Title of Research Study: Psycho-Spiritual Management for Patients with Advanced Cancer and their Family Caregivers

Study Number: 2023-0450

Subtitle: Caregiver

Principal Investigator: Kathrin Milbury

_____ _____
Participant's Name Medical Record Number or Study ID

Key Information

The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

You are invited to take part in this research study because you are a caregiver of a family member diagnosed with a breast, thoracic, gastrointestinal, gynecological, or genitourinary cancer receiving cancer treatment at MD Anderson or Memorial Hermann at the Texas Medical Center or Medical College of Wisconsin in Milwaukee, Wisconsin.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The goal of this behavioral research study is to learn about the effects of two different supportive care programs on patients' and their family caregivers' psychological wellbeing and overall quality of life.

To participate in this study, both you and your family member must agree to take part together. If your family member does not agree to take part, you cannot participate.

How long will the research last and what will I need to do?

You will be asked to answer a set of questionnaires 4 times and you may be asked to attend program sessions. Your participation on this study will be over when you have completed the last questionnaire set about 6 months after you have enrolled in the study.

More detailed information about the study procedures can be found under ***"What happens if I agree to be in this research?"***

Is there any way being in this study could be bad for me?

Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side effects, potential expenses, and time commitment. You may choose not to take part in this study because you are too busy or too distressed.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

Taking part in the intervention sessions may help you feel supported and less overwhelmed. Future patients and their caregivers may benefit from what is learned in this study. However, it cannot be promised that there will be any benefits to you or others from your taking part in this research.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate, not participate, or stop participation at any time without penalty or loss of your regular benefits.

Your alternative to participating in this research study is to not participate.

Detailed Information

The following is more detailed information about this study in addition to the information listed above.

Who can I talk to if I have questions or concerns?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to Dr. Kathrin Milbury at 713-745-2868.

This research has been reviewed and approved by an Institutional Review Board ("IRB" - an ethics committee that reviews research studies). You may talk to them at (713) 792-6477 or IRB_Help@mdanderson.org if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be in this study?

It is expected that about 600 people (300 caregivers and 300 patients, 100 dyads per group) will be enrolled in this research study. It will take place at MD Anderson and Memorial Hermann at the Texas Medical Center and or Medical College of Wisconsin in Milwaukee, Wisconsin.

What happens if I agree to be in this research?

Baseline Assessment

If you agree to take part in this study, you will be asked to complete a baseline assessment of questionnaires that will ask you about your:

- Demographic information (such as your age, sex, and race)
- Psychological and physical health
- Family member's symptoms
- Relationship with patient
- Quality of Life

You will be asked to complete this assessment on your own time, and it should take about 30 minutes. Your family member will also complete a baseline assessment. Do not share your responses with your family member or ask about his or her responses. The study staff will not share your responses with them either.

A link will be sent to your email address to complete these questionnaires electronically. If you prefer, you may ask to fill out a paper copy or complete it over the phone with a study staff member. The study staff will send you up to 3 emails and call you up to 2 times to remind you to complete the assessment.

The surveys and programs may be delivered in English or Spanish based on your preference.

Study Groups

After the baseline assessment is completed, you and your family member will be randomly assigned to 1 of 3 study groups. You will have an equal chance of being assigned to either group. This is done because no one knows if one study group is better, the same, or worse than the other group.

- **If you are enrolled in Group 1**, you will take part in a family-focused meditation program.
- **If you are enrolled in Group 2**, you will take part in a family-focused cancer-related discussion program.
- **If you are enrolled in Group 3**, you will not take part in the family-focused meditation or cancer-related discussion program but will complete the same questionnaires as Group 1 and 2.

All caregivers enrolled in this study will complete the follow-up assessments (described below under “Follow-Up Assessments”).

Meditation and Discussion Program for Group 1

If you are in **Group 1**, you will take part in a meditation program. As part of this program, you will complete up to 4 meditation sessions with a trained counselor. You should attend each session together as a family. All sessions will beonline by videoconference using Zoom.

