CONSENT FORM
Project G.O.H Post-Intervention Interview

Principal Investigators (PI): Susan Reisine

PI Phone Number: 860-679-3823

Co-Investigator(s): Drs. Jean J. Schensul Ruth Goldblatt, Effie Ioannidou, and Ms. Kim Radda

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

Expected Duration of Subject's Participation: 1 45-minute visit

IRB Number: 12-031-6

External Sponsor/Funding Entity: National Institute of Dental and Craniofacial Research

Name of Research Participant: _____

What Is The Purpose Of This Research Study?

This study is 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 currently are a participant in the study, Changing Oral Health Norms and Hygiene Practices among Vulnerable Older Adults (GOH: Good Oral Health). You are part of the study that included participation in 2 surveys about your oral health knowledge and behaviors, 2 oral health screenings, a session where an experienced health educator met with you to discuss how to take better care of your teeth and mouth, and/or oral health fairs in your building. We now are inviting you to participate in an interview that will include questions about, your experience as a participant in the study.

How Many Other People Do You Think Will Participate?

A total of 134 people have participated in the entire study, including people in other buildings. We estimate that approximately 30 people will agree to participate in these interviews at this building.

What will my participation include?

Your participation will include meeting with a member of our staff to discuss your experiences as a participant in the study. We want to get your feedback on the face-to- face oral health education session, the oral health screenings, the oral health fairs, your oral health behaviors, knowledge you may have gained through participation in the study, and your opinions about how the study was understood and received, in general, by residents in your building. We are requesting your permission to digitally audio record this session. This recording will provide a record of our discussions that will help us learn how to improve the study in the future. If you choose not to have the interview audio recorded, you can still participate and we will write down your responses using pen and paper.

I agree to be audio recorded _____

I prefer not to be audio-recorded but wish to participate in the interview_____

How Long Will My Participation Last?

Your participation in this interview will last approximately 45 minutes.

Is Participation Voluntary?

Your participation in this part of the study is completely voluntary. You can refuse to participate in this interview or in the audio recording of the interview. You can stop at any time without penalty, and there are no penalties, loss of services or benefits to which you are otherwise entitled if you choose not to participate.

What Is The Cost For Me To Participate In This Interview?

There is no cost to you for participating in this part of the study.

What Risks Are Involved If I Choose To Participate In This Part Of The Study?

The potential for risk is minimal. Some questions may make you feel uncomfortable, but you don't have to answer any questions that make you feel that way. There is also a possible risk of loss of privacy if a person outside the study hears or sees your responses. Precautions are taken to protect your confidentiality as we review that in this next section.

How Will My Personal Information Be Protected?

The following procedures will be used to protect the confidentiality of the information that we collect from you: 1) all project staff are trained and monitored to protect research participants, and to maintain your confidentiality under the supervision of the University of Connecticut Health Center (UCHC) and the Institute for Community Research (ICR); 2) all project materials will be kept in locked file cabinets or password protected computer data files in secure locations at the UCHC and ICR and will be used only for project purposes by authorized staff; 3) all digitally audio-recorded interviews will be uploaded into password-protected computer files and erased from the recorder – only code numbers introduce the interview on tape; 4) only your individually constructed code number will be used for identification in interview data files; 5) we will not use any information that could personally identify you in project data to be presented to the public. Therefore, you will not be identifiable in any presentations or publications based upon this research. The code assigned to your files consists of the first initial of your first and last name and a number in the order which you were enrolled, beginning with 100.

We will do our best to protect the information that we gather from you but we cannot guarantee 100% confidentiality. You should know that the study sponsor, the National Institute of Dental and Craniofacial Research, and UCONN Health Center's Institutional Review Board (IRB) and Human Subjects Protection Office may inspect records to be sure that the study is being done correctly. Also, if during the course of the study we learn of elder or spousal abuse we are required to report it to State officials.

What Are The Benefits Of Participating In This Part Of The Study?

There is no direct benefit to you. Your contributions during this interview will help us to improve our study and help other people to improve their oral health in the future. There is also the possibility that no benefit will come from this study.

Will I Be Compensated For Participating In This Part Of The Study?

You will receive $15.00 for participating in this interview.

I prefer not to be compensated for this interview. _____

If you receive more than $600.00 for 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 to not participate in this study.

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

If you have an adverse event, you should tell the Principal Investigators as soon as possible. You may contact Dr. Susan Reisine at 860-679-3823 or Dr. Jean J. Schensul at 860-278-2044, ext. 227.

The 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 IRB 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 Investigator is willing to answer any questions you have about the research. You are encouraged to ask questions before deciding whether to participate in this part of the study. You also are 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 J. Schensul at 860-278-2044, ext. 227.

If you have questions about your rights as a research subject you may contact a coordinator at the UCHC IRB 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 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 numbers 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 [the feedback form was given at the time of the original consent] will be provided to the participant.

Role	Printed Name	Signature	Date
Participant			
Person obtaining consent			