**Manual of Procedures (MOP)**

**for**

**Good Oral Health: A Bi-level Intervention**

**to Improve Older Adult Oral Health**

**NIDCR Protocol Number: 14-046-E**

**Draft Number: 0.8**

15 October, 2018

Summary of Changes:

|  |  |  |  |
| --- | --- | --- | --- |
| Number | Date | Affected Chapter(s) | Summary of Revisions Made: |
| V0.2 | 10/29/2014 | All | Changes made to reflect changes in Protocol v0.2 |
| V0.2 | 11/5/2014 | 6 | Timing of assessments |
| V0.7 | 5/25/2017 | 2, 3, 5, 6, 7, 9, 10, 14 | Changes made to reflect changes in Protocol v1.2 and timing of Cycles 1-3 activities |
| V0.8 | 10/15/2018 | 2, 3, 5, 6 | Changes made to reflect changes in Protocol v1.5 and v1.6 |

Chapter/Appendix Version Tracker

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| **Chapter Number / Appendix** | **Title** | **Current, Approved Version** | |
| **Number** | **Date** |
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1. INTRODUCTION TO THE MANUAL OF PROCEDURES

1.1 Purpose

A Manual of Procedures (MOP) is a handbook that guides a study’s conduct and operations. It supplements the study protocol by detailing a study’s organization, operational data definitions, recruitment, screening, enrollment, randomization, intervention procedures and follow-up procedures, data collection methods, data flow, Case Report Forms (CRFs), and quality control procedures. The purpose of the MOP is to facilitate consistency in protocol implementation and data collection across participants and clinical sites. Procedures in the MOP should be followed with the same degree of vigor as those documented in the protocol. Use of the MOP increases the likelihood that the results of the study will be scientifically credible and provides reassurance that participant safety and scientific integrity are closely monitored.

This MOP is to be used as a reference document for policies and procedures related to the study entitled Good Oral Health: a Bi-level Approach to Improve Older Adult Oral Health.

All staff members participating in the conduct of this study at participating institutions should have ready access to the MOP and be familiar with its contents. The current version of the MOP and archived versions are maintained in hard copy in the Essential Documents binder and electronically in the study folder on the ICR network.

1.2 Updating and Version Control

The MOP is a dynamic document that will be updated throughout the conduct of a study to reflect any protocol or consent amendments as well as the refinement of the CRFs and study procedures. As sections/chapters are revised, the MOP version information and date on the cover page and Table of Contents will be updated; the Summary of Changes table on the cover page will list the chapters that have changed and will include a general summary of those changes.

As the study progresses, the field coordinator will be responsible for documenting any recommended and approved changes to the MOP. The field coordinator will incorporate all of the approved changes and will update the MOP semi-annually. When the revisions are final, the MOP will be posted to the study’s website or otherwise made available to all study personnel.

The author of an updated MOP chapter will ensure that all necessary changes are captured in the update and that the document is up-versioned.

The Webmaster is responsible for document control of the MOP on the study website and for filing updates in a timely manner. The Webmaster will post updated MOP chapters on the website within 2 business days of receipt.

The principal investigator or designee is responsible for on-site document control of the MOP and for filing updates in a timely manner.

If paper copies of the MOP are maintained in the binder, the study coordinator will print and store the updated materials in the binder. Remove the outdated materials from the binder, and file in another location clearly marked “obsolete.”

1. ADMINISTRATIVE

2.1 Study Leadership Structure

2.1.1 Organizational Chart

2.1.2 Roles and Responsibilities

This study is a collaborative effort of the University of Connecticut School of Dental Medicine (SDM) and the Institute for Community Research (ICR), Hartford, CT. The primary mission of the SDM is to train dental students and residents to practice dentistry, dental specializations and geriatric dentistry. A second mission is to conduct basic and social science translational research to benefit residents of the state experiencing disparities in oral health and dental health care. The primary mission of ICR is to conduct rigorous research in community settings in collaboration with community partners to address health inequities and disparities, with NIH and other federal and foundation funding. The collaboration of these partners constitutes a major strength of the proposed study. SDM brings its expertise in geriatric oral health, dental care and community based oral health research and ICR brings its expertise in the conduct of theory-driven intervention research with community residents and older adults, especially those residing in senior housing for diverse populations. This team has been working together for the past three years, with NIDCR funding to build research infrastructure in public and publicly funded housing for diverse older populations, and to conduct the R34 pilot of the current study.

|  |  |  |
| --- | --- | --- |
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| **NIDCR Medical Monitor:** | Kevin D. McBryde, MD  Medical Officer  Division of Extramural Research  6701 Democracy Blvd., Rm. 638  Bethesda, MD 20892-4878  Telephone: 301-594-0170  Fax: 301-480-8319  mcbrydekd@mail.nih.gov | |
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| **Institutions:** | University of Connecticut School of Dental Medicine  263 Farmington Avenue, MC3910  Farmington, CT 06030-3910  Susan Reisine, Ph.D., Professor Emeritus  PH: 860 679-3823  FAX: 860 679-1342  [reisine@uchc.edu](mailto:reisine@uchc.edu)  Institute for Community Research  146 Wyllys Street  Hartford, CT 06106-5128  Jean J. Schensul, Ph.D., D.H.L., Senior Scientist and Founding Director  PH: 860 278-2044 x227  FAX: 860 278-2141  [jean.schensul@icrweb.org](mailto:Jean.Schensul@icrweb.org) | |
| **Other Key Personnel:** | Rajesh Lalla, D.D.S., Co-Investigator  University of Connecticut School of Dental Medicine  263 Farmington Avenue, MC 1605  Farmington, CT 06030-3910  PH: 860 679-8007  FAX: 860 676-3454  lalla@uchc.edu  Kim Radda, R.N. M.A., Co-Investigator and IRB administrator at ICR  Institute for Community Research  146 Wyllys Street  Hartford, CT 06106-5128  PH: 860 278-2044  FAX: 860 278-2141  [kim.radda@icrweb.org](mailto:kim.radda@icrweb.org) | |
| **Delegation of Responsibilities** | | |
| Protocol questions | | PIs (Reisine/Schensul) |
| Reporting an adverse event (AE) | | PIs/Kim Radda |
| Request for additional supplies | | Hygienists (Rita Bodea, Amauri Barbosa)/Clinical Director (Lalla) |
| Enrolling/Randomizing a participant | | Colleen Foster-Bey/Zahira Medina |

We will maintain Delegation of Responsibilities Logs in the Regulatory binder.

2.1.3 Steering Committee

This is a single site clinical trial which does not at this time require a steering committee. However, it is our practice for the research team to meet weekly and this group functions as a steering committee. We discuss and monitor:

a) the general design and conduct of the study;

b) preparation of the essential study documents, including the protocol, protocol amendments, MOP and data collection forms;

c) review of data collection practices and procedures; changes in study procedures as appropriate; allocation of resources based on priorities of competing study demands;

d) review of study progress and implementation of necessary steps to ensure the achievement of study goals; review and implementation of necessary steps to ensure achievement of study goals;

e) review and implementation of recommendations from those responsible for safety monitoring.

We submit a monthly report electronically to the NIDCR program officers to keep them advised of our progress.

2.2 Policies and Procedures

2.2.1 Conflict of Interest (COI) and Financial Disclosure Policies

*See -* <http://grants.nih.gov/grants/peer/COI_Information.pdf>

Additionally, all federal and institutional guidelines will be followed related to disclosure of conflict of interest and financial disclosures.

2.2.2 Protocol Amendment Procedures

Protocol amendments require approval by the PIs prior to submitting the amendment to the IRB. Written IRB approval of protocol amendments is required prior to implementation. Any amendment to the protocol will be adhered to by all study staff and will apply to all subjects.

2.2.3 Version Control of Study Documents

Version control procedures will be used to manage changes to all study documents. Version control directions are found at the following site: <http://www.nidcr.nih.gov/ClinicalTrials/ToolkitClinicalResearchers/ClinicalTrialsProtocolTemplate/Version+Control+Guidelines.htm>.

2.2.4 Communication Plan

One member of the research team will take notes at each team meeting to document plans and decisions about protocol changes, recruitment strategies, adverse events and IRB issues. Notes will be emailed to all team members and will be stored on the shared drive at ICR. Issues arising in the field will be referred to PIs for resolution. Any conflicts among team members will be resolved by PIs. Daily communication with SDM personnel will be maintained by Dr. Reisine and at ICR by Dr. Schensul

2.2.5 Clinical Trial Registry/ClinicalTrials.gov and PubMed

Prior to subject enrollment, and after the protocol is IRB approved, this clinical trial will be registered with [ClinicalTrials.gov](http://clinicaltrials.gov) via a web based data entry system called the Protocol Registration System (PRS), which is maintained by the National Library of Medicine. We recognize the importance of dissemination of results and will publish our finding in peer-reviewed scholarly journals as well as making presentations at professional meetings.

Results of select studies must be reported within one year of the completion of the final participant (see <http://prsinfo.clinicaltrials.gov/results_definitions.html> and US Public Law 110-85, Section 805 <http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110.pdf>.

This study will comply with the [NIH Public Access Policy](http://publicaccess.nih.gov/policy.htm), which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive [*PubMed Central*](http://www.pubmedcentral.nih.gov/) upon acceptance for publication.

2.2.6 Data Request Policy

Any individual seeking data for a paper or presentation from this project will need to submit a request for approval from the PIs. In this sheet, the following information should be provided:

Paper/presentation topic

Study hypotheses and expected variables or concepts to be explored

Date of submission to PIs

Expected authors in expected authorship order (please see Authorship Guidelines below.)

Expected Journal or Professional Conference to which the paper will be submitted.

Paper proposals will be discussed during weekly meetings with the research team. After receiving an email from PIs approving the paper proposal, the authors will sign an agreement by which they agree to the roles and responsibilities and the authorship order. This will help prevent future conflicts and delineate the level of contribution each author would be required to make towards the scientific paper/monograph.

The types of data that do not require a formal request include: clinical data requested for quality control processing; information regarding study monitoring, timelines, or other administrative needs; information already listed in periodic reports.

* + 1. Publication and Presentation Policy

**Procedures for Approval of Manuscript/Paper/Presentation Project GOH**

**Acquiring Topic Approval**

Any individual seeking to lead author a paper or presentation from this project will need to submit a request for approval from the PIs. In this sheet, the following information should be provided:

Paper topic

Study hypotheses and expected variables or concepts to be explored

Date of submission to PIs

Expected authors in expected authorship order (please see Authorship Guidelines below.)

Expected Journal or Professional Conference to which you will submit

Paper proposals will be discussed during weekly meetings with the research team. After receiving an email from PIs approving the paper proposal, the authors will sign an agreement by which they agree to the roles and responsibilities and the authorship order. This will help prevent future conflicts and delineate the level of contribution each author would be required to make towards the scientific paper/monograph.

**Authorship Guidelines**

***Authorship and Contributorship***

According to the International Committee on Medical Journal Ethics (ICMJE), an author is defined as one who has made substantial contributions to the conception and development of a manuscript. The ICMJE guidelines state that “authorship credit should be based on all of the following: 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or advising it critically for important intellectual content; and 3) final approval of the version to be published”. All other contributors should be listed as acknowledgements.

This means that, while all project staff and investigators may be included as authors on any publications produced from this study, they will only be included as an author on any given publication or presentation if they meet guidelines for authors as defined by the ICMJE. Otherwise, project investigators and staff will be listed as contributors to a given manuscript, as defined above. HOWEVER, every effort will be made to involve all above listed investigators as authors on each paper produced from this project. It is the responsibility of the lead author on each given paper from this project to ensure such opportunities for involvement are given. A lead author must contact each project investigator to invite them to be an author on the paper and specify their expected role.

***Authorship Order***

**LEAD/FIRST AUTHOR**-- The lead or first author of a given paper or professional presentation will lead conceptualization and writing of the manuscript or presentation. He or she will also decide authorship involvement and order. All of this will be subject to approval from the principal investigators, using the procedure outlined in the Procedures for Approval of Manuscript/Paper/ Presentation. It is the responsibility of the lead author to ensure that all listed authors on the paper or presentation contribute at the level submitted to and approved by the PI. Alteration of authorship order subsequent to this approval will require re-approval by the PI serving as senior author on the paper.

**SECOND AUTHOR**-- The second author of a given paper or professional presentation will support the paper with co-conceptualization and extensive writing, such as taking a leadership role on writing a section of the paper or presentation. Given the nature of partnership between the UCONN SDM and ICR, the second author should be from one of these organizations. This approach will increase the collaboration, knowledge, and perspectives offered by the paper or presentation. For lead authors with less writing experience, inclusion of a more seasoned publication writer is recommended for second authors.

**SENIOR (LAST) AUTHOR**-- Senior authors of papers will be positioned as such due to their oversight of the paper/presentation as a whole and their ability to ensure that the paper/presentation fits within the overall study and the previous and ongoing papers and presentations developed from the initiative. As such, principal investigators are in the optimal position to serve as senior author on all papers and presentations produced from their respective studies.

***Role of the Lead Author to Pursue the Paper/Presentation Once Approved:*** A lead author of an approved paper or presentation will have SIX MONTHS from the date of approval to submit the DRAFT paper or presentation for review. Should the paper or presentation not be completed within that SIX MONTH time frame, rights to lead author this work are relinquished.

***Obligations to Maintain Author Involvement on a Paper:*** In accordance with the guidelines of most journals, authors are required to share revisions and resubmissions with all authors at every resubmission. Nothing should be submitted to any journal or any conference without approval from all authors on the paper or presentation, unless they agree that it may be submitted without their final approval. Each author must be provided with a final copy of any submitted manuscript, report or presentation for their records. The primary author must also provide each author, as well as the PIs, with a full citation of presented or published work.

