Official title: Mealtime Partnerships for People With Dementia in Respite Centers and at Home

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CONSENT TO BE A RESEARCH SUBJECT

Mealtime Partnerships for People with Dementia in Respite Centers and at Home

Caregiver Consent

SUMMARY

You are being asked to volunteer for a research study. Research studies are voluntary and include only people that chose to take part. The purpose of this research study is to see whether training Respite Center Volunteers or staff to work with Caregivers of people with dementia or providing educational training materials to Caregivers is the better way to improve meal-time enjoyment in the home and overall quality of life for both the Caregiver and their loved-one. If you are eligible and agree to take part in this 6-month study, you will be enrolled and, depending on which Respite Center your loved-one attends, you will be assigned to one of two study groups. If you are assigned to Group A, you will receive training materials related to Alzheimer's disease and behavioral challenges, which you will be expected to read and complete on your own. If you are assigned to Group B, you will be partnered and work with a Volunteer or staff member who has received training in meal-time strategies for people with dementia. You will have online monthly meetings with them on the Tablet you will be loaned. Caregivers in both groups may be loaned a tablet if available, which they will use to record mealtime videos and take photos of their loved-one's meals. Caregivers from both groups will also be asked to complete monthly surveys about their overall quality of life and their loved one's mealtime behaviors. As with any activity that collects personal information about you (such as your name and which respite you attend) the greatest risk to you from joining the study is the possibility of loss of confidentiality; however, every effort will be made by the researchers to protect your identity. You may or may not benefit from this study; however, a potential benefit includes receiving training and information about caring for people with dementia. You will also receive study compensation for your time and effort. If you are interested in learning more please continue to read below.

A. PURPOSE OF THE RESEARCH

Please read this consent form carefully and take your time making your decision. As your investigator or the study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand.

The purpose of this research study is to see if training Respite Center Volunteers or Staff Members to work with Caregivers of people with dementia can improve their meal-time enjoyment at home and overall quality of life. For this research study MUSC has partnered with the ARK and Respite Care Charleston. You are being asked to participate in this study because you are a caregiver to a loved-one with dementia who regularly attends a partnering center. The investigators in charge of this study are Teresa Kelechi, PhD, RN and Suparna Qanungo, PhD. A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of Dr. Kelechi's, Dr. Qanungo's, and their research team's salaries will be paid by this grant. The study is will last for 6 months, and about 180 people will take part study-wide and of those, 60 will be caregivers and people with dementia.

B. PROCEDURES

To be eligible to participate in this research study, you must:

1. Be over 18 years old and provide consent for yourself;
2. Be the primary caregiver to individual with dementia
3. Assist with your loved-one's daily living activities, including meals for at least 4hrs a day;
4. Be able to use or learn to use a 'tablet' to take photos of prepared meals and,
5. Be willing to attend all training classes, perform online monthly meetings with an assigned respite center volunteer or staff and take videos of 3 meals monthly with your loved-one (Group B only).

If you are eligible and agree to be in this study, the following will happen:

Visit One

1. You will be asked by the MUSC researchers to provide personal information about yourself and your loved-one. This includes your basic demographics, how long you have been providing care to your loved-one, whether you have had any special training in providing dementia care, and the types of challenges you have been or may be experiencing with your loved-one at meal-times (~10 mins).

2. You will be asked to complete 5 brief surveys (~15 - 20 mins).
    a. A knowledge survey about caring for people with dementia;
    b. A quality of life survey;
    c. A caregiver burden survey caring for people with dementia; and,
    d. A self-efficacy survey; and,
    e. A caregiver mealtime survey.

3. You will then be placed in either study Group A or Group B based on which respite center your loved-one goes to. Centers have been selected by chance as either Group A or Group B study sites. For example, if your loved-one attends a Group A site then you will be placed in Group A, and the same for Group B sites.

Group A

If you are in Group A, the following will then happen:

1. You will be given educational training materials to view and use while in the study;
2. You will be asked to keep a log of 3 meals each month (one breakfast, lunch and dinner each) of your loved-one's meals;
3. You will be asked to take before and after photos with the Tablet of the 3 meals you noted in the log
4. Every month of the 6-month study, you will be asked to complete the same surveys that you did in Visit 1. These may be done either in-person or by phone with the researchers; and,
5. At your last monthly visit, you will also be asked to complete a study satisfaction survey.

