Informed Consent Document

Mindfulness to Enhance Quality of Life and Support Advance Care Planning (MEANING): A Randomized Controlled Pilot Trial for Adults with Metastatic Cancer and Their Family Caregivers

NCT03257007

27 April 2017

INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR

Mindfulness to Enhance Quality of Life and Support Advance Care Planning (MEANING): A Randomized Controlled Pilot Trial for Adults with Metastatic Cancer and Their Family Caregivers

You are invited to participate in a research study for adults living with advanced-stage cancer and their family caregivers. You were selected as a possible subject because you have been diagnosed with advanced-stage cancer. Please read this form and ask any questions you may have before agreeing to be in the study.

The study is being conducted by Dr. Shelley Johns, PsyD, ABPP, Assistant Professor of Medicine, Indiana University School of Medicine. The study is funded by the Walther Cancer Foundation and Indiana University Health.

STUDY PURPOSE

The purpose of this study is to compare the effects of two different treatment approaches on quality of life and other outcomes for adults with advanced-stage cancer and their family caregivers. One approach is based on training in mindfulness meditation and the other approach is standard care that you are currently receiving from your health care team.

NUMBER OF PEOPLE TAKING PART IN THE STUDY

If you agree to participate, you will be one of 60 adults with cancer and 60 family caregivers who will be participating in this research.

PROCEDURES FOR THE STUDY

If you agree to be in the study, you will be asked to invite a family member or close friend to participate in the study with you. Please give preference to the family member or close friend you would choose to make medical decisions for you if you become unable to make your own medical decisions. If a family member or close friend is interested in participating in the study, you will be asked to provide study staff with a way to contact this person so we can discuss the study with them.

If you agree to be in the study, you will be asked to complete a questionnaire on paper or online about your mood, thoughts and feelings about your cancer, and quality of life. You will be asked to complete the study questionnaire three times over approximately a 3-month period. Each study questionnaire will take about 30 minutes to complete. The study questionnaire can be completed on a secure website online, or a paper copy of the questionnaire can be mailed to your home so you may complete it at a time and place convenient for you. If you choose to complete a paper-based survey, you will be asked to mail it back to us in a study-addressed pre-stamped envelope that will be provided to you. You will also be asked to complete a test of your mindfulness ability on a computer.

After you complete the first study questionnaire, you and your family member or friend will be randomly assigned by a computer to one of the two treatment approaches we are testing in this study—either a mindfulness meditation class or standard care.

- If you are assigned to the mindfulness meditation group, you will continue to receive standard care from your health care team and you and your family member or friend who joins the study with you will be asked to attend a mindfulness meditation class. The class will consist of 6 weekly 2-hour group meetings led by an experienced health care provider who has cared for people with cancer. The course will cover mindfulness meditation practices and gentle stretching (with all movements tailored to your specific needs and abilities), education to enhance coping skills, and time for group discussion. In addition to attending the mindfulness sessions, you will be asked to practice mindfulness skills at home 6 days a week for 20 minutes per day, using audio recordings that will be provided to you by the instructor.

- If you are assigned to the standard care group, you will continue to meet with your medical team as usual and continue to receive care from them. At the end of your involvement in the study, you will receive a packet of materials that may be useful to you in coping with cancer.

Regardless of what group you are randomly assigned to, you may also be contacted for an optional, audio-recorded telephone interview approximately 6-8 weeks after enrolling in the study. A member of our research team will call at a conveniently scheduled time for you and ask you additional questions about your experiences participating in the study. The telephone interview is planned to take about 30 minutes.

RISKS OF TAKING PART IN THE STUDY

The risks involved in this study are minimal. You may feel uncomfortable answering some of the questions on the study questionnaire. If so, you can discuss your concerns with a member of the study team and/or skip any of the questions. If you feel sad or distressed during the study, you can discuss your feelings with a member of the study team. You do not have to do any study-related task that feels uncomfortable or upsetting. There is also a risk of possible loss of confidentiality if someone not connected with the study is able to see the information we collect from you. We will follow strict rules to prevent this from happening. For example, we will identify the information you provide to us with a unique number and not your name. We will keep all information collected in databases that require a private passphrase to access or stored in locked filing cabinets in a locked office.

