CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT
200 FR. 1 (2016-2)

YALE UNIVERSITY SCHOOL OF PUBLIC HEALTH

Study Title: Mindfulness Based Stress Reduction for Older Couples with Metabolic Syndrome
Principal Investigator: Joan Monin, PhD
Funding Source: *Yale Pepper Center Pilot Award*

Invitation to Participate and Description of Project

We are inviting you to participate in a research study designed to look at a stress reduction program called Mindfulness-Based Stress Reduction in older couples with metabolic syndrome. You have been asked to participate because you and/or your partner have metabolic syndrome and both of you are 60 years or older. Approximately 80 persons will participate in the study.

In order to decide whether or not you wish to be a part of this research study you should know enough about its risks and benefits to make an informed decision. This consent form gives you detailed information about the research study, which a member of the research team will discuss with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed, any risks of the procedures, possible benefits and possible alternative treatments. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form.

Description of Procedures

If you agree to participating in this study, you will be randomly assigned to (a) start the MBSR program in the next few weeks or in January 2018, OR (b) start the MBSR program after July 2018. (the wait list group). Either way, in the MBSR program you will be asked to participate in groups of other couples receiving stress reduction training focusing on mindfulness meditation.

In the MBSR program, you will be asked to attend a 2½-hour class with 9 other couples once a week for 8 weeks, as well as one half-day retreat during the last few weeks of the course. These classes will take place at the Yale Stress Center at the Yale School of Medicine. The weekly classes will involve mindful meditation, yoga instruction, and guided awareness practices. These will also include discussions about pleasant and/or unpleasant events throughout the week and awareness of routine events. The one-time half-day (4-6 hrs) session will involve the same aspects as the weekly classes in an expanded and more detailed format, with more time dedicated to the various formal and informal mindfulness practice skills. You will also be asked to practice at home for about 30 to 45 minutes at a time throughout the week. You will be asked to fill in a daily log of mindfulness behavior. You will receive reminder calls or texts for sessions from a research assistant.

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The investigators will ask you to fill out questionnaires about your thoughts, feelings, and behaviors at the beginning of the study after eight weeks, and after three months.. You will also have approximately 3 ounces of blood drawn to test for cholesterol, triglycerides, and glucose at the beginning of the MBSR program, at the 8-week and three month visit. A research assistant will call/text to remind you of your three blood draw/questionnaire appointments.

During the course of the study, you can continue with any other treatments you are currently receiving. After 8 weeks, you will also be interviewed about the program and how well it worked for reducing stress and physical symptoms as well as how convenient it was for you.

If you are in the wait list group, you will complete the questionnaires and blood draws before the MBSR program begins. We will schedule one blood draw/questionnaire session now and one blood draw/questionnaire visit 8 weeks from now, and another at three months. You will then have the opportunity to sign up for the MBSR program at your convenience after July 2018.

A description of this study is available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. *(See Clinical Trials Identifier Number* NCT02190474.) This Web site will not include information that can identify you. The purpose of this database is to allow everyone to see information on what studies are being done, and what studies have been done. At most, the Web site will include a summary of the results. You can search this Web site at any time.

You will be told of any significant new findings that are developed during the course of your participation in this study that may affect your willingness to continue to participate. Research results will not be returned to your doctor. If research results are published, your name and other personal information will not be given.

Risks and Inconveniences

Mindfulness-based stress reduction has been studied in a number of clinical trials for many conditions. There are no known side effects of mindfulness-based stress reduction. There are potential risks of increased symptoms because mindfulness training can increase awareness of body sensations. You will also be doing some gentle yoga which has potential physical risks, such as pulled or strained muscles.

There are theoretical risks of meditation programs including increased psychological distress in persons with unstable psychological conditions or that are suicidal. However, persons with these conditions will not be allowed to participate in this study.

Other risks from participating in the study include the breach of confidentiality about your health status and participation in the study. This is very unlikely to occur, as all study investigators are trained and certified in research privacy.

We will also ask you to have your blood drawn at three times during the study. The risks involved in drawing blood from a vein may include, but are not limited to, momentary discomfort at the site of the blood draw, possible bruising, redness, and swelling around the site,

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bleeding at the site, feeling of lightheadedness when the blood is drawn, and rarely, an infection at the site of the blood draw. There are no major risks associated with these procedures.

Benefits

There are potential benefits resulting from the study including decreased physical discomfort and improved quality of life. This study may also provide better insights to mind-body treatments for chronic symptoms that may lead to new treatments in the future.