***Changing Approved Paper Topic, including Hypotheses and Expected Variables to Be Explored, Authors and Authorship Order, Journal or Conference for Submission:***Any changes in information provided and approved via this topic approval process will require resubmission of the Topic Approval Form with specifications as to why these changes are needed. Authors may not alter this information without approval from the PI and the senior author. In such intentions, the lead author should discuss with other authors and send an email to the PIs and get feedback on the suggested change.

* + 1. Organizational Chart

2.2.9 Roles and Responsibilities

Roles and responsibilities include:

Interventionist: The interventionists will be trained in the creation and implementation of the tailored AMI intervention and in working with residents to implement their oral health plan. They also will be trained to administer and score the oral health skills assessment (practice to mastery). Interventionists will also implement the campaigns with building residents. The intervention coordinator will be responsible for coordinating and scheduling and ensuring quality administration of the tailored AMI intervention and the campaigns and storing and integrating fidelity data for the intervention (focal points, implementation plan and practice to mastery pre and post data).

Survey Administrator: The survey administrators will be trained in administering consents, and the survey, saving the QDS files to a backup file in the field and uploading the files to a centralized server at ICR. The survey coordinator will be responsible for coordinating the collection and integration of survey, clinical assessment, and skills assessment data.

Campaign Trainers: Campaign trainers will deliver the campaign curriculum and work with building residents to develop campaign messages and materials for the campaigns (see above for Interventionists).

Dental Examiners: Hygienists will serve as dental examiners and conduct the clinical assessments. They also will be responsible for assuring that clinical data are properly recorded.

Research Assistant/Recruiters: The research assistant/recruiter will assist with recruitment, survey administration, note taking during project and Campaign Committee meetings and transcription.

Data Manager: The data managers will ensure data quality control, organization and monitoring, data cleaning plus regular weekly reporting.

2.2.10 Qualifications

All CVs and licenses for investigators and staff will be filed in the Essential Documents binder and the Regulatory binder.

* 1. Safety Oversight Committee

In addition to the PI’s responsibility for oversight, study oversight will be under the direction of the NIDCR Medical Monitor. The PIs will submit a report every 6 months to the NIDCR Medical Monitor for review. This report will include data regarding enrollment and retention, unanticipated problems and protocol deviations, outcome measures, quality management findings and other relevant parameters. If necessary, additional steps may be taken to ensure data integrity and protocol compliance. In addition, monthly progress reports are submitted electronically through UConn Health to NIDCR.

2.4 Scientific Advisory Board

We will not have a scientific advisory board because this is a single site trial and the PIs together will guide the scientific integrity of the study in collaboration with NIDCR staff who are collaborators in this U grant.

2.4.1 Roles and Responsibilities

not applicable

2.4.2 Membership

not applicable

2.5 Community Advisory Board

A community advisory board provides an opportunity for interested members of a community, especially clinical study participants, to understand the clinical research process and to share their input regarding the development, implementation and outcomes of specific clinical studies. The board may also provide technical assistance on issues related to recruiting and retaining study participants. The Oral Health Research Strategic Alliance (OHRSA) served this purpose in the planning grant and has since been merged with the statewide Task Force on Oral Health for Older Adults to become the Oral Health for Older Adults Consortium to assure sustainability (see letter of support from Linda Ferraro, Connecticut Department of Public Health Dental Director). The membership includes strategic stakeholders, state agencies, and oral health advocacy groups as well as residents of senior housing that reflect the general population of the buildings we are collaborating with. We plan to meet twice a year with this group to review study progress, address any significant issues, and report and discuss interim results.

2.5.1 Roles and Responsibilities

The Oral Health for Older Adults Consortium offers the platform from which researchers and key sectors of the community concerned with reducing geriatric oral health disparities interface, dialogue, plan, conduct research and translate it to broader practice and training initiatives. Subgoals include the creation and institutionalization of strong university/community leadership, regular meeting and program structure, a multi-year action plan, generation of interdisciplinary partnership research ideas, a research agenda and research proposals and a system for recruiting and securing new members. At the present time, the merged OHRSA/Task Force consists of representatives from the University of Connecticut School of Dental Medicine and School of Medicine; Institute for Community Research; North Central Agency Area on Aging; Connecticut Community Health Center organizations; the Connecticut State Department of Public Health; the CT State Dept. on Aging; CT Dept. of Developmental Services; Meriden Department of Health and Human Services; the Connecticut Oral Health Initiative; local health/oral health/social service providers; low income senior housing complexes in central Connecticut; the Connecticut Dental Health Partnership and the Connecticut State Dental Association.

2.5.2 Membership

See appendix for members and contact information.

1. REGULATORY

3.1 Regulations and Regulatory Bodies

The National Institute of Dental and Craniofacial Research (NIDCR) supports clinical research and interventional clinical trials involving human subjects and must ensure compliance with human subjects regulations.

All clinical research and clinical trials supported by NIDCR shall comply with ICH and GCP guidelines.

Institutions engaged in research with NIDCR as a Federal Sponsor must comply with the Office of Human Research Protection (OHRP) regulations which include the relevant parts of 45 CFR 46 : Protection of Human Subjects (the Common Rule) and agree to the Terms of the Health and Human Services (HHS), OHRP Terms of the Federalwide Assurance (FWA).

3.2 Federal Wide Assurance Documentation

All institutions “engaged” in the conduct of the research will have in place a Federal Wide Assurance (FWA) with the DHHS Office for Human Research Protections (OHRP). This assurance documents the institution’s commitment to the human subjects regulations.

Documentation of the following information will be stored in the sites’ files and will be confirmed prior to site activation:

CICATS IRB of UConn Health

IRB00007960

UCH IRB Number 14-188-6

FWA 00006064

3.3 Protection of Human Subjects

The National Institute of Dental and Craniofacial Research (NIDCR) supports clinical research and interventional clinical trials involving human subjects and must ensure compliance with human subjects regulations.

The investigators will ensure that this study is conducted in full conformity with the principles set forth in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, as drafted by the US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (April 18, 1979) and codified in 45 CFR Part 46 and/or the ICH E6; 62 Federal Regulations 25691 (1997).

The protocol, informed consent forms, recruitment materials, and all subject materials will be submitted to the UCHC IRB for review and approval. Approval of both the protocol and the consent forms must be obtained before any subject is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented in the study.

Participant confidentiality is strictly held in trust by the investigators, study staff, and the sponsor and its agents. Data will be collected for research purposes only.

The following procedures will be put in place to protect the confidentiality of data. To avoid loss of confidentiality, participants' names will not appear on any document associated with the project, except for the informed consent document, HIPAA forms and the campaign passport. Unique ID numbers, not participants' names, will appear on all interview records used for computer data entry (see section 6.1.6). Ethnographic observations, field notes and other project records will be kept in locked files and in password protected computer files at UCHC and ICR, to which only project staff will have access. No records will be kept at building sites at any time. Names and apartment numbers, which will be used for creating unique identifier lists and for follow-up, will be kept under lock and key at the ICR project office, under the direct supervision of the Project Coordinators (Medina and Foster-Bey) and used by the study staff only. Digital audio-recordings will be uploaded daily to password protected computer files, and deleted after the interview has been checked for accuracy. All recordings are identified by the participant Master ID only. Therefore, the participant’s name will not be used anywhere in the recording.

The study protocol, documentation, data, and all other information generated will be held in strict confidence. A subject’s participation in this project will be kept confidential within the study team at UCHC and the Institute for Community Research. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the PIs and sponsor, and will be shared only in aggregated form. Study data will be presented in summary form. Participant names or other identifying information will never be included in project data to be presented to the public. Therefore, participants will not be identifiable in presentations or publications based on this research.

The study monitor or other authorized representatives of the sponsor, and the UCHC IRB and Human Subjects Protections Office may inspect all study documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) for the study participants. The clinical study site will permit access to such records.

Knowledge of elder, child or spousal abuse, or participant intent to harm self or someone else, or of certain communicable diseases learned during the course of the study, is required to be reported to State officials.

3.3.1 Informed Consent / Assent Process

The informed consent process is initiated prior to any data collection taking place with any individual and continues throughout study participation. The study interviewer/consentor will explain the research study to the participant and answer any questions that may arise. Each participant will be given a consent form describing in detail

a) Overview of the study,

b) Description of participation,

c) That participation is voluntary,

d) Maintenance of confidentiality,

e) Risks and benefits,

f) Possible termination of participation,

g) Who to contact if questions arise.

We also will review the eligibility criteria to assure that the participant is eligible.

The consent documents will have been reviewed and approved by the University of Connecticut IRB prior to administration with participants. Participants will be asked to read and review the document and/or have the document read to them. Participants will be given the opportunity to discuss the study with a friend or family member or think about it prior to agreeing to participate. During the consent process, and prior to signing, the interviewer/consentor will ask the individual five key questions on topics covered in the consent document:

1) The purpose of the study,

2) What activities participation will entail,

3) Risks that might be encountered,

4) Expected duration of participation

5) Whether participation is voluntary.

Individuals who cannot answer these questions correctly after two attempts will be deemed ineligible to participate. Once deemed able to make an independent and informed decision, eligible participants will be asked to sign a written consent form. Participants who cannot write will be asked to make their mark on the consent document; researchers will co-sign. Participants may withdraw consent at any time throughout the course of the study. The rights and welfare of the participants will be protected by emphasizing to them that the quality of their clinical care will not be adversely affected if they decline to participate in this study. An original signed and dated consent form will remain in the research record, and another signed and dated informed consent document will be given to participants for their records.

***The following steps are in place in order to accurately conduct the consent process for all GOH participants.***

1. A hard copy of each current consent form will be maintained in the Survey Coordinator’s office only.

2. In preparation for participant enrollment, consent forms will be copied and placed in participant folders no more than 1 week prior to the scheduled enrollment date.

3. Each folder will contain 2 copies of all consent forms that will be signed by both the participant and the consentor (1 original for the participant and 1 for our files).

4. Consent process:

a. The consentor will print the name of the individual on the top of the first pageof the consent form (**Name of Research Participant)**. Ask if they are able to sign their name.

b. Review consent form with individual. Provide opportunities for questions.

c. Upon completion of review of each consent form, ONLY the participant will print, sign and date each form in the spaces provided at the bottom of the form (See below - **Participant**).

d. The consentor will sign and date the consent form (See below - **Person Obtaining Consent**) after the participant has signed and dated the form.

|  |  |  |  |
| --- | --- | --- | --- |
| **Role** | **Printed Name** | **Signature** | **Date** |
| Participant |  |  |  |
| Person Obtaining Consent |  |  |  |

e. If the participant cannot print/sign his or her name (disability, not literate), ask him/her to make their mark. The consentor will sign and date as described above. The consentor also will fill in the date for the participant, and initial that he/she has done so. An additional study staff member is required to witness, co-sign and date the form below the consentor line. The consentor may include and then initial a brief note with the reason the participant was unable to sign.

f. A participant MUST sign the general consent form (AB/BA) and the HIPAA form in order to participate in the study.

g. Only blue or black ink will be used on the consent forms.

h. Upon completion of the consent process, and before the participant leaves the appointment, the consentor will review all consent forms to insure that there are no errors (for example, wrong date on the form) and that the name of the participant (filled in by the consenter on Pg. 1 of consent form), participant name and signature (by participant), consentor’s name and signature and correct dates are in place.

i. If an error is made anywhere on the consent form, the correction will be made by drawing one line through the error, and the correction made beside or above the error, checked for legibility, signed and dated by the person correcting the error. If the error was made by the participant (for example, participant puts wrong date on the form) ask the participant, to correct the error. If an error was made by the consentor, he/she makes the correction, as described above. Be sure that the correction is made on both the participant and the study copy.

5. Completed consent forms will be returned to the Survey and/or Intervention Coordinators who will review the consent forms for correct version, names, signatures and proper correction of any errors, if any had been noted.

6. The Survey and/or Intervention Coordinators will scan and upload consent forms onto the Q drive at ICR into the folders: Q→GOH-U→IRB→Scanned Consent (for the appropriate building).

7. The IRB/Human Subjects Coordinator also will review all completed, scanned consent forms each Monday, on a weekly basis.

8. Any revisions to consent forms will be submitted as modifications to the UCHC IRB in a timely manner.

9. Any new versions of consent forms will be copied from IRIS to the hard copy and electronic versions of the Regulatory binder at UCHC. The IRB/Human Subjects Coordinator will upload copies of the new forms to the current approved materials folder, the Regulatory binder folder and the Essential Documents folders on the Q drive at ICR and the older versions will be removed. **The IRB/Human Subjects Coordinator will provide hard copies of new forms to the Survey and Intervention Coordinators who will immediately discard any previous versions and replace them with the new current, UCHC IRB-stamped versions.** The Survey and/or Intervention Coordinators will check all prepared participant folders, discard previous consent form versions and replace them with the current approved and stamped versions. The Intervention Coordinator will add a hard copy of all new versions to the Essential Documents binder. In addition, hard copy versions of all consent forms are maintained in the Regulatory binder in the Dental Clinical Research Center, with electronic versions on Dr. Reisine’s G drive and in the GOH study location in the IRIS system at UCHC.

11. All versions of signed consent forms will be maintained in each participant folder and in the Scanned Consent folder on the Q drive at ICR.