BENEFITS OF TAKING PART IN THE STUDY

If you agree to take part in this study, there may or may not be direct benefit to you. The benefits of participating that are reasonable to expect include an improvement in your quality of life and reduced distress. Your participation may benefit society as a whole because results of this study may help inform the care of others with cancer and their family caregivers in the future.

ALTERNATIVES TO TAKING PART IN THE STUDY

Instead of being in this study, you have the option of not participating. Taking part in the study is voluntary.

CONFIDENTIALITY

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 her research associates, the Indiana University Institutional Review Board or its designees, the study sponsor, Walther Cancer Foundation, and (as allowed by law) state or federal agencies, specifically the Office for Human Research Protections (OHRP) who may need to access your medical and/or research records.

COSTS

Taking part in this study will not lead to any added costs to you or your insurance company.

PAYMENT

You will receive $25 for each of the three study questionnaires you complete, and an additional $25 if you complete a phone interview 6-8 weeks after enrolling in the study. Thus, you will be given a gift card of up to $100 in value at the end of your involvement in the study in approximately 3 months. If you leave the study prior to completing all of the assessments, you will receive a gift card for the value of the assessments you have completed.

COMPENSATION FOR INJURY

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. 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.

CONTACTS FOR QUESTIONS OR PROBLEMS

For questions about the study or a research-related injury, contact the principal investigator, Dr. Shelley Johns, at **317-274-9127**. If you cannot reach the researcher during regular business hours (i.e. 8:00AM-5:00PM), please call the IU Human Subjects Office at (317) 278-3458 or (800) 696-2949.

For questions about your rights as a research participant or to discuss problems, complaints or concerns about a research study, or to obtain information, or offer input, contact the IU Human Subjects Office at (317) 278-3458 or (800) 696-2949.

VOLUNTARY NATURE OF THIS STUDY

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. If you and your family member or friend join the study and you decide to leave the study, your family member or friend can continue to participant in the study. Likewise, if your family member or friend decides to leave the study, you can continue to participate. 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 Melvin & Bren Simon Cancer Center, Indiana University School of Medicine, or Indiana University Health.

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**:_____

INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR

Mindfulness to Enhance Quality of Life and Support Advance Care Planning (MEANING): A Randomized Controlled Pilot Trial for Adults with Metastatic Cancer and Their Family Caregivers

You are invited to participate in a research study for adults living with advanced-stage cancer and their family caregivers. You were selected as a possible subject by your family member or close friend with advanced-stage cancer. Please read this form and ask any questions you may have before agreeing to be in the study.

The study is being conducted by Dr. Shelley Johns, PsyD, ABPP, Assistant Professor of Medicine, Indiana University School of Medicine. The study is funded by the Walther Cancer Foundation and Indiana University Health.

STUDY PURPOSE

The purpose of this study is to compare the effects of two different treatment approaches on quality of life and other outcomes for adults with advanced-stage cancer and their family caregivers. One approach is based on training in mindfulness meditation. The other approach is standard care that you and your family member or friend with cancer is currently receiving from your health care team.

NUMBER OF PEOPLE TAKING PART IN THE STUDY

If you agree to participate, you will be one of 60 adults with cancer and 60 family caregivers who will be participating in this research.

PROCEDURES FOR THE STUDY

If you agree to be in the study, you will be asked to complete a questionnaire on paper or online about your mood, thoughts and feelings about your loved one's cancer, and quality of life. You will be asked to complete the study questionnaire three times over approximately a 3-month period. Each study questionnaire will take about 30 minutes to complete. The study questionnaire can be completed on a secure website online, or a paper copy of the questionnaire can be mailed to your home so you may complete it at a time and place convenient for you. If you choose to complete a paper-based survey, you will be asked to mail it back to us in a study-addressed pre-stamped envelope that will be provided to you. You will also be asked to complete a test of your mindfulness ability on a computer.

