Informed Consent Cover Page for ClinicalTrials.gov posting:

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University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants *–Legally Authorized Representative*

Consent Form Version Date: June 28, 2024
IRB Study # 18-2795
Title of Study: Oral hygiene in assisted living
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What are some general things you should know about research studies?
Your family member is being asked to take part in a research study. To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. Your family member may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your/your family member's relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If your family member is a patient with an illness, your family member does not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this research study is to learn about and improve care and outcomes in assisted living communities. Your family member is being asked to participate in this research study because he/she lives in a participating assisted living community.

Are there any reasons your family member should not be in this study?
Your family member should not be in this study if he/she is younger than 18 years of age, has no teeth or denture, is on hospice or tube-feeding, expected to discharge in the next six months, does not have a diagnosis of dementia, or requires prophylactic antibiotics prior to dental examinations.

How many people will take part in this study?
There will be approximately 720 people in this research study.

How long will your family member's part in this study last?
Your family member's participation will last up to four months.

What will happen if your family member take part in the study?
If your family member takes part in this study, he/she will first receive an oral hygiene screening by a dental hygienist to assess his/her oral health. This person will examine your family member's teeth and gums, and record information about how clean and healthy they are. This examination will last about 20 minutes. Your family member will receive a follow-up oral hygiene screening after beginning the study.

You will also be interviewed about your family member's current cognitive and functional status and your participation in the community. The research team will also contact the Health Care Supervisor regarding whether your family member had pneumonia or experienced an adverse event during the study event (death, hospitalization, experienced a life-threatening event or a new disability, had swallowing problems related to mouth care or allergic reactions to mouth care products).

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge. The benefits to your family member from being in this study may be the identification of serious oral conditions for which he/she need treatment. Although unlikely, if such a condition is found, the dentist or hygienist will advise the assisted living staff.

What are the possible risks or discomforts involved from being in this study?
The oral hygiene screening may be uncomfortable, but the discomfort is expected to be minor and brief. In addition, there may be uncommon or previously unknown risks. You should report any problems to the researcher.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your family member's participation.

How will information about your family member be protected?
Participants will not be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your family member's information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA or NIH) for purposes such as quality control or safety.

Your family member's name will not be connected to the results of the oral hygiene screening. Instead, a number will be used. The data will be secured in a password-protected file and not shared with anyone outside the research team, unless you request otherwise.

What is a Certificate of Confidentiality?

This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

What will happen if your family member is injured by this research?

All research involves a chance that something bad might happen. This may include the risk of personal injury. In spite of all safety measures, your family member might develop a reaction or injury from being in this study. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your family member's insurance company. The University of North Carolina at Chapel Hill has not set aside funds to pay your family member for any such reactions or injuries, or for the related medical care. You do not give up any of your family member's legal rights by signing this form.

What if you want to stop before your family member's part in the study is complete?

You can withdraw your family member from this study at any time, without penalty. The investigators also have the right to stop your family member's participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

Will your family member receive anything for being in this study?

Your family member will not receive anything for taking part in this study.

Will it cost your family member anything to be in this study?

It will not cost your family member anything to be in this study.

Who is sponsoring this study?

This research is funded by the National Institute on Aging. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

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

What if you have questions about your family member's rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your family member's rights and welfare. If you have questions or concerns about your family member's rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Unencrypted Messaging

The study team may want to message you by email about reminders and notifications about the study, however you may say "no" to receiving these messages and still participate in this study. If you say "yes", messages may contain personal information about you and may be sent or received by the study team's personal electronic devices or in a method that is not able to be encrypted (protected) and there is the risk your information could be shared beyond you and the study team.

If, at any point, you wish to stop receiving unprotected communication from the study team, please notify the study team. After the study is complete and all research activities finished, or you withdraw from the study or request to stop receiving un-encrypted (un-protected) communication, you will no longer receive un-encrypted messages specific to this study.

Participant's Agreement:

☐ Check here to allow study staff to be able to email you if necessary.

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____

Signature of Legally Authorized Representative Date

_____

Printed Name of Legally Authorized Representative

_____ _____

Signature of Research Team Member Obtaining Consent Date

_____

Printed Name of Research Team Member Obtaining Consent