3.3.2 Documentation of Consent / Assent

Two copies of the consent form will be signed and dated by participant and consenter. One is kept in the participant’s hard copy file, and scanned for electronic warehousing, and the second is given to the participant. The study Access tracking database will document that consent has been obtained and that forms have been completed and filed. Additionally, a checklist on each participant’s folder will be completed to assure that all required documents are present. (see Appendix for examples of informed consent documents, the format of the database file and the checklist.) These data and entry will be coordinated by the survey coordinator*.*

Consent forms needed for the study include:

1) A general consent form for all participants recruited into the study consenting to participation in all intervention activities including surveys, clinical assessments, one-on-one AMI-PM oral health education sessions, and campaign events/fairs.

2) An Authorization to Use and Disclose Protected Health Information for Research Purposes (HIPAA) form.

3) A consent form for the subsample of participants who choose to become members of the Good Oral Health Campaign Committee in their building, by which they agree to participate in that component of the intervention.

4) A Photograph/Video/Audiotape Authorization form for all participants recruited into the study. Voice and/or images will be used only for teaching or research purposes.

3.3.3 Translation of Consent and Assent Documents

Consent forms, as well as all instruments and project materials, will be available in English and Spanish. Staff members of the study who are fluent in Spanish will consent all Spanish-speaking participants.

3.3.4 Re-consenting for Protocol Changes or Safety Updates

If a consent document is revised due to changes in study procedures, subjects who were enrolled prior to the change, but are affected by the change, will be informed of the changes and will sign the amended consent document. If a consent document is revised due to changes in the risks or safety of the study, all active participants must sign the revised consent.

3.3.5 HIPAA Privacy Rule

Each participant will complete the UCHC approved HIPPA form. This form will be stored in the participant’s hard copy file with the completed consent form(s).

3.4 Essential Documents

Essential documents are those documents that individually and collectively permit evaluation of both the conduct of a clinical trial and the quality of the data produced.

Paper versions of non-subject specific site documents will be filed in the study-specific Essential Documents binder.

3.4.1 Required Documents

The following essential documents must be retained at ICR and the SDM and must be accurately maintained.

Site-specific documents:

The protocol and all protocol amendments

All versions of IRB approved consent documents

IRB documentation, approvals, and correspondence

Delegation of responsibilities log

Documentation of clinical research and study training

Screening and enrollment log

Serious Adverse Events (SAEs)/Unanticipated Problems

Protocol deviations

Documentation of clinical site monitoring visits

Agenda and minutes of study meetings

Subject-specific documents:

I. PROTECTION OF HUMAN SUBJECTS

Study Consent Form (AB Building) – English

Study Consent Form (BA Building) – English

Campaign Committee Consent Form – English

Authorization to Use and Disclose Protected Health Information for Research Purposes (HIPAA) – English

Authorization to Photograph/Video/Audiotape – English

Consent Comprehension Form - General Study Participation

II. STUDY INTRODUCTION

Letter of Introduction to Tenant Association – English

Building-Wide Invitation to Introductory Presentation Flyer – English

Introduction to Study (PPT) – English

III. RECRUITMENT/ENROLLMENT

Study Recruitment Flyer - English

Survey Recruitment Flyer – English

Study Eligibility Form – English

Survey/Dental Exam/AMI Appointment Card – English

Survey/Dental Exam/AMI Telephone Reminder Script – English

Campaign Committee Recruitment Flyer – English

Campaign Committee Recruitment Presentation – English

IV. INDIVIDUAL INTERVENTION (AMI-PM)

AMI Talking Points

Focal Points Checklist – English

Practice to Mastery Score Sheet (Pre & Post) – English

Individual Oral Health Plan – English

Pre-Post Plaque Score Sheet – English

Tooth Brushing (video)

Flossing (video)

Denture Care (video)

Brushing (brochure) – English (N. Carolina Dept. of Public Health)

Flossing (brochure) – English (N. Carolina Dept. of Public Health)

Denture Care (brochure) – English (CT Dept. of Public Health)

Plaque (brochure) – English - (NIDCR)

V. GROUP INTERVENTION (Campaign)

GOH Campaign Committee Training Curriculum

Training Session Agenda (example) – English

Ground Rules – English

Components of the Campaign – English/Spanish

Campaign Committee Training - Keeping our Mouths Clean and Healthy

The Purpose and Role of the Campaign Committee/Components Of the Campaign (PPT) – English

GOH Committee Member Tasks – English/Spanish

Good Oral Health “101” (PPT)

Protecting and Respecting Participants in Research Studies – English

Event Program – English

Oral Health Message Poster – English

Test Your Oral Health Knowledge – English

What Is Your Recipe for Good Oral Health? – English

Oral Health Wheel of Fortune – English/Spanish

Oral Health Fair Passport – English

Oral Health Fair Flyer/Poster – English

Oral Health Bingo (example) – English/Spanish

Good Oral Health “101” – Healthy Mouths Start at Home (PPT)

Oral Health and Diabetes (PPT)

Campaign Committee Certificate of Completion – English

Campaign Committee Debriefing Interview Guide – English/Spanish

VI. EVALUATION

Survey – English

Clinical Assessment Form

Referral Letter – Dentist – English

Referral Letter-Participant – English

Release of Information – English/Spanish

Study Timeline

Data collection forms

Signed consent documents

Surveys completed by the participant

Eligibility screening forms

Clinical assessment forms

AMI forms

Campaign evaluation and passport forms

3.4.2 Document Maintenance

For funded grants, documents must be maintained for 7 years after the grant is officially closed (1 year at the investigative centers and 6 at the federal records center).

SITE QUALITY MANAGEMENT PLANS

4.1 Informed Consent

See section 3.

4.2 Data Management

See section 10.

4.3 Research Specimen Management

not applicable

1. SITE PREPARATION

NIDCR has a responsibility to ensure that mechanisms and procedures are in place to protect the safety of subjects in NIDCR-supported clinical research. Therefore, prior to subject accrual or enrollment the following elements of site preparation will be reviewed and approved by NIDCR:

IRB-approved clinical research protocol identified by version number and date

Documentation of IRB approval, including OHRP FWA number, IRB registration number, and IRB name

IRB-approved consent document that is used to document informed consent, identified by version number, date, or both

Plans for managing adverse events

Procedures for assessing and reporting adverse events

Plans for data and safety monitoring, and for monitoring of the clinical study site

Documentation that the grantee institution and all study staff responsible for the design or conduct of the research have received training in the protection of human subjects.

Supplies for study conduct

Site initiation visit and study-specific training

Contract/grant, technology transfer, clinical trial agreements, and other agreements

5.1 Facilities Requirements

5.1.1 Clinical Research Area

All interviews, clinical assessments and interventions will take place in the senior housing buildings. In the pilot study the management allowed us to use an empty apartment to conduct the surveys and the clinical assessments. We used the larger community room for campaign events. The building managements of participating locations have agreed to make private space available for these purposes. The one-on-one tailored interventions can be completed in the participant’s apartment or a private location in the building.

5.1.2 Secure Document Storage

Hard copies of research records, which will include consent and HIPPA forms, eligibility screener, clinical assessment forms, and AMI-PM forms, will be kept in locked file cabinets at ICR.

5.1.3 Diagnostic Services

not applicable

5.1.4 Pharmacy Services

not applicable

5.1.5 Laboratory Services

not applicable

5.1.6 Courier Services

not applicable

5.1.7 Research Sample Storage

not applicable

5.2 Staff Training

5.2.1 Human Subjects Protection Training

All staff are required to complete Human Subject Protection Training prior to engaging in any study activities. The CITI and NIH trainings are available to meet this requirement. Training must be updated every three years.

5.2.2 Good Clinical Practice Training

All study personnel will be required to complete Good Clinical Practice training prior to commencement of study activities. This training will be documented in the Essential Documents Binder and the Regulatory binder. Training will be repeated annually. In addition, all study staff will complete the NIH-required GCP training that must be renewed every three years. A record of training completion will be kept in the office of the IRB/Human Subjects Coordinator and in the Essential Documents binder at ICR.

5.2.3 Protocol Training

All study staff will receive training on all aspects of the protocol, to include:

* Study Objectives
* Inclusion/Exclusion Criteria
* Protocol Deviations
* Study Timelines
* Data transfer and project tracking
* Subject Visit Schedule
* Screening, Intervention, and End of Study Visits
* Safety Monitoring and Stopping Rules

**Clinical Assessment, Survey Administration, AMI-PM and Campaign Protocols**

Each participant will receive a total of four clinical assessments by a licensed dental hygienist, under the supervision of Dr. Rajesh Lalla, DDS. The assessment will include number of natural teeth, presence of dentures (upper or lower) or partials, soft tissue exam, plaque score and gingival index. The Plaque Score and Gingival Index are the two primary outcome measures.

**Plaque Score** – We will use a plaque scoring scheme developed by O’Leary et al (1972). This index consists of dichotomous presence or absence scores for plaque on each tooth surface. The supragingival bacterial plaque will be assessed with the use of erythrosine disclosing solution in six surfaces of each tooth. The non-toxic vegetable-based solution will be applied to the teeth by the examining hygienist. The number of surfaces stained red will be calculated over the total number of surfaces and the plaque score will be expressed as a percentage of surfaces with plaque as a ratio. We used this measure in the pilot study and demonstrated significant reductions in plaque after the intervention.

**Gingival Index** – The Gingival Index (GI) (Loe & Silness, 1963) will be used to assess the gingival status related to six surfaces of each tooth. Each surface is scored for gingival inflammation: 0=no visual signs of inflammation; 1=slight change in color and texture of the gingiva but no bleeding; 2=visual sign of inflammation and bleeding upon swiping; 3=overt inflammation and spontaneous bleeding. The index is calculated by summing each surface GI and dividing by the total number of surfaces (mean value). Individual scores are summed to obtain a mean. We used this measure in the pilot study and demonstrated significant reductions in the Gingival Index after the intervention.

Clinical Assessment Protocol for Oral Health Examiners

1. The examiner will introduce her/himself to the participant and briefly describe the clinical assessment. All participants will have been consented prior to the clinical assessment.

2. Upper or lower denture/partial assessment – all participants: Ask the participant if they have a removable upper or lower denture or partial denture/s. Offer the patient a clean place to put their denture such as a disposable denture cup or paper towel covered table.

3. Document number of natural teeth.

4. Conduct a soft tissue oral exam and cancer screening (see Protocol template and referral form in Appendix). Refer for care if suspicious lesion is found that fits criteria for referral. Standard referral letters are in the Appendix.

5. Periodontal Status: Gingival Index (*Acta Odontologica.*1963; *21*[6]:533-551) will be used to assess the health of the periodontium. Each surface of each tooth is scored for gingival inflammation by doing a gentle sweep of the pocket with the periodontal probe. 0: no inflammation; 1: gingival erythema but no bleeding; 2: gingival erythema and bleeding upon swiping; 3: erythema and spontaneous bleeding. Chart results.

6. Plaque Score: Apply Vaseline to lips. Apply disclosing solution to teeth. Presence or absence of plaque is determined by presence of disclosed plaque on the gingival third of the natural or crowned tooth. This is documented on six surfaces of each tooth as either present or not present using a mark on the assessment form for present and no mark for absent.

7. For the pre-intervention exams the examiner will determine what oral hygiene aides are appropriate for the Interventionist to recommend to the participant and mark these on the assessment form. Examiner should not provide any dental instruction or commentary to the participant at this time. For the post intervention assessments, the protocol is the same.

**Referrals** – Emergent dental needs are not uncommon in this population; when found, they will be referred to the University of Connecticut School of Dental Medicine or to the nearest Community Health Center. Emergent dental needs include inability to eat due to tooth or mouth pain, visual swelling of the face or mouth and oral lesions located in a high oral cancer risk area. Once the participant has been treated for the emergent dental issue they will be offered the opportunity to continue with the study. Emergent needs will be ranked using the system employed by the NHANES dental teams.

**Training and Calibration for Clinical Assessment (**Adapted from National Health and Nutrition Examination Survey Dental Examiners Procedures Manual)

Training is divided into three phases as follows:

1. The instructional phase in which examination team members are familiarized with research examination procedures and criteria for research assessments.
2. The standardization phase in which they are trained to use standard procedures and apply standard criteria for the oral health assessments.
3. The calibration phase in which the degree of correlation within and among the examiners and the standard examiner is measured.

Instruction

The instructional phase of the training sequence was conducted by Ruth Goldblatt DMD who served as the initial Clinical Director and standardized examiner or gold standard, with experience as a researcher and examiner on the previous pilot study. Rajesh Lalla, DDS is the current Clinical Director and will conduct the instructional phase with any new dental hygienists who join the study. He has appropriate experience both as a researcher and clinician. Instructions are to be conducted in each type of oral health assessment (Gingival Index and Plaque Score). The trainer presents lectures on criteria for each of the oral health assessments to be used in the study. Lectures are accompanied by slides depicting a wide variety of possible observations and illustrating application of assessment criteria to those observations. The lecture-slide presentations on each assessment are followed by instructions on data recording for that assessment. Although the instructional phase consists primarily of lectures and slide presentations, some demonstrations of examination technique and equipment use are conducted. All phases of the training and calibration will be redone anytime there is a change in clinical examiners.

Standardization

The second phase of training is devoted to standardization. During this phase of training, the standard examiner reviews examination procedures and techniques and the criteria for each assessment, stressing the importance of consistency and uniformity among all examiners and the standard examiner in performing the examination and in applying the criteria to observations. Rationale for differences between a research examination and a diagnostic examination are discussed and professional ethics of research examinations reviewed. A demonstration of the examination by the standard examiner and practice examinations by the examiners being trained is among the salient features of this phase. Standardization of all examiners will be achieved by examining 4 patients in the field replicating research subjects and conditions. Discussion will occur to aid standardization. The Clinical Director (standard examiner) will monitor and referee examinations and discussion of observations during these sessions.

