IRB #12-031-6

Principal Investigators (PI): Dr. Susan Reisine

PI Phone Number: 860 679 3823

Co-Investigator(s): Drs. Jean Schensul (Study MI at 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: 2 1-hour interviews

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 approximately 90 people will enroll at this building for different types of participation in the study. In total we expect about 240 people to enroll in the study including people in other buildings..

How Long Will My Participation In This Study Last?

You will be asked to meet with research staff two times, each time to complete a survey. Each survey will last about one hour.

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 a questionnaire two times approximately 3 months apart

Procedure	Questionnaire
Risk -	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

Is Participation Voluntary?

Participation in this study is voluntary. Before making a decision about whether to participate in this study, please read and listen to the reading of this consent form carefully and discuss any questions you have with the researcher. 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 care you receive at the University of Connecticut Health Center/John Dempsey Hospital or any future participation in ICR programs, 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?

There is no direct benefit to you. Other people who may have oral health problems may benefit from this study 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 $15.00 for completing each questionnaire for a possible total of $30.00 for two visits.

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 locked in a secure location. Research records or study records are paper and electronic files where we keep individual research information. Only researchers officially appointed to work on this project, the sponsor (National Institute of Dental and

Craniofacial Research) and agencies or departments with responsibility for research compliance will have access to your information while it is stored in an identifiable format 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.

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 and 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. You may request a report on the overall results of the study when the results become available.

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 nor your relationship with the Institute for Community Research. 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, Suite 100, 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 (the participant, legally authorized representative, parent(s) or guardian) 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			
Witness			