FamTechCare Clinical Trial

Kristine Williams, RN, PhD

NCT02483520

Supporting Family Caregivers with Technology for Dementia Home Care (FamTechCare)

Consents - Last IRB approval date: May 22, 2018

Supporting Family Caregivers with Technology for Dementia Home Care (FamTechCare)
Study Partner/Caregiver Consent

Investigator: Kristine Williams, RN, PhD

Why am I being invited to take part in a research study?
We invite you to take part in a research study because you ("the caregiver") are caring for a family member or friend with dementia at home ("the participant"). This study tests an intervention called FamTechCare that uses hand-held technology to take short videos at home for review by dementia care experts who provide supportive feedback for caregivers providing care for a loved one with dementia at home.

This research study will take place at the University of Kansas Medical Center (KUMC) with Kristine Williams, PhD as the researcher. This research is also being conducted at the University of Iowa with Diane Blyler, PhD as the researcher. This research is being funded by the National Institutes of Health.

What should I know about a research study?
Research is voluntary, and you may change your mind at any time. There will be no penalty to you if you decide not to participate, or if you start the study and decide to stop early. Either way, you can still get medical care and services at KUMC.

This consent form explains what you have to do if you are in the study. It also describes the possible risks and benefits. Please read it carefully and ask as many questions as you need to, before deciding about this research.

You can ask questions now or anytime during the study. The researchers will tell you if they receive any new information that might cause you to change your mind about participating. You may be asked to sign a new consent form if this occurs.

Why is this research being done?
Being a caregiver of a person with dementia is demanding and sometimes stressful and can contribute to physical and mental health problems. Behaviors that commonly occur in persons with dementia can be frustrating. Some caregivers ask for help even with everyday situations that don't seem very stressful. This study will test whether short videos you take at home, of everyday situations associated with dementia, along with expert feedback will reduce stress and help caregivers manage these everyday situations at home. The study will use the latest handheld technology to securely send these short videos, to a panel of experts for feedback to help with everyday situations you want feedback on.

How long will the research last?
We expect that you will be in this research study for about 3 months, depending on scheduling and availability.

How many people will be studied?
We expect about 90 people here at University of Kansas Medical Center will be in this research study out of about 180 people in the entire study nationally.

Supporting Family Caregivers with Technology for Dementia Home Care (FamTechCare)
Participant Consent

Investigator: Kristine Williams, RN, PhD

Why am I being invited to take part in a research study?
We invite you to take part in a research study because you are a person diagnosed with memory and thinking changes due to dementia. This study tests an intervention called FamTechCare that uses hand-held technology to take short videos at home by your caregiver, for review by dementia care experts who provide supportive feedback to your caregiver.

This research study will take place at the University of Kansas Medical Center (KUMC) with Kristine Williams PhD as the researcher. This research is also being conducted at the University of Iowa with Diane Blyler, PhD as the researcher. This research is being funded by the National Institutes of Health.

What should I know about a research study?
Research is voluntary, and you may change your mind at any time. There will be no penalty to you if you decide not to participate, or if you start the study and decide to stop early. Either way, you can still get medical care and services at KUMC.

This consent form explains what you have to do if you are in the study. It also describes the possible risks and benefits. Please read it carefully and ask as many questions as you need to, before deciding about this research.

You can ask questions now or anytime during the study. The researchers will tell you if they receive any new information that might cause you to change your mind about participating. You may be asked to sign a new consent form if this occurs.

Why is this research being done?
Being a caregiver of a person with dementia is demanding and stressful and can contribute to physical and mental health problems. Behaviors that commonly occur in persons with dementia can be frustrating. Some caregivers ask for help even with everyday situations that don't seem very stressful. This study will test whether short videos taken at home, of everyday situations associated with dementia, along with expert feedback will reduce stress and help caregivers manage these everyday situations at home. The study will use the latest handheld technology to securely send these short videos, to a panel of experts for feedback to help with these everyday situations your caregiver wants feedback on.

How long will the research last?
We expect that you will be in this research study for about 3 months, depending on scheduling and availability.

How many people will be studied?
We expect about 90 people here at The University of Kansas Medical Center will be in this research study out of about 180 people in the entire study nationally.

Supporting Family Caregivers with Technology for Dementia Home Care (FamTechCare)
Surrogate Consent for Participant

Investigator: Kristine Williams RN, PhD

Why is the person I make decisions for being invited to take part in a research study?
As a relative or other individual who is making decisions on behalf of a person with dementia ("the participant"), you are being asked to approve their participation in a research study. You may or may not be the person who regularly cares for the individual ("the caregiver"). This study tests an intervention called FamTechCare that uses hand-held technology to take short videos at home for review by dementia care experts who provide supportive feedback for caregivers providing care for a loved one with dementia at home.

This research study will take place at the University of Kansas Medical Center (KUMC) with Kristine Williams PhD as the researcher. This research is also being conducted at the University of Iowa with Diane Blyler, PhD as the researcher. This research is being funded by the National Institutes of Health.

What should I know about a research study?
Research is voluntary, and you may change your mind at any time. There will be no penalty to you if you decide not to participate, or if you start the study and decide to stop early. Either way, you and the person you make decisions for can still get medical care and services at KUMC.

This consent form explains what study participants have to do in the study. It also describes the possible risks and benefits. Please read it carefully and ask as many questions as you need to, before deciding about this research.

You can ask questions now or anytime during the study. The researchers will tell you if they receive any new information that might cause you to change your mind about participation. You may be asked to sign a new consent form if this occurs.

Why is this research being done?
Being a caregiver of a person with dementia is demanding and sometimes stressful and can contribute to physical and mental health problems. Behaviors that commonly occur in persons with dementia can be frustrating. Some caregivers ask for help even with everyday situations that don't seem very stressful. This study will test whether short videos taken at home, of everyday situations associated with dementia, along with expert feedback will reduce stress and help caregivers manage these everyday situations they want feedback on.

How long will the research last?
We expect that the participant and caregiver will be in this research study for about 3 months, depending on scheduling and availability.

How many people will be studied?
We expect about 90 participants here at The University of Kansas Medical Center will be in this research study out of about 180 people in the entire study nationally.

What will people in the study be asked to do?
If the participant and caregiver are eligible and if you agree to have the participant take part in this study, their involvement will last for about 3 months. During this time a research assistant will visit their home at least three times (initially and after one and three months) for one to two hours. The research assistant will teach the caregiver to use the hand-held technology that will be provided for taking short videos of everyday situations in which the caregiver wants weekly expert feedback. The research assistant will teach the caregiver how to submit selected videos over a HIPPA secure website. The research assistant will assist the caregiver to identify three everyday-situations that the caregiver wants expert feedback on. The hand-held technology will be set up in the area of the home these situations typically occur. The caregiver will be contacted by a member of the research team at least weekly.

Audio/Video Recording
One aspect of this study involves making video recordings. These videos are recorded on a mobile device with Behavior Capture software that the research team provides to be used only for the research study. The caregiver controls when these videos are made and what is in them. The caregiver will have the opportunity to review all videos and choose whether they want to delete or submit the video. Only the videos that the caregiver records and chooses to submit will be uploaded over the internet and stored securely on a secure internet server for review by the experts in our research team. These experts provide the caregiver with feedback on ways to handle the situations the caregiver wants help with.

During participation in this study, the caregiver(s) will start a recording when a care situation occurs and the caregiver wants expert feedback. The caregiver can then review the video and decide if they want to submit or delete the video recording by pushing a button. The video recording is not automatically uploaded over the internet, but instead, the caregiver decides which videos to submit and then submits the videos themselves. The submitted videos will be uploaded to a secure site only accessible with a secure login name and password, which is known only by study staff.

The videos submitted are stored for the duration of the study on a secure server provided by the Behavior Imaging Solutions Company. Some of the recordings the caregiver submits will also be saved on secure computer drives at the University of Iowa for future analysis. Video recordings will be destroyed (erased) from files at the University of Iowa seven years after the end of the research study. The caregiver will return the hand-held technology at the end of the study.

Surveys and Questionnaires
The caregiver will complete up to 8 surveys three times during the study (initially and after one and three months), about caring for the participant, their behavior, and their impacts on stress, health, mental health and sleep, and use of medications for stress and anxiety. These surveys will last about 1 hour. At any time during the study, you may chose not to answer any questions if you prefer not to.

Randomization and Treatment Group Assignment
The caregiver and participant will be randomly placed in to one of two treatment groups: Intervention or Standard of Care. The treatment group will be chosen by chance, like flipping a coin. Neither the caregiver, the participant nor the study staff will choose what treatment is assigned. There is an equal chance of being placed in each treatment group.

For both groups, dementia experts will review the videos and a research assistant will provide weekly support via a phone call to the caregiver. For the intervention group participants, the weekly phone call will provide the caregiver expert feedback on the submitted videos. For the Standard of Care group, the weekly phone call will provide standard feedback to the caregiver on the everyday situations you discuss with staff. The Standard of Care group will receive a summary of the experts' feedback at the end of the 3 months of participation. Both groups receive weekly phone calls with support and feedback from a research assistant.

Participation in this study does not change the care that the person you make decisions for receives from their health care provider. The advice the caregivers receive in this study will not address emergency situations and they will need to follow your normal procedures in the event of an emergency. They will return the recording equipment at the end of the study.