Calibration

The reliability of the assessments is measured by determining the degree to which examiners can produce uniform and consistent results when performing independent replicate examinations without discussion. In this phase of training, the standard examiner and all examiners in training will each examine 4 patients who are similar in demographics to the study population. The standard examiner monitors the calibration session without discussing observations with any of the examiners.

Data from the calibration sessions are analyzed to measure correlation within and between each examiner and the standard examiner (e.g., Kappa and McNemar’s Test). If correlations between each of the examiners and the standard examiner are not within acceptable ranges (i.e., Kappa <.75) or some examiners are consistently higher or lower than the standard examiner (i.e., significant McNemar’s test) additional training sessions will be scheduled.

Monitoring and Recalibration

Continual gathering of clean, reliable data in a consistent and uniform manner is one of the main objectives of the clinical control trial. Several quality control procedures will be carried out periodically to assure continuing quality of data gathered by the dental team throughout the duration of the study. As in the initial calibration, the standard examiner and all examiners will each examine 4 patients who are similar in demographics to the study population. Recalibration will occur prior to or at the beginning of each study cycle.

Expert Replication and Monitoring Field Operations

During the field operations, examiners and recorders should periodically review their training manuals to prevent deviation, or “drift” from the standards achieved during the training period. Particular attention should be devoted to uniform adherence to the criteria for making correct decisions about observations such as scoring of gingival indices and presence or absence of plaque. Strict compliance with infection control procedures is another important consideration for dental teams. In order to help the dental teams maintain their standards, the clinical director for the study will make periodic visits to field personnel to observe their performance and offer feedback on the results of their examinations. Field observations occur twice per assessor for each time point. Observation and matched scoring for GI and Plaque Score occur once per assessor per time point. The standard examiner will choose one patient per each of the dental hygienists on whom the examination will be replicated. The replicated exam will be completed in paper format and compared to the one entered on the computer so as not to confound the data collection for the study. The purpose of these so called “expert replications” is to determine whether the examiners are maintaining the examination standards achieved during training, and to measure the degree of deviation, if any, from those standards. If correlation between the standard examiner and the field examiner is not within acceptable limits, retraining will be conducted.

Annual Retraining

The long duration of the study (5 years) requires the need for regularly scheduled retraining periods. In addition to the regularly scheduled recalibration sessions with the standard examiner, there will be an annual retraining session for each dental examiner, also conducted by the standard examiner.

Training and Calibration for Oral Hygiene Skills Assessment (Practice to Mastery and T0–T3)

Training is divided into two phases as follows:

1. The instructional phase in which research interventionists and dental hygienists are familiarized with oral hygiene instruction and oral hygiene practice to mastery skill assessment scale.

2. The standardization phase in which the interventionists and dental hygienists are trained to use standard procedures and apply standard criteria for the oral hygiene skills assessment (and oral hygiene instruction for the interventionists).

Instruction

The instructional phase of the training sequence was conducted by Ruth Goldblatt DMD who served as the initial Clinical Director and standardized examiner or gold standard. Rajesh Lalla, DDS is the current Clinical Director and will conduct the instructional phase with any new intervention staff or dental hygienist. Instructions will be given regarding the Oral Hygiene Skills Assessment Evaluation Form and each mastery level on the form. Demonstrations will be given using the tooth brushing models. Although the instructional phase consists primarily of lecture, slide presentations and video clips, some demonstrations of examination technique and models are conducted. All phases of the training and calibration will be redone anytime there is a change in staff during the study.

Standardization

The second phase of training is devoted to standardization. During this phase of training, the standard examiner reviews oral hygiene instruction procedures and techniques used in oral hygiene education and the criteria for each assessment, stressing the importance of consistency and uniformity among all examiners and the standard examiner in performing the examination and in applying the criteria to observations. Rationale for differences between simple oral hygiene instruction and the practice to mastery evaluation are discussed and reviewed. A demonstration of the practice to mastery evaluation by the standard examiner and a rehearsal practice to mastery by the examiners being trained is among the salient features of this phase. Standardization of all examiners will be achieved by assessing the same 4 subjects in the field, replicating actual research conditions. Discussion will occur to aid standardization. The Clinical Director (standard examiner) will monitor and referee examinations and discussion of observations during these sessions.

Annual Retraining

The long duration of the study (5 years) requires the need for regularly scheduled retraining periods. There will be an annual retraining session for all study staff. conducting the Oral Hygiene Skills Assessment, conducted by the Clinical Director.

In addition to the clinical and skills assessments, there will be annual retraining sessions for all study staff on the conduct of the survey and the AMI and campaign interventions, conducted by the study PIs and expert staff.

Training for Survey Administration

The surveys will be coordinated by the survey coordinator and conducted by research staff, and supervised graduate students trained to administer the survey in a consistent manner using QDS software on portable computers. PIs and data analyst will conduct all trainings. Surveys will be conducted in a confidential location (in a reserved room in the resident building or in the resident’s apartment) preferably immediately following the clinical assessment. Surveys will be downloaded to the QDS warehouse on a weekly basis and stored in separate files by condition and cycle.

Research assistants and graduate students will initially administer the surveys to each other in order to become familiar with the survey and the QDS system. They will practice with co-workers until the PIs and data analyst are satisfied that survey administrators are skilled in their interviewing skills and working with the data entry program. Once in the field, the survey coordinator will supervise RAs and graduate students and other research team members to assure that they are following protocol.

**Training in AMI-PM Administration** (including calibration of Interventionist in behavioral skills assessment.)

See Section 6.5

* + 1. Study-Specific SOP Training

All staff will be oriented to the MOP during initial training to the study. The depth of training will be determined by the role of each staff member as listed below.

5.2.5 Clinical Operations

All study staff will receive training in the following areas of clinical operations:

Communication

Site Visits (Site Initiation Visits (SIVs)

Investigator Responsibilities

Essential Document Collection and Storage

IRB Reporting Requirements

Audits

Good Clinical Practices

* 1. Equipment and Supplies

The Clinical Director will work with the dental hygienists to maintain adequate supplies at each site.

1. PROTOCOL IMPLEMENTATION

6.1 Recruitment, Screening, and Enrollment

Building enrollment time line

| Buildings | T | Month | Activity |
| --- | --- | --- | --- |
| Buildings AB/BA (Pair 1) | T0 | May – Nov, 2015 | Recruitment, surveys, skills assessment and Clinical assessment |
|  | AB | July - Dec, 2015 | Tailored intervention |
|  | BA | July – Sept, 2015  Oct – Dec, 2015 | Campaigns – Training  OH Fairs |
|  | T1 AB | Sept, 2015 – Jan, 2016 | Surveys, skills assessment and clinical assessments |
|  | T1 BA | Jan – Mar, 2016 | Surveys, skills assessment and clinical assessments |
|  | AB | Jan – Feb, 2016  Mar – May, 2016 | Campaigns – Training  OH Fairs |
|  | BA | Feb – Apr, 2016 | Tailored intervention |
|  | T2 AB | June- Aug, 2016 | Surveys, skills assessment and clinical assessment |
|  | T2 BA | Mar – July, 2016 | Surveys, skills assessment and clinical assessment |
|  | T3 | Sept, 2016 – Mar, 2017\* | Clinical assessment, skills assessment, GOHAI |
|  |  |  |  |
| Buildings AB/BA  (pair 2) | T0 | July, 2016 – May, 2017\* | Recruitment, surveys, skills assessment and clinical assessment |
|  | AB | Oct, 2016 – June, 2017\* | Tailored intervention |
|  | BA | Feb – Mar, 2017  Apr – May, 2017 | Campaigns – Training  OH Fairs |
|  | T1 AB | Dec, 2016 – July, 2017 | Surveys, skills assessment and clinical assessment |
|  | T1 BA | June - July, 2017 | Surveys, skills assessment and clinical assessment |
|  | AB | May - July, 2017  Aug – Sept, 2017 | Campaigns – Training  OH Fairs |
|  | BA | Aug – Sept, 2017 | Tailored intervention |
|  | T2 AB | Oct – Dec, 2017 | Surveys, skills assessment and clinical assessments |
|  | T2 BA | Oct – Dec, 2017 | Surveys, skills assessment and clinical assessments |
|  | T3 | May – June, 2018 | Clinical assessment, skills assessment, GOHAI |

|  |  |  |  |
| --- | --- | --- | --- |
| Buildings | T | Month | Activity |
| Buildings AB/BA (pair 3) | T0 | Jan – June, 2018 | Recruitment, surveys, skills assessment and clinical assessment |
|  | AB | Feb – June, 2018 | Tailored intervention |
|  | BA | Mar – May, 2018  June – July, 2018 | Campaigns – Training  OH Fairs |
|  | T1 AB | Mar – July, 2018 | Surveys, skills assessment and clinical assessment |
|  | T1 BA | Aug – Sept, 2018 | Surveys, skills assessment and clinical assessment |
|  | AB | May – July, 2018  Aug – Sept, 2018 | Campaigns – Training  OH Fairs |
|  | BA | Sept – Nov, 2018 | Tailored intervention |
|  | T2 AB | Oct – Nov, 2018 | Surveys, skills assessment and clinical assessments |
|  | T2 BA | Oct – Dec, 2018 | Surveys, skills assessment and clinical assessments |
|  | T3 | Apr – June, 2019 | Clinical assessment, skills assessment, GOHAI |

\* Extended periods for Cycle 1 T3 and Cycle 2 T0 and Tailored Intervention due to temporary halting of study

**6.1.1 Recruitment Methods**

***Recruitment of Buildings***

The GOH target population includes residents living in senior housing in Central Connecticut, consisting of a diverse group of children and adults ages 18 – 61 with disabilities and adults aged 62 and above who meet income requirements. These buildings are located in low income or working class neighborhoods, which often have resource limitations and are typical of other publically funded privately and publically managed housing for similar populations elsewhere in Connecticut and across the United States.

Buildings are very different in structure, ownership and management, internal organization, size and composition. Despite these differences, all low income housing for older adults and those with disabilities is characterized by the following:

a) an administrative structure that may include owners, building managers and resident services coordinators, each of whom should be approached for permission to work in the building. They are responsible for the wellbeing and safety of the residents, and must be convinced that what the project has to offer is beneficial to residents and inclusive.

b) An internal social organization that may include a tenant’s association (formal), or an informal committee or group through which information about activities passes.

External gatekeepers can help in introductions but cannot approve building entry. Building managers often defer to building owners (in the case of private buildings) and public housing authorities (in the case of public housing). So there may be delays in receiving permissions to present to, or work with residents. Private building owners/managers may work in multiple buildings at the same time, so it may take time to arrange appointments with them, and additional time – even days or weeks – to obtain letters of agreement.

To feel confident that new programs serve the residents, building owners/managers and resident services coordinators will be concerned about 1) how the program or study will serve all the residents, not just a few and 2) how the program or study will be tailored to all the residents, by language, ability or other factors pertinent to any specific building.

***Script for contacting management, private and public***

Following the initial contact with prospective building managers asking for their general support for the grant, the next step post-funding will be to officially connect with the management of those buildings that will participate in the project. The contact person may be the Resident Services Coordinator (RSC), or the property manager if there is no RSC. (see Appendix for sample of Project GOH Prospectus that is provided to building management)

At the first meeting with the building management, project staff reviews:

the overall goals and objectives of the project;

the duration of the study;

the components of the study;

space needed for conducting project activities;

the specific responsibilities of the all participants, including residents, building management, and project staff;

any risks, benefits, and incentives, direct or indirect, for the residents.

The project staff should also ascertain information about the dynamics of the building. This is done through observation, informal conversations and meetings with building management and key informants. Important information includes:

any administrative structure that should be recognized by project staff when arranging activities;

any resident-run organizations (e.g., tenant associations);

social activities and schedules;

other events that take place in the building on a regular basis;

logistics involved in entering the building (security process) and use of building facilities for surveys and clinical assessments (this could be an office or vacant apartment that can be designated as a “base” for Project GOH), oral health fairs, equipment storage, etc.

If there is a tenants’ association, project staff should ask the RSC if he/she would arrange a meeting between the association’s officers and the project staff in order to introduce the project and request the association’s support. A form letter has been developed for the tenant association outlining the project’s components and the type of support we would like to have from the association officers. (see Appendix form Letter of Introduction-Tenants’ Association)

Once contact has been made with the association officers, project staff will work with the RSC/building manager to identify dates to hold presentations to introduce all residents to the study. Project staff will conduct 2 presentations 2 weeks apart to inform residents of the study, recruit and enroll potential participants. Study staff will establish a base in a public space in the building, from which to provide information on the study and to recruit and enroll participants. The base (information table and chairs) will include posters, fliers and signup sheet (see below).

All intervention buildings have been identified and agreements reached with them for study implementation through memoranda of agreement. Two backup buildings will be identified.

***Development of Recruitment Material for Study Participants***

In preparation for the introductory presentations, project staff will revise existing materials to announce the events. All material will be in English and Spanish, and submitted to the IRB for review and approval. In submitting materials we should remember to allow sufficient time for the translation, back-translation, and final approval of the materials that will allow activities to proceed as scheduled. Materials to be developed include:

One-page flyers announcing the events. These flyers will be placed in hallways on each floor and other public areas of the building. It is also important that each resident receive a flyer. The RSC as well as the association officers will be asked to identify the most effective, efficient, and timely way to distribute the flyers to the residents. The field staff will assist in the distribution of the flyers. The building management may have a protocol for circulatingthis type of information to residents and we want to make sure that we follow those procedures. Association members will also be asked to talk with their fellow residents about attending the presentations.

Posters announcing the events will also be developed. As with the flyers, the posters will be in English and Spanish and there should be enough for a pair (English/Spanish) to be placed in the community rooms, lobby entrance, laundry rooms, and on each resident floor.

A PowerPoint presentation, presented simultaneously in English and Spanish, will give the residents a brief and concise introduction to the study. In addition to reviewing the study activities, residents will also be informed of the incentives provided for their participation. Two laptops, two PowerPoint projects, and two screens will be used for the presentations. (see Appendix)

Other materials to be prepared for the events include (see Appendix):

* + Attendance sheet to document residents attending the presentation. It is common for the building manager or resident services coordinator to initiate this sheet for any event taking place in the building, as it is used by building management to document attendance numbers for specific building-sponsored or supported activities.
  + Recruitment sheet for residents in attendance. These sheets should include the resident’s name, apt. #, and phone # if available. This information will not be shared with building management.
  + Eligibility forms. These forms are to be used to determine whether each resident who signs up for the study is medically eligible to participate in all components of the study.
  + Appointment cards for residents eligible to participate in study.
  + Schedule sheets to document date and time of pre-intervention survey and clinical assessment.

Light refreshments will be purchased for each of the presentations.

This process will be followed for each of the introductory presentations. Introductory presentations will be continued until the requisite number of 60 participants is obtained and members of a campaign committee are identified.

**Recruitment of Participants**

The study recruitment sample will consist of 360 residents, 60 from each of the six buildings with 120 or more units, paired by size and ethnic/linguistic composition. We anticipate that the population in the study buildings will consist of approximately 40% African American/Caribbean, 45% Latino (mainly Puerto Rican) and 10-15% other ethnic (Euro/Euro-American) residents. Approximately 13% will be under 62 years of age with some form of disability. Most residents are literate in at least one language but many will not have completed high school. Average monthly income is $700.

**Inclusion Criteria include:**

1. Males and females aged 18 years and above;
2. Permanent residence in sample buildings;
3. Independent of conservator;
4. Must be able to speak English or Spanish;
5. Judged competent to participate (based on ability to respond correctly to 5 key questions about information covered during administration of informed consent); and
6. At least two natural teeth.

**Exclusion Criteria include**:

1. Considered by research staff to be cognitively unable to give informed consent;
2. Exhibition of continued disruptive behavior while participating in the project;
3. History of infective endocarditis and/or prosthetic cardiac valve replacement in past 6 months, insertion of an arterial stent in past 6 weeks, myocardial infarction (heart attack) in past 6 weeks;
4. Under conservatorship;
5. Fewer than 2 natural teeth;
6. Currently on dialysis.

During the first five months of each full intervention cycle 120 residents will be enrolled into the study, 60 in each condition – A or B - to which their building has been randomly assigned. Research team members will conduct at least 2 presentations 2 weeks apart to inform residents of the study, recruit and enroll potential participants, and will establish appointments to conduct baseline surveys and clinical assessments within 2 – 3 days of each presentation. Participants will be recruited, enrolled, consented and scheduled for surveys during the first five months regardless of condition. Thus, the timing of all baseline surveys and clinical assessment will be the same for both buildings. In addition, research team members will establish a base in a central location in each of the buildings and use it as a base to continue recruitment, place informational posters in elevators and in other public locations, approach people in public spaces to explain the study, and organize weekly bingo games and other activities during which recruitment and maintenance of participant involvement will occur. Recruitment of participants will follow protocols established in the pilot project. At the same time, residents will also be invited to join a campaign committee to co-plan and facilitate three campaigns. Based on prior experience in similar buildings and the pilot building, **Attrition**, estimated to be approximately 25% based on prior studies, and this study’s pilot effort, is likely to be the result of illness, death, change of residence or seasonal mobility. **Retention** in the study will be accomplished through continuous presence in the intervention buildings, repeated contact through face to face communication and fliers with intervention participants throughout the delivery of each component, active telephone and mail reminders in advance of scheduled appointments for surveys, clinical assessments, individual AMI-PM session and campaigns. The methods have demonstrated intervention acceptability and are expected to result in almost 100% retention among those residents who are not ill, have not passed away, and have not moved elsewhere, based on prior studies in senior housing.

**Recruitment Protocol**

Recruitment for the study will begin immediately following both introductory presentations. After each presentation project staff will be stationed at several tables to answer questions, screen for eligibility to participate in the study, and enroll interested residents. In the period between each introductory presentation, and extending after the presentations, project staff will continue the recruitment process in the building by:

Setting up and manning information tables in the community room or other public area where residents may gather socially. This will not only provide residents the opportunity to ask questions and to sign-up, but also allow project staff a personal glimpse into the dynamics of the building and how its residents interact.

Participating in building-sponsored social events such as bingo and holiday celebrations. Communication with the RSC and tenant association officers is crucial in order to keep aware of the building’s social calendar.

Maintaining an on-going presence in the building by visiting the building 2-3 times weekly to talk informally with residents about the project.

Working with the RSC to create a space in the building that is recognized by the residents as the base for “Project GOH”.

Continuing to advertise the study through posters, flyers and word of mouth.

**AMI-PM (solicitation and follow-up)**

In the buildings where Condition AB is conducted first:

At the conclusion of the pre-intervention survey, clinical assessment, and skills mastery assessment, each resident will be reminded that the next activity will be the one-on-one education session (AMI-PM) and that the resident will be contacted within two to three weeksin order to schedule their session. The AMI-PM will take place within 45 days of administration of the baseline survey and clinical assessment in Condition AB buildings.

**Campaign (recruitment and maintenance)**

In the buildings where Condition BA is conducted first:

At the conclusion of the pre-intervention survey and clinical assessment, residents who signed up earlier to be a part of the campaign committee training will be contacted by project staff to confirm their interest in participating and to arrange a time to meet to review the contents and schedule for this training process. They will meet for 2-hour sessions twice a week, for a minimum five to six week period, to learn how to implement pro-oral health campaigns, to plan an overall blueprint for structuring these 3 campaigns, and to work with study trainers to develop campaign materials, and then continue to meet to implement the campaigns. Field staff will maintain regular communication with them by phone, email and face to face contact to ensure continuing involvement. Study participants who join the committee will be assessed at T0 – T3, but will be excluded from the total sample of 60 (initial) and 45 (final) participants in each building and data collected from committee members will be analyzed separately.

6.1.2 Pre-Screening

not applicable

6.1.3 Screening

See Section 6.1.1.

6.1.4 Rules for Re-screening

not applicable

6.1.5 Establishing Eligibility

See Section 6.1.1.

6.1.6 Assigning Participant Identification (PID) Numbers

PID numbers will be assigned using the first letter of the participant’s first and last name and the month and day of birth. In addition, Master ID numbers will be assigned using the building ID number and consecutive entry numbers starting with 001.

6.2 Enrollment Procedures

An electronic tracking database will be used, as shown in the Appendix, to document participant enrollment. It will include unique study identifiers, date of entry, consent/HIPPA documentation, dates of surveys, oral health skills assessments and clinical assessments, AMI-PM intervention and campaigns. See previous section on recruitment for enrollment procedures.

6.3 Randomization

Randomization will take place at the building level. Buildings will be matched on size and the biostatistician will randomly assign the building to Condition A or B using random numbers or a scientifically equivalent procedure. Participants will not be randomized.

6.4 Detailed Description of the Study Intervention

**Individual Level Intervention – Adapted Motivational Interviewing and Practice to Mastery**

The AMI-PM intervention is a tailored individual-level intervention that will take place within 45 days of administering the baseline survey and clinical assessment in Condition AB buildings, and within 45 days of administration of the T1 survey and clinical assessment in Condition BA buildings. The intervention should take approximately 45-60-minutes. Trained project staff (interventionists) will administer the intervention. Interventionists will make appointments with residents who have completed the baseline or T1 survey and clinical assessment, review assessment materials and survey domains, and construct the intervention checklist specific to that individual based on findings from the survey and the clinical assessment. They will conduct the intervention either in the privacy of the resident’s apartment or in a private location within the building.

The AMI-PM approach is geared toward emphasizing internal locus of control, improving self-efficacy, addressing knowledge gaps, shaping intentions, and improving skills required to conduct oral hygiene behaviors regularly and effectively. Tailoring will be based on: a) each participant’s specific gaps as identified in the survey (inaccurate responses and incorrect or inadequate oral health behavior); b) oral health problems identified in the clinical assessments at baseline; and c) brief conversations with each participant about his or her oral health problems at the start of the intervention. The interventionist will generate a list of specific cognitive and behavioral elements to be addressed for each participant. For example, the clinical assessment will produce information on gingivitis and locations demonstrating accumulation of plaque. The survey will produce information that indicates incorrect beliefs, gaps in knowledge, gaps in self-efficacy and limitations in intentions to practice and gaps in reported skills and specific oral hygiene practices. Interventionists will review these data and generate the individual participant’s Focal Point Checklist (see Appendix) prior to the scheduled AMI-PM session.

The AMI intervention for each participant will consist of the following:

1. Identify the domains that score under the cutoff point, and check them on the Focal Point form. Review RTFs for specific items to cover in AMI (See Appendix C)
2. Reconfirm participant’s agreeing to be audio-recorded. If participant didn’t originally agree to be recorded, ask if he/she would now agree. If so, review consent form with them and have them sign.
3. Explain the importance of taking care of teeth, mouth, gums in keeping one well and healthy; that caring for their mouth will prevent problems if they have cardiovascular problems, diabetes or other health problems that could affect or be affected by their oral health; that it can improve any gum problems that one might have and make it less necessary for emergency dental treatment.
4. Discuss with the participant his/her oral health, oral health problems, concerns and fears, practices and intentions, challenges in performing oral health hygiene.
5. Show the participant how their own concerns connect to their survey responses and domains requiring intervention. Based on the discussion, identify additional areas requiring intervention.
6. Address each of the focal points (domains scoring below the cutoff point on the survey results), using the survey results and scripted set of messages for each domain (see Appendix B). The process calls for correcting misunderstandings, increasing knowledge and addressing barriers to intention (cognitive: knowledge, beliefs, attitudes, fears, worries, efficacy/locus of control, intention) and dealing with any ADL concerns. Probe for reasons that participant has certain concerns, fears etc. As appropriate use talking points to address specific concerns in specific domains.
7. Show participant results of their own clinical assessment illustrating plaque and gingival scores.
8. Review with participant videos demonstrating correct oral hygiene practices.
9. Demonstrate oral hygiene skills using mouth model.
10. Observe participant practice individualized skills to mastery on mouth model. Score ability on P – M form.
11. Review ADL needs, cognitive domains, and behavioral skills and work with participant to build a cognitive behavioral plan for improvement of participant’s oral health.
12. Type and print out 2 copies of the plan. Obtain signature from participant on plans (one copy for participant, one copy for GOH study files).

12. Participant will receive an oral hygiene starter kit (tooth brush, toothpaste, floss, floss holder, tongue cleaner, and denture brush and cup if needed), brushing and flossing handouts and denture care handout if needed.

With participant consent, all AMIs will be audio-recorded for process documentation purposes. Audio recordings and hard copy/digital documentation from 10% of the AMI-PM sessions will be reviewed to measure fidelity.

Materials necessary for each AMI-PM intervention session will be compiled by the Interventionists and will include:

* Completed focal point worksheet
* Copy of initial clinical assessment results
* Practice to Mastery Pre-Post Assessment Form
* Copy of blank Audio consent form
* Practice to Mastery equipment: typodont, tooth/denture brushes, floss
* Laptop loaded with educational videos for instructions on proper brushing and flossing and blank form for Personal GOH Plan
* Audio recorder
* Portable printer
* Handouts with instructions on proper brushing, flossing and denture care
* Oral hygiene kit

The personalized tailored intervention list or Focal Points will be developed based on areas of deficiency identified in the survey. Cutoff points were developed based on 84 interviews conducted in the pilot study as shown in the following table. Individuals who score below the cutoff point on each of the following domains in the survey (see Appendix B) will require cognitive / behavioral intervention.

The forms and associated talking points are in the Appendix.

| **Domain** | **Items** | **Cut-off points** |
| --- | --- | --- |
| 1. ADLs | Need help with grooming, dressing, eating, brushing teeth/cleaning dentures. | Need help on any of these |
| 1. Oral health knowledge | 7-item knowledge test | <5 correct |
| 3a. Oral health self-  efficacy  3b. Locus of control | If you brush and floss correctly, you expect fewer dental problems  You believe that you know how mouth sores can be treated  If someone showed you how to clean your teeth, you would be able to practice better oral health care  If you knew the facts about dental disease, you would be able to practice better oral care  You believe you can remove most of plaque to help prevent cavities and gum disease  You believe tooth loss is a normal part of growing old | Mean of items <3 (disagree and strongly disagree)  If response to this item was agree or strongly agree) |
| 1. Oral Health Norms - Beliefs about Importance of oral hygiene | **How important do you think the following behaviors are**:  Visit the dentist once a year  Brush your teeth at least once a day  Brush with fluoride toothpaste  Floss or clean between teeth at least once a day  Check for sores in the mouth | 1 or 2 on any item (Not at all important; not very important) |
| 1. Oral health Social Support - | Local access to health/oral health information | If all sources are “0” (none) |
| 1. Oral hygiene behaviors | **How often do you:**  Brush in a day | <2 times per day |
| 1. Perceived Oral Health Risks | **What are the chances that you will:**  Get cavities  Get a toothache  Have problems with your gums  Develop oral cancer  Have to go to the hospital for problems related to your teeth, gums or mouth | Mean <3 (4- very unlikely;3- unlikely; 2- likely, 1-very likely) |
| 1. Self-management worries | **How worried are you that**:  You cannot clean your dentures properly  You can’t control your bad breath  Medications you are taking may be affecting your teeth  If you brush your teeth your gums might get irritated  You don’t brush your teeth enough  When you floss there is bleeding  You don’t brush your teeth properly  You are not using the correct toothbrush  You don’t know how to clean your tongue  You don’t know the best time to go to the dentist  If you use mouthwash it might dry out your mouth  Your mouth feels dry all the time  If you take your dentures out you could lose them  You might have to get dentures of false teeth made from dead men’s teeth so you keep your bad teeth  If you go to the dentist you might get a mouth or tooth infection or cancer  You can’t clean the teeth in the back of your mouth  Your teeth may keep you from socializing  Your bad teeth are keeping you from eating foods  Your teeth get discolored  When you try to brush you feel pain  When you put your dentures in it hurts | Mean <3 for scale (4 = not at all; 3= not much) |
| 1. Self-management fears | **You are afraid:**  That bleeding gums may be a serious problem  You cannot clean your dentures properly  Of losing your teeth  Of oral cancer  That problems with yourteeth and gums might affect your general health | Mean < 3 (4= not at all; 3 = not much) |
| 1. Oral Health Self-Management Intentionality | **What is the possibility that:**  You will brush your teeth at least twice a day  You will floss your teeth or clean between your teeth at least once a day  You will clean your mouth daily  You will check your mouth for loose teeth  You will visit the dentist in the next year for a check-up and screening for oral cancer | Mean <1 (0= no possibility; 1= slight possibility) |
| 1. Dry mouth | Do you sip liquids to aid in swallowing dry foods? | Yes |
| 1. Diet | **How often do you:**  Eat sweet snacks  Eat starchy snacks  Suck on hard candies  Drink/eat sweets after brushing at night  Drink fruit juice on an average day | >2-3 times a day on any item |
| Clinical Assessment | Plaque Score and Gingival Index | All participants |

Practice to Mastery for Oral Hygiene Skills.

The following criteria are defined for AMI practice to mastery scores (and for mastery scores during T0, T1, T2 and T3 observation points\*). We are measuring oral hygiene skills at T0 – T3, but do not intend to use the results as a mediating measure in accordance with an NIDCR approved request to remove the OH skills assessment as a mediating variable from the study. It is not an outcome measure.

**Excellent (4):** (P-M) Is able to easily use the appropriate oral hygiene aids and correctly mimic the instruction from the video/live demonstration without additional instruction.

(\*T0-T3) Is able to easily use the appropriate oral hygiene aids.

**Good (3):** (P-M) Is able to use the appropriate oral hygiene aids and requires no more than two corrective instructions to correctly mimic the instruction from the video/live demonstration.

(\*T0-T3) Is able to use the appropriate oral hygiene aids and would require no more than two corrective instructions.

**Fair (2):** (P-M) Has difficulty using the appropriate oral hygiene aids and requires three or more corrective instructions to correctly mimic the instruction from the video/live demonstration.

(\*T0-T3) Has difficulty using the appropriate oral hygiene aids and would require three or more corrective instructions.

**Poor (1):** (P-M) Does not understand the concepts in the video clips. Uses the incorrect brushes to demonstrate on the models. Needs complete instruction or intervention to mimic the oral hygiene instruction from the video clip or live demonstration.

(T0-T3) Does not understand the concepts in correct oral hygiene. Uses incorrect brushes to demonstrate on the models.

[All] Prior to the Practice to Mastery skills assessment, ask if participant is using any modification or adaptive device to his/her toothbrush or denture brush, or using a floss handle in order to better clean their teeth/denture/partial. If yes, provide the participant with the appropriate adaptive device to use during the skills assessment. [For P-M only] If no, and you determine that the client has a physical disability and cannot manage the oral hygiene aids due to arthritis for example, then you may suggest the tubing to adapt their tooth/denture brush or floss holder.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Behavioral skills assessment form checklist** | | | | | |
| Skill | Mastery Level | Lacks manual dexterity due to physical disability (i.e. arthritis, stroke)**\*** | | Sensory impairment limiting or modifying oral hygiene instruction (i.e. visual or aural impairment)**\*\*** | |
|  | Code # | Code # | Comments | Code # | Comments |
| Tooth brushing |  |  |  |  |  |
| Flossing |  |  |  |  |  |
| Cleaning Dentures or Partials |  |  |  |  |  |

**\*Dexterity codes**: **4** = full dexterity; **3** = good dexterity-can manage well without any help; **2** = requires some help, having difficulty if not using any help; **1 =** having high level of difficulty in demonstrating skills.

\*\*Sensory impairment (visual or aural) codes: 4 = no sensory problem apparent for either; 3 = some visual or aural impairment; request for repetition of instructions and vocabulary; some difficulty with print size (not related to literacy); 2 = has difficulty hearing and/or can’t see instructions at all; 1 = cannot hear sufficiently to respond to a question properly (not a language problem), and/or cannot see enough to recognize the pattern of plaque on teeth (not a comprehension problem).

AMI-PM Intervention Training

See Section 5.2

A 3-day training will take place at the start of the study. Training will focus on combination of theory and practice:

* Understanding oral health care needs and disparities faced by target populations
* Reviewing all materials to be used in the intervention
* Conducting mock AMI-PM sessions with feedback

Interventionists will learn to identify the respondent’s focal points for the tailored intervention using information from baseline survey and clinical assessment results and complete the personalized (tailored) intervention checklist. Focal points will be identified based on cut-off points established earlier.

Group Level Intervention – Good Oral Health Campaign

The Good Oral Health Campaign is the group level intervention component of the study. It involves volunteer residents as partners in the building-specific tailoring and implementation of three standardized and scripted pro-oral health campaigns: three health fairs implemented over approximately a three month period. The objectives are: a) to test the effects of a group intervention with the same theoretical framework against an individual level intervention; and b) to build an informed group of residents who have the capacity to sustain the building-level intervention into the future. This study component is specifically targeted to enrolled individual-level intervention participants but may include other building residents. In Condition 1, the Campaign follows the AMI-PM administration; in Condition 2, the Campaign precedes the AMI-PM.

**Training and Preparation of Pro-GOH Campaign Volunteers.** Once recruited and enrolled, Campaign Committee volunteers will meet for 2-hour sessions twice a week or more as required over for a minimum of five to six weeks, to learn how to implement pro-oral health campaigns and to plan an overall blueprint for structuring these campaigns. The committee will include role models who are broadly representative of the composition of the building by age, ethnicity, gender, ability and language. All committees will have bilingual (English/Spanish) capacity.

**Campaign volunteer roles and responsibilities.** The roles of Campaign Committee volunteers are as follows: a) learning about oral health and good oral health hygiene; b) using the AMI Script materials to prepare their own messages for their building campaign; c) raising and addressing any concerns they might have about oral health promotion; d) agreeing to recruit residents to campaign events; e) developing the plan and schedule for the three campaigns, including eliciting the support of building management; f) organizing presentations on oral health topics; g) arranging others’ or presenting their own oral health good practice testimonials; h) staffing oral health practice tables on brushing, flossing and cleaning dentures; i) organizing domain message tables or stations where residents can discuss the message with committee members or staff; j) staffing activities (e.g. games, poster contest, oral health quiz); k) helping to set up campaign space, refreshments and entertainment.

**Campaign volunteer training program.** The Campaign training modules are as follows (see Appendix): Module 1: building group identity and scope of work (committee roles and responsibilities, establishing ground rules and introduction to core theoretical concepts guiding the intervention); Module 2: review of the components of the Pro-G.O.H. Campaign, protecting and respecting study participants, effective communication; Module 3: oral health and oral health self-management (presentation by collaborating dentist), confirmation of campaign event schedule; Module 4: creation of a campaign plan; Module 5: development of campaign material; Module 6: preparation for campaign event. Two additional sessions will focus on finalizing Campaign materials, and practicing testimonials and oral health demonstrations.

**Standardized components of the Campaign.** The core components are developed and structured to standardize the pro-oral health campaign, ensure the inclusion of the theoretical principles, and prepare for fidelity of implementation.

Campaign messages: One message per conceptual domain based on domain scripts.

Campaign Background Materials: include AMI domain specific scripts; domain maps with definitions of domains, fliers and brochures, posters, videos from official oral health sites (e.g. NIDCR).

Campaign recruitment: Resident volunteers will recruit residents to the campaign events using a plan that they devise to market the events and reach all residents in the building. They will prepare and post recruitment materials.

Pro-GOH Campaign Activity Guide and checklist.

The Campaign Passport, a document given to each building resident who attends each fair. It will record their name, attendance, duration of stay, and stamped evidence of participation at each message station during the fair.

**Preparatory Activities:**

1. Assessing expertise and interest of campaign volunteers (committee work, committee leadership, oral health education).
2. Developing a recruitment strategy to reach all residents (e.g. by floor, network, public spaces, etc.).
3. Posting posters and flyers with Pro-GOH messages inviting residents to events.
4. Creating a campaign event program, with detailed guidelines, for use by building volunteers.
5. Developing an introductory script for building volunteers that introduces each of the three campaign events.
6. Defining specific roles designated for volunteers (e.g. recruitment, management of Campaign activities, oral health education).

**Campaign activities with associated theoretical concepts:**

For each domain, key messages will be developed by the committee members with facilitation by interventionists. Materials used to develop the messages will include the Focal Point scripts. Messages will be “staged” on banners with icons identifying them and located on activity “tables” or stations” during each of the 3 fairs that constitute the campaign, and will be integrated into the following activities (by domain).

1. Norms/Intentions: Pro-GOH testimony from building residents, recipes for good oral health.
2. Self-Efficacy: Games repeating Pro-GOH Messages by challenging residents to answer oral health questions (“wheel of fortune”, oral health bingo).
3. Knowledge: competition challenging residents to reflect on and produce the best representation of one or more of the core Pro-GOH messages (e.g. poster competition, oral health quiz).
4. Knowledge/Beliefs/Fears/Worries/perceived risk: “Meet An Expert” informal question/ answer period with a GOH expert from UCHC.
5. Behavioral Norms: screening of oral health self-management videos (brushing, flossing, cleaning dentures)
6. Skills/intentionality/ADLs: demonstration/practice of brushing, flossing, cleaning dentures using toothbrushes, flossing equipment and models, use of special equipment or modifications for people with ADL disabilities.

**Campaign/Fair Passport.** Upon entering each of the three fairs, every resident including those enrolled in the study, will be given a passport reflecting each of the domain tables. They will fill in their names, and will be listed on a master list. As they rotate through the tables/events, their passports will be stamped. They will turn in their passports as they leave. No resident will leave without turning in a passport even if it is blank. (see appendix for passport).

**Reflection and evaluation.** After each campaign event (fair), study staff and volunteers will meet to reflect on the experience and document the results. As part of the reflection/evaluation campaign committee members will be asked to participate in an in-depth interview regarding their experiences.

**Volunteer incentives** include a T-shirt distributed at the first campaign, a framed certificate of recognition and a $100.00 gift certificate after the final campaign. Upon completion of the in-depth interview, campaign committee members will receive an additional $10.00.

6.6 Detailed Description of Study Procedures

not applicable

6.6.1 Schedule of Events

The two intervention components are the individualized AMI-PM (Component A), and the group CA+PM (Component B). To evaluate sequencing we will randomize pairs of senior residences into Condition 1 and Condition 2. Buildings in Condition 1 will initiate with Component A, followed by Component B. Buildings in Condition 2 will initiate with Component B, followed by Component A. This study design will allow us to compare the AMI-PM outcomes to CA+PM outcomes (AIM 1, Question 1), and to determine which condition sequence (A+B or B+A) will produce the best clinical outcomes (AIM 2, Question 2). Each of 3 cycles of Condition 1 (A+B) compared to Condition 2 (B+A) will take place over an 18 month period in two matched buildings with an N of 60 per building (N per cycle of 120; total N for all three cycles approximately 360). We anticipate an attrition rate of approximately 25% and a final N of approximately 270 by the T3 measure, 135 in Condition 1 and 135 in Condition 2. Primary outcomes are improvements in gingival health and decreases in plaque scores.

During the first five-six months of each full intervention cycle 120 residents will be enrolled into the study, 60 in each condition to which their building has been randomly assigned. Research team members will introduce the study in each of the buildings to tenants’ associations and onsite managers, soliciting their support for the study. They will conduct 2 presentations 2 weeks apart to inform residents of the study, recruit and enroll potential participants, and within 2 – 3 days schedule appointments to conduct baseline surveys and clinical assessments. Participants will be recruited, enrolled, consented and scheduled for surveys during the first five to six months regardless of sequence of intervention. Thus, the timing of all baseline surveys and clinical assessments will be the same for both buildings. The face to face intervention in Condition 1 will be scheduled within 45 days after the baseline survey. T1 surveys, clinical assessments and mastery scores will be collected approximately one – three months after the face to face intervention in Condition 1. All T1 clinical assessments and mastery scores for Condition 2 will be collected approximately 1-3 months after the last fair. The face to face intervention in Condition 2 will be scheduled within 45 days of the T1 surveys, clinical assessments and mastery scores. T2 assessments will be conducted approximately 1-3 months post intervention (either the face-to-face intervention or the last campaign). All T3 assessments for both conditions will be collected 6-7 months after T2.

Research team members will establish a base in a central location in each of the buildings from which to continue recruiting, place informational posters in elevators and in other public locations, actively recruit through engaging people in public spaces, and organizing weekly activities such as bingo games through which recruitment and enrollment will occur. These strategies were very successful in the pilot study. At the same time, 5-10 resident volunteers will be invited to join a campaign committee to co-plan and facilitate three building-wide campaigns.

The outcome evaluation consists of three types of data: a) survey data measuring cognitive/behavioral variables, b) clinical assessment data and c) observational data producing scores on oral health skills practice. These three types of data will be collected at three points during each cycle: prior to the administration of the first condition in each of the buildings in each cycle (T0), and post each condition (T1) and three months post T1 (T2); only GOHAI (oral health quality of life scale), clinical assessment data and Mastery data will be collected at T3; and Practice-to-Mastery skills data will also be collected from participants during each AMI-PM.

6.6.2 Visit Windows

As stated above, all individuals in each cycle will be recruited and complete the clinical assessment, skills assessment and survey. The timing of all baseline surveys and clinical assessments will be the same for both buildings. Participants in Condition 1 (Component A building) will be scheduled for the individualized AMI-PM within 45 days of their T0 surveys and clinical assessments. For participants in Condition 2 (Condition B building), participation in CA+PM will follow the pre-intervention survey and clinical assessment within 3 - 6 months of the T0. T1 surveys, clinical assessments and skills assessment scores for Condition 1 will be collected approximately 1 - 3 months after the face to face intervention. All T1 clinical assessments and skills assessment scores for Condition 2 will be collected approximately 1 - 3 months after the last fair. T2 assessments will be conducted approximately 1 - 3 months post intervention either for the face-to-face intervention or the last campaign. All T3 assessments for both conditions will be collected 6 - 7 months after T2.

6.6.3 Rules for Rescheduling Visits

Since we will maintain a presence in the building, our experience shows that it is relatively easy to reschedule visits and events with residents. The rule will be to reschedule within a 2 week timeframe. If that is not possible, we will schedule within 2 weeks of the failed appointment. No more than five attempts will be made to reschedule. Contact attempts are tracked in the study’s ACCESS tracking data base.

6.6.4 Order of Visit Activities

See Section 6.6.2.

6.6.5 Rules for Rescheduling Events

See Section 6.6.3.

6.6.6 Missed Visits and Procedures

Missed visits and procedures will be rescheduled within a two week window.

6.7 Protocol Deviations and Violations

The tracking database will be reviewed by the Survey Coordinator and Data Manager(s) weekly to assure adherence with protocols. Protocol deviations will be reported to the study PIs and the IRB within the required time. Plans to prevent future deviations will be developed and implemented. Deviations will also be reported to the NIDCR Program Official once monthly and to the IRB annually.

1. Procedures for Monitoring Trial Progress

7.1 Enrollment

The Survey and Intervention Coordinators will be responsible for the tracking data base and follow-up of participants. Enrollment reports will be provided to the study team by the Data Manager(s) on a weekly basis as needed.

7.2 Visit Completion

The Survey and Intervention Coordinators will be responsible for the tracking data base and follow-up of participants. Reports will be provided to the study team on a weekly basis by the Data Manager(s) for evaluation (screening, skills assessment, survey, AMI-PM, Campaign), and completion of intervention.

7.3 Outstanding and Missing Data

Interviewers should review the interview before closing the QDS form and assure that there is no missing data on the forms. The Survey Coordinator and Data Manager will review the QDS files weekly to assure that there are no systematic errors in survey administration. The clinical examiners should review the paper or electronic charts and recording forms to assure that all clinical data are complete.

7.4 Data Entry Errors

Interviewers and clinical data recorders are responsible for detecting data entry errors with the supervision of the Survey Coordinator. QDS Data Warehouse will automatically record all corrections of survey entry errors. Once the SPSS files are cleaned, they will be “locked” and copies will be used, named and tracked, for analytic purposes.

7.5 Protocol Deviations/Violations

The tracking database will be reviewed with the Field Coordinator and Data Manager(s) weekly.

to assure adherence with protocols. Protocol deviations will be reported to the study PIs and the IRB within the required time. Plans to prevent future deviations will be developed and implemented. Deviations will also be reported to the NIDCR Program Official once monthly and the IRB annually.

7.6 Serious Adverse Events

Participation in this study meets minimal risk criteria consistent with 45 CFR 46. Thus, safety monitoring for this study will focus on unanticipated problems involving risks to subjects, including unanticipated problems that meet the definition of a serious adverse event.

See Section 9

**Time Period and Frequency for Event Assessment and Follow-Up**

Unanticipated problems will be recorded in the data collection system throughout the study.

The PIs will identify, confirm and record all reportable events with start dates occurring any time after informed consent is obtained until 7 (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation. At each study visit, the investigator will inquire about the occurrence of AE/SAEs since the last visit. Events will be followed for outcome information until resolution or stabilization.

1. SAFETY ASSESSMENT AND REPORTING

Participant safety is of paramount importance in conducting our research project. The tailored one-on-one and building interventions present minimal risk to the participants. Some participants may find some portions of the survey stressful and upsetting. Participants may skip sections that are stressful or discontinue the survey at any point. The clinical assessment may present a very minimal risk of infection. If an infection occurs, the dentists on the study team will prescribe an antibiotic at the expense of the study. If the participant finds the assessment painful, topical anesthetic will be applied. The PIs and the dentists will oversee safety precautions during the study. Participants with emergent dental treatment needs discovered during the clinical assessment will be referred for immediate treatment. Participants will be advised of other treatment needs and will be provided with a referral if needed. As with all research projects, reporting of suspected elder, child or spousal abuse, or of participant intent to harm self or someone else is mandatory and participants are informed of this at the time of informed consent.

**Specification of Safety Parameters**

The safety parameters that will be recorded in the study record are the referral for dental treatment forms and requests to discontinue the clinical assessment, the survey administration or the tailored intervention.

***Unanticipated Problems***

The Office for Human Research Protections (OHRP) considers unanticipated problems involving risks to subjects or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;

related or possibly related to participation in the research (“possibly related” means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

***Adverse Events***

An adverse event is any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject’s participation in the research, whether or not considered related to the subject’s participation in the research.

***Serious Adverse Events***

A serious adverse event (SAE) is one that meets one or more of the following criteria:

Results in death;

Is life-threatening (places the subject at immediate risk of death from the event as it occurred);

Results in inpatient hospitalization or prolongation of existing hospitalization;

Results in a persistent or significant disability or incapacity;

Results in a congenital anomaly or birth defect;

An important medical event that may not result in death, be life threatening, or require hospitalization may be considered an SAE when, based upon appropriate medical judgment, the event may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

**Time Period and Frequency for Event Assessment and Follow-Up**

Unanticipated problems will be recorded in the data collection system throughout the study.

The PI will record all reportable events with start dates occurring any time after informed consent is obtained until 7 (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation. At each study visit, the investigator will inquire about the occurrence of AE/SAEs since the last visit. These events will be reported in writing to NIDCR’s centralized safety system via Rho Product Safety within 5 working days for serious adverse events and within one month for non-serious adverse events. Events will be followed for outcome information until resolution or stabilization.

**Characteristics of an Adverse Event**

***Relationship to Study Intervention***

To assess relationship of an event to study intervention, the following guidelines are used:

* 1. Related (Possible, Probable, Definite)

1. The event is known to occur with the study intervention.
2. There is a temporal relationship between the intervention and event onset.
3. The event abates when the intervention is discontinued.
4. The event reappears upon a re-challenge with the intervention.
5. Not Related (Unlikely, Not Related)
6. There is no temporal relationship between the intervention and event onset.
7. An alternate etiology has been established.

***Expectedness of SAEs***

The NIDCR Medical Monitor and the Study PI will be responsible for determining whether an SAE is expected or unexpected. An adverse event will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the intervention.

***Severity of Event***

The following scale will be used to grade adverse events:

1. Mild: no intervention required; no impact on activities of daily living (ADL)
2. Moderate: minimal, local, or non-invasive intervention indicated; moderate impact on ADL
3. Severe: significant symptoms requiring invasive intervention; subject seeks medical attention, needs major assistance with ADL

***Unanticipated Problem Reporting to IRB and NIDCR***

The UCHC IRB and the NIDCR requires reporting of unexpected adverse events that may represent an unanticipated problem involving risks to subjects or others (UPIRSO). Such events are to be reported using the Problem Report Form available on the UCHC IRIS system. Upon review the IRB and the NIDCR may require changes to informed consent forms and/or protocols or other actions such as increased monitoring. The IRB makes the final determination as to whether an internal adverse event constitutes an unanticipated problem and whether changes to the consent and/or protocol are required. For external events, the sponsor should indicate if they have deemed the event to be a UPIRSO, and if so the IRB is to be informed.

All investigators and study personnel must be familiar with the policy for reporting unanticipated problems, inclusive of unexpected adverse events that may be unanticipated problems, to the IRB. Such events must be reported using the Problem Report Form within 5 working days (7 calendar days) of becoming aware of the event.

Incidents or events that meet the OHRP criteria for unanticipated problems require the creation and completion of an unanticipated problem report form. OHRP recommends that investigators include the following information when reporting an adverse event, or any other incident, experience, or outcome as an unanticipated problem to the IRB:

Appropriate identifying information for the research protocol, such as the title, investigator’s name, and the IRB project number;

A detailed description of the adverse event, incident, experience, or outcome;

An explanation of the basis for determining that the adverse event, incident, experience, or outcome represents an unanticipated problem;

A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the unanticipated problem.

To satisfy the requirement for prompt reporting, unanticipated problems will be reported using the following timeline:

Unanticipated problems that are serious adverse events will be reported to the IRB and to NIDCR within 1 week of the investigator becoming aware of the event.

Any other unanticipated problem will be reported to the IRB and to NIDCR within 2 weeks of the investigator becoming aware of the problem.

All unanticipated problems should be reported to appropriate institutional officials (as required by an institution’s written reporting procedures), the supporting agency head (or designee), and OHRP within one month of the IRB’s receipt of the report of the problem from the investigator.

All unanticipated problems will be reported to NIDCR’s centralized reporting system via Rho Product Safety by fax or email:

* Product Safety Fax Line (US): 1-888-746-3293
* Product Safety Hotline: 1-888-746-7231
* Product Safety Email: [rho\_productsafety@rhoworld.com](mailto:rho_productsafety@rhoworld.com)

General questions about SAE reporting can be directed to the Rho Product Safety Help Line (available 8:00AM – 5:00PM Eastern Time).

***Serious Adverse Event Reporting to NIDCR***

Any AE meeting the specified Serious Adverse Event criteria will be submitted on an SAE form to NIDCR’s centralized safety system via Rho Product Safety. This report may be sent by fax or email. Once submitted, Rho Product Safety will send a confirmation email to the investigator within 1 business day. The investigator should contact Rho Product Safety if this confirmation is not received. This process applies to both initial and follow-up SAE reports.

SAE Reporting Contact Information:

* Product Safety Fax Line (US): 1-888-746-3293
* Product Safety Hotline: 1-888-746-7231
* Product Safety Email: [rho\_productsafety@rhoworld.com](mailto:rho_productsafety@rhoworld.com)

General questions about SAE reporting can be directed to the Rho Product Safety Help Line (available 8:00AM – 5:00PM Eastern Time).

The study clinician will complete a Serious Adverse Event Form and submit via fax or email within the following timelines:

All deaths and immediately life-threatening events, whether related or unrelated, will be recorded on the Serious Adverse Event Form and submitted to Rho Product Safety within 24 hours of site awareness.

Serious adverse events other than death and immediately life-threatening events, regardless of relationship, will be reported by fax within 72 hours of site awareness.

All SAEs will be followed until resolution or stabilization.

**Halting Rules**

Study halting may occur as required by the IRB or NIDCR. The study PIs may temporarily suspend enrollment pending review by these authorities if warranted based on the presence, type, or frequency of SAEs or other changes in the study protocol which may place participants in greater than anticipated risk.

Serious adverse events are highly unlikely. If a serious adverse event were to occur as a result of the clinical assessment, such as repeated infections or adverse reaction to the disclosing solution, clinical assessments would be suspended to review clinical protocols.

**9.1 SAE Reporting**

See Section 9.

**9.2 Expected Adverse Events**

See Section 9.

**9.3 Toxicity Tables**

not applicable

**9.4 Prohibited Medications**

not applicable

**9.5 Unanticipated Problems**

See Section 9.

9.6 Pregnancy Testing and Counseling

not applicable.

1. DATA MANAGEMENT

10.1 Data Collection Methods

The investigators are responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported. All hard copies of source documents will be completed in a neat, legible manner to ensure accurate interpretation of data. Electronic data collection via Questionnaire Development System (QDS) will be used for survey and other quantitative data collection. Paper questionnaires will be available in the event of a computer malfunction. Electronic results of clinical assessments recorded on paper charts will be entered into an electronic data collection system.

Data collection and accurate documentation will be the responsibility of the study staff under the direction of the Survey Coordinator, the Intervention Coordinator, the Data Analyst and the PIs. All source documents will be reviewed by the study team and data management staff, who will ensure that they are accurate and complete. Unanticipated problems and adverse events will be immediately reported to and reviewed by the PIs. The protocol for documentation and reporting of unanticipated problems and adverse events (outlined in Section 7.6 and Section 9) will be followed.

