. Evidence suggests that up to 90% of persons with dementia experience at least one BPSD. Agitation includes various disruptive behaviors, including verbal and physical, aggressive and non-aggressive behaviors, such as screaming, wandering, resisting, grabbing, and hitting. Among the BPSDs, agitation is the most challenging symptom. Agitation occurs in 90% of nursing home residents with dementia. Medications are commonly used as a treatment for agitation but show limited effect and have significant side effects. Non-pharmacological interventions are recommended as the first-line treatment, but most are labor-intensive and show mixed effects. Thus, identifying feasible and effective non-pharmacological interventions to reduce agitation is critical.

Researchers have tested the association between lighting and BPSD, especially agitation and depression. Evidence has shown that circadian disruption, short daylight exposure, and changes in interior daylight conditions are related to agitation. Light is the strongest external stimuli regulating the circadian rhythm, but older adults are at a higher risk for circadian disturbances and need more and brighter light to regulate their circadian rhythm because of reduced suprachiasmatic nuclei (SCN) activity and age-related vision deficiencies. In addition, persons with dementia living in nursing homes do not have sufficient daylight exposure to maintain a stable circadian rhythm. Evidence also shows that many nursing homes are too dim during the day. Therefore, ambient lighting is promising in reducing agitation in dementia, especially for older adults living in nursing home s.

Lighting interventions are not invasive with minimal adverse effects and can help maintain a stable circadian rhythm and thus reduce agitation. Traditional light interventions are light boxes that require participants to sit and keep their eyes towards the light for 1-2 hours. This can lead to compliance issues among persons with dementia and workload issues among their caregivers. Interest has arisen in using ambient lighting in nursing homes. Ambient lightings have shown positive effects on agitation in persons with dementia when targeted at 350-400 lux and circadian stimulus (CS) = 0.3-0.4. However, there are limitations among these studies that tested ambient light in persons with dementia. Window shades were closed to minimize daylight exposure and agitation was not the listed in the inclusion criteria. Daylight exposure has positive impacts on circadian rhythms, sleep quality, and depression. Yet, the daylight effects on other BPSD and affect have not been well evaluated. Additionally, intervention fidelity and feasbility are critical but has not been addressed in prior studies.

2.2 Previous Data

Describe any relevant preliminary data.

Grounded in the theoretical basis of the impact of light on circadian rhythm and aging vision, high-intensity lighting and circadian stimulation during the day and low stimulation with less short-wavelength content at night are recommended for persons with dementia. This 24-hour scheme maintains a bright-dark cycle to regulate rest/activity rhythm, reduces sleep disturbance, and consequently reduces agitation and other behavioral symptoms.

Most lighting studies design lighting interventions based on intensity and can range widely, from 350-1000 lux in the daytime for 4 to 12 hours a day. Also, the measurement method (e.g., horizontal, vertical, floor plane, work plane, or eye level) is often not explicitly specified.

Besides lux, one research group tested lighting interventions based on CS and recommended CS=0.3-0.4 during the daytime and CS≤0.1 during the nighttime.
Ambient lights showed positive effects on depressive symptoms and agitation when targeted at approximately 350-750 lux 4500-9325 K, and/or circadian stimulus (CS) of 0.375-0.4 for 10 to 12 hours a day for more than 4 weeks. For agitation specifically, it has shown positive effects when targeted at 350-400 lux and circadian stimulus (CS) = 0.3-0.4. There is also evidence on other BPSDs with mixed effects and no conclusion can be drawn. These BPSDs include pleasure, general alertness, anxious behaviors, apathy, restlessness, and disturbances of consciousness.

It is believed that our SABL is safe with minimum adverse effects based on existing research evidence. A systematic review of 32 articles concludes that bright light interventions trend toward a positive impact and do not have significant adverse effects for persons with ADRD(Mitolo et al., 2018). Two studies reported negative outcomes of lighting interventions: one study reported deteriorated agitation and depression (Barrick et al., 2010; Hickman et al., 2007) and another study reported increased anxiety (Van Hoof et al., 2009). However, their light designs were very different from this proposed study, with much higher intensity (2000-3000 lux) (Barrick et al., 2010; Hickman et al., 2007) or much higher color temperature (CCT=17000K, very bluish) (Van Hoof et al., 2009). Our proposed lighting scheme (targeted at 400 lux and CS=0.3 during the day and ≤40 lux, CS≤0.1during the night) follows the scientific consensus for persons with ADRD (Figueiro et al., 2016) and the recommendations of the American National Standards Institute and Illuminating Engineering Society (Illuminating Engineering Society of North America, 2020). Ambient light schemes similar to the proposed SABL, but without daylight incorporation, have also been evaluated in multiple studies and did not report any negative effects. (Figueiro et al., 2014; Figueiro et al., 2015; Figueiro et al., 2019; Figueiro et al., 2020) Additionally, the intensity and color of our SABL will be perceived similar to low-level daylight and does not cause any glare. Altogether, evidence suggests that our SABL is safe with minimum adverse effects.

However, there are limitations among these studies that tested ambient light in persons with dementia. Window shades were closed to minimize daylight exposure and agitation was not the listed in the inclusion criteria. Daylight exposure has positive impacts on circadian rhythms, sleep quality, and depression. Yet, the daylight effects on other BPSD and affect have not been well evaluated. Additionally, intervention fidelity and feasbility are critical but has not been addressed in prior studies. Finally, only one study reported that there were no intervention-related side effects, and most studies did not report any information on intervention side effects.

2.3 Study Rationale

Provide the scientific rationale for the research.

Our SABL is the first ambient lighting intervention that utilizes a smart lighting system to accommodate daylight through windows and maintain the lighting condition, without eliminating the daylighting benefits. This approach is more sustainable and potentially maximizes the effect of the ambient lighting interventions.

This SABL is ‘smart’ in two aspects. First, designing for ambient lighting environments, compared with simple light boxes, makes adherence easier. Second, the new tunable LED technologies address implementation barriers by providing new auto-controlling of light intensity, distribution,

and spectra in nursing home buildings. The SABL system has a pre-programmed 24-hour control schedule on illuminance settings to mimic the natural bright-dark cycle. It will regularly monitor the lighting level using customized photosensors and automatically adjust the lights to accommodate the daylight effect, minimizing staff burden and maintenance efforts, while maximizing the LI effect. Moreover, we will work closely with the nursing homes and co-design the SABL and implementation protocol and obtain input from stakeholders (e.g., care providers, directors of maintenance, and administrators). This will be a critical foundation to implement the SABL on a larger scale.

Our proposed SABL will provide bright light with illuminance targeted at 400 lux and high CS of 0.3 at the eye level, and dim light ≤40 lux and low CS ≤0.1 at night to maintain a bright-dark cycle to regulate activity/rest rhythm, improve sleep, and reduce agitation. This dosage selection is based on the current scientific consensus and research evidence. We will measure the light levels received by each participant using a personal, wearable lighting measure device and will use the actual dosage (lux and CS levels) received by participants to analyze the intervention effect. We design the lighting based on lux and CS levels at the eye level in the sitting position, which is more in line with the surrounding surface reflexivity and the lighting the individuals receive.

SABL is a non-invasive, non-labor-intensive, and promising non-pharmacological intervention for persons with dementia and agitation. This is the first study designing an ambient LI for persons with dementia that incorporates daylight and testing the intervention fidelity and feasibility. Findings will inform intervention design, measures, and implementation protocols for future studies.

3.0 Inclusion and Exclusion Criteria

Create a numbered list below in sections 3.1 and 3.2 of criteria subjects must meet to be eligible for study enrollment (e.g., age, gender, diagnosis, etc.).

Vulnerable Populations:

Indicate specifically whether you will include any of the following vulnerable populations in this research. You MAY NOT include members of these populations as subjects in your research unless you indicate this in your inclusion criteria because specific regulations apply to studies that involve vulnerable populations.

The checklists referenced below outline the determinations to be made by the IRB when reviewing research involving these populations. Review the checklists as these will help to inform your responses throughout the remainder of the protocol.

- **Children –**Review “HRP-416- Checklist - Children”
- **Pregnant Women** – Review “HRP-412- Checklist - Pregnant Women”
- **Cognitively Impaired Adults-** Review “HRP-417- Checklist - Cognitively Impaired Adults”
- **Prisoners-** Review “HRP-415- Checklist - Prisoners”
- **Neonates of uncertain viability or non-viable neonates-** Review “HRP-413- Checklist - Non-Viable Neonates” or “HRP-414- Checklist - Neonates of Uncertain Viability”

[Do not type here]

3.1 Inclusion Criteria

Create a numbered list of the inclusion criteria that define who will be included in your final study sample (e.g., age, gender, condition, etc.).

Aims 1 and 2: Residents

We plan to enroll 20 residents with dementia and agitation from each nursing home (Centre Care and Christ the King Manor). Inclusion criteria are as follows:

1. Age≥55
2. English speaking
3. Nursing home residency ≥3 months
4. Presence of dementia. Dementia will be determined based on 1) dementia diagnosis on medical records, 2) a score of ≤12 on the Brief Interview for Mental State (BIMS) on MDS, and 3) a score of ≤22 on the Montreal Cognitive Assessment (MoCA).
5. Presence of agitation over the past week. Agitation will be determined based on 1) presence of agitation symptoms recorded on the most recent Minimum Dataset (MDS) section E, and 2) a score of >45 on the Cohen-Mansfield Agitation Inventory (CMAI).

Aim 3: Staff and administrators

We will enroll 16 staff/administrators from the two nursing homes (Rehabilitation and Skilled Care at Brookline and Centre Care), including three certified nursing assistants (CNAs), one activity staff, one nurse, one director of nursing, one director of maintenance, and one administrator from each nursing home. For CNAs and nurses, priority given to individuals who provide care for the enrolled residents.

Participants inclusion criteria: 1) age ≥18, 2) English speaking, and 3) employed at the facility for ≥3 months.

3.1.1 Does this research involve collecting data from individuals residing outside of the US?

☒ No
☐ Yes – identify the countries where data collection will take place
[Type protocol text here]

3.2 Exclusion Criteria

Create a numbered list of the exclusion criteria that define who will be excluded in your study.

Aims 1 and 2: Residents

Exclusion criteria are major sleep problems, major mental illness, severe vision impairment, and severe acute or terminal illness.

Major sleep problems refer to severe sleep apnea or severe insomnia that affect individuals' physical function and is documented in medical records. Major mental illness includes mental illness that severely impacts their daily function, including schizophrenia and bipolar disorder. Severe acute illness includes health conditions that result in the needs to be hospitalized or hospice care, or individuals being unconscious, or having life expectancy of less than 6 months. Severe vision impairment refers to "severely impaired vision" based on the Minimum Dataset (MDS) or diagnosis of blindness based on medical records.

Aim 3: Staff and administrators

Age < 18 years old and employed at the facility for < 3 months.

3.3 Early Withdrawal of Subjects

3.3.1 Criteria for removal from study

Insert subject withdrawal criteria (e.g., safety reasons, failure of subject to adhere to protocol requirements, subject consent withdrawal, disease progression, etc.).

Aims 1 and 2: Residents:
Participants who fail to adhere to the protocol, consent to withdrawal, or new diagnosis of health conditions meeting exclusion criteria may be removed from the study.

Aim 3: Staff and administrators
Participants who fail to adhere to protocol requirement or consent withdrawal may be removed from the study.

3.3.2 Follow-up for withdrawn subjects

Describe when and how to withdraw subjects from the study; the type and timing of the data to be collected for withdrawal of subjects; whether and how subjects are to be replaced; the follow-up for subjects withdrawn from investigational treatment.

We will collect information about reasons for withdrawal upon the timing of withdraw.

Aims 1 and 2: Residents:
If any residents who did not complete the procedures of the study may be replaced with a new participant. We aim to replace the participant with a resident from the same facility, if possible. All the data collected from the participants prior to the withdrawal may be included for analysis. The new participants will go through the entire 13-week study procedures from baseline through post intervention.

Aim 3: Staff and administrators
Aim 3: Any participants who did not complete the study procedures may be replaced with a new staff or administrators with a similar role/position at the facility. All the data collected from the participants prior to the withdrawal may be included for analysis.

4.0 Recruitment Methods

- Upload recruitment materials for your study in CATS IRB (http://irb.psu.edu). **DO NOT** include the actual recruitment wording in this protocol.
- StudyFinder: If StudyFinder (http://studyfinder.psu.edu) is to be used for recruitment purposes, separate recruitment documents do not need to be uploaded in CATS IRB. The necessary information will be captured from the StudyFinder page in your CATS IRB study.
- Any eligibility screening questions (verbal/phone scripts, email, etc.) used when contacting potential participants must be uploaded to your study in CATS IRB (http://irb.psu.edu).

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4.1 Identification of subjects

Describe the source of subjects and the methods that will be used to identify potential subjects (e.g., organizational listservs, established recruitment databases, subject pools, medical or school records, interactions during a clinic visit, etc.). If not recruiting subjects directly (e.g., database query for eligible records or samples) state what will be queried, how and by whom.

StudyFinder:

- If you intend to use StudyFinder (http://studyfinder.psu.edu) for recruitment purposes, include this method in this section.
- Information provided in this protocol, including the description of study procedures, compensation, and recruitment, needs to be consistent with information provided on the StudyFinder page in your CATS IRB study.

For Penn State Health submissions using Enterprise Information Management (EIM) for recruitment, and for non-Hershey locations as applicable, attach your EIM Design Specification form in CATS IRB (http://irb.psu.edu). See "HRP-103- Investigator Manual, Study Recruitment" for additional information. **DO NOT** include the actual recruitment material or wording in this protocol.

Aims 1 and 2: Residents

We will conduct this study from local nursing home facilities.
We will ask nursing home administrative staff at each facility to help identify potentially eligible residents who meet our broad inclusion criteria: 1) age ≥55, 2) English speaking, 3) long-term stay at the facility for at least 3 months, and 4) diagnosis of dementia.

The eligibility of the potential participants identified by nursing home staff will be confirmed by the research team after consent. The research team will review the residents' medical records for inclusion and exclusion criteria (age≥55, English speaking, nursing homes residency≥3 months, presence of dementia, and presence of agitation over the past week) and collect information on resident's cognitive function and agitation through the proxy report of their primary caregivers (CNA or nurse) to confirm eligibility. Eligible participants will be approached for consent once their contact information is obtain

Aim 3: Staff and administrators

We will ask nursing home administrative staff to help identify potentially eligible staff/administrators for the criteria of interest: age ≥18, English speaking, employed for ≥3 months, and in the position of interest at the facilities. Their eligibility will be verified by the research team.

