IRB #12-031-6

Principal Investigators (PI): Dr. Susan Reisine

PI Phone Number: 860 679 3823

Co-Investigator(s): Drs. Jean Schensul (Study MI, Institute for Community Research) Ruth Goldblatt, Effie Ioannidou and Ms. Kim Radda

Title of Research Study: Changing Oral Health Norms and Hygiene Practices among Vulnerable Older Adult (GOH- Good Oral Health)

Expected Duration of Subject's Participation: 4 2-hour visits

IRB Number:12-031-6

Name of Research Participant: _____

What Is The Purpose Of This Research Study?

This study is a collaboration between the University of Connecticut Dental School and the Institute for Community Research. The purpose is to improve the ways older adults and adults with disabilities care for their teeth and mouths.

Why Am I Invited To Participate?

You are invited to take part in this study because you are an older adult or a person with a disability living in low income senior housing.

How Many Other People Do You Think Will Participate?

We estimate that 90 people will enroll for different types of participations at this building. In total we expect about 240 people to enroll in the study including people at other residences.

How Long Will My Participation In This Study Last?

You will be asked to meet with research staff for up to four visits. Each visit will last about an hour. The last visit will take place about three months after the second one. The first visit will be a survey, the second will be a dental examination, the third will be an educational program to help you improve your oral health and the fourth, three months later, will be a dental exam and and a survey.

What Are the Costs To Me For Participating In This Study?

There will be no cost to you for participating in the research

What Procedures Will Be Done? Are They Safe?

The study will involve completing questionnaires twice, having a dentist examine your mouth two times, giving a spit sample and discussing plans on how to take better care of your teeth and mouth.

Procedure	**Mouth examination**
Procedure	A dental exam is a standard clinical procedure. This procedure will be done at your building at time that is convenient for you. We will assess the health of your gums, look for injuries in the mouth and check the amount of saliva you have. A red dye will be applied to your teeth to see the amount of plaque each tooth
Risk - Infection	The potential risk for infection is minimal and is the same as brushing your teeth. If such an infection should occur, antibiotics will be prescribed without cost to you. The study will pay for the antibiotic.
Safeguard	Licensed dentists enrolled in the Periodontal Residency Training program or the Advanced Education in General Dentistry program at the UCONN School of Dental Medicine will perform the clinical exams under the direction of Drs. Goldblatt and Ioannidou. Sterile procedures will be observed during examinations including use of new latex or plastic gloves, disposable instruments for the exams and sterile gauzes.
Cost to Participant	There will be no cost to you.
Procedure	**Mouth examination**
Risk - Pain	Individuals vary in their experience of pain during dental exams.
Safeguard	We will numb your gums during the dental exam to minimize pain and discomfort. Topical anesthetic benzocaine 20% will be used. It will be applied with a Q-tip on the cheek and tongue side of the gum tissue prior to the examination if the area is sensitive.
Cost	No cost to participant
Procedure	**Questionnaire**
Risk - minimal	There are no physical risks associated with the questionnaire. You may feel uncomfortable answering some of the questions.
Safeguard	You may always choose not to answer a question that makes you feel uncomfortable.

Cost to Participant	No Cost
Procedure	**Individual level tailored intervention**
	An experienced health educator will meet with you to discuss how to take better care of your teeth and mouth. He or she will ask you about what prevents you from taking better care of your teeth and mouth and what helps you. The educator will help you to improve your own care of your mouth and gums based on your dental exam and survey responses. The educator will ask you to show that you understand clearly how to clean your teeth, gums and mouth. You and the educator will make a plan together to improve the way you take care of your teeth and mouth.
Risk - minimal	There are no physical risks associated with the intervention. You may feel uncomfortable answering some of the questions.
Safeguard	You may always choose not to answer a question that makes you feel uncomfortable.
Cost to Participant	No Cost

Is There any Reason Why I May Not Be Eligible to Participate in this Study?

If you have ever had a heart valve or joint replacement, an infection in your heart, a stent (a small tube that keeps your arteries open) placed in your heart in the past 6 months or a heart attack (known as an MI) in the past 6 months, you are not eligible to participate in the dental examination or individual oral health education program. However, you are eligible to participate in the survey part of the study.

Is Participation Voluntary?

Participation in this study is voluntary. Before making a decision about whether to participate in this research study, please read and listen to the reading of this consent form carefully and discuss any questions you have with the interviewer. You may also want to talk with family members, or a friend before making a decision.

If you decide to participate in the study, you are free to withdraw from it at any time. If you decide not to participate or you withdraw from the study, your decision will not affect your present or future medical or dental care you receive at the University of Connecticut Health Center/John Dempsey Hospital or any future participation in ICR programs and services and there will be no penalty or loss of benefits to which you are otherwise entitled.

What Are the Benefits Of Participating In This Study?

You may benefit from the dental exams. You will be provided with the results of the exams and you will be referred for dental care if we find a need for care. You will be responsible for paying for dental care. Other people who may have the same oral health problems may benefit in the future. We might find a better way to diagnose or treat oral health problems. There is also the possibility that no benefit will come from this study.

Will I Be Compensated For Participating In This Study?

You will receive $15 for each of two clinical exams and $15 for completing each of two surveys for total of $60.

I prefer not to receive compensation for this study. _____

If you receive over $600 from participating in research studies over the course of the calendar year that money must be reported to the IRS as income.

What Alternative Procedures or Treatments Are Available To Me?

You have the option not to participate in this study.

How Will My Personal Information Be Protected?

The following procedures will be used to protect the confidentiality of your data. The study staff will keep all study records (including any codes to your data) locked in a secure location. Research records or study records are paper and electronic files where we keep individual research information. Research records will be labeled with a code and all contents of the research record will be labeled with only that code. The code will be derived from your first and last initial followed by a sequential 3 digit number that reflects how many people have enrolled in the study. A master key that links names and codes will be maintained in a separate and secure location. All electronic files (e.g., database, spreadsheet, etc.) containing identifiable information will be password protected. Any computer hosting such files will also have password protection to prevent access by un-authorized users. Data that will be shared with others will be coded as described above to help protect your identity. Any lab results will be stored in your research record.

We will do our best to protect the confidentiality of the information we gather from you but we cannot guarantee 100% confidentiality. You should know that the sponsor, NIDCR, the Department of Health and Human Services, the Health Center's Institutional Review Board and the Human Subjects Protection Office may inspect records. They may inspect records to ensure that the study is being done correctly. Also, if during the course of this study we learn of elder, or spousal abuse or of communicable diseases we are required to report it to State officials.

At the conclusion of this study the researchers may publish their findings in journals or magazines. Information will be presented in summary format and you will never be identified in any publications or presentations.

All information related to your participation in this study will be kept in a research record, apart from your medical record. The research record and its contents will be labeled with a code and kept locked in file cabinet in the office of the principal investigator. Only researchers officially appointed to work on this project, the sponsor and agencies or departments with responsibility for research compliance (e.g. FDA) will have access to your information while it is stored in an identifiable format.

What Will Happen to the Samples I Give During the Study?

We plan to measure the volume or amount of saliva you make by collecting it in a test tube. After we measure it we will freeze the saliva sample you provide us. We will analyze the samples for the amount and types of microbes (germs) that are in the saliva to better understand oral diseases and determining if improved oral hygiene will reduce the amount of microbes in the mouth. Upon completion of the study the sample will be destroyed.

Will I Find Out the Results Of This Research Study?

You will be provided with information if the results apply to you and the health of your teeth and mouth.

What If I Decide To Stop Participating In The Study?

You are free to stop taking part in this study at any time. If you decide to stop taking part in the study, your relationship with your doctors or the University of Connecticut Health Center will not be affected. If you decide to withdraw we ask that you let us know by calling Dr. Susan Reisine at 860 679 3823 or by sending a written notice to Dr. Susan Reisine, 263 Farmington Ave., MC3910, Farmington, CT 06030.

What If I Experience An Adverse (Bad) Event Related To My Participation?

If you have an adverse event you should tell one of the principal investigators as soon as possible. You may contact Dr. Susan Reisine at 860-679-3823 or by sending a written notice to her at The University of Connecticut School of Dental Medicine, 263 Farmington Ave., MC3910, Farmington, CT 06030, or you may contact Dr. Jean J. Schensul (who speaks Spanish) at 860-278-2044 ext. 227 or in writing at The Institute for Community Research, 2 Hartford Square West, Suite 100, Hartford, CT 06106.

The University of Connecticut Health Center (UCHC) does not provide insurance coverage to compensate for injuries incurred during this research. However, compensation may still be available. A claim may be filed against the State of Connecticut seeking compensation. For a description of this process contact a representative of the UCHC Institutional Review Board at 860-679-1019 or 860-679-4851.

The UCHC does not offer free care. However, treatment for a research related injury can be obtained at the UCHC for the usual fee.

What If You Learn About Something That May Make Me Change My Mind?

We will tell you about any new information that may affect your willingness to participate. If we think you need to know quickly the researcher or study coordinator may call you or send you a letter. If we do not think you need to know quickly, we will tell you at your next visit. If you still want to participate we will ask you to sign a new consent form.

What if I Have Questions?

The Principal Investigators and Co-Investigators are willing to answer any questions you have about the research, in English or Spanish. You are encouraged to ask questions before deciding whether to take part. You are also encouraged to ask questions during your study participation. If you have questions, complaints or concerns about the research, you should call the Principal Investigators Dr. Susan Reisine at 860-679-3823 or Dr. Jean Schensul (who speaks Spanish) at ICR, 860-278-2044, ext 227; or by sending a written notice to Dr. Susan Reisine, 263 Farmington Ave., MC3910, Farmington, CT 06030 or Dr. Jean Schensul at ICR, 2 Hartford Square West, Hartford, CT 06106.

If you have questions about your rights as a research subject you may contact a coordinator at the Institution Review Board at 860-679-1019 or 860-679-4851. You may also call a coordinator at the Institutional Review Board if you want to talk to someone who is not a member of the research team in order to pass along any suggestions, complaints, concerns or compliments about your involvement in the research, or to ask general questions or obtain information about participation in clinical research studies.

Please do not call the IRB number for medical related issues or to schedule or cancel an appointment.

Consent To Participation:

By signing this form you acknowledge that you have read, or have had read to you, this informed consent document, have talked with research personnel about this study, have been given the opportunity to ask questions and have them satisfactorily answered, and voluntarily consent to participate in this project as described in this form.

By signing this form the individual obtaining consent is confirming that the above information has been explained to the subject and that a copy of this document, signed and dated by both the person giving consent and the person obtaining consent, along with a copy of the Research Participant Feedback Form, will be provided to the participant The handout regarding the Genetic Information Non-Discrimination Act has also been provided to the subject.

Role	Printed Name	Signature	Date
Participant			

Person Obtaining Consent			