Group B
If you are in Group B, the following will happen:

1. You will be paired with a volunteer or staff person that has also agreed to be in the study.
2. You will then be contacted by the volunteer or staff member to schedule two in-person meetings personalized training in strategies to enhance meal-times will be provided to you (~30 mins each meeting).
3. You will be asked to develop an initial meal-time plan with the volunteer/staff at the 2nd meeting (~20 mins).
4. You will be asked to keep a log of 3 meals each month (one breakfast, lunch and dinner each) that goes along with the photos
5. You will be given a tablet to use to have online monthly meetings with your assigned volunteer/staff member. At these meetings you will:
    a. Review your caregiver Meal Assessment and Meal Plan, along with the meal videos with your assigned Volunteer (~15 mins)
    b. Review and revise your loved-one's current Meal Plan as needed, based on your progress, and any identified meal-time problems. (~30 mins).
6. You will be asked to take before and after photos of 3 meals and to video record 3 meals on the tablet;
7. Every month of the 6-month study, you will be asked to complete the same surveys that you did in Visit 1. These may be done either in-person or by phone with the researchers;
8. At the end of the study, you will be asked to complete a study satisfaction survey and to return the tablet that was loaned to you while you were in the study (~5 mins).

C. DURATION

The study last 6 months, and there are 7 monthly visits. The monthly surveys take about 20 mins and can be done either by phone or in-person, if you prefer. If you are in Group B, the 2 training sessions with your volunteer will last about 45 mins each, and the online monthly meetings will take about 30 mins each in addition to the monthly paperwork visits.

D. RISKS AND DISCOMFORTS

Emotional Discomfort - Some of the questions the researchers ask you may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you can skip it and go to the next question.

Loss of Confidentiality - There is a risk of a loss of confidentiality of your personal information as a result of participation in this study.

E. MEDICAL RECORDS AND/OR CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the Federal government. This means that the researchers may not disclose information or biospecimens that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other

proceedings, nor can the information or biospecimens be used as evidence, unless you have consented to this disclosure. Information or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless you have consented to the disclosure. More specifically, identifiable information or biospecimens will not be shared with your medical providers who are not involved in this research unless you authorize the study to disclose information to them, or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

Information about your study participation will not be in your MUSC medical record. This means that neither your research participation nor any of your research results will be included in any MUSC medical record. A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must authorize the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law. Examples of required disclosure include: child abuse and neglect, or harm to self and others, but there could be others. Finally, a Certificate may not be used to withhold information from the Federal government needed for auditing or evaluating Federally funded projects or information needed by the FDA.

F. BENEFITS

There will be no direct benefit to you from participating in this study. However, we hope that you find the training and information you receive about caring for people for dementia useful. It is also hoped that the information gained from the study will help the researchers learn more about mealtime issues among people with dementia.

G. COSTS

There will be no cost to you as a result of participation in this study.

H. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will be paid $50 for every study visit. This means the most you can receive is $350 for completing all 7 visits over the 6-month study. Payment to you will be made in the form of gift card.

Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

I. ALTERNATIVES

Your alternative is to not participate in this study.

J. DATA SHARING

Information about you (including your identifiable private information and/or any identifiable biospecimens) may have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you or your legally authorized representative.

K. DISCLOSURE OF RESULTS

The researchers will share the overall results of this study with you. Your individual research results will not be disclosed.

L. AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, the research team will keep records of your participation in this study, but no health information about you will be collected or disclosed. No publication or public presentation about the research study will reveal your identity without another signed authorization from you. If you have questions or concerns about your privacy rights, please contact MUSC's Privacy Officer at (843) 792-8740.

Regulations require that you be given a copy of the MUSC Notice of Privacy Practices (NPP) describing the practices of MUSC regarding your health information. One can be found at the end of this form.

M. CLINICAL TRIALS.GOV

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

N. FUTURE CONTACT

The researcher in charge of this study might like to contact you in the future about other research opportunities. Please initial by your choice below, or scroll down to the bottom of the screen and select your choice electronically:

____Yes, I agree to be contacted

____No, I do not agree to be contacted

MUSC STANDARD PARAGRAPHS

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event that you are injured as a result of participation in this study, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangement for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact Teresa Kelechi, PhD, RN at (843) 792-4602 or Suparna Qanungo, PhD at 843-876-1125. I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records. Please sign below for paper consents or scroll to the bottom of the screen to provide an electronic signature.

