INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR
Mindfulness Management of Low Risk Chest Pain Associated with Anxiety

ABOUT THIS RESEARCH

You are invited to participate in a research study of chest pain. You were selected as a possible subject because you presented to the Emergency Department with a chief complaint of chest pain**.** Please read this form and ask any questions you may have before agreeing to be in the study.

The study is being conducted by Paul I. Musey, MD of Indiana University School of Medicine. This study is being funded by Indiana University Health Values Fund and the National Institute of Health.

Taking Part in this Research Study is Voluntary

You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with your health care providers and staff.

How many people will take part in this study?

If you agree to participate, you will be one of 40 subjects who will be participating in this research.

Why is this research being done?

This research is being conducted to better understand the underlying characteristics of people who present to the Emergency Department with low risk chest pain associated with stress or anxiety, including how often they use the healthcare system for their pain and any outcomes relevant to patient care in the Emergency Department. Additionally, we hope to explore options for treatment of chest pain thought to be low risk for heart attack or other conditions of the heart when patients are referred from the Emergency Department.

What will happen to me during the study?

If you agree to be in the study, you will do the following things:

Be assigned to one of two study arms based on a blinded recruitment schedule. Thus we are unable to tell you which treatment group you will be assigned to. You may be assigned to the Mindfulness Based Stress Reduction (MBSR) Arm of this study, in which case you would be asked to attend group MBSR sessions with a trained therapist that we will supply to you. This training program will consist of 8 weekly group therapy sessions 2.5 hours in length and one 7 hour retreat over the course of 8 weeks. MBSR has been used widely to manage pain, anxiety, depression and chronic disease process, and focuses on mindfulness skills aimed at facilitating adaptive coping strategies for stress and anxiety. The therapist will encourage you to practice mindfulness at home.

You may be assigned to the Standard of Care arm of this study, in which case you will receive a standard of care referral from your ED physician to your PCP and/or Psychiatry for follow up and further evaluation and management of your symptoms. It will be up to you to make your PCP and/or Psychiatry follow up appointments, although we will provide you with information to help you do so. If you choose to utilize this referral you will be expected to make all appointments with a trained psychiatrist if and when you deem necessary.

Take part in questionnaires administered by one of our research personnel in the Emergency Department at time of enrollment into the study. These questionnaires consist of questions regarding your:

- Current chest pain
- Levels of stress or anxiety you have been experiencing
- Past medical history
- Medications you may be taking
- Healthcare use over the past year
- The effect the pain has on your quality of life
- The psychological and physical impact of your pain

Additionally, we will access your medical record for up to a year from your ED visit to see what your ultimate diagnosis was in addition to any lab work, imaging, other tests used, and the costs associated with helping to

determine what caused your chest pain.

We will contact you by phone or e-mail around 45 days, 3 months, 6 months, and 1 year from your ED visit to check on how you are doing using the same questionnaires described above, as well as to see if your chest pain required any further evaluations in the Emergency Department or with consultants. These follow up questionnaires are expected to take approximately 30 minutes to complete at each time point. Please indicate below your preference for being contacted. A phone call would include us asking the questions over the phone. Email would allow us to send the questionnaires to you to fill out and then return. Please note that email is not considered a secure form of communication and we cannot guarantee absolute confidentiality. Indicate your preference by circling your preferences below. You can circle more than one.

Phone contact: 1st choice 2nd choice do not call me to do the questionnaires

Email contact: 1st choice 2nd choice do not email me to do the questionnaires

Initial_____Date: _____

How long will I participate?

Your participation will last for one year.

Will I benefit from the study?

It is possible that you may benefit from taking part in this study; however, there is no guarantee that it will help you.

- It is possible that you may benefit from the treatment options involved with taking part in this study as you are being referred to your PCP and/or Psychiatry. If you do follow up, it is possible that you may have improvement in your symptoms while under the care of these professionals. However, there is no guarantee that it will help you.
- This information will help us to determine how to best allocate resources to help patients like you in the future.

Will taking part expose me to risks?

While on the study, the risks are:

- A minor risk of completing the questionnaires is being uncomfortable answering some of the questions.
- A minor risk, if you are assigned to the MBSR group, is being uncomfortable talking about your experiences in a group setting.
- A risk of possible loss of confidentiality.

To help minimize these risks:

- While completing the questionnaires, you can tell the researcher if you feel uncomfortable or do not want to answer a particular question.
- During the MBSR therapy, if you experience discomfort you will be able to take a break from the therapy session or you have the option of withdrawing from the study at any time.
- Your records will be protected to help prevent loss of confidentiality.

WILL I RECEIVE MY RESULTS?

We may learn things about you from the study activities which could be important to your health or to your treatment. If this happens, this information will be provided to you. Specifically, if your survey answers reveal possible severe depression or suicidal thoughts we will notify you and provide instructions on how to seek help. You may need to meet with professionals with expertise to help you learn more about your research results. The study team/study will not cover the costs for any medical evaluations.

Do I have other options besides taking part in this study?

Instead of being in the study, you have the option not to participate. Your decision will not change your

relationship with your doctors or IU Health.

Will I be paid to participate?

You will receive compensation for the time you spend answering interview questions. You will be eligible for a total of $160. You will receive $40 for completing the interview in the Emergency Department and another $30 upon completion of each of the four possible follow-ups and questionnaires. Additionally, if you are assigned to the MBSR arm, you will receive $10 per session you attend to defray your transportation costs because the classes are typically held at locations other than the hospital. This will be provided at the end of the MBSR sessions. Compensation will be in the form of gift cards or disbursement voucher.

Will it cost me anything to participate?

You will not be responsible for any costs related to the research; however, you or your insurance company will still be responsible for the cost of your normal medical care.

HOW WILL MY INFORMATION BE PROTECTED?

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Your identity will be held in confidence in reports in which the study may be published.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, Indiana University Health and (as allowed by law) state or federal agencies, specifically the Office for Human Research Protections (OHRP), the NIH etc., who may need to access your medical and/or research records.

A description of this clinical trial will be available on 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.

For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:

1. If there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
2. if you consent to the disclosure, including for your medical treatment;
3. if it is used for other scientific research in a way that is allowed by the federal regulations that protect research subjects
4. for the purpose of auditing or program evaluation by the government or funding agency

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?

Private identifiable information about you (e.g., name, date of birth, contact information) will not be used for future research studies or shared with other researchers.

WHO WILL PAY FOR MY TREATMENT IF I AM INJURED?

As this study is observational only, we do not expect you to have any injuries related to your study participation. In the event of physical injury resulting from your participation in this research, necessary medical treatment will be provided to you and billed as part of your medical expenses. If you have a government insurer, your insurer will not be billed and you may be responsible for those costs. Costs not covered by your health care insurer will

be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. There is no program in place for other monetary compensation for such injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, contact the researcher, Paul Musey, MD at 317-880-3900. If you cannot reach the researcher during regular business hours (i.e., 8 a.m. to 5 p.m.), please call the IU Human Subjects Office at 800-696-2949 or at irb@iu.edu. After business hours, please call the Methodist Hospital operator at 317-962-2000 and request that Dr. Musey be paged.

In the event of an emergency, you may contact Paul Musey, MD at 678-358-9814.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or offer input, contact the IU Human Subjects Office at 800-696-2949 or at irb@iu.edu.

CAN I WITHDRAW FROM THE STUDY?

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Your decision whether or not to participate in this study will not affect your current or future relations with Indiana University Health. The study team will help you withdraw from the study safely. If you wish to withdraw from this study at any time, we ask that you contact our research team to do so at 317-962-5024

At the discretion of the investigator, your participation may be terminated under the following circumstances:

- If you miss the first MBSR session and will not be able or willing to join a different therapy group in the future.
- If we detect severe depression, psychosis or suicidal ideation, we can withdraw you from the study and try to get you emergent treatment.
- If we are unable to contact you for follow-up calls.

SUBJECT'S CONSENT

In consideration of all of the above, I give my consent to participate in this research study.

I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

Subject's Printed Name:_____

Subject's Signature:_____ **Date**:_____
(must be dated by the subject)

Printed Name of Person Obtaining Consent: _____

Signature of Person Obtaining Consent:_____ **Date**:_____