Subject Name: _____ **Date:** _____

Title of Study: Mindfulness Based Stress Reduction for Women at Risk for Cardiovascular Disease

Principal Investigator: Karen L. Saban, PhD, RN **VAMC:** VAH Hines, IL

DESCRIPTION OF RESEARCH BY INVESTIGATOR

PRINCIPLES CONCERNING RESEARCH: You are being asked to take part in a research project. It is important that you read and understand these principles that apply to all individuals who agree to participate in the research project below:

1. Taking part in the research is entirely voluntary.

2. You may not personally benefit from taking part in the research but the knowledge obtained may help the health professionals caring for you better understand the disease/condition and how to treat it.

3. You may withdraw from the study at any time without anyone objecting and without penalty or loss of any benefits to which you are otherwise entitled.

4. The purpose of the research, how it will be done, and what your part in the research will be, is described below. Also described are the risks, inconveniences, discomforts, and other important information, which you need to make a decision about whether or not you wish to participate. You are urged to discuss any questions you have about this research with the staff members.

SUBJECT'S IDENTIFICATION *(I.D. plate or give name-last, first, middle)*

Subject Name: _____ **Date:** _____

Title of Study: Mindfulness Based Stress Reduction for Women at Risk for Cardiovascular Disease

Principal Investigator: Karen L. Saban, PhD, RN **VAMC:** VAH Hines, IL

PURPOSE:

The purpose of this study is to determine how a stress reduction program, called Mindfulness Based Stress Reduction (MBSR), compared to a health education program, improves well being and reduces the risk of heart disease in women Veterans. This study, sponsored by the VA Nursing Research Initiative (NRI), is being done for research purposes and will not be used in the diagnosis and/or treatment of study participants.

This study will describe women Veteran's experience as it relates to early life stress, daily stressors, depression, anxiety, anger, health-promoting behaviors (the activities you do to try to stay healthy), and quality of life. This study will also examine hormones related to stress found in your blood and saliva to look at the effects of stress. In addition, your heart will be examined using an instrument called the Endo-PAT, which measures how the lining of your blood vessels, called the endothelium, is functioning. Stress, as well as other factors, may contribute to the endothelium becoming abnormal and lead to heart disease. The Endo-PAT is a noninvasive (there are no needles or instruments inserted in the body) device to measure how your blood vessels are functioning. This research study will provide information about how a stress reduction program may help women Veterans in managing their stress and reducing their risk of heart disease.

Approximately 224 women Veterans will be enrolled in this study at the Edward Hines Jr. Hospital. Participants will be randomly enrolled (assigned in a random manner) in the 8-week stress reduction program (MBSR) or a health education program. The MBSR program will focus on teaching participants how to reduce their stress levels while the health education program will focus on teaching participants how to better care for their health. Both programs (stress reduction and health education) will meet weekly for approximately 2 hours for 8 weeks for a total of 16 hours. Participants who are assigned the MBSR program will also attend a retreat. The retreat will be held on a weekend day at Hines VA and will last 4 to 6 hours.. In addition, you will be asked to come to the Edward Hines clinic to collect data four times during the study (prior to the MBSR or health education), 4 weeks after starting the program, 2 weeks after completing the program and 6 months after completing the program. These visits will each last approximately 2 hours. Furthermore, at each of these four time points, you will be asked to collect a small sample (about a teaspoon) of your saliva 5 times a day. You will be asked to bring your saliva samples with you to each of your four visits. Total time commitment to the study, including the educational program (MBSR or health education program), collection of saliva samples at home, and visits to the Hines clinic to collect data (Endo-Pat, blood test, and completion of written questionnaires) is approximately 32 hours over a 6 month period.

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PROCEDURES: You will be asked to participate in either a stress reduction program (Mindfulness Based Stress Reduction) or a health education program. Both programs will consist of meeting weekly at the Hines VA for approximately 2 hours a week for 8 weeks. The meetings will take place on the Hines VA campus. Women who participate in the MBSR program will be called by the psychologist (Dr. Chris Chroniak) prior to the start of the MBSR program. During this telephone call, Dr. Chroniak will ask questions about your general health, sleep patterns and eating habits. Dr.,Chroniak will use this information to help tailor the MBSR program to the participants' needs. In addition to participating in one of these programs, participants will be asked to complete a written questionnaire, provide a blood sample, collect saliva samples at home 5 times a day for 2 consecutive days, and undergo a non-invasive measure of their blood vessels at 4 time points during the study (just prior to starting one of the programs, mid-way through the program, at time of completion of the program, and 6 months after completing the program. Participants will be provided a private area in the Physical Performance laboratory located on the 1st floor of Building 1 on the Hines VA campus, to collect data, complete the written questionnaires, and complete the Endo-Pat.