_____ _____

Signature of Person Obtaining Consent Date *Name of Participant

_____

Signature of Participant Date

NOTICE OF PRIVACY PRACTICES

MUSC Organized Health Care Arrangement (OHCA)

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESSS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

The Medical University of South Carolina and its affiliates (including but not limited to the Medical University Hospital Authority, MUSC Physicians, and MUSC Physicians Primary Care) participate in a clinically integrated health care setting. As a result of this clinical integration, these organizations function as an Organized Health Care Arrangement (OHCA) as defined by the Health Insurance Portability and Accountability Act (HIPAA). For purposes of this notice, the members of the MUSC OHCA are collectively referred to in this document as "MUSC." **We collect or receive this information about your past, present or future health condition to provide health care to you, to receive payment for this health care, or to operate the hospital and/or clinics.**

HOW WE MAY USE AND RELEASE YOUR PROTECTED HEALTH INFORMATION (PHI)

A. The following uses do NOT require your authorization, except where required by SC law:

1. For treatment. Your PHI may be discussed by caregivers to determine your plan of care. For example, the physicians, nurses, medical students and other health care personnel may share PHI in order to coordinate the services you may need.

2. To obtain payment. We may use and disclose PHI to obtain payment for our services from you, an insurance company or a third party. For example, we may use the information to send a claim to your insurance company.

3. For health care operations. We may use and disclose PHI for hospital and/or clinic operations. For example, we may use the information to review our treatment and services and to evaluate the performance of our staff in caring for you.

4. For public health activities. We report to public health authorities, as required by law, information regarding births, deaths, various diseases, reactions to medications and medical products.

5. Victims of abuse, neglect, domestic violence. Your PHI may be released, as required by law, to the South Carolina Department of Social Services when cases of abuse and neglect are suspected.

6. Health oversight activities. We will release information for federal or state audits, civil, administrative or criminal investigations, inspections, licensure or disciplinary actions, as required by law.

7. Judicial and administrative proceedings. Your PHI may be released in response to a subpoena or court order.

8. Law enforcement or national security purposes. Your PHI may be released as part of an investigation by law enforcement.

9. Uses and disclosures about patients who have died. We provide coroners, medical examiners and funeral directors necessary information related to an individual's death.

10. For purposes of organ donation. As required by law, we will notify organ procurement organizations to assist them

in organ, eye or tissue donation and transplants.

11. Research. We may use your PHI if the Institutional Review Board (IRB) for research reviews, approves and establishes safeguards to ensure privacy.

12. To avoid harm. In order to avoid a serious threat to the health or safety of a person or the public, we may release limited information to law enforcement personnel or persons able to prevent or lessen such harm.

13. For workers compensation purposes. We may release your PHI to comply with workers compensation laws.

14. Marketing. We may send you information on the latest treatment, support groups and other resources affecting your health.

15. Fundraising activities. We may use your PHI to communicate with you to raise funds to support health care services and educational programs we provide to the community. You have the right to opt out of receiving fundraising communications with each solicitation.

16. Appointment reminders and health-related benefits and services. We may contact you with a reminder that you have an appointment.

B. You may object to the following uses of PHI:

1. Hospital directories. Unless you object, we may include your name, location, general condition and religious affiliation in our patient directory for use by clergy and visitors who ask for you by name.

2. Information shared with family, friends or others. Unless you object, we may release your PHI to a family member, friend, or other person involved with your care or the payment for your care.

3. Health plan. You have the right to request that we not disclose certain PHI to your health plan for health services or items when you pay for those services or items in full.