4.2 Recruitment process

Describe how potential subjects first learn about this research opportunity or indicate 'not applicable' if subjects will not be prospectively recruited to participate in the research. Subject recruitment can involve various methods (e.g., approaching potential subjects in person, contacting potential subjects via email, letters, telephone, ResearchMatch, or advertising to a general public via flyers, websites, StudyFinder, newspaper, television, and radio etc.). **DO NOT** include the actual recruitment material or wording in this protocol.

[Do not type here]

4.2.1 How potential subjects will be recruited.

Aims 1 and 2: Residents

Referral of nursing staff. Once the potentially eligible residents are identified, recruitment will be conducted in a few ways.

First, the he nursing home staff will send out a resident recruitment letter (see document attached) to the family/legally authorized representative of the potentially eligible residents. The letter includes the information about a brief

overview of the study and the research team's contact information. The letter also asks the family/LAR to contact the research team if they are interested in letting the residents to participating in the study.

Next, the research team will hold one or more recruitment meetings in person and/or virtually to meet with family, provide an overview about the study, and answer any questions they may have. The research team will ask the family/LAR to provide their contact information, if they are interested in letting the residents to participate in the study or discussing the research further. The Study Overview Slides for the recruitment meetings are attached.

Finally, the research team will post recruitment flyers (see attachment) at the facility and invite family/LAR to contact the research team or leave contact information for the research team to contact them.

Aim 3: Staff and administrators
Flyers will be created and posted in the facility to recruit staff. The research team will hold one or more recruitment meetings at the facility to introduce the study, answer questions, and recruit staff participants. The Study Overview Slides for the recruitment meetings are attached.

4.2.2 Where potential subjects will be recruited.

We plan to recruit participants from local nursing homes. The potential nursing homes we plan to recruit are 1) Centre Care and 2) Christ the King Manor.

4.2.3 When potential subjects will be recruited.

Participants will be recruited as soon as we have IRB approval and permission from nursing homes.

4.2.4 Describe the eligibility screening process. Screening begins when the investigator obtains information about or from a prospective participant in order to determine their eligibility.

☒ Eligibility screening is occurring *before* consent* - describe the process below
☒ Eligibility screening is occurring *after* consent - describe the process below
☐ Eligibility screening is occurring, consent is not being obtained in this research - describe the process below
☐ Not applicable - Eligibility screening is not being done in this research

Aims 1 and 2: Residents
The screening process for residents involves three steps: 1) initial screening conducted by nursing home staff, 2) chart reviews conducted by the research team, and 3) interviews with primary staff/caregivers conducted by the research team. The step 1 screening will be conducted prior to the consent, and the steps 2 and 3 will be conducted after consent.
For step 1, the nursing home staff will conduct an initial screening based on our broad inclusion criteria: 1) age ≥55, 2) English speaking, 3) long-term stay at the facility for at least 3 months, and 4) diagnosis of dementia.

For step 2, after the informed consent is obtained from LAR or resident as appropriate, the research team will review the residents' medical records to verify their eligibility based on the inclusion and exclusion criteria.

If the resident is not capable to consent and does not have a LAR to provide consent, they will not be eligible to participate in the study.

For residents who pass the step 2 screening, the research team will proceed with the screening and conduct additional assessments to confirm the presence of dementia and agitation. Specifically, the research team will assess residents' cognitive function by interviewing the residents and assess the residents' agitation symptoms based on inputs from the primary staff caregivers, which includes but is not limited to certified nurse assistants (CNAs), licensed practical nurses (LPNs), and registered nurse (RNs).

We will assess residents' cognitive impairment using the Montreal Cognitive Assessment (MoCA). A score of ≤22 on the Montreal Cognitive Assessment (MoCA) is considered cognitive impairment and eligible for this research study. We will assess residents' agitation symptoms using the Cohen-Mansfield Agitation Inventory (CMAI), based on the residents' behaviors over the past week. A CMAI score of ≥ 45 is considered presence of agitation and is eligible for this study. Residents who have cognitive impairment (MoCA score ≤22) and agitation (CMAI score ≥ 45) are considered eligible and will be enrolled for the study.

Aim 3: Staff and administrators

The screening for staff and administrators will be conducted after consent has been provided. Our inclusion criteria are as below: a) nursing home employed healthcare workers employed for ≥ 3 months, b) age≥ 18, and c) English speaking. We will provide the inclusion criteria to the staff during the recruitment meeting and, if they are potentially eligible and interested in participating, the research team will ask them to provide their contact information. Next the research team will reach out to them individually to obtain consent.

In some studies, these procedures may not take place unless HIPAA Authorization is obtained OR a waiver of HIPAA Authorization when applicable for the screening procedures is approved by the IRB.

*Unless informed consent is waived by the IRB, screening before consent is only permitted when screening activities are limited to the collection of information through oral or written communication OR when identifiable private information or identifiable biospecimens is obtained by accessing records or stored identifiable biospecimens. Screening before consent is not permitted if data will be used for activities other than eligibility screening/recruitment (e.g., data analysis).

5.0 Consent Process and Documentation

Refer to the following materials:

- The "HRP-090- SOP - Informed Consent Process for Research" outlines the process for obtaining informed consent.
- The "HRP-091– SOP - Written Documentation of Consent" describes how the consent process will be documented.

- The "HRP-314- Worksheet - Criteria for Approval" section 7 lists the required elements of consent.
- The "HRP-312- Worksheet - Exemption Determination" includes information on requirements for the consent process for exempt research. In addition, the CATS IRB Library contains consent guidance and templates for exempt research.
- The CATS IRB library contains various consent templates for expedited or full review research that are designed to include the required information.
- Add the consent document(s) to your study in CATS IRB (http://irb.psu.edu). Links to Penn State's consent templates are available in the same location where they are uploaded. **DO NOT** include the actual consent wording in this protocol.

[Do not type here]

5.1 Consent Process:

Check all applicable boxes below:

☒ **Informed consent will be sought and documented with a written consent form** *[Complete Sections 5.2 and 5.6; If this is the only box checked, mark Sections 5.3, 5.4 and 5.5 as 'Not applicable']*

☐ **Implied or verbal consent will be obtained – subjects will not sign a consent form (waiver of written documentation of consent)** *[Complete Sections 5.2, 5.3 and 5.6; If this is the only box checked, mark Sections 5.4 and 5.5 as 'Not applicable']*

☐ **Informed consent will be sought but some of the elements of informed consent will be omitted or altered (e.g., deception).** *[Complete section 5.2, 5.4 and 5.6; If this is the only box checked, mark Section 5.5 as 'Not applicable']*

☐ **Informed consent will not be obtained – request to completely waive the informed consent requirement.** *[Complete Section 5.5; If this is the only box checked, mark Sections 5.2, 5.3, 5.4 and 5.6 as 'Not applicable']*

5.2 Obtaining Informed Consent

5.2.1 Consent Process

Describe the consent process, including when and where it will take place.

Aims 1 and 2: Residents

For each resident who is potentially eligible, the informed consent process will begin prior to research team's screening (screening steps 2 and 3).

Prior to consenting, the research team will assess the resident's capacity to consent for research. All potentially eligible resident participants will be approached to assess their capability of providing consent using the Evaluation to Sign Consent (ESC). The ESC is a five-item measure and its psychometrics have been established in assessing older adult's capacity to consent for research (Resnick et al., 2007). The details of this assessment instrument are provided in section 5.6.2.1. Based on the assessment, if the resident is determined to be capable of consenting, the research team will proceed with the informed consent process with the resident. Resident consent will be conducted in-person and will take place at the facility. We will meet with the resident at the nursing home facility and explain the study to the resident using the consent form. If the resident agrees to participate, we will ask him/her to sign the consent forms in-person.

For residents who are not capable of consenting and/or have a LAR, we will contact the LAR to provide consent for the resident after completing the first two steps of screening.

To obtain informed consent from the LAR, the study team will conduct the following protocol. First, the research team will obtain the LAR's name and contact information from nursing home staff under the residents' permission or directly from the LAR. Second, we will consent the LAR in-person or remotely via phone . In-person consent will take place either at the facility, our research office, or location of their choice with privacy. For in-person consent, we will ask the LAR to sign the consent forms in-person. For remote consent, we will ask the LAR to sign the consent forms, scan the forms, and then either send back the signed consent forms either via mail, email, or in person.

Aim 3: Staff and administrators

We will provide staff and administrators the consent forms in person or via mail or email and obtain their consent in person or remotely via phone or videoconference (e.g., zoom). In-person consent will take place either at the facility, our research office, or location of their choice with privacy and will ask them to sign the consent forms in-person.

5.2.2 Coercion or Undue Influence during Consent

Describe the steps that will be taken to minimize the possibility of coercion or undue influence in the consent process.

For consent of all research participants (i.e., the residents, staff, and administrators), in the course of explaining the study, all participants will be told that participation in this research study is totally voluntary, and they are free to withdraw at any time. The research team will emphasize to residents and family members that participation will not influence the quality of care the resident receives in any way. We will also emphasize to staff that their participation decision will in no way impact their job status or performance review.

5.3 Waiver of Written Documentation of Consent

Review "HRP – 411 – Checklist – Waiver of Written Documentation of Consent."

5.3.1 Indicate which of the following conditions applies to this research:

☐ The research presents no more that minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

OR

☐ The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern. (*Note: This condition is not applicable for FDA-regulated research. If this category is chosen, include copies of a consent form and /or parental permission form for participants who want written documentation linking them to the research.)*

OR

☐ If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained. (*Note: This condition is not applicable for FDA-regulated research.)*

For distinct cultural groups describe the alternative mechanism for documenting that informed consent was obtained:

Not applicable

5.3.2 Indicate what materials, if any, will be used to inform potential subjects about the research (e.g., a letter accompanying a questionnaire, verbal script, or implied consent form)
Not applicable

5.4 Informed consent will be sought but some of the elements of informed consent will be omitted or altered (e.g., deception).

Review "HRP-410-Checklist -Waiver or Alteration of Consent Process" to ensure that you have provided sufficient information.

5.4.1 Indicate the elements of informed consent to be omitted or altered
Not applicable

5.4.2 Indicate why the research could not practicably be carried out without the omission or alteration of consent elements
Not applicable

5.4.3 Describe why the research involves no more than minimal risk to subjects.
Not applicable

5.4.4 Describe why the alteration/omission will not adversely affect the rights and welfare of subjects.
Not applicable

5.4.5 If the research involves using identifiable private information or identifiable biospecimens, describe why the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

Not applicable

5.4.6 Debriefing

Explain whether and how subjects will be debriefed after participation in the study. If subjects will not be debriefed, provide a justification for not doing so. Add any debriefing materials to the study in CATS IRB.

Not applicable

5.5 Informed consent will not be obtained – request to completely waive the informed consent requirement

Review "HRP-410-Checklist -Waiver or Alteration of Consent Process" to ensure that you have provided sufficient information.

5.5.1 Indicate why the research could not practicably be carried out without the waiver of consent

[Type protocol text here or indicate as not applicable]

5.5.2 Describe why the research involves no more than minimal risk to subjects.

[Type protocol text here or indicate as not applicable]

5.5.3 Describe why the alteration/omission will not adversely affect the rights and welfare of subjects.

[Type protocol text here or indicate as not applicable]

5.5.4 If the research involves using identifiable private information or identifiable biospecimens, describe why the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

[Type protocol text here or indicate as not applicable]

5.5.5 Additional pertinent information after participation

Explain if subjects will be provided with additional pertinent information after participation.

Not applicable

5.6 Consent – Other Considerations

5.6.1 Non-English-Speaking Subjects

Indicate what language(s) other than English are understood by prospective subjects or representatives.

If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate the language that will be used by those obtaining consent.

Indicate whether the consent process will be documented in writing with the long form of the consent documentation or with the short form of the consent documentation. Review "HRP-091 –SOP- Written Documentation of Consent" and "HRP-103 -Investigator Manual" to ensure that you have provided sufficient information.

We do not plan to enroll participants who do not speak English at this time due to limited translation resources. We hope to expand the study population to non-English-speaking population in future research studies.

5.6.2 Cognitively Impaired Adults

Refer "HRP-417 -CHECKLIST- Cognitively Impaired Adults" for information about research involving cognitively impaired adults as subjects.

5.6.2.1 Capability of Providing Consent

Describe the process to determine whether an individual is capable of consent.

All potentially eligible resident participants will be approached to assess their capability of providing consent using the Evaluation to Sign Consent (ESC). The ESC is a five-item measure and its psychometrics have been established in assessing older adult's capacity to consent for research (Resnick et al., 2007). The first item evaluates whether the individual is alert and able to communicate. The other four items assess the individual's understanding of the research study, including naming at least two potential risks incurred as a result of participating in the study, naming two things that will be expected of them related to participation, explaining what he/she could do if no longer interested in participating in the study, and what he/she could do if any distress or discomfort was experienced associated with study participation. Evidence of ability to sign consent is based on correct responses to all five items on the ESC.

5.6.2.2 Adults Unable to Consent

Describe whether and how informed consent will be obtained from the legally authorized representative. Describe who will be allowed to provide informed consent. Describe the process used to determine these individual's authority to consent to research.

For research conducted in the state of Pennsylvania, review "HRP-013 -SOP- Legally Authorized Representatives, Children and Guardians" to be aware of which individuals in the state of Pennsylvania meet the definition of "legally authorized representative."

For research conducted outside of the state of Pennsylvania, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of "children" in "HRP-013 - SOP- Legally Authorized Representatives, Children, and Guardians."

For residents who are assessed as not capable of providing consent, we will ask their LARs to provide signed informed consent on the resident participant's behalf. Once we obtain their contact information, we will reach out to them for consent. The research team will confirm with the LAR that they have the legal authorization to consent for the resident. The research team will confirm the LAR status based on the definition of HRP-013. For residents who are assessed as capable of providing informed consent for research and who also have a documented LAR according to their medical records review, we will still obtain a written consent from their LAR. For the specific procedures of the consent process please see section 5.2 above.