1. You will be asked to complete a written questionnaire booklet 4 different times during the study. The questionnaire booklet includes questions about your feelings, your heath and your quality of life. The written questionnaire booklet includes short paper and pencil questionnaires. They will ask you about your stress levels, depression, anger, anxiety, and early life stress as well as your physical activity levels, health behaviors, and quality of life.

   Your blood will be drawn at 4 different times during the study at Hines VA. About 3 tablespoons of blood will be drawn each time for a total of about ¾ cup of blood collected over the 6 month study period. A trained nurse or phlebotomist (someone who is trained to draw blood) will draw your blood. Blood samples will be measured to assess several stress-related hormones and measures related to your risk for heart disease (for example, cholesterol levels). Blood drawn to assess your heart disease risk will be analyzed at the Hines VA and blood drawn to examine stress-related hormones will be analyzed at Loyola University Medical Center, Maywood, IL in the research laboratory. Findings from blood samples analyzed at the Hines VA to assess your heart disease risk (such as cholesterol levels) will be include in your medical record at the VA and will be made available to your VA physician or clinical provider. Blood analyzed at the VA will be destroyed once analysis is completed.

   Blood and saliva samples analyzed at Loyola University Medical Center are for research purposes only (you and your doctor will not be told results). These samples will be identified

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only by your research study number (which will be a code that does not contain your name, initials, SSN, date of birth, or other unique identifiers). This code will be linked to your clinical research data but only the research team will know who you are. Your blood and saliva samples will be stored in a freezer in a secured laboratory within the U.S and will be analyzed for the purposes of this study. In addition, samples will be stored up to 10 years or until none are left (whichever comes first) for future studies of inflammatory-related disease, such as heart disease. Permission will be obtained from the appropriate VA authorities to store these samples after the 4th year of the study, if needed. No genetic or drug testing will be done on your blood or saliva samples. Your samples will not be shared with any other researchers besides our research team. Samples will be destroyed after 10 years.

2. Blood vessel function will be measured using the Endo-PAT. You will be asked to complete this test prior to beginning the stress reduction or health education program and about 2 weeks after completing one of these programs. These measurements are done with the use of a blood pressure cuff and monitors placed on your fingers. The blood pressure cuff will be placed on one of your arms and inflated for 5 minutes during the exam. Measurements will be recorded several times during the test. No needles are used. The test takes about 10 minutes to complete.

3. You will be asked to collect you saliva at home using swabs that will be provided for you. You will gently hold the swab under your tongue for 60 to 90 seconds at five different times throughout the day for **two consecutive** days:
    1) within 15 minutes of awakening,
    2) thirty minutes after awakening,
    3) midday,
    4) late afternoon, and
    5) at bedtime.

4. Study participants who participate in the Mindfulness Based Stress Reduction program will be asked to keep a daily diary of the time spend practicing Mindfulness Based Stress Reduction, etc.
5. Women participating in the MBSR classes, who own a smartphone, will be asked to download a free mindfulness application, Stop, Breathe & Think (SBT). After session 6, participants will be given written and oral instructions regarding the use of this application, which provides mindfulness education, activities and a log for documenting mindfulness practice. It does not collect personal identifiable data. Participants will be encouraged to use the SBT application at each of their weekly class meetings at Hines VA. Upon completion of

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formal classes, monthly calls will be made by staff to participants to remind them to use smartphone application.
Participants will also complete a short survey regarding use of the smartphone application at 4 weeks, 8 weeks and 6 months post intervention.

6. Study participants will be asked to complete program evaluation forms after completing the MBSR or health education program.

RISKS:

A possible risk associated with the study are that you might experience emotional upset since you will be thinking about your emotions and stress that you may have experienced as a child. It is important that you understand that if you feel you need assistance with the management of your emotions, such as medications or counseling, you should speak with your health or mental health care provider. If you do not have a provider, we will refer you to one at the VA.

If you say during the study that you have thoughts of harming yourself or others, we will contact your health care or mental health provider to communicate our concerns. We may have one of our mental health care research team members contact you for further information. In addition, we provide all participants with a list of Resources which includes telephone numbers to the VHA Suicide Hotline, National Crisis Hotline as well as other resources related to support for substance abuse issues. If it is determined you are an immediate threat to yourself or others, emergency services (911) will be contacted or you will be accompanied to the Hines VA Emergency room. Signing this consent document gives us permission to contact your health care provider and/or call 911 as necessary.

