

# **Testing a Multi-behavioral Intervention to Improve Oral Health Behaviors in the Pediatric Dental Surgery Population**

**NIDCR Protocol Number: 22-134-E**

**NIDCR Award UH3 DE032003**

**NCT07220850**

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**Draft or Version Number: 1.2**

**April 10, 2025**

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## **STATEMENT OF COMPLIANCE**

The study will be conducted in accordance with the International Council for Harmonisation guidelines for Good Clinical Practice (GCP) (ICH E6) and the Code of Federal Regulations on the Protection of Human Subjects (45 CFR Part 46). National Institutes of Health (NIH)-funded investigators and clinical trial site staff who are responsible for the conduct, management, or oversight of NIH-funded clinical trials have completed Human Subjects Protection and ICH GCP Training.

## SIGNATURE PAGE

The signature below constitutes the approval of this protocol and the attachments, and provides the necessary assurances that this study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines.

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## TABLE OF CONTENTS

	PAGE
STATEMENT OF COMPLIANCE .....	I
SIGNATURE PAGE .....	II
TABLE OF CONTENTS .....	III
LIST OF ABBREVIATIONS .....	VI
PROTOCOL SUMMARY .....	VIII
1 KEY ROLES AND CONTACT INFORMATION.....	1
2 INTRODUCTION: BACKGROUND INFORMATION AND SCIENTIFIC RATIONALE .....	3
2.1 Background Information .....	3
2.2 Rationale .....	5
2.3 Potential Risks and Benefits.....	6
2.3.1 Potential Risks.....	6
2.3.2 Potential Benefits.....	7
3 OBJECTIVES AND OUTCOME MEASURES.....	8
3.1 Primary .....	8
3.2 Secondary .....	9
4 STUDY DESIGN .....	10
4.1 Overall Design.....	10
4.2 Scientific Rationale for Study Design .....	11
4.3 Justification for Dose .....	11
5 STUDY POPULATION .....	13
5.1 Participant Inclusion Criteria.....	13
5.2 Participant Exclusion Criteria .....	13
5.3 Strategies for Recruitment and Retention .....	14
5.4 Treatment Assignment Procedures .....	17
5.4.1 Randomization Procedures .....	17
5.4.2 Blinding Procedures .....	17
5.5 Participant Withdrawal or Discontinuation from Study Procedures/Intervention ....	18
5.5.1 Reasons for Participant Withdrawal or Discontinuation from Study Procedures/Intervention .....	18
5.6 Premature Termination or Suspension of Study .....	20
6 STUDY INTERVENTION .....	21
6.1 Study Behavioral or Social Intervention(s) Description .....	21
6.2 Administration of Intervention.....	22
6.3 Procedures for Training Interventionists and Monitoring Intervention Fidelity.....	24
6.4 Assessment of Participant Compliance with Study Intervention .....	25
7 STUDY SCHEDULE .....	26
7.1 Screening / Enrollment (All participant dyads) .....	26
7.2 Baseline. (All participant dyads).....	26
Baseline Data Visit (T1) (Data Visit 1, -3 to 0 months).....	26
7.3 Intermediate Visits (Day of Surgery through T2 Data Collection).....	26

7.4	Final Study Visit (All participants).....	31
7.5	Withdrawal Visit.....	31
7.6	Unscheduled Visit.....	31
8	STUDY PROCEDURES/EVALUATIONS .....	32
8.1	Study Procedures/Evaluations .....	32
9	ASSESSMENT OF SAFETY.....	34
9.1	Specification of Safety Parameters .....	34
9.1.1	Unanticipated Problems .....	34
9.1.2	Adverse Events .....	34
9.1.3	Serious Adverse Events .....	34
9.2	Time Period and Frequency for Event Assessment and Follow-Up.....	35
9.3	Characteristics of an Adverse Event .....	36
9.3.1	Relationship to Study Intervention .....	36
9.3.2	Expectedness .....	36
9.3.3	Severity of Event .....	36
9.4	Reporting Procedures .....	37
9.4.1	Unanticipated Problem Reporting.....	37
9.4.2	Serious Adverse Event Reporting .....	38
9.4.3	Reporting of Pregnancy.....	38
9.5	Halting Rules.....	38
10	STUDY OVERSIGHT .....	39
11	CLINICAL SITE MONITORING.....	40
12	STATISTICAL CONSIDERATIONS .....	41
12.1	Study Hypotheses .....	41
12.2	Sample Size Considerations .....	41
12.3	Final Analysis Plan .....	42
13	SOURCE DOCUMENTS AND ACCESS TO SOURCE DATA/DOCUMENTS .....	46
14	QUALITY CONTROL AND QUALITY ASSURANCE.....	47
15	ETHICS/PROTECTION OF HUMAN SUBJECTS .....	49
15.1	Ethical Standard .....	49
15.2	Institutional Review Board.....	49
15.3	Informed Consent Process.....	49
15.4	Subject Confidentiality .....	51
15.5	Future Use of Stored Specimens and Other Identifiable Data .....	53
16	DATA HANDLING AND RECORD KEEPING.....	54
16.1	Data Management Responsibilities .....	54
16.2	Data Capture Methods .....	54
16.3	Types of Data .....	55
16.4	Schedule and Content of Reports .....	57
16.5	Study Records Retention .....	57
16.6	Protocol Deviations .....	58
17	PUBLICATION/DATA SHARING .....	59
18	LITERATURE REFERENCES .....	60

SUPPLEMENTAL MATERIALS.....	<b>ERROR! BOOKMARK NOT DEFINED.</b>
APPENDICES.....	<b>ERROR! BOOKMARK NOT DEFINED.</b>
APPENDIX A: SCHEDULE OF EVENTS .....	<b>ERROR! BOOKMARK NOT DEFINED.</b>

## LIST OF ABBREVIATIONS

AE	Adverse Event
ADL	Activities of Daily Living
BMI	Body Mass Index
BRFQ	Basic Research Factors Questionnaire
CCTS	Center for Clinical and Translational Science
CFR	Code of Federal Regulations
CHW	Community Health Worker
CITI	Collaborative Institutional Training Initiative
CMP	Clinical Monitoring Plan
COC	Certificate of Confidentiality
Co-I	Co-Investigator
CRC	Clinical Research Coordinator
CRF	Case Report Form
CROMS	Clinical Research Operations and Management Support
DGA	Dental surgery under General Anesthesia
DHHS	Department of Health and Human Services
DMFT	Decayed, Missing, Filled Teeth
DSMB	Data Safety Monitoring Board
FFR	Federal Financial Report
GCP	Good Clinical Practice
HHS	Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
ICC	Intraclass Correlation Coefficient
ICH	International Conference on Harmonisation
IHRP	Institute for Health Research and Policy
IRB	Institutional Review Board
ITT	Intention-To-Treat
MAPS	Multidimensional Assessment of Parenting Scale
mITT	Modified Intention-To-Treat
MOP	Manual of Procedures
MRC	Methodology Research Core
MPI	Multiple Principal Investigators
NDSR	Nutrition Data System for Research
NHANES	National Health and Nutrition Examination Survey
NIDCR	National Institute of Dental and Craniofacial Research
NIH	National Institutes of Health
OHRP	Office for Human Research Protections
PI	Principal Investigator

PM	Project Manager
PROTECT	Preventing Recurrent Operations Targeting Early Childhood Caries Treatment
QC	Quality Control
RA	Research Assistant
REDCap	Research Electronic Data Capture
SAE	Serious Adverse Event
SCT	Social Cognitive Theory
S-ECC	Severe Early Childhood Caries
SESMO	Self-Efficacy Scale for Maternal Oral Care
SOA	Schedule of Activities
SOP	Standard Operating Procedure
UC	Usual Care
UIC	University of Illinois Chicago
UP	Unanticipated Problem
US	United States

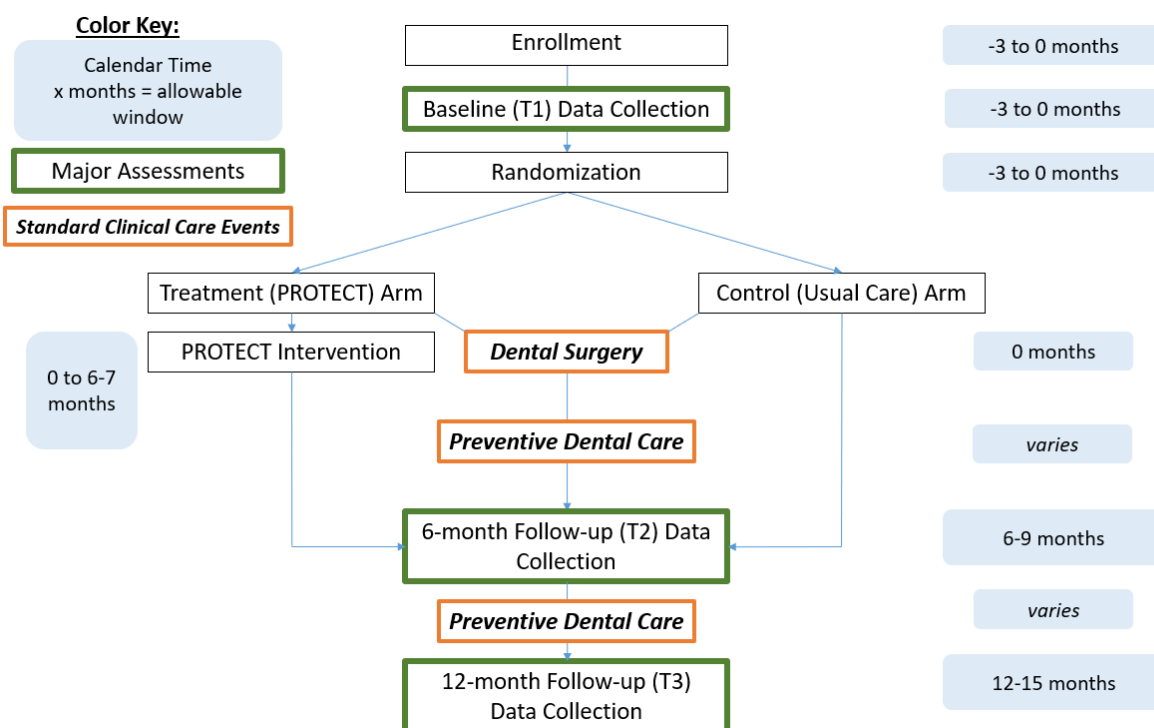
## PROTOCOL SUMMARY

<b>Title:</b>	Testing a Multi-behavioral Intervention to Improve Oral Health Behaviors in the Pediatric Dental Surgery Population
<b>Précis:</b>	This study aims to test the efficacy of the 6-month <b>PROTECT</b> intervention compared to Usual Care (UC) to improve behavioral oral health outcomes. Investigators will conduct a randomized clinical trial to test the efficacy of PROTECT (n = 210) compared to UC (n = 210) in the pediatric DGA (dental surgery under general anesthesia) population. Primary outcomes include tooth brushing frequency and percentage of total calories derived from added sugars, collected prior to surgery, at 6-months and 12-months post-surgery.
<b>Objectives:</b>	<p><b>Primary:</b> To assess the efficacy of the PROTECT intervention, compared to Usual Care, measured at 6 months following a child's dental surgery (end of intervention). Sustained behavior change will be measured 12 months following a child's dental surgery (6 months after intervention ends).</p> <p><b>Secondary:</b> The mechanistic role of behavioral change targets in influencing intervention effectiveness will be examined and determined. Per Social Cognitive Theory (SCT), Investigators will estimate a mediation model of positive parenting and self-efficacy as mediators in the pathway to behavioral change.</p>
<b>Population</b>	<p>The population includes 420 dyads (210 dyads intervention arm, 210 usual care arm; dyads are caregivers and child patients scheduled for dental surgery).</p> <p>Inclusion criteria for participant dyads (caregiver and child) include: Caregivers who are in same household as the child &gt; 50% of the week, who are aged &gt; 18 years and &lt; 90 years, and with access to a computer/internet/telephone. The child is scheduled for dental surgery under general anesthesia at UIC Pediatric Dentistry Clinic and is &lt; 96 months of age at the time of enrollment.</p> <p>Exclusion criteria for participant dyads (caregiver and child) include: Dyads of foster parents and foster children; families who are planning to move out of state within the six-month period; child with behavioral/developmental/neurodivergent issues that may impact brushing or dietary habits, (e.g. severe autism spectrum disorder, oppositional defiance disorder, sensory processing disorder); and adults unable to consent (e.g. unable to read and/or understand the consent form through reading and discussion).</p>

<b>Phase or Stage:</b>	UH3 / Phase 2 Clinical Trial
<b>Number of Sites:</b>	(1) University of Illinois Chicago (UIC) College of Dentistry - Pediatric Dentistry Clinic
<b>Description of Intervention:</b>	PROTECT, or Preventing Recurrent Operations Targeting Early Childhood Caries Treatment, is a novel, 6-month parenting intervention that focus on harnessing evidence-based parenting strategies to increase a child's tooth brushing and decrease a child's sugar consumption. The intervention will be delivered by community health workers (CHWs) who have social proximity (e.g. shared life experiences) to our participants. The CHW will meet (in person or remote) with a caregiver over the six-month intervention program for 10 sessions, working with each family to apply positive parenting skills to help their child consume less sugar and assist with daily toothbrushing. Sessions will last 30-60 minutes and will address knowledge, application to daily life, and reflections on challenges to behavior change.
<b>Study Duration:</b>	The estimated time from when the study opens to enrollment until completion of data analyses is 48 months.
<b>Subject Participation Duration:</b>	The time it will take to conduct the study (enrollment to last data collection visit) for each individual participant will be 12-18 months.
<b>Estimated Time to Complete Enrollment:</b>	Estimated time from first to last participant enrollment is 30 months.

## Schematic of Study Design:

### Timeline of Study Activities, by Individual Participant



## Figure Legend

Timeline, listed in months, are relative to the actual dental surgery event. Enrollment, T1 data collection and randomization occurs prior to dental surgery. Investigators refer to the scheduled dental surgery as the reference event, designated “day 0” because time between enrollment and dental surgery can be highly variable. Operationalizing the scheduled dental surgery event as “day 0” allows us to standardize data collection visits in the same timeline across arms. Typically, children present to surgery within 1 month after presenting to the UIC dental clinic. However, surgical dates may require rescheduling due to child illness or caregiver-related scheduling requests, resulting in possible intervals of 3 months between enrollment and dental surgery (labelled as “-3 to 0 months” relative to dental surgery event).

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## **2 INTRODUCTION: BACKGROUND INFORMATION AND SCIENTIFIC RATIONALE**

### **2.1 Background Information**

Dental caries is the most common chronic disease of early childhood, disproportionately affecting children who have been systemically oppressed (ethnic/racial minority groups, families of low-income, and those who live in rural areas; Edelstein & Chinn, 2009; US DHHS, 2000; Dye, 2015). Young children who have poor oral health behaviors (e.g., inadequate tooth brushing, diet high in added sugar) are at risk for developing severe early childhood caries (S-ECC), which is an indication for dental surgery (Anil & Anand, 2017; Marshall, 2019; Kumar et al., 2016). Prevalence of S-ECC has declined and utilization of preventive dental care has increased over time (Schroth et al., 2014). However, inequities in disease burden persist, and demand for dental surgery under general anesthesia (DGA) is increasing (Dye, 2015; Schroth et al., 2014). The impact of S-ECC on a child's health ripples out across systemic and psychosocial well-being, with links to childhood obesity and oral health quality of life (Williamson et al., 2008; Schroth et al., 2009; Davidson et al., 2016; Finlayson et al., 2007). Surgical events have inherent safety risks with the potential for iatrogenic harm (Lee et al., 2013; FDA, 2017). Further, surgical intervention is expensive and ineffective in the long term (Buen et al., 2016; Lee et al., 2020). Because the intervention does not directly address the etiologic factors, which are largely behavioral, approximately 50% of children have recurrent disease within 12 months after DGA (Foster et al., 2006). Dental surgery is risky, expensive, and not effective for S-ECC treatment in the long term (Lee et al., 2013; Buen et al., 2016; Kanellis et al., 2000; Foster et al., 2006). To reduce the demand for surgery, Investigators must focus first on surgical patients and their oral health behaviors (Thornton-Evans et al., 2019; Moynihan & Kelly, 2014). Given that parenting behaviors influence a child's oral health status, caregivers are an important catalyst for promoting child behavior changes (Amin & Harrison, 2007; Castilho et al., 2013). Positive parenting, such as appropriate monitoring of a child during tooth brushing or negotiating conflicts when children want sugary snacks, influences child health behaviors (Amin & Harrison, 2006).