5.6.2.3 Assent of Adults Unable to Consent

Describe the process for assent of the subjects. Indicate whether assent will be required of all, some, or none of the subjects. If some, indicate which subjects will be required to assent and which will not.

If assent will not be obtained from some or all subjects, provide an explanation of why not.

Describe whether assent of the subjects will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require subjects to sign assent documents.

Assent will not be obtained for this study. In my experience, when people with dementia are not capable of providing consent, that usually means that their cognitive function is too impaired to have a good understanding of the research (e.g., purposes and procedures). In that case, they would not be able to provide a meaningful assent either. Thus, in this study, when the residents cannot provide consent, we will not ask for their assent. Alternatively, when we interact with them and conduct research procedures, such as asking questions for cognitive assessment and putting on the lighting monitor, we will ask their permission and observe their verbal response and non-verbal behavioral cues. When the resident verbally agrees or does not show observable resistance for the monitor. If they express observable verbal or non-verbal resistance to the procedures, such as stating "go away" "I don't want that" or push away the monitor, we will not proceed with the procedures and may approach the resident at a later time.

5.6.3 Subjects who are not yet adults (infants, children, teenagers)

5.6.3.1 Parental Permission

Describe whether and how parental permission will be obtained. If permission will be obtained from individuals other than parents, describe who will be allowed to provide permission. Describe the process used to determine these individual's authority to consent to each child's general medical care.

For research conducted in the state of Pennsylvania, review "HRP-013-SOP- Legally Authorized Representatives, Children and Guardians" to be aware of which individuals in the state of Pennsylvania meet the definition of "children."

For research conducted outside of the state of Pennsylvania, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of "children" in "HRP-013-SOP- Legally Authorized Representatives, Children, and Guardians."

Not applicable

5.6.3.2 Assent of subjects who are not yet adults

Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent. When assent of children is obtained describe whether and how it will be documented.

Not applicable

6.0 HIPAA Research Authorization and/or Waiver or Alteration of Authorization

This section is about the access, use or disclosure of Protected Health Information (PHI). PHI is individually identifiable health information (i.e., health information containing one or more 18 identifiers) that is transmitted or maintained in any form or medium by a Covered Entity or its Business Associate. A Covered Entity is a health plan, a health care clearinghouse or health care provider who transmits health information in electronic form. See "HRP-103 -Investigator Manual" for a list of the 18 identifiers.

If requesting a waiver/alteration of HIPAA authorization, complete sections 6.2 and 6.3 in addition to section 6.1. The Privacy Rule permits waivers (or alterations) of authorization if the research meets certain conditions. Include only information that will be accessed with the waiver/alteration.

[Do not type here]

6.1 Authorization and/or Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

Check all that apply:

☐ **Not applicable, no identifiable protected health information (PHI) is accessed, used, or disclosed in this study.** *[Mark all parts of sections 6.2 and 6.3 as not applicable]*

☒ **Authorization will be obtained and documented as part of the consent process.** *[If this is the only box checked, mark sections 6.2 and 6.3 as not applicable]*

☒ **Partial waiver is requested for recruitment purposes only (Check this box if patients' medical records will be accessed to determine eligibility before consent/authorization has been obtained).** *[Complete all parts of sections 6.2 and 6.3]*

☐ **Full waiver is requested for entire research study (e.g., medical record review studies).** *[Complete all parts of sections 6.2 and 6.3]*

☐ **Alteration is requested to waive requirement for written documentation of authorization (verbal or implied authorization will be obtained).** *[Complete all parts of sections 6.2 and 6.3]*

6.2 Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

6.2.1 Access, use or disclosure of PHI representing no more than a minimal risk to the privacy of the individual

6.2.1.1 Plan to protect PHI from improper use or disclosure

Include the following statement as written – DO NOT ALTER OR DELETE unless this section is not applicable because the research does not involve a waiver of authorization. **If the section is <u>not</u> applicable, <u>remove</u> the statement and <u>indicate as not applicable</u>.**

Information is included in the "Confidentiality, Privacy and Data Management" section of this protocol or in "HRP-598 – Research Data Plan Review Form".

6.2.1.2 Plan to destroy identifiers or a justification for retaining identifiers

Describe the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research. Include when and how identifiers will be destroyed. If identifiers will be retained, provide the legal, health or research justification for retaining the identifiers.

We are requesting a partial waiver of consent for nursing home staff to screen residents' medical records for the purpose of identifying potential residents' eligibility to participate in this study and for recruitment.

6.2.2 Explanation for why the research could not practicably be conducted without access to and use of PHI

Provide reasons why this research could not practicably be carried out without access to and use of PHI.

The research team needs the nursing home staff to review the medical records to screen the participants for eligibility to participate in the study. This research study could not practicably be conducted without the nursing home staff to access to the residents' PHI information for recruitment and screening for several reasons. First, the inclusion and exclusion criteria are specific (e.g., dementia diagnosis) and require clinical judgement for screening. Second, once the resident passes the initial screening, nursing home staff will need to check if the resident has a LAR and, if so, the nursing home staff will need to have the LAR's name and contact information to send the resident recruitment letter for recruitment. Thus, we need to have HIPPA waiver to conduct the screening and recruitment.

6.2.3 Explanation for why the research could not practicably be conducted without the waiver or alteration of authorization

Provide reasons why this research could not practicably be carried out without the waiver or alternation of authorization.

We are requesting partial waiver of consent for recruitment and screening purposes. This research study could not practicably be conducted without the waiver of authorization for two main reasons. First, we need the nursing home staff to review the PHI information to initially screen the resident's eligibility for the study. The inclusion and exclusion criteria are very specific and clinical judgement for screening. Moreover, it is estimated that less than 50% of nursing home residents will meet the criteria for the study, it is not practical to consent all residents prior to screening. Especially, the consent process for nursing home residents with dementia and their LARs are very time consuming. Consenting prior to the nursing home staff's initial screening will require considerable time and could cause too much unnecessary burden for the nursing home staff, the residents, and their LARs. Third, once the resident passes the initial screening, the nursing home staff will need to check if the resident has a LAR and, if so, they will need to have the LAR's name and contact information to contact them and send the resident recruitment letter to facilitate the recruitment and consent. .

6.3 Waiver or alteration of authorization statements of agreement

By submitting this study for review with a waiver of authorization, you agree to the following statement – DO NOT ALTER OR DELETE unless this section is not applicable because the research does not involve a waiver or alteration of authorization. **If the section is <u>not</u> applicable, <u>remove</u> the statement and <u>indicate as not applicable.</u>**

Protected health information obtained as part of this research will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other permitted uses and disclosures according to federal regulations.

The research team will collect only information essential to the study and in accord with the 'Minimum Necessary' standard (information reasonably necessary to accomplish the objectives of the research) per federal regulations.

Access to the information will be limited, to the greatest extent possible, within the research team. All disclosures or releases of identifiable information granted under this waiver will be accounted for and documented.

7.0 Study Design and Procedures

Data collection materials that will be seen or used by subjects in your study must be uploaded to CATS IRB (http://irb.psu.edu). **DO NOT** include any actual data collection materials in this protocol (e.g., actual survey or interview questions).

[Do not type here]

7.1 Study Design

Describe and explain the study design.

Aim 1: Pilot test the effect of SABL in reducing agitation in persons with dementia. This is a crossover, cluster randomized control trial to pilot test the effect of SABL in NHs. This design includes a 4-week intervention period and 2-week washout period. This design will allow for participants to act as their own control and thus reduce the needed sample size and strengthen the research rigor. The study procedures include five phases over 13 weeks. We will recruit a total sample of 40 nursing home residents with dementia and agitation from the 2 nursing homes, 20 residents from each nursing home. The two NHs will be randomly assigned into different sequences for intervention and control. Otherwise, the same study procedures will be

conducted simultaneously at the two NHs. During the daytime, participants will be guided and encouraged to spend time in the designated areas in the dining room and activity room for their meals and daily activities. For blinding prior to control period, we will perform installation procedures with non-SABL light bulbs. We will evaluate the effect of SABL on agitation, other BPSD, affect, and sleep, based on the actual lighting levels participants receive measured by personal light monitors. The study procedures include five phases: 1) baseline, 2) intervention, 3) post intervention/washout, 4) control, and 5) post control/washout. The sequence of intervention and control differs between the two NHs based on randomized assignment. Agitation and lighting will be measured at baseline and then once every two weeks throughout the study. We hypothesize that participants will show less agitation during and after SABL compared to baseline and control periods. We will also explore the intervention effect on other BPSD and affect and monitor adverse effects. **Aim 2: Evaluate the fidelity of the SABL delivery.** We will evaluate the fidelity of SABL delivery by measuring lighting intensity (lux) and CS levels in two ways: 1) on-site light measurements, and 2) a personal light monitor. The actual lighting data will be compared to the intended SABL design.

Four strategies will be implemented to ensure the actual lighting condition the SABL delivers is as designed. First, SABL system has a pre-programmed 24-hour control schedule on illuminance settings to automatically maintain the target lighting dosage. The SABL include photosensors to measure the lighting every 10 minutes and will automatically adjust tunable LED lights through wireless communication to accommodate the daylight effect. Second, the wall-mounted photosensors can detect any problematic lighting events (e.g., <400lux or CS<0.3 during the day) in real-time and will trigger alerts to the research team for trouble shooting. Third, a comprehensive in field lighting measurement will be performed by the research team twice a week during the intervention and control periods to confirm the designed conditions and address any lighting system issues. Fourth, we will remotely monitor the lighting data from the personal light monitors and then analyze the daily data during the data collection week to detect any individual compliance issues and potential device or lighting problems.

The following will describe the installation of SABL system.

First, the SABL system will be installed in resident participants' bedrooms, and designated areas in the hallways, dining rooms, and activity rooms to cover areas that resident participants usually spend time with. Specifically, in the dining room and activity room, the lighting system will only cover the participating residents' tables and areas where they sit. Note that residents and staff typically only spend minimal time in hallways. As a check, prior to installation, the SABL system will be verified via the computer simulation in a lab setting to ensure it only covers the designed areas for participants.

Second, prior to the study, we will announce the general timeline of the study period and will post signs in the dining rooms and activity rooms to notify people that lighting interventions are taking place. While nonparticipants and staff are not restricted from entering the rooms with SABL lighting, they can opt out of the specific areas in the rooms with SABL if they prefer. Non-participating residents will be informed the research areas and the priority of the areas will be given to participants.

Third, in bedrooms with two occupants, the SABL will be limited to the participants' bed area and will not be in common areas in the room (e.g., bathrooms). This will minimize potential impact of the SABL on the other resident and minimize the interference with their daily routine. Privacy curtains can be kept closed between the two sleeping areas to reduce SABL spill-over.

Finally, our proposed lighting scheme of the SABL (targeted at 400 lux and CS=0.3 during the day and ≤40 lux, CS≤0.1during the night), follows the scientific consensus for persons with dementia (Figueiro et al., 2016) and the recommendations of the American National Standards Institute and Illuminating Engineering Society (Illuminating Engineering Society of North America, 2020). Also, the intensity and color of our SABL will be perceived like low-level daylight and does not cause any glare. In addition, the lighting scheme will meet the state requirement of minimum lighting levels for long-term care facilities in Pennsylvania (Commonwealth of Pennsylvania, 2022). Thus, even if the non-participant residents and staff are exposed to the lights, we believe the lighting is safe with minimal risk.

Aim 3: Evaluate the feasibility of implementing the SABL. We will use convergent mixed methods to evaluate the acceptability, feasibility, and appropriateness of the intervention. We will enroll at least 16 NH employees, including certified nursing assistants, activity staff, nurses, directors of nursing, director of maintenance, and NH administrators. We will survey and individually interview participants to collect quantitative and qualitative data on their experiences. Also, we will calculate the total hours and cost of installing and maintaining the SABL.

7.2 Study Procedures

Provide a step-by-step description of all research procedures being conducted (broken down by visit, if applicable) including such information as below (where and when applicable); describe the following:

- HOW: (e.g., data collection via interviews, focus groups, forms such as surveys and questionnaires, medical/school records, audio/video/digital recordings, photographs, EKG procedures, MRI, mobile devices such as electronic tablets/cell phones, observations, collection of specimens, experimental drug/device testing, manipulation of behavior/use of deception, computer games, etc.) For surveys, indicate if subjects are able to skip questions that they don't want to answer.

- WHERE: (e.g., classrooms, labs, internet/online, places of business, medical settings, public spaces, etc.)

The intervention testing procedures (aims 1 and 2) are summarized in table 1. Data collection procedures (for all three aims) are summarized in Table 2.

Aims 1 and 2: Residents

Aim 1: We will evaluate the effect of SABL on agitation, other BPSD, affect, sleep, and adverse effect.

After the informed consent is obtained, we will conduct steps 2 and 3 screening procedures. For step 2, the research team will review the residents' medical records to verify their eligibility based on the inclusion and exclusion criteria. To evaluate the resident's eligibility, we need the resident's name and medical record number to access their medical records. We will review medical records to extract information about whether the residents speak English, are a long-term resident who have lived in the facility for at least 3 months, have a diagnosis of dementia, and presence of dementia and agitation based on the MDS to meet the inclusion criteria.

For residents who pass the step 2 screening, the research team will proceed with the step 3 screening and conduct additional assessments to confirm the presence of dementia and agitation. Specifically, the research team will assess residents' cognitive function by interviewing the residents and assess the residents' agitation symptoms based on inputs from

the primary staff caregivers, which includes but is not limited to certified nurse assistants (CNAs), licensed practical nurses (LPNs), and registered nurse (RNs).

We will assess residents' cognitive impairment using the Montreal Cognitive Assessment (MoCA). A score of ≤22 on the Montreal Cognitive Assessment (MoCA) is considered cognitive impairment and eligible for this research study. We will assess residents' agitation symptoms using the Cohen-Mansfield Agitation Inventory (CMAI), based on the residents' behaviors over the past week as reported by the staff. A CMAI score of ≥ 45 is considered presence of agitation and is eligible for this study. Residents who have cognitive impairment (MoCA score ≤22) and agitation (CMAI score ≥ 45) are considered eligible and will be enrolled for the study.

Only residents who past all three steps of screening will continue study participation in the study visits for the lighting intervention procedures.