During the meditation sessions, you will be asked to take part in relaxation training including deep breathing and visualization exercises. You will discuss your experiences and observations afterwards and engage in structured discussion with your familymember and program leader. Each session will last 45-60 minutes.

You will be asked to continue daily meditation practice and some other short exercises at home outside of the classes. You will receive audio files and printed/electronic materials to help with your home practice.

Cancer-Related Discussion Program for Group 2

If you are in **Group 2**, you will take part in a discussion program. You will be asked to complete 4 discussion sessions with a trained counselor over a course of a 4 week period. You should attend each session together as a family.

During the discussion sessions, you will discuss common concerns for families coping with cancer. Each session will last about 45-60 minutes.

For Groups 1 and 2

All meditation and discussion sessions will be audio recorded. This is so the researchers can keep track of the quality of the sessions. The audio files are digital and will be deleted after all the data are studied.

Follow-Up Assessments

About 8 weeks, 12 weeks, and 6 months after completing the baseline assessment, you will be asked to complete a follow-up assessment of questionnaires. The survey will ask you about your psychological health, physical symptoms, and quality of life. These should take about 15 minutes to complete.

EOL Transition Assessment and Interview

If a patient transitions to hospice care within one year of participation, we will contact you by phone to learn about your experience with the care transition within about 2 weeks of this transition.

What happens if I say yes, but I change my mind later?

You can leave the research at any time; it will not be held against you.

You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits.

If you stop being in the research, already collected data may not be removed from the study database.

Is there any way being in this study could be bad for me? (Detailed Risks)

You should discuss the risks of **program sessions** and **questionnaires** with the study doctor. The known risks are listed in this form, but they will vary from person to person. You may discuss topics and be asked questions that are sensitive in nature. Some questions may make you feel upset or uncomfortable. You may refuse to answer any question. If you have concerns about completing the sessions or questionnaires, you are encouraged to contact the study chair.

If your questionnaire responses show that you may be having emotional difficulties, depression, or risk of harm to yourself, the study staff will contact your supportive care physician and you may be contacted by a psychologist working in the Department of Palliative Care.

Although every effort will be made to keep **study data** safe, there is a chance that your personal health information could be lost or stolen, which may result in a **loss of confidentiality**. All study data will be stored in password-protected computers and/or locked file cabinets and will continue to be stored securely after the study. Only staff members involved with this research study will have access to the study data.

This study may involve unpredictable risks to the participants.

You will be told about any new information that may affect your health, welfare, or choice to stay in the research.

Will it cost anything to be in this study? Will I be paid to be in this study?

There is no cost to you for taking part in this study.

As compensation for your time and effort, you will receive a gift card for $40 after completing the baseline assessment, and if it applies to you, care transition assessment. You will receive a $20 gift card upon completion of the Week 6, Week 12, and 6 month follow-up assessments (up to $140 total in gift cards per person).

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who need to review this information. Complete secrecy cannot be promised. Organizations that may inspect and copy your information include the IRB and other representatives of this organization

A participant study number will be assigned to you once you have been enrolled in the study. This participant study number will be used to identify your data in the study report and when reporting any data from the study.

Any personal information that could identify you will be removed or changed before data are shared with other researchers or results are made public.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm

yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Federal law provides additional protections of your medical records and related health information. These are described below.

Will my data be used for future research?

Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson, the National Institutes of Health, or shared with other researchers and/or institutions for use in future research.

In some cases, all of your identifying information may not be removed before your data is used for future research. If future research is performed at MD Anderson, the researchers must get approval from the MD Anderson IRB before your data can be used. At that time, the IRB will decide whether or not further permission from you is required. If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data.

If identifiers are removed from your identifiable private information that are collected during this research, that information could be used for future research studies or shared with another researcher for future research studies without your additional informed consent.

Can I be removed from the research study without my permission?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include if you are unable to follow study directions or if the study is stopped.

What happens if I get hurt from being in this study?

