IRB #12-0313-6

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Co-Investigator(s): Jean Schensul, Ph.D. (ICR). Ruth Goldblatt, DMD, Effie Ioannidou, DDS, MDS and Kim Radda, M.A., R.N.

Title of Research Study: Changing Oral Health Norms and Hygiene Practices among Vulnerable Older Adult

Expected Duration of Subject's Participation: Eight months– including 8-10 two hour training sessions, 4 – 10 two hour sessions to create a campaign plan, video (optional) and planning and implementation meetings.

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 senior housing.

How Many Other People Do You Think Will Participate?

We estimate that 5 - 10 people will enroll in the Good Oral Health (GOH) Campaign Committee at this building. In total we expect about 240 people to enroll in the study.

What Will My Participation Include?

The specific role of the campaign volunteers includes:

- learning about oral health and good oral health hygiene;
- raising and addressing any concerns they might have about oral health promotion;
- helping to organize 1 to 2 campaigns with multiple parts in their building.
- agreeing to recruit residents to campaign events;
- working with intervention staff on an oral health movie (optional);

- Working with project staff to implement one to two 2 – 3 hour long campaigns and their constituent activities including: staffing information tables and game and poster contest activities at the oral health fairs;
    - helping to set up food and entertainment;
    - presenting testimonies
- participating in focus group discussions after the campaigns to evaluate their accomplishments.
- completing a study survey before and after the intervention phase, along with other building participants;

The 8-10 training sessions include:

- Discussions of committee roles and responsibilities
- Explanations of the main ideas behind the intervention
- Demonstrations of oral health and oral health self management behaviors and volunteer practice for the behaviors;
- Review of the components of the Pro-GOH campaign;
- Creation of a Campaign plan.

Four additional sessions involve the creation of Pro-GOH campaign materials such as posters, flyers, and games in English and Spanish that will include Pro-GOH messages and graphics portraying oral health practices. Project staff will work with you to create these materials.

How Long Will My Participation In This Study Last?

Participation will last eight months.

Is Participation Voluntary?

Participation in this study is voluntary. Before making a decision about whether to participate in this research study, please read 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 or dental care you receive at the University of Connecticut Health Center/John Dempsey Hospital and there will be no penalty or loss of benefits to which you are otherwise entitled.

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

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

What Risks Are Involved If I Choose To Participate?

Some questions may make you feel uncomfortable, but you do not have to answer any questions that make you feel that way. The other possible risk is that your personal information may be seen or heard by people other than the researchers.

What Are the Benefits Of Participating In This Study?

You will not benefit directly from the information we gather in the study other than learning information you did not know about taking care of your oral health. Your contribution may help other people to improve their oral health self-care in the future. There is also the possibility that no benefit will come from this study.

Will I Be Compensated For Participating In This Study?

At the end of the campaign activities you will receive $75.00 for your participation on the Campaign Committee.

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?

For you and other building residents who complete the survey, the following procedures will be used to protect the confidentiality of your data that will be collected as a member of the GOH Campaign Committee. All information related to your participation in this study will be kept in a research record. The study staff will keep all study records (including any codes to your data) locked in a secure location. All paper documents containing identifiable information (e.g., signed consent forms) will be kept in locked files that are separate from other study records. 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., computerized 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. 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.

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 United States Department of Health and Human Services, the UCONN Health Center's Institutional Review Board and the Human Subjects Protection Office 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. Information will be presented in summary format and you will not be identified in any publications or presentations. No individual persons will ever be named or referred to in these presentations of intervention results.

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.

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

If you have an adverse event you should tell the principal investigator 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 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 about this new information, the principal investigators 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 the next time we are at your building. If you still want to participate we will ask you to sign a new consent form. If you think you have something that needs to be answered quickly, we will be available to answer your questions or concerns.

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, 146 Wyllys Street, Hartford, CT 06106.

If you have questions about your rights as a research subject you may contact a coordinator at the University of Connecticut Health Center Institution Review Board (IRB) at 860-679-1019 or 860-679-4851. You may also call a coordinator at the IRB 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	Time
Participant				
Witness				