C. Your prior written authorization is required (to release your PHI) in the following situations:

You may revoke your authorization by submitting a written notice to the privacy contact identified below. If we have a written authorization to release your PHI, it may occur before we receive your revocation

1. Any uses or disclosures beyond treatment, payment or healthcare operations and not specified in parts A & B above.

2. Psychotherapy notes.

3. Any circumstance where we seek to sell your information.

WHAT RIGHTS YOU HAVE REGARDING YOUR PHI

Although your health record is the physical property of MUSC, the information belongs to you, and you have the following rights with respect to your PHI:

A. The Right to Request Limits on How We Use and Release Your PHI. You have the right to ask that we limit how we use and release your PHI. We will consider your request, but we are not always legally required to accept it. If we accept your request, we will put any limits in writing and abide by them except in emergency situations. Your request must be in writing and state (1) the information you want to limit; (2) whether you want to limit our use, disclosure or both; (3) to whom you want the limits to apply, for example, disclosures to your spouse; and (4) an expiration date.

B. The Right to Choose How We Communicate PHI with You. You have the right to request that we communicate with you about PHI in a certain way or at a certain location (for example, sending information to your work address rather than

your home address). You must make your request in writing and specify how and where you wish to be contacted. We will accommodate reasonable requests.

C. The Right to See and Get Copies of Your PHI. You have the right to inspect and receive a copy of your PHI (including an electronic copy), which is contained in a designated record set that may be used to make decisions about your care. You must submit your request in writing. If you request a copy of this information, we may charge a fee for copying, mailing or other costs associated with your request. We may deny your request to inspect and receive a copy in certain very limited circumstances. If you are denied access to PHI, you may request that the denial be reviewed.

D. The Right to Get a List of Instances of When and to Whom We Have Disclosed Your PHI. This list may not include uses such as those made for treatment, payment, or health care operations, directly to you, to your family, or in our facility directory as described above in this Notice of Privacy Practices. This list also may not include uses for which a signed authorization has been received or disclosures made more than six years prior to the date of your request.

E. The Right to Amend Your PHI. If you believe there is a mistake in your PHI or that a piece of important information is missing, you have the right to request that we amend the existing information or add the missing information. You must provide the request and your reason for the request in writing. We may deny your request in writing if the PHI is correct and complete or if it originated in another facility's record.

F. The Right to Receive a Paper or Electronic Copy of This Notice: You may ask us to give you a copy of this Notice at any time. For the above requests (and to receive forms) please contact: Health Information Services (Medical Records), Attention: Release of Information / 169 Ashley Avenue / MSC 369 / Charleston, SC 29425. The phone number is (843) 792-3881.

G. The Right to Revoke an Authorization. If you choose to sign an authorization to release your PHI, you can later revoke that authorization in writing. This revocation will stop any future release of your health information except as allowed or required by law.

H. The Right to be Notified of a Breach. If there is a breach of your unsecured PHI, we will notify you of the breach in writing.

HEALTH INFORMATION EXCHANGES
MUSC, along with other health care providers belongs to health information exchanges. These information exchanges are used in the diagnosis and treatment of patients. As a member of these exchanges, MUSC shares certain patient health information with other health care providers. Should you require treatment at another location that is a part of one of these exchanges, that provider may gather historical health information to assist with your treatment. You have the option of saying that this cannot be done. If you choose not to take part in these alliances, please contact the MUSC Privacy Office at 792-4037.

HOW TO COMPLAIN ABOUT OUR PRIVACY PRACTICES
If you think your privacy rights may have been violated, or you disagree with a decision we made about access to your PHI, you may file a complaint with the office listed in the next section of this Notice. Please be assured that you will not be penalized and there will be no retaliation for voicing a concern or filing a complaint. We are committed to the delivery of quality health care in a confidential and private environment.

PERSON TO CONTACT FOR INFORMATION ABOUT THIS NOTICE OR TO COMPLAIN ABOUT OUR PRIVACY PRACTICES
If you have any questions about this Notice or any complaints about our privacy practices please call the Privacy Officer (843) 792-4037, the Privacy Hotline (800) 296-0269, or contact in writing: HIPAA Privacy Officer / 169 Ashley Avenue / MSC 332 / Charleston SC 29425. You also may send a written complaint to the Office of Civil Rights. The address will be provided at your request.

CHANGES TO THIS NOTCE
We reserve the right to change the terms of this Notice at any time. We also reserve the right to make the revised or changed Notice effective for existing as well as future PHI. This Notice will always contain the effective date. You may view this notice and any revisions to it at: http://www.musc.edu/privacy.

EFFECTIVE DATE OF THIS NOTICE
This Notice went into effect on April 14, 2003.
Revised September 2013.