Confidentiality
To help protect confidentiality, we will keep all written records secure in locked containers during transportation from the participant's home to the research laboratory and these hard copies will remain in secure files at the University of Kansas. Information about the caregiver and participant will be stored in computer files that do not link to your identity and require logons and passwords for the research team to access them.

If we write a report or article about this study or share the study data set with others, we will do so in such a way that you, the caregiver and participant cannot be directly identified.

These videos may be able to help health care providers and other family caregivers. If we use portions of the video recordings in the future for digital publication or to train health care providers or other family caregivers, we will blur facial features so that individuals in the video cannot be identified.

☐ Yes I will **allow my de-identified videos to be used for training health care providers and other caregivers.**

☐ No, I **will not allow my de-identified videos to be used for training health care providers and other caregivers.**

Will being in this study help the person I make decisions for any way?
We don't know if the participant or caregiver will benefit from being in this study. However, we hope that, in the future, other people might benefit from this study because we will find out if video recording can improve care by linking caregivers to experts for guidance. This may

reduce the stress or help the caregiver feel more confident in caring for a loved one with dementia at home.

Is there any way being in this study could be bad for the person I make decisions for?
The caregiver and participant may experience one or more of the following risks by being in this study. In addition, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

The participant and/or caregiver may feel uncomfortable about being video recorded during daily activities such as personal care. Caregivers decide when and what is recorded and submitted and videos are securely stored and only viewed by the research team of dementia experts. The information in the videos helps the experts make recommendations for your specific situation at home. We use security precautions to prevent release of the video recordings submitted that could be embarrassing and stressful.

What happens if someone is hurt by the study?
If the person you make decisions for has any problem during the study, you should immediately contact Dr. Williams' research team at 913-938-6267. This number will always reach someone associated with the study regardless of time or day. If the problem is a medical emergency, call 911.

If you or the participant have been harmed as a result of participating in research at the University of Kansas Medical Center (KUMC), you should contact the Director, Human Research Protection Program, Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160. Under certain conditions, Kansas state law or the Kansas Tort Claims Act may allow payment to persons who are injured in research at KUMC.

What other choices to do I have?
This research project is voluntary. The alternative to this study is for the person you make decisions for to receive the usual care from their clinician.

What happens if I say yes, but I change my mind later?
You may withdraw your consent for the person you make decisions for to be in the study at any time. Your decision to stop will not prevent the person you make decisions for from getting treatment or services at KUMC.

You have the right to cancel your permission for researchers to use the health information of the person you make decisions for. If you want to cancel that permission, please write to Dr. Vidoni. The mailing address is Dr. Kristine Williams, 3043 University of Kansas School of Nursing, 3901 Rainbow Blvd., Kansas City, KS 66160. If you cancel permission to use his or her health information, he or she will be withdrawn from the study. The researchers will stop collecting any additional information about the participant unless they need information about a side effect of the intervention. They may use and share information that was gathered before they received your cancellation.

Can participation be stopped early?
The person in charge of the research study or the sponsor can remove the participant from the research study without your approval. Possible reasons for removal include failure to comply

with study procedures, inappropriate behavior towards study staff or the end of funding for the study.

Neither the sponsor, nor the investigator, nor the University of Kansas Medical Center will be obligated to provide the patient and caregiver with the study treatment if the study is stopped early. The participant's physician will decide about future treatment, if it is needed.

Will it cost anything to be in the study?
There is no cost to be in the study. The participant's insurance company will be charged for the health care services that they would ordinarily be responsible to pay.

Will I be compensated for being in the study?
Yes, you and the participant will receive compensation of $75 for completing baseline visits, 1 and 3 month visits. Completing study visits includes uploading weekly videos and completing data forms. If you complete the entire study, payment may be up to $225.00. If your participation in this study ends early, you will be paid only for the visits you have completed.

You will be given a ClinCard, which works like a debit card. After a study visit, payment will added onto your card by computer. The money will be available within 1 business day. You can use the ClinCard at a bank, a store, or at an ATM. No one at KUMC will know where you spent the money.

You will be given one card during the study. If your card is lost or stolen, please call (866) 952-3795.

The KUMC Research Institute will be given your name, address, social security number, and the title of this study to allow them to set you up in the ClinCard system. Study payments are taxable income. A Form 1099 will be sent to you and the Internal Revenue Service if your payments are $600 or more in a calendar year.

Your personal information will be kept on a secure computer. It will be removed from the computer after the study is over and the money on the card has been used. Your information will not be shared with other businesses. It will be kept completely confidential.

What happens to the information collected for the research?
Study records that identify research participants will be kept confidential as required by law. Researchers cannot guarantee absolute confidentiality. Efforts will be made to keep personal information confidential. If the results of this study are published or presented in public, information that identifies participants will be removed.

The privacy of health information is protected by a federal law known as the Health Insurance Portability and Accountability Act (HIPAA). By signing this consent form, you are giving permission ("authorization") for KUMC to use and share health information about the participant for purposes of this research study. If you decide not to sign the form, the person for whom you are making decisions cannot be in the study.

To do this research, the research team needs to collect health information that identifies participants. The information may include items such as name, address, phone, date of birth,

or other identifiers. The research team will collect information from study activities described in the Procedures section of this form and information that relate to study participation. The health information will be used at KUMC by Dr. Williams, members of the research team, the KUMC Research Institute and officials at KUMC who oversee research, including members of the KUMC Human Subjects Committee and other committees and offices that review and monitor research studies.

By signing this form, you are giving Dr. Williams and the research team permission to share information about the participant with persons or groups outside KUMC. The information will be shared with representatives of The National Institutes of Health (the sponsor of the study), the monitoring company that inspects study data, and the Data Coordinating Center at the University of Iowa, the Data and Safety Monitoring Board, Behavioral Imaging Solutions, Inc., and U.S. agencies that oversee human research (if a study audit is performed). These groups or entities may make copies of study records for audit purposes. The purpose for using and sharing the information is to make sure the study is done properly and to evaluate the safety and effectiveness of this new intervention. The information may also be shared with other research groups doing similar work

Some of the persons or groups who receive the health information, including the sponsor, may not be required by law to protect it. Once the information has been shared outside of KUMC, it might be disclosed by others and no longer protected by the federal privacy laws or this authorization.

Your permission to use and share the participant's health information will not expire unless you or the participant cancels it. Any research information that is placed in the medical record will be kept indefinitely. During the study, participants will have access to any study information that is placed in their KUMC medical record. However, some research-specific information is kept only by the researcher. Access to all of the research-specific information may not be available until the end of the study.

We are obligated to disclose to the proper authority any information you share with us concerning adult or child abuse.

Who can I talk to about the study?

Before you sign this form, Dr. Williams or other members of the study team should answer all your questions. You can talk to the researchers if you have any more questions, suggestions, concerns or complaints after signing this form. If you have any questions about your rights as a research subject, or if you want to talk with someone who is not involved in the study, you may call the Human Subjects Committee at (913) 588-1240. You may also write the Human Subjects Committee at Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160.

CONSENT

Dr. Williams or the study team has given you information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study. If the participant becomes able to consent to research during the course of the study, the information in this form will be presented to them for their consent.

On behalf of the person for whom you are making decisions, you freely and voluntarily consent to participate in this research study. You have read and understand the information in this form and have had an opportunity to ask questions and have them answered. ***You will be given a signed copy of the consent form to keep for your records.***

As legal guardian or representative, I,_____,
Type/Print Name of Guardian/Representative

authorize the participation of_____in this research study.
Type/Print Name of Participant

I understand that I may not authorize participation in this study if the individual has previously expressed wishes to the contrary, either orally or in writing.

I am (please initial one of the following categories):

_____ *Legal guardian or Durable Power of Attorney for Healthcare Decisions*

_____ *Adult or emancipated minor's spouse (unless legally separated)*

_____ *Adult child*

_____ *Parent*

_____ *Adult relative by blood or marriage*

_____ _____
Signature of Legal Guardian/ Representative Date

_____
Type/Print Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

Participant Assent

I am being asked to be in a research study that uses in-home video data collection for review by dementia care experts who provide supportive feedback for caregivers providing care for a loved one with dementia at home.

If I decide to be part of this study, I understand that those who care for me will make video recordings of me in my home from time to time. I understand that these recordings will be shown to health care professionals who will watch the videos and make suggestions to those who care for me about how to minimize stressful and frustrating situations.

The person who may make decisions on my behalf has read the consent form and has agreed for me to do this research study. If I sign my name, I am saying that I want to be in the study. I know that I don't have to be in the study even if the person who may make decisions for me has given their permission. I know that I can stop being in this study even if I signed my name. If I want to stop at any time, all I have to do is tell my caregiver or the person who may make decisions on my behalf, or any one on the study team.

_____
Print subject's name

_____ _____
Signature of Participant Date

What will I be asked to do?

If you and the person who cares for you are eligible, and if you both agree to take part in this study, your involvement will last for about 3 months. During this time a research assistant will visit you in your home at least three times (initially and after one and three months) for one to two hours. The research assistant will teach your caregiver to use the hand-held technology to take the short videos of everyday situations in which your caregiver wants weekly expert feedback. The research assistant will assist your caregiver to identify everyday situations for expert feedback. The hand-held technology will be set up in the area of your home where these situations typically occur. Your caregiver will be contacted by a member of the research team at least weekly.