If you get sick or hurt and it is related to your participation in this study, you will be given care at MD Anderson (if you are at the clinic when you are sick or hurt). If you get hurt or sick and you are not at the clinic (for example, you are at home or at another doctor's office):

- call your personal doctor right away (or in an emergency, call 911)
- tell your personal doctor or ER staff that you are in this study (try to give them a copy of this consent form or show them your participant card)

- call the study doctor (Dr. Kathrin Milbury, at 713-745-2868)

You will not be reimbursed for expenses or compensated financially by MD Anderson for this injury. Costs of treatment received because you were hurt or sick will be billed to you or your insurance company. No other form of payment is available.

You may also contact the MD Anderson IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

What else do I need to know?

This research is being funded by the National Institutes of Health.

MD Anderson may benefit from your participation and/or what is learned in this study.

Your information (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

Optional Procedures for the Study

You do not have to agree to the optional procedure in order to take part in this study. There are no benefits to you for taking part in the optional procedure. Future patients and caregivers may benefit from what is learned. You may stop taking part at any time. There will be no cost to you for taking part in the optional procedures.

Optional Procedure #1: Participants in all three arms will wear a smart phone device called the Electronically Activated Recorder (EAR) as much as possible during your waking hours for 2 weekend days at the T1 and T2 assessment point. The EAR is a tool to assess your daily life that records sounds from your environment for 30 seconds at a time, which is approximately 5% of the time you will wear it. While you wear the EAR, it will record parts of your spoken conversations and sounds from your immediate environment (e.g., television or radio). You will be given specific instructions about how to wear the EAR and how to use the ‘privacy button’ to temporarily mute the device if you do not want it to record.

At the end of the study, you will have the opportunity to listen to your audio recordings remotely or in a private room in the research laboratory or clinic and tell the research team if you wish to delete any of them before anyone on the research team listens to them. The researchers will not ask you anything about the deleted sound files other than which ones to delete.

Participants can opt out of this procedure while still participating in this study.

Optional Procedure Risks

EAR Audio Recordings:

There is a possibility that the EAR could record information that State or Federal law requires to be reported to other officials (such as child or elder abuse) or ethically requires action (such as suicidal or homicidal thoughts). The researchers will not listen to the audio recordings until months after your involvement in the study is complete, so even if this information was recorded, the research team would not be able to report it until well after the actual event(s). The researchers are thus instructed to call 911 in case of an emergency.

You may feel a loss of privacy in your conversations with family, friends, or others with whom you may interact socially while wearing the EAR device. The EAR will be programmed to record for 30 seconds at a time so that the broader context of your conversations is less detectable by the researchers. At the end of the study, you will have the opportunity to listen to your audio recordings remotely or in a private room in the research laboratory or clinic and tell the research team if you wish to delete any of them. The researchers will not listen to any of your audio recordings until after you have given your permission.

CONSENT/PERMISSION/AUTHORIZATION FOR OPTIONAL PROCEDURES

Circle your choice of "yes" or "no" for each of the following optional procedures:

Optional Procedure #1: Do you agree to participate in the EAR audio recordings as described above?

YES NO

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:
   - The Office for Human Research Protections (OHRP)
   - The IRB and officials of MD Anderson
   - National Institutes of Health, who is a sponsor or supporter of this study, and/or any future sponsors/supporters of the study, and/or licensees of the study technology
   - Research collaborators (including Dr. Kelly Rentscher's team at Medical College of Wisconsin [MCW] at Dr. Meagan Whisenant at UT Health in Houston Texas)
   - Study monitors and auditors who verify the accuracy of the information

- Individuals who put all the study information together in report form

Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it.

The audio recordings collected during this study will be made available electronically to Dr. Rentscher's team at MCW. The recordings will be de-identified as much as possible, so that your identifying information will not be shared. Dr. Rentscher's team will transcribe (type out the words/descriptions) and code the audio files before returning them to Dr. Milbury's team in order to complete the study analysis.

The interview recordings collected during this study will be made available electronically to Dr. Whisenant at UTHealth. The recordings will be de-identified as much as possible, so that your identifying information will not be shared.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible (according to state and federal law).

   Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT

Title of Research Study: Psycho-Spiritual Management for Patients with Advanced Cancer and their Family Caregivers

Study Number: 2023-0450

Subtitle: Patient

Principal Investigator: Kathrin Milbury

_____ _____
Participant's Name Medical Record Number or Study ID

Key Information

The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

You are invited to take part in this research study because you have been diagnosed with a breast, thoracic, gastrointestinal, gynecological, or genitourinary cancer and are receiving cancer treatment at MD Anderson or Memorial Hermann at the Texas Medical Center or Medical College of Wisconsin in Milwaukee, Wisconsin.

What should I know about a research study?

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- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The goal of this behavioral research study is to learn about the effects of two different supportive care programs on patients' and their family caregivers' psychological wellbeing and overall quality of life.

To participate in this study, both you and your caregiver must agree to take part together. If your caregiver does not agree to take part, you cannot participate.

How long will the research last and what will I need to do?

You will be asked to answer a set of questionnaires 4 times and you may be asked to attend program sessions. Your participation on this study will be over when you have completed the last questionnaire set about 6 months after you have enrolled in the study.

More detailed information about the study procedures can be found under ***"What happens if I agree to be in this research?"***

Is there any way being in this study could be bad for me?

Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side effects, potential expenses, and time commitment. You may choose not to take part in this study because you are too busy or too distressed.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

By taking part in the intervention sessions, you may feel supported and less overwhelmed which may help to improve your psychological and physical health. Future patients and their caregivers may benefit from what is learned in this study. However, it cannot be promised that there will be any benefits to you or others from your taking part in this research.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate, not participate, or stop participation at any time without penalty or loss of your regular benefits.

Your alternative to participating in this research study is to not participate.

Detailed Information

The following is more detailed information about this study in addition to the information listed above.

Who can I talk to if I have questions or concerns?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to Dr. Kathrin Milbury 713-745-2868.

This research has been reviewed and approved by an Institutional Review Board ("IRB" - an ethics committee that reviews research studies). You may talk to them at (713) 792-6477 or IRB_Help@mdanderson.org if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be in this study?

It is expected that about 600 people (300 caregivers and 300 patients, 100 dyads per group) will be enrolled in this research study. It will take place at MD Anderson and Memorial Hermann at the Texas Medical Center and or Medical College of Wisconsin in Milwaukee, Wisconsin.

What happens if I agree to be in this research?

Baseline Assessment

If you agree to take part in this study, you will be asked to complete a baseline assessment of questionnaires that will ask you about your:

- Demographic information (such as your age, sex, and race)
- Psychological and physical health
- Relationship with family caregiver
- Quality of Life

You will be asked to complete this assessment on your own time, and it should take about 30 minutes. Your family member will also complete a baseline assessment. Do not share your responses with your caregiver or ask your caregiver about his or her responses. The study staff will not share your responses with them either.

A link will be sent to your email address to complete these questionnaires electronically. If you prefer, you may ask to fill out a paper copy or complete it over the phone with a study staff member. The study staff will send you up to 3 emails and call you up to 2 times to remind you to complete the assessment.

The surveys and programs may be delivered in English or Spanish based on your preference.

Study Groups

After the baseline assessment is completed, you and your family caregiver will be randomly assigned to 1 of 3 study groups. You will have an equal chance of being assigned to either group. This is done because no one knows if one study group is better, the same, or worse than the other group.

- **If you are enrolled in Group 1**, you will take part in a family-focused meditation program.
- **If you are enrolled in Group 2**, you will take part in a family-focused cancer-related discussion program.
- **If you are enrolled in Group 3**, you will not take part in the family-focused meditation or cancer-related discussion program but will complete the same questionnaires as Group 1 and 2.

All patients enrolled in this study will complete the follow-up assessments and have health information collected (described below under “Follow-Up Assessments” and “Health Information Collection”).

Meditation and Discussion Program for Group 1

If you are in **Group 1**, you will take part in a meditation program. As part of this program, you will complete up to 4 meditation sessions with a trained counselor. You should attend each session together as a family. All sessions will beonline by videoconference using Zoom.