After you complete the first study questionnaire, you and your family member or friend with cancer will be randomly assigned by a computer to one of the two treatment approaches we are testing in this study—either a mindfulness meditation class or standard care.

- If you are assigned to the mindfulness meditation group, you and your loved one will continue to receive standard care from your health care team and you both will be asked to attend a mindfulness meditation class. The class will consist of 6 weekly 2-hour group meetings led by an experienced health care provider who has cared for people with cancer. The course will cover mindfulness meditation practices and gentle stretching (with all movements tailored to your specific needs and abilities), education to enhance coping skills, and time for group discussion. In addition to attending the mindfulness sessions, you will be asked to practice mindfulness skills at home 6 days a week for 20 minutes per day, using audio recordings that will be provided to you by the instructor.

- If you are assigned to the standard care group, your loved one with cancer will continue to meet with your medical team as usual and continue to receive care from them. At the end of your involvement in the study, you will receive a packet of materials that may be useful to you in coping with your loved one's cancer.

Regardless of what group you are randomly assigned to, you may also be contacted for an optional, audio-recorded telephone interview approximately 6-8 weeks after enrolling in the study. A member of our research team will call at a conveniently scheduled time for you and ask you additional questions about your experiences participating in the study. The telephone interview is planned to take about 30 minutes.

RISKS OF TAKING PART IN THE STUDY

The risks involved in this study are minimal. You may feel uncomfortable answering some of the questions on the study questionnaire. If so, you can discuss your concerns with a member of the study team and/or skip any of the questions. If you feel sad or distressed during the study, you can discuss your feelings with a member of the study team. You do not have to do any study-related task that feels uncomfortable or upsetting. There is also a risk of possible loss of confidentiality if someone not connected with the study is able to see the information we collect from you. We will follow strict rules to prevent this from happening. For example, we will identify the information you provide to us with a unique number and not your name. We will keep all information collected in databases that require a private passphrase to access or stored in locked filing cabinets in a locked office.

BENEFITS OF TAKING PART IN THE STUDY

If you agree to take part in this study, there may or may not be direct benefit to you. The benefits of participating that are reasonable to expect include an improvement in your quality of life and reduced distress. Your participation may benefit society as a whole because results of this study may help inform the care of others with cancer and their family caregivers in the future.

ALTERNATIVES TO TAKING PART IN THE STUDY

Instead of being in this study, you have the option of not participating. Taking part in the study is voluntary.

CONFIDENTIALITY

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 her research associates, the Indiana University Institutional Review Board or its designees, the study sponsor, Walther Cancer Foundation, and (as allowed by law) state or federal agencies, specifically the Office for Human Research Protections (OHRP) who may need to access your medical and/or research records.

COSTS

Taking part in this study will not lead to any added costs to you or your insurance company.

PAYMENT

You will receive $25 for each of the three study questionnaires you complete, and an additional $25 if you complete a phone interview 6-8 weeks after enrolling in the study. Thus, you will be given a gift card of up to $100 in value at the end of your involvement in the study in approximately 3 months. If you leave the study prior to completing all of the assessments, you will receive a gift card for the value of the assessments you have completed.

COMPENSATION FOR INJURY

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. 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.

CONTACTS FOR QUESTIONS OR PROBLEMS

For questions about the study or a research-related injury, contact the principal investigator, Dr. Shelley Johns, at **317-274-9127**. If you cannot reach the researcher during regular business hours (i.e. 8:00AM-5:00PM), please call the IU Human Subjects Office at (317) 278-3458 or (800) 696-2949.

For questions about your rights as a research participant or to discuss problems, complaints or concerns about a research study, or to obtain information, or offer input, contact the IU Human Subjects Office at (317) 278-3458 or (800) 696-2949.

VOLUNTARY NATURE OF THIS STUDY

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. If you and your family member of friend with cancer join the study and you decide to leave the study, your loved one with cancer can continue to participant in the study. Likewise, if your loved one with cancer decides to leave the study, you can continue to participate. 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 Melvin & Bren Simon Cancer Center, Indiana University School of Medicine, or Indiana University Health.

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**:_____