There is a small risk that you may experience some discomfort or bruising from the blood draw. There is a small risk that you could develop an infection at the site where the blood was drawn. We will make every effort to make you comfortable during the blood draw and steps will be taken to prevent infection, such as cleaning your skin prior to drawing the blood.

There is a risk that inflation of the blood pressure cuff during the Endo-Pat exam will feel temporarily uncomfortable. We will make every effort to make you comfortable during the Endo-Pat procedure.

An unlikely risk in participating in this study is loss of confidentiality. However, we will make every effort to protect your confidentiality and make sure that your identity does not become

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known. All written information will be stored in a locked file cabinet, and electronic data will be encrypted. Dr. Chroniak (psychologist providing MBSR program) may take handwritten notes during the telephone conversation he has with participants prior to beginning the MBSR program. These notes will be temporarily kept in a locked file cabinet in his locked private office located outside of the VA until the first MBSR session. At this time Dr. Chroniak will give the notes to the research study team. The notes will then be maintained with the research study participant's research record at the Hines VA. A limited number of research team members will have access to the data.

BENEFITS:
You may not directly benefit from the study. We will provide you with information related to ways that you can reduce your heart disease risk. Knowledge gained from this study may help other women Veterans who may be at risk for heart disease.

Your blood and saliva specimens will be used for research and use may result in inventions or discoveries that could become the basis for new products or diagnostic or therapeutic agents. In some instances, these inventions and discoveries may be of potential commercial value. You will not receive any money or other benefits derived from any commercial or other products that may be developed from the use of your blood and saliva samples.

ALTERNATIVES:
You do not have to participate in this study if you do not want to. No loss of VA services or eligibility for care will happen if you decide not to join the study.

STUDY WITHDRAWAL:
Participation is voluntary and you can withdraw from the study at any time. You may stop completing the questionnaires if you experience emotional upset. Please notify Dr. Karen Saban (708-202-5264) to withdraw from the study. Your blood and saliva samples and all links to clinical data and any data obtained from this research study will be destroyed.

You do not have to take part in this study, and refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without consequences or loss of VA benefits.

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Principal Investigator: Karen L. Saban, PhD, RN **VAMC:** VAH Hines, IL

If you are a VA employee, your refusal to participate in this study will not affect your employment at the VA in any way (such as job status, promotion, salary). In addition, you may withdraw from this study at any time without any consequences to your VA employment.

The investigator may withdraw you from the study at anytime. This may occur if the questionnaire booklet is more than 50% incomplete or you do not attend most of the educational or MBSR sessions.

If you decide to withdrawal from the study, no additional follow up is necessary.

CONFIDENTIALITY:
Any information obtained about you in this study will be treated as confidential and will be safeguarded in accordance with the Privacy Act of 1974. Information published or presented about the results of the study will be in a form that does not identify any particular participant. In order to comply with federal regulations, records identifying you may be reviewed by the members of the research team, the representatives of the sponsor or sponsors (Hines Veterans Administration) authorized representatives of the IRB, VA, FDA, the Office for Human Research Protection (OHRP) and the Government Accounting Office (GAO). By signing this document, you consent to such inspection.

We will collect some protected health information (PHI) about you such as your name, address, phone number, social security number. We will collect information from your VA medical record including results of blood samples. This information is necessary to collect as part of this research study. However, all safeguards will be taken to protect this information, such as locking the information in a file cabinet in the investigator's locked office and not sharing the information with individuals or groups that are part of the study.

FINANCIAL COMPENSATION:
You will be provided a total of $395 (cash), through the Agent Cashier, for your complete participation in this study. Payments will be distributed throughout the course of this study for completion of data collection visits and to defray travel costs.
Reimbursement is as follows: Baseline Data Collection: $25 (completion of written questionnaires, blood samples, Endo-Pat exam, salivary samples, medical history (including vital signs, height, weight, waist and hip measurements), 4 Week Data Collection: $100 (completion of written questionnaires, blood samples, salivary samples and medical history); 8 Week Data Collection: $75 (completion of written questionnaires, blood samples, Endo-Pat exam, salivary

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samples and medical history); 6 Months Data Collection: $75 (completion of written questionnaires, blood samples, salivary samples and medical history).
In addition, you will be provided $15 to defray travel costs each week you attend the MBSR or health education sessions.

RESEARCH SUBJECT COSTS:
You will not be required to pay for medical care or services received as a participant in a VA research project except as follows: some Veterans are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study.