Audio/Video Recording

One aspect of this study involves making video recordings. These videos are recorded on a mobile device with Behavior Capture software that the research team provides to be used only for the research study. Your caregiver controls when these videos are made and what is in them. Your caregiver will have the opportunity to review all videos and choose whether he/she wants to delete or submit the video. Only the videos that your caregiver records and chooses to submit will be uploaded over the internet and stored securely on a secure internet server for review by the experts in our research team. These experts provide your caregiver with feedback on ways to handle the situations.

During your participation in this study, your caregiver will start a recording when a care situation occurs and the caregiver wants expert feedback. Your caregiver can then review the video and decide to submit or delete the video recording by pushing a button. The video recording is not automatically uploaded over the internet, but instead, your caregiver will decide which videos to submit. The submitted videos will be uploaded to a secure site only accessible with a secure login name and password, which is known only by study staff.

The videos submitted by your caregiver are stored for the duration of the study on a secure server provided by the Behavior Imaging Solutions Company. Some of the videos will also be saved on secure computer drives at the University of Iowa for future analysis. Video recordings will be destroyed (erased) from files at the University of Iowa seven years after the end of the research study. The hand-held technology will be returned at the end of the study.

Surveys and Questionnaires

Your caregiver will complete up to 8 surveys three times during the study (initially and after one month and three months), about caring for you, behaviors and their impacts on stress, health, mental health and sleep, and use of medications for stress and anxiety. These surveys will last about 1 hour. At any time during the study, you may chose not to answer any questions if you prefer not to.

Randomization and Treatment Group Assignment

You and your caregiver will be randomly placed in to one of two treatment groups: Intervention or Standard of Care. The treatment group you get will be chosen by chance, like flipping a

coin. Neither you nor the study staff will choose what treatment you get. You will have an equal chance of being placed in each treatment group.

For both groups, dementia experts will review the videos and a research assistant will provide weekly support via a phone call to the caregiver. For the intervention group participants, the weekly phone call will provide the caregiver with expert feedback on the submitted videos. For the Standard of Care group, the weekly phone call will provide standard feedback to the caregiver on the everyday situations discussed with staff. The Standard of Care group will receive a summary of the experts' feedback at the end of the 3 months of participation. Caregivers in both groups receive weekly phone calls with support and feedback from a research assistant.
Participation in this study does not change the care you or your caregiver receives from your health care providers. The advice your caregiver receives in this study will not address emergency situations and they will need to follow your normal procedures in the event of an emergency.

Confidentiality
To help protect your confidentiality, we will keep all written records secure in locked containers during transportation from your home to the research laboratory and these hard copies will remain in secure files at the University of Kansas. Information about you and your caregiver will be stored in computer files that do not link to your identity and require logons and passwords for the research team to access them.

If we write a report or article about this study or share the study data set with others, we will do so in such a way that you and your caregiver cannot be directly identified.

These videos may be able to help health care providers and other family caregivers. If we use portions of the video recordings in the future for digital publication or to train health care providers or other family caregivers, we will blur facial features so that individuals in the video cannot be identified.

☐ Yes I will **allow my deidentified videos to be used for training health care providers and other caregivers.**

☐ No, I **will not allow my deidentified videos to be used for training health care providers and other caregivers.**

Will being in this study help me in any way?
We don't know if you will benefit from being in this study. However, we hope that, in the future, other people might benefit from this study because we will find out if video recording can improve care by linking caregivers to experts for guidance. This may reduce the stressor help your caregiver feel more confident in caring for you or another loved one with dementia at home.

Is there any way being in this study could be bad for me?
You or your caregiver may experience one or more of the following risks by being in this study. In addition, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

You or your caregiver may feel uncomfortable about being video recorded during daily activities such as personal care. Caregivers decide when and what is recorded and submitted and videos are securely stored and only viewed by the research team of dementia experts. The information in the videos helps the experts make recommendations for your specific situation at home. We use security precautions to prevent release of the video recordings your caregiver submits that could be embarrassing and stressful to you or your family member.

What happens if I am hurt by the study?
If you have any problem during the study, you should immediately contact Dr. Williams' research team at 913-938-6267. This number will always reach someone associated with the study regardless of time or day. If the problem is a medical emergency, call 911.

If you think you have been harmed as a result of participating in research at the University of Kansas Medical Center (KUMC), you should contact the Director, Human Research Protection Program, Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160. Under certain conditions, Kansas state law or the Kansas Tort Claims Act may allow payment to persons who are injured in research at KUMC.

What other choices to do I have?
This research project is voluntary. The alternative to this study is to receive your usual care from your clinician.

What happens if I say yes, but I change my mind later?
You can leave the research at any time. If you leave, your caregiver will also have to withdraw from the study. Your decision to stop will not prevent you from getting treatment or services at KUMC.

You have the right to cancel your permission for researchers to use your health information. If you want to cancel your permission, please write to Dr. Williams. The mailing address is Dr. Kristine Williams, 3043 University of Kansas School of Nursing, 3901 Rainbow Blvd., Kansas City, KS 66160. If you cancel permission to use your health information, you will be withdrawn from the study. The researchers will stop collecting any additional information about you unless they need information about a side effect of the intervention. They may use and share information that was gathered before they received your cancellation.

Can my participation be stopped early?
This study might be stopped, without your consent, by the investigator or the sponsor. Possible reasons for removal include failure to comply with study procedures, inappropriate behavior towards study staff or the end of funding for the study.

Neither the sponsor, nor the investigator, nor the University of Kansas Medical Center will be obligated to provide you with the study treatment if the study is stopped early. Your physician will decide about future treatment, if it is needed.

Will it cost anything to be in the study?
There is no cost to be in the study. You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay.

Will I be compensated for being in the study?
Yes, you and the participant will receive compensation of $75 for completing baseline visits, 1 and 3 month visits. Completing study visits includes uploading weekly videos and completing data forms. If you complete the entire study, payment may be up to $225.00. If your participation in this study ends early, you will be paid only for the visits you have completed.

You will be given a ClinCard, which works like a debit card. After a study visit, payment will added onto your card by computer. The money will be available within 1 business day. You can use the ClinCard at a bank, a store, or at an ATM. No one at KUMC will know where you spent the money.

You will be given one card during the study. If your card is lost or stolen, please call (866) 952-3795.

The KUMC Research Institute will be given your name, address, social security number, and the title of this study to allow them to set you up in the ClinCard system. Study payments are taxable income. A Form 1099 will be sent to you and the Internal Revenue Service if your payments are $600 or more in a calendar year.

Your personal information will be kept on a secure computer. It will be removed from the computer after the study is over and the money on the card has been used. Your information will not be shared with other businesses. It will be kept completely confidential.

What happens to the information collected for the research?
Study records that identify research participants will be kept confidential as required by law. Researchers cannot guarantee absolute confidentiality. Efforts will be made to keep your personal information confidential. If the results of this study are published or presented in public, information that identifies participants will be removed.

The privacy of health information is protected by a federal law known as the Health Insurance Portability and Accountability Act (HIPAA). By signing this consent form, you are giving permission (“authorization”) for KUMC to use and share health information about you for purposes of this research study. If you decide not to sign the form, the person for whom you care for cannot be in this study unless another eligible caregiver consents to be in the study.

To do this research, the research team needs to collect health information that identifies caregivers and participants. The information may include items such as name, address, phone, date of birth, or other identifiers. The research team will collect information from study activities described in the Procedures section of this form and information that relate to study participation. The health information will be used at KUMC by Dr. Williams, members of the research team, the KUMC Research Institute and officials at KUMC who oversee research, including members of the KUMC Human Subjects Committee and other committees and offices that review and monitor research studies.

By signing this form, you are giving Dr. Williams and the research team permission to share information about you with persons or groups outside KUMC. The information will be shared with representatives of The National Institutes of Health (the sponsor of the study), the monitoring company that inspects study data, and the Data Coordinating Center at the University of Iowa, the Data and Safety Monitoring Board, Behavioral Imaging Solutions, Inc., and U.S. agencies that oversee human research (if a study audit is performed). These groups or entities may make copies of study records for audit purposes. The purpose for using and sharing the information is to make sure the study is done properly and to evaluate the safety and effectiveness of this new intervention. The information may also be shared with other research groups doing similar work.

Some of the persons or groups who receive the health information, including the sponsor, may not be required by law to protect it. Once the information has been shared outside of KUMC, it might be disclosed by others and no longer protected by the federal privacy laws or this authorization.

Your permission to use and share your health information will not expire unless you or cancel it. Any research information that is placed in the medical record will be kept indefinitely. During the study, you will have access to any study information that is placed in the participants KUMC medical record if you have been granted legal access to the record. However, some research-specific information is kept only by the researcher. Access to all of the research-specific information may not be available until the end of the study.

We are obligated to disclose to the proper authority any information you share with us concerning adult or child abuse.

Who can I talk to about the study?

Before you sign this form, Dr. Williams or other members of the study team should answer all your questions. You can talk to the researchers if you have any more questions, suggestions, concerns or complaints after signing this form. If you have any questions about your rights as a research subject, or if you want to talk with someone who is not involved in the study, you may call the Human Subjects Committee at (913) 588-1240. You may also write the Human Subjects Committee at Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160.

CONSENT

Dr. Williams or the research team has given you information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study.

By signing this form, you say that you freely and voluntarily consent to participate in this research study. You have read the information and had your questions answered.
You will be given a signed copy of the consent form to keep for your records.

_____
Print Participant's Name

_____ _____ _____
Signature of Participant Time Date

_____
Print Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

What will I be asked to do?

