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| | |
|---|---|
| **Protocol Title:** | Enhancing Sleep Quality for Nursing Home Residents with Dementia: Pragmatic Trial of an Evidence-Based Frontline Huddling Program (Pilot Phase-R61) ["40 Winks Study"] |
| **Protocol Status:** | SUBMITTED TO IRB |
| **Date Submitted:** | 03/22/2022 |
| **Approval Period:** | Draft |
| **Important Note:** | This Print View may not reflect all comments and contingencies for approval. Please check the comments section of the online protocol. Questions that appear to not have been answered may not have been required for this submission. Please see the system application for more details. |

## * * * Amendment * * *

### Amendment

Complete this form and with it, submit any affected IRB materials needing revision. Please provide the entire revised documents (not just revised pages). Protocol amendments must receive IRB review and approval before they are implemented, unless an immediate change is necessary to eliminate an apparent hazard to the participants.

1) **Number of accrued participants**

11

2) **Status of Study (check one):**

X Continuing to accrue study participants.

Closed to accrual. Date closed:

3) **Special populations (mark as applicable):**

Children (<18 years of age)

Prisoner population targeted or study participant became a prisoner

4) **Summarize the proposed changes to the protocol in lay terms including the type of change AND what the change involves.**

1. Modifying our LAR Script to include teleform to our list of ways that Legally Authorized Representatives can return completed consent forms.
2. Adding an option for regular group interviews of the NH leadership team to the NH Staff section of the Informed Consent section in protocol
3. Modifying the NH staff informed consent information document to reflect the addition of NH leadership team group interviews
4. Correcting the NH Staff section of the Informed Consent section to accurately reflect that a waiver of written consent was obtained from IRB in 2019

(Please note: the Updates (current) box below indicates that changes were made to several sections such as Background, but these were not actual changes to the protocol. We have been using the method of ALL CAPS to indicate all protocol changes for reviewer convenience. We have gone through the protocol and changed ALL CAPS from the last amendment (12/22) to "sentence case" so that the ALL CAPS CHANGES in this March amendment will stand out for the reviewer.)

5) **What is the stimulus for this/these proposed changes - check all that apply:**

Unanticipated or adverse events have arisen

X Prospects' questions suggest ways to improve study explanation and consent form

Participants' responses suggest that data collection instruments or procedures should be changed.

Recruitment is going very slowly (Please provide numerical details about your recruitment, enrollment, retention, or completion in #3 below.)

New information has arisen that suggests an additional population or category of participant should be included or deleted.

New information has arisen that prospective or current participants should know.

Reduce participant burden

Changes in funding require adjustments in study

Requirement of sponsor

COI issue requires change in procedure or disclosure to participants

X OTHER: As this pilot study has progressed, we have realized that additional group interviews of the NH Leadership Team will help us better meet one of our original study goals of understanding the implementation process.

**5.a) Provide justification/explanation for the proposed changes.**

1. Modifying our LAR Script to include teleform to our list of ways that Legally Authorized Representatives can return completed consent forms: Some LARs have struggled with submitting their consent electronically and yet have not wanted to receive a paper copy in the mail -- we hope the addition of the teleform option will be helpful to these LARs

2. Adding an option for regular group interviews of the NH leadership team to the NH Staff section of the Informed Consent section in protocol: The NH Leadership Team meets regularly with the research staff for planning and review of intervention implementation efforts. The addition of a regular group interview option to these meetings will allow the research team to capture NH Leadership Team reflections on facilitators and barriers to implementation in an ongoing way that will be more nuanced as it will allow for real-time data capture.

3. Modifying the NH staff informed consent information document to reflect the addition of NH leadership team group interviews: This change is necessary to enact #2 above.

4. Correcting the NH Staff section of the Informed Consent section to accurately reflect that a waiver of written consent was obtained from IRB in 2019: In making changes #2 and #3 above we realized that this section of the protocol had been written in future tense "we will ask the IRB to approve a waiver of written consent" that was confusing because in fact the waiver of written consent had been submitted to the IRB and approved back in 2019.

**5.b) What is the effect of the requested changes on participant burden?**

X None

Increases

Decreases

**6) Will currently accrued participants need to be notified of changes?** N

If no, please justify why not.

Changes only affect research operations going forward, they do not change the conditions under which previously consented participants operate

If yes, please explain how AND when notification or re-consenting will occur.

7) **Will the proposed change(s) affect the risk-benefit ratio for participants?** N

What is your specific appraisal of the new risk-benefit ratio?

Minimal Risk

Greater than Minimal Risk but has potential direct benefit

Provide Justification

Greater than minimal risk and no direct benefit but with potential to yield generalizable knowledge about the participants' disorder or condition

Provide Justification

Proceed to appropriate section(s) of the electronic application and make your changes. Also make necessary changes in the protocol, Consent Form(s), Assent Form(s), Recruitment Statement, or other attachments, if applicable. Use track changes in uploaded documents being revised. Please upload a clean copy of each revised document to be stamped upon IRB approval.

Sponsored Studies: Remember to update the Sponsor's Protocol version number and date in Funding section of the protocol.

NOTE: Protocol amendments must receive IRB review and approval before they are implemented, unless an immediate change is necessary to eliminate an apparent hazard to the participants.

Background , Purpose , Study Procedures
Benefits/Alternatives,Procedures to main
Informed Consent
Attachments
Subject Population(n)

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* * * Personnel Information * * *

Study Personnel Roles:
-Principal Investigator: accepts responsibility for study, can edit protocol, must submit to IRB
-Administrative Contact: additional study contact, can edit/prepare protocol, may or may not also be member of research team
-Key Personnel (Research Team): University of Alabama member of research team, can view protocol (not edit)
-Non-Alabama Collaborator: member of research team from another institution or organization outside of University of Alabama, has no access to system, must be provided with PDF of protocol.
-Department Chair: Official Department Chair, may or may not also be a member of research team, can view the protocol (not edit). NOTE: a proxy may be listed if the Chair is the PI.

IMPORTANT NOTE: Human Participants Protection Training is mandatory for all research team personnel.

Principal Investigator Mandatory

**PI must be University of Alabama affiliate.**

**Name of Principal Investigator Degree (MD/PhD/Other) Title (Faculty, Staff or Student)**

| | | |
|---|---|---|
| Snow, Andrea | PhD | Professor |
| **Email** | **Phone** | **Fax** |
| LSNOW@ua.edu | +1 205 348 7518 | +1 205 348 7520 |

**Department Name**
Psychology

**Please indicate your status** Faculty

**Is the (Role) also a Department Chair?** N

**Human Subjects Training Completed?** Y

**If you have completed training that is not auto-populated below, upload a copy in the Attachments section.**

**Research Team Member Duties Picklist**

| | | | | | |
|---|---|---|---|---|---|
| 1. | X | Recruitment | 2. | X | Obtains consent |
| 3. | X | Determine participant Eligibility for Accrual | 4a. | | Participant Physical Examinations |
| 4b. | | Follow-up Visits including physical assessments | 5. | X | Perform study procedures or Specimen Collection |
| 6a. | | Administer and/or Dispense Study Drugs, Biologics or Devices | 6b. | | Receive, Store, Manipulate or Account for Study Drugs, Biologics or Devices |
| 7. | X | Participant Randomization or Registry | 8. | X | Collection of Participant Data |
| 9. | X | Report Data (CRFs, e-CRFs, Spreadsheets) | 10. | X | Data Analysis |
| 11a. | X | Review Adverse Events | 11b. | | Treat and Classify Adverse Events |
| 12. | | Other (Please insert explanation below.) | | | |

No training data is available.

Administrative Contact

| Name of Administrative Contact. | Degree (MD/PhD/Other) | Title | Department Name |
|---|---|---|---|
| Cox, Brian | MS | Research Project Coord PT | Ctr for Mental Health & Aging-CMHA |

Key Personnel (Research Team)

| Name of Key Personnel (Research Team) | Degree (MD/PhD/Other) | Title | Department Name |
|---|---|---|---|
| Smith, Katelyn | MS | Research Assistant | Psychology |
| George, Regina | MS | Research Assistant | Psychology |
| Cassell, Jack | | Research Assistant | Psychology |
| Blankenbeker, Richard | | Research Assistant | Psychology |
| Loup, Julia | MS | Research Assistant | Psychology |

Non - Alabama Collaborator

| Name of Non - Alabama Collaborator | Degree (MD/PhD/Other) | Title | Department Name |
|---|---|---|---|
| Christine Hartmann | PhD | Associate Professor, UMass Lowell | Other |
| Kathy Richards | PhD MSN BSN | Professor, University of Texas School of Nursing | Other |
| Liam Fry | MD | Professor, Dell Medical School, University of Texas | Other |
| Robert Morgan | PhD | Professor, University of Texas School of Public Health | Other |
| Megan McCullough | PhD | Research Assistant Professor, UMass Lowell | Other |
| Rosa Baier | PhD | Associate Director, Brown Center for Long-Term Care Quality & Innovation | Other |
| Ellen McCreedy | PhD | Assistant Professor, Brown University | Other |
| Barbara Frank | MPA | Co-Founder, B&F Consulting | Other |
| Cathie Brady | MS | Co-founder, B&F Consulting | Other |

Department Chair Mandatory

**The official Department Chair should be listed here. If the Department Chair is the PI, a proxy may be listed.**

| Name of Department Chair | Degree (MD/PhD/Other) | Title |
|---|---|---|
| Davis, Thompson | PhD | New Faculty-PA Not Receive |

| Email | Phone | Fax |
|---|---|---|
| tedavis10@ua.edu | 205-348-5083 | |

**Department Name**
Psychology

**Human Subjects Training Completed?** N

If you have completed training that is not auto-populated below, upload a copy in the Attachments section.

**Is Chair a member of the study team?** N

**Research Team Member Duties Picklist**

| | | | |
|---|---|---|---|
| 1. | Recruitment | 2. | Obtains consent |
| 3. | Determine Participant Eligibility for Accrual | 4a. | Participant Physical Examinations |
| 4b. | Follow-up Visits including physical assessments | 5. | Perform study procedures or Specimen Collection |
| 6a. | Administer and/or Dispense Study Drugs, Biologics or Devices | 6b. | Receive, Store, Manipulate or Account for Study Drugs, Biologics or Devices |
| 7. | Participant Randomization or Registry | 8. | Collection of Participant Data |
| 9. | Report Data (CRFs, e-CRFs, Spreadsheets) | 10. | Data Analysis |
| 11a. | Review Adverse Events | 11b. | Treat and Classify Adverse Events |
| 12. | Other (Please insert explanation below.) | | |

No training data is available.

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*** * * Subject Population * * ***

**Subject Population(s) Checklist**

Select All That Apply:

- [X] Adult Volunteers
- [X] Cognitively Impaired Participants
- [X] Employees
- [ ] Fetuses
- [ ] Minors (under 18)
- [ ] Pregnant Women
- [ ] Prisoners
- [ ] Students (Note: If students will be compensated extra-credit or course credit for participation in the research, they must be given a non-research alternative for obtaining the same amount of credit, which is of comparable time and effort as is required by the research activity.)
- [ ] Terminally Ill Participants
- [ ] Wards of the State (Note: Please consider whether the research population may also be considered "prisoners" or "cognitively impaired." If so, please mark the appropriate corresponding categories in the Subject Population Checklist)
- [ ] Non-English Speakers (Note: Please provide copies of all correspondence that will be used as a part of the research in English as well as in the native language of participants. Please also attach a copy of the

Translator's Declaration.)

Other (any population that is not specified above)

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## * * * Study Location * * *

### Study Location(s) Checklist

Indicate where the study will be conducted. Select all that apply:

| | | |
|---|---|---|
| X | The University of Alabama | |
| | Another University or College | |
| | VA Center | |
| | Hospital | |
| X | Other | Community Nursing Homes in the Vivage Corporation (Colorado: https://www.vivage.com), Caraday Corporation (https://caradayhealth.com/), and White Oak Management Corporation (https://whiteoakmanor.com/) |

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## * * * General Checklist * * *

### General Checklist

Select All That Apply :

- Study Eligible for Exempt Review
- Non-human participants research
- Collection of Specimens
- Data collection via e-mail or the Internet
- FDA Approved Device
- FDA approved drugs, reagents, other chemicals administered to participants (even if they are not being studied), or biologic products
- Genetic Testing
- HIV Testing
- Human blood, cells, tissues, or body fluids
- Investigational drugs, reagents, chemicals, or biologic products
- Investigational Device
- X Investigator Initiated Study
- X Medical Records
- X Photography, Video, or Voice-Recording Participants
- X Questionnaires and/or tests
- Radioisotopes/radiation-producing machines, even if standard of care
- rDNA/Gene Transfer Therapy
- Registry or Repository Creation
- Specimens to be stored for future research projects (must be in consent form)
- Study of existing data or specimens

Other (clarify in text box to the right)

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## * * * Funding * * *

### Funding Checklist

NONE

Funding - Grants/Contracts

| Funding Type | Funded By |
|---|---|
| Government | National Institute of Health |

NOTE: Applicable grant application, contract or subcontract, investigator's brochure, and sponsor's protocol (for all industry sponsored clinical trials) must be attached. Click "Add" to attach the documents.

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## * * * Expedited Review * * *

To request an Expedited Review, check the appropriate category(ies) below. Provide justification for your request for Expedited Review.

To qualify for expedited review, research activities must (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the categories below.

Select one or more of the following paragraph(s):

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
   a) Research on drugs for which an investigational new drug application (21 CFR Part 31, 32) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
   b) Research on medical devices for which
      i) An investigational device exemption application (21 CFR Part 812) is not required; or
      ii) The medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   a) From healthy, nonpregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or
   b) From other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

   Children are "persons who 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 the research will be conducted."

3. Prospective collection of biological specimens for research purposes by non-invasive means.

   EXAMPLES: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or

wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra-and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. **Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving X-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)**

   EXAMPLES: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participants' privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiology; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight and health of the individual.

5. **Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human participants. 45CFR 46.101(b)(4). This listing refers only to research that is not exempt.)**

6. **Collection of data from voice, video, digital, or image recordings made for research purposes. This category should only be selected if the present research will involve analysis of data that has been previously recorded.**

7. **Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human participants. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)**

8. **[FOR IRB use only]. Continuing review of research previously approved by a convened IRB only when condition (a), (b), or (c) is met.**

   a) Previously approved research where
      (i) The research is permanently closed to the enrollment of new participants;
      (ii) All participants have completed all research-related interventions; and
      (iii) The research remains active only for the long term follow-up of participants.
   b) Previously approved research where no participants have been enrolled and no additional risks have been identified.
   c) Previously approved research where the remaining research activities are limited to data analysis.

9. [FOR IRB use only]. Continuing review or research not conducted under an investigational new drug application or investigational drug exemption where expedited

categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

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*** * * Background , Purpose , Study Procedures * * ***

**Study Title**

Enhancing Sleep Quality for Nursing Home Residents with Dementia: Pragmatic Trial of an Evidence-Based Frontline Huddling Program (Pilot Phase-R61) ["40 Winks Study"]

**Complete Sections 1 - 15. Specify N/A as appropriate. Do not leave any required sections blank.**

**1) Background**

**a) Describe past experimental and/or clinical findings leading to the formulation of the study, if applicable.**

<PLEASE NOTE THAT ALL CAPS IS USED THROUGHOUT TO INDICATE PROPOSED CHANGES IN 3/21/21 AMENDMENT. CHANGES THAT WERE IN ALL CAPS IN PREVIOUS VERSIONS AND SUBSEQUENTLY APPROVED HAVE BEEN MOVED TO sentence case.>

A layman's case for the benefits of a good night's sleep is easy to make: imagine someone woke you last night every two hours. How do you feel? Now imagine that routine continues every night for the next month. For many residents of nursing homes (NHs), such awakening is standard practice.

NHs implement such routines to address various challenges (e.g, incontinence), even though evidence from both objective and subjective measures identifies disturbed sleep as a key contributor to many types of physical, emotional, and cognitive decline.[1-4] Disturbed sleep places individuals at higher risk for frailty, morbidity, and even mortality.[5-10] And individuals with Alzheimer's disease or related dementias (ADRD)—almost two-thirds of long-stay NH residents[11]—are likely to be particularly affected by sleep disturbance.[12,13]

Ample evidence underscores the negative health effects of sleep disturbance (lower total sleep time, increased sleep fragmentation, etc.) in older adults. Poor sleep quality in this population is associated with increases in self-reported fatigue, difficulties with activities of daily living (ADLs), depression, and risk of falling, and with decreases in memory, mobility, morbidity, and even survival.[3,41-44] Yet nursing home (NH) residents with Alzheimer's disease and related dementias (ADRD) experience suboptimal sleeping conditions at best. They spend much of their day without engaging in physical activity.[45,46] In addition, stimuli inherent in most traditional NH environments, including frequent noise and light [47-49] as well as, for example, efforts to reduce incontinence,[50] may also exacerbate sleep disturbance. A 2018 systematic review of nonpharmacological sleep interventions in NHs indicated promise for increased daytime light exposure, nighttime use of melatonin, and acupressure.[51] But because sleep itself results from a complex interplay of resident, staff-generated, and environmental factors,[52] sleep regimens for residents may work best when individualized instead of applied generically.[53,54] Yet healthcare workers, including those working in NHs, have generally poor knowledge of the relationship between sleep disturbance and clinical conditions, the availability of evidence-based interventions and assessment tools, and the environment's impact on sleep,[55] thus limiting their ability to intervene.

NH residents with ADRD are more likely to receive antipsychotic or antidepressant medications than other residents.[56] Yet antipsychotic or antidepressant use may worsen nighttime sleep for residents with ADRD,[57] while withdrawal from

antipsychotic medication may also, at least temporarily, worsen sleep.[58] Pain may also affect sleep. The American Geriatrics Society and National Institute on Aging 2016 conference on sleep called for more research into the relationship between sleep disturbance and pain.[59] A critical review examining prospective studies from 2005 to 2012 found significant support for—in what is a bidirectional relationship between sleep and pain—sleep disturbance as the stronger predictor.[60] The relationship between sleep quality and physical functioning (e.g., ADLs) is well-established. Poorer objective sleep is associated with poorer physical functioning in older adults [3,6,44,61] and those with ADRD.[62]

Engagement in meaningful activity may play a critical role in improving resident sleep. Providing individualized activities can reduce daytime sleeping and improved circadian rhythm (Richards et al., 2005) as well as increased duration and improved quality of sleep (Richards et al., 2011; Namazi et al., 1995; Naylor et al., 2000). These findings are of particular importance as NHs face unique challenges brought on by the covid-19 virus. Many aspects of NH residents' environments have changed to improve infection control; however, these changes have produced unprecedented barriers to address the social and personal needs of residents (Iaboni et al., 2020; Wu, 2020). While limited daylight exposure, social isolation, and disruption of previous routines are known to increase sleep disturbances (Lorenz et al., 2011), many of these practices have been put in place to limit resident exposure. By increasing engagement in meaningful activities, this may address the logical and practical concerns of the covid-19 response as well as residents disturbed sleep.

Despite the common knowledge that sleep disturbance has negative impacts on NH residents, and despite the availability of easy ways to measure (e.g., actigraphy) and intervene to increase sleep, little has been done to improve the situation. In NHs, barriers to quality improvement (QI) such as staffing problems and top-down approaches hamper efforts to enhance care quality.[14,15] Studies in NHs also underscore the importance of open communication and relationship-building to improve resident clinical outcomes.[14,16,17] A recent systematic review highlighted key components for successful NH QI: changing staff behavior, targeting specific care tasks, and using intervention theories.[18] One QI practice that capitalizes on this evidence and therefore has potential to meaningfully impact resident sleep is frontline staff huddling—brief, stand-up meetings to facilitate efficient, collaborative information exchange. Frontline staff huddling promotes communication across clinical roles[19-21] and improvements in clinical outcomes.[22-24] In NHs, it can improve quality of care and help sustain changes.[25] But use of frontline staff huddling in NHs remains limited.

Our research team standardized a NH frontline staff huddling program building on the theory of relational coordination, which posits that high-quality communication and relationships improve outcomes.[26] The program, known as LOCK (see Figure 1), is derived from evidence supporting strengths-based learning,[27,28] systematic observation[29] relationship-based teamwork,[30,31] and efficiency.[32,33] In LOCK, staff (A) "Learn from bright spots" (focus on evidence of positive change); (B) "Observe" (collect data through systematic observation); (C) "Collaborate in huddles" (conduct frontline huddles); and (D) "Keep it bite-size" (limit activities to 5-15 minutes for efficiency). The program's methods have improved clinical care in community NHs, even in those with a history of serious, intransigent quality issues. [35,36] The program guides frontline staff on how to address a particular resident outcome of concern, in the case of this pilot study, sleep (LOCK sleep program).

