Informed Consent/Authorization for Participation in Research

Title of Research Study: Simulation-Based Caregiving Skills Training for Family Members of High Grade Glioma Patients

Study Number: 2022-0377

Subtitle: Patient, Trial 2

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 high grade glioma (HGG) and are receiving cancer treatment at MD Anderson.

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 research study is to explore the usefulness of intervention sessions for family caregivers of patients with HGG.

Researchers also want to learn if:

- Family caregivers are interested in participating in this type of intervention, find the materials and training helpful, and are able to use the information in their daily lives.
- The intervention can reduce common concerns, improve communication between family caregivers and patients about cancer, and improve the overall psychological wellbeing of caregivers.

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 3 times. Your participation on this study will be over when you have completed the last questionnaire set about 16 weeks 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, your caregiver 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 120 people (60 caregivers and 60 patients) will be enrolled in this research study. All will take part at MD Anderson.

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

You will be asked to complete this assessment on your own time, and it should take about 40 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 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.

Study Groups

After the baseline assessment is completed, you and your family caregiver will be randomly assigned (as in the flip of a coin) to 1 of 2 study groups. You will have an equal chance (50/50) 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**, your family caregiver will take part in the caregiver intervention sessions (described below under "Caregiver Intervention Sessions").
- **If you are enrolled in Group 2**, your family caregiver will not take part in the caregiver intervention sessions during this study.

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").

Caregiver Intervention Sessions
If you are enrolled in Group 1, your family caregiver will take part in 4 caregiver intervention sessions to help them learn how to support you with daily living and how to cope with their caregiving role. One (1) or two (2) sessions will take place in the Behavioral Research and Treatment Center (BRTC) at the hospital or at the Cizik School of Nursing (located next door to MD Anderson) when you are scheduled for treatment or a follow-up appointment or using a videoconference platform (such as Zoom). These sessions will involve simulation-based, caregiving skill training, and your caregiver will be taught skills to help support you (such as feeding, hygiene, mobility, medication administration, and care coordination). Two (2) or three (3) sessions will be done remotely using a videoconference platform (such as Zoom) and will focus on discussing your caregiver's role and experiences and suggesting coping and self-care strategies.

You will not take part in the caregiver intervention sessions.

Follow-Up Assessments
About 12 and 16 weeks after completing the baseline assessment, you will be asked to complete a follow-up assessment of questionnaires. It will ask you about your psychological health, thoughts on your role as a caregiver, and family member's symptoms. These should take about 15 minutes to complete.

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 **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 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. If your physician and/or the psychologist thinks it is needed, you may be seen by a doctor in the Department of Psychiatry.

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. 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.

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 $20 after completing the baseline, Week 12, and Week 16 follow-up assessments (up to $60 total in gift cards).

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.

In the event of injury resulting from this research, UTHealth Houston are not able to offer financial compensation nor to absorb the costs of medical treatment. However, necessary facilities, emergency treatment, and professional services will be available to you, just as they are to the general community. You or your insurance company will be billed for any treatment.

You should report any such injury to Dr. Kathrin Milbury at 713-745-2868 and to the Committee for the Protection of Human Subjects at 713-500-7943. You will not give up any of your legal rights by signing this consent form.

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.

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, TX).
   - 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 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

Informed Consent/Authorization for Participation in Research

Title of Research Study: Simulation-Based Caregiving Skills Training for Family Members of High Grade Glioma Patients

Study Number: 2022-0377

Subtitle: Caregiver, Trial 2

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 with high grade glioma (HGG) receiving cancer treatment at MD Anderson.

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 research study is to explore the usefulness of intervention sessions for family caregivers of patients with HGG.

Researchers also want to learn if:

- Family caregivers are interested in participating in this type of intervention, find the materials and training helpful, and are able to use the information in their daily lives.
- The intervention can reduce common concerns, improve communication between family caregivers and patients about cancer, and improve the overall psychological wellbeing of caregivers.

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 3 times, and you may be asked to attend 4 caregiver intervention sessions. Your participation on this study will be over when you have completed the last questionnaire set about 16 weeks 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 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 120 people (60 caregivers and 60 patients) will be enrolled in this research study. All will take part at MD Anderson.