If you and the person you care for are eligible and if you both agree to take part in this study, your involvement will last for about 3 months. During this time a research assistant will visit you in your home at least three times (initially and after one and three months) for one to two hours. The research assistant will teach you to use the hand-held technology that will be provided to you for taking short videos of everyday situations in which you want weekly expert feedback. The research assistant will teach you how to submit your selected videos over a HIPPA secure website. The research assistant will assist you to identify three everyday-situations that you want feedback. The hand-held technology will be set up in the area of the home these situations typically occur. A member of the research team will call you weekly to provide support and feedback.

Audio/Video Recording

One aspect of this study involves making video recordings. These videos are recorded on a mobile device with Behavior Capture software that the research team provides to be used only for the research study. You control when these videos are made and what is in them. You will have the opportunity to review all videos and choose whether you want to delete or submit the video. Only the videos that you record and choose to submit will be uploaded over the internet and stored securely on a secure internet server for review by the experts in our research team. These experts provide you with feedback on ways to handle the situations you want help with.

During your participation in this study, you, or any consented caregivers will start a recording when a care situation occurs and the caregiver wants expert feedback. You can then review the video and decide if you want to submit or delete the video recording by pushing a button. The video recording is not automatically uploaded over the internet, but instead, you decide which videos to submit and then submit the videos yourself. The submitted videos will be uploaded to a secure site only accessible with a secure login name and password, which is known only by study staff.

The videos you submit are stored for the duration of the study on a secure server provided by the Behavior Imaging Solutions Company. Some of the recordings you submit will also be saved on secure computer drives at the University of Iowa for future analysis. Video recordings will be destroyed (erased) from files at the University of Iowa seven years after the end of the research study. You will return the hand-held technology at the end of the study.

Surveys and Questionnaires

You will complete up to 8 surveys three times during the study (initially and after one and three months), about caring for the participant, their behavior, and their impacts on stress, health, mental health and sleep, and use of medications for stress and anxiety. These surveys will last about 1 hour. At any time during the study, you may chose not to answer any questions if you prefer not to.

Randomization and Treatment Group Assignment

You will be randomly placed in to one of two treatment groups: Intervention or Standard of Care. The treatment group you get will be chosen by chance, like flipping a coin. Neither you nor the study staff will choose what treatment you get. You will have an equal chance of being placed in each treatment group.

For both groups, dementia experts will review the videos and a research assistant will provide weekly support via a phone call to the caregiver. For the intervention group participants, the weekly phone call will provide you with expert feedback on the submitted videos. For the Standard of Care group, the weekly phone call will provide standard feedback to you on the everyday situations you discuss with staff. The Standard of Care group will receive a summary of the experts' feedback at the end of the 3 months of participation. Both groups receive weekly phone calls with support and feedback from a research assistant.

Participation in this study does not change the care you or the person you care for receives from your health care providers. The advice you receive in this study will not address emergency situations and you will need to follow your normal procedures in the event of an emergency.

Confidentiality

To help protect your confidentiality, we will keep all written records secure in locked containers during transportation from your home to the research laboratory and these hard copies will remain in secure files at the University of Kansas. Information about you and the person you care for will be stored in computer files that do not link to your identity and require logons and passwords for the research team to access them.

If we write a report or article about this study or share the study data set with others, we will do so in such a way that you and the person you care for cannot be directly identified.

These videos may be able to help health care providers and other family caregivers. If we use portions of the video recordings in the future for digital publication or to train health care providers or other family caregivers, we will blur facial features so that individuals in the video cannot be identified.

☐ Yes I will **allow my de-identified videos to be used for training health care providers and other caregivers.**

☐ No, I **will not allow my de-identified videos to be used for training health care providers and other caregivers.**

Will being in this study help me in any way?

We don't know if you will benefit from being in this study. However, we hope that, in the future, other people might benefit from this study because we will find out if video recording can improve care by linking caregivers to experts for guidance. This may reduce the stress or help you feel more confident in caring for a loved one with dementia at home.

Is there any way being in this study could be bad for me?
You or the person you care for may experience one or more of the following risks by being in this study. In addition, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

You or the participant may feel uncomfortable about being video recorded during daily activities such as personal care. Caregivers decide when and what is recorded and submitted and videos are securely stored and only viewed by the research team of dementia experts. The information in the videos helps the experts make recommendations for your specific situation at home. We use security precautions to prevent release of the video recordings submitted that could be embarrassing and stressful.

What happens if I am hurt by the study?
If you have any problem during the study, you should immediately contact Dr. Williams' research team at 913-938-6267. This number will always reach someone associated with the study regardless of time or day. If the problem is a medical emergency, call 911.

If you think you have been harmed as a result of participating in research at the University of Kansas Medical Center (KUMC), you should contact the Director, Human Research Protection Program, Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160. Under certain conditions, Kansas state law or the Kansas Tort Claims Act may allow payment to persons who are injured in research at KUMC.

What other choices to do I have?
This research project is voluntary. The alternative to this study is to have the person you care for receive the usual care from their clinician.

What happens if I say yes, but I change my mind later?
You may stop being in the study at any time. Your decision to stop will not prevent you from getting treatment or services at KUMC.

You have the right to cancel your permission for researchers to use your health information. If you want to cancel your permission, please write to Dr. Williams. The mailing address is Dr. Kristine Williams, 3043 University of Kansas School of Nursing, 3901 Rainbow Blvd., Kansas City, KS 66160. . If you cancel permission to use your health information, you will be withdrawn from the study. The researchers will stop collecting any additional information about you unless they need information about a side effect of the intervention. They may use and share information that was gathered before they received your cancellation.

Can my participation be stopped early?
This study might be stopped, without your consent, by the investigator or the sponsor. Possible reasons for removal include failure to comply with study procedures, inappropriate behavior towards study staff or the end of funding for the study.

Neither the sponsor, nor the investigator, nor the University of Kansas Medical Center will be obligated to provide you with the study treatment if the study is stopped early. Your physician will decide about future treatment, if it is needed.

Will it cost anything to be in the study?
There is no cost to be in the study. You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay.

Will I be compensated for being in the study?
Yes, you and the participant will receive compensation of $75 for completing baseline visits, 1 and 3 month visits. Completing study visits includes uploading weekly videos and completing data forms. If you complete the entire study, payment may be up to $225.00. If your participation in this study ends early, you will be paid only for the visits you have completed.

You will be given a ClinCard, which works like a debit card. After a study visit, payment will added onto your card by computer. The money will be available within 1 business day. You can use the ClinCard at a bank, a store, or at an ATM. No one at KUMC will know where you spent the money.

You will be given one card during the study. If your card is lost or stolen, please call (866) 952-3795.

The KUMC Research Institute will be given your name, address, social security number, and the title of this study to allow them to set you up in the ClinCard system. Study payments are taxable income. A Form 1099 will be sent to you and the Internal Revenue Service if your payments are $600 or more in a calendar year.

Your personal information will be kept on a secure computer. It will be removed from the computer after the study is over and the money on the card has been used. Your information will not be shared with other businesses. It will be kept completely confidential.

What happens to the information collected for the research?
Study records that identify research participants will be kept confidential as required by law. Researchers cannot guarantee absolute confidentiality. Efforts will be made to keep your personal information confidential. If the results of this study are published or presented in public, information that identifies participants will be removed.

The privacy of health information is protected by a federal law known as the Health Insurance Portability and Accountability Act (HIPAA). By signing this consent form, you are giving permission (“authorization”) for KUMC to use and share health information about you for purposes of this research study. If you decide not to sign the form, the person for whom you care for cannot be in this study unless another eligible caregiver consents to be in the study.

To do this research, the research team needs to collect health information that identifies caregivers and participants. The information may include items such as name, address, phone, date of birth, or other identifiers. The research team will collect information from study activities described in the Procedures section of this form and information that relate to study participation. The health information will be used at KUMC by Dr. Williams, members of the research team, the KUMC Research Institute and officials at KUMC who oversee research, including members of the KUMC Human Subjects Committee and other committees and offices that review and monitor research studies.

By signing this form, you are giving Dr. Williams and the research team permission to share information about you with persons or groups outside KUMC. The information will be shared with representatives of The National Institutes of Health (the sponsor of the study), the monitoring company that inspects study data, and the Data Coordinating Center at the University of Iowa, the Data and Safety Monitoring Board, Behavioral Imaging Solutions, Inc., and U.S. agencies that oversee human research (if a study audit is performed). These groups or entities may make copies of study records for audit purposes. The purpose for using and sharing the information is to make sure the study is done properly and to evaluate the safety and effectiveness of this new intervention. The information may also be shared with other research groups doing similar work.

Some of the persons or groups who receive the health information, including the sponsor, may not be required by law to protect it. Once the information has been shared outside of KUMC, it might be disclosed by others and no longer protected by the federal privacy laws or this authorization.

Your permission to use and share your health information will not expire unless you or cancel it. Any research information that is placed in the medical record will be kept indefinitely. During the study, you will have access to any study information that is placed in the participants KUMC medical record if you have been granted legal access to the record. However, some research-specific information is kept only by the researcher. Access to all of the research-specific information may not be available until the end of the study.

We are obligated to disclose to the proper authority any information you share with us concerning adult or child abuse.

Who can I talk to about the study?