Previous work (Lee et al., 2019) identified the need for interventions to change oral health behaviors for the surgical population that are evidence-based, supportive, educational, responsive to health literacy, and adaptive to various psychosocial factors and household dynamics. Findings from this study suggested possible targets for intervention such as toothbrushing routine and supportive parenting techniques. In order to change oral health behaviors such as tooth brushing and sugar consumption, a 6-month parenting intervention called Preventing Recurrent Operations Targeting Early Childhood Caries Treatment (PROTECT) was developed. The goals of PROTECT are to reduce S-ECC and DGA by providing parents with evidence-based support regarding toothbrushing, sugar consumption, and parenting during the 6-month postoperative period. A trained community health worker will deliver the intervention and provide additional resources to caregivers and families.

Our team conducted preliminary qualitative research with caregivers while their children were undergoing DGA and found that parenting behaviors contribute significantly to poor oral health behaviors (Lee et al., 2019). Specifically, caregivers reported offering a sugary snack to avoid a tantrum or scolding their child when they did not brush their teeth. This preliminary work, as well as other supportive studies, identified barriers to changing oral health behaviors: parenting style, dental self-efficacy, and oral health knowledge (Lee et al., 2019; Wilson et al., 2016; Evans et al., 2013). Our primary outcomes (tooth brushing frequency and % total calories from added sugar) are associated with S-ECC and have been identified as predominant behavior challenges for surgical families (Boustedt et al., 2020; Marshall et al., 2005; Anil & Anand, 2017). PROTECT, informed by Social Cognitive Theory (SCT), will be delivered by trained community health workers (CHWs) who have social proximity to our participants: CHWs have shared experiences and an understanding of clients and clients' communities, which reduces stigma and aligns services with community norms (Gustafson et al., 2018; Barnett et al., 2018; Bandura, 1991). PROTECT will be delivered over a six-month interval beginning at the surgical event. This time period coincides with when many parents report high motivation to change behaviors and improve oral health (Amin & Harrison, 2006; Lee et al., 2019). Behavioral parenting interventions have been validated in mental health and childhood obesity, and Investigators believe will impact S-ECC (Mehta et al., 2019; Buscemi et al., 2016; Buscemi et al., 2014; Kong et al., 2016).

In Phase I, Investigators conducted semi-structured interviews with key constituents (dentists, CHWs, and caregivers of children undergoing DGA) to identify the acceptability, feasibility, and appropriateness of the content and timing of the proposed 6-month parenting behavioral support program, PROTECT: Preventing Recurrent Operations Targeting Early Childhood Caries Treatment, for dental surgical families. Qualitative analysis of the interview transcripts identified that the PROTECT program was wanted, needed, and seen as acceptable by dentists, CHWs, and caregivers in the pediatric surgical population. Barriers to behavioral change were identified (e.g., multigenerational caregiving and caregiver discord, social determinants of health, incomplete health knowledge, and caregiver resistance to change). Investigators adjusted the program content and schedule to address barriers and increase engagement based on what Investigators learned prior to conducting a pilot study to test feasibility with 12 caregivers.

The development of PROTECT was informed by (1) our own work on this population; (2) the evidence on parenting practices, dietary recommendations, and children's oral health; and (3) formative interviews (Phase I). Investigators will collect measures that may relate to behavior change. These measures were informed by prior work. Interviews with DGA families whose child experienced either caries recurrence ("relapse") or remained caries-free ("non-relapse") differed in several ways, including dental beliefs, self-efficacy related to dental care as well as parenting, and overcoming barriers to behavior change. Regardless of post-surgical outcomes, all parents expressed a need for continued support throughout the perioperative experience.

Parents expressed that practical help regarding behavioral change was preferable to a “lecture” from dentists or oral health information gleaned from pamphlets. The PROTECT program aims to target areas that may help parents change behaviors through parenting support provided by the CHW’s behavior change coaching and the knowledge/education provided by the PROTECT curriculum. Our Stage I work also identified that caregivers require flexibility in intervention fidelity to maintain engagement.

There are several innovations in the current study. For example, investigators plan to target a population with the most severe disease to implement a CHW-led behavioral intervention in the time after dental surgery. Investigators focus on surgical families because they have greatest potential to benefit and have previously expressed a desire for parenting support at the exact time of their child’s dental surgery (Amin & Harrison, 2007). Children living with severe disease and presenting for DGA experience poor quality of life related to their caries (pain, difficulty chewing; Finlayson et al., 2007; Schroth et al., 2009). Their parents are motivated to improve their child’s oral health and are receptive to help in changing behaviors (Lee et al., 2020). The surgical event is an ideal time to intervene, not only because parents are receptive to change, but also because they are already engaged in the health system as part of the DGA experience (Lee et al., 2020). Finally, investigators believe involving CHWs to implement our intervention will be a critical part of success. CHWs promote greater engagement and help mitigate barriers to health services faced by minoritized populations by leveraging their social proximity – relating to parents through shared similarities and experiences (e.g., understanding of culture, parenthood, life hardships), creating a sense of equality and “being on their level” (Gustafson et al., 2018).

## **2.2 Rationale**

Tertiary prevention among young children with S-ECC, with a focus on parenting behaviors around oral health, is essential to promoting health and preventing future surgeries. Because behavior patterns established in early childhood tend to persist into adulthood (e.g., tooth brushing, dietary habits), early intervention is not only warranted, but potentially the most cost-effective, when targeted to parents of young children in the high-risk surgical population.

To reduce the demand for surgery, investigators must focus on surgical patients and their oral health behaviors. Given that parenting behaviors influence a child’s oral health status, caregivers are an important catalyst for promoting child behavior changes. In order to change oral health behaviors such as tooth brushing and sugar consumption, a 6-month parenting intervention called Preventing Recurrent Operations Targeting Early Childhood Caries Treatment (PROTECT) was developed. The goals of PROTECT are to reduce severe early childhood caries and DGA by coaching parents through application of positive parenting skills to children’s behaviors (toothbrushing, sugar consumption), during the 6-month postoperative period. A trained community health

worker will deliver the intervention and provide additional resources to caregivers and families.

Investigators hypothesize that participants in the PROTECT group will increase tooth brushing and decrease added sugar intake to a greater degree than those in the usual care (UC) group. Baseline assessments will occur up to 3 months prior to dental surgery (see Study Schematic Timeline, where dental surgery is reference timeline=0). The timeline for data collection visits (T1-3) is as follows: prior to surgery (T1, -3 to 0 months), 6-months post-surgery (T2), and 6 months after intervention completion (i.e., 12 months post-surgery, T3). Investigators also aim to determine the mechanistic role of behavioral change targets in influencing intervention effectiveness. Per Social Cognitive Theory, investigators will estimate a mediation model with positive parenting and self-efficacy as mediators in the pathway to behavioral change (i.e., increases in positive parenting and self-efficacy leading to positive behavioral change – increases in toothbrushing and decreases in add sugar consumption).

## **2.3 Potential Risks and Benefits**

### **2.3.1 Potential Risks**

This study is no more than minimal risk. Children and caregivers will be subject to minimal risks throughout this trial. They may include inconvenience or embarrassment involved in talking with CHWs during the program sessions or during data collection while completing questionnaires. During the program sessions, sensitive topics may come up as families discuss topics and barriers to behavioral change, and parents may become emotional. The caregivers will not be required to answer any questions (or conduct any part of the study) that they are reluctant to discuss/conduct (participants are not considered withdrawn unless they explicitly request withdrawal, see Section 5.5). Research assistants and community health workers will note on data collection forms when participants decline to answer any questions to distinguish these instances from error or missingness.

A risk of this study is breaches of privacy and/or confidentiality. Efforts will be made to keep personal information confidential (see Section 15.4).

All participant information, including contact information, questionnaires, and clinical data will be stored on an encrypted, password-protected, HIPAA-compliant secure platform, monitored by study staff, and only available to them. All involved staff will be instructed in Health Insurance Portability and Accountability Act (HIPAA), Human Subjects Research, and Good Clinical Practice Training at the start of the project and again yearly. Research team members will only access coded, de-identified data for their specified data analysis tasks. Efforts will be made to keep personal information confidential (see Section 15.4 for confidentiality and privacy information). Study reports will not contain any identifiable information and will present findings in aggregate. To

protect against potential emotional distress, participants may skip and/or not respond to any questions or topics that make them feel uncomfortable (see Section 5.5 for missingness and withdrawal). CHWs will be trained to provide support to parents and to understand when participants need to be connected with additional outside services. Investigators have a clinical psychologist on our scientific team who will oversee the CHW training and implementation of the program and will provide additional support throughout the program. Additionally, investigators have established a relationship with the social worker at the dental clinic with whom investigators can connect parents if additional support services are required.

### **2.3.2 Potential Benefits**

There are no known benefits at this time.

This intervention was informed by prior work with surgical families. Caregivers identified the need for parenting support, oral health information, and assistance in applying that information to daily life. Additionally, caregivers reported stressors related to social determinants of health. PROTECT will provide participants' parenting skills, directed and tailored oral health education, and support in changing their child's health behaviors. If caregivers indicate a need, the CHWs will also provide assistance for issues such as connecting to resources related to sources for healthy foods, navigating the health care delivery system, or simply acknowledging the impact of stress as a barrier to parenting. Based on discussions between the CHW and a clinical psychologist, caregivers may also be referred to a social worker who is integrated in the UIC Pediatric Dentistry Clinic to provide care coordination and therapy. Participants who engage with CHWs and the intervention are more likely to benefit. The duration and magnitude of benefits will be variable across households. The benefits related to their child's health behaviors (brushing and dietary intake) will be measured as part of research activities. Investigators hope that being in this research study will benefit participants directly because they will be provided direct support, resources, and education from a community health worker. The goal of the program is to increase caregiver-assisted, high-quality tooth brushing and to decrease intake of added sugars. These behaviors may prevent future cavities and dental surgeries. Investigators do not guarantee direct benefits.

### 3 OBJECTIVES AND OUTCOME MEASURES

#### 3.1 Primary

Objective	Brief Description/Justification of Outcome Measure	Outcome Measured By	Time Frame
To assess the efficacy of the PROTECT intervention, compared to Usual Care, measured at 6 months (end of intervention). Sustained behavior change will be measured 12 months following a child's dental surgery (6 months after intervention ends).	<p>The primary outcomes of the intervention include tooth brushing frequency and percentage of total calories derived from added sugars.</p> <p>Young children who have poor oral health behaviors (e.g., inadequate tooth brushing, diet high in added sugar) are at risk for developing severe early childhood caries (S-ECC), which is an indication for dental surgery. Previous work suggests toothbrushing as a possible target for intervention.</p>	<p>Child and caregiver brushing behaviors (11 items) are included in the Basic Research Factors Questionnaire (BRFQ), a validated questionnaire to assess dental knowledge, attitudes, and behaviors of caregivers with young children.</p> <p>To assess added sugar consumption, the Nutrition Data System for Research (NDSR) data capture and analysis software is used to conduct a standardized multiple pass 24-hour dietary recall with great accuracy. Dietary recall data will be used to calculate % kcal from total sugars and added sugars.</p>	Outcomes are measured at 3 time-points: Baseline (prior to surgery; T1), 6-months post-surgery (T2), 12-months post-surgery (T3).

### 3.2 Secondary

Objective	Brief Description/ Justification of Outcome Measure	Outcome Measured By	Time Frame
To determine the mechanistic role of behavioral change targets in influencing intervention effectiveness.	Per Social Cognitive Theory, positive parenting and self-efficacy are mediators in the pathway to behavioral change.	<p>The Multidimensional Assessment of Parenting Scale (MAPS) measures parenting practices, including positive and negative dimensions.</p> <p>The Self-Efficacy Scale for Maternal Oral Care (SESMO) consists of 2 subscales: self-efficacy for toothbrushing and for dietary habits.</p>	Measured at 3 time-points: Baseline (prior to surgery; T1), 6-months post-surgery (T2), 12-months post-surgery (T3).

## 4 STUDY DESIGN

### 4.1 Overall Design

This study aims to test the efficacy of the PROTECT (Preventing Recurrent Operations Targeting Early Childhood Caries Treatment) intervention compared to Usual Care (UC) to improve behavioral oral health outcomes. Investigators propose conducting a single-site Stage II two-arm randomized controlled trial, which tests the efficacy of the PROTECT intervention administered by community health workers (CHWs) for the pediatric DGA (dental surgery under general anesthesia) population. This is a prospective, individually randomized group treatment trial that will implement a behavioral parenting intervention (PROTECT). Enrollment, baseline (T1) data collection, and randomization occurs prior to dental surgery (-3 months to 0) for participants in both study arms. Investigators refer to the scheduled dental surgery as “day 0” because time between enrollment and dental surgery can be highly variable. Operationalizing the scheduled dental surgery event as “day 0” allows us to standardize follow-up data collection visits in the same timeline across arms. Participants in the PROTECT intervention arm will engage with a CHW and begin the intervention at the time of DGA (see Study Schematic, timeline “0 months”). The PROTECT intervention includes 10 sessions over the six months after surgery. Participants in both the Usual Care and PROTECT intervention arms will have follow-up data collection visits at six-months after dental surgery (T2) and 12-months after dental surgery (T3). Primary outcomes include tooth brushing frequency and percentage of total calories derived from added sugars; mechanisms of change will also be examined.

Investigators hypothesize that participants in the PROTECT group will increase tooth brushing and decrease added sugar intake to a greater degree than those in the UC group. Investigators also aim to determine the mechanistic role of behavioral change targets in influencing intervention effectiveness. Per Social Cognitive Theory, investigators will estimate a mediation model with positive parenting and self-efficacy as mediators in the pathway to behavioral change (i.e., increases in positive parenting and self-efficacy leading to positive behavioral change – increases in toothbrushing and decreases in add sugar consumption).

As this study is testing only one intervention, masking procedures are not applicable. In this protocol, investigators define blinding procedures as processes to limit the bias of research assistants who are collecting T2 and T3 follow-up data from all participants across study arms (intervention vs. usual care). Research assistants will be blinded to randomization of participants. Separate from T2 and T3 data collection visits, unblinded research team members will collect retrospective clinical data (DMFT, caries, dental care utilization) from dental records of all participants at months 6-9 and 12-15. Following the T2 data collection visits with a blinded research assistant, an unblinded research team member will conduct an end-of-intervention interview (months 6-9) with intervention arm participants to assess intervention feasibility, acceptability, and challenges/strengths.

## **4.2 Scientific Rationale for Study Design**

Investigators have prepared for a Stage II trial by completing formative assessment interviews with key constituents [dental providers, community health workers (CHWs), and caregivers of pediatric surgical patients] and a pilot study of the intervention to determine feasibility and acceptability.

Investigators propose a two-arm randomized controlled trial to test the efficacy of the behavioral intervention administered by CHWs (PROTECT) compared to usual care to improve behavioral (and clinical) oral health outcomes. The control group will be the same pediatric surgical population and participate in the same data collection visits at the same schedule as the treatment group. Investigators propose a randomized controlled trial to establish a causal relationship between the PROTECT intervention and improved oral health outcomes.