Data collection procedures will include

1) Data extraction from CMS Nursing Home Compare Website (https://www.medicare.gov/care-compare/): Data on facility characteristics, including number of certified beds, ownership, quality rating, participation in Medicaid, staffing, COVID-related data is publicly available and can be accessed through the link provided above.
2) Chart reviews: Data on resident characteristics, including age, race, sex, diagnoses, level of cognitive impairment, current medication use, current listed comorbidity and physical function, BPSD in the past two weeks, pain in the past two weeks, current vision status, current hearing status, and other clinical conditions.
3) Surveys based on staff caregivers' reports: The surveys will be conducted on paper and in-person with researcher administering the survey to the staff caregiver for proxy report of residents' dementia stage, agitation, other BPSD, affect, and side effects.
4) Personal light monitor, LYS button, placed on individual resident participants to measure lighting intensity (lux) and CS levels participants receive.

There will be seven visits for data collection throughout the 13-week of the study: baseline visit (week 1) and six follow-up visits, every other week (weeks 3, 5, 7, 9, 11, 13). The procedures for each visit are as followings:

Baseline visit: Procedures 1 through 4.

Follow-up visits: Procedures 3 and 4.

For the procedure 4, the light monitor will be worn 7 days a week during the data collection weeks (week 1, 3, 5, 7, 9, 11, & 13).

Aim 2: We will evaluate the fidelity of SABL delivery by measuring lighting intensity (lux) and CS levels.
Data collection procedures s will include the following:

1) on-site manual light measurements
2) personal light monitor, LYS button, placed on individual resident participants (same as the procedure 4 in aim 1).

The procedures will be conducted primarily on site at the nursing home facilities.

The procedure 1 will be conducted twice a week throughout the 13-week study period.

For the procedure 2, as mentioned in aim 1, the light monitor will be worn 7 days a week during the data collection weeks (week 1, 3, 5, 7, 9, 11, & 13).

Aim 3: Staff and Administrators

Data collection methods include the following:

1) Surveys: Surveys will be administered to staff in-person and on paper to collect their characteristics (e.g., age, race, gender, education, & professional experiences) and their evaluation on the acceptability, feasibility, and appropriateness of the SABL lighting intervention.
2) Qualitative interviews: Staff's and administrators' inputs on the acceptability, feasibility, and appropriateness of the SABL lighting intervention.
3) We will also calculate the total hours and cost of installing and maintaining the SABL.

The procedures can be conducted either in person at the facility or via virtual conference (e.g., zoom). The procedure will be conducted in one visit scheduled in week 13.

Table 1. Intervention testing procedures and timeline.

Week		1	2	3	4	5	6	7	8	9	10	11	12	13
Study phases	NH A	Baseline	Intervention				Post intervention/washout		Control				Post control	
	NH B		Control				Post control/washout		Intervention				Post intervention	
Lighting		Usual light	I: SABL C: Usual light				Usual light		C: Usual light I: SABL				Usual light	
Data collection		Baseline, L&E		L&E		L&E		L&E		L&E		L&E		L&E

L=lighting measured via individual light monitor, E=effect outcomes (e.g., agitation, BPSD, affect, and sleep) and adverse effects

Table 2 Summary of Variables, Measures, and Data Collection.

Aim	Variables	Measures	Data collection methods	Timing
Aim 1	Facility characteristics	# of certified beds, ownership, quality rating, participation in Medicaid, staffing, COVID-related data.	CMS Medicare NH Compare Rating System.	Baseline.
	Resident characteristics	Age, race, sex, diagnoses, medication use, comorbidity, physical function, pain, vision, and dementia stage based on CDR.	Data extraction from medical records and MDS. CDR ratings will be measured via inputs from staff caregivers (e.g., nurse or CNAs).	
	Agitation, BPSD, affect, sleep & adverse effects	CMAI, NPI-NH, ARS, sleep & adverse events checklist.	Inputs from staff caregivers (e.g., nurse or CNAs) based on participants' conditions in past week.	Baseline & every two weeks.
Aims 1 & 2	Light level (lux & CS).	Lighting level each participant receives.	Personal light monitor, LYS button, every 10 minutes, 24 hours/day, 7 days/week.	
Aim 2	Light level (lux & CS).	Lighting level SABL delivers.	Manual on-site measurements.	Baseline & twice a week.
Aim 3	NH employee characteristics	Age, race, gender, education, & professional experiences.	Surveys.	Week 13.
	Acceptability, feasibility, & appropriateness	AIM, FIM, & IAM.[60]	Surveys & qualitative interviews with staff & administrators.	
	Time & cost	Time & cost for implementing SABL.	Calculate by the research team.	

AIM= Acceptability of Intervention Measure
ARS=Philadelphia Geriatric Center Affect Rating Scale
BPSD=Behavioral and psychological symptoms of dementia.
CDR=Clinical Dementia Rating
CMAI=Cohen-Mansfield Agitation Inventory
CMS=Centers for Medicare and Medicaid Services
CNA=certified nurse assistant
FIM= Feasibility of Intervention Measure
IAM= Intervention Appropriateness Measure
MDS-Minimum Data Set
NPI-NH= Neuropsychiatric Inventory-Nursing Home version
PSQI=Pittsburgh Sleep Quality Index

7.2.1 Visit 1 or Day 1 or Pre-test, etc.

Provide a description of what procedures will be performed on visit 1 or day 1 or pre-test in order of how these will be done. If your study only involves one session or visit, use this section only and delete 7.2.2.

Aims 1 and 2: Residents

Baseline visit/visit 1: We will collect data on 1) facility characteristics, 2) resident baseline characteristics, and 3) resident baseline agitation, BPSD, affect, and sleep, 4) lighting levels.

For facility characteristics, we will extract data from the website of the Centers for Medicare and Medicaid Services (CMS). Information extracted include number of certified beds, ownership, quality rating, participation in Medicaid, staffing, COVID-related information, health inspections, fire safety inspections and emergency preparedness, penalties, and available of resident and family council..

For resident characteristics, we will review residents' medical records and minimum dataset (MDS) to collect data on resident characteristics, including age, race, sex, diagnoses, medication use, comorbidity, physical function, pain, vision, and other medical conditions, symptoms, and functional levels. Additionally, we will evaluate resident participants' dementia stage, based on the residents' staff caregivers' inputs and observations of the residents using the Clinical Dementia Rating (CDR).

We will evaluate resident participants' baseline agitation, BPSD, affect, and sleep, based on the residents' staff caregivers' inputs and observations of the residents. We will assess agitation, BPSD, affect, and sleep using the Cohen-Mansfield Agitation Inventory (CMAI), Neuropsychiatric Inventory-Nursing Home version (NPI-NH), Philadelphia Geriatric Center Affect Rating Scale (ARS), and Pittsburgh Sleep Quality Index (PSQI), respectively,

We will measure lighting level by 1) on-site manual light, and 2) a personal light monitor, LYS button during the baseline week. The LYS button is small (1 inch), light weighted (4g), and user friendly. It has a clip at the back of the button and can be easily clipped on clothes. For a resident who does not mind having the sensor placed on clothing, we may place it on the shirt collar or shoulder. We will communicate with their caregivers so that

they are aware of the button when clothes are being changed and make sure the button is clipped back on. We will check the device on site at least twice per week and will retrieve data after each week of data collection. We will pre-set a series of algorithms determining the device use status. If the device appears not to be placed or functioning properly, the system will send a warning message to the team and we will make all attempts to check the device on site. We will manually measure light level twice a week during the baseline week. In addition, we will place a personal light monitor, LYS button, on participants, all day, 7 days a week, during the baseline week.

Aim 3: Staff and administrators

1. Screening survey: We will ask participants to fill out the survey to confirm their eligibility. If they are eligible, we will continue to the next steps.
2. Baseline survey: we will ask participants to fill out a survey to collect data about their demographics and relevant work experiences (e.g., age, race, gender, education, and professional experiences).
3. Feasibility surveys: we will ask participants to fill out the Acceptability of Intervention Measure (AIM), Feasibility of Intervention Measure (FIM), and Intervention Appropriateness Measure (AIM) to evaluate the acceptability, appropriateness, and appropriateness of the SABL intervention.
4. Qualitative interview: their evaluation on the acceptability, feasibility, and appropriateness of the SABL lighting intervention.
5. We will also calculate the total hours and cost of installing and maintaining the SABL.

We expect that in most cases, the study procedures can be completed in one visit. In the case that one visit is insufficient to complete all procedures, one additional visit may be conducted to complete the procedures.

7.2.2 Visit 2 or Day 2 or Post-test, etc. (If applicable)

Provide a description of what procedures will be performed on visit 2 or day 2 or post-test in order of how these will be done. If your study involves more than two sessions or visits replicate this section for each additional session or visit (e.g., 7.2.3, 7.2.4, etc.). If your study involves only one session or visit, delete this section.

Aim 1:
Visits 2-6: After the intervention starts, we will measure agitation, BPSD, affect, and sleep, and intervention-related adverse effects using the CMAI, NPI-NH, ARS, PSQI, and adverse effect checklist once every two weeks.

Aim 2:
Visits 2-6: After light is installed, we will monitor the lighting by 1) on-site manual light measurements twice a week for 13 weeks, and 2) a personal light monitor, LYS button, placed on participants, all day, 7 days a week, every two weeks for 13 weeks.

7.3 Duration of Participation

Describe how long subjects will be involved in this research study. Include the number of sessions and the duration of each session - consider the total number of minutes, hours, days, months, years, etc.

Aims 1 and 2: Residents
The study lasts 13 weeks with baseline data collection: one week for baseline, four weeks for intervention (SABL), two weeks for post intervention/washout period, four weeks for control, and two weeks for post control. The baseline survey of the residents regarding cognitive function and agitation may take 10 minutes to complete.

Aim 3: Staff and administrators 1-2 visits for a total of 1-2 hours. The surveys will take approximately 10-15 minutes to complete, and the interview will take about 1 hour.

7.4 Test Article(s) (Study Drug(s) and/or Study Device(s))

7.4.1 Description

Provide a brief description of all test articles (drugs (including any foods and dietary supplements), devices and/or biologics) used in the research including the purpose of their use and their approval status with the Food and Drug Administration (FDA). Include information about the form of the drug product (e.g., tablets, capsules, liquid).

The SABL system has a pre-programmed 24-hour control schedule on illuminance settings to mimic the natural bright-dark cycle. While research evidence suggests the potential positive effect of the lighting intervention on people with dementia, the lighting device being used in this research is not currently FDA approved for the use of improving behavioral symptoms of dementia. It will regularly monitor the lighting level using customized photosensors and automatically adjust the lights to accommodate the daylight effect, minimizing staff burden and maintenance efforts, while maximizing the LI effect. Our proposed SABL will provide bright light with illuminance targeted at 400 lux and CS ≥ 0.3 at the eye level, and dim light ≤40 lux and low CS ≤0.1 at night to maintain a bright-dark cycle to regulate activity/rest rhythm, improve sleep, and reduce agitation. We will measure the light levels received by each participant using a personal, wearable lighting measure device, LYS button, and will use the actual dosage (lux and CS levels) received by participants to analyze the intervention effect.

The lighting intervention, SABL, design and installation will involve five phases:

1) **Developing an implementation protocol**. PIs Jao and Wang will set up an advisory board at each NH that includes a certified nursing assistant (CNA), a nurse, the director of nursing (DON), the director of maintenance (DOM), and the administrator (NHA). Through the advisory board, we will obtain input from NH stakeholders about implementation procedures. Next, we will develop a protocol that lists the workflow, key steps, and associated personnel customized to each facility. Dr. Julian Wang will work with the DOM at each facility to finalize the plan for SABL installation and maintenance and to ensure the installation follows NH regulations.

2) **Observing resident routines and preference to tailor SABL design**. We will observe each participant, in terms of their daily routine, activities, and habitual behaviors on 2 weekdays and 1 weekend day and fine tune the lighting intervention design. In addition, switches and wireless dimmers will be supplied in case residents or staff need to manually override the lighting conditions. The pre-programmed settings will be auto-resumed after

1 hour.

3) **Measuring and simulating the existing daylighting**. Using lighting simulation software, PI Wang will develop a digital model, including accurate building models, local weather files, and interior design to predict the indoor daylight distribution.

4) **Designing and simulating the SABL**. Lighting distribution, with selected sources and shields, will be designed by conducting a series of computational simulations to avoid unwanted lighting penetration to non-participants' use areas.

5) **Installing the SABL system**. The system will be integrated into the existing electrical systems by replacing existing light sources (e.g., bulbs, tubes) without incurring labor costs for installation, disruption to the facility's operation, or inconvenience to residents and staff. New stable floor-standing luminaires may be added only if the light source replacements on existing luminaries are not able to meet the design levels.

7.4.2 Treatment Regimen

Describe dose, route of administration and treatment duration. Include information about dose adjustments.

The SABL system includes tunable LED lights, photosensors, and controllers and will be installed by replacing the bulbs of the existing fixtures. The SABL will provide bright light targeted at 400 lux and CS≥0.3 in participant bedrooms and designated areas in the dining room and activity room during the day and provide dim light ≤40 lux and CS≤0.1 in participant bedrooms at night. The intensity and color of our SABL will be perceived like low-level daylight and does not cause glare.

We estimate each resident will be exposed to the bright light for at least 4 hours per day (2 hours during three mealtimes and 2 hours during other daily activities). The photosensors will continuously monitor daylight situations and adjust accordingly. It is possible that participants may receive >400lux and CS>0.3 from daylight. However, based on the on-site measurements and observations, it is unlikely participants will receive overly high lighting conditions.

7.4.3 Method for Assigning Subject to Treatment Groups

Describe the randomization process and how the associated treatment assignment will be made.

The study design is a crossover, cluster randomized controlled trial. We plan to conduct the study in two nursing homes. The study procedures include five phases over 13 weeks (Table). The two NHs will be randomly assigned into different sequences for intervention and control. Otherwise, the same study procedures will be conducted simultaneously at the two nursing homes. During the daytime, participants will be guided and encouraged to spend time in the designated areas in the dining room and activity room for their meals and daily activities.

Table. Intervention testing procedures and timeline.