Before you sign this form, Dr. Williams or other members of the study team should answer all your questions. You can talk to the researchers if you have any more questions, suggestions, concerns or complaints after signing this form. If you have any questions about your rights as a research subject, or if you want to talk with someone who is not involved in the study, you may call the Human Subjects Committee at (913) 588-1240. You may also write the Human Subjects Committee at Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160.

CONSENT

Dr. Williams or the research team has given you information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study.

By signing this form, you say that you freely and voluntarily consent to participate in this research study. You have read the information and had your questions answered.
You will be given a signed copy of the consent form to keep for your records.

_____
Print Participant's Name

_____ _____ _____
Signature of Participant Time Date

_____
Print Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

Supporting Family Caregivers with Technology for Dementia Home Care (FamTechCare)
Study Partner/Caregiver Consent

Investigator: Kristine Williams, RN, PhD

Why am I being invited to take part in a research study?
We invite you to take part in a research study because you ("the caregiver") are caring for a family member or friend with dementia at home ("the participant"). This study tests an intervention called FamTechCare that uses hand-held technology to take short videos at home for review by dementia care experts who provide supportive feedback for caregivers providing care for a loved one with dementia at home.

This research study will take place at the University of Kansas Medical Center (KUMC) with Kristine Williams, PhD as the researcher. This research is also being conducted at the University of Iowa with Diane Blyler, PhD as the researcher. This research is being funded by the National Institutes of Health.

What should I know about a research study?
Research is voluntary, and you may change your mind at any time. There will be no penalty to you if you decide not to participate, or if you start the study and decide to stop early. Either way, you can still get medical care and services at KUMC.

This consent form explains what you have to do if you are in the study. It also describes the possible risks and benefits. Please read it carefully and ask as many questions as you need to, before deciding about this research.

You can ask questions now or anytime during the study. The researchers will tell you if they receive any new information that might cause you to change your mind about participating. You may be asked to sign a new consent form if this occurs.

Why is this research being done?
Being a caregiver of a person with dementia is demanding and sometimes stressful and can contribute to physical and mental health problems. Behaviors that commonly occur in persons with dementia can be frustrating. Some caregivers ask for help even with everyday situations that don't seem very stressful. This study will test whether short videos you take at home, of everyday situations associated with dementia, along with expert feedback will reduce stress and help caregivers manage these everyday situations at home. The study will use the latest handheld technology to securely send these short videos, to a panel of experts for feedback to help with everyday situations you want feedback on.

How long will the research last?
We expect that you will be in this research study for about 3 months, depending on scheduling and availability.

How many people will be studied?
We expect about 90 people here at University of Kansas Medical Center will be in this research study out of about 180 people in the entire study nationally.

Supporting Family Caregivers with Technology for Dementia Home Care (FamTechCare)
Participant Consent

Investigator: Kristine Williams, RN, PhD

Why am I being invited to take part in a research study?
We invite you to take part in a research study because you are a person diagnosed with memory and thinking changes due to dementia. This study tests an intervention called FamTechCare that uses hand-held technology to take short videos at home by your caregiver, for review by dementia care experts who provide supportive feedback to your caregiver.

This research study will take place at the University of Kansas Medical Center (KUMC) with Kristine Williams PhD as the researcher. This research is also being conducted at the University of Iowa with Diane Blyler, PhD as the researcher. This research is being funded by the National Institutes of Health.

What should I know about a research study?
Research is voluntary, and you may change your mind at any time. There will be no penalty to you if you decide not to participate, or if you start the study and decide to stop early. Either way, you can still get medical care and services at KUMC.

This consent form explains what you have to do if you are in the study. It also describes the possible risks and benefits. Please read it carefully and ask as many questions as you need to, before deciding about this research.

You can ask questions now or anytime during the study. The researchers will tell you if they receive any new information that might cause you to change your mind about participating. You may be asked to sign a new consent form if this occurs.

Why is this research being done?
Being a caregiver of a person with dementia is demanding and stressful and can contribute to physical and mental health problems. Behaviors that commonly occur in persons with dementia can be frustrating. Some caregivers ask for help even with everyday situations that don't seem very stressful. This study will test whether short videos taken at home, of everyday situations associated with dementia, along with expert feedback will reduce stress and help caregivers manage these everyday situations at home. The study will use the latest handheld technology to securely send these short videos, to a panel of experts for feedback to help with these everyday situations your caregiver wants feedback on.

How long will the research last?
We expect that you will be in this research study for about 3 months, depending on scheduling and availability.

How many people will be studied?
We expect about 90 people here at The University of Kansas Medical Center will be in this research study out of about 180 people in the entire study nationally.

Supporting Family Caregivers with Technology for Dementia Home Care (FamTechCare)
Surrogate Consent for Participant

Investigator: Kristine Williams RN, PhD

Why is the person I make decisions for being invited to take part in a research study?
As a relative or other individual who is making decisions on behalf of a person with dementia ("the participant"), you are being asked to approve their participation in a research study. You may or may not be the person who regularly cares for the individual ("the caregiver"). This study tests an intervention called FamTechCare that uses hand-held technology to take short videos at home for review by dementia care experts who provide supportive feedback for caregivers providing care for a loved one with dementia at home.

This research study will take place at the University of Kansas Medical Center (KUMC) with Kristine Williams PhD as the researcher. This research is also being conducted at the University of Iowa with Diane Blyler, PhD as the researcher. This research is being funded by the National Institutes of Health.

What should I know about a research study?
Research is voluntary, and you may change your mind at any time. There will be no penalty to you if you decide not to participate, or if you start the study and decide to stop early. Either way, you and the person you make decisions for can still get medical care and services at KUMC.

This consent form explains what study participants have to do in the study. It also describes the possible risks and benefits. Please read it carefully and ask as many questions as you need to, before deciding about this research.

You can ask questions now or anytime during the study. The researchers will tell you if they receive any new information that might cause you to change your mind about participation. You may be asked to sign a new consent form if this occurs.

Why is this research being done?
Being a caregiver of a person with dementia is demanding and sometimes stressful and can contribute to physical and mental health problems. Behaviors that commonly occur in persons with dementia can be frustrating. Some caregivers ask for help even with everyday situations that don't seem very stressful. This study will test whether short videos taken at home, of everyday situations associated with dementia, along with expert feedback will reduce stress and help caregivers manage these everyday situations they want feedback on.

How long will the research last?
We expect that the participant and caregiver will be in this research study for about 3 months, depending on scheduling and availability.

How many people will be studied?
We expect about 90 participants here at The University of Kansas Medical Center will be in this research study out of about 180 people in the entire study nationally.

What will people in the study be asked to do?
If the participant and caregiver are eligible and if you agree to have the participant take part in this study, their involvement will last for about 3 months. During this time a research assistant will visit their home at least three times (initially and after one and three months) for one to two hours. The research assistant will teach the caregiver to use the hand-held technology that will be provided for taking short videos of everyday situations in which the caregiver wants weekly expert feedback. The research assistant will teach the caregiver how to submit selected videos over a HIPPA secure website. The research assistant will assist the caregiver to identify three everyday-situations that the caregiver wants expert feedback on. The hand-held technology will be set up in the area of the home these situations typically occur. The caregiver will be contacted by a member of the research team at least weekly.

Audio/Video Recording
One aspect of this study involves making video recordings. These videos are recorded on a mobile device with Behavior Capture software that the research team provides to be used only for the research study. The caregiver controls when these videos are made and what is in them. The caregiver will have the opportunity to review all videos and choose whether they want to delete or submit the video. Only the videos that the caregiver records and chooses to submit will be uploaded over the internet and stored securely on a secure internet server for review by the experts in our research team. These experts provide the caregiver with feedback on ways to handle the situations the caregiver wants help with.

During participation in this study, the caregiver(s) will start a recording when a care situation occurs and the caregiver wants expert feedback. The caregiver can then review the video and decide if they want to submit or delete the video recording by pushing a button. The video recording is not automatically uploaded over the internet, but instead, the caregiver decides which videos to submit and then submits the videos themselves. The submitted videos will be uploaded to a secure site only accessible with a secure login name and password, which is known only by study staff.

The videos submitted are stored for the duration of the study on a secure server provided by the Behavior Imaging Solutions Company. Some of the recordings the caregiver submits will also be saved on secure computer drives at the University of Iowa for future analysis. Video recordings will be destroyed (erased) from files at the University of Iowa seven years after the end of the research study. The caregiver will return the hand-held technology at the end of the study.

Surveys and Questionnaires
The caregiver will complete up to 8 surveys three times during the study (initially and after one and three months), about caring for the participant, their behavior, and their impacts on stress, health, mental health and sleep, and use of medications for stress and anxiety. These surveys will last about 1 hour. At any time during the study, you may chose not to answer any questions if you prefer not to.

Randomization and Treatment Group Assignment
The caregiver and participant will be randomly placed in to one of two treatment groups: Intervention or Standard of Care. The treatment group will be chosen by chance, like flipping a coin. Neither the caregiver, the participant nor the study staff will choose what treatment is assigned. There is an equal chance of being placed in each treatment group.

For both groups, dementia experts will review the videos and a research assistant will provide weekly support via a phone call to the caregiver. For the intervention group participants, the weekly phone call will provide the caregiver expert feedback on the submitted videos. For the Standard of Care group, the weekly phone call will provide standard feedback to the caregiver on the everyday situations you discuss with staff. The Standard of Care group will receive a summary of the experts' feedback at the end of the 3 months of participation. Both groups receive weekly phone calls with support and feedback from a research assistant.