Due to the population, retention may be challenging. According to clinic data, about 27% of surgical families return for 6-month follow-up. Investigators will ask for several forms of contact information from the caregiver (e.g., phone, email) and two other family members to facilitate continued contact and retention, a routine part of clinical practice.

## **4.3 Justification for Dose**

The intervention group will receive the PROTECT intervention which is a CHW-led parenting intervention focused on positive parenting as a tool to reduce consumption of added sugars and increase frequency of caregiver assisted tooth brushing. The CHW will meet (in-person or remote) with a caregiver over the six-month intervention program for 10 sessions, as is consistent with other intervention schedules. Sessions will last 30-60 minutes and will address knowledge, application to daily life, and reflections on challenges to behavior change. CHW's may provide the first intervention visit to parents in-person at the time of their child's surgery [60 minutes] and all other sessions will be remote (e.g. via phone or videoconference) for a shorter duration [30 minutes]. Utilization of CHWs to implement interventions can support the sustainability of intervention delivery and can aid in the dissemination and implementation of evidence-based interventions. CHWs are an ideal workforce to provide interventions in a clinical setting because they allow specialized clinical providers, such as dentists, to focus on the complexities of clinical care, and their services are currently covered by the Affordable Care Act. The CHWs complement clinical efforts through provision of messages consistent with provider education. An important advantage of CHW intervention delivery is that they are a workforce that has social proximity to families (CHWs have shared experiences and an understanding of clients; for example, living in the same neighborhood or having the same racial, ethnic, or cultural background). Social proximity allows CHWs to quickly build relationships and deliver content that closely aligns with a family's social, cultural, and health literacy needs. As a result, CHWs are able to overcome several psychosocial barriers to chronic disease management.

The intervention group will also receive usual clinical care (described below).

Families randomized to the Usual Care (UC), or control, arm will receive the usual standard of care, which consists of education during and immediately after surgery. Clinical education is provided by pediatric dental residents to all patients (regardless of study participation).

As part of standard clinical care, all participants complete at least one pre-surgical visit, which is designed to allow families to discuss how their oral health behaviors contribute to caries and answer any questions regarding changing oral health behaviors. The surgical visit consists of education around expectations and after-care for surgery. The post-surgical visit is an optional visit which typically occurs within 1-2 weeks after surgery and is intended to be a brief exam focused on determining if there are any complications related to the procedures (e.g. infection). The post-surgical visit is offered to all patients by the pediatric dental care team as part of routine clinical practice, regardless of study arm assignment, and is not associated with study activities or study participation; no research data is collected at this time. Further, all families who are experiencing significant social issues which interfere with their ability to care for their child's teeth are identified by clinic staff and referred to a full-time social worker employed by the dental clinic.

UC arm participants will be offered the opportunity to meet with a CHW and review program curriculum and materials once they have completed all study activities (after T3 data collection).

Participant dyads will be designated as "study completion" status after participating in phases of the study, including the last visit in the Schedule of Activities (SoA, Appendix A). End of the study is defined as the completion of T3 data collection.

## **5 STUDY POPULATION**

### **5.1 Participant Inclusion Criteria**

Participant dyads (caregiver and child) will be recruited.

Screening inclusion criteria includes:

- Caregivers who are in same household as the child > 50% of the week,
- Caregivers who are aged  $\geq 18$  years and < 90 years,
- Caregivers with access to a computer/internet/telephone.
- Child is scheduled for dental surgery under general anesthesia at UIC Pediatric Dentistry Clinic,
- Child is < 96 months of age at the time of enrollment.

Screening inclusion criteria may be assessed via caregiver report for inclusion criteria related to the caregiver and child and also via dental record for inclusion criteria related to the child.

This study will include participant dyads, which includes individuals who are not yet adults (i.e., pediatric dental surgical patients) and at least one adult caregiver. Once enrolled, with parental consent and permission, investigators will collect clinical information from children's dental chart for non-screening study purposes such as clinical outcomes. If the caregiver is not the parent, investigators will seek consent from the parent/guardian.

### **5.2 Participant Exclusion Criteria**

A dyad who meets any of the following criteria will be excluded from participation in this study (exclusion criteria will be assessed via caregiver report):

- Dyads of foster parents and foster children given that foster children technically are wards of the state (the psychosocial environment and relationship dynamics of foster families are beyond the scope of this intervention);
- Families who are planning to move out of state within the six-month period;
- Child with behavioral/developmental/neurodivergent issues that may impact brushing or dietary habits, (e.g. severe autism spectrum disorder, oppositional defiance disorder, sensory processing disorder). Caregivers will be asked, "Does this child have a behavioral disorder that disrupts brushing or eating?"
- Adults unable to consent (e.g. unable to read and/or understand the consent form through reading and discussion).

### **5.3 Strategies for Recruitment and Retention**

#### **Number of subjects.**

Based on our sample size calculation, investigators plan to enroll 420 child/caregiver dyads. Investigators may eligibility screen up to 4200 records (pilot study experience of 10% recruitment/enrollment) and accrue up to 420 dyad-participants. Our sample size calculations are based upon 420 dyad participants. However, if enrollment or retention are challenging, investigators will adjust recruitment strategies and allow for possibility of >420 enrolled dyads.

#### **Source of participants.**

The University of Illinois Chicago (UIC) currently provides dental surgery to healthy children in an office location in the College of Dentistry (referred to as “the clinic”). All potential participants will be sourced from the UIC Pediatric Dentistry Clinic population, specifically the patients who come for dental surgery. The clinic schedules ~ 27-30 children for dental surgery every week, totaling ~1200 surgical events per year. Investigators plan to recruit 420 families over the course of 2.5 years.

Participant dyads will consist of the caregivers of children who are scheduled for dental surgery under general anesthesia at the clinic and the child undergoing surgery.

#### **Identification of potential participants.**

Informational posters and fliers will be available to potential participants that come to UIC, which include language for patients to opt out of recruitment. IRB has determined that obtaining consent prior to reviewing dental records for eligibility screening purposes is not required. Posters and informational fliers will be available to potential participants that come to UIC and includes language for patients to opt out of recruitment. Select members of the research team have access to AxiUm, the dental electronic record-keeping and scheduling software used by the College of Dentistry. These members will identify potential participants for screening activities.

The recruitment poster and flier have a QR code that leads to an eligibility screening and contact form on REDCap. Potential participants will be given sufficient time to read and consider all information. Potential participants may choose to complete the Eligibility Screening Form and provide contact information for screening and enrollment. The poster and flier notify potential participants that a research team member will reach out to provide more information about the study and discuss full eligibility. These documents also provide potential participants with the opportunity to be placed on a do not contact list to opt out of discussing the study/participation.

Before consent is obtained, potential participants will be screened for eligibility based on inclusion/exclusion criteria (Enrollment Screening and Understanding Form, details below).

## **Recruitment.**

Recruitment involves exposing potential participants to the study through informational fliers, posters, and reviewing dental records. The purpose of recruitment efforts is to identify eligible participants within the clinic population. Screening processes involve research team members engaging with potential participants to confirm eligibility and interest in study participation.

Investigators plan to use multiple recruitment strategies. First, as part of standard care at the UIC Pediatric Dentistry Clinic, patients are required to visit the clinic prior to scheduling the pediatric dental surgery. All patient families will see an informational poster in the waiting area of the dental clinic. At this appointment, all potential participants – children who are determined to be surgical patients and their caregivers – will be directed to review a large poster (English and Spanish) that will explain the study rationale and eligibility criteria posted in the patient waiting area of the UIC Pediatric Dentistry Clinic. Informational recruitment fliers (English and Spanish) may also be provided. Potential participants will be given sufficient time to read and consider all information. The fliers and poster will direct those who are interested or have questions to contact the study team via email or by scanning a QR code that leads to an Eligibility Screening Form, which includes an option to be put on a no-contact list if a participant decides not to participate. Researchers will follow-up with interested potential participants to set up a virtual screening/enrollment visit.

Second, when the patient is identified as a surgical candidate during the appointment, a member of the research team will screen these surgical patients for eligibility based on child age. Eligible patients may be approached in the clinic by the member of the research team and provided the recruitment flier, additional information about the study, and an option to be put on a no-contact list. Interested individuals will be directed to scan the QR code that leads to the Eligibility Screening Form. The research team member may describe the study procedures, ask further screening questions to determine eligibility, and discuss the benefits/risks of research activities, as well as provide a copy of the informed consent document for interested patients to review. The research team member will obtain and document verbal consent from the potential participant to schedule a study enrollment visit for individuals who are eligible, interested, and available for the duration of the study. Potential participants will be given sufficient time to review materials, and research team members will follow up to enroll interested participants.

Third, research team members will review patients scheduled for surgery and screen for child age eligibility. These patients would have been exposed to the recruitment poster and flier during their pre-surgical visit and given the option to be put on a no-contact list. Eligible families who have not indicated a desire to be on the no-contact list will be contacted by research team members. Investigators define recruitment as the process of screening for eligibility and attempting to reach out for enrollment. Members of the research team may reach out to caregivers prior to the day of surgery to discuss the

voluntary research opportunity, provide information about the study and procedures, and provide a copy of the informed consent document for interested patients to review. Potential participants will be given sufficient time to review materials, and research team members will follow up to enroll interested participants. Finally, patients may be approached on the day of surgery for recruitment and enrollment.

Months 7-12: Screening 100 participant dyads/month (assuming , enroll 8-10/month [total=60]

Months 13-24: Screening 100 participant dyads/month, enroll 15/month [180+60=total=240]

Months 25-36: Screening 100 participant dyads/month, enroll 15/month [180+240=total=420]

Investigators proposed enrolling a total of 420 caregiver-child dyads.

In the event of inadequate enrollment or unexpected retention issues, following are possible strategies, which may be activated sequentially or in parallel:

Drs. Buscemi, Lee and project manager will review enrollment by research staff members. Any differences in recruitment, screening, or enrollment rates/staff member will be assessed for timing, approach, and interpersonal techniques. Targeted staff training may ensue.

## **Enrollment**

Enrollment status is confirmed after obtaining informed consent. Regardless of recruitment method, interested individuals will be screened by a member of the research team to verify inclusion and exclusion criteria (eligibility) using the Enrollment Screening and Understanding Form. Once full eligibility status is determined, the consent document will be discussed. Informed consent will be obtained and documented. If not in-person, consent will be obtained through an online link to a consent form on REDCap (described in Section 15.3). Assuming a 10% screening rate, targets for monthly enrollment rate is based on current eligibility criteria.

Enrollment occurs when informed consent is obtained. Baseline data collection may occur immediately after consent or occur in a separate future visit. Baseline data collection must occur prior to the day of surgery. Baseline data collection involves a research team member, who would obtain self-reported data via verbal questionnaires; this practice is common and helpful for populations with low literacy levels. Some questionnaires may also be taken as REDCap surveys directly by the participant if they prefer, which will be noted in the participant's record by the team member who sends the surveys. Data collected would include demographic information, oral health behaviors, parenting style, and nutrition/dietary habits. (Caregivers will be compensated

upon completion of the data collection visit, described below). Caregivers who do not complete baseline data collection (survey and/or NDSR) will not be randomized.

## **Compensation.**

Participants will receive monetary compensation in the form of electronic Amazon gift cards following each data collection session. The first session will be at baseline (prior to surgery; \$45), the second at 6 months (after surgery; \$45), and the final at 8-12 months following the dental surgery (\$55). If participants complete all data assessment time points, they will receive a total of \$145. Investigators will monitor retention rates throughout this clinical trial and may provide additional compensation (e.g. toothbrush and toothpaste or additional gift cards, per IRB modification) related to data collection activities, CHW visits, or retention-related activities in the period between 6 to 12 months of a participant's study participation (e.g. <70% retention).

## **5.4 Treatment Assignment Procedures**

### **5.4.1 Randomization Procedures**

Following the baseline assessment, participants will be randomized to one of two arms: 1) PROTECT (intervention) or 2) Usual Care (UC; control). A random allocation table with 4 block size will be generated in Excel using pseudo-random number generator and implemented in the REDCap randomization module.

Once a research assistant has completed the baseline visit, an automatic alert will be immediately sent to the CRC or PM to review the eligibility, consent, and primary outcomes for completion. They will then randomize the participant using the randomization module in REDCap. If the participant is randomized into the intervention arm, the CRC will inform the CHW of the surgical date and time.

### **5.4.2 Blinding Procedures**

Research assistants who are responsible for collecting data (T1, T2 and T3) will be blinded to participant arm assignment (intervention vs. usual care). The REDCap data collection tool has been programmed to remove data related to intervention visits.

The Clinical Research Coordinator will remain unblinded, as this individual will coordinate the initial meeting between intervention arm participants and the CHW during the child's surgical event. The CRC may collect intervention feasibility and acceptability data as well as conduct the end-of-intervention interviews with intervention arm participants at the end of intervention (defined as months 6-7 of study participation for intervention arm. RAs (blinded) will conduct a separate T2 data collection visit prior to the collection of intervention-specific follow-up data.

The project manager and co-PI's (Drs. Lee and Buscemi) will remain unblinded. Like the CRC, they may also conduct end-of-intervention interviews with intervention arm participants (separate from T2 data collection visits conducted by blinded RAs).

Dental clinic providers will remain unblinded to randomization of participants. Assignment of participants into clinical trial arms and clinical care are not associated with each other. The study protocol does not include any communication or discussion with dental providers about patient enrollment status.

## **5.5 Participant Withdrawal or Discontinuation from Study Procedures/Intervention**

### **5.5.1 *Reasons for Participant Withdrawal or Discontinuation from Study Procedures/Intervention***

Participants can withdraw from study under the following circumstances: participant expresses to research team that they no longer consent to study participation; participant is no longer eligible; or participation is associated with a clinical adverse event or safety issue. After documenting withdrawal, participants will not be contacted by research team members.

Participants are free to withdraw from participation in the study at any time upon request. Reasons for withdrawal may include, but are not limited to, lack of time, no longer interested, or discomfort with any of the study procedures.

An investigator may withdraw an individual from the study if:

- Any clinical adverse event (AE), laboratory abnormality, or other medical condition or situation occurs such that continued participation in the study would not be in the best interest of the participant.
- The participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation. For example, if a child is diagnosed with an acute health issue that interferes with caregiver's ability to participate in research activities.

### **Handling of Participant Withdrawals from Study or Participant Discontinuation of Study Intervention**

Withdrawal means either the participant withdraws consent or the investigator withdraws the participant (generally for safety/exclusion criteria). In these cases, the participant will not be contacted. Discontinued means either the participant discontinues from the intervention but is still followed (data are still collected at subsequent T1, T2 and/or T3 visits); or discontinued due to lost to follow-up (unable to contact participant to return to subsequent visits).

Data collected prior to withdrawal may be analyzed. At the moment of documenting withdrawal, participants will be given an opportunity to report reason for withdrawal. Research team members will complete a Withdrawal Form on REDCap noting the details around the participants' withdrawal from the study. If participants discontinue the intervention and chose withdraw from the study, they will be given the opportunity to report reasons in order to improve retention and for reporting purposes at the time of withdrawal.

Participants who discontinue from intervention activities will be asked if they want to continue with data collection visits (i.e., or withdraw from the study) and reason(s) for discontinuation from intervention. If participants discontinue the intervention, but agree to continue with study procedures (i.e., data collection visits), they will be followed by research team members to complete data collection visits within the appropriate time windows (section 7 Study Schedule).

### **Lost to follow-up.**

A participant who discontinues from research activities will be considered lost to follow-up if he or she fails to show for 3 scheduled sessions and is unable to be contacted by the research team after 10 contact attempts.