10.2 Source Documentation Requirements

Data to be collected in this project includes in-person interviews, clinical assessments and staff observations.

Data collected through interviews will include:

Personal demographics;

Health history and current health status, including oral health status, history, experience and decision-making;

Self-reported information regarding knowledge, beliefs and attitudes about oral health;

Self-report information on access to oral health care;

Digitally and form recorded AMI individualized oral health education sessions and plans of care;

Attendance at oral health activities assessed through stamped passports indicating participation at specific activities.

Staff observations will include:

Building characteristics including size, structure, demographics, social organization and social infrastructure, management support, social and health-related activities;

Research staff observations at campaign events, text documentation, checklists and indices on training, campaign implementation, intervention adaptation, maintenance/sustainability activities and feasibility/acceptability of intervention in intervention site;

Scoring of oral hygiene skills assessments (T0 – T3 and AMI-PM).

Clinical assessments will include:

Soft tissue exam (external palpation of lymph nodes, lips and labial mucosa, tongue, floor of mouth, hard palate, soft palate);

Presence and absence of natural teeth;

Presence or absence of full, partial dentures;

Gingival Index;

Plaque score.

10.3 Study Forms

Survey data collection will be accomplished using the Questionnaire Development System (QDS) electronic data collection system installed on individual password-protected laptop computers backed up on password-protected flash drives, and downloaded each day into a study designated directory and database on a password-protected computer by the study data manager. Each interviewer will have her/his own designated laptop computer and flash drive. After comparing each interviewer’s laptop and flash drive files to confirm that all survey data collected each day have been entered into the database, the data manager will erase the survey data from each flash drive.

Individual AMI-PM session data will be captured electronically on individual password-protected laptop computers, backed up on password-protected flash drives, and uploaded daily to password-protected computer files. Paper forms will be filed in the research record.

Digital audio-recordings will be uploaded daily to password protected computer files, and deleted from the recorders after computer file storage is completed. Audio-recordings are for purposes of monitoring, feedback and fidelity checks and will be used for training purposes, but will not be transcribed.

Clinical assessment data will be entered into an electronic data collection system on password-protected laptops and then uploaded daily to password-protected computer files.

The oral hygiene skills assessment will be conducted by research staff at the time of the clinical assessment and recorded on the data form for the clinical assessment. Data will be tracked in an ACCESS data file.

Individual Passports for each person attending each of the fairs in the campaign will include the person’s name, time of arrival and time of leaving. The passport will collect information on what activities they participated in. The Passport will be stamped at each activity. Passports will be collected at the end of each fair during the building campaign and the number of activities and other data will be recorded in an ACCESS file as a measure of dosage of the intervention and linked to the individual’s ID.

The research record will include a checklist (shown in Appendix) to assure that all data are complete for each participant. The research record and the ACCESS tracking data base will document when a participant has been lost to follow-up.

10.4 Case Report Form Completion Guidelines

not applicable

10.5 Data Error Detection and Correction

The Survey Coordinator will review surveys, clinical assessment forms and intervention forms at the completion of each part of the study protocol. The Survey Coordinator will be responsible for detection and correction of errors once discovered. QDS Data Warehouse will automatically record all corrections of survey entry errors. Once the SPSS files are cleaned, they will be “locked” and copies will be used, named and tracked, for analytic purposes.

10.6 Data Quality Management

Quality control and quality assurance begins with adequate training and calibration of the interventionists and assessors, both clinical examiners and interviewers. Quality assurance is further addressed by monitoring fidelity throughout the study. These issues are discussed in Section 6.5.

**Monitoring and Recalibration of oral health assessment process**

Continual gathering of clean, reliable data in a consistent and uniform manner is one of the main objectives of the clinical control trial. Several quality control procedures will be carried out periodically to assure continuing quality of data gathered by the dental team throughout the duration of the study.

**Expert Replication and Monitoring Field Operations**

During the field operations, examiners and recorders should periodically review their training manuals to prevent deviation, or “drift” from the standards achieved during the training period. Particular attention should be devoted to uniform adherence to the criteria for making correct decisions about observations such as scoring of gingival indices and presence or absence of plaque. Strict compliance with infection control procedures is another important consideration for dental teams. In order to help the dental teams maintain their standards, the clinical director for the study project will make periodic visits to field personnel to observe their performance and offer feedback on the results of their examinations. Field observations occur twice per assessor for each time point. Observation and matched scoring for GI and Plaque Score occur once per assessor per time point. The standard examiner will choose one patient per each of the dental hygienists on whom the examination will be replicated. The replicated exam will be completed in paper format and compared to the one entered on the computer so as not to confound the data collection for the study. The purpose of these so called “expert replications” is to determine whether the examiners are maintaining the examination standards achieved during training, and to measure the degree of deviation, if any, from those standards. If correlation between the standard examiner and the field examiner is not within acceptable limits, retraining will be conducted.

Data collection and accurate documentation will be the responsibility of the study staff under the direction of the Intervention Coordinator, the Survey Coordinator and the Data Analyst and the supervision of the PIs. All source documents reports will be reviewed by the study team and data management staff, who will ensure that they are accurate and complete. The Data Analyst will maintain an Access tracking database to assure that all necessary documents are completed for each participant, follow-up surveys and clinical assessments are completed on time, and AMI sessions are completed on schedule. This electronic file will have participant names and study identifiers; it will be password protected. Additionally, each research record will have a checklist on the inside cover to assure that all necessary documents are completed for each participant, follow-up surveys and clinical assessments are completed on time, and AMI-PM sessions are completed on schedule. The format for both documents is shown in the Appendix.

Survey data collection will be accomplished using the Questionnaire Development System (QDS) electronic data collection system installed on individual password-protected laptop computers, backed up on password-protected flash drives, and downloaded each day into a study designated directory (L drive). The data manager then will transfer the survey data to the study database. The data directories are backed-up automatically each day. Each interviewer will have her/his own designated laptop computer and flash drive. Interviewers will check each interview file for missing data and completeness before saving to the data directories. These computers will also be used to enter intervention fidelity data, and to update Access data base (See Appendix - Survey Data Flowchart).

Random audits of participant research records will take place quarterly to assure that all documents are filed properly in the research record. Ten records will be selected each quarter for review. Corrective actions will be taken if problems are found.

QDS will be used to enter and store data. The QDS data will be transferred to SPSS data files for analysis.

10.7 Data Provided from an Entity Other than the Clinical Site

Not applicable

10.8 Data Collection and Data Processing Flowchart

Participant confidentiality is strictly held in trust by the investigators, study staff, and the sponsor and its agents. This confidentiality is extended to cover testing of biological samples in addition to any study information relating to participants. Data will be collected for research purposes only.

The following procedures will be put in place to protect the confidentiality of data. To avoid loss of confidentiality, participants' names will not appear on any document associated with the project, except for informed consent and HIPAA forms and Campaign Passport. Unique ID numbers, not participants' names, will appear on all interview records used for computer data entry. Ethnographic observations, field notes and other project records will be kept in locked files and in password protected computer files at UCHC and ICR, to which only project staff will have access. No records will be kept at building sites at any time. Names and apartment numbers, which will be used for creating unique identifier lists and for follow-up, will be kept in a locked filing cabinet at the ICR project office, under the direct supervision of the Survey Coordinator, and used by the Survey Coordinator, Intervention Coordinator, interventionists and field interviewers only. Digital audio-recordings will be uploaded daily to password protected computer files, and deleted after the interview has been checked for accuracy. Participants will be identified by Master ID and any identifier information will be removed from the recording. Therefore, the participant’s name will not be used anywhere in the recording.

The study protocol, documentation, data, and all other information generated will be held in strict confidence. A subject’s participation in this project will be kept confidential within the study team at the SDM and ICR. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the PIs and sponsor, and will be shared only in aggregated form. Study data will be presented in summary form. Participant names or other identifying information will never be included in project data to be presented to the public. Therefore, participants will not be identifiable in presentations or publications based on this research.

The study monitor or other authorized representatives of the sponsor, and the UCHC IRB and Human Subjects Protections Office may inspect all study documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) for the study participants. The clinical study site will permit access to such records.

Knowledge of elder, child or spousal abuse, or participant intent to harm self or someone else, or of certain communicable diseases learned during the course of the study, is required to be reported to State officials.

10.9 Creating and Distributing Revised Case Report Forms

not applicable

10.10 Long Term Storage of Case Report Forms

Research records will be maintained in locked files at ICR for 7 years after the close of the study.

10.11 Maintaining Data Privacy

See Section 3.3.

1. SITE MONITORING

Clinical site monitoring will not be done for this study; however, the NIDCR reserves the right to conduct independent audits or clinical monitoring as necessary. PIs Reisine and Schensul, PIs on the prior NIDCR funded studies will lead the study. The field team will be directed by the Intervention Coordinator and the Survey Coordinator. Both will work closely with the Data Analyst who will be responsible for tracking field progress and reporting to the study team. The PIs will remain in close contact with the field administrative team.

12.1 Purpose of Site Monitoring

not applicable – only one site

12.2 Clinical Monitoring Logistics

not applicable – only one site

12.2.1 Frequency of Visits

not applicable – only one site

12.2.2 Scope of Monitoring Activities

not applicable – only one site

12.2.3 Monitoring Reports

not applicable – only one site

12.2.4 Communication Plan

not applicable – only one site

12.3 Facilitating the Site Monitoring Visit

not applicable – only one site

12.3.1 Scheduling the Visit

not applicable – only one site

12.3.2 Securing Space for Monitors

not applicable – only one site

12.3.3 Preparing Study Documentation for Review

not applicable – only one site

12.3.4 Arranging for Access to Medical Records

not applicable – only one site

12.3.5 Wrap-Up Meeting

not applicable – only one site

12.3.6 Responding to Request for Corrective Action

not applicable – only one site

12.4 Preparing for Audits by Regulatory Authorities

not applicable – only one site

12.4.1 Sponsor Notification

not applicable – only one site

12.4.2 Communicating and Interacting with Auditors

not applicable – only one site

12.4.3 Responding to Audit Findings

not applicable – only one site

1. STUDY COMPLETION AND CLOSE-OUT PROCEDURES

The PIs will notify the IRB and NIDCR of study completion. The PIs will be responsible for all reports to the IRB and the funding agency.

13.1 Participant Notification

Participants will be convened at the end of T3 assessment in their respective buildings to debrief and to be presented with summary findings. We have conducted a de-briefing session/preliminary outcomes presentation at the pilot study site. There was good attendance and participants were pleased to hear about the positive preliminary results.

13.2 Site Procedures

Not applicable

13.2.1 Data Locking Procedures

Prior to data locking, the study team will confirm that all subjects have completed the study, withdrawn, or have been terminated by the PI. All data will be reviewed and accounted for, including any safety events (SAEs UPs). All outstanding queries will be resolved.

Final datasets will be saved electronically, clearly labeled and stored in a secure project folder on the Q drive of ICR’s server accessible only to study staff. The file for sharing will be de-identified and in read only format.

13.2.2 Return / Destruction of Remaining Test Article

Not applicable

13.2.3 Final Disposition of Study Supplies

Not applicable

13.2.4 Close-Out Monitoring Visit

Not applicable

13.2.5 Final Study Report

Final close out reports will be provided to NIDCR and the IRB(s).

13.2.6 Long Term Storage of Study Documentation

For funded grants, documents must be maintained for 7 years after the grant is officially closed (1 year at the investigative centers and 6 at the federal records center).Research records will be maintained in locked files at ICR for 7 years after the close of the study and then destroyed.

1. Appendices

Appendix A: List of Abbreviations

|  |  |
| --- | --- |
| ADLs | Activities of Daily Living |
| AE / SAE | Adverse Event / Serious Adverse Event |
| AMI-PM  CA | Adapted Motivational Interviewing and Practice-to-Mastery  Campaign |
| DAS | Dental Anxiety Scale |
| DMFS | Decayed, missing, and filled tooth surfaces |
|  |  |
| FAQs | Frequently Asked Questions |
| GI  GOH | Gingival Index  Good Oral Health |
| GOHAI | General Oral Health Assessment Inventory |
| ICF | Informed Consent Form |
| ICR | Institute for Community Research |
| IM | Integrated Model of Behavioral Prediction |
| IRB  MMOR | Institutional Review Board  Medical Monitor Oversight Report |
| NIDCR | National Institute of Dental and Craniofacial Research, NIH, DHHS |
| NIH | National Institutes of Health |
| OCTOM | Office of Clinical Trials Operations and Management, NIDCR, NIH |
| OHRQoL | Oral Health Related Quality of Life |
| OHRSA | Oral Health Research Strategic Alliance |
| OHRP | Office for Human Research Protections |
| PHI | Protected Health Information |
| PI  Pro-GOH | Principal Investigator  Project Good Oral Health |
| QDS | Questionnaire Development System |
| SDM | University of Connecticut School of Dental Medicine |
| SOP | Standard Operating Procedure |
| SPSS | Statistical Package for the Social Sciences |
| TPB | Theory of Planned Behavior |
| TRA | Theory of Reasoned Action |
| UCHC  UPIRSO  US | University of Connecticut Health Center  Unanticipated Problem Involving Risk to Subjects or Others  United States |
| WHO | World Health Organization |

Appendix B: Dynamic References List

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The documents contained in this Appendix were developed for the pilot study, Changing Oral Health Norms and Hygiene Practices among Vulnerable Older Adults (NIDCR R34DE022271-1), and serve as examples and references. All materials will be revised as necessary to conform to the design, methodology and aims of the proposed study, and will be submitted for review and approval by the UCHC IRB prior to use.