During the meditation sessions, you will be asked to take part in relaxation training including deep breathing and visualization exercises. You will discuss your experiences and observations afterwards and engage in structured discussion with your family member and program leader. Each session will last 45-60 minutes .

You will be asked to continue daily meditation practice and some other short exercises at home outside of the classes. You will receive audio files and printed/electronic materials to help with your home practice.

Cancer-Related Discussion Program for Group 2

If you are in **Group 2**, you will take part in a discussion program. You will be asked to complete 4 discussion sessions with a trained counselor over a course of a 4 week period. You should attend each session together as a family.

During the discussion sessions, you will discuss common concerns for families coping with cancer. Each session will last about 45-60 minutes.

For Groups 1 and 2
All meditation and discussion sessions will be audio recorded. This is so the researchers can keep track of the quality of the sessions. The audio files are digital and will be deleted after all the data are studied.

Follow-Up Assessments
About 8 weeks, 12 weeks, and 6 months after completing the baseline assessment, you will be asked to complete a follow-up assessment of questionnaires. The survey will ask you about your psychological health, physical symptoms, and quality of life. These should take about 15 minutes to complete.

EOL Transition Assessment and Interview
If a patient transitions to hospice care within one year of participation, we will contact you by phone to learn about your experience with the care transition within about 2 weeks of this transition.

Health Information Collection
The study team will also collect personal health information from your medical record about your cancer (such as the tumor location, stage, and diagnosis date) and treatments you have received (such as the type of radiotherapy or chemotherapy, treatment dates, hospitalizations, and emergency department visits).

What happens if I say yes, but I change my mind later?

You can leave the research at any time; it will not be held against you.

You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you withdraw from this study, you can still choose to be treated at MD Anderson.

If you stop being in the research, already collected data may not be removed from the study database.

Is there any way being in this study could be bad for me? (Detailed Risks)

You should discuss the risks of **program sessions** and **questionnaires** with the study doctor. The known risks are listed in this form, but they will vary from person to person. You may discuss topics and be asked questions that are sensitive in nature. Some questions may make you feel upset or uncomfortable. You may refuse to answer any question. If you have concerns about completing the sessions or questionnaires, you are encouraged to contact the study chair.

If your questionnaire responses show that you may be having emotional difficulties, depression, or risk of harm to yourself, the study staff will contact your supportive care physician and you may be contacted by a psychologist working in the Department of Palliative Care.

Although every effort will be made to keep **study data** safe, there is a chance that your personal health information could be lost or stolen, which may result in a **loss of confidentiality**. All study data will be stored in password-protected computers and/or locked file cabinets and will continue to be stored securely after the study. Only staff members involved with this research study will have access to the study data.

This study may involve unpredictable risks to the participants.

You will be told about any new information that may affect your health, welfare, or choice to stay in the research.

Will it cost anything to be in this study? Will I be paid to be in this study?

There is no cost to you for taking part in this study.

As compensation for your time and effort, you will receive a gift card for $40 after completing the baseline assessment, and if it applies to you, care transition assessment. You will receive a $20 gift card upon completion of the Week 6, Week 12, and 6 month follow-up assessments (up to $140 total in gift cards per person).

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Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who need to review this information. Complete secrecy cannot be promised. Organizations that may inspect and copy your information include the IRB and other representatives of this organization

A participant study number will be assigned to you once you have been enrolled in the study. This participant study number will be used to identify your data in the study report and when reporting any data from the study.

Any personal information that could identify you will be removed or changed before data are shared with other researchers or results are made public.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An

example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Federal law provides additional protections of your medical records and related health information. These are described below.

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In some cases, all of your identifying information may not be removed before your data is used for future research. If future research is performed at MD Anderson, the researchers must get approval from the MD Anderson IRB before your data can be used. At that time, the IRB will decide whether or not further permission from you is required. If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data.

If identifiers are removed from your identifiable private information that are collected during this research, that information could be used for future research studies or shared with another researcher for future research studies without your additional informed consent.

