	CONSENT TO PARTICIPATE IN A RESEARCH STUDY (HFH IRB form rev: 02/2012)	DATE: MRN: NAME:

APPROVAL PERIOD Apr 19, 2017 – Apr 18, 2018 INSTITUTIONAL REVIEW BOARD	**PROJECT TITLE:** **Behavioral Treatment of Menopausal Insomnia; Sleep, Depression, Daytime Outcomes**

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1. WHY IS THIS RESEARCH BEING DONE?

To make reading this consent form easier, the word "you" refers to you throughout the consent form. You have been asked to take part in a research study because you have menopausal related insomnia and have decided to use behavioral therapy as a treatment for your sleep problem. This therapy for insomnia involves altering sleep patterns in specific ways to improve your ability to fall asleep and stay asleep throughout the night. The purpose of this research study is to determine if there are sleep improvements associated with your therapy option. There will be approximately 170 people including you in this research study at Henry Ford Health System (HFHS).

2. WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

There will be 3 groups in the study. The group you are assigned to will be chosen by chance (like rolling a 3 sided die). You will have an equal chance of being assigned to each particular group. The groups are: Cognitive Behavioral Therapy for treatment of Insomnia (CBT-I), Sleep Restriction Therapy (SRT) or Sleep Education. Treatment will last 2-6 weeks depending on which group you are assigned to.

1. **Sleep Education:** This treatment will involve reading weekly informative pamphlets sent to you by e-mail. These pamphlets will contain information about the science of sleep and tips for improving your sleep at home. This treatment will last 6 weeks, and your time commitment is approximately 30 minutes per week to study the materials we send to you.

2. **Sleep Restriction Therapy**: We will focus on adjusting your sleep schedule to improve your ways of falling asleep and staying asleep. This treatment is 2 weeks long which will include 2 one-on-one instructional sessions (~1 hour) and 2 phone contacts (~20 minutes).

3. **Cognitive Behavioral Therapy for Insomnia:** This treatment will involve 6 one-on-one weekly instructional sessions (~1 hour) with a sleep specialist who will help you use specific behavioral techniques, adjustments of sleep habits and ways of thinking about your sleep to improve your ability to fall asleep and stay asleep throughout the night.

We will then measure sleep in two different ways during the study:
1. You will be emailed a digital sleep diary that is to be filled out every morning during the study. This diary will tell us about your sleep about the night before.
2. You will sleep overnight at the sleep center a total of 4 times during the study. These overnights will occur every few weeks. We will measure sleep on these nights with sensors. This will occur twice before treatment and twice after treatment.

We will also be assessing your daytime functioning with questionnaires and a laboratory procedure, which uses sensors to measure your sleepiness (9:00 a.m.- 4:00 p.m.) For this you will come into the sleep center during the day (3 separate occasions). These days will be combined with the study overnights.

For all three treatment groups, we will also assess your daytime functioning after 6 months to see if any improvements have been maintained.

3. WHAT ARE THE RISKS OF THE STUDY?

You should tell the person obtaining your consent about any other medical research studies you are involved in right now. You may experience some sleepiness in any of the protocols and this will be carefully monitored during the study. No person's time in bed will be reduced below 5 hours per night. You may feel some minor skin irritations due to the sensors on your sleep center visits. There may be additional risks or discomforts that are not known at this time.

4. WHAT ARE THE BENEFITS TO TAKING PART IN THE STUDY?

The benefits of participating in this study may include: improvements in the ability to fall asleep and stay asleep throughout the night on a nightly basis. You might not be helped by participating in this study. However, others may be helped by what is learned from this research.

5. WHAT OTHER OPTIONS ARE THERE?
You do not have to participate in this study. Your other choices may include:

- Getting treatment for insomnia without being in a study (e.g., receiving drugs to improve your sleep)
- Taking part in another study

Talk to your doctor about your choices before you decide if you will take part in this study.