Participation in this study does not change the care that the person you make decisions for receives from their health care provider. The advice the caregivers receive in this study will not address emergency situations and they will need to follow your normal procedures in the event of an emergency. They will return the recording equipment at the end of the study.

Confidentiality
To help protect confidentiality, we will keep all written records secure in locked containers during transportation from the participant's home to the research laboratory and these hard copies will remain in secure files at the University of Kansas. Information about the caregiver and participant will be stored in computer files that do not link to your identity and require logons and passwords for the research team to access them.

If we write a report or article about this study or share the study data set with others, we will do so in such a way that you, the caregiver and participant cannot be directly identified.

These videos may be able to help health care providers and other family caregivers. If we use portions of the video recordings in the future for digital publication or to train health care providers or other family caregivers, we will blur facial features so that individuals in the video cannot be identified.

☐ Yes I will **allow my de-identified videos to be used for training health care providers and other caregivers.**

☐ No, I **will not allow my de-identified videos to be used for training health care providers and other caregivers.**

Will being in this study help the person I make decisions for any way?
We don't know if the participant or caregiver will benefit from being in this study. However, we hope that, in the future, other people might benefit from this study because we will find out if video recording can improve care by linking caregivers to experts for guidance. This may

reduce the stress or help the caregiver feel more confident in caring for a loved one with dementia at home.

Is there any way being in this study could be bad for the person I make decisions for?
The caregiver and participant may experience one or more of the following risks by being in this study. In addition, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

The participant and/or caregiver may feel uncomfortable about being video recorded during daily activities such as personal care. Caregivers decide when and what is recorded and submitted and videos are securely stored and only viewed by the research team of dementia experts. The information in the videos helps the experts make recommendations for your specific situation at home. We use security precautions to prevent release of the video recordings submitted that could be embarrassing and stressful.

What happens if someone is hurt by the study?
If the person you make decisions for has any problem during the study, you should immediately contact Dr. Williams' research team at 913-938-6267. This number will always reach someone associated with the study regardless of time or day. If the problem is a medical emergency, call 911.

If you or the participant have been harmed as a result of participating in research at the University of Kansas Medical Center (KUMC), you should contact the Director, Human Research Protection Program, Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160. Under certain conditions, Kansas state law or the Kansas Tort Claims Act may allow payment to persons who are injured in research at KUMC.

What other choices to do I have?
This research project is voluntary. The alternative to this study is for the person you make decisions for to receive the usual care from their clinician.

What happens if I say yes, but I change my mind later?
You may withdraw your consent for the person you make decisions for to be in the study at any time. Your decision to stop will not prevent the person you make decisions for from getting treatment or services at KUMC.

You have the right to cancel your permission for researchers to use the health information of the person you make decisions for. If you want to cancel that permission, please write to Dr. Vidoni. The mailing address is Dr. Kristine Williams, 3043 University of Kansas School of Nursing, 3901 Rainbow Blvd., Kansas City, KS 66160. If you cancel permission to use his or her health information, he or she will be withdrawn from the study. The researchers will stop collecting any additional information about the participant unless they need information about a side effect of the intervention. They may use and share information that was gathered before they received your cancellation.

Can participation be stopped early?
The person in charge of the research study or the sponsor can remove the participant from the research study without your approval. Possible reasons for removal include failure to comply

with study procedures, inappropriate behavior towards study staff or the end of funding for the study.

Neither the sponsor, nor the investigator, nor the University of Kansas Medical Center will be obligated to provide the patient and caregiver with the study treatment if the study is stopped early. The participant's physician will decide about future treatment, if it is needed.

Will it cost anything to be in the study?
There is no cost to be in the study. The participant's insurance company will be charged for the health care services that they would ordinarily be responsible to pay.

Will I be compensated for being in the study?
Yes, you and the participant will receive compensation of $75 for completing baseline visits, 1 and 3 month visits. Completing study visits includes uploading weekly videos and completing data forms. If you complete the entire study, payment may be up to $225.00. If your participation in this study ends early, you will be paid only for the visits you have completed.

You will be given a ClinCard, which works like a debit card. After a study visit, payment will added onto your card by computer. The money will be available within 1 business day. You can use the ClinCard at a bank, a store, or at an ATM. No one at KUMC will know where you spent the money.

You will be given one card during the study. If your card is lost or stolen, please call (866) 952-3795.

The KUMC Research Institute will be given your name, address, social security number, and the title of this study to allow them to set you up in the ClinCard system. Study payments are taxable income. A Form 1099 will be sent to you and the Internal Revenue Service if your payments are $600 or more in a calendar year.

Your personal information will be kept on a secure computer. It will be removed from the computer after the study is over and the money on the card has been used. Your information will not be shared with other businesses. It will be kept completely confidential.

What happens to the information collected for the research?
Study records that identify research participants will be kept confidential as required by law. Researchers cannot guarantee absolute confidentiality. Efforts will be made to keep personal information confidential. If the results of this study are published or presented in public, information that identifies participants will be removed.

The privacy of health information is protected by a federal law known as the Health Insurance Portability and Accountability Act (HIPAA). By signing this consent form, you are giving permission ("authorization") for KUMC to use and share health information about the participant for purposes of this research study. If you decide not to sign the form, the person for whom you are making decisions cannot be in the study.

To do this research, the research team needs to collect health information that identifies participants. The information may include items such as name, address, phone, date of birth,

or other identifiers. The research team will collect information from study activities described in the Procedures section of this form and information that relate to study participation. The health information will be used at KUMC by Dr. Williams, members of the research team, the KUMC Research Institute and officials at KUMC who oversee research, including members of the KUMC Human Subjects Committee and other committees and offices that review and monitor research studies.

By signing this form, you are giving Dr. Williams and the research team permission to share information about the participant with persons or groups outside KUMC. The information will be shared with representatives of The National Institutes of Health (the sponsor of the study), the monitoring company that inspects study data, and the Data Coordinating Center at the University of Iowa, the Data and Safety Monitoring Board, Behavioral Imaging Solutions, Inc., and U.S. agencies that oversee human research (if a study audit is performed). These groups or entities may make copies of study records for audit purposes. The purpose for using and sharing the information is to make sure the study is done properly and to evaluate the safety and effectiveness of this new intervention. The information may also be shared with other research groups doing similar work

Some of the persons or groups who receive the health information, including the sponsor, may not be required by law to protect it. Once the information has been shared outside of KUMC, it might be disclosed by others and no longer protected by the federal privacy laws or this authorization.

Your permission to use and share the participant's health information will not expire unless you or the participant cancels it. Any research information that is placed in the medical record will be kept indefinitely. During the study, participants will have access to any study information that is placed in their KUMC medical record. However, some research-specific information is kept only by the researcher. Access to all of the research-specific information may not be available until the end of the study.

We are obligated to disclose to the proper authority any information you share with us concerning adult or child abuse.

Who can I talk to about the study?

Before you sign this form, Dr. Williams or other members of the study team should answer all your questions. You can talk to the researchers if you have any more questions, suggestions, concerns or complaints after signing this form. If you have any questions about your rights as a research subject, or if you want to talk with someone who is not involved in the study, you may call the Human Subjects Committee at (913) 588-1240. You may also write the Human Subjects Committee at Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160.

CONSENT

Dr. Williams or the study team has given you information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study. If the participant becomes able to consent to research during the course of the study, the information in this form will be presented to them for their consent.

On behalf of the person for whom you are making decisions, you freely and voluntarily consent to participate in this research study. You have read and understand the information in this form and have had an opportunity to ask questions and have them answered. ***You will be given a signed copy of the consent form to keep for your records.***

As legal guardian or representative, I,_____,
Type/Print Name of Guardian/Representative

authorize the participation of_____in this research study.
Type/Print Name of Participant

I understand that I may not authorize participation in this study if the individual has previously expressed wishes to the contrary, either orally or in writing.

I am (please initial one of the following categories):

_____ *Legal guardian or Durable Power of Attorney for Healthcare Decisions*

_____ *Adult or emancipated minor's spouse (unless legally separated)*

_____ *Adult child*

_____ *Parent*

_____ *Adult relative by blood or marriage*

_____ _____
Signature of Legal Guardian/ Representative Date

_____
Type/Print Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

Participant Assent

I am being asked to be in a research study that uses in-home video data collection for review by dementia care experts who provide supportive feedback for caregivers providing care for a loved one with dementia at home.

If I decide to be part of this study, I understand that those who care for me will make video recordings of me in my home from time to time. I understand that these recordings will be shown to health care professionals who will watch the videos and make suggestions to those who care for me about how to minimize stressful and frustrating situations.

The person who may make decisions on my behalf has read the consent form and has agreed for me to do this research study. If I sign my name, I am saying that I want to be in the study. I know that I don't have to be in the study even if the person who may make decisions for me has given their permission. I know that I can stop being in this study even if I signed my name. If I want to stop at any time, all I have to do is tell my caregiver or the person who may make decisions on my behalf, or any one on the study team.

_____
Print subject's name

_____ _____
Signature of Participant Date

What will I be asked to do?

If you and the person who cares for you are eligible, and if you both agree to take part in this study, your involvement will last for about 3 months. During this time a research assistant will visit you in your home at least three times (initially and after one and three months) for one to two hours. The research assistant will teach your caregiver to use the hand-held technology to take the short videos of everyday situations in which your caregiver wants weekly expert feedback. The research assistant will assist your caregiver to identify everyday situations for expert feedback. The hand-held technology will be set up in the area of your home where these situations typically occur. Your caregiver will be contacted by a member of the research team at least weekly.