Week	1	2	3	4	5	6	7	8	9	10	11	12	13

Study phases	NH A	Baseline	Intervention				Post intervention/washout		Control				Post control	
	NH B		Control				Post control/washout		Intervention				Post intervention	
Lighting		Usual light	I: SABL C: Usual light				Usual light		C: Usual light I: SABL				Usual light	
Data collection		Baseline, L&E		L&E		L&E		L&E		L&E		L&E		L&E

L=lighting measured via individual light monitor, E=effect outcomes (e.g., agitation, BPSD, affect, and sleep) and adverse effects

7.4.4 Subject Compliance Monitoring

Insert the procedures for monitoring subject compliance.

Each participant will wear the personal light monitor, LYS Button (Figure) to measure lighting intensity (lux) and CS level received. The data will be used to further calculate participants' hours of intervention exposure per day. Lighting will be measured once every 10 minutes, all day, 7 days a week, every other week over the 13-week study period. The monitor is small (1 inch), lightweight (4g), and user-friendly and will be placed on participants' shirt collar or shoulder.

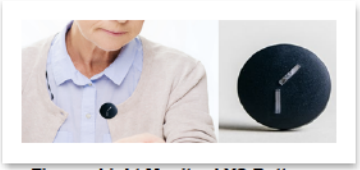

Figure . Light Monitor LYS Button

In addition, the light monitor enables real-time remote checking. Wang will pre-set a series of algorithms determining the device use status. If the device appears not to be placed or functioning properly (e.g., lighting data remains completely unchanged for over 1 hour during daytime), the system will send a warning message to the team (including Jao and Wang). We will make all attempts to check the device on site.

7.4.5 Blinding of the Test Article

Describe how the test article is blinded.

For blinding purposes, prior to the control period, we will perform the lighting installation procedure, similar to the intervention period, though with baseline/non-SABL light bulbs, to blind the research assistants who collect data, participants, and nursing home staff. Also, we will provide minimal details about the study design and lighting condition sequence. In statistical analysis, diagnostic analyses will be carried out to examine underlying assumptions, detect any violations, and identify the most appropriate modeling approach.

7.4.6 Receiving, Storage, Dispensing and Return

7.4.6.1 Receipt of Test Article

Describe how the test article will be obtained and from what source. Describe how the study test article will be packaged along with amounts (e.g., number of tablets/capsules or volume of liquid) and labeling. If drug kits are used, describe all the contents of the kit and associated labeling.

Dr. Julian Wang will purchase and design the lighting system, including

the tunable LED lights, photosensors, and controllers. The SABL system will be integrated into the existing electrical systems by replacing existing light sources (e.g., bulbs, tubes). New stable floor-standing luminaires may be added only if the light source replacements on existing luminaries are not able to meet the design levels. Wang will work with the nursing home director of maintenance (DOM) to install the lighting system.

The lighting dosage will target at 400 lux and CS=0.3 during the day and provide dim light ≤40 lux and CS≤0.1 in participant bedrooms at night. The intensity and color of our SABL will be perceived like low-level daylight and does not cause any glare. We estimate each resident will be exposed to the bright light for at least 4 hours per day (2 hours during three mealtimes and 2 hours during other daily activities). The photosensors will continuously monitor daylight situations and adjust accordingly. It is possible that participants may receive >400lux and CS>0.3 from daylight.

7.4.6.2 Storage

Describe the plans to store, handle the test article so they will be used only on subjects and only by authorized investigators. Describe storage temperature requirements and how temperature will be monitored and recorded.

Wang will be responsible for storing and handling the lighting related equipment. He may work with nursing home director of maintenance (DOM) and designated research team member to handle the lighting system. Only authorized researchers will handle the lighting system, including transporting and installing it in the site.

7.4.6.3 Preparation and Dispensing

Describe how the test article will be assigned to each subject and dispensed. Describe the steps necessary to prepare the test article. Include where the test article preparation will be done and by whom. Fully describe how the study treatment is to be administered and by whom.

In preliminary measures, the average nursing home lighting is 250 (±105) lux in bedroom, 193 (±122) lux at corridor, 170-288 (±106-123) lux at the dining room, and 285 (±91) lux. The measures are consistent with a prior study showing that the lighting in nursing homes is largely insufficient to meet the visual needs to older adults (De Lepeleire et al., 2007).
In this study, the lighting dosage will target at 400 lux and CS=0.3 during the day and provide dim light ≤40 lux and CS≤0.1 in participant bedrooms at night. The intensity and color of our SABL will be perceived like low-level daylight and does not cause any

glare. We estimate each resident will be exposed to the bright light for at least 4 hours per day (2 hours during three mealtimes and 2 hours during other daily activities). The photosensors will continuously monitor daylight situations and adjust accordingly. It is possible that participants may receive >400lux and CS>0.3 from daylight.

7.4.6.4 Return or Destruction of the Test Article

Describe the procedures for final reconciliation of the test article supply at the end of the study and whether the test article is to be shipped back to a source or destroyed on site.

Dr. Julian Wang and his designated research assistant will collect the lighting system at the end of the study and bring it back to the lab.

7.4.6.5 Prior and Concomitant Therapy

Describe what prior and/or concomitant medical therapy will be collected. Describe which concomitant medicines/therapies are permitted during the study. Describe which concomitant medicines are not permitted during the study.

No prior or concomitant medical therapy will be provided or prohibited.

8.0 Number of Subjects and Statistical Plan

8.1 Number of Subjects

Indicate the maximum number of subjects to be accrued/enrolled, to include all persons who sign consent for the study. If applicable, distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures (i.e., numbers of subjects excluding screen failures.)

Aims 1 and 2: Residents

Resident: The target sample size is 40 nursing home residents. We expect to screen 80 potential residents to identify and enroll 40 eligible residents.

Aim 3: Staff and Administrators

Staff: We plan to enroll 16 NH staff/administrators, including three CNAs, one activity staff, one nurse, one DON, one DOM, and one NHA.

8.2 Sample Size Determination

If applicable, provide a justification of the sample size outlined in section 8.1 to include reflections on, or calculations of, the power of the study.

Aims 1 and 2: Residents

We will recruit 40 residents with ADRD and agitation, 20 from each NH. The two NHs have at least a floor or a wing that is primarily dedicated to residents with ADRD, where we plan to

install the lighting and carry out the study. As attrition is expected to be around 10%, based on prior studies with a similar population, this will result in a final sample size of 36. This sample size was calculated based on a significance level of α=.05, medium effect size Cohen's d=0.53, reported in previous studies, power=0.92.

Aim 3: Staff and Administrators

CNAs, activity staff, and nurses provide the most direct care. Priority will be given to individuals who provide care for resident participants. DONs, DOMs, and NHAs are decision makers for intervention implementation. The DOMs can provide feedback on the feasibility of installing and maintaining the lighting system and ensure the installation follows NH regulations. Potential participants will be initially identified by NH staff and confirmed by the research team. Sample size may be increased to reach data saturation.

8.3 Statistical or Analytic Methods

Describe the statistical methods (or non-statistical methods of analysis) that will be employed.

Aim 1

All data will initially be assessed with descriptive techniques to determine distributions and identify outliers. Baseline to post-intervention changes in participants' CMAI, NPI-NH, and ARS scores will be used as the outcomes in all subsequent analyses. To conduct the group analysis, each participant will serve as their own control, which allows minimal use of control variables. The effect of the intervention will be analyzed using multi-level modeling to adjust for clustering of participants at the facility level. We will use the daytime and nighttime average of lighting dosages (lux and CS) from the personal light monitors as the independent variable to analyze the effect of SABL on changes in CMAI, NPI, and ARS. Although not powered for a detailed analysis, we will explore the impact of participant characteristics (sex, age, race, ethnicity, ADRD stage, and daylight exposure) on the intervention effect by adding them as covariates to the regression model.

Aim 2

All data will initially be assessed using descriptive techniques to examine underlying assumptions and detect any violations. To assess the intervention fidelity, the lux and CS data measured via manual measurements will be analyzed using one sample t-tests to analyze lighting levels during the day and nighttime, compared to the target levels. The data from personal light monitors will be analyzed similarly at individual level. Although not powered for a detailed analysis, we will explore the impact of participant characteristics (e.g., sex, age, race, dementia stage, co-morbidity, facility, and daylight conditions) on the lighting received based on the personal light monitor.

Aim 3

Quantitative Analysis: The data include ratings of acceptability, feasibility, appropriateness, time, and cost of installing and maintaining the intervention. All data will be analyzed using descriptive analyses. Although not powered for a detailed analysis, we will explore differences in perceptions of intervention feasibility and acceptability between sexes as well as the difference across professional roles and between facilities.

Qualitative Analysis: The data include statements about SABL's acceptability, feasibility, and appropriateness by NH employees. All interviews will be analyzed to identify patterns of feedback in implementation outcomes. We will use the five phases of thematic analysis in an iterative process: 1) transcripts and field notes will be read and reread, 2) building on the notes and ideas generated, the analysis will be coded, 3) identifying themes or patterns in the data that are relevant to the research question, 4) naming and defining each theme, 5) extracting analytic narrative and exemplar data to illustrate the themes. This approach will reveal themes related to the acceptability, feasibility, and appropriateness of the intervention.

Mixed Methods Analysis: After quantitative and qualitative data are analyzed, the data will be merged by PI Jao and Co-I Boltz, using the spiraled analysis to compare and contrast the results. The data will be evaluated for convergence, divergence, relationships, contradictions, and new findings. Merged results will be reported in a joint display.

9.0 Data and Safety Monitoring Plan

This section is required when research involves more than Minimal Risk to subjects as defined in "HRP-001 SOP- Definitions."

Minimal Risk is defined as the probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For research involving prisoners, Minimal Risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

Please complete each section below if the research involves more than minimal risk to subjects or indicate not applicable.

[Do not type here]

9.1 Periodic evaluation of data

Describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.

Not applicable.

9.2 Data that are reviewed

Describe the data that are reviewed, including safety data, untoward events, and efficacy data.

Not applicable.

9.3 Method of collection of safety information

Describe the method by which the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls and with subjects).

Not applicable.

9.4 Frequency of data collection

Describe the frequency of data collection, including when safety data collection starts.

Not applicable.

9.5 Individuals reviewing the data

Identify the individuals who will review the data. The plan might include establishing a data and safety monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor.

Not applicable.

9.6 Frequency of review of cumulative data

Describe the frequency or periodicity of review of cumulative data.

Not applicable.

9.7 Statistical tests

Describe the statistical tests for analyzing the safety data to determine whether harms are occurring.

Not applicable.

9.8 Suspension of research

Describe any conditions that trigger an immediate suspension of research.

Not applicable.

10.0 Risks

List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects' participation in the research. Include as may be useful for the IRB's consideration, a description of the probability, magnitude, duration, and reversibility of the risks. Consider all types of risk including physical, psychological, social, legal, and economic risks. **Note: Loss of confidentiality is a potential risk when conducting human subject research and must be listed here.**

- If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.
- If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.
- If applicable, describe risks to others who are not subjects.

Aims 1 and 2: Residents

It is believed our SABL is safe with minimum adverse effects based on existing research evidence. Our proposed lighting scheme follows the scientific consensus for persons with dementia and the recommendations of the American National Standards Institute and Illuminating Engineering Society. Ambient light schemes similar to the proposed SABL have also been evaluated in a few studies and did not report any negative effects. Additionally, the intensity and color of our SABL will be perceived similar to low-level daylight and does not cause any glare. Also, for lighting installation, Dr. Julian Wang will work with the director of maintenance (DOM) at each facility to ensure the installation follows NH regulations. Altogether, evidence suggests that our SABL is safe with minimum adverse effects.

Potential but rare risks of exposure to the SABL may include increased agitation, skin rash, eye irritation, dizziness, and nausea. Another potential risk for participating in this study is loss of identifiable information. Because the smart lighting system will operate automatically, we anticipate the burden on supporting the operation of the intervention will be very minimal.

It is believed our SABL is safe, and we do not expect any risks occur caused by our proposed SABL based on current research evidence. The list of rare risks listed in this study was based on the adverse effect checklist used in other studies and we plan to monitor unexpected but possible risks to be extra cautious in this study despite that we do not expect any side effects.

A systematic review of 32 articles concludes that bright light interventions trend toward a positive impact and do not have significant adverse effects for persons with dementia (Mitolo et al., 2018). Currently, to our knowledge, only two prior studies reported adverse effects: one study reported deteriorated agitation and depression (Barrick et al., 2010; Hickman et al., 2007) and one study reported increased anxiety (Van Hoof et al., 2009). However, their light designs were very different from this proposed study, with much higher intensity (2000-3000 lux) (Barrick et al., 2010; Hickman et al., 2007), or much higher color temperature (CCT=17000K, very bluish) (Van Hoof et al., 2009). Our proposed lighting scheme follows the scientific consensus for persons with dementia (Figueiro et al., 2016), and the recommendations of the American National Standards Institute and Illuminating Engineering Society (Illuminating Engineering Society of North America, 2020). Moreover, the ambient light schemes and schedule similar to our proposed SABL, but without daylight incorporation, have also been evaluated in a few studies and did not report any negative effects (Figueiro et al., 2014; Figueiro et al., 2015; Figueiro et al., 2019; Figueiro et al., 2020). Additionally, the intensity and color of our SABL will be perceived similar to low-level daylight and does not cause any glare. Altogether, evidence suggests that our SABL is safe with minimum adverse effects.

Aim 3: Staff and administrators

The risks to participants are very minimal. There is a potential of increased burden for staff and administrators from completing the surveys and participating in the interviews. We anticipate the study procedures will not take more than 2 hours to complete. We will make every attempt to work around their schedule and will conduct the interview during times that work best for them, including evenings and weekends.

11.0 Potential Benefits to Subjects and Others

11.1 Potential Benefits to Subjects

Describe the potential benefits that individual subjects may experience from taking part in the research. If there is no direct benefit to subjects, indicate as such. Compensation is not considered a benefit. Compensation should be addressed in section 13.0.

Aims 1 and 2: Residents

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

Aim 3: Staff and Administrators

Participants will not benefit from this research study.

11.2 Potential Benefits to Others

Describe the potential benefits to society or others.

The results of this research study may benefit other people in the future by helping us learn more about the use of lighting interventions in residents with dementia. The results may help further refine the lighting intervention to be more effective and practical to use for residents with dementia in nursing homes improved BPSD, sleep, quality of life, and health outcomes.

12.0 Sharing Results with Subjects

Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how information will be shared.

This study will not share individual participant results with the participating nursing homes, participants, staff caregivers, residents, and family. However, we can share the aggregate results of the study with the participating facilities, participants, or family, if they are interested.

13.0 Subject Payment and/or Travel Reimbursements

Describe the amount, type (cash, check, gift card, other) and timing of any subject payment or travel reimbursement. If there is **no** subject payment or travel reimbursement, indicate as not applicable.

Extra or Course Credit: Describe the amount of credit **and** the available alternatives. Alternatives should be equal in time and effort to the amount of course or extra credit offered. It is not acceptable to indicate that the amount of credit is to be determined or at the discretion of the instructor of the course.

Approved Subject Pool: Indicate which approved subject pool will be used; include in response below that course credit will be given and alternatives will be offered as per the approved subject pool procedures.

For resident, we will not provide any reimbursement.

For staff and administrators, we will provide an honorarium for individuals who help with resident assessment for aim 1 or intervention feasibility assessment for aim 3. For staff caregivers who provide information for one resident assessment, including assessment on agitation, other BPSD, affect, sleep, and intervention side effects, we will provide a gift card of $15for each assessment visits for each resident. For staffs and interviews to evaluate intervention feasibility,we will provide a gift card of $15 . There is no limit of the number of assessments that an individual staff member will help with. If an individual staff member earns more than $300 over the course of one calendar year, the study team will need to pay the reimbursement by check. Use of small financial honoraria is reasonable to convey respect to staff caregivers' participation in the research in exchange for their time and associated workload burden and has been found to enhance participation.

14.0 Economic Burden to Subjects

14.1 Costs

Describe any costs that subjects may be responsible for because of participation in the research.

Participants will not have any research-related costs.

14.2 Compensation for research-related injury

If the research involves more than Minimal Risk to subjects, describe the available compensation in the event of research related injury.

If there is no sponsor agreement that addresses compensation for medical care for research subjects with a research-related injury, include the following text as written - DO NOT ALTER OR DELETE:
It is the policy of the institution to provide neither financial compensation nor free medical treatment for research-related injury. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. Costs for the treatment of research-related injuries will be charged to subjects or their insurance carriers.

For sponsored research studies with a research agreement with the sponsor that addresses compensation for medical care for research-related injuries, include the following text as written - DO NOT ALTER OR DELETE:
It is the policy of the institution to provide neither financial compensation nor free medical treatment for research-related injury. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. Such charges may be paid by the study sponsor as outlined in the research agreement and explained in the consent form.

It is the policy of the institution to provide neither financial compensation nor free medical treatment for research-related injury. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. Costs for the treatment of research-related injuries will be charged to subjects or their insurance carriers.

15.0 Resources Available

15.1 Facilities and locations

Identify and describe the facilities, sites, and locations where recruitment and study procedures will be performed.

If research will be conducted outside the United States, describe site-specific regulations or customs affecting the research, and describe the process for obtaining local ethical review. Also, describe the principal investigator's experience conducting research at these locations and familiarity with local culture.

The study will be conducted in nursing homes in local central Pennsylvania: 1) Christ the King Manor and 2) Centre Care. These two facilities have agreed to be the clinical sites for this study and the administrator has provided a letter of support. Additional nursing homes may be identified as needed. The PI has established research relationships with these two sites and other long-term care facilities in central PA.

15.2 Feasibility of recruiting the required number of subjects

Indicate the number of potential subjects to which the study team has access. Indicate the percentage of those potential subjects needed for recruitment.

Christ the King Manor has the capacity to house 160 residents and approximately 70% of residents are living with dementia.

Centre Care has the capacity to house 240 residents and approximately 65% of the residents have dementia.

15.3 PI Time devoted to conducting the research

Describe how the PI will ensure that a sufficient amount of time will be devoted to conducting and completing the research. Consider outside responsibilities as well as other on-going research for which the PI is responsible. Please only provide a response for the principal investigator – do **not** include information about any other study team members.

The PI Jao has secured at least 15% of her time and Wang has secured at least 8% of his time to be devoted to conducting and completing this research study.

15.4 Availability of medical or psychological resources

Describe the availability of medical or psychological resources that subjects might need as a result of their participation in the study.

Not applicable.

15.5 Process for informing Study Team

Describe the training plans to ensure members of the research team are informed about the protocol and their duties.

All research team members will be trained by the PI Jao and/or Wang prior to the start of the study. Additionally, PI Jao and Wang will conduct weekly meetings with the research team who are directly involved in data collection and study procedures and monthly meetings with all study team members.

16.0 Other Approvals

16.1 Other Approvals from External Entities

Describe any approvals that will be obtained prior to commencing the research (e.g., from engaged cooperating institutions IRBs who are also reviewing the research and other required review committees, community leaders, schools, research locations where research is to be conducted by the Penn State investigator, funding agencies, etc.).

The clinical facilities have provided a letter of support for conducting the study at the site.

16.2 Internal PSU Ancillary Reviews

DO NOT ALTER OR DELETE:
Ancillary reviews are reviewed by other compliance groups or individuals within Penn State that inform the IRB's review of a new study or a modification to an existing study.

PSU IRB may set applicable ancillary reviews for your study. Please refer to the HRP-309 Worksheet – Ancillary Review Matrix for more information (found in the CATS Library).

[Do not type here]

17.0 Multi-Site Study

If this is a multi-site study (i.e., a study in which two or more institutions coordinate, with each institution completing all research activities outlined in a specific protocol) and **the Penn State PI is the lead investigator**, describe the processes to ensure communication among sites in the sections below.

[Do not type here]

17.1 Other sites

List the name and location of all other participating sites. Provide the name, qualifications and contact information for the principal investigator at each site and indicate which IRB will be reviewing the study at each site.

Not applicable.

17.2 Communication Plans

Describe the plan for regular communication between the overall study director and the other sites to ensure that all sites have the most current version of the protocol, consent document, etc. Describe the process to ensure all modifications have been communicated to sites. Describe the process to ensure that all required approvals have been obtained at each site (including approval by the site's IRB of record). Describe the process for communication of problems with the research, interim results, and closure of the study.

Not applicable.

17.3 Data Submission and Security Plan

Describe the process and schedule for data submission and provide the data security plan for data collected from other sites. Describe the process to ensure all engaged participating sites will safeguard data as required by local information security policies.

Not applicable.

17.4 Subject Enrollment

Describe the procedures for coordination of subject enrollment and randomization for the overall project.

Not applicable.

17.5 Reporting of Adverse Events and New Information

Describe how adverse events and other information will be reported from the clinical sites to the overall study director. Provide the timeframe for this reporting.

Not applicable.

17.6 Audit and Monitoring Plans

Describe the process to ensure all local site investigators conduct the study appropriately. Describe any on-site auditing and monitoring plans for the study.

Not applicable.

18.0 Adverse Event Reporting

18.1 Adverse Event Definitions

For drug studies, incorporate the following definitions into the below responses, as written:	
Adverse event	Any untoward medical occurrence associated with the use of the drug in humans, whether or not considered drug related
Adverse reaction	Any adverse event caused by a drug
Suspected adverse reaction	Any adverse event for which there is a reasonable possibility that the drug caused the adverse event. Suspected adverse reaction implies a lesser degree of certainty about causality than "adverse reaction". • *Reasonable possibility*. For the purpose of IND safety reporting, "reasonable possibility" means there is evidence to suggest a causal relationship between the drug and the adverse event.
Serious adverse event or Serious suspected adverse reaction	Serious adverse event or Serious suspected adverse reaction: An adverse event or suspected adverse reaction that in the view of either the investigator or sponsor, it results in any of the following outcomes: Death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.
Life-threatening adverse event or life-threatening suspected adverse reaction	An adverse event or suspected adverse reaction is considered "life-threatening" if, in the view of either the Investigator (i.e., the study site principal investigator) or Sponsor, its occurrence places the patient or research subject at immediate risk of death. It does not include an adverse event or suspected adverse reaction that had it occurred in a more severe form, might have caused death.
Unexpected adverse event or Unexpected suspected adverse reaction.	An adverse event or suspected adverse reaction is considered "unexpected" if it is not listed in the investigator brochure, general investigational plan, clinical protocol, or elsewhere in the current IND application; or is not listed at the specificity or severity that has been previously observed and/or specified.

For device studies, incorporate the following definitions into the below responses, as written:	
Unanticipated adverse device effect	Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or IDE application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

18.2 Recording of Adverse Events

Address the frequency and process for eliciting adverse event information from research subject, e.g., "Research subjects will be routinely questioned about adverse events at study visits."

In the response, incorporate the following as written:
All adverse events (serious or non-serious) and abnormal test findings observed or reported to study team believed to be associated with the study drug(s) or device(s) will be followed until the event (or its sequelae) or the abnormal test finding resolves or stabilizes at a level acceptable to the investigator.

An abnormal test finding will be classified as an adverse event if one or more of the following criteria are met:

- The test finding is accompanied by clinical symptoms
- The test finding necessitates additional diagnostic evaluation(s) or medical/surgical intervention; including significant additional concomitant drug treatment or other therapy
  NOTE: Simply repeating a test finding, in the absence of any of the other listed criteria, does not constitute an adverse event.
- The test finding leads to a change in study drug dosing or discontinuation of subject participation in the clinical research study
- The test finding is considered an adverse event by the investigator.

All adverse events (serious or non-serious) and abnormal test findings observed or reported to study team believed to be associated with the lighting intervention will be followed until the event (or its sequelae) or the abnormal test finding resolves or stabilizes at a level acceptable to the investigator. Research team members will visit the site biweekly during the 13 weeks of study period to monitor any adverse events.

An abnormal test finding will be classified as an adverse event if one or more of the following criteria are met:

- The test finding is accompanied by clinical symptoms. We will not be able to completely distinguish whether a clinical symptom is resulted from dementia or other comorbidities, or it is resulted from the SABL treatment. We will assess dementia-related symptoms, including behavioral and psychological symptoms at baseline and every other week throughout the 13-week study period. Also, during the 13-week study period, the SABL will only be provided for 4 weeks. When a clinical symptom occurs during those 4 weeks, we will compare the participant's symptoms with the baseline and non-intervention period to examine if the symptoms are possibly SABL-related. In addition, we will examine other comorbidities that may contribute to the clinical symptoms, such as delirium, urinary tract infection, and a new medical condition/procedure that may cause pain (e.g., tooth extraction, fall). We will collect all relevant information and document it and will observe if the same symptom occurs to other participants.

- The test finding necessitates additional diagnostic evaluation(s) or medical/surgical intervention; including significant additional concomitant drug treatment or other therapy.

NOTE: Simply repeating a test finding, in the absence of any of the other listed criteria, does not constitute an adverse event.

- The test finding leads to a change in study drug dosing or discontinuation of subject participation in the clinical research study

The test finding is considered an adverse event by the investigator.

18.3 Causality and Severity Assessments

By submitting this study for review, you agree to the following statement – DO NOT ALTER OR DELETE:

The investigator will promptly review documented adverse events and abnormal test findings to determine 1) if the abnormal test finding should be classified as an adverse event; 2) if there is a reasonable possibility that the adverse event was caused by the study drug(s) or device(s); and 3) if the adverse event meets the criteria for a serious adverse event.

If the investigator's final determination of causality is "unknown and of questionable relationship to the study drug(s) or device(s)", the adverse event will be classified as associated with the use of the study drug(s) or device(s) for reporting purposes. If the investigator's final determination of causality is "unknown but not related to the study drug(s) or device(s)", this determination and the rationale for the determination will be documented in the respective subject's case history.

18.4 Reporting of Adverse Reactions and Unanticipated Problems to the FDA

18.4.1 Written IND/IDE Safety Reports

For a drug study under an IND, incorporate the following from 21 CFR 312.32 as written – DO NOT ALTER OR DELETE:
The Sponsor-Investigator will submit a written IND Safety Report (i.e., completed FDA Form 3500A) to the responsible new drug review division of the FDA for any observed or volunteered adverse event that is determined to be a serious and unexpected, suspected adverse reaction. Each IND Safety Report will be prominently labeled, "IND Safety Report", and a copy will be provided to all participating investigators (if applicable) and sub-investigators.

Written IND Safety Reports will be submitted to the FDA as soon as possible and, in no event, later than 15 calendar days following the Sponsor-Investigator's receipt of the respective adverse event information and determination that it meets the respective criteria for reporting.

For each written IND Safety Report, the Sponsor-Investigator will identify all previously submitted IND Safety Reports that addressed a similar suspected adverse reaction experience and will provide an analysis of the significance of newly reported, suspected adverse reaction in light of the previous, similar report(s) or any other relevant information.

Relevant follow-up information to an IND Safety Report will be submitted to the applicable review division of the FDA as soon as the information is available and will be identified as such (i.e., "Follow-up IND Safety Report").

If the results of the Sponsor-Investigator's follow-up investigation show that an adverse event that was initially determined to not require a written IND Safety Report does, in fact, meet the requirements for reporting; the Sponsor-Investigator will submit a written IND Safety Report as soon as possible, but in no event later than 15 calendar days, after the determination was made.

For a device study under an IDE, incorporate the following from 21 CFR 812.150 as written – DO NOT ALTER OR DELETE:
The Sponsor-Investigator will submit a completed FDA Form 3500Ato the FDA's Center for Devices and Radiological Health for any observed or volunteered adverse effect that is

determined to be an unanticipated adverse device effect. A copy of this completed form will be provided to all participating sub-investigators.

The completed FDA Form 3500Awill be submitted to the FDA as soon as possible and, in no event, later than 10 working days after the Sponsor-Investigator first receives notice of the adverse effect.

If the results of the Sponsor-Investigator's follow-up evaluation show that an adverse effect that was initially determined to not constitute an unanticipated adverse device effect does, in fact, meet the requirements for reporting; the Sponsor-Investigator will submit a completed FDA Form 3500Aas soon as possible, but in no event later than 10 working days, after the determination was made.

For each submitted FDA Form 3500A, the Sponsor-Investigator will identify all previously submitted reports that that addressed a similar adverse effect experience and will provide an analysis of the significance of newly reported adverse effect in light of the previous, similar report(s).

Subsequent to the initial submission of a completed FDA Form 3500A, the Sponsor-Investigator will submit additional information concerning the reported adverse effect as requested by the FDA.

The Sponsor-Investigator will submit a completed FDA Form 3500Ato the FDA's Center for Devices and Radiological Health for any observed or volunteered adverse effect that is determined to be an unanticipated adverse device effect. A copy of this completed form will be provided to all participating sub-investigators.

