Participant Name: _____ Date:_____

Title of Study: Promoting cognition and reducing frailty in older Veterans with bright light therapy

Principal Investigator: Bruce R. Troen, MD VA Facility: VA Kansas City Healthcare System (Station #589)

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by the VA Rehabilitation Research and Development (RR&D) Service. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you and any potential benefits you might receive. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

This trial will determine if bright light therapy (BLT), a strategy to improve sleep quality, has potential to improve cognition and quality of life in older Veterans. This trial will last two years. Your participation in this trial will be about 12 weeks.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

Your participation will help to test if BLT can be given successfully to older Veterans. This will help to design a larger trial to examine the benefits of BLT and then use in larger VA programs to aid Veteran health. Individually you will receive a check-up on your health. This evaluation includes the following:

- Cognition
- Frailty status (grip strength, gait speed, endurance, fatigue)
- Quality of life
- For a complete description of benefits, refer to the Detailed Consent below.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

As with most clinical trials there are some risks to your health. These risks include, but are not limited to, the possibility of injury from functional assessments or blood draw. Additionally, you will need to return to the VA four (4) times.

There is also the possibility that you will be assigned to our control group. The control group will receive BLT but at a non-therapeutic dose. Your contribution as a participant

in the control group is still vitally important in order to understand the benefits of BLT for Veteran health. *For a complete description of risks refer to the detailed information section below.*

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

It is important to tell the study team if you are taking part in another research study.

WILL I BE PAID FOR PARTICIPATING?

You will receive a total of $300 for travel expenses and time in the study. If you do not complete all visits, your payment will be prorated based on the visits completed.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

Dr. Bruce Troen is the lead investigator of the trial. If you have need to reach out to him please call (913) 574 4897.

DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to test bright light therapy (BLT) in older Veterans. We also hope to test endurance and cognition. Ultimately, this project we help prepare for a larger trial that determines the health benefits of BLT.

HOW LONG WILL I BE IN THE STUDY?

Your participation will last about 12 weeks.

HOW MANY PEOPLE WILL PARTICIPATE?

We aim to recruit 36 people in this research study.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

Our study will require your participation for 12 weeks. This includes a total of 4 assessment visits. You will first take part in a screening visit. Here you will undergo assessments to make sure you qualify to be in the study. If you meet all eligibility criteria, you will be randomly assigned to one of two groups, both receiving BLT glasses that we ask that you wear for 30-minutes a day when you first wake up. We will ask you to wear these glasses for approximately 4 weeks. We will then take follow-up assessments that are similar to those given on baseline. We will then ask you to return one month later for an additional follow-up.

Our tests throughout the study include the following:

- Cognitive assessment
- Frailty measurement (gait speed test, grip strength test, and survey questions)
- Function capacity and Quality of Life Surveys
- Serum Collection
- Activity levels assessment

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

Screening

First we will ask that you review and sign this Informed Consent document. We will the provide several tests to see if you qualify for the study. This includes a cognitive survey, and questions about medical history. We will also collection information about your weight, activity levels, and energy levels. We will measure your grip strength and walking speed. Finally, if you qualify for the study, you will be provided with a monitoring device, called an Actigraph, that will track your daily activity and sleep patterns.

One week following your screening visit, we will contact you by telephone to check on your status and assess if you are having any difficulties with the monitor. We will ask you to wear the device the entire 12-weeks of your study participation.

Baseline

You will then be invited back for baseline tests. These tests will take about 2 hours of your time. The tests include:

Cognition: We will give you a survey that asks a range of questions that test memory and processing. We will also give you a computer test that measures reaction time and other aspects of cognition over a 10-minute time.

Frailty: frailty test includes a grip strength and walking speed test, and questions about body weight, endurance, and activity levels.

Quality of life surveys: We will survey participants their feelings on their quality of life.

Functional capacity and quality of life surveys: We will survey participants regarding ability to perform daily living tasks and their feelings on their quality of life.

Activity and Sleep Monitoring: Following completion of screening you will wear a (FDA approved) small physical activity monitoring device, called an Actigraph. This is a safe device used to assess a person's activity habits and sleep patterns. This device is worn around your wrist and will measure your sleep duration and efficiency but will also be able to measure your energy expenditure, number of footsteps, and physical activity duration and intensity. You will be provided with detailed instructions regarding the device, (including the option to remove the device if it becomes a problem). The ActiGraph is waterproof and you will be able to keep it on during bathing, swimming, and household chores involving water, such as washing dishes. We will ask you to wear the device for the entire 12-weeks of your participation in the study, to obtain activity information outside of the laboratory environment. The device does not display any data, however we will collect the information from the device during each of your in-person visits. You will not be able to keep the device as it will need to be used by other participants throughout this research project.

Dual-Task Challenge: We will test your ability to perform STROOP test before and after a heel raise test (rising heels up and down in a standing position). The Stroop test will ask you to identify the words printed in the same color of the word, and color name of a word printed in black, and lastly, say the word and not the ink color it is printed.

Balance Test: We will test your ability to maintain your balance while standing on a platform that detects and measures your body sway. We will ask you to do this while standing in various foot positions with your eyes closed or open.

Health status: We will measure body weight, pulse rate, and blood pressure.

Endurance: Participant is asked to walk at a brisk pace for a 6-minute period.

Sleep quality: Surveys called the Insomnia Sleep Index, Pittsburgh Sleep Quality Index, Epworth sleepiness survey, and the Morningness versus Eveningness questionnaire will be used to understand your sleep quality and habits.

Blood collection: We will collect 40 milliliters (mL, about 8 tablespoons) of blood at the beginning and 40 mL at the end of the study. This will allow measurement of Vitamin D levels and inflammation markers C-reactive protein, Interleukin-6 and interleukin-10. It will also be used to study microRNA as a possible marker for healthy aging status. Additionally, immune system cells (neutrophils) will be isolated to assess your cell metabolism. You will also be asked to fast from midnight the night prior to the blood draw, which is then taken the following morning.

Intervention Period

After baseline tests, you will then enter the 4-week intervention period. You will be assigned randomly (by chance, like flipping of a coin) to one of two groups: Bright light therapy treatment group or a control group. Both groups will receive glasses that deliver a blue light and be asked to wear the glasses daily for 30-minutes during the treatment phase.

The control glasses differ by providing the blue light at a lower, non-therapeutic dose. While wearing the glasses, you will be able to perform most daily activities including watching TV, using electronic devices, or reading. However, please do not expose the glasses to water or drive a vehicle while wearing the glasses.

Post-treatment, Midpoint, and End of Study Visits

You will return every 4 weeks for follow-up tests. These tests will take about 2 hours of your time at each of these visits.

If you have any questions about any of the tests above, please contact the study coordinator or study principal investigator. The contact information can be found below in this Consent Form.

Please do not take part in any other research project without informing our study group. This is to protect you from possible injury from things such as extra blood drawing. Additionally, taking part in other research studies may affect the results of this study, as well as the other studies.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Any procedure has possible risks and discomforts. Although we expect the trial to be low risk, rare or unexpected events may occur, including:

1. Exercise Tests

This study involves exercise-based tests including, balance, chair rising, and walking. As with any exercise there exists a possibility of risk. These include, but are not limited to:

- Falls
- Abnormal blood pressure
- Fainting
- Dizziness
- Heart rhythm disorders
- Injuries to muscles, ligaments, tendons, and joints of the body
- and in very rare instances heart attack, stroke, and even death.

We will reduce risks by asking how you feel before and after each exercise assessment. We will also check your heart rate for recovery from exercise before being released.

2. Blood Collection

There also exists risk associated with the collection of blood. These include some pain at the injection site, risk of bruising and fainting, and a rare risk of infection. To minimize these risks only trained research personnel will perform the blood draws.

3. Questionnaires

You may feel uncomfortable answering some questions in the surveys; if, for any reason, you wish not to answer specific questions or you wish to terminate the session, you will be able to do so.

4. Bright light therapy

BLT emits a constant blue light just above your field of view for 30 minutes. Harm from the glasses is highly unexpected, although can't be ruled out. If you are experience any questions regarding BLT please contact the study team (information below).

5. Other Risks

In addition to health risks, other risks include the unlikely event of loss of confidentiality. Also, taking part in this research study may lead to added costs to you that include travel expenses. Patient remuneration will be provided to offset some of these costs.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

BLT may improve sleep quality and quality of life as we age. Your participation will understand the use BLT in older adults. This trial would then be used to design larger trials to test the health benefits of BLT. In turn, this will lead to large-scale programs provided by the VA to aid Veteran health.

In addition, you may also receive some direct benefits from participating. These include your experience as a volunteer in a scientific study. You will also receive a health exam for healthy aging status. This includes an examination of your cognitive and functional capacity, as well as important serum blood markers like vitamin D. Finally, you may request research results once all participants have completed the study.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

You may choose not to participate in this study. If this is your decision, you may discuss what other options you have with your doctor.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Your information will be treated as confidential and stored as stated in the Privacy Act of 1974. To secure your privacy, the handling of your records may be inspected by:

- **The VA Medical Center Research and Development Committee and its Subcommittees**
- **VA Research Staff and Research Compliance Officer**
- **The Office for Human Research Protections (OHRP)**
- **VA Office of Research Oversight (ORO)**
- **Office of the Inspector General (OIG)**

Your data will be stored securely in a locked cabinet within a locked office. Any electronic records are stored securely on VA owned SharePoint drives. Your personal information will be removed from study data or samples.

We will also ask if you want to sign a "Separate Consent for Biospecimens". This will allow your data and samples to be used for future studies without need to contact you in the future.

You will also be asked to sign a form entitled, "Department of Veterans Affairs HIPAA Authorization for Release of Protected Health Information for Research Purposes". This form will allow the study team to review your medical history. It also will provide information for how your data will be shared. You do not have to sign the authorization form. However, if you do not sign, you will not be able to participate in the study. We will also note your study participation in your medical record.

A description of this clinical trial is available on http://www.ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most,

the website will include a summary of the results. You can search this website at any time.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You will not be charged for any part of this study. Although there are no costs as part of the study, you will be responsible for arranging travel to the VA medical center.

WILL I BE PAID FOR PARTICIPATING?

You will receive payment after each in-person study visit. This payment ($300 total) is for time spent and travel expenses. Payment will be a check issued by the Federal Treasury.

If you do not complete the study, you will be paid based on visits completed. This includes:

- Screening - $50
- Baseline $50
- Follow-up 1 ($100)
- Endpoint ($100).

Your social security number will be needed to process your payment.
Participants will receive remuneration in the form of a voucher after completion of baseline ($100) and endpoint assessments ($200). This compensation ($300 total) is for time spent, travel expenses, and participation in the study. If a participant does not complete all assessments or visits per protocol requirements, the payment will be prorated based on the assessments/visits completed as follows. Screening - $50, baseline assessments - $50, follow-up 1($100), and final assessment ($100).

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you are injured, the VA will provide treatment at no cost to you. This does not apply if the injury is due to non-compliance or injuries unrelated to the study. VA will provide treatment for research related injury in accordance with applicable federal regulations (38 CFR 17.85).

Financial compensation for study related injuries is not available. However, by signing this form, you do not give up your legal rights to seek compensation through the courts.

If you should have a medical concern or get injured as a result of taking part in this study, please call:

DURING THE DAY:
Bruce R. Troen, MD at (913) 574-4896 during the day and
AFTER HOURS: Kenneth Seldeen, PhD at 805-405-0766.

DO I HAVE TO TAKE PART IN THE STUDY?

Your participation on the study is voluntary. You do not need to be in the study to please the study doctor or the research staff. Your refusal to take part in the study will involve no penalty or loss of benefits to which you are otherwise entitled.

If you decide NOT to take part:

- You will not be in trouble or lose any rights you normally have.
- You will still have the same services you would normally have.
- You can still get your regular medical care from your regular health care practitioner.

You may leave the study at any time without any penalty or loss of benefits.

You can decide after signing this informed consent document that you no longer want to be in this study. We will also tell you about any new developments which might affect your willingness to continue to participate in the study. However, you can decide you want to stop taking part in the study for any reason, at any time. If you decide you want to stop being in the study, tell the study staff as soon as you can.

- We will tell you how to stop safely. We will tell you if there are any dangers if you stop suddenly.
- If you decide to stop, you can continue getting care from your regular health care practitioner.

If you do leave the study the study team will not collect further information about you. However, the study team may continue to review data that has already been collected. Your samples that have been used cannot be withdrawn. You can request that remaining biological samples be destroyed.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION:

Even if you want to stay in the study, there may be reasons we will need to take you out of it. You may be taken out of this study if:

- We find out it is not safe for you to stay in the study. For example, your health may worsen.
- You are not coming for your study visits when scheduled or completing study tasks as needed.
- The funding for the study is stopped.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

Principal Investigator: Bruce R. Troen, MD – (913) 574-4897

You may also contact the Research Compliance Officer at (816) 861-4700 x57043. The officer of the Institutional Research Board (IRB) will address questions or concerns you may have. Please note the IRB is independent of the study team.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

You will be told about new information that may affect your willingness to continue participation. New information will also be disclosed if the study team believes it may affect your health or safety. Study results may be told to you if you wish to be informed.

SPECIMEN BANKING AND FUTURE USE OF DATA AND RE-CONTACT

All blood samples obtained for this study will be destroyed upon final analysis for the study and will not be stored for future use. Any electronic data stored for future use will be placed in secured SharePoint folders and entered into a VA-secured REDCap database. Physical data will be stored in locked cabinets and locked rooms within the Medical Center.

Participant Name: _____ Date:_____

Title of Study: Promoting cognition and reducing frailty in older Veterans with bright light therapy

Principal Investigator: Bruce R. Troen, MD VA Facility: VA Kansas City Healthcare System (Station #589)

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms. _____
has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it. A copy of this signed consent will also be put in your medical record.

I agree to participate in this research study as has been explained in this form.		
_____ Participant's Name	_____ Participant's Signature	_____ Date