IRB Review
IRB NUMBER: 14-188-6
IRB APPROVAL DATE: 05/17/2018

Principal Investigator (PI): Susan Reisine, Ph.D.

Back-up Principal Investigator: Jean Schensul, Ph.D.

PI Phone Number: 860 679 3823

Title of Research Study: GOH- Good Oral Health – A Bi-level Intervention to Improve Older Adult Oral Health

Expected Duration of Subject's Participation: 8 visits – 3 surveys for about 1 hour each; 1 education session for about 1 hour; 4 dental exams and oral hygiene skills assessments for about 20 minutes each; and 3 campaign events (or oral health fairs) that last about 2 hours each over about 2 months. The study will last 16-18 months at your building.**

Sponsor/Funding Agency: National Institute of Dental and Craniofacial Research

IRB Number: 14-188-6

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 60 people will enroll for participation at this building. In total we expect about 360 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 eight visits. Three visits for the surveys and one visit for the educational session will last about an hour each. Four visits for the dental exam and oral hygiene skills assessment will last about 20 minutes each. There will be 3 campaign events or oral health fairs at the building which we ask that you attend and complete information about what activities you participated in. The following table shows how the visits will occur.

Visit	Activity	Timing	Compensation
1.-T0	Survey – 1 hour	Entry to study	$15.00

2.-T0	Dental exam and assessment of oral hygiene skills on a mouth model – 20 minutes	Entry to study	$15.00
	3 Campaign Events/Oral health fairs – 2-3 hours	3-6 months after study entry	None
3.-T1	Survey– 1 hour	1-3 months after campaigns completed	$15.00
4.-T1	Dental exam and assessment of oral hygiene skills on a mouth model – 20 minutes	1-3 months after campaigns completed	$15.00
5.	Tailored educational session	Up to 45 days after T1	None
6.-T2	Survey – 1 hour	1-3 months after educational session	$15.00
7.-T2	Dental exam and assessment of oral hygiene skills on a mouth model – 20 minutes	1-3 months after educational session	$15.00
8.-T3	Dental exam, brief survey and assessment of oral hygiene skills on a mouth model – 20 minutes	6-7 months after T2	$20.00

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

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

What Will I Be Asked to Do?

The study will involve:

- completing questionnaires three times;
- having a dental hygienist examine your mouth four times;
- assessing your oral hygiene skills on a mouth model four times;
- meeting with a health educator for a one-on-one oral health educational session to discuss plans on how to take better care of your teeth and mouth and show you how to brush and floss your teeth;
- attending the 3 campaign events (oral health fairs) that will take place in your building.
- A dentist from our study may conduct an additional dental exam.**

With your permission the educational session will be audio recorded to assure consistency across educators.

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 and look for injuries in the mouth. A red dye will be applied to your teeth to see the amount of plaque on 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 dental hygienists will perform the clinical exams under the direction of the Clinical Director. 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	If you experience pain, 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. Loss of privacy is possible if an unauthorized person would hear your responses
Safeguard	You may always choose not to answer a question that makes you feel uncomfortable. Questionnaires will be administered in a private area to protect privacy.
Cost to Participant	No Cost
Procedure	**Oral Hygiene Skills Assessment**
Risk - none	There are no risks associated with this assessment. You will be asked to show how you brush and floss on a mouth model.
Safeguard	None needed
Cost to Participant	No cost to participant
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. . A health educator will show you how to brush and floss your teeth. Then, using a mouth model, you will practice the brushing and flossing as shown by the educator.
Risk - minimal	There are no physical risks associated with the intervention. You may feel uncomfortable answering some of the questions.
Safeguard	You can refuse to participate.
Cost to Participant	No Cost
Procedure	**Completing Passports at Oral Health Fairs**
Risk - minimal	There are no physical risks associated with completing the forms. You may feel uncomfortable answering some of the questions.
Safeguard	You can refuse to complete the forms or refuse to answer any of the questions on the forms
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 an infection in your heart, a heart valve replacement in the past 6 months, a stent (a small tube that keeps your arteries open) placed in your heart in the past 6 weeks, a heart attack (known as an MI) in the past 6 weeks, have fewer than two of your natural teeth, if you have a conservator (a guardian appointed by a judge to protect and manage your financial affairs and/or your daily life), or you are currently on dialysis (a medical process that takes over the role of your kidneys when they can no longer work properly; you have a tube or other form of access through your arm, leg, neck or abdomen) you are not eligible to participate

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 the Institute for Community Research 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 four clinical exams, $15 for completing each of three surveys and $5 for completing one brief questionnaire for a total of $110.

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. Signing a W-9 may be required.

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, where we keep individual research information, are both paper and electronic files. Research records will be labeled with a code and all contents of the research record will be labeled with only that code. A 6-digit code will be derived from your first and last initial and the month and day you were born. 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.), including those 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.

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, child or spousal abuse, the intent to harm yourself or others 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.

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, dentists 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.

Can Someone Make Me Stop Participating in the Study?

We may ask you to stop participating if, during the study period, you have 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, a heart attack (known as an MI), have fewer than two of your natural teeth, if a conservator is appointed to you, or you are on dialysis. We also may ask you to stop participating if you no longer live in the building, you exhibit continued disruptive behavior while participating in the study or you become unable to complete the surveys.

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), the Institute for Community Research (ICR) and your building management do 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 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 or dental 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.

Role	Printed Name	Signature	Date
Participant			
Person Obtaining Consent			