RESEARCH-RELATED INJURIES:

This study is being financially supported by the Veterans Administration. According to the federal regulations, (Title 38 Code of Federal Regulations (CFR) 17.85), the VA will provide necessary medical treatment to you as a research subject if you are injured by participation in this research project. Except in limited circumstances, this care will be provided at this VA facility. This requirement does not apply to treatment for injuries that result from non-compliance by you with study procedures. The Department of Veterans Affairs does not normally provide any other form of compensation for injury. You have not released this institution from liability for negligence.

Participation in this research may involve risks that are currently unforeseeable.

RESEARCH SUBJECT'S RIGHTS
You have read, or have had read to you all of the above information. _____ has explained the study to you and has answered all of your questions. The risks or discomforts and possible benefits and the alternatives of the study have been explained to you.

The results of this study may be published but your identity and records will not be revealed unless required by law.

In case (If) there are any medical problems, complaints, concerns, or if you have questions about the research, you can call Dr. Karen Saban at 708-202-5264 during the day, or 630-880-3785 off hours and weekends.

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Title of Study: Mindfulness Based Stress Reduction for Women at Risk for Cardiovascular Disease

Principal Investigator: Karen L. Saban, PhD, RN **VAMC:** VAH Hines, IL

Additionally, if you have any questions about the research, your rights as a research subject, want to discuss problems with the research process, offer input or have other concerns, you may contact the Chair of the Institutional Review Board or Research Staff at 708/202-5701.

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 results. You can search this Web site at any time.

VA EMPLOYEE PARTICIPATION IN STUDY

VA employees may participate in this study during their off-duty time. Employee participation in this study is completely voluntary and decision to participate or not participate in this study will not affect your job status, salary, opportunity for promotion, etc. You may withdraw from the study at anytime without affecting your job status at the VA.

STATEMENT OF CONSENT:

I voluntarily consent to participate in this study. This research study and my rights as a research participant have been explained to me.

I will receive a copy of this consent form and a copy will be placed in my research file and additional copies will be filed in the Research Office. A copy of the consent will be placed in your Medical Record.

_____ _____

Subject's Signature

Last 4 Digits of Subject's Social Security Number

_____ _____

Subject's Telephone Number

Date

– _____

Signature of Person Obtaining Consent Date

Subject Name: _____ **Date:** _____

Title of Study: Mindfulness Based Stress Reduction for Women at Risk for Cardiovascular Disease

Principal Investigator: Karen L. Saban, PhD, RN **VAMC:** VAH Hines, IL

By signing this form, you are agreeing to the following:

1). Your blood and saliva samples may be kept by the research team for use later in research to learn about, prevent and /or treat inflammatory-related disease, such as heart disease.

Yes_____ No_____ Initials_____ Date _____

Informed Consent Addendum of Supplement Study

PURPOSE:
The purpose of this supplemental study is to examine sleep and cognition (for example, memory and attention) in a sample of women Veterans (approximately 32 women) who are participating in the Mindful Heart Study.

PROCEDURES:
At the time you enroll in the Mindful Heart study, you will also be eligible to participate in this supplemental study if you do not have a diagnosis of sleep apnea or are not deemed to be at high risk for sleep apnea. You will be asked to do the following (this is in addition to your participation in the Mindful Heart study):

1).Wear an Actiwatch, which is a small wristband to collect information on your sleep habits (for example, the time you go to bed, how often you wake up during the night, and what time you get up in the morning), continually for 7 days at two time points – just prior to starting the program and at the end of the program.

2). Maintain a sleep diary for 7 days while you are wearing the Actiwatch. You will record information about when you go to bed and when you get up in the sleep diary.

3). Complete a written questionnaire that includes questions about your sleep and levels of fatigue at two time points – just prior to starting the program and at the end of the program.

4). Cognition (such as your memory and ability to maintain attention) will be measured with a series of paper and pencil tests provided by a trained neuropsychology assistant. This testing will take

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approximately 30 minutes and will be done at two time points – prior to starting the program and at the end of the program.

RISKS:
There is a chance that an illness may be uncovered during the course of the study (such as mild cognitive impairment). If this occurs, you will be referred to your clinical provider for further assessment. It is important to note that the cognitive testing used in this study will not be used to diagnose any specific medical condition but could potentially suggest symptoms that would require further assessment by your clinical provider.

BENEFITS:
You may not directly benefit from the study. Knowledge gained from this study may help other women Veterans who may be at risk for heart disease.

ALTERNATIVES:
You do not have to participate in this study if you do not want to. No loss of VA services or eligibility for care will happen if you decide not to join the study.

STUDY WITHDRAWAL:
Participation is voluntary and you can withdraw from the study at any time. You may stop completing the questionnaires if you experience emotional upset. Please notify Dr. Karen Saban (708-202-5264) to withdraw from the study. Your blood and saliva samples and all links to clinical data and any data obtained from this research study will be destroyed.

You do not have to take part in this study, and refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without consequences or loss of VA benefits.

If you are a VA employee, your refusal to participate in this study will not affect your employment at the VA in any way (such as job status, promotion, salary). In addition, you may withdraw from this study at any time without any consequences to your VA employment.

The investigator may withdraw you from the study at anytime. This may occur if the questionnaire booklet is more than 50% incomplete or you do not attend most of the educational or MBSR sessions.

If you decide to withdrawal from the study, no additional follow up is necessary.

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Principal Investigator: Karen L. Saban, PhD, RN **VAMC:** VAH Hines, IL

CONFIDENTIALITY:

Any information obtained about you in this study will be treated as confidential and will be safeguarded in accordance with the Privacy Act of 1974. Information published or presented about the results of the study will be in a form that does not identify any particular participant. In order to comply with federal regulations, records identifying you may be reviewed by the members of the research team, the representatives of the sponsor or sponsors (Hines Veterans Administration) authorized representatives of the IRB, VA, FDA, the Office for Human Research Protection (OHRP) and the Government Accounting Office (GAO). By signing this document, you consent to such inspection.

We will collect some protected health information (PHI) about you such as your name, address, phone number, social security number. We will collect information from your VA medical record including results of blood samples. This information is necessary to collect as part of this research study. However, all safeguards will be taken to protect this information, such as locking the information in a file cabinet in the investigator's locked office and not sharing the information with individuals or groups that are part of the study.

FINANCIAL COMPENSATION:

You will be provided $50 (cash) through the Agent Cashier for participating in this study each time (two time points) you come to Hines for data collection (which consists of wearing the Actiwatch, completing written questionnaires, and undergoing cognitive testing). You will receive a maximum of $100 for participating in the supplementary study (this is in addition to the compensation you will receive for the Mindful Heart study).

RESEARCH SUBJECT COSTS:

You will not be required to pay for medical care or services received as a participant in a VA research project except as follows: some Veterans are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study.

RESEARCH-RELATED INJURIES:

This study is being financially supported by the Veterans Administration. According to the federal regulations, (Title 38 Code of Federal Regulations (CFR) 17.85), the VA will provide necessary

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medical treatment to you as a research subject if you are injured by participation in this research project. Except in limited circumstances, this care will be provided at this VA facility. This requirement does not apply to treatment for injuries that result from non-compliance by you with study procedures. The Department of Veterans Affairs does not normally provide any other form of compensation for injury. You have not released this institution from liability for negligence. Participation in this research may involve risks that are currently unforeseeable.

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RESEARCH SUBJECT'S RIGHTS

You have read, or have had read to you all of the above information. _____ has explained the study to you and has answered all of your questions. The risks or discomforts and possible benefits and the alternatives of the study have been explained to you.

The results of this study may be published but your identity and records will not be revealed unless required by law.

In case (If) there are any medical problems, complaints, concerns, or if you have questions about the research, you can call Dr. Karen Saban at 708-202-5264 during the day, or 630-880-3785 off hours and weekends.

Additionally, if you have any questions about the research, your rights as a research subject, want to discuss problems with the research process, offer input or have other concerns, you may contact the Chair of the Institutional Review Board or Research Staff at 708/202-5701.

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 results. You can search this Web site at any time.

VA EMPLOYEE PARTICIPATION IN STUDY

VA employees may participate in this study during their off-duty time. Employee participation in this study is completely voluntary and decision to participate or not participate in this study will not affect your job status, salary, opportunity for promotion, etc. You may withdraw from the study at anytime without affecting your job status at the VA.

STATEMENT OF CONSENT:

Subject Name: _____ **Date:** _____

Title of Study: Mindfulness Based Stress Reduction for Women at Risk for Cardiovascular Disease

Principal Investigator: **Karen L. Saban, PhD, RN** **VAMC:** **VAH Hines, IL**

I voluntarily consent to participate in this study. This research study and my rights as a research participant have been explained to me.

I will receive a copy of this consent form and a copy will be placed in my research file and additional copies will be filed in the Research Office.

_____	_____
Subject's Signature	Last 4 Digits of Subject's Social Security Number
_____	_____
Subject's Telephone Number	Date
_____	_____
Signature of Person Obtaining Consent	Date