If a participant fails to be present for scheduled intervention or data collection visits, the following actions will be taken:

1. Members of the research team will contact the participant to reschedule the missed visit within one week, counsel the participant on the importance of maintaining the planned visit schedule and ascertain if the participant wishes to and/or should continue in the study.
2. Before a participant is deemed lost to follow-up, the investigator will make every effort to regain contact with the participant (where possible, including phone calls and text messaging). These contact attempts will be documented in the participant's study file.
3. Should the participant continue to be unreachable, they will be considered to have withdrawn from the study with a primary reason of lost to follow-up.

To minimize loss to follow-up, investigators will ask for contact information of the caregiver (phone numbers and emails) and two other family members for tracking purposes and to facilitate continued contact and retention. Research team members that interact with participant's family members will disclose the participant's name and participation in the UIC PROTECT study, then request an additional mode of communication with the participant. In addition, investigators are providing incentives in the form of electronic gift card compensation following each data collection visit.

## **5.6 Premature Termination or Suspension of Study**

This study may be suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to (NIDCR). The principal investigator will also promptly inform the IRB and NIDCR and will provide the reason(s) for the termination or suspension. NIDCR and/or the DSMB may also recommend/require early termination or suspension.

Circumstances that may warrant termination include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants.
- Insufficient adherence to protocol requirements.
- Data that are not sufficiently complete and/or evaluable.
- Determination of futility.

## 6 STUDY INTERVENTION

### 6.1 Study Behavioral or Social Intervention(s) Description

PROTECT, or Preventing Recurrent Operations Targeting Early Childhood Caries Treatment, is a novel, 6-month parenting intervention that focuses on harnessing evidence-based parenting strategies to increase a child's tooth brushing and decrease a child's sugar consumption. In addition to oral health and nutrition, sessions will cover topics such as positive parenting, goal setting, stress management, and problem-solving. The intervention will be delivered by community health workers (CHWs) who have social proximity to our participants, some who are fluent in Spanish. CHWs will be hired as part of the research team. CHWs will be paired with families with a child who is scheduled to have dental surgery at UIC. A CHW will work with each family to apply positive parenting skills to help their child consume less sugar and assist with daily toothbrushing. The CHW will meet (in person or remote) with a caregiver over the six-month intervention program for 10 (5 informational and 5 maintenance or check-in) sessions. Sessions will last 30-60 minutes and will address knowledge, application to daily life, and reflections on challenges to behavior change. The CHW is prepared to connect a caregiver to social agencies, public programs, and assist in finding a dental provider, at the request of a caregiver. Any safety events identified that fall under the requirements stated in sections 9, Safety Assessment, will be recorded and reported.

PROTECT, the behavioral intervention, was developed by members of the scientific team based upon prior work, current evidence, and existing materials from oral health curricula (e.g., Oral Health Forum, Heartland Alliance) and CHW training curricula (e.g., CO-OP). The intervention was further refined through formative interviews with dental providers, community health workers, and caregivers of children undergoing DGA. The intervention includes 10 sessions delivered by a CHW. Over the course of the intervention, the CHW will present the following topics/activities: oral health & behaviors, healthy eating and drinking, positive parenting, rewards, routines, problem solving, monitoring behaviors, self-efficacy around behavior change, and goal setting.

Families randomized to the Usual Care (UC), or control, arm will receive the usual standard of care, which consists of education during and immediately after surgery. Clinical education is provided by pediatric dental residents to all patients (regardless of study participation). At least one pre-surgical visit is designed to allow families to discuss how their oral health behaviors contribute to caries and answer any questions regarding changing oral health behaviors. The surgical visit consists of education around expectations and after-care for surgery. The post-surgical visit typically occurs within 1-2 weeks after surgery and is intended to be a brief exam focused on determining if there are any complications related to the procedures (e.g. infection). The post-surgical visit is an optional visit offered to all patients by the pediatric dental care team, regardless of study arm assignment; no research data is collected at this visit. All families who are experiencing significant social issues which interfere with their ability to care for their child's teeth are identified by clinic staff and referred to a full-time social

worker employed by the dental clinic. [Families randomized to the PROTECT intervention arm will also receive usual clinical care.]

UC arm participants will be offered the opportunity to meet with a CHW and review program curriculum and materials once they have completed all study activities (after T3 data collection).

## **6.2 Administration of Intervention**

The 10 sessions are scheduled over the 6 months following dental surgery. The schedule of intervention delivery is presented in the table below.

The first PROTECT session with the CHW will be about 60 minutes and may occur at the time of the child's dental surgery, and the rest of the 9 sessions will be about 30 minutes each. These sessions will occur every week for the first month or so following surgery, and then about once a month for the remaining 5 months of the program (additional details in Section 7.3).

**Table 1. Intervention Visit Schedule, Session Time, and Content**

<b>Session #</b>	<b>Target Schedule</b>	<b>Session Type</b>	<b>Session Time</b>	<b>Session Content</b>
1	Baseline	In-Person (during child's dental surgery) or virtual	60 minutes	Tooth Health, Toothbrushing, Eating and Drinking
2	1 week	Phone (or in-person)	30 minutes	Parenting Skills to Support Tooth Health
3	2 weeks	Phone/Zoom	30 minutes	Rewards and Routines
4	3 weeks	Phone/Zoom	30 minutes	Managing your Emotions
5	4 weeks	Phone/Zoom	30 minutes	Monitoring and Problem-Solving
6	2 months	Phone/Zoom	30 minutes	Maintaining Behavior Change
7	3 months	Phone/Zoom	30 minutes	Maintaining Behavior Change
8	4 months	Phone/Zoom	30 minutes	Maintaining Behavior Change
9	5 months	Phone/Zoom	30 minutes	Maintaining Behavior Change
10	6 months	Phone/Zoom	30 minutes	Graduation Session

The term “flexibility within fidelity” refers to an approach to intervention delivery that both honors the fidelity of the manual (e.g., the importance of closely following a manualized behavioral intervention) and the importance of flexibility within that model. CHWs will cover all of the topics included in this manual and keep track of what is introduced and covered with each participant using a checklist (recorded in the implementation diary in REDCap, described below). However, delivery is not so rigid that investigators miss

opportunities to present content when it arises (and thus damage participant engagement). For example, if a participant introduces a barrier to the CHW in session, the CHW is encouraged to engage in on-the-spot problem solving with the participant even if introduction of the problem-solving skill comes later in the manual. Based on interviews with caregivers and CHWs in UG3 formative assessments, allowing CHWs to deliver topics in variable order will translate to greater participant relevance and engagement. CHWs will make sure to cover all of the checklist items and content with consistent messaging.

Participants in the control (UC) arm and PROTECT arm will receive standard clinical care at the point of surgery, during their post-surgical visit at two weeks, and any preventive dental care. Dental residents are trained and monitored by UIC to provide standardized care. Select team members have access to records noting care deviations for participating patients.

### **6.3 Procedures for Training Interventionists and Monitoring Intervention Fidelity**

#### **Interventionist training and competence.**

The CHWs will be hired based on their knowledge of oral health. Prior to implementation, CHWs will be trained in PROTECT intervention delivery and study content and motivational interviewing, completing at least 3 practice sessions reviewed by the clinical psychologist (Co-PI) to ensure competence and fidelity to the intervention. Fidelity will be monitored throughout the implementation, and additional training, guidance and support for CHWs will be available as needed based on fidelity assessments: Twenty percent of all intervention visits will be audio-recorded and reviewed by the clinical psychologist to assess fidelity of CHW competence using the Fidelity Assessment Form. Within the form, CHW skills (e.g., clarity of content, interpersonal effectiveness) are assessed on a scale from 1-5. An average score of < 4 requires evaluation and possible remediation. Remediation can range from directed feedback during regular meetings with the CHW, repeated practice sessions for specific topics or skills, and/or shadowed visits. Audio files will be immediately uploaded into REDCap and reviewed by the clinical psychologist monthly. Ongoing training for the CHWs will be provided through regularly monthly meetings with the clinical psychologist supervisor. Any audio files of PROTECT program sessions between a CHW and family will only be shared with the clinical psychologist on our team to assess CHW competence and fidelity to the intervention.

#### **Intervention fidelity and compliance.**

The CHW will complete an Implementation Diary following each session to track which and how much content was delivered to participants. Documentation after every encounter will record the date, curriculum topics covered, resources utilized, amount of time spent, and issues encountered after each visit. The Implementation Diary will track

fidelity, adaptations, and adherence to the intervention protocol, as well as barriers related to behavior change. The Implementation Diary forms will be reviewed monthly by unblinded staff to ensure fidelity and also to inform the study team on areas of focus and challenge. The clinical psychologist may review the accompanying Implementation Diary when reviewing a session and completing the Fidelity Assessment Form to assess CHW competence and accuracy. The data will also be used in final analyses to determine “dose” of intervention and to assess the influence of specific topics/skills on outcomes.

#### **6.4 Assessment of Participant Compliance with Study Intervention**

About once a month, CHWs will also complete a Caregiver Key Skills and Progress Form to evaluate the participant’s (caregiver’s) uptake and progress toward meeting their behavior goals. Forms will be completed by the CHW on REDCap.

## **7 STUDY SCHEDULE**

### **7.1 Screening / Enrollment (All participant dyads)**

#### **Screening/Enrollment Visit (Day -3 to 0 months)**

- Review medical/dental history to determine eligibility based on inclusion/exclusion criteria.
- Verify inclusion/exclusion criteria with potential participant.
- Obtain and document consent from caregiver participant on study consent form.
- Obtain surgical event information.
- Schedule baseline visit for individuals who are eligible and consented.
- Note: Baseline data collection (i.e., the first study visit) may occur at the time of enrollment if desired by the caregiver participant and must be completed by the day of the surgical event. In advance of every data collection visit, caregiver participants will be instructed that they will need to recall their child's dietary intake over a 24 hour period.

### **7.2 Baseline. (All participant dyads)**

#### **Baseline Data Visit (T1) (Data Visit 1, -3 to 0 months)**

- Obtain dyad demographic information, outcome, and caregiver efficacy assessments.
- Confirm child's surgical event information.
- Provide caregiver participant compensation for data visit.

#### **Randomization (-3 to 0 months)**

- Confirm signed consent form completeness.
- Confirm baseline data completeness.
- Randomize into study arm.

### **7.3 Intermediate Visits (Day of Surgery through T2 Data Collection)**

#### **Day of Surgery. Day 0 (reference time point for All participant dyads)**

- Confirm the surgical event took place.

- Record results of dental examination (clinical outcome measures collected as part of standard clinical care).

### **Post-Surgical Visit. Day 14 (All participant dyads)**

- Clinical visit to assess for any surgical complications, per standard clinical practice

### **Preventive Dental Care. Variable (All participant dyads)**

- Patients may return to clinic (Pediatric Dentistry Clinic or Mile Square) for preventive dental care. Timing is dependent on Medicaid policy (minimum of six-month intervals between clinical care), which does not relate to timing of dental surgery.

### **Intervention Arm Participants Only**

For participants in the intervention arm, the 10 PROTECT intervention visits are considered intermediate visits. Pilot study participants found it challenging to adhere to a strict intervention schedule. Therefore, Target windows, defined as the priority/ideal time interval for CHW engagement, and Acceptable windows, defined as a broader window for intervention visits, are depicted in Table 2 below. The intervention is expected to be completed in 6 months, with the maximum intervention period as 7 months. CHW visits that occur outside the Acceptable Window will be classified as a protocol deviation and will be handled accordingly (reported to DSMB on routine reporting schedule). Below investigators state the target schedule for intervention visits.

### **Intervention Visit 1, Day of Surgery. Day 0. (Intervention Arm Participants)**

- Administer the PROTECT intervention.
- Record participant's compliance with PROTECT.
- Record adverse events as reported by participant.
- Schedule next intervention visit.

### **Intervention Visit 2, Week 1 (i.e., 1 week after day of surgery). (Intervention Arm Participants)**

- Administer the PROTECT intervention.
- Record participant's compliance with PROTECT.
- Record adverse events as reported by participant.
- Schedule next intervention visit.

### **Intervention Visit 3, Week 2. (Intervention Arm Participants)**

- Administer the PROTECT intervention.
- Record participant's compliance with PROTECT.
- Record adverse events as reported by participant.
- Schedule next intervention visit.

**Intervention Visit 4, Week 3. (Intervention Arm Participants)**

- Administer the PROTECT intervention.
- Record participant's compliance with PROTECT.
- Record adverse events as reported by participant.
- Schedule next intervention visit.

**Intervention 5, Week 4. (Intervention Arm Participants)**

- Administer the PROTECT intervention.
- Record participant's compliance with PROTECT.
- Record adverse events as reported by participant.
- Schedule next intervention visit.
- Following administration of PROTECT:
  - CHW records Caregiver Key Skills and Progress

**Intervention Visit 6, Month 2 (i.e., 2 months after day of surgery). (Intervention Arm Participants)**

- Administer the PROTECT intervention.
- Record participant's compliance with PROTECT.
- Record adverse events as reported by participant.
- Schedule next intervention visit.
- Following administration of PROTECT:
  - CHW records Caregiver Key Skills and Progress

**Intervention 7, Month 3. (Intervention Arm Participants)**

- Administer the PROTECT intervention.
- Record participant's compliance with PROTECT.

- Record adverse events as reported by participant.
- Schedule next intervention visit.
- Following administration of PROTECT:
  - CHW records Caregiver Key Skills and Progress

#### **Intervention Visit 8, Month 4. (Intervention Arm Participants)**

- Administer the PROTECT intervention.
- Record participant's compliance with PROTECT.
- Record adverse events as reported by participant.
- Schedule next intervention visit.
- Following administration of PROTECT:
  - CHW records Caregiver Key Skills and Progress

#### **Intervention Visit 9, Month 5. (Intervention Arm Participants)**

- Administer the PROTECT intervention.
- Record participant's compliance with PROTECT.
- Record adverse events as reported by participant.
- Schedule next intervention visit.
- Following administration of PROTECT:
  - CHW records Caregiver Key Skills and Progress

#### **Intervention Visit 10, Month 6. (Intervention Arm Participants)**

- Administer the PROTECT intervention.
- Record participant's compliance with PROTECT.
- Record adverse events as reported by participant.
- Following administration of PROTECT:
  - CHW records Caregiver Key Skills and Progress

#### **End of Intervention Interview, Months 6-9.**

- CRC, PM, or co-PIs will schedule and conduct interview to assess intervention

**Table 2. Target and Acceptable windows for CHW intervention visits.**

Session #	Target Schedule	Approximate Acceptable Window
1	Scheduled surgical date (Reference Time 0)	0-3 weeks after surgical date
2	1 week (after surgical date)	1-4 weeks
3	2 weeks	2-5 weeks
4	3 weeks	3-6 weeks
5	4 weeks	4-7 weeks
6	2 months [8 weeks]	6-12 weeks
7	3 months [12 weeks]	10-16 weeks
8	4 months [16 weeks]	14-20 weeks
9	5 months [20 weeks]	18-24 weeks
10	6 months [24 weeks]	22-28 weeks

## **ALL PARTICIPANTS**

**6-month Follow-up Visit (T2) (Data Visit 2, [Acceptable Window = 6 months to 9 months]). (All participants))**

- Collect efficacy assessments.
- Record adverse events as reported by participant or observed by investigator.
- Provide participant compensation for data visit.

Investigators will also conduct retrospective clinical data collection:

- Record clinical data from preventive dental care (part of standard clinical care, variable).
- Record receipt of care for recurrent caries (variable)

#### **7.4 Final Study Visit (All participants)**

##### **Final Study Visit (T3) (Data Visit 3, [Acceptable Window = 12 months to 15 months])**

- Collect efficacy assessments and study-exit information from participant.
- Record adverse events as reported by participant or observed by investigator.
- Provide participant compensation for data visit.
- Provide final instructions to participant, including an opportunity to meet with a CHW for those in usual care arm.

Investigators will also conduct retrospective clinical data collection:

- Record clinical data from preventive dental care (part of standard clinical care, variable).
- Record receipt of care for recurrent caries (variable)

Participants will not be informed of results on an individual level. All findings and reports will be in aggregate.

#### **7.5 Withdrawal Visit**

If a participant withdraws early or investigator terminates subject participation, they will be given an opportunity to report reasons for study withdrawal at the time of withdrawal in order to improve retention in the future and for reporting purposes. Withdrawn participants will not be contacted for any follow up data or study activities.

If a participant discontinues the intervention visits, they will be given the opportunity to complete data visits (see section 5.5).

#### **7.6 Unscheduled Visit**

Unscheduled visits will be executed according to visit protocols and will be recorded as unscheduled in REDCap. Providing flexibility to participants is appropriate for this population.

## 8 STUDY PROCEDURES/EVALUATIONS

### 8.1 Study Procedures/Evaluations

Potential participants will be given a chance to review the informed consent and complete an eligibility screening form to ensure they meet the study's inclusion/exclusion criteria prior to enrollment. Eligible, interested persons will then complete the enrollment process and be given the opportunity to complete the first data collection visit immediately or schedule it prior to or on the day of surgery. Randomization occurs after baseline data collection and prior to the day of surgery.. Participants in the intervention arm will complete baseline data collection prior to receiving the intervention.

Data in both arms will be collected during 3 visit periods: at baseline (around time of surgery), 6-months following surgery, and 12-months following surgery. The table below outlines what data will be collected at each time-point. Following are descriptions of each assessment.

Time	Location	Timing	Assessments
<b>Time 1: Baseline</b>	<b>Phone or video</b>	<b>60-90 minutes</b>	<p>All participants will complete questionnaires about demographics, caregiver and child height and weight, oral health behaviors (BRFQ), self-efficacy (SESMO), household food security, and parenting (MAPS). Research assistants will conduct a dietary recall interview (using NDSR software).</p> <p>Clinical data related to the number of teeth with decay, fillings, or missing will be extracted from the electronic dental record by research team members and entered into REDCap.</p>
<b>Time 2: ~6 months after surgery</b>	<b>Phone or video</b>	<b>60-90 minutes</b>	<p>All participants will complete questionnaires about caregiver and child height and weight, oral health behaviors (BRFQ), self-efficacy (SESMO), household food security, and parenting (MAPS). Research assistants will conduct a dietary recall interview (using NDSR software).</p> <p>Clinical data related to the number of teeth with decay, fillings, or missing and additional caries-related dental visits, as well as subsequent preventive and restorative dental care, will be</p>

			<p>extracted from the electronic dental records of all participants by research team members and entered into REDCap.</p> <p>Intervention arm participants will also complete measures of the intervention's feasibility and acceptability and an intervention-exit interview about the program.</p>
<b>Time 3:</b> <b>~12</b> <b>months</b> <b>after</b> <b>surgery</b>	<b>Phone or</b> <b>video</b>	<b>60-90</b> <b>minutes</b>	<p>All participants will complete questionnaires about caregiver and child height and weight, oral health behaviors (BRFQ), self-efficacy (SESMO), household food security and parenting (MAPS). Research assistants will conduct a dietary recall interview (using NDSR software). A study exit interview will also be conducted with all participants.</p> <p>Clinical data related to the number of teeth with decay, fillings, or missing and additional caries-related dental visits, as well as subsequent preventive and restorative dental care, will be extracted from the electronic dental records of all participants by research team members and entered into REDCap.</p>

All questionnaire/survey data will be collected by trained research team members through participant phone/videoconference/in-person visits and directly entered into REDCap (Research Electronic Data Capture), a secure web application used by UIC for managing surveys and databases that can be used to collect any type of data in compliance with HIPAA (<https://www.project-redcap.org/>). Dietary (NDSR) data is stored on the NDSR software on a password-protected, encrypted computer. Clinical data related to the child's oral health will be collected from dental records and stored in REDCap.

Details about each assessment is found in Section 16.3.

## **9 ASSESSMENT OF SAFETY**

### **9.1 Specification of Safety Parameters**

#### **9.1.1 *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.

#### **9.1.2 *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 (21 CFR 312.32 (a)).

This study is no more than minimal risk.

#### **9.1.3 *Serious Adverse Events***

An adverse event (AE) or suspected adverse reaction is considered “serious” if, in the view of either the investigator or sponsor, it results in any of the following outcomes: death, a life-threatening (places the subject at immediate risk of death from the event as it occurred) adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect.

Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse event (SAE) when, based upon

appropriate medical judgment, they may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

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

The occurrence of an adverse event (AE) or serious adverse event (SAE) may come to the attention of study personnel during study visits and interviews of a study participant presenting for medical care, or upon review by a study monitor. CHWs meet with the clinical psychologist for weekly supervision. The purpose of these meetings is to provide resources, information, guidance, and support as the participants move through the study. CHWs will be trained to contact Dr. Buscemi at any time for urgent safety issues (e.g. mandated reporting) that may require follow up; other issues will be discussed at weekly supervision meetings. The clinical psychologist will determine if CHW observations/interactions warrant a social work consult at the UIC Pediatric Dentistry Clinic. This social work team is already integrated into the pediatric dentistry clinic to provide care coordination and therapy to clinic families.

All AEs including local and systemic reactions not meeting the criteria for SAEs will be captured on the appropriate case report form (CRF). Information to be collected includes event description, time of onset, clinician's assessment of severity, relationship to study product (assessed only by those with the training and authority to make a diagnosis), and time of resolution/stabilization of the event. All AEs occurring while on study must be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution.

Any medical condition that is present at the time that the participant is screened will be considered as baseline and not reported as an AE. However, if the study participant's condition deteriorates at any time during the study, it will be recorded as an AE.

Changes in the severity of an AE will be documented to allow an assessment of the duration of the event at each level of severity to be performed. AEs characterized as intermittent require documentation of onset and duration of each episode.

Co-PIs 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 research team members will inquire about the occurrence of AE/SAEs since the last visit. Events will be followed for outcome information until resolution or stabilization.

### **9.3 Characteristics of an Adverse Event**

Each event will be recorded on an appropriate case report form (the Report of Adverse Events form) that includes assessment of the characteristics defined below. These characteristics, along with the frequency of an event's occurrence, will be considered in determining if the event is an AE, SAE, or UP.

#### **9.3.1 Relationship to Study Intervention**

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

1. Related (Possible, Probable, Definite)
  - a. The event is known to occur with the study intervention, and/or
  - b. There is a temporal relationship between the intervention and event onset and/or
  - c. The event abates when the intervention is discontinued, and/or
  - d. The event reappears upon a re-challenge with the intervention.
2. Not Related (Unlikely, Not Related)
  - a. There is no temporal relationship between the intervention and event onset, and/or
  - b. An alternate etiology has been established.

#### **9.3.2 Expectedness**

The Study PI and/or study-appointed, clinically/medically responsible individual will determine whether an AE is expected or unexpected. An AE 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.

#### **9.3.3 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

## **9.4 Reporting Procedures**

All AEs (both serious and non-serious), and Unanticipated Problems (UPs) will be reported to the DSMB via the DSMB Report during regular reporting. SAEs and UPs will be reported promptly to NIDCR (and to the IRB, as applicable) within 5 business days of the investigator becoming aware of the event.

### **9.4.1 Unanticipated Problem Reporting**

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. The investigator will report unanticipated problems (UPs) to the reviewing Institutional Review Board (IRB), OHRP, NIDCR and DSMB. The UP report will include the following information:

- appropriate identifying information for the research protocol, such as the title, investigator's name, and the IRB project number;
- a detailed description of the Unanticipated Problem, 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, including those that are serious AEs will be promptly reported to the IRB and NIDCR within 5 days of the investigator becoming aware of the problem.
- Any other unanticipated problem will be reported to NIDCR and the IRB within 5 days 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 concurrently with reporting to the IRB. These reports will be made to NIDCR's centralized reporting system via the NIDCR

Clinical Research Operations and Management Support (CROMS) contractor as outlined in the Manual of Operations (MOP).

#### **9.4.2 Serious Adverse Event Reporting**

The research team member will complete a Report of Adverse Events form in REDCap immediately upon discovery of an SAE and notify the PI's. (The Report of Adverse Events form uses form logic to identify if the event is a serious adverse event or not). PI's will alert the IRB and NIDCR within 5 business days of the investigator becoming aware of the event. Reports to the DSMB will follow regular reporting schedules.

#### **9.4.3 Reporting of Pregnancy**

Pregnancy will not be reported. Caregivers who are pregnant women are eligible to participate if they meet the eligibility criteria. Caregivers who become pregnant during the study may continue in the behavioral intervention. The study team will not screen or test for pregnancy. CHWs are prepared to link pregnant caregivers to the UIC clinic social worker and other resources if requested.

### **9.5 Halting Rules**

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to study participants, investigator, funding agency and it's representatives (e.g., the DSMB), the IRB and the regulatory authorities. If the study is prematurely terminated or suspended, the Principal Investigator (PI) will promptly inform study participants, the IRB, and NIDCR and will provide the reason(s) for the termination or suspension. Study participants will be contacted, as applicable, and be informed of changes to study visit schedule.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Demonstration of efficacy that would warrant stopping
- Insufficient compliance to protocol requirements
- Data that are not sufficiently complete and/or evaluable
- Determination that the primary endpoint has been met
- Determination of futility

Study may resume once concerns about safety, protocol compliance, and data quality are addressed and satisfy NIDCR, DSMB and institutional IRB.

## **10 STUDY OVERSIGHT**

In addition to the PI's responsibility for oversight, study oversight will be under the direction of a Data and Safety Monitoring Board (DSMB) composed of members with expertise, Biostatistics, Epidemiology, Nutrition, Maternal & Child Health, and Food Security. >. Members of the DSMB should be independent from the study conduct and free of conflict of interest, or measures should be in place to minimize perceived conflict of interest. The DSMB will meet at intervals determined by the DSMB and NIDCR, typically semiannually to assess safety and efficacy data (if applicable), study progress, and data integrity for the study. If safety concerns arise, more frequent meetings may be held. The DSMB will operate under the rules of an NIDCR-approved charter that will be approved at the organizational meeting of the DSMB. At this time, most data elements that the DSMB needs to assess will be clearly defined. The DSMB will provide recommendations to the NIDCR.

## **11 CLINICAL SITE MONITORING**

Clinical site monitoring is conducted to ensure that the rights of human subjects are protected, that the study is implemented in accordance with the protocol and/or other operating procedures, and that the quality and integrity of study data and data collection methods are maintained. Monitoring for this study will be performed by the NIDCR Clinical Research Operations and Management Support (CROMS) contractor. The monitor will evaluate study processes and documentation based on the International Council for Harmonisation (ICH), E6: Good Clinical Practice guidelines (GCP).

Details of clinical site monitoring will be documented in a Clinical Monitoring Plan (CMP). The CMP will specify the frequency of monitoring, monitoring procedures, the level of clinical site monitoring activities (e.g., the percentage of participant data to be reviewed), and the distribution of monitoring reports. Some monitoring activities may be performed remotely, while others will take place at the study site(s). Staff from NIDCR-CROMS will conduct monitoring activities and provide reports of the findings and associated action items in accordance with the details described in the CMP. Documentation of monitoring activities and findings will be provided to the site study team, the study PIs, NIDCR-OCTOM, and NIDCR Program staff.

The NIDCR reserves the right to conduct independent clinical site monitoring as necessary.

## 12 STATISTICAL CONSIDERATIONS

### 12.1 Study Hypotheses

Primary Efficacy Endpoint(s):

Investigators hypothesize that participants in the PROTECT group will increase tooth brushing to a greater degree than those in the UC group. Assessments will occur throughout the 6-month intervention and 6 months after intervention completion.

*Null Hypothesis: There is no difference in twice/day brushing habits between participant dyads in the intervention and usual care arms.*

*Alternative Hypothesis: Participant dyads that complete the PROTECT intervention will more frequently have twice/day brushing habits.*

Investigators hypothesize that participants in the PROTECT group will decrease added sugar intake to a greater degree than those in the UC group. Assessments will occur throughout the 6-month intervention and 6 months after intervention completion.

*Null Hypothesis: There is no difference in % daily added sugar intake between participant dyads in the intervention and usual care arms.*

*Alternative Hypothesis: Participant dyads that complete the PROTECT intervention will have lower added sugar intake than participant dyads in the usual care arm.*

Secondary Efficacy Endpoint(s):

Investigators also aim to determine the mechanisms of behavioral change. Per Social Cognitive Theory, investigators will estimate a mediation model with positive parenting and caregiver self-efficacy as mediators to primary outcomes.

### 12.2 Sample Size Considerations

The sample size calculation was based on a two-arm parallel design for evaluating PROTECT versus UC effects on percent calories from added sugar intake and frequency of tooth brushing. Investigators account for cluster sizes of 41-48 children per CHW in the intervention arm and assume independent observations in the control arm. Adjusting for retention of 85% at 12 months, the cluster size will be 48-56 participants per CHW in the intervention arm. The mean % energy contributed by added sugars is 14.3, SD=10.7 among 2–8-year-old according to NHANES 2009–2012 data. It is possible that there are demographic differences between a nationally representative study and the primarily Medicaid-enrolled patients who present to UIC. Investigators acknowledge that basing a sample size upon NHANES will likely underestimate added

sugar intake and overestimate brushing frequency. However, our estimates will bias to a larger sample than needed, which is preferred. To our knowledge, there are no estimates related to our primary oral health behavior outcomes in the pediatric DGA population, which simply highlights the understudied nature of pediatric oral health. The sample size calculation was based on formula from Campbell and Walters (2014) and Ahn, Heo, and Zhang (2015) implemented in PASS 15 software. The power calculation is based on group difference at the end of the intervention period relative to any difference at the baseline that might not be fully controlled by randomization. It is formalized as an additional change (increase or decrease) in the intervention arm relative to any change in the control arm (Group x Time interaction). The calculation takes into account partial clustering due to participants clustered in CHWs in the intervention arm only. Investigators assume a 0.01 – 0.02 intra-class correlation coefficients due to CHW clustering, yielding sample size ranges. The significance level alpha was adjusted by Bonferroni correction to account for our two primary outcomes. With equal group allocation and a two-sided significance level of  $\alpha=0.025$  (it is a conservative assumption given the hypothesized improvement in the primary outcomes in the PROTECT arm), investigators will target our intervention to bring the participants to the recommended guideline of 10% calories from the added sugars in the PROTECT arm. Hence, to detect a 4.3% change in calories from added sugars at 12 month follow-up (6-month post intervention) with 0.85 power, investigators would need 164-196 participants in each arm. Taking into account 85% retention rate at 12 month follow up, investigators will need to recruit 386-462 participants across two arms. Twice a day brushing frequency is 55% amongst high-risk toddlers in Chicago. The sample size calculation utilized test for difference in two proportions with unpooled standard deviations. The formula was adjusted to account for clustering in the intervention arm whereas the usual care arm assumed independent observations. Investigators assumed equal group allocation and a two-sided significance level of  $\alpha=0.025$ . Investigators assumed 0.01 – 0.02 intraclass correlation coefficients for the partial clustering effect. To detect 20% increase in twice a day brushing frequency in the PROTECT arm, bringing it to 75%, with 0.85 power, investigators will need 316-365 participants across two arms. Taking into account 85% retention rate at 12-month follow up (6 months post-intervention), and combining sample size estimates from the two outcomes, investigators will recruit 420 participants across two arms (midpoint of higher range).

### **12.3 Final Analysis Plan**

#### **Analysis of the primary efficacy endpoint(s).**

Primary outcomes: frequency of tooth brushing (BRFQ) and % of daily calorie consumption from added sugar (NDSR).

Data measurements: outcomes will be evaluated at baseline, 6 months post-surgery, and 12 month follow up (6 months post-surgery). The main evaluation point is the 12-month follow-up.

Investigators will examine baseline descriptive statistics for primary outcome as well as at each evaluation points. Descriptive statistics of demographic, child and caregiver characteristics, household food security and proposed mechanisms of change will be calculated at the baseline by two groups to evaluate any considerable imbalance post randomization.

Frequency of tooth brushing is ordinal measure and to fully utilize the ordinal nature it will be analyzed by cumulative logistic regression with group as the main predictor. First, investigators will test for group differences in outcomes (brushing frequency) at 12-month follow-up.

Investigators will follow up with mixed effect cumulative logistic model that will use all evaluations of the primary outcomes over time. Time by group interaction will be the main parameter of interest. Different variance-covariance structure, such as AR(1), Toeplitz, and unstructured, will be considered to fully account for repeated measurements. Investigators will consider non-linear trend to explore diminishing effect of intervention over 6-month post intervention period.

As a check for robustness of the primary analysis results, investigators will consider adjusting for covariates with large imbalance at the baseline. In a similar manner, investigators will evaluate intervention effect on the second primary outcome with the exception of using statistical methods for a continuous measure. The added sugar outcome will be derived to determine percent of calories consumed from added sugars from the 24-hour recall measure and is a continuous outcome. Specifically, the 6-month intervention effect will be evaluated with a t-test and a linear regression model will be used throughout. Residual diagnostic will be performed to check for deviations from normality. If considerable deviations are found, variable transformation will be attempted to bring original distribution close to normal. All statistical tests and models will adjust for factors used in stratified randomization. To control for multiple outcomes, the intervention effect will be declared significant at 0.025 level according with Bonferroni correction. Secondary outcomes will be analyzed following similar steps outlined above. These analyses will be conducted in SAS (v.9.4 or later).

The analysis will be carried out under intention-to-treat (ITT) principles, implying that respondents who are randomized must be represented in analysis and therefore have missing data imputed. Investigators will follow the approach of Little and Yau, whose approach to ITT conducts a sensitivity analysis to various missing data scenarios. Research assistants will assist with collecting data and will enter data into REDCap, hence investigators anticipate a very small fraction of missing data. ITT will include participant dyads that were assigned to intervention but did not complete a CHW visit. Investigators recognize the impact on analysis will skew towards the null hypothesis. If

the number of participant dyads who did not complete a CHW visit approach 5% of the total intervention arm, investigators will conduct sub-analysis that will include only participant dyads who have completed at least one CHW visit. This modified ITT (mITT) dataset will omit those who were assigned to intervention but did not complete any CHW visits. Sensitivity analysis using the datasets will probe for patterns of missingness.

Investigators recognize possible clustering effect in the intervention arm due to CHW delivering the intervention. To account for the partial clustering, investigators will extend models to 3-level mixed-effect models with participants clustered in CHW as highest level of clustering. Investigators will extend model with random slope for treatment effect (group) not random intercept, which amounts to random intercept in the intervention arm only. The model estimates ICC in the intervention arm only and ICC in the control arm is modeled to be zero. In a trial with CHW delivering an intervention in the treatment arm and usual care in the control arm investigators might expect participants to have different variability between arms. The model further can be extended to allow for heterogeneous variance. This model will be estimated in R. Investigators will correct degrees of freedom with Kenward-Roger approximation to control for Type 1 error rate which could be inflated with few clusters.

### **Analysis of the secondary endpoint(s).**

Investigators will analyze the roles of caregiver self-efficacy (SESMO) and positive parenting (MAPS) scores as mediators in caregiver ability to change children's oral health behaviors (brushing frequency and added sugar intake). Potential mediators will be evaluated longitudinally and their effects will be evaluated one at a time using a longitudinal mediation model formulated via latent growth curve model. The model will control for a rich set of variables (caregiver demographics, child's baseline DMFT) on the mediator-outcome pathway. The model will be estimated in the Mplus structural equation program, which provides bootstrap-based tests of indirect and direct effects. Investigators will also consider multiple sequential mediators in a single model, such as intervention will change caregiver's self-efficacy, which will change their parenting strategy, which will result in more frequent tooth brushing and reduction of added sugar consumption

### **Safety analyses.**

In accordance with UIC Institutional Review Board (IRB) policies, all adverse events (AEs) and serious AEs (SAEs) will be recorded and assessed for relatedness to the ongoing study. As the study does not involve a biomedical intervention, the risk to participants is very low and hence the number of safety events is expected to be very low, as well. The frequency and seriousness (AE vs. SAE) of any reportable events will be shown in tabular form. Investigators may also describe these events in narrative form.

### **Baseline descriptive statistics.**

The variables collected at baseline will be described according to their level of measurement: continuous variables will be described using mean, median, standard deviation, and inter-quartile range; categorical variables (binary, ordinal, count) will be described in frequency tables. Intervention and comparison groups will be described separately – in the biomedical literature this presentation is often called “Table 1.” Differences between experimental groups will not be tested variable-by-variable: this practice is deprecated. Examination of our Table 1 will allow readers to judge the apparent similarity of experimental groups.

### **13 SOURCE DOCUMENTS AND ACCESS TO SOURCE DATA/DOCUMENTS**

Study staff will maintain appropriate medical and research records for this study, in compliance with ICH E6, Section 4.9 and regulatory and institutional requirements for the protection of confidentiality of participants. Study staff will permit authorized representatives of NIDCR and regulatory agencies to examine (and when required by applicable law, to copy) research records for the purposes of quality assurance reviews, audits, and evaluation of the study safety, progress, and data validity.

## 14 QUALITY CONTROL AND QUALITY ASSURANCE

The clinical site will perform internal quality management of study conduct, data collection, documentation and completion. An individualized quality management plan will be developed to describe the site's quality management.

- Monitoring for this study will be performed by the Clinical Research Coordinator (CRC) under the oversight of Dr. Lee (co-PI) and Dr. Avenetti (co-I).
- Monitoring of clinical data and schedules in REDCap will be conducted throughout the study via random review (the CRC will spend a certain amount of hours each month reviewing records at random, targeting clinical data at each timepoint).
- The CRC will be provided copies of monitoring reports within 30 days of review.
- Both the Intervention and Usual Care arms will interact with the UIC College of Dentistry's clinic personnel. Training and clinical monitoring of dental residents is conducted by UIC to provide standardized care. Select team members have access to records noting care deviations for participating patients.

Clinical monitoring of intervention delivery: CHWs will be trained in PROTECT content, delivery, and implementation, completing at least 3 mock practice sessions reviewed by the clinical psychologist (Co-PI) to ensure competence and fidelity to the intervention. Twenty percent of all intervention visits will be audio-recorded and reviewed by the clinical psychologist to assess fidelity of CHW competence using the Fidelity Assessment Form. Within the form, CHW skills (e.g., clarity of content, interpersonal effectiveness) are assessed on a scale from 1-5. An average score of < 4 requires evaluation and possible remediation (e.g., directed feedback during regular meetings with the CHW, repeated practice sessions for specific topics or skills, and/or shadowed visits). Audio files will be immediately uploaded into REDCap and reviewed by the clinical psychologist monthly. Ongoing training for the CHWs will be provided through regularly monthly meetings with the clinical psychologist supervisor.

Quality control (QC) procedures will be implemented beginning with the data entry system and data QC checks that will be run on the database will be generated. Any missing data or data anomalies will be communicated to the contact PI for clarification/resolution (see Clinical Data Management Plan Section 6.5 for details).

Following written Standard Operating Procedures (SOPs), the monitors will verify that the clinical trial is conducted and data are generated / collected, documented (recorded), and reported in compliance with the protocol, International Conference on Harmonisation Good Clinical Practice (ICH GCP), and applicable regulatory requirements.

The investigational site will provide direct access to all trial related sites, source data/documents, and reports for the purpose of monitoring and auditing by the sponsor, and inspection by local and regulatory authorities.

Data management support for this project will be provided by the Methodology Research Core (MRC) in the Institute for Health Research and Policy at UIC. The MRC also serves as the Design and Analysis Core of the University of Illinois Chicago Center for Clinical and Translational Science (CCTS) which is supported by NIH funding through a Clinical and Translational Science Award as well as strong institutional commitment. The MRC has extensive experience in the acquisition, maintenance, and analysis of both large and small clinical trial databases. It is directed by Michael Berbaum who is a co-investigator on this proposal. The MRC faculty and staff are located in the same offices as the other UIC investigators. The MRC is part of the research team which supports the ready exchange of any needed resources.

All data will be linked to a PROTECT unique ID. All data related to health behaviors, socio-demographics, and clinical outcomes (participant DMFT index, new caries, urgent care visits) will be coded and stored in REDCap.

## **15 ETHICS/PROTECTION OF HUMAN SUBJECTS**

### **15.1 Ethical Standard**

The investigator 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.

### **15.2 Institutional Review Board**

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

### **15.3 Informed Consent Process**

Informed consent is a process that is initiated prior to the individual agreeing to participate in the study and continues throughout study participation. Extensive discussion of risks and possible benefits of study participation will be provided to participants and their families, if applicable. A consent form describing in detail the study procedures and risks will be given to the participant. The consent form provides a detailed description of the study intervention, schedule, and procedures, as well as potential risks, benefits, and other details necessary for the potential participant to make an informed decision. Consent forms will be IRB-approved, and the participant is required to read and review the document or have the document read to him or her in their preferred language. The investigator or designee will explain the research study to the participant and answer any questions that may arise. The participant will sign the informed consent document prior to any study-related assessments or procedures. The Participants will be given the opportunity to discuss the study with their surrogates or think about it prior to agreeing to participate. They may withdraw consent at any time throughout the course of the study. A copy of the signed informed consent document will be given to participants for their records. 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.

The consent process will be documented in the clinical or research record.

Note that assent is not used in this study because all children will be too young to provide assent.

A member of the research team will obtain written informed consent and parental permission from the caregiver before the start of the data collection via the REDCap e-

consent module. If the caregiver participant is not the legal guardian of the child but is the primary caregiver agreeing to participate, separate consent forms will be completed by the caregiver participant and legal guardian. An example of this is that sometimes grandmothers do the majority of the day-to-day care of a child but the mother is the legal guardian. In this instance, investigators would ask the mother to sign the parental permission informed consent for the child and the grandmother to sign the informed consent for herself. The participant is required to read and review the IRB-approved consent form or have the document read to him or her. The participant will sign the informed consent document (electronically on REDCap, in-person on a research tablet/laptop or virtually via an email link) prior to conducting any study-related assessments or procedures.

E-Consent process: Electronic-Consent (e-Consent) is a platform on REDCap for consenting patients or research subjects either on site or at home using a computer-based consent form rather than traditional paper documentation. Consent forms can be implemented in a REDCap survey via computer, mobile phone, or tablet. The research team member obtaining consent may email or text the link to the participant, and then discuss the consent components over the phone with the participant. (The research team will be trained to always explain that consent will be obtained prior to starting any research when scheduling the data collection visit.) Before a participant completes the survey, an extra certification page is added to end of the survey that displays an in-line PDF copy of their survey responses in which they will be asked to confirm that all information in the document is correct. Once they confirm all is correct, the survey (consent form) will then be marked as complete. The survey will not be considered complete until they fulfill the certification step. Upon completion of the survey, a static copy of their responses in the form of a consent-specific PDF will be emailed to participants, as well as stored in the project's File Repository.

The consent process will be documented in the research record. All research staff, investigators, and clinical staff with access to data will undergo HIPAA, Information Privacy and Security, and human subjects research training. Training is provided at the University of Illinois Chicago through the CITI Program ([www.citiprogram.org](http://www.citiprogram.org)). Ongoing consent will be assessed by CHWs throughout the 10 visits over a 6-month period. It is assumed that if participants agree to meet with their CHW, that they consent to research activities. If a participant does not arrange a meeting with their CHW, research team members will contact the participant to determine ongoing consent status. Coercion or undue influence will be addressed in recruitment materials and consent processes. Research staff and CHWs will make it clear that participation in PROTECT is voluntary and will not be overtly shared with clinical providers throughout the UI system, government agencies, public programs, or other patients (i.e. lists of study participants will not be accessible to individuals outside the PROTECT team; UIC pediatric dental providers will be unblinded to participant status).

Subjects who are not yet adults: The participants in the study will be the child undergoing dental surgery and their caregiver(s). Participants must be caregivers of the

child and with them more than 50% of the week. Investigators will also be collecting data on these children, who will be < 96 months old. The data investigators collect will be their height and weight (to calculate BMI), DMFT Index, health behaviors, and clinical data. This information is provided in the caregiver consent form. Parental permission will be obtained from the parent, caregiver or legal guardian participating in the study. These signed forms will be kept securely on REDCap under the supervision of Dr. Lee. As this study is no more than minimal risk, permission of only one caregiver is deemed sufficient.

#### **15.4 Subject Confidentiality**

All participant information, including contact information, questionnaires, and clinical data will be monitored by study staff and only available to them. All involved staff will be instructed in HIPAA, Human Subjects Research, and Good Clinical Practice Training at the start of the project and again yearly. Data will be stored on REDCap, an encrypted, password-protected, HIPAA-compliant secure platform used by the University of Illinois Chicago (UIC). Only authorized study staff will have access to study data (i.e., REDCap requires a login and specific access to study data). Within REDCap, each participant is assigned a unique ID, and all identifiable data is hidden unless granted explicit permission (determined by the Project Manager). Only necessary personnel will have access to identifiers such as contact information to reach participants to arrange data collection or intervention session visits. Participant data collected via the NDSR software is de-identified (i.e., labeled by participant's unique ID).

Research staff access to participant data will be determined by the Project Manager (PM) and PIs, based upon their roles and current activities. Research assistants will most frequently access REDCap in the process of data collection. Research staff in the Methodology Research Core will help manage data. The PI and PM will access data in the process of fidelity, quality assurance, adjudication processes, and data analysis.

Research team members will only access de-identified data for their specified data/statistical analysis and scientific reporting tasks. De-identified data for statistical analyses will be exported from NDSR and REDCap and uploaded into the IHRP i:drive, a secure network drive behind the UIC firewall that requires password-protected, role assignable access, and includes instantaneous local back-up with version control and daily offsite back-up.

Study reports will not contain any identifiable information and findings will be presented in aggregate.

The study participant's contact information will be securely stored during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the reviewing IRB, Institutional policies, or sponsor requirements. At the end of the study, all study databases will be de-identified and archived at the Methodology Research Core or Data Management Core.

Recruitment and consent forms will state that study participation will not influence clinical care. Study participation status will not be discussed with UIC clinical providers. Recruitment, consent, and CHW training will include language that study participation status will be confidential and will not interfere with participation in other public programs, such as WIC. Study participation status will not be communicated with other government entities and will not influence citizenship status. The study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the sponsor. All research activities will be conducted in as private a setting as possible.

The study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the study sponsor.

#### Certificate of Confidentiality

To further protect the privacy of study participants, the Secretary, Health and Human Services (HHS), has issued a Certificate of Confidentiality (CoC) to all researchers engaged in biomedical, behavioral, clinical, or other human subjects research funded wholly or in part by the federal government. Recipients of NIH funding for human subjects research are required to protect identifiable research information from forced disclosure per the terms of the NIH Policy (<https://humansubjects.nih.gov/coc/index>). As set forth in [45 CFR Part 75.303\(a\)](#) and [NIHGPS Chapter 8.3](#), recipients conducting NIH-supported research covered by this Policy are required to establish and maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the award is managed in compliance with Federal statutes, regulations, and the terms and conditions of award. It is the NIH policy that investigators and others who have access to research records will not disclose identifying information except when the participant consents or in certain instances when federal, state, or local law or regulation requires disclosure. NIH expects investigators to inform research participants of the protections and the limits to protections provided by a Certificate issued by this Policy.

#### NIH Data Sharing Policies

As described in section 17, it is NIH policy that the results and accomplishments of the activities that it funds should be made available to the public (see <https://grants.nih.gov/policy/sharing.htm>). PIs and funding recipient institutions will ensure that all mechanisms used to share data include proper plans and safeguards to protect the rights and privacy of individuals who participate in NIH-sponsored research.

### **15.5 Future Use of Stored Specimens and Other Identifiable Data**

Data will not be banked for future use. No specimens will be collected during this study.

## **16 DATA HANDLING AND RECORD KEEPING**

The investigators are responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported. All source documents should be completed in a neat, legible manner to ensure accurate interpretation of data. The investigators will maintain adequate case histories of study participants, including accurate case report forms (CRFs), and source documentation.

### **16.1 Data Management Responsibilities**

Data collection and accurate documentation are the responsibility of the study staff under the supervision of the investigator. All source documents and laboratory reports must be reviewed by the study team and data entry staff, who will ensure that they are accurate and complete. Unanticipated problems and adverse events must be reviewed by the investigator or designee. The investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported

### **16.2 Data Capture Methods**

All questionnaire/survey data will be collected by research team members through participant phone/zoom/in-person visits and directly entered into REDCap (Research Electronic Data Capture), an encrypted, password-protected, HIPAA-compliant secure web-based platform used by UIC for building and managing online surveys and databases for the collection and entry of research data. UIC's installation of REDCap is hosted by the UIC Institute for Health Research and Policy (IHRP). All data collected through REDCap are stored on a secured MySQL database server that is monitored by an intrusion detection system. The database server does not have an externally translatable IP address and access to the server is controlled by Microsoft Active Directory. Permission controls and passwords will assure that only authorized personnel will have the ability to access study data. Account creation to the REDCap web server is managed by UIC's Center for Clinical and Translational Science (CCTS; UL1TR002003). The data system includes password protection and internal quality checks, such as automatic range checks, to identify data that appear inconsistent, incomplete, or inaccurate. Clinical data related to the child's oral health will be collected from dental records and stored in REDCap. Clinical data may be entered directly from the source documents.

The child's dietary intake from the previous day (12:00A – 11:59P) will be captured over telephone or zoom using Nutrition Data System for Research (NDSR) data capture and analysis software, stored on a password-protected, encrypted computer. NDSR is housed on the IHRP network drive which is password protected. NDSR data is labeled with the participant ID.

### 16.3 Types of Data

Clinical Outcomes: The Decayed, Missing, Filled Teeth Index (DMFT) will be used to assess disease severity for primary and any permanent teeth. Scores range from 1-20 if in the primary dentition. Receipt of urgent/emergent dental care or sedation or caries will also be documented. Select members of the research team will extract data from electronic dental records after a child has a preventive dental visit (UIC Pediatric Dentistry Clinic or Mile Square) and enter into REDCap. Investigators will use this data to calculate the DMFT score, which will be stored in REDCap.

Primary Outcomes: Our primary outcomes include tooth brushing frequency and percentage of total calories derived from added sugars.

To assess toothbrushing frequency, items from the BRFQ will be used.

Child and caregiver brushing behaviors (11 items) are included in the Basic Research Factors Questionnaire (BRFQ). The BRFQ is a validated questionnaire to assess dental knowledge, attitudes, and behaviors of caregivers with young children. Investigators will also assess frequency of brushing, assistance with brushing, and use of fluoridated toothpaste. The BRFQ is validated in English and has been translated into Spanish (not yet validated) by members of the research team.

To assess percentage of total calories derived from added sugars, investigators conduct a 24-hour dietary recall interview at baseline, the 6-month follow-up, and the 12-month follow-up. The child's dietary intake from the previous day (12:00A – 11:59P) will be captured in-person/telephone/zoom using Nutrition Data System for Research (NDSR) data capture and analysis software. The software uses interview prompts to conduct a standardized multiple pass 24-hour dietary recall. The multi-pass approach enables respondents to recall foods and beverages consumed with greater accuracy. The parent/caregiver will be asked to use the food amounts booklet to aid the diet interview. A bilingual team member will use the Spanish interviewer prompts provided as an option in the NDSR system for all recalls that are conducted in Spanish. Data collection staff will be trained to conduct dietary recalls by Tussing-Humphreys' team (co-Investigator). Dietary recall data will be used to calculate nutrient intake (e.g., kcal, fat, protein, carbohydrate) and % kcal from total sugars and added sugars. NDSR is housed on the IHRP network drive which is password protected. Data will be downloaded from the NDSR software package and uploaded to the i:drive. The dietary recall interview is validated in both English and Spanish.

Mechanisms of Behavioral Change: In addition to subscales in the above-described BRFQ, two additional assessments will be used to measure mechanisms of change, including self-efficacy and positive parenting.

The Self-Efficacy Scale for Maternal Oral Care (SESMO) was designed for mothers of children up to 8 years old. It consists of 12 items (on a 4-point Likert scale), divided into

two self-efficacy domains (subscales): (i) self-efficacy for tooth brushing and (ii) self-efficacy for dietary habits. This measure has been validated in English and Spanish.

The Multidimensional Assessment of Parenting Scale (MAPS) measures parenting practices and includes measures of positive and negative dimensions of warmth/hostility and behavioral control. It includes 34 items on a 5-point Likert scale and has been validated in English and translated into Spanish (not yet validated) by members of the research team.

Demographics: Investigators will collect child/caregiver race/ethnicity, date of birth, height/weight (to calculate BMI), and dental insurance status, as well as caregiver marital status, education, occupation, household income, household structure and size, household food security, and caregiver language preference. Investigators will also ask for contact information for the parent and two other family members for tracking purposes (i.e., to facilitate continued contact and retention).

Household Food Security: The US Household Food Security Survey Module: Six-Item Short Form is a validated measure (English and Spanish) that will be used to assess food security. The survey module was developed by researchers at the National Center for Health Statistics in collaboration with Abt Associates Inc. and documented in “The effectiveness of a short form of the household food security scale,” by S.J. Blumberg, K. Bialostosky, W.L. Hamilton, and R.R. Briefel (published by the American Journal of Public Health, vol. 89, pp. 1231-34, 1999).

Those in the intervention arm will also complete measures of Acceptability and Feasibility, as well as a intervention-exit interview questionnaire to discuss their thoughts on the program. PROTECT participants will complete a validated self-report measure of intervention feasibility. Above average scores (3 or above on a 5-point scale) will be considered acceptable. PROTECT participants will also be asked to complete a validated acceptability measure assessing usefulness and satisfaction of the intervention. Above average scores will be considered acceptable (3 or above on a 5-point scale). Both measures are validated in English and have been translated into Spanish (not yet validated) by members of the research team. The intervention-exit interview questionnaire contains items assessing specific intervention components of PROTECT to identify which components were most helpful and led to acceptability of the program. Questions also address barriers to and facilitators of behavioral change.

Note: All measures received by both arms will be collected by Research Assistants. To maintain RA blinding at T2 and T3, the acceptability, feasibility, and intervention-exit questionnaires will be sent via survey link to be completed by participants. The Project Manager will receive an alert – programmed into REDCap – once T2 forms are completed by the RA and send the final intervention-specific forms via survey to participants. Instead of sending the forms via survey, the CRC (unblinded) may collect feasibility and acceptability data as well as conduct the end-of-intervention interviews with intervention arm participants after the T2 data collection visit with the RA (6-9

months). RA blinding for the primary outcomes (toothbrushing and diet) remains the priority over potentially missing feasibility data.

### *Other Assessments*

#### Screening and Eligibility

Before consent is obtained, potential participants will be screened for eligibility based on inclusion/exclusion criteria.

#### Assessment of Adverse Events/Unanticipated Problems

Documentation of any adverse events will be reported in REDCap. If the adverse event is reportable to the IRB and NIDCR, an automated message will be sent to the project manager and co-PI's, who will report to the IRB and NIDCR within 5 business of becoming aware of the event.

#### Fidelity of Implementation

Implementation data will also be collected to measure fidelity to the program. CHWs will complete and submit (on REDCap) an Implementation Diary following each session (see Sections 6.3 and 6.4) and a Caregiver Key Skills and Progress Form every month (forms attached).

To ensure fidelity of CHW competency, 20% of all intervention visits will be audio-recorded (and directly uploaded to REDCap) so our clinical psychologist may assess and record fidelity using the Fidelity Assessment Form (form attached).

Clinical data gathered as part of regular medical care will be extracted from participants' medical charts by select members of the research team and stored in HIPAA-compliant software according to relevant laws and requirements. All data will be de-identified prior export for statistical analyses.

### **16.4 Schedule and Content of Reports**

The schedule and content for data review and reports can be found in Section 3.1 of the Clinical Quality Data Management Plan and Section 10 of the Data Management Plan.

### **16.5 Study Records Retention**

Study records will be maintained for at least three years from the date that the last grant federal financial report (FFR) is submitted to the NIH.

No records will be destroyed without the written consent of the sponsor, if applicable. It is the responsibility of the sponsor to inform the investigator when these documents no longer need to be retained.

## 16.6 Protocol Deviations

The term “flexibility within fidelity” refers to an approach to intervention delivery that both honors the fidelity of the manual (e.g., the importance of closely following a manualized behavioral intervention) and the importance of flexibility within that model. CHWs will cover all of the topics included in this manual and keep track of what is introduced and covered with each participant using a checklist (in the Implementation Diary, described in Sections 6.2 and 6.3). However, delivery is not so rigid that investigators miss opportunities to present content when it arises. For example, if a participant introduces a barrier to the CHW in session, the CHW is encouraged to engage in on the spot problem solving with the participant even if they have not yet introduced the problem solving skill and it comes later in the manual. This will allow for more relevance to and engagement from the participants. CHWs will make sure to cover all of the checklist items and content with consistent messaging. Following each session, CHWs will complete an Implementation Diary, which indicates adherence and adaptations to the implementation protocol and will allow us to track the number of sessions and content each participant receives. Implementation Diaries and other data collected in REDCap will allow investigators to identify protocol deviations.

A protocol deviation is any noncompliance with the clinical trial protocol or International Conference on Harmonisation Good Clinical Practice (ICH GCP) requirements. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions are to be developed by the site and implemented promptly.

It is the responsibility of the site investigator to use continuous vigilance to identify and report all protocol deviations. All protocol deviations, including those considered Unanticipated Problems, will be reported to the DSMB through routine DSMB reports. Protocol deviations considered Unanticipated Problems will be reported as outlined in the Assessment of Safety section of the protocol. All deviations must be addressed in study source documents. Privacy protocol deviations must be sent to the reviewing IRB per their policies. The site investigator is responsible for knowing and adhering to the reviewing IRB requirements. Further details about the handling of protocol deviations will be included in the MOP.

## 17 PUBLICATION/DATA SHARING

This study will comply with all applicable NIH Data Sharing Policies. See <https://grants.nih.gov/policy/sharing.htm> for policies and resources. This study will be conducted in accordance with the following publication and data sharing policies and regulations:

### NIH Public Access Policy

The NIH *Public Access Policy* requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to *PubMed Central* immediately upon acceptance for publication. This ensures that the public has access to the published results of NIH funded research.

### NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information

The study is a clinical trial and will comply with the NIH policy that establishes the expectation that all investigators conducting clinical trials funded in whole or in part by the NIH will ensure that these trials are registered at ClinicalTrials.gov, and that results of these trials are submitted to ClinicalTrials.gov.

In addition, every attempt will be made to publish results in peer-reviewed journals. Data from this study may be requested from other researchers 3 years after the completion of the primary endpoint by contacting Dr. Lee.

See the Manual of Procedures Sections 2.1.9 and 2.1.10 for more.

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**University of Illinois at Chicago (UIC) and/or  
University of Illinois Hospital & Health Sciences System (UI Health)  
Research Information and Consent, Parental Permission, and Authorization for  
Participation in Social, Behavioral, or Educational Research  
“Testing a Multi-behavioral Intervention to Improve Oral Health Behaviors in the  
Pediatric Dental Surgery Population”**

**Principal Investigator/Researcher Name and Title:** Dr. Helen H. Lee (Co-Principal Investigator Dr. Joanna Buscemi)

**Department and Institution:** Department of Anesthesiology, College of Medicine; Institute for Health Research and Policy

**Address and Contact Information:** 1740 W. Taylor Street, MC 515, Chicago, IL 60612

**Sponsor:** National Institutes of Health (NIH) #NCT07220850

**About this research study**

Participants are being asked to take part in a research study. Research studies answer important questions that might help change or better the way we do things in the future.

**Taking part in this study is voluntary**

Being part of this research study is voluntary. Participants may choose to not take part in this study or may choose to leave the study at any time. Choosing not to participate, or choosing to leave the study later, will not result in any penalty or loss of benefits to which participants are entitled and will not affect participant relationship with the University of Illinois Hospital and Health Sciences System (UI Health) and/or University of Illinois at Chicago (UIC).

This consent form will give participants information about the research study to help participants decide whether participants want to participate. Please read this form and ask any questions participants have before agreeing to be in the study.

Participants are being asked to participate in this research study because participants are the parent or caregiver of a young child whose cavities will be/were treated under general anesthesia.

Up to 420 participant dyads (caregiver/child pairs and family members) will be enrolled in this research study.

Note: This research includes participants who are too young to be able to consent for themselves. If participants are a parent, guardian, or legal representative, the terms “participants child” or “participants child’s” refer to the research participant for whom participants are responsible.

**Important Information**

This information gives participants an overview of the research. More information about these topics may be found in the pages that follow.

<p><b>WHY IS THIS STUDY BEING DONE?</b></p>	<p>We want to find out if our parenting program, PROTECT (Preventing Recurrent Operations Targeting Early Childhood Caries Treatment), improves tooth health behaviors such as children’s toothbrushing and diet. The program involves meeting with a community health worker (CHW) by phone or zoom several times over 6 months.</p> <p>All participants in the study will meet with research assistants over 12 months to answer questions.</p> <p><b>Half of study participants will meet with a CHW as part of the research study to receive the PROTECT program. The other half of study participants will not meet with a CHW and will not receive the program. All participants will meet with research assistants to provide us information for the study.</b></p>
<p><b>WHAT WILL I BE ASKED TO DO DURING THE STUDY?</b></p>	<p><u>All participants</u></p> <p>We will collect information from participants and child during 3 data collection visits: before or during surgery, about 6 months following participants child’s dental surgery, and about 12 months after surgery. Participants will be asked questions (by phone or by zoom) about tooth health behaviors, parenting, and what participants child eats and drinks. We will also collect information about participants child’s teeth and dental care from participants child’s UIC dental records.</p> <p>After participants first data collection visit, participants will be randomly put in one of two research groups: those receiving program calls from the CHW and those who do NOT receive calls from the CHW.</p> <p><u>For participants receiving calls from the CHW:</u></p> <p>Participants will be asked to meet with a CHW (in-person, by phone, or by zoom) 10 times over the 6 months following participants child’s dental surgery. During these sessions, the CHW will provide participants and family with education, support, and coaching as participants are changing participants child’s toothbrushing and eating/drinking habits.</p>

	<p>Some sessions will be audio-recorded for quality assurance purposes.</p> <p>For more detailed information, please see the “What Procedures Are Involved?” section below.</p>
<p><b>HOW MUCH TIME WILL I SPEND ON THE STUDY?</b></p>	<p><u>Data collection for all participants</u>          Participants will meet with one of our research assistants three times during this 12-month study: when participants start the study, 6 months after surgery, and 12 months after surgery. Data collection visits will take 60-90 minutes to complete. Total data collection time is about 4 hours over the 12 months of the study.</p> <p><u>Participants not receiving CHW calls:</u>          Participants will spend about 4 hours total in the study. At the end of the study (following the 12-month data collection visit), we will provide participants with the program curriculum and participants will have the chance to discuss the content with a research team member.</p> <p><u>For participants receiving CHW calls:</u>          In addition to meeting with our research assistants for data collection, participants will also meet with a CHW, who will guide participants through our program (PROTECT). The first PROTECT session with the CHW will be about 60 minutes and the rest of the 10 sessions will be about 30 minutes each. These sessions will occur every week for the first month or so following surgery, and then about once a month for the remaining 4-5 months of the program. Total program time with the CHW is about 6 hours over the 6 months. Participants receiving the CHW calls will spend about 10 hours total (program and data collection sessions) in the study.</p>
<p><b>18.1 ARE THERE ANY BENEFITS TO TAKING PART IN THE</b></p>	<p>We cannot promise any benefits to participants or others from taking part in this research.</p> <p>Being in this research study may not benefit participants directly, but it is possible that the PROTECT program being evaluated may turn out to be more effective than usual care. If participants are not assigned to receive CHW calls, we will</p>

<b>STUDY?</b>	provide participants the program curriculum at the end of the study. We hope participation in the study will help us improve the program and benefit other families like participants in the future.
<b>WHAT ARE THE MAIN RISKS OF THE STUDY?</b>	<p>The main risks presented by this research study are breaches of privacy (others outside of the study may find out participants are a subject) and/or confidentiality (others outside of the study may find out what participants did, said, or information that was collected about participants during the study). We have trained our staff and thought through all of our activities to minimize these risks.</p> <p>Participants may be uncomfortable with some of the questions participants may be asked and/or asked to discuss. This research includes some items about toothbrushing behaviors, parenting, and food habits. Participants can skip and/or not respond to any questions that may make participants uncomfortable.</p>
<b>DO I HAVE OTHER OPTIONS BESIDES TAKING PART IN THE STUDY?</b>	Participants have the option to not participate in this study. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which participants are entitled and will not affect participants relationship with the University of Illinois Hospital and Health Sciences System (UI Health) and/or University of Illinois at Chicago (UIC). Participants can continue to receive dental care from UIC and UI Health if participants choose not to participate in this study.
<b>QUESTIONS ABOUT THE STUDY?</b>	<p>For questions, concerns, or complaints about the study, please contact Helen Lee at 312-996-4020 or email at <a href="mailto:leehelen@uic.edu">leehelen@uic.edu</a>.</p> <p>If participants have questions about participants rights as a study participant; including questions, concerns, complaints, or if participants feel participants have not been treated according to the description in this form; or to offer input participants may call the UIC Office for the Protection of Research Subjects (OPRS) at 312-996-1711 or 1-866-789-6215 (toll-free) or e-mail OPRS at <a href="mailto:uicirb@uic.edu">uicirb@uic.edu</a>.</p>

	If participants have questions or concerns regarding participant privacy rights under HIPAA, participants should contact the University of Illinois HIPAA Privacy Office at (844) 341-2201 or <a href="mailto:hipaa@uillinois.edu">hipaa@uillinois.edu</a> .
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**Please review the rest of this document for details about these topics and additional things participants should know before making a decision about whether to participate in this research. Please also feel free to ask the researchers questions at any time.**

### **What procedures are involved?**

All participants will meet with a research assistant (by phone or Zoom) for data collection purposes. Data collection visits include answering questionnaires and completing an interview. Participants will have a total of three data collection visits over the 12-month study. A member of the research team will also collect information from participants child's dental records. During these data collection sessions, Dr. Lee and their research team will collect information about participants and child for research purposes. The tentative schedule for these data collection meetings is as follows:

<b>Time</b>	<b>Location</b>	<b>Timing</b>	<b>Assessments</b>
<b>Time 1: Baseline</b>	Phone or zoom	60-90 minutes	Participants will complete questionnaires about demographics, tooth health behaviors, and parenting. Research assistants will also conduct a diet interview. We will collect information on participants child's teeth from their dental record.
<b>Time 2: about 6 months after surgery</b>	Phone or zoom	60-90 minutes	Questionnaires about demographics, tooth health behaviors, parenting, and the program. Research assistants will also conduct a diet interview. We will collect information on participants child's teeth from their dental record.
<b>Time 3: about 12 months after surgery</b>	Phone or zoom	60-90 minutes	Questionnaires about demographics, tooth health behaviors, and parenting. Research assistants will also conduct a diet interview. We will collect information on participants child's teeth from their dental record.

The information that the research team will collect and use for this research study include the following:

- Participants demographic information (e.g., age, race, ethnicity, gender, marital status, income, education, household food security, and employment),
- Information about participants child's and participants diet,
- Participants child's and participants BMI,
- Information about participants child's tooth brushing,
- Participants tooth health and nutrition knowledge,
- Participants parenting styles and comfort with changing behaviors,
- Clinical measures from participants child's dental chart.

For participants receiving CHW calls, participants will also meet (in-person, by phone, or by zoom) for 10 program sessions during the 6 months following participants child's dental surgery. During these sessions, a CHW will provide education, support, and resources on topics related to improving participants child's tooth health. The tentative schedule for these PROTECT sessions is as follows:

Session #	Schedule	Session Type	Session Time	Session Content
1	Day of surgery	In-Person (during child's dental surgery) or virtual	60 minutes	Tooth Health, Toothbrushing, Eating and Drinking
2	1 week	Phone/Zoom	30 minutes	Parenting Skills to Support Tooth Health
3	2 weeks	Phone/Zoom	30 minutes	Rewards and Routines
4	3 weeks	Phone/Zoom	30 minutes	Managing Participants Emotions
5	4 weeks	Phone/Zoom	30 minutes	Monitoring and Problem-Solving
6	2 months	Phone/Zoom	30 minutes	Maintaining Behavior Change
7	3 months	Phone/Zoom	30 minutes	Maintaining Behavior Change
8	4 months	Phone/Zoom	30 minutes	Maintaining Behavior Change
9	5 months	Phone/Zoom	30 minutes	Maintaining Behavior Change
10	6 months	Phone/Zoom	30 minutes	Graduation Session

We will also collect additional information on participants thoughts about the program and participants attendance and engagement with the program sessions. This information will help us understand if our program is working in the ways we think it should.

### **What will happen with my information used in this study?**

The information collected for this study may be used for future research studies and/or shared with other researchers in the future. If this happens, information which could identify participants will be removed before any information is shared. Once the

identifying information is removed, the information cannot be withdrawn from further use. Participants will not be asked for additional consent.

**Will I receive the results (including any psychological, health results) from the study?**

At the end of the study, we will tell participants the overall results of the study for all participants. If infection or caries or other serious problems are seen during a preventive dental visit, the dental provider will manage these issues, not research staff.

Participants will not receive any other personal results.

**What about privacy and confidentiality?**

Efforts will be made to keep participants personal information confidential; however, we cannot guarantee absolute confidentiality. In general, information about participants, or provided by participants, during the research study, will not be disclosed to others without participants written permission. Participants study participation status will not be shared with other government assistance programs. However, laws and state university rules might require us to tell certain people about participants. For example, study information which identifies participants and the consent form signed by participants may be looked at and/or copied for quality assurance and data analysis by:

- Representatives of the university committee and office that reviews and approves research studies, the Institutional Review Board (IRB) and Office for the Protection of Research Subjects.
- Other representatives of the State and University responsible for ethical, regulatory, or financial oversight of research.
- Government Regulatory Agencies, such as the Office for Human Research Protections (OHRP).
- The National Institutes of Health

A possible risk of the study is that participants participation in the study or information about participants might become known to individuals outside the study. Participants personal information; participants answers to questionnaires, surveys, interviews; any audio recordings; and participants child's data collected from

records will be stored on REDCap, an encrypted password-protected secure platform for

managing data to prevent access by unauthorized personnel. Each participant will be assigned a

unique ID, stripped of any identifiable information. Once the study is over, anything that personally identifies participants will be removed from the data. The coded data then may be shared with other researchers.

When the results of the study are published or discussed in conferences, no one will know that participants were in the study.

Please remember that there is an exception to protecting subject privacy and confidentiality if child, elder, and/or disabled adult abuse or neglect of an identifiable individual, or the threat of imminent self-harm or harm to others is disclosed. If such information is disclosed, the researchers may be obligated to inform the appropriate authorities.

To help us protect participants and the information we will be collecting from participants, this research has been given a Certificate of Confidentiality by the National Institutes of Health (NIH). This Certificate means that researchers cannot be forced, even by courts or the police, to disclose information, documents, that may identify participants. However, participants information may be given to personnel of the United States Government to audit or evaluate projects that are federally funded or to meet other regulatory requirements.

The Certificate does not stop participants or a family member from disclosing, or agreeing in writing to allow researchers to disclose, information, documents, about participants, including participants participation in this research. For example, if participants would like an employer or insurer to know something about participants that is documented in this research, participants can write and sign a statement telling the researchers it is okay to give participants employer or insurance company information. Even if the research has a Certificate, the research or any member of the study staff must report (even if it is without participants consent) evidence of harm to self or others, including actual or suspected abuse, neglect, or exploitation of a child, or disabled or elderly adult. In addition, if the research shows that participants have a reportable communicable disease (for example, tuberculosis [TB] or HIV/AIDS), the researchers may report this to the appropriate authorities.

A description of this study will be available on <http://www.ClinicalTrials.gov>, as required by U.S. law. This website will not include information that can identify participants. At most, the website will include a summary of the results. Participants can search this website at any time.

**What are the costs for participating in this research?**

There are no costs to participants for participating in this research.

**Will I be reimbursed for any of my expenses or paid for my participation in this research?**

Participants will receive monetary compensation in the form of an electronic Amazon eCode for each completed data collection time point: \$45 for baseline around the time of surgery, \$45 at 6 months after surgery, and \$55 at 12 months after surgery. If participants do not finish the study, participants will be compensated for the visits participants have completed. If participants complete the study, participants will receive a total of \$145. Participants will receive participants payment within approximately 24 hours of each data collection session via email. Participants personal email will be collected at each data collection session solely for the purpose of sending participants the compensation.

**Can I withdraw or be removed from the study?**

If participants decide to participate, participants have the right to withdraw participants consent and leave the study at any time without penalty. Participants can withdraw via phone or email by contacting Dr. Helen Lee at leehelen@uic.edu.

The researchers and NIH/NIDCR also have the right to stop participants participation in this study without participants consent if they believe it is in participants best interests.

If participants choose to no longer be in the study and participants do not want any of participants future information to be used, participants must inform the researchers in writing at the address on the first page. The researchers may use participants information that was collected prior to participants written notice.

For participants receiving CHW calls: If participants decide to withdraw from the study during the first 6 months or prior to completing the program sessions, participants will no longer meet with or receive resources, support, and education from the community health worker because this is part of the research.

**Will health information about participants be created, used or shared with others during this study?**

State and federal laws, including the Health Insurance Portability and Accountability Act (HIPAA), require researchers to protect participants health information. This section of this form describes how researchers, with participants authorization (permission), may use and release (disclose or share) participants protected health information in this research study. By signing this form participants are authorizing Dr. Helen Lee and their research team to create, get, use, store, and share protected health information that identifies participants for the purposes of this research.

The health information includes all information created and/or collected during the research as described within this consent form and/or any health information in participants medical record. If participants receive medical care from other institutions and participants have agreed to share participants medical record information through EPIC Care Everywhere (as described further in the UI Health Notice of Privacy Practices), the information from the other institution(s) may be used in this research.

The specific information includes:

- Personal identifiers (participants name, address, phone number, date of birth, social security number, medical record number), dates of service, and demographic information (e.g., race, ethnicity, financial information)
- Results of physical examinations (e.g., the Decayed, Missing, Filled Tooth/Surfaces Index)
- Dental history and results of dental examinations
- Medical history

During the conduct of the research, the researchers may use or share participants health information:

- With each other and with other researchers involved with the study.
- With law enforcement or other agencies, when required by law.
- With the sponsor/funding agency of the research, NIH/ National Institute for Dental and Craniofacial Research (NIDCR), as required to conduct the research and/or confirm the results of the research.
- With non-UIC collaborators of the research study: Dr. Joanna Buscemi and her research assistants, DePaul University, Department of Psychology.
- Representatives of the university committee and office that reviews and approves research studies, the Institutional Review Board (IRB) and Office for the Protection of Research Subjects.
- Other representatives of the State and University responsible for ethical, regulatory, or financial oversight of research.
- United States Government Regulatory Agencies, including but not limited to the Office for Human Research Protections (OHRP) and Food and Drug Administration (FDA).

If all information that identifies participants is removed from the research data, the remaining information is no longer subject to the limits of this Authorization or to the HIPAA privacy laws. Therefore, the de-identified information may be used and released by the researchers (as permitted by law) for other purposes, such as other research projects.

During participants participation in this research, participants will not have access to the research records or information that is not usually kept in participants clinical records. However, this information is available to participants dentist in the case of an emergency. The researcher may provide participants with access to the research records or information related to this research once the study is done.

### **How will participants health information be protected?**

The researchers and NIH/NIDCR agree to protect participants health information and will only share this information as described within this research consent/authorization form.

Participants Authorization for release of health information for this research study expires at the end of the study, but can be canceled sooner if participants decide to withdraw participants permission.

Participants may change participants mind and cancel this Authorization at any time. To cancel this Authorization, participants must write to Dr. Helen Lee via email at [leehelen@uic.edu](mailto:leehelen@uic.edu) or via mail at 1747 W. Roosevelt Road, MC 524, Chicago, IL, 60608.

If participants cancel this Authorization, participants may no longer be allowed to take part in the research study. Even if participants cancel this Authorization, the researchers may still use and disclose de-identified health information they have already obtained as necessary to maintain the integrity and reliability of the research and to report any adverse (bad) effects that may have happened to participants.



## 20 **RIGHT TO REFUSE TO SIGN THIS AUTHORIZATION**

Participants do not have to sign this Consent/Authorization. However, because participants health information is required for research participation, participants cannot be in this research study if participants do not sign this form. If participants decide not to sign this Consent/Authorization form, it will only mean participants cannot take part in this research. Not signing this form will not affect participants clinical treatment, payment or enrollment in any health plans or participants eligibility for other medical benefits.

Parents/Guardians, please be aware that under the Protection of Pupil Rights Act, 20 USC 1232(c)(1)(A), participants have the right to review a copy of the questions asked of or materials that will be used with participants child. If participants would like to do so, participants should contact Dr. Helen Lee at [leehelen@uic.edu](mailto:leehelen@uic.edu) to obtain a copy of the questions or materials.

### **Remember:**

Participants participation in this research is voluntary. Participants decision whether or not to participate will not affect participants current or future relations with the University. If participants decide to participate, participants are free to withdraw at any time without affecting that relationship.

### **Signature of Participant / Parent/Guardian/Legal Representative**

I have read the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research. I will be given a copy of this form.

#### **20.1**

**20.2 If participants have not already received a copy of the Notice of Privacy Practices, participants should ask for one.**

Participants signature below indicates that participants are providing consent to participate in the research study [and authorization for the researcher to use and share participants health information for the research].

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name

\_\_\_\_\_  
Printed Name of Minor

\_\_\_\_\_  
Signature of Parent, Guardian, Legal Representative

\_\_\_\_\_  
Date of Signature

\_\_\_\_\_  
Printed Name of Parent, Guardian, Legal Representative

Describe relationship to subject including the legal authority this individual has to act on behalf of the subject. (Check one below)

- ☐ Parent  
☐ Legal guardian  
☐ Health care surrogate  
☐ Other; specify

Caregiver's preferred language: ☐ English ☐ Spanish

Name of Person Obtaining Consent: \_\_\_\_\_

I have read the above information. I have been given an opportunity to contact the researchers and ask questions, and my questions have been answered to my satisfaction. I agree to participate in this research. **PLEASE PRINT OUT A COPY OF THIS DOCUMENT FOR PARTICIPANTS RECORDS.**