The LOCK program was implemented to target NH staff-resident interactions in a

successful
6-site pilot study in VA NHs. [34] Our LOCK program pilot targeting staff-resident interactions enabled 6 Veterans Health Administration (VA) NHs to make meaningful quantitative and qualitative improvements in communication frequency, communication quality, staff QI mindset, and staff QI capabilities.[34]

In 2017, based on these results, VA rolled the LOCK program out to all its 134 VA NHs. We achieved this roll-out with the support of B&F Consulting (national experts in NH QI implementation, and consultants for this current pilot study). The initial rollout was performed using a train-the-trainer approach, [37-39,81] with 4 participants from each NH attending a regional training led by B&F Consulting. The program then expanded to focus on other clinical issues, e.g., pain, catheter use, and pressure ulcers. Because all NHs in the VA system were exposed, a matching analysis of exposed vs. control NHs was not possible. Semi-structured qualitative interviews with staff at 12 VA NHs that excelled in the program revealed a wide range of improvements including the following: increases in resident engagement, staff morale, and staff engagement; reductions in falls and catheter-associated urinary tract infections; and increases in use of appropriate infection control, appropriate analgesic documentation, nonpharmacologic pain management, and pressure ulcer prevention.

We next conducted a preliminary adaptation of the LOCK program methods to address
resident sleep in a group of 8 VA NHs. Qualitative data based on field notes from two 1.5-day site visits to each of the 8 NHs provide preliminary evidence of the program's acceptability, feasibility, and positive outcomes. Across all 8 NHs, we found consistent uptake of sleep intervention efforts, including resident sleep assessments (sleep behavior tracking/actigraph use/sunlight exposure tracking), individualized reduction of night-time incontinence care practices, alterations of medication administration schedules, reduction of night-time blue light and noise, and alterations of daytime activity schedules and natural light exposure. Outcomes include reduced pain, reduced psychotropic use, increased daytime activity, and resident and family enthusiasm for sleep program participation.

In sum, this preliminary work (1) enabled us to standardize the LOCK program, (2) resulted in qualitative data on best LOCK program implementation practices, and (3) generated implementation materials, all of which we will use for this current pilot study. During this pilot study, we will refine the LOCK program to focus on sleep and meaningful activity in non-VA NHs.

[SELECTED REFERENCES]:
1. McCrae CS, McNamara JP, Rowe MA, et al. Sleep and affect in older adults: using multilevel modeling to examine daily associations. Journal of sleep research. 2008;17(1):42-53.
2.Song Y, Blackwell T, Yaffe K, Ancoli-Israel S, Redline S, Stone KL. Relationships between sleep stages and changes in cognitive function in older men: the MrOS Sleep Study. Sleep. 2015;38(3):411-421.
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4.Suh SW, Han JW, Lee JR, et al. Sleep and cognitive decline: A prospective nondemented elderly cohort study. Annals of neurology. 2018;83(3):472-482.
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between sleep and physical function in older men: the osteoporotic fractures in men sleep study. J Am Geriatr Soc. 2008;56(9):1665-1673.
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8.Miner B, Kryger MH. Sleep in the Aging Population. Sleep medicine clinics. 2017;12(1):31-38.
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11.Harris-Kojetin L SM, Park-Lee E, Valverde R. Long-term care services in the United States: 2013 overview. National Center for Health Statistics. Vital Health Stat 3(37). 2013.
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13.Wennberg AMV, Wu MN, Rosenberg PB, Spira AP. Sleep Disturbance, Cognitive Decline, and Dementia: A Review. Semin Neurol. 2017;37(4):395-406.
14.Arling G, Cooke V, Lewis T, Perkins A, Grabowski DC, Abrahamson K. Minnesota's provider-initiated approach yields care quality gains at participating nursing homes. Health Aff (Millwood). 2013;32(9):1631-1638.
15.Collier E, Harrington C. Staffing characteristics, turnover rates, and quality of resident care in nursing facilities. Res Gerontol Nurs. 2008;1(3):157-170.
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MEANINGFUL ACTIVITY REFERENCES ADDED IN 10/20/20 AMENDMENT:
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**b) Describe any animal experimentation and findings leading to the formulation of the study, if there is no supporting human data.**

N/A

## 2) Purpose of the study

**a) Provide a brief lay summary of the project in <200 words. The lay summary should be readily understandable to the general public.**

This study will improve clinical outcomes for an important, growing, and vulnerable population—nursing home (NH) residents with Alzheimer's disease or related dementias (ADRDs)—by implementing an evidence-based intervention (LOCK) to improve these residents' sleep and increase meaningful activity. It will also significantly increase our understanding of how to implement and sustain nursing home interventions.

**b) List your research objectives (specific aims & hypotheses of the study).**

In community (non-VA) NHs [one from each of 3 NH corporations, still to be recruited], our multi-disciplinary team proposes to (1) refine the LOCK sleep program to improve sleep and increase meaningful activity for residents with ADRD during this pilot (R61) phase, (2) which will prepare the team for the next phase of this NIH-funded grant (the R33 phase, to be described in a follow-up IRB protocol when this phase is completed, in approximately one year) to test the impact and sustainability of this intervention for NH residents with ADRD in an incomplete stepped-wedge randomized controlled trial.

(This study is funded by a National Institute of Aging pragmatic clinical trial RFA and grant mechanism called R61/R33, in which the R61 is a pilot grant for one year. The investigator team submits a report after the R61 phase indicating what was learned during the pilot phase and showing evidence that the pilot milestones are achieved. Then NIA funds the next four years of the randomized controlled trial

with the R33 mechanism. The current proposal only describes the pilot study (R61 phase). A separate proposal will be submitted for the randomized controlled trial (R33) when the R61 phase is close to completion. We will wait to submit the R33 proposal because National Institute of Aging wishes for modifications to the R33 design and intervention to be made based on the R61 data collection/intervention experience and the R61 quantitative and qualitative data analyses.)

This current pilot study R61 phase (1 year; n = 3 NHs; 1 NH per corporation) has the following specific aims:
1. Refine the LOCK sleep program train-the-trainer protocol by implementing and pilot-testing in three NHs.
2. Test and refine the research methods to: effectively identify eligible NHs and residents; obtain consent; collect primary data from residents and staff; explore staff impressions of additional sleep measurement devices (Fitbits); transfer primary and secondary data to our data center; and merge all data.

**c) Describe the study design (e.g., single/double blind, parallel, crossover, control, experimental, observational, etc.)**

N/A
Single blind
Double blind
Parallel
Crossover
Control group
Experimental group
Observational
X Other

This is a pilot study (R61 phase) to pilot the methods for an upcoming randomized controlled trial (see study funding mechanism explanation in previous section #2B above). The upcoming randomized controlled trial will be an incomplete stepped-wedge, cluster randomized controlled trial (RCT) design in which each nursing home (NH) serves as its own control. Our design can be classified in the NIH Model for Behavioral Intervention Development as Stage III, real world-based hybrid efficacy-effectiveness research.

This pilot study (R61 phase) pilots the methods for this design in 3 NHs. In this pilot we will use a convenience sample of three nursing homes (NHs), one recruited from each of three different NH corporations that are anticipated to participate in the eventual randomized controlled trial.

Each nursing home will serve as its own control. Control data will be collected for 1 week, then the intervention will begin and intervention data will be collected for 6 weeks, then the sustainment phase will begin and sustainment data will be collected for 8 weeks.

**d) Provide a timeline for individual participant recruitment and follow-up (analysis for the study is required).**

Each site will serve as its own control.

Control data will be collected for 1 week, then the intervention will begin and intervention data will be collected for 6 weeks, then the sustainment phase will begin and sustainment data will be collected for 8 weeks for a total of 15 weeks per participant.

The duration of the intervention period for any NH is 15 weeks, which includes three 7-day sleep measurement periods (baseline measurement before week 1, post-intervention measurement at week 8, and sustainment measurement at week 15).

e) **Will participant be randomized?** N

f) **If participants will be given placebo, please justify placebo use, and describe contents of the placebo.**

N/A

3) Study Procedures

a) **Is this project a multicenter study (i.e., same project is conducted elsewhere by a different investigator)?** N

**Is University of Alabama acting as a coordinating center for other sites?**

**Will the University of Alabama site be participating in all parts/procedures/arms of the study?**

**If No, explain what University of Alabama will NOT participate in:**

b) **Describe all the procedures, from screening through end-of-study, that the human participant must undergo in the research project, including study visits, drug treatments, randomization and the procedures that are part of standard of care. Specify which procedures are for research and which are standard of care. If study involves only retrospective record review, describe that review process here, including how records will be selected for review. Please note: The box below is for text only. If you would like to add tables, charts, etc., Click "Add" to attach the documents.**

Research Study Team: The study leadership team will be led by Dr. Snow (UA; LOCK sleep program co-developer, clinical geropsychologist, NH field expert) and will include Dr. Richards (Univ. TX School of Nursing; nurse, clinical NH and dementia sleep expert), Dr. Fry (Univ. TX Medical School, geriatrician, clinical geriatrics NH expert); Dr. Morgan (Univ TX School of Public Health, study statistician, data center lead), Dr. Hartmann (UMass Lowell; LOCK sleep program co-developer; social worker; implementation science expert), Dr. MCullough (UMass Lowell, medical anthropologist, qualitative expert), Ms. Baier and Dr. McCreedy (Brown University's Long-Term Care Quality and Innovation Center; NH implementation experts, NH recruitment experts), and B&F Consulting (national experts in NH quality improvement implementation). The project team, comprising Drs. Snow and Hartmann, Brian Cox, and research assistants, will meet weekly. The following teams will each meet bi-weekly: NH staff training team (Snow, B&F Consulting); Quantitative/Clinical Data Team (Hartmann, Richards, Morgan, Fry, research staff). This following team will meet monthly: Qualitative/Implementation Team (Hartmann, McCullough, Baier, McCreedy). The entire investigator team will meet monthly.

Collaborating Sites and Roles:
The research will be performed by the research study team located at the University of Alabama, University of Massachusetts-Lowell, Brown University, University of Texas at Austin (School of Nursing and Dell Medical School), and the University of Texas at Houston (School of Public Health). Only the University of Alabama site will enroll human subjects and the University of Alabama IRB will serve as the single IRB. Dr. Snow at the University of Alabama will be responsible for oversight of the entire project. Collaborating sites where human subjects research will be performed are the NHs from the three corporations who are participating. These nursing homes will be drawn from three separate NH corporations.

NH Recruitment:
We have recruited three NH corporations for this study: Vivage, Caraday, and White Oak.

We will work closely with the 3 recruited corporations to identify 3 NHs (1 per corporation) to participate in this pilot study. Stakeholder engagement will occur at both the corporate and the NH levels. At the corporate level, each corporation will assign a corporate coach who will attend all study staff training visits to their corporation's NH to learn how to prepare NHs for and support NHs in the implementation of the LOCK sleep program (the corporate coach is an employee of the nursing home corporation. Determination of if that coach enters the facility or works only virtually with staff will rely on corporation policy re who is allowed to enter facilities according to their covid-era infection control procedures). At the NH level, each NH will create LOCK sleep program NH Leadership and NH Implementation teams and will support frontline staff involvement in the LOCK sleep program.

•NH Leadership Team: Each NH will establish a NH leadership team consisting at least of the Director of Nursing, the NH administrator, the staff educator, and the QI designee (additional members may be added if needed to assist with limited study support activities as described below). The NH leadership team will be trained by the study team in protection of human subjects and limited applicable study procedures, i.e., (1) mailing introductory letters to resident LARs; (2) mailing of actigraphs/Fitbits and global rating forms to research staff; and (3) helping researchers arrange telephone calls with NH residents who may have capacity to provide their own consent.

•NH Leadership Teams will engage in limited study support activities, as follows:
(1) Mailing an IRB-approved study introduction letter to the legally authorized representative (LAR) of each NH resident with an ADRD diagnosis and providing all NH staff with a study introduction letter.
(2) Collecting and mailing outcome data (e.g., actigraphs at completion of a 7-day measurement period, completed staff ratings of resident sleep global change) to the University of Alabama project office using UA-supplied self-addressed postage-paid mailers from a tracked express mailing service (e.g., UPS).
(3) Assisting in telephone appointment arrangements and logistical support so that study team members can conduct telephone-based informed consent for NH residents who may have capacity to provide their own consent.

•NH leadership teams will not engage in research study tasks which will be completed exclusively by research study team members with appropriate study protection training:
(1) Conducting informed consent with staff, LARs, and residents.
(2) Conducting staff interviews: staff decisions whether or not to participate in interviews will be kept confidential from NH leadership teams to protect staff from potential coercion to participate in research.

Subject Populations and Anticipated Numbers:
(1) NH Residents. Primary outcomes are measured at the level of NH residents. We anticipate enrolling 57 residents (approximately 19 per each of 3 NHs) in this pilot study (R61 phase).
(2) NH Staff.
a. Training and Intervention Participation.
We will invite all NH staff to participate in the training and intervention. In the 3 NHs in this pilot study (R61 phase) we anticipate enrolling 120 NAs, 45 LPNs, 5 RNs, and 30 interdisciplinary treatment team/leadership team members. There are no known risks to the nursing staff associated with the training, intervention, and resident assessment activities requested of the NH staff. These are resident care and quality improvement activities that are fully within their job descriptions.

Consequently, consent for participation from the NH staff in these activities is not considered necessary as these activities are not human subjects research. In our past funded research involving NH staff, consent for these types of activities has also not been considered necessary. The nursing staff should benefit greatly from learning frontline huddling and sleep intervention skills. If successful, their application of these interventions will result in stronger NH staff teamwork and communication and healthier and less distressed NH residents and thus contribute to a less stressful and dangerous work environment.
b. Interview Participation.
We anticipate inviting 20 NH staff per NH (10 frontline staff engaged in the intervention, 10 LOCK sleep program leadership and intervention team members) to participate in interviews. In the 3 NHs in this pilot study (R61 phase) we anticipate enrolling 60 staff total. Because participation in qualitative interviews is outside of the usual work activities of the NH staff, we will obtain informed consent from NH staff before asking them to voluntarily participate in these activities. The NH staff will be informed of the purpose of all procedures: there is no element of deception. They will not be identified personally in any data collection used for research purposes. There will be no adverse consequences for NH staff refusing to take part in these activities.

NH Resident Inclusion and Exclusion Criteria: In the potential participant pool, we will include all NH residents aged >=50 years with an ADRD diagnosis. We include residents across the range of ADRD severity because this is consistent with the LOCK sleep program, in which staff will focus on residents with ADRD who have the greatest sleep problems without differentiating by ADRD severity. To identify participants, NH staff will use frontline staff huddles. NH staff will be trained to use the STOP-Bang screening tool to identify NH residents with high risk of obstructive sleep apnea (OSA) [82-84] and will be trained on appropriate procedures for referring any positively screened residents for medical evaluation. We will exclude residents with a high risk of OSA who are not being treated for OSA because actigraph measurements are inaccurate in that population.[85] Staff will also exclude residents who have a persistent bilateral resting tremor or paralysis in both arms (a subset of persons with Parkinson's disease and related significant tremor-causing diagnoses), due to actigraph measurement inaccuracies.[86]

NH Staff Inclusion and Exclusion Criteria:
Staff will not be excluded on the basis of race, ethnicity, gender, or age. As described above, a subset of NH staff will be recruited for interview participation based upon job type and intervention engagement (e.g., frontline staff versus leadership/interdisciplinary team members).

OBTAINING NH Staff and Resident Consent:
NH Resident Consent:
We will ask the administration department at each NH to compile a list of all NH residents with an ADRD or related dementia/cognitive impairment diagnosis. The administration department will send a letter to each resident's legally authorized representative (LAR) informing them of the study and inviting the LAR to opt out if they do not wish to be contacted by research staff. Opt-out procedures have been demonstrated to yield higher response rates and lower rates of non-response bias compared to opt-in procedures, and to be acceptable to participants, with no difference in rates of reported distress or complaints compared to opt-in procedures.[105-108] In our past federally funded research involving people with dementia, opt-out consent has been approved by multiple IRBs and worked well. Contact information of those LARs not opting out will be shared with University of Alabama (UA) study staff. We are requesting of this IRB a waiver of consent and HIPAA authorization for screening purposes regarding the sharing of these contact

information. Research staff will contact all LARs who do not opt out, inviting the LAR to consent to the NH resident's participation. The consent process will be described in more detail in the consent portion of this IRB proposal.

NH Staff Consent:
The NH leadership team or their designees will provide to all NH staff an IRB-approved study introduction letter (including option to opt out within two weeks if they do not wish to be contacted by study staff). Contact information of those NH staff not opting out will be shared with UA study staff. We are requesting of this IRB a waiver of consent and HIPAA authorization for screening purposes regarding the sharing of these contact information.
Research study staff will contact NH staff (via email and/or phone) to invite them to participate in mid-implementation and/or post-implementation interviews about their experiences with the LOCK sleep program and Fitbits. The list of NH staff who agree and decline interview participation will remain confidential to protect NH staff from any possible coercion to participate. The consent process will be described in more detail in the consent portion of this IRB proposal.
NOTE: The LOCK sleep program itself comprises clinical practices common in NH QI efforts. These clinical practices that will be taught via the LOCK sleep program training thus fall within the scope of staff positions and require no consent.

Sources of Research Data (see Table 1):
NH Resident Data will be collected for consented NH residents from Brief interview of family/friends (see attachment), NH staff interview of the resident (see attachment), NH staff ratings (clinical global assessments of change in overall sleep quality and sleep-related conditions - see Appendix; NH staff sleep reports - see attachment); through primary data collection (actigraph/Fitbit measurements; these are wristwatch-sized devices worn on the wrist); through medical records (age, diagnoses, medical history, and medications); and through NH secondary data from the Minimum Data Set (MDS; all Medicare-reimbursed NHs are required to collect MDS assessments on all residents; the MDS contains information on resident medical conditions, functioning, cognition, psychotropic and pain/analgesic medication use, activities of daily living decline, and sleep-, mood-, and activity-related items). Table 1 summarizes the primary and secondary outcomes and data sources.

NH Staff Data: staff interview data will be collected via audiorecorded qualitative interview (see Appendix).

Data Collection Procedures:
NH Resident Primary Research Data Collection: will consist only of actigraph/fitbit data.

We will measure total sleep time (TST) with data from Micro-Mini Motionlogger Actigraphs (Ambulatory Monitoring Inc., Ardsley, NY).[87] We will define nighttime as 10pm to 6am and will compute TST as the total number of minutes asleep during a nighttime period. We will measure sleep for 7 days at each measurement period (see Figure 2) to obtain reliable measurements and will use the average TST across this period. We will also examine the following: wake after sleep onset (total number of minutes awake during nighttime), how often the resident awoke during the nighttime, sleep efficiency (the ratio of
minutes asleep to minutes awake over the period), and sleep fragmentation (an index of restlessness computed as the percentage of one-minute epochs scored as awake). Sensitivity of actigraph measurement for sleep is very good (actigraphy = sleep when polysomnography = sleep was 0.97). [88]

We will also explore measuring sleep time using Fitbits. Fitbits are known to be inferior to actigraphs for sleep research measurement purposes because Fitbits tend to overestimate total sleep time, among other limitations.[70,71] But Fitbits are considerably less expensive than actigraphs, offer an easy user interface, and collect data on sleep plus multiple other dimensions, making them potentially useful to NH staff for non-research purposes. Studies are lacking on NH staff impressions of the perceived potential usefulness of Fitbits for informal measurement. We will therefore explore staff impressions of Fitbits through semi-structured interviews after the R61's 22-week measurement period. If staff find Fitbit information of added use and staff and residents consistently find it acceptable to use 2 devices at the same time (actigraph plus Fitbit), we will consider use Fitbits beyond this pilot study into the randomized controlled trial (R33 phase).

Dr. Kathy Richards, PhD MSN (nurse co-investigator with extensive NIA and VA principal investigator experience using objective sleep measurements including actigraphs in studies with NH residents and people with dementia, who tolerated the devices well without removing them.[109-111] NH staff will assist residents to wear both an actigraph and a Fitbit side by side on a wrist for 7 days during each of the 3 measurement periods (weeks 1, 8, AND 15). We will use Dr. Richards' effective procedures for assuring that NH staff maintain charge and do not lose actigraphs or Fitbits (e.g., Nighttime Agitation and Restless Legs Syndrome in People with Alzheimer's disease, R01 AG051588-01A1, NIH-funded).