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 health
- Confidence in dealing with caregiving situations
- Thoughts on your role as a caregiver
- Family member's symptoms

You will be asked to complete this assessment on your own time, and it should take about 40 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 can 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.

Study Groups

After the baseline assessment is completed, you and your family member will be randomly assigned (as in the flip of a coin) to 1 of 2 study groups. You will have an equal chance (50/50) 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 the caregiver intervention sessions (described in detail below under "Caregiver Intervention Sessions").
- **If you are enrolled in Group 2**, you will not take part in the caregiver intervention sessions during this study.

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

Caregiver Intervention Sessions

If you are enrolled in Group 1, you will take part in the caregiver intervention sessions. These sessions are designed to help you support your family member with daily living and help you cope with your caregiving role.

You will take part in 4 caregiver intervention sessions. Each session will last about 60 minutes and will be led by a licensed Registered Nurse (also called the "interventionist").

One (1) or two (2) sessions will take place in the Behavioral Research and Treatment Center (BRTC) at the hospital or at the Cizik School of Nursing (located next door to MD Anderson) when your family member is scheduled for treatment or a follow-up appointment or using a videoconference platform (such as Zoom). These sessions will involve simulation-based, caregiving skill training. You will be taught skills to help support your family member with daily living (such as feeding, hygiene, mobility, medication administration, and care coordination). The interventionist will also talk to you about your needs and concerns.

Two (2) or three (3) sessions will be done remotely using a videoconference platform, such as Zoom. These sessions will focus on discussing your role changes as a caregiver to help you process your experience as well as suggesting coping and self-care strategies to help address your concerns and feelings. If you do not have a computer that you can use for these remote sessions, a device will be loaned to you, and you will return it after your last session.

All caregiver intervention sessions will be audio-recorded. The recordings will be saved for 7 years after the study is complete and then stored.

You will have no more than 1 session per week. The schedule for these sessions will depend on when you and/or your family member are available. You will receive a master schedule of your sessions at the beginning of the program. If you are not able to attend the scheduled session(s), please let your interventionist know, and they will reschedule the session(s).

While taking part in this study, you are encouraged to share verbal feedback with the interventionist about the intervention sessions.

Follow-Up Assessments
About 12 and 16 weeks after completing the baseline assessment, you will be asked to complete a follow-up assessment of questionnaires. It will ask you about your psychological health, thoughts on your role as a caregiver, and family member's symptoms. These should take about 15 minutes to complete.

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 **caregiver intervention 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. If your physician and/or the psychologist thinks it is needed, you may be seen by a doctor in the Department of Psychiatry.

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. 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.

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 questionnaires and a $20 gift card after completing the Week 12 and Week 16 follow-up questionnaires (up to $80 total in gift cards).

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.

In the event of injury resulting from this research, UTHealth Houston are not able to offer financial compensation nor to absorb the costs of medical treatment. However, necessary facilities, emergency treatment, and professional services will be available to you, just as they are to the general community. You or your insurance company will be billed for any treatment.

You should report any such injury to Dr. Kathrin Milbury at 713-745-2868 and to the Committee for the Protection of Human Subjects at 713-500-7943. You will not give up any of your legal rights by signing this consent form.

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 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: If you agree, about 12 weeks after you are enrolled in this study, you will have an interview to discuss your experiences as a family caregiver. If you are enrolled in Group 1, you will also be asked to share your opinions about the caregiver intervention sessions.

The interview can be done over Zoom or by phone, depending on what is convenient for you, and will take about 30-45 minutes. You will be interviewed individually. Your family member will not take part in your interview.

Interviews will be done by research staff trained in interviewing. The interview will be digitally recorded and professionally transcribed (written down) for review. You will not receive a copy of the transcripts. The digital recording will be archived after 7 years. The transcripts will not be destroyed.

Optional Procedure Risks

Interviews may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about completing the questionnaire, you are encouraged to contact the study chair.

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 have an interview 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 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 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