Economic Considerations

The stress reduction classes (or support group) will be provided to you free of charge. There are no other costs associated with your participation in the study.
To thank you for participation, we will pay you with a visa gift card of $ 50 for your baseline visit, $50 for your eight week visit, and $50 for your three month visit. Parking will be provided free of charge.

Treatment Alternatives/Alternatives

If you choose not to participate in this study, there are no alternative treatments available, except those that are already being administered by your physician including pharmacotherapy (medications/drugs), exercise plans, and psychological treatments. You may choose not to participate.

Confidentiality and Privacy

Any identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission or as required by U.S. or State law. Examples of information that we are legally required to disclose include abuse of a child or elderly person, or certain reportable diseases. Information will be kept confidential by using only identification numbers on study forms, storing signed forms in locked cabinets, and password protecting data stored on a computer. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific permission for this activity is obtained.

We understand that information about your health is personal, and we are committed to protecting the privacy of that information. If you decide to be in this study, the researcher will get information that identifies your personal health information. This may include information that might directly identify you, such as his or her name and address, telephone number, and email address, or mobile phone number. This information will be de-identified at the earliest reasonable time after we receive it, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator will keep a link that identifies you and your coded information, and this link will be kept secure and available only to the principal investigator or selected members of the research team. Any information that can identify you will remain confidential. Information will be kept confidential by using only identification numbers on study forms, storing signed forms in locked cabinets, and password

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protecting data stored on a computer. The research team will only give this coded information to others to carry out this research study. The link to your personal information will be kept for 5 years, after which time the link will be destroyed and the data will become anonymous. The data will be kept in this anonymous form indefinitely.

The information about your health that will be collected in this study includes:

- Research study records
- Records about phone calls made as part of this research
- Records about your study visits

Information about your health which might identify your child may be used by or given to:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University, the Yale Human Research Protection Program and the Yale Human Investigation Committee (the committee that reviews, approves, and monitors research on human subjects), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- Those individuals at Yale who are responsible for the financial oversight of research including billings and payments
- The Principal Investigator (Dr. Joan Monin)
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team

By signing this form, you authorize the use and/or disclosure of the information described above for this research study. The purpose for the uses and disclosures you are authorizing is to ensure that the information relating to this research is available to all parties who may need it for research purposes.

All health care providers subject to HIPAA (Health Insurance Portability and Accountability Act) are required to protect the privacy of your information. The research staff at the Yale School of Medicine are required to comply with HIPAA and to ensure the confidentiality of your child's information.

If you choose to participate in this study, the investigators will check your electronic medical record at Yale (EPIC) to make sure you qualify. Any access to your electronic medical record will be done consistent with HIPAA regulations.

Some of the individuals or agencies listed above may not be subject to HIPAA and therefore may not be required to provide the same type of confidentiality protection. They could use or disclose your information in ways not mentioned in this form. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

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You have the right to review and copy your health information in your medical record in accordance with institutional medical records policies. This authorization to use and disclose your health information collected during your participation in this study will never expire.

Voluntary Participation and Withdrawal

You are free to choose not to participate in this study. Your health care outside the study, the payment for your health care, and your health care benefits will not be affected if you do not agree to participate. However, you will not be able to enroll in this research study and will not receive study procedures as a study participant if you do not allow use of your information as part of this study. You do not give up any of your legal rights by signing this form.

Withdrawing From the Study

If you do not become a subject, you are free to stop and withdraw from this study at any time during its course.

To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part. This will cancel any future appointments.

The researchers may withdraw you from participating in the research if necessary. This will only occur if you do not attend the assigned weekly sessions.

If you choose not to participate or if you withdraw it will not harm your relationship with your own doctors or with the Yale School of Medicine and Yale New-Haven Hospital.

Withdrawing Your Authorization to Use and Disclose Your Health Information

You may withdraw or take away permission to use and disclose your health information at any time. You do this by calling or sending written notice to the Principal Investigator, Dr. Joan Monin Department of Social and Behavioral Sciences, Yale School of Public Health, 60 College Street, New Haven, CT 06520.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to insure the integrity of the study and/or study oversight.

You do not give up any of your legal rights by signing this form.

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Questions

We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider this research and the permission form carefully – as long as you feel is necessary – before you make a decision.

Authorization

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the particulars of my involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

Name of Subject:_____

Signature:_____

Relationship:_____

Date:_____

_____ _____
Signature of Principal Investigator Date

or

_____ _____
Signature of Person Obtaining Consent Date

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator, Dr. Joan Monin at 203 785 2895.

If, after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at 203-432-5919. If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Investigation Committee at (203) 785-4688.

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