Due to covid-era infection prevention restrictions in nursing homes, research staff will not enter nursing home. The study was already designed as a pragmatic trial relying on nursing home staff rather than research staff activity for data collection and intervention, so the modifications required are minor. All training will be conducted virtually through zoom or similar teleconference platforms. Nursing home staff will collect data and mail via tracked mailers. All actigraphs/fitbits will be single-resident use (no resident sharing).

NH Staff Data About NH Residents: The NH Leadership and NH Implementation teams will be trained by our research study team on the LOCK Sleep Program methods (see Figure 1), including how to facilitate and implement front-line staff huddles to discuss resident sleep issues. Once this training is complete, we will ask NH huddle facilitators to use a huddle to establish a team consensus rating of each enrolled NH resident's overall sleep quality and up to 2 additional symptoms or behaviors of concern potentially related to sleep quality (e.g., agitation, pain). Ratings will be obtained using the using the Clinical Global Impression of Change rating scale (CGIC; see Appendix); CGIC ratings evidence high reliability and responsivity under a wide range of circumstances and are frequently used as outcomes in clinical trials. [97-104] Each LOCK sleep program huddle facilitator will lead their huddle team to complete clinical global impression of change ratings of enrolled residents' overall sleep quality at the end of each 7-night sleep measurement period and at the end of each week of the 6-week sleep intervention period. These rating forms will be part of the standard care practices being taught to the NH staff -- such assessments are within the typical scope of staff responsibilities. The NH clinical team will file these assessments in the NH residents' medical chart. The NH Leadership team will copy these rating forms and share with the research team. NH staff will also record resident sleep reports in a study binder kept at the nurse's station during the three assessment weeks (week 1, 8, & 15) [see attachment].

NH Staff Interviews: We will recruit and consent a sample of NH staff engaged in huddles to participate in virtual interviews at mid- and post-implementation semi-

structured interviews to explore staff perceptions of the LOCK sleep intervention's effectiveness, feasibility, facilitators, and challenges, as well as their impressions of the interview process itself to inform for the upcoming randomized controlled trial (R33 phase) (e.g., length, location, etc. for busy NH staff) and use of Actigraphs and Fitbits (see Appendices for interview guides). These interviews will be conducted by a research staff member trained to conduct qualitative interviews remotely. For both interviews, we will recruit the LOCK sleep program leadership and implementation team members, as well as a sample of frontline staff, with an approximate sample size of 20 staff per NH.

Medical Record/Secondary Data About NH Residents: To assess inter-resident variability in sleep, a research assistant will work with NH staff remotely to guide the NH at the end of the 15-week measurement period to collect data from the NH's medical record on the following for the entire period: (a) changes in any sedating medications and changes in dosages; (2) incidents of delirium; (3) any urinary tract infections; (4) doses of any sedating medications, including as needed ones. Also collected from medical records will be information to characterize the NH residents (age, diagnoses, medical history, and medications). NH secondary data will be collected also from the NH Minimum Data Set (MDS; all Medicare-reimbursed NHs are required to collect MDS assessments on all residents; the MDS contains information on resident medical conditions, functioning, cognition, psychotropic and pain/analgesic medication use, activities of daily living decline, and sleep-, mood-, and activity-related items).

Extracting, transferring, and merging data: Every week, the NH Leadership team will use a researcher-provided tracked insured express mail service (e.g., UPS) to send the research team at the University of Alabama all completed Clinical Global Impressions of Change staff rating forms and any actigraphs and Fitbits for which the assessment periods are complete. Research staff will mail back actigraphs and Fitbits after download and maintenance. We considered electronic data transmission options but opted for mail for the following reasons: (a) We will be able to assure equipment maintenance and appropriate data downloads, reducing missing data errors. (b) For busy NH staff, copying and packaging will take significantly less time and technological skill than scanning, uploading, and transmitting electronic data. Thus, after research staff upload the data at the University of Alabama, they will transfer the data to the University of Texas Health Science Center at Houston School of Public Health (UTHealth SPH) Data Center via secure file transfer procedures established by the Data Center. The data transfer and data security processes will be discussed in more detail in Section #10 (Procedures To Maintain Confidentiality).

Study Staff Training:
This study does involve the vulnerable population of nursing home residents with dementia. This study also involves NH employees, who are vulnerable to the extent that they may feel coerced to participate in research activities by their supervisors given that the NH leaders and parent corporation are supportive of overall study participation. To protect all vulnerable subjects, in addition to the NIH-required computer-based trainings (on the protection of human research participants, HIPAA, and Good Clinical Practice), the UA study staff will attend a 2-day training session specific to the proposed project led by Dr. Snow. The PI will review the overall goals of the study, study policies and procedures, data collection manuals, adverse event identification and reporting, subject confidentiality, communication techniques and principles for working with persons with dementia, and appropriate procedures for working by telephone with LARs for consent, for working by telephone with people with dementia for consent and for determining capacity to consent. Procedures will be reviewed for protecting employees from possible

coercion for participation from supervisors including maintaining confidentiality of those employees who do and do not consent to research interviews. During these training sessions, professionally produced videotapes of staff interactions with persons with dementia will be shown and the PI and study staff will role play all informed consent, capacity assessment, and data collection processes. Drs. McCullough and Hartmann will provide training on appropriate procedures for NH staff interviews. Dr. Morgan will provide training on appropriate procedures for data safety and security.

Dr. Richards will work together to provide training on appropriate assessment equipment (e.g., actigraph, fitbit) maintenance and data downloading. For example, staff will be instructed that: (A) each actigraph should be used for only one resident. All actigraphs will be shipped to NHs in subpackage of storage envelopes wth a space for resident name so that they can be identifiably stored when resident is not wearing. Multiple actigraphs will be shipped to each NH every week or two weeks to assure that there is always enough new actigraphs available for use to prevent any possibility of staff sharing across residents; (B) all portions of the bands and backs of the actigraph/fitbits should be carefully and thoroughly disinfected with a Sani-Cloth prime germicidal disposable wipe (or similar product that is appropriate for healthcare equipment that comes into patient contact such as stethoscopes) and left on the device for 1 minute as per product instructions to reach maximum bactericidal/fungicidal/virucidal/tubercolocidal effectiveness. The watch front of the actigraph/fitbits should be disinfected with a Sani-Cloth Easy Screen Cleaning Wipe (or similar product that is a 70% isopropyl alcohol solution and is designed for use on touch screens and other electronic devices that are degraded by more intensive chemicals).

NH Leadership Team Training:
Study staff will provide a 2-hour virtual training on procedures to protect vulnerable subjects, as follows: proper procedure for, and importance of only using IRB-approved procedures and letters when sending study opt-out letters to LARs; proper procedures for maintaining security and privacy of data packages mailed to the University of Alabama project office; proper procedures for avoiding coercion or appearance of coercion of research participation when working with NH staff (e.g., not asking staff about research interview participation); proper procedures for assisting in telephone appointment arrangements and providing logistical support when study team members conduct telephone-based NH resident consenting and capacity to consent assessment; importance of only study team members conducting actual consent procedures of anyone (LARs, NH residents, NH staff); importance of only properly trained NH leadership team members participating in study procedures.

Dr. Richards will work together to provide virtual training on the appropriate application of actigraphs and Fitbits to promote comfort and prevent adverse experiences, as well as appropriate assessment equipment maintenance and data mailing. For example, the NH leadership team will be trained on the appropriate actigraph/fitbit cleaning as described in the previous subsection (Staff Training). They will also be taught that actigraphs/fitbits should only be applied to dry, clean skin. The skin should be gently washed with the skin cleanser approved for facility use for the nursing home resident (typically a non-soap cleanser such as cetaphil, but this may differ depending upon the specific resident), gently rinsed with a clean damp washcloth, and then carefully dried to avoid trapping moisture between the actigraph/fitbit and skin. Similarly, when the actigraph/fitbit is removed in the morning, the skin should be again cleansed and dried.

NH Staff Intervention Training and Intervention Implementation:

NH Staff Training will follow train-the-trainer principles, an established, effective mechanism for training NH staff.[37-39,81] To prepare for the training, B&F Consulting (Barbara Frank & Cathie Brady, research study team members, national NH quality improvement implementation experts, authors of two books on their method which highly influenced the development of the LOCK Sleep Program [25,35]) will guide each NH in the establishment of LOCK sleep program teams: (a) a NH Leadership team consisting of the Director of Nursing, the NH administrator, the staff educator, and the QI designee and (b) an implementation team consisting, at minimum, of the Minimum Data Set (MDS) coordinator, unit managers, and the medical director. B&F Consulting will visit each NH 5 times over the course of the R61 phase to train and support the NHs; Dr. Snow and other research staff will also virtually attend several visits and will attend all phone calls with the sites. The corporate coaches will attend all B&F consulting virtual visits to their corporation's NH to prepare for the subsequent randomized controlled trial (the R33 phase), when the corporate coaches will assume leadership of the training with B&F support. B&F Consulting's will conduct visits to train leadership and staff and begin the implementation, in and then conduct virtual visits to support implementation, and then then finally a virtual visit to support sustainment.

The 3 NHs will implement the program starting at approximately the same time. Based on prior
experience (both in VA and in B&F's experience in non-VA NHs), we anticipate an initial 8-week period in which each NH builds its frontline staff huddle practice across all units (pre-implementation). After this, each NH will begin the LOCK sleep intervention on all its units. For each resident, their involvement in the study will be 15 weeks -- 1 week of baseline assessment, 6 weeks of active intervention focus in the staff huddles with a 1-week post-intervention measurement period, and 8-weeks of sustainment with a final post-sustainment 1-week measurement period. The leadership team will communicate broadly about the program, ensuring all staff (including new hires) are introduced to and maintain implementation of the LOCK sleep program and perform the periodic sleep measurements.

The training will include the following components. B&F Consulting will virtually train the leadership and implementation teams to guide staff to use huddles to identify residents with ADRD whose sleep is
disrupted, explore residents' personal histories with help from family, and develop action plans to
pilot test individualized, person-centered sleep improvement approaches. B&F Consulting will also
guide the teams to teach staff to use observation and data collection to monitor the impact of
their action plans and change the plans as appropriate. The training will also instruct staff in
actigraph/fitbit use. It will include information on why good sleep is important for residents with ADRD,
the etiology of poor sleep, evidence-based sleep improvement interventions (e.g., good sleep hygiene, minimizing noise and light and resident disturbance at night, maximizing engaging activity during the day, good nutrition and hydration practices to promote sleep). As an example of training in techniques to reduce night-time interruption, nursing staff will be trained on procedures for checking on the resident without disturbing them if asleep, such as the use of small flashlights pointed toward the floor using use amber illumination (rather than turning on overhead sleep disruptive blue lights) to allow the nursing staff to check the resident and room without awakening a sleeping resident. This increases safety because sleeping residents are residents who are not getting up. Whereas waking a resident to use the restroom can result in the resident not being able to easily go

back to sleep, which then puts them at risk of getting up due to restlessness or agitation after the nurse leaves.

The training will emphasize the importance of customized individualized care, incremental approaches to treatment changes, and how to use huddles to integrate such interventions into individualized treatment plans. For example, "decrease in nighttime interruption" does not mean never checking on the resident during the night. Staff will be trained on the importance of using small PDSA (plan-do-study-act) cycles to assure that all care changes are pursued incrementally in an individualized, customized manner. This is not about one-size-fits-all care. There is no blanket edict to not interrupt the patient for the entire night. Rather, the instruction is for the team to consider and explore ways of promoting longer periods of uninterrupted sleep, and to test these innovations in incremental trials over a period of days or weeks.

NH Staff Trained Trainers Providing Training:
After B&F Consulting has trained the NH Leadership and implementation teams, those teams will then be responsible for training others in the NH. As part of the intervention training, NH staff will be trained by their NH Leadership or implementation teams or their trained designees on proper use and placement and cleaning of actigraphs and Fitbits, verbal and behavioral signs of distress that might indicate actigraph/Fitbit-related discomfort/distress, and appropriate modification techniques to try to relieve such distress. NH staff will be informed that the devices should be removed in the unlikely event that distress behaviors are not relieved by modification techniques. NH staff will be trained on importance of NH resident autonomy, and will be engaged in a discussion of how to assess for and honor NH resident assent or lack thereof with regard to the devices.

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c) **Provide stopping rules for the study, If the proposed study is a clinical trial where a drug, vaccine, device or other treatment is compared to a placebo group or comparison treatment group, what are the guidelines or endpoints by which early decisions regarding efficacy or lack of efficacy can be made? For example, it may be reasonable to stop enrollment on a study when efficacy has already been clearly demonstrated, to avoid unnecessary enrollments of additional participants. Alternatively, it may be reasonable to stop enrollment when it is clear that efficacy will never be demonstrated, given the statistical power of the study as designed. Describe the guidelines that are in place to assist in making these determinations, if relevant to the proposed study.**

We will exclude residents with a high risk of OSA who are not being treated for OSA because actigraph measurements are inaccurate in that population.85 Staff will also exclude residents who have a persistent bilateral resting tremor or paralysis in both arms (a subset of persons with Parkinson's disease and related significant tremor-causing diagnoses), due to actigraph measurement inaccuracies.

d) **Describe how data analysis will be performed (statistical tests, methods of evaluating data) and indicate the smallest group/unit for which separate reporting will occur. For studies involving a questionnaire, if data and reliability information are available, please describe or provide references. (Page numbers from a sponsor's protocol/grant may be referenced in this section).**

Data analysis for this pilot study (R61 phase) will inform revisions to our upcoming randomized controlled trial (R33 phase). We will conduct a preliminary assessment of our outcome measures, particularly our primary outcomes from the actigraphy TST measurements and fitbit sleep time measurements, and secondary outcomes from the MDS and our supplementary sleep data (see Table 1). We will examine ranges, indicators of variability (change over time), and rates of missing data. We will also examine indicators by demographic characteristics (e.g., age, gender) and level of dementia severity (mild, moderate, severe). To test the sensitivity of our secondary outcomes and supplementary sleep data to individual differences in TST and change in TST, we will preliminarily examine the relationships of these with average TST and variability in TST.

For the qualitative interviews, all interviews will be audio recorded and transcribed and Dr. McCullough will guide the experienced qualitative team in using a rapid appraisal template analysis,[112,113] a rigorous technique for thematically organizing and analyzing data. The analysis will identify, in particular, areas for modifications to the LOCK sleep program training. Interviews will also inform our decision of whether or not to include Fitbits as part of the subsequent randomized controlled trial (R33 phase), based on staff members' impressions of the value of Fitbits and their impressions of the feasibility of using both devices. We will also modify interview guides (see Appendix) for the next phase, as necessary.

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*** * * Radioisotopes or Radiation Machines * * ***

### 4) Radioisotopes or Radiation Machines

Please note: For projects requiring radiation procedures, please contact the UA Environmental Health and Safety Office at 348-6010

a) **If applicable, summarize in lay language the radiographic diagnostic and therapeutic procedures associated with this protocol. (X-ray, fluoroscopy, CT, radioactive materials, nuclear medicine, PET-CT, radiation oncology, accelerator, Cyber Knife procedures, etc.).**

b) **Are the radiation procedures being performed a normal part of the clinical management for the medical condition that is under study (Standard of Care), or are the procedures being performed because the research participant is participating in this project (extra CT scans, more fluoroscopy time, additional Nuclear Medicine Studies, etc.) (Not Standard of Care)? If some procedures are Standard of Care and some are Not Standard of Care, check both boxes.**

| NOT STANDARD OF CARE | STANDARD OF CARE |
|---|---|
| If it is not standard of care,complete the rest of this section. Provide the University of Alabama RSC approval information below. | If it is only standard of care, skip the rest of this section. |

c) **Are research-related radiation procedures limited to X-rays only?**

Yes (Complete X-ray table).

No (Skip X-ray table).

d) **Total Radiation Exposure (in mRems) from x-ray procedures:**

To calculate radiation exposure from x-rays only, University of Alabama allows use of the Duke University Radiation Safety Committee dose estimate calculator. University of Alabama does not allow use of this website to calculate any other type of radiation exposure.

To determine the dose estimate, click on the appropriate links, below (you will be taken to the Duke University Radiation Safety Committee website). Enter the x-ray procedures into the appropriate fields of the website and click "create statement". Enter the dose estimate from the statement in the table above.

For studies involving adults, please click here.

For pediatric studies, please click here..

e) **Please list all radiation procedures (including x-ray) that are research-related (not standard of care). Include the anatomical location and specify the number of times that each procedure will be conducted throughout the entire study.**

NOTE: The IRB will determine if this study requires radiation safety review by the Radiation Safety Officer or the Radiation Safety Committee.

For more information on how to submit for radiation safety review, contact the Radiation Safety Officer.

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*** * * Drugs, Reagents, Chemicals, or Biologic Products * * ***

### 5. Drugs, Reagents, Chemicals, or Biologic Products

| | | |
|---|---|---|
| Pilot | Phase I | Phase II |
| Phase III | Phase IV | Not Phased |

a) Please list in the space below all investigational drugs, reagents or chemicals to be administered to participants during this study.

b) Please list in the space below all FDA approved drugs, reagents, chemicals to be administered to participants during this study.

Please read the IND Statement 1 and IND Statement 2.

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*** * * Devices * * ***

6. Devices

a) Please list in the space below all investigational devices to be used on participants during this study.

b) Please list in the space below all FDA approved devices to be used on participants during this study.

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*** * * Subject Population(a-h) * * ***

7. Subject Population - In the space below, please detail the participants that you are requesting to recruit (include description of each group requested)

a) Expected age range of participants. (For example - 19 yrs to 90 yrs).

In the potential participant pool, we will include all NH residents aged >=50 years with an ADRD diagnosis.

| | | | |
|---|---|---|---|
| b) | i) Number to be directly solicited for this research. | N/A | all res. at 3 NHs |
| | ii) Number to be consented (including withdrawals or screen failures) | N/A | 70 |
| | iii)Number expected to complete the study. | | 57 |
| c) | If this is multi-center study, number of participants to complete the study study-wide | N/A | 57 |
| d) | If study involves review of medical or other records, number of records to be reviewed. | N/A | 70 |

e) If women, minorities, or minors are excluded, a clear compelling rationale must be provided unless not applicable. Examples for not including minors: disease does not occur in children; drug or device would interfere with normal growth and development; etc.

1. Inclusion of Women and Minorities
Participants will be selected according the inclusion/exclusion criteria described in the methods section. We aim to recruit a sample that will be representative of the national nursing home (NH) population. Based upon the 2015 Centers for Medicaid and Medicare Nursing Home Compendium,122 we will aim to enroll approximately 67% women and 33% men. The national figures for 2015 were: 79% White not Hispanic, 13.8% Black not Hispanic, 4.9% Hispanic, 1.6% Asian, .4% American Indian/Alaskan Native, .1% Native Hawaiian Pacific Islander, and .3% more than one race.
We will make every effort to include a representative sample of minorities. Men and members of minority groups will be actively recruited during this protocol.
We will use unbiased statistical analyses and proper methods of inference to estimate and compare intervention effects by sex/gender, race, and/or ethnicity. We will conduct exploratory analyses to detect any differences in intervention effect among these groups, because prior studies do not strongly indicate nor negate the existence of such effects.
2. Inclusion of Children
Children will not be included in this study. Children are unlikely to live or work in NHs and unlikely to have dementia.

f) Describe how potential participants will be identified for recruitment (e.g., chart review, referral from individual's treating physician, those individuals answering an ad). How will potential participants learn about the research, and how will they be recruited (e.g., flyer, e-mail, web posting, telephone, etc.)? State where recruitment materials will be located. Click "Add" to upload recruitment materials document.

Important to remember: Study Activities cannot begin until IRB approval is granted.

In the potential participant pool, we will include all NH residents aged >=50 years with an ADRD diagnosis. We include residents across the range of ADRD severity because this is consistent with the LOCK sleep program, in which staff will focus on residents with ADRD who have the greatest sleep problems without differentiating by ADRD severity. To identify participants, NH staff will use frontline staff huddles.

Research staff will recruit and consent a sample of NH staff at mid- and post-implementation for (mid-) and (post-) PHONE interviews about their experiences with the LOCK sleep program and Fitbits. NOTE: The LOCK sleep program itself comprises clinical practices common in NH QI efforts. These practices thus fall within the scope of staff positions and require no consent.

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* * * Subject Population(i-l) * * *

7. Subject Population (continued)

i) Inclusion and Exclusion Criteria.

Identify inclusion criteria.

In the potential participant pool, we will include all NH residents aged >=50 years with an ADRD diagnosis. We include residents across the range of ADRD severity because this is consistent with the LOCK sleep program, in which staff will focus on residents with ADRD who have the greatest sleep problems without differentiating by ADRD severity. To identify participants, NH staff will use frontline staff huddles. NH staff will be trained to use the STOP-Bang screening tool to identify NH residents with high risk of obstructive sleep apnea (OSA) 82-84 and will be trained on appropriate procedures for referring any positively screened residents for medical evaluation

Identify exclusion criteria.