Audio/Video Recording

One aspect of this study involves making video recordings. These videos are recorded on a mobile device with Behavior Capture software that the research team provides to be used only for the research study. Your caregiver controls when these videos are made and what is in them. Your caregiver will have the opportunity to review all videos and choose whether he/she wants to delete or submit the video. Only the videos that your caregiver records and chooses to submit will be uploaded over the internet and stored securely on a secure internet server for review by the experts in our research team. These experts provide your caregiver with feedback on ways to handle the situations.

During your participation in this study, your caregiver will start a recording when a care situation occurs and the caregiver wants expert feedback. Your caregiver can then review the video and decide to submit or delete the video recording by pushing a button. The video recording is not automatically uploaded over the internet, but instead, your caregiver will decide which videos to submit. The submitted videos will be uploaded to a secure site only accessible with a secure login name and password, which is known only by study staff.

The videos submitted by your caregiver are stored for the duration of the study on a secure server provided by the Behavior Imaging Solutions Company. Some of the videos will also be saved on secure computer drives at the University of Iowa for future analysis. Video recordings will be destroyed (erased) from files at the University of Iowa seven years after the end of the research study. The hand-held technology will be returned at the end of the study.

Surveys and Questionnaires

Your caregiver will complete up to 8 surveys three times during the study (initially and after one month and three months), about caring for you, behaviors and their impacts on stress, health, mental health and sleep, and use of medications for stress and anxiety. These surveys will last about 1 hour. At any time during the study, you may chose not to answer any questions if you prefer not to.

Randomization and Treatment Group Assignment

You and your caregiver will be randomly placed in to one of two treatment groups: Intervention or Standard of Care. The treatment group you get will be chosen by chance, like flipping a

coin. Neither you nor the study staff will choose what treatment you get. You will have an equal chance of being placed in each treatment group.

For both groups, dementia experts will review the videos and a research assistant will provide weekly support via a phone call to the caregiver. For the intervention group participants, the weekly phone call will provide the caregiver with expert feedback on the submitted videos. For the Standard of Care group, the weekly phone call will provide standard feedback to the caregiver on the everyday situations discussed with staff. The Standard of Care group will receive a summary of the experts' feedback at the end of the 3 months of participation. Caregivers in both groups receive weekly phone calls with support and feedback from a research assistant.
Participation in this study does not change the care you or your caregiver receives from your health care providers. The advice your caregiver receives in this study will not address emergency situations and they will need to follow your normal procedures in the event of an emergency.

Confidentiality
To help protect your confidentiality, we will keep all written records secure in locked containers during transportation from your home to the research laboratory and these hard copies will remain in secure files at the University of Kansas. Information about you and your caregiver will be stored in computer files that do not link to your identity and require logons and passwords for the research team to access them.

If we write a report or article about this study or share the study data set with others, we will do so in such a way that you and your caregiver cannot be directly identified.

These videos may be able to help health care providers and other family caregivers. If we use portions of the video recordings in the future for digital publication or to train health care providers or other family caregivers, we will blur facial features so that individuals in the video cannot be identified.

☐ Yes I will **allow my deidentified videos to be used for training health care providers and other caregivers.**

☐ No, I **will not allow my deidentified videos to be used for training health care providers and other caregivers.**

Will being in this study help me in any way?
We don't know if you will benefit from being in this study. However, we hope that, in the future, other people might benefit from this study because we will find out if video recording can improve care by linking caregivers to experts for guidance. This may reduce the stressor help your caregiver feel more confident in caring for you or another loved one with dementia at home.

Is there any way being in this study could be bad for me?
You or your caregiver may experience one or more of the following risks by being in this study. In addition, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

You or your caregiver may feel uncomfortable about being video recorded during daily activities such as personal care. Caregivers decide when and what is recorded and submitted and videos are securely stored and only viewed by the research team of dementia experts. The information in the videos helps the experts make recommendations for your specific situation at home. We use security precautions to prevent release of the video recordings your caregiver submits that could be embarrassing and stressful to you or your family member.

What happens if I am hurt by the study?
If you have any problem during the study, you should immediately contact Dr. Williams' research team at 913-938-6267. This number will always reach someone associated with the study regardless of time or day. If the problem is a medical emergency, call 911.

If you think you have been harmed as a result of participating in research at the University of Kansas Medical Center (KUMC), you should contact the Director, Human Research Protection Program, Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160. Under certain conditions, Kansas state law or the Kansas Tort Claims Act may allow payment to persons who are injured in research at KUMC.

What other choices to do I have?
This research project is voluntary. The alternative to this study is to receive your usual care from your clinician.

What happens if I say yes, but I change my mind later?
You can leave the research at any time. If you leave, your caregiver will also have to withdraw from the study. Your decision to stop will not prevent you from getting treatment or services at KUMC.

You have the right to cancel your permission for researchers to use your health information. If you want to cancel your permission, please write to Dr. Williams. The mailing address is Dr. Kristine Williams, 3043 University of Kansas School of Nursing, 3901 Rainbow Blvd., Kansas City, KS 66160. If you cancel permission to use your health information, you will be withdrawn from the study. The researchers will stop collecting any additional information about you unless they need information about a side effect of the intervention. They may use and share information that was gathered before they received your cancellation.

Can my participation be stopped early?
This study might be stopped, without your consent, by the investigator or the sponsor. Possible reasons for removal include failure to comply with study procedures, inappropriate behavior towards study staff or the end of funding for the study.

Neither the sponsor, nor the investigator, nor the University of Kansas Medical Center will be obligated to provide you with the study treatment if the study is stopped early. Your physician will decide about future treatment, if it is needed.

Will it cost anything to be in the study?
There is no cost to be in the study. You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay.

Will I be compensated for being in the study?
Yes, you and the participant will receive compensation of $75 for completing baseline visits, 1 and 3 month visits. Completing study visits includes uploading weekly videos and completing data forms. If you complete the entire study, payment may be up to $225.00. If your participation in this study ends early, you will be paid only for the visits you have completed.

You will be given a ClinCard, which works like a debit card. After a study visit, payment will added onto your card by computer. The money will be available within 1 business day. You can use the ClinCard at a bank, a store, or at an ATM. No one at KUMC will know where you spent the money.

You will be given one card during the study. If your card is lost or stolen, please call (866) 952-3795.

The KUMC Research Institute will be given your name, address, social security number, and the title of this study to allow them to set you up in the ClinCard system. Study payments are taxable income. A Form 1099 will be sent to you and the Internal Revenue Service if your payments are $600 or more in a calendar year.

Your personal information will be kept on a secure computer. It will be removed from the computer after the study is over and the money on the card has been used. Your information will not be shared with other businesses. It will be kept completely confidential.

What happens to the information collected for the research?
Study records that identify research participants will be kept confidential as required by law. Researchers cannot guarantee absolute confidentiality. Efforts will be made to keep your personal information confidential. If the results of this study are published or presented in public, information that identifies participants will be removed.

The privacy of health information is protected by a federal law known as the Health Insurance Portability and Accountability Act (HIPAA). By signing this consent form, you are giving permission (“authorization”) for KUMC to use and share health information about you for purposes of this research study. If you decide not to sign the form, the person for whom you care for cannot be in this study unless another eligible caregiver consents to be in the study.

To do this research, the research team needs to collect health information that identifies caregivers and participants. The information may include items such as name, address, phone, date of birth, or other identifiers. The research team will collect information from study activities described in the Procedures section of this form and information that relate to study participation. The health information will be used at KUMC by Dr. Williams, members of the research team, the KUMC Research Institute and officials at KUMC who oversee research, including members of the KUMC Human Subjects Committee and other committees and offices that review and monitor research studies.

By signing this form, you are giving Dr. Williams and the research team permission to share information about you with persons or groups outside KUMC. The information will be shared with representatives of The National Institutes of Health (the sponsor of the study), the monitoring company that inspects study data, and the Data Coordinating Center at the University of Iowa, the Data and Safety Monitoring Board, Behavioral Imaging Solutions, Inc., and U.S. agencies that oversee human research (if a study audit is performed). These groups or entities may make copies of study records for audit purposes. The purpose for using and sharing the information is to make sure the study is done properly and to evaluate the safety and effectiveness of this new intervention. The information may also be shared with other research groups doing similar work.

Some of the persons or groups who receive the health information, including the sponsor, may not be required by law to protect it. Once the information has been shared outside of KUMC, it might be disclosed by others and no longer protected by the federal privacy laws or this authorization.

Your permission to use and share your health information will not expire unless you or cancel it. Any research information that is placed in the medical record will be kept indefinitely. During the study, you will have access to any study information that is placed in the participants KUMC medical record if you have been granted legal access to the record. However, some research-specific information is kept only by the researcher. Access to all of the research-specific information may not be available until the end of the study.

We are obligated to disclose to the proper authority any information you share with us concerning adult or child abuse.

Who can I talk to about the study?

Before you sign this form, Dr. Williams or other members of the study team should answer all your questions. You can talk to the researchers if you have any more questions, suggestions, concerns or complaints after signing this form. If you have any questions about your rights as a research subject, or if you want to talk with someone who is not involved in the study, you may call the Human Subjects Committee at (913) 588-1240. You may also write the Human Subjects Committee at Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160.

CONSENT

Dr. Williams or the research team has given you information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study.