The completed FDA Form 3500Awill be submitted to the FDA as soon as possible and, in no event, later than 10 working days after the Sponsor-Investigator first receives notice of the adverse effect.

If the results of the Sponsor-Investigator's follow-up evaluation show that an adverse effect that was initially determined to not constitute an unanticipated adverse device effect does, in fact, meet the requirements for reporting; the Sponsor-Investigator will submit a completed FDA Form 3500Aas soon as possible, but in no event later than 10 working days, after the determination was made.

For each submitted FDA Form 3500A, the Sponsor-Investigator will identify all previously submitted reports that that addressed a similar adverse effect experience and will provide an analysis of the significance of newly reported adverse effect in light of the previous, similar report(s).

Subsequent to the initial submission of a completed FDA Form 3500A, the Sponsor-Investigator will submit additional information concerning the reported adverse effect as requested by the FDA.

18.4.2 Telephoned IND Safety Reports – Fatal or Life-threatening Suspected Adverse Reactions

For a drug study under an IND, incorporate the following from 21 CFR 312.32 into the response, as written:
In addition to the subsequent submission of a written IND Safety Report (i.e., completed FDA Form 3500A), the Sponsor-Investigator will notify the responsible review division of the FDA by telephone or facsimile transmission of any unexpected, fatal, or life-threatening suspected adverse reaction.

The telephone or facsimile transmission of applicable IND Safety Reports will be made as soon as possible but in no event later than 7 calendar days after the Sponsor-Investigator's receipt of the respective adverse event information and determination that it meets the respective criteria for reporting.

Not applicable.

18.5 Reporting Adverse Reactions and Unanticipated Problems to the Responsible IRB

By submitting this study for review, you agree to the following statement – DO NOT ALTER OR DELETE:

In accordance with applicable policies of The Pennsylvania State University Institutional Review Board (IRB), the investigator will report, to the IRB, any observed or reported harm (adverse event) experienced by a subject or other individual, which in the opinion of the investigator is determined to be (1) unexpected; and (2) probably related to the research procedures. Harms (adverse events) will be submitted to the IRB in accordance with the IRB policies and procedures.

18.6 Unblinding Procedures

Describe the procedures for unblinding study therapy on a subject, including documentation of this in the subject's source document. Include example(s) here why someone might unblind a study. In most cases, the unblinding will be part of managing a serious adverse reaction and will be reported with the serious adverse event. However, in cases where unblinding was not associated with a serious adverse event, such actions should be reported in a timely manner.

In rare cases, if any resident participants are determined by the research team to have a serious adverse reaction directly related to the lighting intervention, we will unblind the participants' lighting conditions.

18.7 Stopping Rules

In studies with a primary safety endpoint or studies with high risk to study subjects, provide the rules that define the circumstances and procedures for interrupting or stopping the study. If an independent Data and Safety Monitoring (DSMB) or Committee (DSMC) is set up for the study, the same stopping rules should be incorporated into the safety analysis plan as well.

Not applicable.

19.0 Study Monitoring, Auditing and Inspecting

19.1 Study Monitoring Plan

19.1.1 Quality Assurance and Quality Control

Include this section if FDA regulations apply to this study (see "WORKSHEET: Drugs (HRP-306)" and "WORKSHEET: Devices (HRP-307)". HRP-306 and HRP-307 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

Describe how you will ensure that this study is conducted, and that the data are generated, documented (recorded) and reported in compliance with this protocol, with institutional and IRB policies, with Good Clinical Practice guidelines and any other applicable regulatory requirements.

Indicate who is responsible for monitoring the conduct of the study and specify how often the study will be monitored.

For single-site studies with low risk, it may be appropriate for the principal investigator to monitor the study.

For multi-center studies or single site studies involving significant risk, an independent monitor may be required (e.g., monitoring by the staff of the PSU quality assurance program office(s) or by a clinical research organization).

PI Jao and Dr. Julian Wang are responsible for monitoring the conduct of the study weekly during the 13 weeks of the study. PI Jao will ensure that all surveys, lighting data, and assessments collected from the research team follows protocols and securely locked in the office through weekly review of collected data. Additionally, we will have Excel sheets to keep track of the progress of data collection to ensure all necessary data are collected.

19.1.2 Safety Monitoring

Include this section if FDA regulations apply to this study (see "WORKSHEET: Drugs (HRP-306)" and "WORKSHEET: Devices (HRP-307)". HRP-306 and HRP-307 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

Indicate the process for identifying, recording, and reporting adverse events.

Specify roles for adverse event recording and monitoring. Indicate each staff member's role in the adverse event reporting process. Include the following if applicable:

The **Principal Investigator** will confirm that all adverse events (AE) are correctly entered into the AE case report forms by the coordinator; be available to answer any questions that the coordinators may have concerning AEs; and will notify the IRB, FDA, sponsor and/or DSMB of all applicable AEs as appropriate. All assessments of AEs will be made by a licensed medical professional who is an investigator on the research.

The **Research Coordinator** will complete the appropriate report form and logs; assist the PI to prepare reports and notify the IRB, FDA and/or DSMB of all Unanticipated Problems/SAE's.

The **Monitor** will confirm that the AEs are correctly entered into the case report forms. The Monitor will also confirm that the adverse events are consistent with the source documents and are reported to the appropriate regulatory bodies as required.

During the 13 weeks of lighting intervention, the research team will identify adverse events through interviews with CNAs using a checklist, which includes deteriorated BPSDs, skin rash, eye irritation, dizziness, nausea, or any other reactions. Data will be collected routinely once every two weeks throughout the study period or as needed by staff reporting. If there is a report of adverse events, PI Jao will ensure that these adverse events are correctly logged and entered into the AE case report forms and notify the IRB, FDA, and NIH. The research coordinator will keep track of the adverse event and assist PO Jao to prepare reports to notify IRB, FDA, and NIH.

20.0 Future Undetermined Research: Data and Specimen Banking

If this study is collecting **identifiable** data and/or specimens that will be banked for **future undetermined research**, please describe this process in the sections below. This information should not conflict with information provided in section 22 below OR the "HRP-598 – Research Data Plan Review Form" regarding whether or not data and/or specimens will be associated with identifiers (directly or indirectly). If there are no plans to use identifiable data/specimens for future, undetermined research, then this section is **NOT applicable**.

[Do not type here]

20.1 Data and/or specimens being stored

Identify what data and/or specimens will be stored, and the data associated with each specimen.

Not applicable.

20.2 Location of storage

Identify the location where the data and/or specimens will be stored.

Not applicable.

20.3 Duration of storage

Identify how long the data and/or specimens will be stored. If data and/or specimens will be stored indefinitely, indicate such.

Not applicable.

20.4 Access to data and/or specimens

Identify who will have access to the data and/or specimens.

Not applicable.

20.5 Procedures to release data or specimens

Describe the procedures to release the data and/or specimens, including: the process to request a release, approvals required for release, who can obtain data and/or specimens, and the data to be provided with the specimens.

Not applicable.

20.6 Process for returning results

Describe the process for returning results about the use of the data and/or specimens.

Not applicable.

21.0 References

List relevant references in the literature which highlight methods, controversies, and study outcomes.

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3. Czunyi, L., & Craib, D. (2016). Lighting the way to independent living: Preventative methods for senior health inspired by daylight. (pp. 339-348). *Springer International Publishing.* https://doi.org/10.1007/978-3-319-41661-8_33
4. Cerejeira, J., Lagarto, L., & Mukaetova-Ladinska, E. B. (2012). Behavioral and psychological symptoms of dementia, *Frontiers in Neurology, 3*, 73, 1-21.
5. Canevelli, M., Valletta, M., Trebbastoni, A., Sarli, G., D'Antonio, F., Tariciotti, L., de Lena, C., & Bruno, G. (2016). Sundowning in dementia: Clinical relevance, pathophysiological determinants, and therapeutic approaches. *Frontiers in Medicine, 3*, 73. https://doi.org/10.3389/fmed.2016.00073

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6. De Lepeleire, J., Bouwen, A., De Coninck, L. & Buntinx, F. (2007). Insufficient lighting in nursing homes. *Journal of the American Medical Directors Association, 8*(5), 314-317.
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9. Figueiro, M. G. (2020). Future directions for lighting environments. In *Circadian Rhythm Sleep-Wake Disorders* (pp. 221-240). Springer, Cham.
10. Figueiro, M. G., Hunter, C. M., Higgins, P. A., Hornick, T. R., Jones, G. E., Plitnick, B., Brons, J., & Rea, M. S. (2015). Tailored lighting intervention for persons with dementia and caregivers living at home. *Sleep Health, 1*(4), 322-330. doi: 10.1016/j.sleh.2015.09.003.
11. Figueiro, M. G., Nagare, R., & Price, L. L. A. (2018). Non-visual effects of light: How to use light to promote circadian entrainment and elicit alertness. *Lighting Research & Technology*, *50*(1), 38-62.

12. Figueiro, M. G., Plitnick, B. A., Lok, A., Jones, G. E., Higgins, P., Hornick, T. R., & Rea, M. S. (2014). Tailored lighting intervention improves measures of sleep, depression, and agitation in persons with Alzheimer's disease and related dementia living in long-term care facilities. *Clinical Interventions in Aging*, *9*, 1527-1537. doi: 10.2147/CIA.S68557.
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22.0 Confidentiality, Privacy and Data Management

IMPORTANT: The following section is required for all locations EXCEPT Penn State Health and the College of Medicine. Penn State Health and College of Medicine should skip this section and complete "HRP-598 Research Data Plan Review Form." In order to avoid redundancy, for this section state "See the Research Data Plan Review Form" if you are conducting Penn State Health research. Delete all other sub-sections of section 22.

For research being conducted at Penn State Health or by Penn State Health researchers only: The research data security and integrity plan is submitted using "HRP-598 – Research Data Plan Review Form Application Supplement."

In order to avoid redundancy, for this section state "See the Research Data Plan Review Form" if you are conducting Penn State Health research. Delete all sub-sections of section 22.

For all other research: Complete the following section. Please refer to PSU Policy AD95 for information regarding information classification and security standards and requirements. It is recommended that you work with local IT staff when planning to store, process, or access data electronically to ensure that your plan can be carried out locally and meets applicable requirements. If you have questions about Penn State's Policy AD95 or standards or need a consultation regarding data security, please contact Penn State IT – Information Security at security@psu.edu.

22.1 Which of the following identifiers will be recorded for the research project? Check all that apply. If none of the following identifiers will be recorded, do not check any of the boxes.

	Hard Copy Data	Electronic Stored Data
Names and/or initials (including on signed consent documents)	☒	☒
All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes,	☒	☒
All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older	☒	☒
Telephone numbers	☒	☒
Fax numbers	☐	☐
Electronic mail addresses	☒	☒

Social security numbers	☐	☐
Medical record numbers	☐	☐
Health plan beneficiary numbers	☐	☐
Account numbers	☐	☐
Certificate/license numbers	☐	☐
Vehicle identifiers and serial numbers, including license plate numbers	☐	☐
Device identifiers and serial numbers	☐	☐
Web Universal Resource Locators (URLs)	☐	☐
Internet Protocol (IP) address numbers	☐	☐
Biometric identifiers, including finger and voice prints	☐	☐
Full face photographic images and any comparable images	☐	☐
Any other unique identifying number, characteristic, or code (such as the pathology number)	☐	☐
Study code number with linking list	☒	☒
Genomic sequence data	☐	☐
State ID numbers	☐	☐
Passport numbers	☐	☐
Driver's license numbers	☐	☐

22.2 If storing paper records of research data, answer the following questions:

22.2.1 Where will the paper records, including copies of signed consent forms, associated with this research study will be stored?

All hardcopy documents with identifiable information will be stored in locked, secure cabinets to which only IRB-approved research team members will have access. The location of the cabinet is in PI Jao's office.

22.2.2 How will the paper records be secured?

All hardcopy documents with identifiable information will be stored in locked, secure cabinets to which only IRB-approved research team members will have access.

22.2.3 How will access to the paper records be restricted to authorized project personnel?

All hardcopy documents with identifiable information will be stored in locked, secure cabinets to which only IRB-approved research team members will have access to the key to unlock the cabinets.

22.3 If storing electronic records of research data, indicate where the electronic data associated with this research study will be stored. Check all that apply.

☒ Penn State-provided database application. Check which of the following database applications are being used (check all that apply):

- ☒ Penn State REDCap
- ☐ Other – Specify - provided and approved database application:
  [Type protocol text here if box checked]

☐ Penn State, College, or Department IT file server
☒ Penn State OneDrive or SharePoint
☐ Penn State GoogleDrive
☐ Web-based system provided by the sponsor or cooperative group - Specify URL and contact information:
[Type protocol text here if box checked]

☐ Other – Specify the database application or server:
[Type protocol text here if box checked]

Provide details about the data security features or attach security documentation provided by sponsor or group:
[Type protocol text here if box checked]

Please visit datastoragefinder.psu.edu for assistance with identifying appropriate data storage options. If the software to be used does not appear on that site, a software request form must be completed.

If there is a list/key that links indirect identifiers (code numbers, participant IDs, etc.) to direct identifiers, that list must not be comingled (i.e., stored in the same location) as the identifiable data, including copies of signed informed consent forms. Additionally, access to that list/key must be restricted to authorized project personnel.

22.4 Is there a list/key that links code numbers to identifiers?

☒ Yes - explain how the list that links the code to identifiers is stored separately from coded data:

1. The hardcopy list will be stored in a locked, secure cabinet, separate from other hard copy documents. Only the PI and PI designated team members will have access to the list. The cabinet is located in PI Jao's office.

The electronic file will be stored electronically in a secure research drive at Penn State (e.g., OneDrive). The file will be stored in a password-protected folder separate from the folder for other research data. Only the PI and PI designated team members will have access to the list.

☐ Not applicable, there is no list that links code numbers to identifiers. Skip to section 22.6.

22.5 Is there a list of people who have access to the list/key?

☒ Yes – explain how access to that list is restricted and why certain persons require access.
[Type protocol text here if box checked]

☐ No – explain why not:
[Type protocol text here if box checked]

22.6 Describe the mechanism in place to ensure only approved research personnel have access to the stored research data (electronic and paper).

☒ Password-protected files
☐ Role-based security
☒ Specify all other mechanisms used to ensure only permitted users have access to the stored research data.

The hardcopy documents will be stored in a locked, secured cabinet. For electronic files, only research team members will be granted access to the files. The cabinet is located in PI Jao's office .

The use of mobile devices or wireless activity trackers to collect identifiable research data may have to be approved by Penn State IT - Information Security.

22.7 Will research data be collected and/or stored on a wireless activity tracker or mobile application or will the study team enter research data on a mobile device, such as an electronic tablet or cell phone?

☒ No – skip to 22.8
☐ Yes - answer the following questions:

22.7.1 Specify the provider of the tracker or mobile devices(s)/application

☐ Supplied by the sponsor
☐ Penn State owned device
☐ A personal device
☐ Other – Please specify source: [Type protocol text here if box is checked]

22.7.2 Specify the type(s) of tracker or mobile device(s)/application that will be used to capture data and all identifiers captured on the mobile device(s)/application. Please list all devices, and if more than one, the identifiers to be collected on each.

[Type protocol text here]

22.7.3 Specify the type of data collected on the tracker or mobile devices(s)/application.

[Type protocol text here]

22.7.4 Specify the application or website used to collect the data from the tracker or mobile device, if applicable.

[Type protocol text here]

22.7.5 Describe the measures taken to protect the confidentiality of the data collected on the tracker or mobile device(s)/application. Please address physical security of the device(s), electronic security, and secure transfer of data from device(s) to the previously indicated data/file storage location provided in section 22.3.

[Type protocol text here]

The use of online survey tools and email to collect or send research data containing identifiers that represent more than minimal risk to subjects may have to be approved by Penn State IT - Information Security.

22.8 Will any research data be directly entered/sent by subjects over the internet or via email (e.g., data capture using on-line surveys/questionnaires, surveys via email, observation of chat rooms or blogs)?

☒ No – skip to 22.9
☐ Yes - answer the following questions:

22.8.1 Specify the identifiers collected over the internet or via email (Including IP addresses if IP addresses will be collected).

[Type protocol text here]

22.8.2 Specify the type of data collected over the internet or via email.
[Type protocol text here]

22.8.3 Describe the measures taken to protect the confidentiality of the data collected?

[Type protocol text here]

22.8.4 Describe how the research team will access the data once data collection is complete.

[Type protocol text here]

22.8.5 If the research involves online surveys, list the name(s) of the service provider(s) that will be used for the survey(s) (e.g., REDCap, Penn State licensed Qualtrics, Survey Monkey, Zoomerang)? (Note: The IRB strongly recommends the use of REDCap for online surveys that obtain sensitive identifiable human subjects data.)

☐ Penn State REDCap
☐ Penn State Qualtrics
☐ Penn State Microsoft Forms
☐ Penn State Google Forms
☐ Other - Please specify:
Application: [Type protocol text here]
URL (If applicable): [Type protocol text here]

22.8.6 If the answer above is "Other" contact security@psu.edu for approval of an alternative data capture method

[Type protocol text here]

Depending on the nature of the subject matter involved, certain security requirements must be in place for the audio and/or video recording or photographing of subjects. If the subject matter presents more than minimal risk to the subjects, then, before completing the section below, please contact Penn State IT - Information Security at security@psu.edu to confirm whether these requirements are required.

22.9 Will any type of recordings (e.g., audio or video) or photographs of the subjects be made during this study?

☐ No - skip to section 22.10
☒ Yes - answer the following questions:

22.9.1 What will be used to capture the audio/video/images? Give a brief description of content.

☒ Audio – Describe the intended content of the audio recording:
We will conduct qualitative interviews with the staff and administrators with open-ended questions about the feasibility of implementing and maintaining the SABL

lighting intervention. A handheld audio recorder will be used to record the interview is in-person. Zoom audio recording will be utilized if the interview is conducted online.

☐ Video – Describe the intended content of the video recording:
[Type protocol text here]

☐ Photographs of the subjects – Describe the intended content of the photographs:
[Type protocol text here]

☐ 3-D Images – Describe the intended content of the of 3-D images:
[Type protocol text here]

☐ Other - Specify:
[Type protocol text here]

22.9.2 How will the recordings/photographs/images be stored (electronically or physically)?

The audio recordings and transcriptions of the recordings will be stored electronically.

22.9.3 Where will the recordings/photographs/images be stored?

The audio recordings and transcriptions of the recordings will be stored electronically in Penn State OneDrive.

22.9.4 Who will have access to the recordings/photographs/images?

Only IRB-approved research team members will have access to the audio recordings and transcriptions.

22.9.5 Will any of the recordings be transcribed?

☐ Not applicable
☐ No
☒ Yes – indicate who will be doing the transcribing?
IRB-approved research team members will transcribe the audio rerecording

22.9.6 Will the recordings/photographs be used for purposes other than this research study?

☐ No
☒ Yes - specify purpose(s) (e.g., publication, presentations, educational training, future undetermined research):
The transcriptions will be used for publications, presentations, educational trainings, and future undermined research

22.10 Certificate of Confidentiality (COC) - Is the research biomedical, behavioral, clinical or other research that is funded by the National Institutes of Health (NIH)?

☒ Yes - check one of the following:
- ☒ The research involves human subjects as defined by the DHHS regulations (See Worksheet HRP-310).
- ☐ The research involves collecting or using biospecimens that are identifiable to an individual.

☐ If collecting or using biospecimens as part of the research, there is a small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual.
☐ The research involves the generation of individual level, human genomic data.

Note: If <u>any</u> of the 4 items above are checked, a COC is automatically issued by NIH and applies to the research. Information about the COC must be included in the consent form.

☐ No - answer the following question.

If the research is not funded by NIH, will the investigator apply for a COC for this research study?
☐ No
☐ Yes

Note: For research not funded by NIH, the IRB may require a COC if the research is collecting personally identifiable information and the information is sensitive and/or the research is collecting information that if disclosed could significantly harm or damage the subject.

22.11 What steps will be taken to protect subjects' privacy interests? (Check all that apply.)
☒ Identification and recruitment of potential subjects follows procedures consistent with privacy standards
☒ Consent discussion and research interventions will take place in a private setting
☒ Limiting the information being collected to only the minimum amount of data necessary to accomplish the research purposes
☒ Limiting the people with access to the identifiable research data to the minimum necessary as specified in the application and consent process
☐ Other – Specify:
[Type protocol text here]

22.12 What is the process for ensuring correctness of data entry?
☐ Double data entry to reduce risk of errors
☒ Electronic edit checks to ensure data being entered are not obviously incorrect
☒ Random internal quality and assurance checking of research data
☐ Direct entry by subjects
☐ Other - Specify:
[Type protocol text here]

22.13 Does this research involve the generation of large-scale human genomic data as defined in NIH Genomic Data Sharing Policy (http://gds.nih.gov)?
☒ No
☐ Yes – describe the plan for de-identifying the dataset before sharing it with NIH-designated data repositories.
[Type protocol text here]

Note: Data sharing with an NIH-designated data repository may require execution of an institutional certificate. Please review the 'Institutional Certification for NIH Genomic Data Sharing' section of the Investigator's Manual for information about seeking institutional certification.

22.14 Does this research involve data sharing to public/restricted data repositories or as part of a journal requirement?

Data sharing is an important part of rigorous scientific discovery and the validation of results. Planning for data sharing is *strongly recommended*.

Data sharing includes sharing of identifiable, coded, or de-identified data. The data can be shared with public or restricted data repositories. Increasingly, journals require the sharing of data as a stipulation for publication. NIH-funded studies **require data sharing**, unless explicitly granted an exception from the NIH.

☐ Yes (may be required for publication and future grant submission)
☒ No

22.15 Does this research involve transfer or disclosure of data and/or specimens to and/or from Penn State?

☐ No - skip the rest of section 22.14
☒ Yes - answer the following questions:

Check all that apply:

22.15.1 ☒ **Data** are being transferred or disclosed **to** Penn State
What is the name of the third party(ies) (the institution, sponsor, etc.) sending or providing the data?

Christ the King Manor and Centre Care.
We will obtain the permission from each clinical site to access the medical records.

Is the third party requiring us to sign a contract regarding the data?
22.15.1.1 ☐ Yes - this contract must go through the Office of Sponsored Programs
https://www.research.psu.edu/osp/overview-pages/data-use-agreements
22.15.1.2 ☒ No

22.15.2 ☐ **Data** are being transferred or disclosed **from** Penn State
What is the name(s) of the third party(ies) (the institution, sponsor, etc.) receiving or accessing the data?

[Type protocol text here]

Note: Data transfers or disclosures may require a Data Use Agreement (DUA).

22.15.3 ☐ **Specimens** are being transferred **to** Penn State
What is the name(s) of the third party(ies) (the institution, sponsor, etc.) sending the specimens?

[Type protocol text here]

22.15.4 ☐ **Specimens** are being transferred **from** Penn State
What is the name(s) of the third party(ies) (the institution, sponsor, etc.) receiving the specimens?

[Type protocol text here]

Note: All material transfers, either sending or receiving, require a Material Transfer Agreement (MTA). Please contact the Office of Technology Management for more information.

22.15.5 Describe how the data/specimens will be securely transferred or disclosed to/from the third party(ies).

Data extraction from medical records will be conducted in the following two ways. The facility may provide us a login to their secure server to access potential resident participants' medical records, and/or provide residents' hard copies of the medical records for the research team to extract the data. Data extracted from the medical record will be entered and stored in REDCap and/or OneDrive.

22.15.6 How are the research data/specimens being transferred from and/or sent to the third party(ies)? Complete the appropriate section(s) and check all that apply within each completed section.

22.15.6.1 Data being transferred or disclosed **to** Penn State:

- ☐ Data are being received in aggregate/metrics (just counts, no individual data)
- ☐ De-identified individual data are being received and there is no linking list at either institution (no identifiers, or links to identifiers, such as code numbers)
- ☐ Coded research data without any identifiers are being received and the linking list remains with the entity sending the data; the recipient of the data will not have access to the linking list
- ☐ Coded research data with identifiers (such as dates and/or any of the identifiers listed in section 22.14.7 aside from Study Code) are being received and the linking list remains with the entity sending the data; the recipient of the data will not have access to the linking list
- ☐ Data with identifiers (such as dates and/or any of the identifiers listed in section 22.14.7) are being received and the linking list remains with the entity sending the data; the recipient of the data will have access to the linking list
- ☒ Data with identifiers along with the linking list are being received
- ☐ Other – Specify:
  [Type protocol text here]

22.15.6.2 Data being transferred or disclosed **from** Penn State:

- ☐ Data are being sent in aggregate/metrics (just counts, no individual data)
- ☐ De-identified individual data are being sent and there is no linking list at either institution (no identifiers, or links to identifiers, such as code numbers)
- ☐ Coded research data without any identifiers are being sent and the linking list remains with the entity sending the data; the recipient of the data will not have access to the linking list
- ☐ Coded research data with identifiers (such as dates and/or any of the identifiers listed in section 22.14.7 aside from Study Code) are being sent

and the linking list remains with the entity sending the data; the recipient of the data will not have access to the linking list

- ☐ Data with identifiers (such as dates and/or any of the identifiers listed in section 22.14.7) are being sent and the linking list remains with the entity sending the data; the recipient of the data will have access to the linking list
- ☐ Data with identifiers along with the linking list are being sent
- ☐ Other – Specify:
  [Type protocol text here]

22.15.6.3 Specimens being transferred or disclosed **to** Penn State:

- ☐ De-identified specimens are being received and there is no linking list at either institution (no identifiers, or links to identifiers, such as code numbers)
- ☐ Coded specimens without any identifiers are being received and the linking list remains with the entity sending the specimens; the recipient of the specimens will not have access to the linking list
- ☐ Coded specimens with identifiers (such as dates and/or any of the identifiers listed in section 22.14.7 aside from Study Code) are being received and the linking list remains with the entity sending the specimens; the recipient of the specimens will not have access to the linking list
- ☐ Coded specimens with identifiers (such as dates and/or any of the identifiers listed in section 22.14.7) are being received and the linking list remains with the entity sending the specimens; the recipient of the specimens will have access to the linking list
- ☐ Coded specimens with identifiers along with the linking list are being received
- ☐ Other – Specify:
  [Type protocol text here]

22.15.6.4 Specimens being transferred or disclosed **from** Penn State:

- ☐ De-identified specimens are being sent and there is no linking list at either institution (no identifiers, or links to identifiers, such as code numbers)
- ☐ Coded specimens without any identifiers are being sent and the linking list remains with the entity sending the specimens; the recipient of the specimens will not have access to the linking list
- ☐ Coded specimens with identifiers (such as dates and/or any of the identifiers listed in section 22.14.7 aside from Study Code) are being sent and the linking list remains with the entity sending the specimens; the recipient of the specimens will not have access to the linking list
- ☐ Coded specimens with identifiers (such as dates and/or any of the identifiers listed in section 22.14.7) are being sent and the linking list remains with the entity sending the specimens; the recipient of the specimens will have access to the linking list
- ☐ Coded specimens with identifiers along with the linking list are being sent
- ☐ Other – Specify:
  [Type protocol text here]

22.15.7 If transferring data/specimens with identifiers to or from Penn State, which of the following identifiers will be included with the data/specimens? Check all that apply:

☒ Names	☐ Medical record numbers
☒ Initials	☐ Health plan beneficiary numbers
☒ Street address	☐ Account numbers
☒ City	☐ Certificate/license numbers
☐ Driver's License numbers	☐ Passport numbers
☒ State	☐ State ID numbers
☒ Zip Codes	☐ Vehicle identifiers and serial numbers, including license plate numbers
☐ County	☐ Device identifiers and serial numbers
☐ Geocodes	☐ Web Universal Resource Locators (URLs)
☐ Precincts	☐ Internet Protocol (IP) address numbers
☒ All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death	☐ Biometric identifiers, including finger and voice prints
☒ Ages > 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older	☐ Full face photographic images and any comparable images
☒ Telephone numbers	☐ Any other unique identifying number, characteristic, or code (such as the pathology number) Specify: [Type protocol text here]
☐ Fax numbers	☒ Study code numbers
☒ Electronic mail addresses	☒ Master list linking study code numbers to subject(s)
☐ Social security numbers	☐ Genomic sequence data
	☐ Other – specify: [Type protocol text here if box is checked]