We will exclude residents with a high risk of OSA who are not being treated for OSA because actigraph measurements are inaccurate in that population.85 Staff will also exclude residents who have a persistent bilateral resting tremor or paralysis in both arms (a subset of persons with Parkinson's disease and related significant tremor-causing diagnoses), due to actigraph measurement inaccuracies.

j) Compensation. Explain the amount and schedule of compensation, if any, that will be paid for participation in the study. Include provisions for prorating payment.

N/A

k) Describe who will cover study related costs. Explain any costs that will be charged to the participant.Include provisions for prorating payment.

All study related costs will be covered by the NIA grant funding.

l) Estimate the probable duration of the entire study including data analysis and publication. This estimate should include the total time each participant is to be involved and the duration the data about the participant is to be collected. If the study is Investigator-initiated, a timeline for individual participant recruitment, follow-up, total time for participant accrual, and data analysis for the study is required.

The entire pilot study will last 1 year. Each NH resident participant will be involved in a 15 week data collection period.

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* * * Subject Population(m) * * *

Research Involving Children

NOTE: Investigators, please include this information with the e-Protocol application if your research involves children. In Alabama a child is an individual less than 18 years of age unless the child is legally emancipated. If your research involves children with more than one vulnerability (e.g., children who are pregnant, incarcerated, or cognitively impaired) attach the supplementary information for that vulnerable population as well.

Minimal risk means that the probability and magnitude of the harm or discomfort anticipated in

the research are not greater in and of themselves than those ordinarily encountered in daily life of a healthy child or during the performance of routine physical or psychological exams or tests.

Section 1.

Select and complete the category that applies to your research.

Category 1 (45 CFR 46.404; 21 CFR 50.51) My research does not involve greater than minimal risk.

a) My research falls under this category because:

b) Describe what provisions will be made for soliciting the assent of the children, and the permission of both parents, or the legal guardian. (Permission from both parents must be obtained unless one parent/guardian is deceased, unknown, incompetent, or not reasonably available, or when only one parent/guardian has legal responsibility for the care and custody of the child). Justify reason(s) if seeking permission from only one parent.

Category 2 (45 CFR 46.405; 21 CFR 50.52) My research involves greater than minimal risk but presents the prospect of direct benefit to the individual participants.

a) My research falls under this category because:

b) Justify the risk(s) by explaining the anticipated benefit to the participants:

c) Explain how the relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches:

d) Describe what provisions will be made for soliciting the assent of the children, and the permission of at least one parent/guardian. (Permission from both parents must be obtained unless one parent/guardian is deceased, unknown, incompetent, or not reasonably available, or when only one parent/guardian has legal responsibility for the care and custody of the child). Justify reason(s) if seeking permission from only one parent.

Category 3 (45 CFR 46.406; 21 CFR 50.53) My research involves greater than minimal risk, and no prospect of direct benefit to individual participant, but likely to yield generalizable knowledge about the participant's disorder or condition.

a) My research falls under this category because:

b) Describe how the risks for participating in your research represent a minor increase over minimal risk (i.e., the children being recruited have a disorder or condition that would place them in a group other than an average healthy child; therefore, the research qualifies as a minor increment over minimal risk. This risk is slightly more than what the average healthy child would experience, but is reasonable for these participants because it is not more than they would experience or expect given their condition.).

c) Describe how the research intervention(s)/procedure(s) present experiences to participants that are reasonably commensurate to those inherent in their actual or expected medical, dental, psychological, social, or educational situations:

d) Explain why the intervention or procedure is likely to yield generalizable knowledge about the participants' disorder or condition, which is of vital importance for the understanding or amelioration of the participants' disorder or condition:

e) Describe what provisions will be made for soliciting the assent of the children, and the permission of both parents/guardians. (Permission from both parents must be obtained unless one parent/guardian is deceased, unknown, incompetent, or not reasonably available, or when only one parent/guardian has legal responsibility for the care and custody of the child). Justify reason(s) for seeking permission from only one parent.

Category 4 (45 CFR 46.407; 21 CFR 50.54) My research does not fall under Category 1, 2, or 3 listed above. However, the research presents a reasonable opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

(NOTE: If your research is funded by, or funding has been sought from the Department of Health and Human Services (DHHS), Department of Education, or is FDA regulated, a report must be sent for review to the DHHS Secretary, Secretary of the US Department of Education, or Commissioner of FDA. If this category is applicable, the Office of Research Compliance will prepare and submit a report of IRB review to the appropriate federal official(s)).

a) My research falls under this category because:

b) Describe what provisions will be made for soliciting the assent of the children, and the permission of both parents/guardians. (Permission from both parents must be obtained unless one parent/guardian is deceased, unknown, incompetent, or not reasonably available, or when only one parent/guardian has legal responsibility for the care and custody of the child). Justify reason(s) if seeking permission from only one parent.

Section 2.

In order to effectively assess and evaluate the risk of your proposed research to children, the IRB requires the following information. Respond to all items.

a) Provide justification for the participation of children as research participants in your study.

b) Has this research been conducted in adults?

If yes, is there any indication that the proposed research would benefit, or at least not be harmful to children?

c) Indicate how many children you propose to enroll in the study and justify this number (whenever possible, involve the fewest number of children necessary to obtain statistically significant data which will contribute to a meaningful analysis relative to the purpose of the study).

d) Describe how assent of a child will be obtained and documented (if applicable). If not applicable, explain why.

I am requesting waiver of the requirement for assent.

Justify:

OR

I have attached an assent form/assent script for IRB review.

e) Explain what methods will be used for evaluating dissent (i.e., description of behaviors that would indicate child does not want to participate (such as moving away, certain facial expressions, head movements, etc...).

f) Describe how parental permission will be obtained. [Note: If you propose to waive the requirement for parental permission (i.e., getting parental permission may be against the best interest of the child, i.e., a study of abused or neglected children), describe what measures will be taken to protect the rights and welfare of the children.]

I am requesting waiver of the requirement for parental permission.

Justify:

OR

I have attached a parental permission form for IRB review.

g) Describe measures that will be taken to ensure that a parent is present when the child participates in any research interventions or procedures. [Note: If the nature of the research is such that it is not appropriate to have a parent present (i.e., research into sensitive personal issues, physical examinations of teenagers, etc...) please explain why.]

h) Describe the expertise of the research staff/study personnel for dealing with children at the ages included and whether they are knowledgeable and sensitive to the physical and psychological needs of the children and their families. Describe the appropriateness of facility in which the research will be conducted in relation to environment and/or equipment accommodating to children.

i) If applicable, provide any additional information that may support your request to involve children in this research.

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## * * * Subject Population(n) * * *

### Research with cognitively impaired persons

**NOTE: Investigators, please include this form with IRB application if your research involves cognitively impaired (decisionally impaired or decisionally challenged) persons. If your research involves people with more than one vulnerability, please complete the supplementary form for that population as well.**

**The IRB may ask you to designate an impartial observer to monitor the consent process or it may send its own representative to do so.**

**Section 1.**

Note:Check the box next to the category that in your best judgment applies to your research, and provide the information requested in the space provided.

Note: Minimal risk means that the probability and magnitude of the harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological exams

or tests. (i.e., daily life of health persons)

X **Category 1 My research does not involve greater than minimal risk.**

Explain. If appropriate, describe what provisions are in place for allowing a Legally Authorized Representative (LAR) or other person with the participant's best interests at heart to assist the participant in navigating the research process:

As described in Section 2 sub-section #2 below, LARs will always be contacted and taken through a proxy consent process before NH residents with ADRD diagnoses are contacted.

**Category 2 My research presents greater than minimal risk and prospect of direct benefit to the participants.**

Explain. If appropriate, describe what provisions are in place for allowing a Legally Authorized Representative (LAR) or other person with the participant's best interests at heart to assist the participant in navigating the research process.

**Category 3 My research presents greater than minimal risk and no prospect of direct benefit to the participants, but likely to yield generalizable knowledge about the participant's disorder or condition, because:**

Explain. If appropriate, describe what provisions are in place for allowing a Legally Authorized Representative (LAR) or other person with the participant's best interests at heart to assist the participant in navigating the research process.

**Category 4 My research does not fall under Category 1, 2, or 3, listed above.**

If you check this category, the IRB determines additional safeguards on a case-by-case basis.

**Section 2.**

1. Explain why individuals with impaired decision-making capacity are suitable for this research. If the objective(s) of the study allow for inclusion of competent participants, provide compelling justification for inclusion of incompetent participants.

This study does involve the vulnerable population of nursing home residents with dementia. Sleep problems and related issues in NH residents with dementia is a well-documented problem. This study implements an intervention to improve the sleep experience for these residents and increase engagement in meaningful actvities. To evaluate the effects of the sleep program for people with dementia, people with dementia must be enrolled. If the LOCK sleep program is found to be effective in enhancing clinical care and outcomes, the approach can be shared with other NHs and incorporated into general NH practice. The risks in this study for NH residents are minimal, and the knowledge gained may result in improved quality of sleep, and ultimately improved quality of life for NH residents with dementia.

2. Describe who will determine individuals' competency to consent and the criteria to be used in determining competency (e.g., use of standardized measurements, consults with another qualified professional, etc...).

All consents as described below will be conducted by an IRB-approved study staff member who has been trained by Dr. Snow (principal investigator). The study staff member will be responsible for explaining the study, answering questions, and obtaining informed consent.

Cognitively Impaired NH Resident Consent – Step 1. Legally Authorized Representative Consent
NH leadership team [see Section #3B-Study Procedures] or their designees will identify all NH residents with an ADRD diagnosis and mail to their legally authorized representatives (LARs) an IRB-approved study introduction letter (including option to opt out within one month if they do not wish to be contacted by study staff). Opt-out procedures have been demonstrated to yield higher response rates and lower rates of

non-response bias compared to opt-in procedures, and to be acceptable to participants, with no difference in rates of reported distress or complaints compared to opt-in procedures.[105-108] In our past federally funded research involving people with dementia, opt-out consent has been approved by multiple IRBs and worked well. Contact information of those LARs not opting out will be shared with University of Alabama (UA) study staff. We will request of the IRB a waiver of consent and HIPAA authorization for screening purposes regarding the sharing of these contact information.

Study staff will mail an IRB-approved study information packet via a tracked, express mailing service to all LARs who do not opt out. These materials will include a cover letter, an IRB-approved informed consent form (ICF), and an express mail return envelope so the LAR can send the signed ICF to the UA study office. LARs will be encouraged to contact study staff via phone or email for an appointment to discuss the study and go through the consent form together before signing the ICFs. Study staff will contact the LARs via phone and/or email within one week of sending the packet and will re-contact the LAR up to 6 times within the next month as needed to establish contact (if contact has not been established within one month, and NH staff are not able to determine that the LAR's contact information has changed, then the lack of contact will be considered a soft refusal and no other contact will be attempted).

During a phone appointment, study staff will review all important elements of the ICF with the LAR, including the following: description of the study, information on how to contact the investigators and the NH administrator and director of nursing, a statement that there is no prejudice for refusal to participate, a statement that the subject may withdraw from the study at any time without prejudice, and statement regarding risk and benefit of participation. The LAR will be encouraged to ask questions. The LAR will be encouraged to call the PI if they have any remaining questions before signing the consent form.

Cognitively Impaired NH Resident Consent – Step 2. Screening for Capacity for NH Resident Consent/NH Resident Assent
Some NH residents with mild ADRD may have the capacity to provide their own consent. For residents with likely mild ADRD and a LAR who can be contacted, a conservative two-step process will be used to address the ethical balance of the beneficence of assuring that residents who do not have the capacity to consent are protected by LAR oversight with the promotion of autonomy for residents who do have capacity to consent. Once LAR consent is received for a resident, the NH leadership team will be asked to identify that resident's most recent MDS Brief Interview for Mental Status score[120] (BIMS; see Appendix for measure), a cognitive screening measure with good reliability and validity. For residents with BIMS scores in the mild range (above 10), the NH leadership team will be asked to arrange and support a telephone appointment between that resident and a study staff person (if the resident turns out to NOT have the cognitive ability to participate in the following telephone-based procedure, then they would also NOT have the cognitive capacity to provide informed consent, which requires higher level cognitive abilities).

In the telephone appointment, the study staff member will provide information about the study and will screen for capacity to consent by assessing the following. Does the resident respond appropriately to a social greeting? Is the resident oriented to place? Does the resident understand who the study team member is after the team member explains their identity? During the course of this introductory conversation, was the resident able to respond fluently and socially appropriately? If so, the team member will go through the consent form with them. Residents will then be asked a series of questions to assure their understanding. These questions are as follows:
Describe in your own words what this study is about?
Describe what I am asking you to do to participate in this study?
Are you required to do this interview with me?

What will happen if you don't talk to me?
What happens if you decide you don't want to participate once we get started?
What will I do with the information you give me?

The NH leadership team member will support this telephone conversation by assuring that the resident has a quiet environment to have the telephone conversation and that the resident has in front of them a printed large-font version of the ICF written in first person with the signature area flagged. If the resident is able to respond appropriately to all the capacity screening questions, and they do wish to participate, then the resident will be instructed to sign the ICF. The study staff person will contact the NH leadership team member and ask them to make a copy of the ICF for the resident to keep, place a copy in the medical chart, and express mail the original to the UA study office using a provided pre-paid envelope. If the resident is able to respond appropriately to all the capacity screening questions and does not wish to participate then they will not be enrolled in the study, regardless of the LAR's consent. In this case, the study team member will let the NH leadership team and the LAR know that the resident has declined participation.

Under all circumstances, the NH resident's autonomy will be respected. For NH residents without capacity to consent, their assent to participate will be obtained whenever possible, and their decision to withdraw at any time (whether expressed verbally or by resistance to participation) will be honored (see also staff training in Section #3B-Study Procedures).

For residents with likely mild ADRD (BIMS score above 10) but no lar, the nursing home leadership team and study staff will go directly to the resident to invite their participation and screen their capacity to consent using the same process described above.

All above procedures apply to securing consent for the research study team to have access to NH resident personally identifiable data.

NOTE: the LOCK sleep program does not include any activities that are outside of standard NH practice, therefore NH staff will be free to enroll any NH residents that they believe will benefit into the LOCK sleep program regardless of resident consent status; however the NH leadership team will only be allowed to share with the research study team data for residents who are consented for the study.

3. It should be recognized that decision-making capacity may fluctuate, requiring ongoing assessment during the course of the research. Is it reasonable to expect that during the course of the research, subjects may lose their capacity to consent or their ability to withdraw? Y

   a) Describe what provisions are in place for periodic re-consent. Include the rationale and procedure, the proposed interval, any changes in behavior that might signal the need to re-consent whether or not the proposed interval has elapsed, and any consultative resources that are available for these decisions. Describe the process for re-consent or re-assent, or reassessment of willingness to continue participation.

   Re-consenting provisions will not be included because the course of the study is a relatively short 22 weeks (5.5 months), an amount of time in which it is unlikely, although possible, that cognitive capacity will significantly change. Further, the main focus of the intervention is with staff behavior. Staff will be implementing interventions that are considered good standard clinical practice, such as providing meaningful activities during the day to help reduce resident daytime napping and reducing noise and resident interruptions at night to promote uninterrupted sleep. Therefore, is is unlikely, although possible, that resident willingness to continue participation will change over this relatively short amount of time.

The most likely cause of resident unwillingness to continue participation would be over the wearing of the actigraph and/or fitbit. NH staff will be trained by their NH leadership teams or their trained designees (who will have been trained by Dr. Snow or her study team designees) on proper use and placement of actigraphs and Fitbits, verbal and behavioral signs of
distress that might indicate actigraph/Fitbit-related discomfort/distress [e.g., verbal indicators such as words (e.g., "take it off!"), distress sounds (e.g., crying, moaning, groaning), physical movements (e.g., picking at the device, shaking the arm)], and appropriate modification techniques to try to relieve such distress. NH staff will be informed that the devices should be removed in the unlikely event that distress behaviors are not relieved by modification techniques. NH staff will be trained on importance of NH resident autonomy, and will be engaged in a discussion of how to assess for and honor NH
resident assent or lack thereof with regard to the devices.

b) Describe what provisions are in place to protect the participants' rights in the event they lose their capacity to consent or their capacity to withdraw during the course of the research. (e.g., power of attorney, consent a caregiver as well as the patient, etc.).

Most residents will not have the capacity to consent. As described above, behavioral indicators of withdraw of assent will be honored and NH staff will be carefully trained to recognize these indicators. In addition, LARs will have the study team's contact information and a copy of their consent form which clearly indicates how they can reach the study team and withdrawn consent at any time. These procedures will be reviewed with LARs as part of the consent process.

c) Describe what provisions are in place for use of additional waiting periods to allow potential participants time to consult with family members about whether or not to participate.

Most residents will not have the capacity to consent, and LARs will be consenting. LARs will always be contacted about potential participation before the NH resident is contacted. As described above, if it becomes apparent that the NH resident is able to consent for themselves, their decision will be honored even if it is discrepant from that of the LAR (i.e., if LAR says yes but resident decides no).

4. Explain how you will identify who is authorized to give legally valid consent on behalf of any individual(s) determined to be incapable of consenting on their own behalf.

We will be guided by the medical chart documentation of who is identified as the legally authorized representative (LAR), combined with guidance from the nursing home staff who know the NH resident and family the best regarding who is the appropriate LAR.

5. Explain the criteria you will use for determining when assent is required for participants who are not competent.

We will always look for assent for participants who are not competent to consent. The behavioral indicators of lack of assent for the actigraph/fitbit are described above.

There are no study self-report data collected from residents. All resident data involved in this study are data that the NH collects as part of their standard clinical practices (e.g., Minimum Data Set (MDS) data that is mandated data collected as per Medicare/Medicaid reimbursement rules). All other resident involvement is concordant with clinical best practice. The main focus of the intervention is with staff behavior. Staff will be implementing interventions that are considered good standard clinical practice, such as providing meaningful activities during the day to help reduce resident daytime napping and reducing noise and resident interruptions at night to promote uninterrupted sleep.

6. Explain what methods will be used for evaluating dissent (e.g., description of behaviors

that would indicate individual does not want to participate (such as moving away, certain facial expressions, head movements, etc...).

Verbal and behavioral signs of distress that might indicate actigraph/Fitbit-related discomfort/distress include: verbal indicators such as words (e.g., "take it off!"), distress sounds (e.g., crying, moaning, groaning), and physical movements (e.g., picking at the device, shaking the arm)].

7. The research protocol should include someone who can be reasonably assumed to have the participant's best interest in mind and can assist the participant in navigating the consent and research process. A person holding durable power of attorney or other legal designee, spouse, close relative who is involved in ongoing care of participant, other person with a personal or blood relationship who is involved in ongoing care of participant, or other close relatives or friends may assume this role. Describe how individuals will be identified to serve in this capacity. If this request is not appropriate for this study, justify why it should be waived.

As described in #4 above, we will be guided by the medical chart documentation of who is identified as the legally authorized representative (LAR), combined with guidance from the nursing home staff who know the NH resident and family the best. LARs will always be contacted about potential participation before the NH resident is contacted.

8. If applicable, describe when and how the individual's health care provider will be consulted prior to participation in the research. NOTE: If the Principal Investigator (PI) is also the individual's health care provider, address how the PI will separate the roles of clinician and researcher.

The medical director of the nursing home will be consulted before NH residents are enrolled in the study. By law, NH residents may use any physician they would like and therefore the medical director may not be their personal physician, but would still have medical oversight over their well-being and would be able to offer recommendations if for any reason a particular resident had contraindications for participation. Similarly, the director of nursing and the entire NH clinical interdisciplinary team will be consulted before NH residents are enrolled in the study, providing adequate opportunity for any clinical team member to indicate if participation of a particular resident would be contraindicated.

9. Will the research interfere with current therapy or medications? N

If yes, describe what the changes may entail (i.e., if the subjparticipantl be removed from routine drugs/treatments, wash out periods, etc.) and the potential risks.

10. Does your research involve institutionalized individuals? Y

a) Justify the use of institutionalized individuals and explain why non-institutionalized individuals can not be substituted.

This is a study of how to improve nursing home treatment. Because the factors that affect nursing home treatment are systemic, investigation of interventions to improve nursing home treatment can only occur within the system of the nursing home itself.

**Section 3.**

Complete this section if your research involves individuals from the Department of Veterans Affairs (VA).

1. Address procedures you will use to ensure the participant's representative is informed regarding his/her role and obligation to protect the incompetent participant or person with impaired decision-making capacity.