By signing this form, you say that you freely and voluntarily consent to participate in this research study. You have read the information and had your questions answered.
You will be given a signed copy of the consent form to keep for your records.

_____
Print Participant's Name

_____ _____ _____
Signature of Participant Time Date

_____
Print Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

What will I be asked to do?

If you and the person you care for are eligible and if you both agree to take part in this study, your involvement will last for about 3 months. During this time a research assistant will visit you in your home at least three times (initially and after one and three months) for one to two hours. The research assistant will teach you to use the hand-held technology that will be provided to you for taking short videos of everyday situations in which you want weekly expert feedback. The research assistant will teach you how to submit your selected videos over a HIPPA secure website. The research assistant will assist you to identify three everyday-situations that you want feedback. The hand-held technology will be set up in the area of the home these situations typically occur. A member of the research team will call you weekly to provide support and feedback.

Audio/Video Recording

One aspect of this study involves making video recordings. These videos are recorded on a mobile device with Behavior Capture software that the research team provides to be used only for the research study. You control when these videos are made and what is in them. You will have the opportunity to review all videos and choose whether you want to delete or submit the video. Only the videos that you record and choose to submit will be uploaded over the internet and stored securely on a secure internet server for review by the experts in our research team. These experts provide you with feedback on ways to handle the situations you want help with.

During your participation in this study, you, or any consented caregivers will start a recording when a care situation occurs and the caregiver wants expert feedback. You can then review the video and decide if you want to submit or delete the video recording by pushing a button. The video recording is not automatically uploaded over the internet, but instead, you decide which videos to submit and then submit the videos yourself. The submitted videos will be uploaded to a secure site only accessible with a secure login name and password, which is known only by study staff.

The videos you submit are stored for the duration of the study on a secure server provided by the Behavior Imaging Solutions Company. Some of the recordings you submit will also be saved on secure computer drives at the University of Iowa for future analysis. Video recordings will be destroyed (erased) from files at the University of Iowa seven years after the end of the research study. You will return the hand-held technology at the end of the study.

Surveys and Questionnaires

You will complete up to 8 surveys three times during the study (initially and after one and three months), about caring for the participant, their behavior, and their impacts on stress, health, mental health and sleep, and use of medications for stress and anxiety. These surveys will last about 1 hour. At any time during the study, you may chose not to answer any questions if you prefer not to.

Randomization and Treatment Group Assignment

You will be randomly placed in to one of two treatment groups: Intervention or Standard of Care. The treatment group you get will be chosen by chance, like flipping a coin. Neither you nor the study staff will choose what treatment you get. You will have an equal chance of being placed in each treatment group.

For both groups, dementia experts will review the videos and a research assistant will provide weekly support via a phone call to the caregiver. For the intervention group participants, the weekly phone call will provide you with expert feedback on the submitted videos. For the Standard of Care group, the weekly phone call will provide standard feedback to you on the everyday situations you discuss with staff. The Standard of Care group will receive a summary of the experts' feedback at the end of the 3 months of participation. Both groups receive weekly phone calls with support and feedback from a research assistant.

Participation in this study does not change the care you or the person you care for receives from your health care providers. The advice you receive in this study will not address emergency situations and you will need to follow your normal procedures in the event of an emergency.

Confidentiality

To help protect your confidentiality, we will keep all written records secure in locked containers during transportation from your home to the research laboratory and these hard copies will remain in secure files at the University of Kansas. Information about you and the person you care for will be stored in computer files that do not link to your identity and require logons and passwords for the research team to access them.

If we write a report or article about this study or share the study data set with others, we will do so in such a way that you and the person you care for cannot be directly identified.

These videos may be able to help health care providers and other family caregivers. If we use portions of the video recordings in the future for digital publication or to train health care providers or other family caregivers, we will blur facial features so that individuals in the video cannot be identified.

☐ Yes I will **allow my de-identified videos to be used for training health care providers and other caregivers.**

☐ No, I **will not allow my de-identified videos to be used for training health care providers and other caregivers.**

Will being in this study help me in any way?

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Is there any way being in this study could be bad for me?
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You or the participant may feel uncomfortable about being video recorded during daily activities such as personal care. Caregivers decide when and what is recorded and submitted and videos are securely stored and only viewed by the research team of dementia experts. The information in the videos helps the experts make recommendations for your specific situation at home. We use security precautions to prevent release of the video recordings submitted that could be embarrassing and stressful.

What happens if I am hurt by the study?
If you have any problem during the study, you should immediately contact Dr. Williams' research team at 913-938-6267. This number will always reach someone associated with the study regardless of time or day. If the problem is a medical emergency, call 911.

If you think you have been harmed as a result of participating in research at the University of Kansas Medical Center (KUMC), you should contact the Director, Human Research Protection Program, Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160. Under certain conditions, Kansas state law or the Kansas Tort Claims Act may allow payment to persons who are injured in research at KUMC.

What other choices to do I have?
This research project is voluntary. The alternative to this study is to have the person you care for receive the usual care from their clinician.

What happens if I say yes, but I change my mind later?
You may stop being in the study at any time. Your decision to stop will not prevent you from getting treatment or services at KUMC.

You have the right to cancel your permission for researchers to use your health information. If you want to cancel your permission, please write to Dr. Williams. The mailing address is Dr. Kristine Williams, 3043 University of Kansas School of Nursing, 3901 Rainbow Blvd., Kansas City, KS 66160. . If you cancel permission to use your health information, you will be withdrawn from the study. The researchers will stop collecting any additional information about you unless they need information about a side effect of the intervention. They may use and share information that was gathered before they received your cancellation.

Can my participation be stopped early?
This study might be stopped, without your consent, by the investigator or the sponsor. Possible reasons for removal include failure to comply with study procedures, inappropriate behavior towards study staff or the end of funding for the study.

Neither the sponsor, nor the investigator, nor the University of Kansas Medical Center will be obligated to provide you with the study treatment if the study is stopped early. Your physician will decide about future treatment, if it is needed.

Will it cost anything to be in the study?
There is no cost to be in the study. You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay.

Will I be compensated for being in the study?
Yes, you and the participant will receive compensation of $75 for completing baseline visits, 1 and 3 month visits. Completing study visits includes uploading weekly videos and completing data forms. If you complete the entire study, payment may be up to $225.00. If your participation in this study ends early, you will be paid only for the visits you have completed.

You will be given a ClinCard, which works like a debit card. After a study visit, payment will added onto your card by computer. The money will be available within 1 business day. You can use the ClinCard at a bank, a store, or at an ATM. No one at KUMC will know where you spent the money.

You will be given one card during the study. If your card is lost or stolen, please call (866) 952-3795.

The KUMC Research Institute will be given your name, address, social security number, and the title of this study to allow them to set you up in the ClinCard system. Study payments are taxable income. A Form 1099 will be sent to you and the Internal Revenue Service if your payments are $600 or more in a calendar year.

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What happens to the information collected for the research?
Study records that identify research participants will be kept confidential as required by law. Researchers cannot guarantee absolute confidentiality. Efforts will be made to keep your personal information confidential. If the results of this study are published or presented in public, information that identifies participants will be removed.

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To do this research, the research team needs to collect health information that identifies caregivers and participants. The information may include items such as name, address, phone, date of birth, or other identifiers. The research team will collect information from study activities described in the Procedures section of this form and information that relate to study participation. The health information will be used at KUMC by Dr. Williams, members of the research team, the KUMC Research Institute and officials at KUMC who oversee research, including members of the KUMC Human Subjects Committee and other committees and offices that review and monitor research studies.

By signing this form, you are giving Dr. Williams and the research team permission to share information about you with persons or groups outside KUMC. The information will be shared with representatives of The National Institutes of Health (the sponsor of the study), the monitoring company that inspects study data, and the Data Coordinating Center at the University of Iowa, the Data and Safety Monitoring Board, Behavioral Imaging Solutions, Inc., and U.S. agencies that oversee human research (if a study audit is performed). These groups or entities may make copies of study records for audit purposes. The purpose for using and sharing the information is to make sure the study is done properly and to evaluate the safety and effectiveness of this new intervention. The information may also be shared with other research groups doing similar work.

Some of the persons or groups who receive the health information, including the sponsor, may not be required by law to protect it. Once the information has been shared outside of KUMC, it might be disclosed by others and no longer protected by the federal privacy laws or this authorization.

Your permission to use and share your health information will not expire unless you or cancel it. Any research information that is placed in the medical record will be kept indefinitely. During the study, you will have access to any study information that is placed in the participants KUMC medical record if you have been granted legal access to the record. However, some research-specific information is kept only by the researcher. Access to all of the research-specific information may not be available until the end of the study.

We are obligated to disclose to the proper authority any information you share with us concerning adult or child abuse.

Who can I talk to about the study?

Before you sign this form, Dr. Williams or other members of the study team should answer all your questions. You can talk to the researchers if you have any more questions, suggestions, concerns or complaints after signing this form. If you have any questions about your rights as a research subject, or if you want to talk with someone who is not involved in the study, you may call the Human Subjects Committee at (913) 588-1240. You may also write the Human Subjects Committee at Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160.

CONSENT

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By signing this form, you say that you freely and voluntarily consent to participate in this research study. You have read the information and had your questions answered.
You will be given a signed copy of the consent form to keep for your records.

_____
Print Participant's Name

_____ _____ _____
Signature of Participant Time Date

_____
Print Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date