6. WHAT ABOUT CONFIDENTIALITY?

By signing this consent form, you agree that we may collect, use and release your personal and health information for the purpose of this research study.

We may collect and use:

- New health information created during this study.

We may release this information to the following people:

- The Principal Investigator and his/her associates who work on, or oversee the research activities.
- Government officials who oversee research (Food and Drug Administration).
- The research sponsor National Institute of Nursing Research (National Institutes of Health).
- Your insurance company or others responsible for paying your medical bills.
- Other researchers at other institutions participating in the research.

Once your information has been released according to this consent form, it could be released again and may no longer be protected by federal privacy regulations.

This consent form, test results, medical reports and other information about you from this study may be placed into your medical record. Generally, you are allowed to look at your medical record. During the research study, you will not be allowed to look at your research study information that is not in your medical record.

HFHS or others may publish the results of this study. No names, identifying pictures or other direct identifiers will be used in any public presentation or publication about this study unless you sign a separate consent allowing that use.

This consent to use and release your personal and health information will expire at the end of this research study. You do not have to sign this consent to release your medical information and may cancel it at any time. If you decide not to sign this consent or cancel your consent, you cannot participate in this study. If you notify us that you wish to stop participating in this study, we may continue to use and release the information that has already been collected. To cancel your consent, send a written and dated notice to the principal investigator at the address listed on the first page of this form.

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

7. WHAT IF I AM INJURED?

There is no federal, state, or other program that will compensate you or pay for your medical care if you are injured as a result of participating in this study. You and/or your medical insurance may have to pay for your medical care if you are injured as a result of participating in this study. You are not giving up any of your legal rights by signing this consent form.

8. WHO DO I CALL WITH QUESTIONS ABOUT THE STUDY OR TO REPORT AN INJURY?

Christopher Drake, PhD, or his/her staff member has explained this research study and has offered to answer any questions. If you have questions about the study procedures, or to report an injury you may contact Dr. Drake at (248) 344-6672. Medical treatment is available to you in case of an injury. If you have questions about your rights as a research subject you may contact the Henry Ford Health System IRB Coordinator at (313) 916-2024. The IRB is a group of people who review the research to protect your rights.

9. DO I HAVE TO PARTICIPATE IN THIS STUDY?

No, your participation in this research study is voluntary. If you decide to participate, you can stop at any time. If this happens, you may be asked to return for a visit for safety reasons. You will get the same medical care from HFHS whether or not you participate in this study. There will be no penalties or loss of benefits to which you would otherwise be entitled if you choose not to participate or if you choose to stop your participation once you have started. You will be told about any significant information that is discovered that could reasonably affect your willingness to continue being in the study.

10. WHO ELSE CAN STOP MY PARTICIPATION?

The Principal Investigator, sponsor or your doctor can end your participation in the research study at any time. If this happens, you may be asked to return for a visit for safety reasons.

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11. WILL IT COST ANYTHING TO PARTICIPATE?

We do not expect there to be any costs to you if you participate in this study. Items related to the routine medical care that you would receive even if you did not participate in this study will be billed to you or your insurance company. You have the right to ask what it will cost you to take part in this study.

12. WILL I BE PAID TO PARTICIPATE?

If you complete the study, you will be paid a total of $900.00. You will be paid by check in three stages: $200.00 after your physical appointment and the two screening sleep studies; $500.00 after you complete your assigned treatment; and $200.00 after the six-month followup. It takes 3-4 weeks to receive your checks after a staff member requests each payment. If you do not finish the study, you will be paid for the part that you did complete.

13. CONSENT

You have read this consent form or it has been read to you. You understand what you are being asked to do. Your questions have been answered. Any technical terms you did not understand have been explained to you. You agree to be in this study. You will be given a copy of this consent form.

_____ Signature of Subject	_____ Date	_____ Time
_____ Print Name of Subject		
_____ Witness to Signature	_____ Date	_____ Time
_____ Print Name of Person Obtaining Consent		
_____ Signature of Person Obtaining Consent	_____ Date	_____ Time