N/A

2. Address procedures you will use to ensure the participant's representative has been told of his/her obligation to try to determine what the prospective participant would do if competent, or if the prospective participant's wishes cannot be determined, what the participant's representative thinks is in the incompetent person's best interests:

| |
|---|
| N/A |

3. The VA has specific requirements and procedures for determining and documenting in the person's medical record that an individual is incompetent or decisionally-impaired. There are additional requirements if the lack of decision-making capacity is based on diagnoses of mental illness. These requirements are outlined in the Veterans Health Administration (VHA) Handbook 1200.5, Section II. Have you reviewed these requirements and included them in your procedures? N

4. Justify that the research involves no significant risks, or if the research presents probability of harm, justify that there is at least a greater probability of direct benefit to the participant:

| |
|---|
| N/A |

Note:[Veterans Health Administration Handbook 1200.5, July 15, 2003, Section 11 - Research Involving Human participants with Surrogate Consent, and Appendix D Vulnerable Populations, Section 6(c)]

**Section 4.**

For research involving cognitively impaired persons outside the state of Alabama, also complete this section.

a) Provide information regarding the state definition of legally authorized representative, child, decisionally-impaired, or guardian, as applicable to the research and to the federal definitions. [If the research is to be conducted in more than one state outside of Alabama, provide this information for each state.]

| |
|---|
| Three states are involved – Colorado, South Carolina, and Texas. The definitions of Legally Authorized Representative and decisionally-impaired person for these states are consistent with those used in Alabama as described in the definitions section below (i.e., Alabama law does not specify who may make such decisions. UA legal counsel recommends the following in this order of preference: A legally appointed guardian, a health care proxy or person authorized to make medical decisions in conjunction with a durable power of attorney, a spouse, an adult child, next of kin, or a person or agency acting in loco parentis).<br><br>References:<br>Colorado: https://casetext.com/statute/colorado-revised-statutes/title-15-probate-trusts-and-fiduciaries/declarations-future-medical-treatment/article-185-proxy-and-surrogate-decision-makers-for-medical-treatment-and-for-health-care-benefit-decisions<br>South Carolina: https://www.palmettohealthfoundation.org/document-library/research/policies-pgrs<br>Texas:<br>https://www.uthscsa.edu/sites/default/files/Services/forms/irbconsentpolicyattachment1.pdf |

**Definitions:**

Assent - is defined as a child's or decisionally-challenged individual's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

Competence "Technically, a legal term, used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice." [OHRP Institutional Review Board Guidebook, Chapter VI, Section D]

Permission is defined as the agreement of parent(s) or guardian to the participation of their child or ward in research or clinical investigation. Permission includes the element of consent set forth in federal regulations and outlined in the informed consent template included in the IRB expedited and full review applications.

In Alabama child/children refers to all individuals less than 18 years of age unless the individual(s) is/are legally emancipated. (See Guidance: Alabama Law on Children, Minors, Consent, and Other Research-Related Topics. Individuals less than 18 years of age who are not emancipated meet the federal definition for "child" (e.g., Department of Health and Human Services (DHHS), Food and Drug Administration (FDA), and U.S. Department of Education).

Legally authorized representative (LAR) is an individual who has the authority to make research participation decisions on behalf of another. Alabama law does not specify who may make such decisions. UA legal counsel recommends the following in this order of preference: A legally appointed guardian, a health care proxy or person authorized to make medical decisions in conjunction with a durable power of attorney, a spouse, an adult child, next of kin, or a person or agency acting in loco parentis.

NOTE: Consent from a legally authorized representative involves all the ethical and regulatory concerns that apply to consent from the prospective participant.

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## * * * Subject Population(p) * * *

### Research Involving Prisoners

**NOTE: Investigators, please include this information with the e-Protocol application if your research involves prisoners. This includes studies of known prisoners and studies recruiting participants at risk of becoming involuntary prisoners, such as participants with histories of substance abuse. Remember that persons involuntarily committed to mental health facilities (Taylor Hardin Secure Mental Health Facility, Mary Starke Harper, etc.) by the courts are also prisoners.**

**If participants unexpectedly become prisoners, go directly to SECTION FOUR of this form.**

**If your research involves prisoners with more than one vulnerability (i.e., prisoners who are also children or pregnant, are involuntarily committed to mental health facilities), attach the supplementary form for that vulnerable population as well.**

**Regardless of the category of your research, be sure that your application makes clear why the research must be done on prisoners.**

**Indicate the category that best represents your research by checking the applicable box below, and explain in the space provided for that category why your research meets the criteria.**

Note: For research involving prisoners, the definition of minimal risk refers to 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.

**Category 1 (45 CFR 46.306(a)(2)(i))**

My research involves the study of possible causes, effects, processes of incarceration, and of criminal behavior. (Processes of incarceration can be interpreted broadly to include substance abuse research, half-way houses, counseling techniques, criminal behavior, etc.)

**Justify how the research presents no more than minimal risk and no more than inconvenience to the participants:**

**Category 2 (45 CFR 46.306(a)(2)(ii))**

My research involves the study of prisons as institutional structures, or of prisoners as incarcerated persons. (This category is usually used fairly narrowly as when looking at prisoner diet and conditions of prison life.)

**Justify how the research presents no more than minimal risk and no more than inconvenience to the participants**

**Category 3 (45 CFR 46.306(a)(2)(iii))**

My research involves the study of conditions particularly affecting prisoners as a class. (This category is less frequently used than the previous ones and refers to such research as vaccine trials, research on hepatitis, and social and psychological problems such as alcoholism, drug addiction, and sexual assaults. Minimal risk studies should not go under this category.) For DHHS-funded research, OHRP has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of its intent to approve such research.

Note: Contact the Office of Research Compliance at (205) (348-8461 for more information

**Explain what condition(s) will be studied and provide rationale for each:**

**Category 4 (45 CFR 46.306(a)(2)(iv))**

My research involves the study of practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant. (Note: It is rare for research involving placebo or control groups to fall in this category because of the difficulty in justifying improvement of the health or well-being of the participant being given placebo or in a control group.) For DHHS-funded research which requires the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after OHRP has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of its intent to approve such research.

Note: Contact the Office of Research Compliance at (205) 348-8461 for more information.

**Explain the research practices that will be used in this study and how they are intended to improve the health and well-being of the participants:**

Section 2. [45 CFR 46.305]

Note: When an IRB is reviewing a protocol in which a prisoner will be a participant, the IRB must find and document justification that six additional conditions are met. Describe in the space provided how each condition applies to your research.

1. Advantages acquired through participation in the research, when compared to the prisoners' current situation, are not so great that they impair their ability to weigh risks.

   **Describe the possible advantages that can be expected for prisoner participants:**

2. Risks are the same as those that would be accepted by non-prisoners.

   **Describe the possible risks that can be expected for prisoner participants and justify that they are the same as for non-prisoners:**

3. Procedures for selection are fair to all prisoners and are immune from intervention by prison authorities in prisons; control participants must be randomly selected.

   a) **Describe how prisoners will be selected for participation:**

   b) **Describe what measures will be taken to prevent intervention by prison authorities in the selection process:**

4. Parole boards cannot take into consideration a prisoner's participation in research. Informed consent must state participation will not affect length of sentence or parole.

5. For studies that require follow-up, provisions are made including consideration for the length of individual sentences; informed consent must reflect provisions for follow-up.

**Describe what provisions have been made for follow-up and how this information will be relayed to the prisoner participants:**

6. Information about the study is presented in a language understandable to prisoners.

Describe what efforts have been made to present information about the study in a language that is understandable to the prisoner population. This may mean a non-English language or an appropriate reading level in whatever language the prisoner uses.:

**Section 3. Only complete if applicable: Epidemiologic Research Involving Prisoners and Funded by the Department of Health and Human Services (DHHS)**

Note: Effective June 20, 2003, DHHS adopted policy that allows waiver of the requirement for documenting applicability of a 45 CFR 306(a)(2) category (as found in Section 1 of this form) for certain epidemiologic research involving prisoners. This waiver applies to DHHS conducted or supported epidemiologic research on prisoners that presents no more than minimal risk and no more than inconvenience to the prisoner-participants.

Check the box below if your research meets the listed criteria, then provide justification in the space provided.

1. My research is funded by HHS and I request a waiver for meeting the category conditions under Section 1 of this form.
2. My research involves epidemiologic research intended to describe the prevalence/incidence of a disease by identifying all cases, or to study potential risk factor associations for a disease; and
3. Prisoners are not the sole focus of my research.

**Justify how the research presents no more than minimal risk and no more than inconvenience to the participants:**

**Section 4. Complete if applicable:**

**Prisoners are not the targeted population**

Note: Although prisoners may not be the target population for your research, a participant could become a prisoner during the course of the study (particularly if studying a subject population at high-risk of incarceration).

Note: If you did not receive IRB approval for involvement of prisoners, and a participant becomes a prisoner during the study, all research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated participant must cease until IRB approval has been issued for their continuation in the research. If you need IRB approval for a prisoner participant to continue participation in your research, select and complete the applicable category from Section 1, complete section 2 and this section, then submit for IRB review.

In special circumstances in which the Principal Investigator asserts that it is in the best interest of the participant to remain in the research study while incarcerated, the IRB Chairperson may determine that the participant may continue to participate in the research prior to satisfying the requirements of Subpart C. However, subsequent IRB review and approval of this completed form, documenting that the requirements of Subpart C are met, is required.

Prisoners are not a target population for my research, but a participant became a prisoner during the study and I am seeking IRB approval so the participant can continue

during the study and I am seeking IRB approval so the participant can continue participation in the research.

**Explain the importance of continuing to intervene, interact, or collect identifiable private information during the participant's incarceration:**

Note: Prisoner: An individual involuntarily confined in a penal institution, including persons: (1) sentenced under a criminal or civil statue; (2) detained pending arraignment, trial, or sentencing; and (3) detained in other facilities (e.g., for drug detoxification or treatment of alcoholism,) under statutes or commitment procedures providing such alternatives to criminal prosecution or incarceration in a penal institution [45 CFR 46.303(c)]. Note: Persons on Probation and parole are usually NOT considered to be prisoners.

If you will receive or are seeking Department of Health and Human Services (HHS) funding for this study, a certification letter must be submitted to the Office for Human Research Protections (OHRP). The research cannot be initiated until OHRP issues approval. The Office of Research Compliance (ORC) will prepare and submit the certification report to OHRP. Contact the Director for the Office of Research Compliance at 205-348-8461 8641 for more information.

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*** * * Risks * * ***

## 8. Risks

There is no research that can be considered totally risk free (e.g., a potential risk of breach of confidentiality). Therefore, when describing the risk, the lowest level of risk is "no more than minimal risk".

a) **For the following categories include a scientific estimate of the frequency, severity, and reversibility of potential risks. Wherever possible, include statistical incidence of complications and the mortality rate of proposed procedures. Where there has been insufficient time to accumulate significant data on risk,a statement to this effect should be included. (In describing these risks in the consent form to the participant, it is helpful to use comparisons which are meaningful to persons unfamiliar with medical terminology).**

**Address any risks related to (input N/A if not applicable):**

1. Use of investigational drugs. Please include the clinical adverse events (AEs) associated with each of the drugs with an indication of frequency, severity and reversibility. This information can often be found in the Investigator(s) brochure. NOTE: Include any likely adverse effects associated with placebos or washout periods that participants may experience while in the study.

   N/A

2. Use of investigational devices. Please include the clinical adverse events (AEs) associated with each of the devices with an indication of frequency, severity and reversibility. This information can often be found in the Investigator(s) brochure. NOTE: Include any likely adverse effects associated with procedures that participants may experience while in the study.

   No investigational devices will be used.

3. Use of FDA approved drugs, reagents, chemicals, or biologic products. Please include the clinical adverse events (AEs) associated with each of the drugs with an indication of frequency, severity and reversibility. This information can often be found in the package insert provided by the manufacturer. NOTE: Include any likely adverse effects associated with placebos or washout periods that participants may experience while in the study.

   N/A

4. Use of FDA approved devices. Please include the clinical adverse events (AEs) associated with each of the devices with an indication of frequency, severity and reversibility. This information can often be found in the Investigator(s) brochure. NOTE: Include any likely adverse effects associated with procedures that participants may

experience while in the study.

N/A

5. Describe any risks related to performing study procedures. Please include all investigational, non-investigational, and non-invasive procedures (e.g., surgery, blood draws, treadmill tests).

No more than minimal risk.

Regarding psychological risks to NH residents, the LOCK sleep program including frontline huddling provides a sequence of steps for the process of assessing and responding to sleep problems. During the intervention period NH residents enrolled in the LOCK sleep program will receive actigraph and Fitbit assessment, and although our teams' experience with use of these devices in hundreds of people with dementia indicates that they are widely tolerated as comfortable, there is a small risk a resident may find the devices to be uncomfortable or otherwise distressing. As part of their intervention training, staff will be instructed on behavioral signs of distress. If a participant exhibits significant behavioral distress due to assessment, staff will be instructed on modifications and alternatives. If the distress does not subside, staff will be instructed to discontinue the assessment.

6. Describe any risks related to the use of radioisotopes/radiation-producing machines (e.g., X-rays, CT scans, fluoroscopy).

N/A

7. For clinical studies (of a drug, vaccine, device or treatment), describe any alternative procedure(s) or course(s) of treatment. List important risks and benefits of these alternatives in order to compare to study procedure(s) or course(s) of treatment. This information MUST be included here. Any standard treatment that is being withheld must be disclosed and the information must be included in the consent form.

The intervention described will be implemented NH-wide. The study is a pilot (R61) for the methods for a subsequent randomized controlled trial (R33 -- an incomplete stepped-wedge cluster randomized controlled trial design in which each NH serves as its own control). There will therefore be no alternative treatments. NH residents and their legally authorized representatives will have the right to refuse participation in any portion of their care just as they would with usual NH care, including use of actigraphs and Fitbits. NH staff will have the right to refuse any interviews.

8a. Describe any other physical, psychological, social or legal risks the participant may experience.

No more than minimal risk.

The risks for participants in this trial are minimal. There are no anticipated physical or economic risks associated with this study. There are no psychological risks beyond what was described in Risks sub-item #5 above.

For both NH residents and staff, an unlikely legal or social risk associated with participating in this study would be invasion of privacy in the remote chance that there is a loss or lack of protection of data containing personally identifiable information. These are research risks, not therapeutic risks. The study team will use careful procedures to guard the security and confidentiality of all data.

For both NH residents and staff, a potential risk is that a person may not want to participate in the study and may feel coerced to do so. Therefore, to minimize this type of risk, all informed consent contact with potential participants will come through the study staff only, and all NH staff participation discussions and decisions will be kept confidential.

8b. Data Safety Monitoring

Is there a Data Monitoring Committee (DMC) or Board (DSMB)? Y

If yes, describe its role, if it is independent of the sponsor or research team, the make-up of the Board and their qualifications, and how often the Board will meet.

1 Frequency of Data and Safety Monitoring
The Principal Investigator (PI) will be responsible for ensuring participants' safety on a daily basis. The Data and Safety Monitoring Board will meet at least once a year by teleconference (and more often as needed). The DSMB will act in an advisory capacity to the NIA Director by monitoring participant safety; evaluating the progress of the study; and reviewing procedures for maintaining the confidentiality of data and the quality of data collection, management, and analyses.

2 Content of Data and Safety Monitoring Report
The content of the data and safety monitoring report will include: protocol synopsis, study status, summary of past DSMB meetings, recruitment and participant status, data quality status, and safety information. Blinded reports will be produced for open sessions and unblinded reports for closed sessions. The DSMB will be guided by the NIA DSMB Report Template.

3 DSMB Membership and Affiliation
All members of the DSMB will have extensive experience in the conduct and analysis of clinical trials and/or clinical expertise in the study population. The committee will be named in conjunction with the NIA Program Officer. The board will comprise a physician with geriatrics or nursing home (NH) expertise, a nurse scientist with expertise in geriatrics or NHs, a behavioral clinician with expertise in geriatrics or NHs, a biostatistician, and an additional clinician scientist with sleep expertise. They will be completely independent of the study investigators and staff and have no scientific, financial, or other conflict of interest with the study.
DSMB membership will be reviewed and approved by the NIA. Should there be any questions regarding the independence of the DSMB, it will be addressed and corrected if necessary at that time.

4 Conflict of Interest for DSMB
Each DSMB member will sign a Conflict of Interest Statement which includes current affiliations, if any, with pharmaceutical and biotechnology companies (e.g., stockholder, consultant), and any other relationship that could be perceived as a conflict of interest related to the study and / or associated with commercial interests pertinent to study objectives.

5 Protection of Confidentiality
Data will be presented in a blinded manner during the open sessions of the DSMB. At DSMB meetings, data and discussion are confidential. Participant identities will not be known to the DSMB members.

6 DSMB Responsibilities and Procedures
The DSMB will be responsible for reviewing the research protocol and informed consent documents, and developing plans for data safety and monitoring. They will evaluate the progress of the trial, including periodic assessments of data quality and timeliness, recruitment, accrual and retention, participant risk versus benefit, performance of the trial sites, and other factors that can affect study outcome; consider factors external to the study when relevant information becomes available, such as scientific or therapeutic developments that may have an impact on the safety of the participants or the ethics of the trial; review study performance and make recommendations; and assist in the resolution of problems reported by the Principal Investigator (PI). The DSMB will report on the safety and progress of the trial to the NIA Program Officer and make

recommendations to the Program Officer and the PI concerning continuation, termination, or other modifications of the trial based on the observed beneficial or adverse effects. They will ensure the confidentiality of the results by monitoring all study data and analysis.

The DSMB will meet at least once a year, or more frequently as determined by the board at the first meeting. Emergency meetings also may be called at any time by the DSMB Chairperson or by NIA. A majority of members must be present for called meetings in order to constitute a quorum. The NIA Program Officer or designee will be invited to attend all meetings.

DSMB meetings will consist of open and closed sessions. Open session discussion will focus on the conduct and progress of the study, including participant accrual, protocol compliance, and problems encountered. The closed sessions will be attended by the DSMB members and the study statistician. Meetings shall be closed to the public because discussions may address confidential participant data. During the closed sessions, data will be presented and discussed. An executive, open session may follow a closed session at request of PI or DSMB; at that time, the Board will inform the NIA Program Officer and PI of their recommendation to continue or to terminate the study as was decided by the formal DSMB vote in closed session. The PI and key members of the study team will generally attend the open and executive sessions of the meetings.

At their first meeting, the DSMB will discuss the protocol and establish guidelines for study monitoring. The DSMB Chairperson, in consultation with the PI and the NIA Program Officer as needed, will prepare the agenda. Unless otherwise designated by the DSMB, the DSMB Chair will serve as the contact person for unanticipated problem and serious adverse event reporting. Procedures for notifying the Chair of the DSMB and the NIA Program Official of any such events will also be discussed. The format and content of the reports for both the open and closed sessions will be finalized and approved, although additional changes and requests can be addressed throughout the study. At the first meeting, the Board will decide if an interim analysis will take place (e.g. after n participants have been accrued or completed the trial). Interim analyses of efficacy data will only be performed if planned and approved in advance, and when criteria for possible stopping are clearly defined. Well-defined stopping rules will be established during the first DSMB meeting to guide expected causes of termination.

The PI and Dr. Morgan (study statistician) will be responsible for coordinating activities of the DSMB including the following: 1) Arranging DSMB meetings and communications. 2) Identifying and reviewing open session materials to be presented to the DSMB. DSMB meeting materials to be reviewed by the DSMB members will be prepared by Dr. Morgan and sent to members at least 7 days before the meeting. Interim data reports will consist of two parts: Part 1 –Open Session Reports (for example, accrual, participant baseline characteristics, adverse events, serious adverse events); and Part 2 - Closed Session Reports.

The Chair of the DSMB will be responsible for the following: 1) developing the meeting agenda; 2) requesting information for the meetings from the PI and the study statistician; 3) overseeing the meetings; 4) verifying that the reports and recommendations prepared are an accurate and complete record of the DSMB's deliberations; 5) serving as contact person for unanticipated problem and serious adverse event reporting.

The DSMB members will 1) familiarize themselves with the research protocol and consent forms, 2) review interim reports of adverse events, 3) review interim analyses of outcome data as it relates to safety, 4) review interim reports of trial participant accrual, and 5) make recommendations to the investigators concerning continuation,

termination, or modification of the trial.

Between meetings of the DSMB and throughout the course of the trial, information regarding issues deemed critical to the trial or to the safety of research participants will be provided to the Chair of the DSMB and the Program Officer by the PI.

A formal report containing the recommendations for continuation or modifications of the study will be prepared by the DSMB Chairperson. This draft report will be sent to the DSMB members within 7 days after the meeting. Once approved by the DSMB members, and no later than 2 weeks after the DSMB meeting, the DSMB Chair will forward the formal DSMB recommendation to the NIA Program Officer and PI. It is the responsibility of the PI to distribute the DSMB recommendation to all co-investigators and to ensure that copies are submitted to all the IRBs associated with the study when necessary.

If study termination is ever considered by the DSMB, the full vote of the DSMB will be required. A recommendation to terminate the study will be made by a majority vote. The DSMB Chair will provide the tiebreaking vote in the event of a 50-50 split vote. In the event of a majority vote for continuation with at least one vote for study termination, a written statement with accompanying reasons for the vote(s) to terminate should be contained within the report issued by the DSMB. In the event of a recommendation to modify the protocol or to terminate the study, the PI may disagree with the recommendation of the DSMB. If the PI does not concur with the recommendation of the DSMB, then the IRB, the institution official, and the funding agency must be notified in writing of this disagreement and the reason for it. The PI may appeal the decision and offer an alternative to termination or study modification for consideration by the DSMB. If an impasse is reached, the appeal will be forwarded to the Chair of the Institutional IRB who will review the case under advisement from the PI and the Chair of the DSMB and will recommend a course of action. This course of action will be recorded by the DSMB and the NIA Program Officer.

If no, please justify why not.

Is there a Data Safety Monitoring Plan (DSMP)? Y

If yes, describe the data and safety monitoring plan developed to ensure the safety of participants and the validity and integrity of research data. Monitoring should be commensurate with risks and with the size and complexity of the trials. As such, state that SAEs will be reviewed by a qualified MD in real time and indicate how often aggregate data will be reviewed for safety trends.

Data and Safety Monitoring Plan

1.0 Participant Safety

1.1 Potential Risks and Benefits for Participants

Potential Risks
The risks for participants in this trial are minimal. There are no anticipated physical or economic risks associated with this study. Regarding psychological risks to NH residents, the LOCK sleep program including frontline huddling provides a sequence of steps for the process of assessing and responding to sleep problems. During the intervention period NH residents enrolled in the LOCK sleep program will receive actigraph and Fitbit assessment, and although our team's experience with use of these devices in hundreds of people with dementia indicates that they are widely tolerated as comfortable, there is a small risk a resident may find the devices to be uncomfortable or otherwise distressing. As part of their intervention training, staff will be instructed on

behavioral signs of distress. If a participant exhibits significant behavioral distress due to assessment, staff will be instructed on modifications and alternatives. If the distress does not subside, staff will be instructed to discontinue the assessment (staff training also discussed in 1.3.b. Protection Against Risks).

For both NH residents and staff, an unlikely legal or social risk associated with participating in this study would be invasion of privacy in the remote chance that there is a loss or lack of protection of data containing personally identifiable information. These are research risks, not therapeutic risks. The study team will use careful procedures to guard the security and confidentiality of all data (see 1.3.b. Protection Against Risks).

For both NH residents and staff, a potential risk is that a person may not want to participate in the study and may feel coerced to do so. Therefore, to minimize this type of risk, all informed consent contact with potential participants will come through the study staff only, and all NH staff participation discussions and decisions will be kept confidential (see 1.3.b. Protection Against Risks).

Potential Benefits
The intervention may benefit NH residents by leading to better and earlier detection and treatment of sleep problems and from increased attention to their conditions. The intervention may benefit NH staff by improving communication and teamwork, thereby improving the work experience.

1.2 Adverse Event/Serious Adverse Event/Unanticipated Problem Collection and Reporting
Definitions
We will follow OHRP and UA IRB guidance and policies regarding definitions, collection, and reporting of Adverse Events (AEs), Serious Adverse Events (SAEs), and Unanticipated Problems (UPs). We expect that there will potentially be four categories of events/problems as follows: 1) Anticipated AEs unrelated to the intervention, 2) Anticipated AEs related to the intervention, 3) Unanticipated AEs and unanticipated problems unrelated to the intervention, and 4) Unanticipated AEs and unanticipated problems related to the intervention.

Reporting
As per National Institute on Aging (NIA) policy, all deaths will be reported within 24 hours of the study staff's knowledge of death to the NIA Program Officer and the DSMB Chair. Unanticipated SAEs related to the intervention will be reported within 48 hours of the study staff's knowledge of death to the NIA Program Officer and the DSMB Chair. A summary of all other SAEs will be reported quarterly to the NIA Program Officer and the DSMB Chair.

Study staff will continue to follow up with the participant and their treating clinical team until any clinical events have resolved. If there is a SAE that is thought by a treating clinician, co-investigator nurse scientist Dr. Richards, study consultant geriatrician Dr. Fry, or Dr. Snow to be possibly or probably related to the intervention, the PI will immediately notify the DSMB and NIA Program Officer. The PI or designee will also immediately communicate with the NH leadership team and corporate coach at the NH for immediate investigation by the relevant treating team. Any insights about any possible iatrogenic effects of any components of the intervention will be immediately shared with all active NH intervention sites.

Grading Scale and Study Relatedness Criteria

Anticipated AEs unrelated to the intervention:  NH residents enrolled in the trial will have dementia and likely will have other pre-existing significant health issues that require NH

placement. It is anticipated that some participants will experience health events (new conditions or worsening of previous conditions), hospitalization, or death during the trial that will be due to the dementia and/or other pre-existing significant health issues and unrelated to the intervention. As per NIA policy, all deaths will be reported to the NIA and IRB within 24 hours, regardless of relation to intervention.

Anticipated AEs related to the intervention: Intervention-related AEs for NH residents might include: a) actigraph/fitbit-related skin reactions such as redness, itching, or other skin conditions or discomfort; b) distress or discomfort associated with actigraph/fitbit-related wear or NH staff attention; c) distress or discomfort associated with other LOCK sleep intervention NH staff attention or requests. Intervention-related AEs for NH staff might include: distress related to interview questions. Such events may be reportable depending upon the seriousness of the event and increase of risk to participant. The NH's treating clinical team's opinion of the seriousness of the event will be solicited and the PI, co-investigator nurse scientist Dr. Richards and study co-investigator geriatrician Dr. Fry will be consulted to determine seriousness and reportability of the event.

Unanticipated AEs and unanticipated problems related to the intervention: As with intervention-related AEs, unanticipated AEs and unanticipated problems will be evaluated for seriousness with input from the NH's treating clinical team (if applicable), the PI and clinical study team members Drs. Richards and Fry (if applicable) or data-related study team members including data coordinating center leader and study statistician Dr. Morgan (if applicable).

1.3 Protection Against Study Risks

a. Informed Consent and Assent
Study staff will obtain all necessary IRB authorizations for protocols and materials described below. All consents will be conducted by an IRB-approved study staff member who has been trained by Dr. Snow. The study staff member will be responsible for explaining the study, answering questions, and obtaining informed consent.

NH Resident Consent – Step 1. Legally Authorized Representative Consent
NH leadership team or their designees will identify all NH residents with an ADRD diagnosis and mail to their legally authorized representatives (LARs) an IRB-approved study introduction letter (including option to opt out within one month if they do not wish to be contacted by study staff). Opt-out procedures have been demonstrated to yield higher response rates and lower rates of non-response bias compared to opt-in procedures, and to be acceptable to participants, with no difference in rates of reported distress or complaints compared to opt-in procedures.105-108 In our past federally funded research involving people with dementia, opt-out consent has been approved by multiple IRBs and worked well. Contact information of those LARs not opting out will be shared with University of Alabama (UA) study staff. We will request of the IRB a waiver of consent and HIPAA authorization for screening purposes regarding the sharing of these contact information.

Study staff will mail an IRB-approved study information packet via a tracked, express mailing service to all LARs who do not opt out. These materials will include a cover letter, an IRB-approved informed consent form (ICF), and an express mail return envelope so the LAR can send the signed ICF to the UA study office. LARs will be encouraged to contact study staff via phone or email for an appointment to discuss the study and go through the consent form together before signing the ICFs. Study staff will contact the LARs via phone and/or email within one week of sending the packet and will re-contact the LAR up to 6 times within the next month as needed to establish contact (if contact has not been established within one month, and NH staff are not able to determine that the LAR's contact information has changed, then the lack of contact will

be considered a soft refusal and no other contact will be attempted).

During a phone appointment, study staff will review all important elements of the ICF with the LAR, including the following: description of the study, information on how to contact the investigators and the NH administrator and director of nursing, a statement that there is no prejudice for refusal to participate, a statement that the subject may withdraw from the study at any time without prejudice, and statement regarding risk and benefit of participation. The LAR will be encouraged to ask questions. The LAR will be encouraged to call the PI if they have any remaining questions before signing the consent form.

NH Resident Consent – Step 2. Screening for Capacity for NH Resident Consent/NH Resident Assent
Some NH residents with mild ADRD may have the capacity to provide their own consent. FOR RESIDENTS WITH LIKELY MILD ADRD AND AN LAR WHO CAN BE CONTACTED, a CONSERVATIVE two-step process will be used to address the ethical balance of the beneficence of assuring that residents who do not have the capacity to consent are protected by LAR oversight with the promotion of autonomy for residents who do have capacity to consent. Once LAR consent is received for a resident, the NH leadership team will be asked to identify that resident's most recent MDS Brief Interview for Mental Status (BIMS) [reference #120] , a cognitive screening measure with good reliability and validity. For residents with BIMS scores in the mild range (above 10), the NH leadership team will be asked to arrange and support a telephone appointment between that resident and a study staff person (if the resident turns out to not have the cognitive ability to participate in the following telephone-based procedure, then they would also not have the cognitive capacity to provide informed consent, which requires higher level cognitive abilities).

In the telephone appointment, the study staff member will provide information about the study and will screen for capacity to consent by assessing the following. Does the resident respond appropriately to a social greeting? Is the resident oriented to place? Does the resident understand who the study team member is after the team member explains their identity? During the course of this introductory conversation, was the resident able to respond fluently and socially appropriately? If so, the team member will go through the consent form with them. Residents will then be asked a series of questions to assure their understanding. These questions are as follows:
Describe in your own words what this study is about?
Describe what I am asking you to do to participate in this study?
Are you required to do this interview with me?
What will happen if you don't talk to me?
What happens if you decide you don't want to participate once we get started?
What will I do with the information you give me?

The NH leadership team member will support this telephone conversation by assuring that the resident has a quiet environment to have the telephone conversation and that the resident has in front of them a printed large-font version of the ICF with the signature area flagged. If the resident is able to respond appropriately to all the capacity screening questions, and they do wish to participate, then the resident will be instructed to sign the ICF. The study staff person will contact the NH leadership team member and ask them to make a copy of the ICF for the resident to keep, place a copy in the medical chart, and express mail the original to the UA study office using a provided pre-paid envelope. If the resident is able to respond appropriately to all the capacity screening questions and does not wish to participate then they will not be enrolled in the study, regardless of the LAR's consent. In this case, the study team member will let the NH leadership team and the LAR know that the resident has declined participation.

Under all circumstances, the NH resident's autonomy will be respected. For NH residents without capacity to consent, their assent to participate will be obtained whenever possible, and their decision to withdraw at any time (whether expressed verbally or by resistance to participation) will be honored (see also staff training in 1.3.b. Protection Against Risks).

FOR RESIDENTS WITH LIKELY MILD ADRD (BIMS SCORE ABOVE 10) BUT NO LAR, THE NURSING HOME LEADERSHIP TEAM AND STUDY STAFF WILL GO DIRECTLY TO THE RESIDENT TO INVITE THEIR PARTICIPATION AND SCREEN THEIR CAPACITY TO CONSENT USING THE SAME PROCESS DESCRIBED ABOVE.

All above procedures apply to securing consent for the study team to have access to NH resident personally identifiable data. We note that because the LOCK sleep program does not include any activities that are outside of standard NH practice, NH staff will be free to enroll any NH residents that they believe will benefit into the LOCK sleep program regardless of resident consent status; but the NH leadership team will only share with researchers data from residents who are consented for the study.

NH Staff Consent
The NH leadership team or their designees will provide to all NH staff an IRB-approved study introduction letter (including option to opt out within two weeks if they do not wish to be contacted by study staff). Contact information of those NH staff not opting out will be shared with UA study staff. We will request of the IRB a waiver of consent for screening purposes regarding the sharing of these contact information.

UA Study staff will contact NH staff (via email and/or phone, see next paragraph) to invite them to participate in mid-implementation phone interviews. Study staff will also contact NH staff to invite them to participate in post-implementation interviews (phone). The list of NH staff who agree and decline interview participation will remain confidential to protect NH staff from any possible coercion to participate (see 1.3.b. Protection Against Risks).

For mid-implementation interviews, study team members will, on the PI's behalf, send out e-mails to all NH staff who do not opt out. The first e-mail will contain text from Dr. Snow soliciting voluntary participation in the telephone interviews. E-mail reminders will be sent, one in each of the four weeks after the initial e-mail, with follow up phone calls to the participant's work phone to remind them about the email. All emails will include information on how to opt out of the study. We will continue recruitment until we have recruited the desired sample size or until one month has passed. To facilitate staff involvement, we will secure permission from the director of each NH that staff may take part in the study during their normal hours of work. For post-implementation interviews, study team members will follow these same procedures. In addition, a study team member will virtually visit each NH in person at the end of the intervention period to work with NH staff to collect information from the enrolled NH residents' medical record and also to recruit for and conduct any needed remaining post-implementation phone interviews. The study staff person will virtually attend change of shift meetings, huddles, and other staff meetings to invite interview participation and will also invite staff to contact research staff for virtual one-on-one discussions if staff member has questions about volunteering to participate. We have successfully used similar procedures in our previous federally funded studies involving NH staff.

In all recruitment activities, it will be made clear that participation is strictly voluntary and no adverse consequences to the person's job status or any other adverse consequences will occur if the person declines to participate in these activities and that their final decision to participate or not will be kept confidential from all NH and

corporate staff.

Mid-implementation interviews will take place via telephone or teleconference platform. Post-implementation interviews will take place via telephone or teleconference platform.

We will apply for a waiver of documentation of informed consent for the 1-hour, audio-recorded mid-implementation and post-implementation interviews, allowing us to obtain verbal consent. We will provide a consent information sheet to potential participants in the stead of an informed consent document that requires signature. We will record each subject giving permission to be recorded on the audio recording.

The study staff member will review with the NH staff member all relevant elements of consent on the consent information sheet, including the following: description of the study activities, time requirement, information on how to contact the investigators, a statement that there is no prejudice for refusal to participate, a statement that the subject may withdraw from the study at any time without prejudice, a statement encouraging the reader to ask questions, and a statement regarding risk and benefit of participation. All informed consent guidelines of the IRB will be followed. If at any time during the interview the staff member indicates a desire to stop participating, the participant will be withdrawn from the interview portion of the study. Confidentiality of all interview data will be protected by using participant code numbers on the data collection forms.

b. Protection Against Risks
Study staff training
To protect all vulnerable subjects, in addition to the NIH-required computer-based trainings (on the protection of human research participants, HIPAA, and Good Clinical Practice), the UA study staff will attend a 2-day training session specific to the proposed project led by Dr. Snow. The PI will review the overall goals of the study, study policies and procedures, data collection manuals, adverse event identification and reporting, subject confidentiality, communication techniques and principles for working with persons with dementia, and appropriate procedures for working by telephone with LARs for consent, for working by telephone with people with dementia for consent and for determining capacity to consent. Procedures will be reviewed for protecting employees from possible coercion for participation from supervisors including maintaining confidentiality of those employees who do and do not consent to research interviews. During these training sessions, professionally produced videotapes of staff interactions with persons with dementia will be shown and the PI and study staff will role play all informed consent, capacity assessment, and data collection processes. Dr. Richards will provide training on appropriate assessment equipment maintenance and data downloading. Drs. McCullough and Hartmann will provide training on appropriate procedures for NH staff interviews.

NH leadership team training: The NH leadership team will complete NIH-required computer-based trainings (on the protection of human research participants, HIPAA, and Good Clinical Principles). Study staff will also provide a 2-hour training on procedures to protect vulnerable subjects, as follows: proper procedure for, and importance of only using IRB-approved procedures and letters when sending study opt-out letters to LARs; proper procedures for maintaining security and privacy of data packages mailed to the University of Alabama project office; proper procedures for avoiding coercion or appearance of coercion of research participation when working with NH staff (e.g., not asking staff about research interview participation); proper procedures for assisting in telephone appointment arrangements and providing logistical support when study team members conduct telephone-based NH resident consenting and capacity to consent assessment; importance of only study team members conducting actual consent procedures of anyone (LARs, NH residents, NH staff);

importance of only properly trained NH leadership team members participating in study procedures. Dr. Richards (via zoom teleconference) will work together to provide training on the appropriate application of actigraphs and Fitbits to promote comfort and prevent adverse experiences, as well as appropriate assessment equipment maintenance and data mailing.

NH staff training: As part of the intervention training, NH staff will be trained by their NH leadership teams or their trained designees on proper use and placement of actigraphs and Fitbits, verbal and behavioral signs of distress that might indicate actigraph/Fitbit-related discomfort/distress, and appropriate modification techniques to try to relieve such distress. NH staff will be informed that the devices should be removed in the unlikely event that distress behaviors are not relieved by modification techniques. NH staff will be trained on importance of NH resident autonomy, and will be engaged in a discussion of how to assess for and honor NH resident assent or lack thereof with regard to the devices.

Personally Identifiable Information: Access, Management, and Protection
The study staff will have access to individually identifiable data about participants. The NH leadership team will have access to individually identifiable data about participants (see also Protection of Human Subjects, section 1.a, sub-sections Subject Populations and Collaborating Sites and Roles). To protect against the risk of accidental access to or inappropriate divulging of identifiable data, the flow of individually identifiable data and steps to assure its appropriate access, management, and protection, are outlined below.

1. NH Residents
a. Study staff will successfully obtain all necessary IRB authorizations for protocols and materials described below

b. NH leadership team or their designees will identify all NH residents with an ADRD diagnosis and the NH leadership team will mail to those residents' legally authorized representatives (LARs) an IRB-approved study introduction letter (including option to opt out within one month if they do not wish to be contacted by study staff). Contact information of those LARs not opting out will be shared with University of Alabama (UA) study staff.

c. UA study staff will contact LARs and attempt to gain informed consent for NH resident participation. Study staff will weekly provide an updated list of consented residents with study identification numbers to the NH leadership team along with copies of all completed informed consent forms so that a copy can be filed in the resident's medical records and a copy can be stored along with the complete list and other IRB approvals and relevant study information in an essential documents binder (electronic or physical) at the NH. These processes will assure that NH staff will be able to easily verify that study staff only have access to personally identifiable data of residents are involved in the study.

d. NH staff will work together in frontline huddles to complete screening of all eligible residents, identify residents with sleep problems to enroll in the LOCK sleep program, and collect assessment data for enrolled residents.

e. Every week, the NH leadership team will use researcher-provided tracked express mail service envelopes to send the UA study staff the following: 1) all completed staff rating forms, identified by NH resident subject number; and 2) any actigraphs and Fitbits for which the assessment periods are complete, identified by subject number. Research staff will mail back actigraphs and Fitbits after data download, deletion of data from the devices, and maintenance.

f. UA study staff will conduct a virtual visit to each NH during the post-intervention period to work with NH staff to extract information from the medical records of consented NH residents.

g. UA study staff will upload all data at UA and then transfer to the University of Texas School of Public Health (UTHealth SPH) Data Center via secure file transfer procedures as established by Dr. Morgan and the Data Center.

h. MDS data will be obtained by Dr. Morgan and the UTHealth SPH Data Center through data use agreement for use of personally identifiable information from CMS. MDS data for consented NH residents will be linked and merged with the other data described above.

i. When data are reported in publication and presentation they will only be reported in aggregate form, and neither NH nor participant will be identifiable.

2. NH Staff for interviews
a. Study staff will successfully obtain all necessary IRB authorizations for protocols and materials described below.

b. NH leadership team will provide to all NH staff an IRB-approved study introduction letter (including option to opt out within one month if they do not wish to be contacted by study staff). Contact information of those NH staff not opting out will be shared with UA study staff.

c. UA Study staff will contact NH staff to invite them to participate in mid-implementation virtual interviews. Study staff will also contact NH staff to invite them to participate in post-implementation interviews. The list of NH staff who agree and decline interview participation will remain confidential to protect NH staff from any possible coercion to participate (see 1.3.b. Protection Against Risks).

d. UA study staff will conduct virtual interviews with consented NH staff. Interviews will be audio recorded. Recordings will be uploaded at UA, identified only by subject number, and shared with a university-approved transcription service via secure file transfer procedures as established by Dr. Morgan and the UTHealth SPH Data Center. Transcribed files, identified only by subject number, will be returned via the same secure file transfer procedures to UA for tracked storage and analysis and to Drs. McCullough and Hartmann at Boston University for analysis.

e. When data are reported in publication and presentation they will only be reported in aggregate form, and neither NH nor participant will be identifiable.

3. Data Management and Protection. Dr. Morgan and the UTHealth SPH Data Center will create protocols for overseeing the security and protection of all data collected for this study. Personally identifiable information will be only be stored in the secure and securely backed up UA data server and UTHealth SPH Data Center in password protected files. Other collaborating sites (Boston University, Brown University, and University of Texas at Austin) will only work with data identified by subject number.

2.0 Interim Analysis
At the first meeting, the Data Safety and Monitoring Board (DSMB) will decide if an interim analysis will take place (e.g. after n participants have been accrued or completed the trial). Interim analyses of efficacy data will only be performed if planned and approved in advance, and when criteria for possible stopping are clearly defined.

It is not anticipated that interim analyses will be undertaken given the minimal potential risks to participants in this trial.

3.0 Data and Safety Monitoring
The DSMB procedures are described above in the Risks Sub-section #8b.

If no, please justify why not.

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*** * * Benefits/Alternatives, Procedures to Maintain Confidentiality * * ***

## 9. Benefits/Alternatives

a) **Benefits. Describe the potential benefit(s) to be gained by the participants and how the results of the study may benefit future participants and/or society in general. Indicate if there is no direct benefit to the participants.**

The intervention may benefit NH residents by leading to better and earlier detection and treatment of sleep problems and from increased attention to their conditions. The intervention may benefit NH staff by improving communication and teamwork, thereby improving the work experience.

Sleep problems and related issues in NH residents with dementia is a well-documented problem. This study implements an intervention to improve the sleep experience for these residents and increase access to meaningful activities. If the LOCK sleep program is found to be effective in enhancing clinical care and outcomes, the approach can be shared with other NHs and incorporated into general NH practice. The risks in this study for NH residents are minimal, and the knowledge gained may result in improved quality of sleep, and ultimately improved quality of life for NH residents with dementia. Similarly the risks for NH staff are minimal, and the knowledge to be gained may result in a more effective and enjoyable workplace experience. Thus, the potential benefits exceed risks.

b) **Alternatives. Describe any alternative treatments and procedures available to the participants should they choose not to participate in the study. If no such alternatives exist, please state that the alternative is nonparticipation. For some studies, such as record reviews, a description of alternatives would not be applicable.**

The intervention described will be implemented NH-wide. The study uses an incomplete stepped-wedge cluster randomized controlled trial design in which each NH serves as its own control. There will therefore be no alternative treatments. NH residents and their legally authorized representatives will have the right to refuse participation in any portion of their care just as they would with usual NH care, including use of actigraphs and Fitbits. NH staff will have the right to refuse any interviews.

## 10. Procedures to Maintain Confidentiality

Federal regulations require that study data and consent documents be kept for a minimum of three (3) years, and HIPAA documents be kept for a minimum of six (6) years after the completion of the study by the PI. For longitudinal or sponsored projects, the PI may be required to keep the data and documents for a longer time period.

**Data Security**

Please indicate how information will be secured. All information must be stored using at least two of the following safeguards and must be kept in accordance with the University of Alabama Information Security Policies. (If you are using both electronic data and hard copy data, you will need two safeguards for each type).

a) Electronic Data: (mark all that apply - at least 2 - or indicate not applicable)

- [ ] Not applicable
- [X] Password access

X Coded, with a master list kept as a hardcopy or on a secure network (confidential)
Data collected anonymously
Secure network (e.g., firewall)
Data are de-identified by PI or research team
Other

**Please specify:**

b) Hardcopy Data: (mark all that apply - at least 2 - or indicate not applicable))

Not applicable
Locked suite
X Locked office
X Locked file cabinet
X Coded, with a master list secured and kept separately (confidential)
Data collected anonymously
24 hour personnel supervision
Data are de-identified by PI or research team
Other

**Please specify:**

c) Describe measures employed to protect the identity of the participants, their responses, and any data that you obtain from private records (e.g., identifiers will be stripped so data cannot be linked to participants, or code numbers will be used, etc.). If data will be coded, specify the procedures for coding the data so that confidentiality of individual participants is protected. If you will keep a master list linking study codes to participant identifiers, explain why this is necessary, how and where you will secure the master list, and how long it will be kept.

Sources of Materials
NH resident data will be collected for consented NH residents from NH staff ratings (global assessments of change in overall sleep quality and sleep-related conditions; Sleep reports from NH staff), NH staff sleep interview of resident, family/friend sleep interview about resident, and actigraph/Fitbit measurements (wristwatch-sized devices worn on the wrist); medical records (age, diagnoses, medical history, and medications); and MDS assessments (Brief Interview for Mental Status score, psychotropic medication use, pain and analgesic medication use, activities of daily living decline, sleep-related items). NH staff interview data will be collected via audiorecorded qualitative interview. See Table 1 in Attachments for a listing of all study outcomes and data sources.

Personally Identifiable Information: Access, Management, and Protection
The study staff will have access to individually identifiable data about participants. The NH leadership team will have access to individually identifiable data about participants. The flow of individually identifiable data and steps to assure its appropriate access, management, and protection, are outlined below.

1. NH Residents
a. Study staff will successfully obtain all necessary IRB authorizations for protocols and materials described below

b. NH leadership team or their designees will identify all NH residents with an ADRD diagnosis and the NH leadership team will mail to those residents' legally authorized representatives (LARs) an IRB-approved study introduction letter (including option to opt

representatives (LARs) an IRB-approved study introduction letter (including option to opt out within one month if they do not wish to be contacted by study staff). Contact information of those LARs not opting out will be shared with University of Alabama (UA) study staff.

c. UA study staff will contact LARs and attempt to gain informed consent for NH resident participation (see 2.a. Informed Consent and Assent). Study staff will weekly provide an updated list of consented residents with study identification numbers to the NH leadership team along with copies of all completed informed consent forms so that a copy can be filed in the resident's medical records and a copy can be stored along with the complete list and other IRB approvals and relevant study information in an essential documents binder (electronic or physical) at the NH. These processes will assure that NH staff will be able to easily verify that study staff only have access to personally identifiable data of residents are involved in the study.

d. NH staff will work together in frontline huddles to complete screening of all eligible residents, identify residents with sleep problems to enroll in the LOCK sleep program, and collect assessment data for enrolled residents.

e. Every week, the NH leadership team will use researcher-provided tracked express mail service envelopes to send the UA study staff the following: 1) all completed staff rating forms, identified by NH resident subject number; and 2) any actigraphs and Fitbits for which the assessment periods are complete, identified by subject number. Research staff will mail back actigraphs and Fitbits after data download, deletion of data from the devices, and maintenance.

f. UA study staff will conduct a virtual visit to each NH once during the post-intervention period to work with NH staff to extract information from the medical records of consented NH residents (this process and the information to be extracted will be clearly described in IRB-approved protocols and consent forms).

g. UA study staff will upload all data at UA and then transfer to the University of Texas School of Public Health (UTHealth SPH) Data Center via secure file transfer procedures as established by Dr. Morgan and the Data Center.

h. MDS data will be obtained by Dr. Morgan and the UTHealth SPH Data Center through data use agreement for use of personally identifiable information from CMS. MDS data for consented NH residents will be linked and merged with the other data described above.

i. When data are reported in publication and presentation they will only be reported in aggregate form, and neither NH nor participant will be identifiable.

2. NH Staff for interviews
a. Study staff will successfully obtain all necessary IRB authorizations for protocols and materials described below.

b. NH leadership team will provide to all NH staff an IRB-approved study introduction letter (including option to opt out within one month if they do not wish to be contacted by study staff). Contact information of those NH staff not opting out will be shared with UA study staff.

c. UA Study staff will contact NH staff to invite them to participate in mid-implementation virtual interviews. Study staff will also contact NH staff to invite them to participate in post-implementation virtual interviews. The list of NH staff who agree and decline interview participation will remain confidential to protect NH staff from any possible

coercion to participate.

d. UA study staff will conduct interviews with consented NH staff. Interviews will be audio recorded. Recordings will be uploaded at UA, identified only by subject number, and shared with a university-approved transcription service via secure file transfer procedures as established by Dr. Morgan and the UTHealth SPH Data Center. Transcribed files, identified only by subject number, will be returned via the same secure file transfer procedures to UA for tracked storage and analysis and to Dr. Hartmann at UMass Lowell for analysis.

e. When data are reported in publication and presentation they will only be reported in aggregate form, and neither NH nor participant will be identifiable.

3. Data Management and Protection. Dr. Morgan and the UTHealth SPH Data Center will create protocols for overseeing the security and protection of all data collected for this study. Personally identifiable information will be only be stored in the secure and securely backed up UA data server and UTHealth SPH Data Center in password protected files. Other collaborating sites (UMass Lowell, Brown University, and University of Texas at Austin) will only work with data identified by subject number.

d) If data or specimens are being shared outside of the research team, indicate who will receive the material and specifically what they will receive (data or specimens).

N/A. Data will be shared across different sites that are all part of the research team -- this is described above.

e) If samples or data will be provided from an outside source, indicate whether you will have access to identifiers, and, if so, how identifiable information is protected. Please provide a letter from the appropriate persons indicating that data will be provided in a de-identified manner.

Data will be collected from NH medical records and from NH Minimum Data Set (MDS) records. We will have access to identifiers, and are submitting the appropriate HIPPAA authorizations. We will protect data by separating identifiers from the data itself using subject IDs and a master coding checklist kept locked in a separate location.

f) If data will be collected via e-mail or the internet, how will anonymity or confidentiality be protected? Describe how data will be protected during electronic transmission and how data will be recorded (i.e., will internet protocol (IP) address and/or e-mail addresses be removed from data?).

g) If you will be audio/video recording or photographing participants, provide a rationale for recording/photographing. Describe confidentiality procedures, including the final disposition of the recordings/photos (destruction, archiving, etc.) and a reasonable timeline by which this disposition will occur.

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## * * * Potential Conflict of Interest * * *

### 11) Potential Conflict of Interest

Federal regulations and UA policy require all investigators to disclose their significant financial interests to allow a review of potential conflicts of interest. If a potential conflict of interest is identified, a formal plan must be developed and implemented to manage, reduce, or eliminate the conflict.

Examples of significant financial interests include receipt of income, honoraria, and stock or stock options from a public or private entity sponsoring the research. They may also include a consulting arrangement or membership on an advisory board of the entity. Significant

consulting arrangement or membership on an advisory board of the entity. Significant financial interests are reported on the UA Statement of Financial Interest.

All members of the research team who are involved in the design, conduct, or reporting of research (i.e., senior/key personnel) should have a current Statement of Financial Interest and conflict of interest training on file prior to submitting the IRB protocol. Please refer to the Office for Research Compliance website for additional information regarding the financial conflict of interest requirements, as well as links to the disclosure form and training at (http://osp.ua.edu/site/RC_CoI.html).

The Statement of Financial Interest must be submitted annually and within 30 days of discovering or acquiring a new or increased financial interest. Conflict of interest training must be completed once every four years.

If such a relationship as described above exists between a member of the research team and the sponsor of the research, the investigator is also required to disclose this relationship and identify the entity involved on the informed consent form. For questions regarding Conflict of Interest consult the Conflict of Interest in Research Policy.

**Check one of the following:**

1) X No Financial Interest or Financial interest less than or equal to $5K
2) Financial Interest exceeding $5K but not exceeding $25K, and/or more than 5 percent equity interest in aggregate
3) Financial Interest exceeding $25K

**Check all those that apply:**

Consulting

Speaking Fees or Honoraria

Gifts

Patent

Copyright

Licensing agreement or royalty income

Equity interests, (including stock, stock options, warrants, partnership or equitable ownership interests), or serving on a scientific advisory board or board of directors

Other fees/compensation

Describe financial interests(s) and indicate specific amounts for each subcategory checked. Be sure to describe how these financial interests relate to the protocol being submitted.

**Note to Investigator(s) Reporting a Potential Conflict of Interest**

Investigator(s) must have:

1) Current, up-to-date Conflict of Interest Disclosure Form on file with the University of Alabama Conflict of Interest Committee (COIC) that describes any financial relationship indicated above.

. This information must be disclosed on the University of Alabama confidential Conflict of Interest Disclosure Form for review by the COIC before accruing research participants in this study. If your current Disclosure Form does not contain this information, you are required to submit an updated Disclosure Form to the COIC.

2) Financial disclosure statement incorporated into the consent document. Please see Model Consent for suggested language.

3) You may not begin your study until your disclosure form has been reviewed and any required management plan has been approved by the COIC.

**Does any member of the study team, members' spouses, or members' dependent children have any** N

significant financial interests related to the work to be conducted as part of the above-referenced project?

Name of Personnel with Financial Conflict of Interest

Other research staff that may have a conflict. Please specify below.

Any member of the study team who answers in the affirmative must be listed in the box below.

A staff person will contact any researcher listed above to obtain additional information regarding the specific financial interest(s).

I certify that all members of the study team have answered the financial interests question and only those individuals listed in the box above have disclosed any financial interest related to this study. Y

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* * * Informed Consent * * *

12 Informed Consent

Federal regulations require that informed consent be obtained from individuals prior to their participation in research unless the IRB grants a waiver of consent. Answer the questions, below, then click Add to provide the necessary consent documents and information regarding participant consent. Multiple consents/waivers may be added, but they must be uploaded one at a time.

NOTE: You may refer to the University of Alabama IRB Guidance for Obtaining Informed Consent for considerations regarding the consent/assent process.

State N/A if not applicable.

1) How is consent being obtained? When and where will the discussion take place?

Informed Consent and Assent
Study staff will obtain all necessary IRB authorizations for protocols and materials described below. All consents will be conducted by an IRB-approved study staff member who has been trained by Dr. Snow. The study staff member will be responsible for explaining the study, answering questions, and obtaining informed consent.

NH Resident Consent:
Step 1. Legally Authorized Representative Consent
NH leadership team or their designees will identify all NH residents with an ADRD diagnosis and mail to their legally authorized representatives (LARs) an IRB-approved study introduction letter (including option to opt out within one month if they do not wish to be contacted by study staff). Opt-out procedures have been demonstrated to yield higher response rates and lower rates of non-response bias compared to opt-in procedures, and to be acceptable to participants, with no difference in rates of reported distress or complaints compared to opt-in procedures.105-108 In our past federally funded research involving people with dementia, opt-out consent has been approved by multiple IRBs and worked well. Contact information of those LARs not opting out will be shared with University of Alabama (UA) study staff. We will request of the IRB a waiver of consent and HIPAA authorization for screening purposes regarding the sharing of these contact information.
Study staff will mail an IRB-approved study information packet via a tracked, express mailing service to all LARs who do not opt out. These materials will include a cover letter, an IRB-approved informed consent form (ICF), and an express mail return envelope so the LAR can send the signed ICF to the UA study office. LARs will be encouraged to contact study staff via phone or email for an appointment to discuss the study and go through the consent form together before signing the ICFs. Study staff will contact the LARs via phone and/or email within one week of sending the packet and will re-contact the LAR up to 8 times within the next month as needed to establish contact (if contact has not been established within one month, and NH staff are not able to determine that the LAR's contact information has changed, then the lack of contact will be considered a

soft refusal and no other contact will be attempted).

During a phone appointment, study staff will review all important elements of the ICF with the LAR, including the following: description of the study, information on how to contact the investigators and the NH administrator and director of nursing, a statement that there is no prejudice for refusal to participate, a statement that the subject may withdraw from the study at any time without prejudice, and statement regarding risk and benefit of participation. The LAR will be encouraged to ask questions. The LAR will be encouraged to call the PI if they have any remaining questions before signing the consent form.

NH Resident Consent:
Step 2. Screening for Capacity for NH Resident Consent/NH Resident Assent
Some NH residents with mild ADRD and available LARs may have the capacity to provide their own consent. A conservative two-step process will be used to address the ethical balance of the beneficence of assuring that residents who do not have the capacity to consent are protected by LAR oversight with the promotion of autonomy for residents who do have capacity to consent. Once LAR consent is received for a resident, the NH leadership team will be asked to identify that resident's most recent MDS Brief Interview for Mental Status [120] (BIMS; see Appendix for copy of measure) score, a cognitive screening measure with good reliability and validity. For residents with BIMS scores in the mild range (above 10), the NH leadership team will be asked to arrange and support a telephone appointment between that resident and a study staff person (if the resident turns out to not have the cognitive ability to participate in the following telephone-based procedure, then they would also not have the cognitive capacity to provide informed consent, which requires higher level cognitive abilities).

In the telephone appointment, the study staff member will provide information about the study and will screen for capacity to consent by assessing the following. Does the resident respond appropriately to a social greeting? Is the resident oriented to place? Does the resident understand who the study team member is after the team member explains their identity? During the course of this introductory conversation, was the resident able to respond fluently and socially appropriately? If so, the team member will go through the consent form with them. Residents will then be asked a series of questions to assure their understanding. These questions are as follows:
- Describe in your own words what this study is about?
- Describe what I am asking you to do to participate in this study?
- Are you required to do this interview with me?
- What will happen if you don't talk to me?
- What happens if you decide you don't want to participate once we get started?
- What will I do with the information you give me?

The NH leadership team member will support this telephone conversation by assuring that the resident has a quiet environment to have the telephone conversation and that the resident has in front of them a printed large-font version of the ICF with the signature area flagged. If the resident is able to respond appropriately to all the capacity screening questions, and they do wish to participate, then the resident will be instructed to sign the ICF. The study staff person will contact the NH leadership team member and ask them to make a copy of the ICF for the resident to keep, place a copy in the medical chart, and express mail the original to the UA study office using a provided pre-paid envelope. If the resident is able to respond appropriately to all the capacity screening questions and does not wish to participate then they will not be enrolled in the study, regardless of the LAR's consent. In this case, the study team member will let the NH leadership team and the LAR know that the resident has declined participation.
Under all circumstances, the NH resident's autonomy will be respected. For NH residents without capacity to consent, their assent to participate will be obtained whenever possible, and their decision to withdraw at any time (whether expressed verbally or by

resistance to participation) will be honored (see also staff training in 2.c Vulnerable Subjects).

For residents with likely mild ADRD (BIMS score above 10) but no lar, the nursing home leadership team and study staff will go directly to the resident to invite their participation and screen their capacity to consent using the same process described above.

All above procedures apply to securing consent for the study team to have access to NH resident personally identifiable data. We note that because the LOCK sleep program does not include any activities that are outside of standard NH practice, NH staff will be free to enroll any NH residents that they believe will benefit into the LOCK sleep program regardless of resident consent status; but the NH leadership team will only share with researchers data from residents who are consented for the study.

NH Staff Consent:
The NH leadership team or their designees will provide to all NH staff an IRB-approved study introduction letter (including option to opt out within two weeks if they do not wish to be contacted by study staff). Contact information of those NH staff not opting out will be shared with UA study staff. We HAVE RECEIVED FROM THE IRB (IN 2019) a waiver of consent for screening purposes regarding the sharing of these contact information.

UA Study staff will contact NH staff (via email and/or phone, see next paragraph) to invite them to participate in mid-implementation interviews (VIA PHONE OR VIRTUALLY). Study staff will also contact NH staff to invite them to participate in post-implementation virtual interviews. The list of NH staff who agree and decline interview participation will remain confidential to protect NH staff from any possible coercion to participate.

For mid-implementation interviews, study team members will, on the PI's behalf, send out e-mails to all NH staff who do not opt out. The first e-mail will contain text from Dr. Snow soliciting voluntary participation in the PHONE OR VIRTUAL interviews. E-mail reminders will be sent, one in each of the four weeks after the initial e-mail, with follow up phone calls to the participant's work phone to remind them about the email. All emails will include information on how to opt out of the study. We will continue recruitment until we have recruited the desired sample size or until one month has passed. To facilitate staff involvement, we will secure permission from the director of each NH that staff may take part in the study during their normal hours of work. For post-implementation interviews, study team members will follow these same procedures. In addition, a study team member will virtually visit each NH at the end of the intervention period to work with NH staff to collect information from the enrolled NH residents' medical record and also to recruit for any needed remaining post-implementation virtual interviews. The study staff person will virtually attend change of shift meetings, huddles, and other staff meetings to invite interview participation and will also invite staff virtual contact for one-on-one to discuss interviews and to ask if the staff member would like to volunteer to participate. We have successfully used these procedures in our previous federally funded studies involving NH staff.

In all recruitment activities, it will be made clear that participation is strictly voluntary and no adverse consequences to the person's job status or any other adverse consequences will occur if the person declines to participate in these activities and that their final decision to participate or not will be kept confidential from all NH and corporate staff.

Mid-implementation interviews will take place virtually. Post-implementation interviews will take place virtually.

NH LEADERSHIP TEAM MEMBERS WILL ALSO BE INVITED TO PARTICIPATE IN IMPLEMENTATION INTERVIEWS, AND WILL ALSO BE INVITED TO PARTICIPATE IN

GROUP INTERVIEWS. BECAUSE WE ARE ALREADY IN DIRECT EMAIL CONTACT WITH NH LEADERSHIP TEAM MEMBERS TO WORK WITH THEM FOR THE REGULAR LEADERSHIP TEAM MEETINGS REGARDING THEIR ROLES IN INTERVENTION IMPLEMENTATION, WE WILL ALREADY HAVE THEIR EMAIL INFORMATION AND WILL REACH OUT DIRECTLY VIA EMAIL TO THEM TO INVITE THEM TO BOTH THE IMPLEMENTATION INTERVIEWS AND THE GROUP INTERVIEWS. WE WILL USE THE SAME METHODS DESCRIBED ABOVE TO ASSURE PARTICIPANTS RIGHTS FOR THE NH LEADERSHIP TEAM MEMBERS DURING THEIR INVITATIONS:
A) ALL EMAILS WILL INCLUDE INFORMATION ON HOW TO OPT OUT OF THE STUDY. IN ALL RECRUITMENT ACTIVITIES, IT WILL BE MADE CLEAR THAT PARTICIPATION IS STRICTLY VOLUNTARY AND NO ADVERSE CONSEQUENCES TO THE PERSON'S JOB STATUS OR ANY OTHER ADVERSE CONSEQUENCES WILL OCCUR IF THE PERSON DECLINES TO PARTICIPATE IN THESE ACTIVITIES AND THAT THEIR FINAL DECISION TO PARTICIPATE OR NOT WILL BE KEPT CONFIDENTIAL FROM ALL OTHER NH AND CORPORATE STAFF.

FOR GROUP INTERVIEWS OF NH LEADERSHIP TEAM MEMBERS, ALL LEADERSHIP TEAM MEMBERS WILL BE INVITED TO PARTICIPATE IN PERIODIC (APPROXIMATELY BI-WEEKLY) SHORT INTERVIEWS AT THE END OF THE REGULAR LEADERSHIP TEAM MEETINGS. TEAM MEMBERS WILL BE INVITED TO "THINK ALOUD" REGARDING THEIR EXPERIENCES WITH THE PROCESS OF INTERVENTION IMPLEMENTATION TO DATE AND TO SHARE REFLECTIONS ON FACILITATORS AND BARRIERS TO IMPLEMENTATION TO DATE.

We HAVE RECEIVED FROM THE IRB (IN 2019) a waiver of documentation of informed consent for the interviews, allowing us to obtain verbal consent. We will provide a consent information sheet to potential participants in the stead of an informed consent document that requires signature. We will record each subject giving permission to be recorded on the audio recording.

The study staff member will review with the NH staff member all relevant elements of consent on the consent information sheet, including the following: description of the study activities, time requirement, information on how to contact the investigators, a statement that there is no prejudice for refusal to participate, a statement that the subject may withdraw from the study at any time without prejudice, a statement encouraging the reader to ask questions, and a statement regarding risk and benefit of participation. All informed consent guidelines of the IRB will be followed. If at any time during the interview the staff member indicates a desire to stop participating, the participant will be withdrawn from the interview portion of the study. Confidentiality of all interview data will be protected by using participant code numbers on the data collection forms.

SELECTED REFERENCES
120.Chodosh J, Edelen MO, Buchanan JL, et al. Nursing home assessment of cognitive impairment: development and testing of a brief instrument of mental status (BIMS). J Am Geriatr Soc. 2008;56(11):2069-2075.

2) **Explain how risks, benefits, and alternatives will be discussed.**

Risks will be described first. Efforts to mitigate risk (e.g., data security procedures to ensure confidentiality of data, procedures to keep employee participation information confidential, staff training to ensure that cognitively impaired individuals' autonomy and potential withdrawal of assent are honored).

Benefits will then be described in an appropriately tentative manner, as follows. Sleep problems and related issues in NH residents with dementia is a well-documented problem. This study implements an intervention which may improve the sleep experience for these residents. If the LOCK sleep program is found to be effective in enhancing

for these residents. If the LOCK sleep program is found to be effective in enhancing clinical care and outcomes, the approach could be shared with other NHs and incorporated into general NH practice. The risks in this study for NH residents are considered minimal, but risk cannot be eliminated. The knowledge gained may result in improved quality of sleep, and ultimately improved quality of life for NH residents with dementia, but benefits cannot be guaranteed. Similarly the risks for NH staff are minimal, but risk cannot be eliminated, and the knowledge to be gained may result in a more effective and enjoyable workplace experience, but these benefits cannot be guaranteed.

Regarding alternatives to participation, the LOCK sleep program intervention described will be implemented NH-wide. The study uses an incomplete stepped-wedge cluster randomized controlled trial design in which each NH serves as its own control. There will therefore be no alternative treatments. NH residents and their legally authorized representatives will have the right to refuse participation in any portion of their care just as they would with usual NH care, including use of actigraphs and Fitbits. NH staff will have the right to refuse any interviews.

**Informed Consent**

| Title | Consent Type | Attached Date |
|---|---|---|
| Waiver of written consent for NH staff | Waiver of Written Consent | 10/16/2019 |
| NH Staff Consent 40Winks Oct2020 Approved_NO CHANGES | Consent | 12/21/2021 |
| LAR Consent - Track Changes | Consent | 12/21/2021 |
| LAR Consent - Clean | Consent | 12/21/2021 |
| Resident Self-Consent if have capacity_TRACK CHANGES STARTING FROM LAR CONSENT | Consent | 12/21/2021 |
| Resident Self-Consent if have capacity_CLEAN | Consent | 12/21/2021 |
| NH Staff Consent 40Winks TRACK CHANGES TO Oct2020 Approved _ ver03.21.22 | Consent | 03/22/2022 |
| NH Staff Consent 40Winks CLEAN CHANGES ACCEPTED TO Oct2020 Approved _ ver03.21.22 | Consent | 03/22/2022 |

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*** * * Assent * * ***

## 13 Assent

**Complete this section if your study includes minors. An assent document should be used if participants are 6 to 18 years of age. The Assent Form Template provides guidelines for writing assent documents.**

1) **Will minors be asked to give assent? If not, please justify.**

Note: For studies that require a discussion about reproductive risks, note that the conversation

with the minor should take place separately from the parents. Also, if a minor will reach adulthood (18 in Missouri) during the course of the study, they will need to be asked to consent as an adult at that time to continue in the study.

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* * * HIPAA * * *

## 14 HIPAA

Studies that receive or create protected health information (PHI) are subject to HIPAA regulations. PHI is health information with one or more personal identifiers. For more information see: http://www.ua.edu/research/index.html If you are working with UMC, then a separate IRB approval is required. This must be obtained prior to IRB submission and attached.

1) **Will health information be accessed, received or collected?**

   No health information. HIPAA does not apply.

   X Yes (continue to question 2).

2) **Which personal identifiers will be accessed, received or collected?**

   No identifiers. I certify that no identifiers from the list below will be received or collected and linked to health information. HIPAA does not apply (skip remainder of page).

   X Names

   Social Security numbers

   X Telephone numbers

   Linkable code or any other unique identifying number (note this does not mean the unique code assigned by the Investigator(s) to code the research data)

   All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if, according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000

   X 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

   Fax numbers

   X Electronic mail addresses

   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 Locations (URLs)

   Internet Protocol (IP) address numbers

   Biometric identifiers, including finger and voice prints

   Full face photographic images and any comparable images

**If you are receiving or collecting health information and at least one personal identifier, HIPAA applies to your study. Please continue to complete the sections, below.**

3) **Sources of Protected Health Information:**

X Hospital/medical records for in or out patients
X Physician/clinic records
Laboratory, pathology and/or radiology results
Biological samples
X Interviews or questionnaires/health histories
Mental health records
Data previously collected for research purposes
Billing records
X Other Please describe:

Our secondary outcomes come from the MDS 3.0. Every Medicare-certified NH is required to complete
an MDS assessment for every resident at admission, quarterly, and at discharge, in addition to
whenever the resident's status changes.

4) **If data will be shared outside the research team and the study involves PHI indicate how the research team will share the information. Contact the University of Alabama Privacy Officer for guidance on the proper procedures for sharing of protected health information. http://hipaa.ua.edu/**

X Not applicable (continue to question 5).
Only linkable code that can link data to the identity of the participant. A code access agreement or business associate agreement may be needed when data are shared with other non-University of Alabama entities. If necessary, the agreement can be added and uploaded in item #5, below.
Limited identifiers: Zip codes, dates of birth, or other dates only. The study qualifies as a Limited Data Set. A data use agreement may be needed when data are shared with other non-AlaUniversity of Alabamatities. If necessary, the agreement can be added and uploaded in item #5, below.
With unlimited identifiers. The consent document and HIPAA Authorization form must describe how the information will be disclosed.

5) **A HIPAA Authorization Form or Waiver of HIPAA Authorization is required for this study. Use the table below to add HIPAA Documents for your study. If you are accessing medical records, or other health records that include PHI, you must complete a waiver of HIPAA authorization.**

**HIPAA Documents**

| HIPAA Documents | Title | Attached Date |
|---|---|---|
| HIPAA Authorization | HiPAA Authorization | 10/16/2019 |
| Waiver of Authorization | Waiver HiPAA Authorization for Screening | |
| HIPAA Authorization | HIPAA TRACK CHANGES 12.20.21 | 12/21/2021 |
| HIPAA Authorization | HIPAA CLEAN COPY 12.20.21 | 12/21/2021 |

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* * * Attachments * * *

15) Attachments

**In this section, please upload additional documents associated with your protocol. Failure to attach files associated with the protocol may result in the protocol being returned to you.**

**Possible documents for this protocol could include:**

Bibliography
Cooperating Institution's IRB Approval
Data Collection Sheet
Debriefing Script
Device Information/Documentation
Grant Proposal/Sub-Contract
Human Participants Training Certificate/Proof of Training
IND Application Letter
Information Sheet/Brochure
Interview/Focus Group Questions
Investigator's Brochure
Letter of Agreement/Cooperation
Package Insert
Patient Diary Form
Phone Script
Questionnaire/Survey
Recruitment Material (e.g., flyers, ads, e-mail text)
Recruitment Statement (if there is no waiver of written consent)
Scientific/PPC Review
Sponsor's Protocol
Sponsor's Protocol Amendment
Study Design Chart/Table
Waiver Request
Other files associated with the protocol (most standard formats accepted: pdf, jpg, tif, mp3, wmv, etc.)

**To update or revise any attachments, please delete the existing attachment and upload the revised document to replace it.**

| Document Type | Document Name | Attached Date | Submitted Date |
|---|---|---|---|
| Questionnaire/Survey | IRB protocol appendices measures | 10/15/2019 | 10/16/2019 |
| Human Subjects Training Certificate/Proof of Training | 11. Snow - CITI | 10/15/2019 | 10/16/2019 |
| Human Subjects Training Certificate/Proof of Training | 5. Hartmann -CITI | 10/15/2019 | 10/16/2019 |
| Human Subjects Training Certificate/Proof of Training | 10. Richards - CITI | 10/15/2019 | 10/16/2019 |
| Human Subjects Training Certificate/Proof of Training | 4. Fry - CITI | 10/15/2019 | 10/16/2019 |

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|---|---|---|---|
| Human Subjects Training Certificate/Proof of Training | 8. Morgan - CITI | 10/15/2019 | 10/16/2019 |
| Other | Figure 1 LOCK Elements | 10/15/2019 | 10/16/2019 |
| Other | Table 1 Outcome measurements and sources | 10/15/2019 | 10/16/2019 |
| Grant Proposal/Sub-Contract | Research Plan_Bibliography_NIA 1R61AG065619-01 | 10/15/2019 | 10/16/2019 |
| Grant Proposal/Sub-Contract | NIH_Notice of Award_1R61AG065619-01 | 10/15/2019 | 10/16/2019 |
| Other | All Investigator Biosketches_Bundled | 10/15/2019 | 10/16/2019 |
| Human Subjects Training Certificate/Proof of Training | 1. Baier - CITI | 10/15/2019 | 10/16/2019 |
| Human Subjects Training Certificate/Proof of Training | 2. Brady - CITI | 10/15/2019 | 10/16/2019 |
| Human Subjects Training Certificate/Proof of Training | 3. Frank - CITI | 10/15/2019 | 10/16/2019 |
| Human Subjects Training Certificate/Proof of Training | 6. McCreedy - CITI | 10/15/2019 | 10/16/2019 |
| Human Subjects Training Certificate/Proof of Training | 7. McCullough - CITI | 10/15/2019 | 10/16/2019 |
| Other | Snow 19-024-ME 11-18-19 Notification | 11/18/2019 | 11/18/2019 |
| Other | B&F Consulting LOS Excerpt | 11/26/2019 | 11/26/2019 |
| Other | Biosketch CathieBrady_20190219 | 11/26/2019 | 11/26/2019 |
| Other | Biosketch BarbaraFrank_20190218 | 11/26/2019 | 11/26/2019 |
| Other | 19-024-ME_response cover letter_11.26.19 | 11/26/2019 | 11/26/2019 |
| Other | Snow 19-024-ME Approval | 12/12/2019 | 12/12/2019 |

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|---|---|---|---|
| Other | Snow 19-024-ME-R1 Approval | 11/09/2020 | 11/09/2020 |
| Other | Brookshire_LOS | 04/05/2021 | 04/05/2021 |
| Other | Snow 19-024-ME-R1-A Approval | 04/16/2021 | 04/16/2021 |
| Human Subjects Training Certificate/Proof of Training | George Medical Research | 09/17/2021 | 09/17/2021 |
| Human Subjects Training Certificate/Proof of Training | J Cassell CITI - 5.9.24 | 09/17/2021 | 09/17/2021 |
| Human Subjects Training Certificate/Proof of Training | J Loup - CITI - 8.28.2024 | 09/17/2021 | 09/17/2021 |
| Other | 40Winks Caraday Letter of Support 060221 | 09/17/2021 | 09/17/2021 |
| Other | 40 Winks Letter of Support_White Oak | 09/17/2021 | 09/17/2021 |
| Other | 40Winks Vivage LOS Final april 2021 | 09/17/2021 | 09/17/2021 |
| Other | NIA to Snow_DSMB Meeting Summary_2021_05_17 | 09/17/2021 | 09/17/2021 |
| Other | NIA to Snow_Intro DSMB Meeting Summary Final_2020_11_11 | 09/17/2021 | 09/17/2021 |
| Other | NIATOS~3 | 09/17/2021 | 09/17/2021 |
| Other | 40 Winks IRB Approval and Consent Forms exp11.04.21 | 09/17/2021 | 09/17/2021 |
| Other | Snow 19-024-ME-R2 Approval | 10/15/2021 | 10/15/2021 |
| Data Collection Sheet | Sleep Interview Resident ver12.2021 | 12/21/2021 | 12/21/2021 |
| Data Collection Sheet | Sleep Report Family ver12.20.21 | 12/21/2021 | 12/21/2021 |
| Data Collection Sheet | Sleep Report Staff ver12.20.21 | 12/21/2021 | 12/21/2021 |
| Recruitment Material (e.g., flyers, ads, e-mail text) | LAR Letter from Nursing home ver12.20.21 | 12/21/2021 | 12/21/2021 |

| | | | |
|---|---|---|---|
| Recruitment Material (e.g., flyers, ads, e-mail text) | LAR Phone Script ver12.20.21 | 12/21/2021 | 12/21/2021 |
| Recruitment Material (e.g., flyers, ads, e-mail text) | LAR Packet from Research Team ver12.20.21 | 12/21/2021 | 12/21/2021 |
| Other | IRB COVER LETTER Amendment ver12.15.21 | 12/21/2021 | 12/21/2021 |
| IRB Approval | Snow 19-024-ME-R2-A Revision Approval | 01/18/2022 | 03/22/2022 |
| Phone Script | LAR Phone Script ver12.20.21 TRACK CHANGES ver03.21.22 | 03/22/2022 | 03/22/2022 |
| Phone Script | LAR Phone Script ver12.20.21 CLEAN CHANGES ACCEPTED ver03.21.22 | 03/22/2022 | 03/22/2022 |

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*** PI Obligations ***

PI Obligations

By clicking the box below, you indicate that you accept responsibility for and will follow the ethical guidelines.

1) Have you completed the annual Statement of Financial Interest (i.e., disclosure)? Y

NOTE: An annual disclosure must be completed by all faculty, staff, and students who are identified as senior/key personnel receiving federal funding for research. The disclosure can be completed online at https://www.formstack.com/forms/index.php?1338617-e6Kw9EILFS.

2) Have your financial interests changed significantly since you completed the annual disclosure form? N

According to the UA policy on conflict of interest, it is the PI's responsibility to inform co-investigators, staff, or students involved in the design, conduct, or reporting of federally sponsored research of their requirement to complete the Statement of Financial Interest.

X **I accept this responsibility.**

By submitting this form, the PRINCIPAL INVESTIGATOR certifies that he/she has read the UA policy on conflict of interest and has a current Statement of Financial Interest on file. In addition, the PI certifies that, to the best of his/her knowledge, no person working on this project at UA has a conflict of interest or, if a conflict of interest does exist, an appropriate management plan is in place.

X **The Principal Investigator has read and agrees to abide by the above obligations.**

**The Department Chair has read and agrees to abide by the above obligations.**

**The Faculty Sponsor / Mentor has read and agrees to abide by the above obligations.**

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*** Event History ***

Event History

| Date | Status | View Attachments | Letters |
|---|---|---|---|
| 09/22/2019 | NEW FORM CREATED | | |
| 10/16/2019 | NEW FORM SUBMITTED | Y | |
| 10/31/2019 | NEW FORM PANEL ASSIGNED | | |
| 11/01/2019 | NEW FORM REVIEWER(S) ASSIGNED | | |
| 12/12/2019 | NEW FORM PANEL REASSIGNED | | |
| 12/12/2019 | NEW FORM REVIEWER(S) ASSIGNED | | |
| 12/12/2019 | NEW FORM APPROVED | Y | Y |
| 10/27/2020 | AMENDMENT 1 FORM CREATED | | |
| 10/28/2020 | AMENDMENT 1 FORM DELETED | | |
| 10/28/2020 | CONTINUING REVIEW 1 FORM CREATED | | |
| 10/28/2020 | CONTINUING REVIEW 1 FORM SUBMITTED | Y | |
| 11/02/2020 | CONTINUING REVIEW 1 FORM PANEL REASSIGNED | | |
| 11/02/2020 | CONTINUING REVIEW 1 FORM REVIEWER(S) ASSIGNED | | |
| 11/09/2020 | CONTINUING REVIEW 1 FORM PANEL REASSIGNED | | |
| 11/09/2020 | CONTINUING REVIEW 1 FORM REVIEWER(S) ASSIGNED | | |
| 11/09/2020 | CONTINUING REVIEW 1 FORM APPROVED | Y | Y |
| 01/21/2021 | AMENDMENT 2 FORM CREATED | | |
| 04/05/2021 | AMENDMENT 2 FORM SUBMITTED | Y | |

| | | | |
|---|---|---|---|
| 04/15/2021 | AMENDMENT 2 FORM REVIEWER(S) ASSIGNED | | |
| 04/16/2021 | AMENDMENT 2 FORM APPROVED | Y | Y |
| 09/09/2021 | CONTINUING REVIEW 2 FORM CREATED | | |
| 09/17/2021 | CONTINUING REVIEW 2 FORM SUBMITTED | Y | |
| 10/07/2021 | CONTINUING REVIEW 2 FORM PANEL REASSIGNED | | |
| 10/07/2021 | CONTINUING REVIEW 2 FORM REVIEWER(S) ASSIGNED | | |
| 10/15/2021 | CONTINUING REVIEW 2 FORM APPROVED | Y | Y |
| 11/28/2021 | AMENDMENT 3 FORM CREATED | | |
| 12/21/2021 | AMENDMENT 3 FORM SUBMITTED | Y | |
| 01/06/2022 | AMENDMENT 3 FORM REVIEWER(S) ASSIGNED | | |
| 01/18/2022 | AMENDMENT 3 FORM PANEL REASSIGNED | | |
| 01/18/2022 | AMENDMENT 3 FORM REVIEWER(S) ASSIGNED | | |
| 01/18/2022 | AMENDMENT 3 FORM APPROVED | Y | Y |
| 02/15/2022 | AMENDMENT 4 FORM CREATED | | |
| 03/22/2022 | AMENDMENT 4 FORM SUBMITTED | Y | |