Can I be removed from the research study without my permission?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include if you are unable to follow study directions or if the study is stopped.

What happens if I get hurt from being in this study?

If you get sick or hurt and it is related to your participation in this study, you will be given care at MD Anderson (if you are at the clinic when you are sick or hurt). If you get hurt or

sick and you are not at the clinic (for example, you are at home or at another doctor's office):

- call your personal doctor right away (or in an emergency, call 911)
- tell your personal doctor or ER staff that you are in this study (try to give them a copy of this consent form or show them your participant card)
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You may also contact the MD Anderson IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

What else do I need to know?

This research is being funded by the National Institutes of Health.

MD Anderson may benefit from your participation and/or what is learned in this study.

Your information (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

Optional Procedures for the Study

You do not have to agree to the optional procedure in order to take part in this study. There are no benefits to you for taking part in the optional procedure. Future patients and caregivers may benefit from what is learned. You may stop taking part at any time. There will be no cost to you for taking part in the optional procedures.

Optional Procedure #1: Participants in all three arms will wear a smart phone device called the Electronically Activated Recorder (EAR) as much as possible during your waking hours for 2 weekend days at the T1 and T2 assessment point. The EAR is a tool to assess your daily life that records sounds from your environment for 30 seconds at a time, which is approximately 5% of the time you will wear it. While you wear the EAR, it will record parts of your spoken conversations and sounds from your immediate environment (e.g., television or radio). You will be given specific instructions about how to wear the EAR and how to use the 'privacy button' to temporarily mute the device if you do not want it to record.

At the end of the study, you will have the opportunity to listen to your audio recordings remotely or in a private room in the research laboratory or clinic and tell the research team if you wish to delete any of them before anyone on the research team listens to them. The researchers will not ask you anything about the deleted sound files other than which ones to delete.

Participants can opt out of this procedure while still participating in this study.

Optional Procedure Risks

EAR Audio Recordings:

There is a possibility that the EAR could record information that State or Federal law requires to be reported to other officials (such as child or elder abuse) or ethically requires action (such as suicidal or homicidal thoughts). The researchers will not listen to the audio recordings until months after your involvement in the study is complete, so even if this information was recorded, the research team would not be able to report it until well after the actual event(s). The researchers are thus instructed to call 911 in case of an emergency.

You may feel a loss of privacy in your conversations with family, friends, or others with whom you may interact socially while wearing the EAR device. The EAR will be programmed to record for 30 seconds at a time so that the broader context of your conversations is less detectable by the researchers. At the end of the study, you will have the opportunity to listen to your audio recordings remotely or in a private room in the research laboratory or clinic and tell the research team if you wish to delete any of them. The researchers will not listen to any of your audio recordings until after you have given your permission.

CONSENT/PERMISSION/AUTHORIZATION FOR OPTIONAL PROCEDURES

Circle your choice of "yes" or "no" for each of the following optional procedures:

Optional Procedure #1: Do you agree to participate in the EAR audio recordings as described above?

YES NO

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the

research team may share your PHI with:

- The Office for Human Research Protections (OHRP)
- The IRB and officials of MD Anderson
- National Institutes of Health, who is a sponsor or supporter of this study, and/or any future sponsors/supporters of the study, and/or licensees of the study technology
- Research collaborators (including Dr. Kelly Rentscher's team at Medical College of Wisconsin [MCW]) at Dr. Meagan Whisenant at UT Health in Houston, Texas)
- Study monitors and auditors who verify the accuracy of the information
- Individuals who put all the study information together in report form

Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it.

The audio recordings collected during this study will be made available electronically to Dr. Rentscher's team at MCW. The recordings will be de-identified as much as possible, so that your identifying information will not be shared. Dr. Rentscher's team will transcribe (type out the words/descriptions) and code the audio files before returning them to Dr. Milbury's team in order to complete the study analysis.

The interview recordings collected during this study will be made available electronically to Dr. Whisenant at UT Health. The recordings will be de-identified as much as possible, so that your identifying information will not be shared.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible (according to state and federal law).

   Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT