Dear <Dentist or Hygienist>

I am a Regional Node Coordinator with the National Dental Practice-Based Research Network (National Dental PBRN).

As a **practicing dentist or hygienist** and a member of the National Dental PBRN, you may be eligible to participate in an upcoming study entitled, "Free Samples for Health (FreSH) Study 3;" IRB-300010014. This study is being conducted by Hennepin Healthcare, the University of Alabama and the National Dental PBRN. The study sponsor is the National Institutes of Health.

General Information	You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. Procedures, risks, and benefits are fully described further in this document.
Purpose	The purpose of this study is to understand factors that would affect the feasibility and acceptability for implementing nicotine replacement therapy sampling vs. electric toothbrushes in changing patients' smoking habits in oral healthcare settings.
Duration & Visits	You will be asked to complete questionnaires two times during the study, before starting recruitment for the FreSH patient study and after completing recruitment. We estimate the questionnaires will take about 20 minutes to complete each time. You may also be invited to take part in a 60 minute interview. Finally, you will be asked to give permission to collect administrative data on the time required to deliver the study interventions.
Overview of Procedures	If you agree to participate, you will be sent questionnaires via email before and after serving as a study site for the FreSH patient study. The data collection system will track the amount of time spent on each screen. Following the end of recruitment at your site, you may be asked to participate in an interview over the phone.
Risks	The most common risk is loss of confidentiality.
Benefits	You will not benefit from participating in this study.
Alternatives	Being in this research study is voluntary. You do not have to take part in this study if you do not want to, it is your choice.

The FreSH trial will test the effectiveness of providing patients with samples of nicotine replacement therapy vs. electric toothbrushes on abstinence from tobacco.

Approximately 50 participating dental practices comprising up to 150 practitioner members of the National Dental PBRN will participate in this study.

If you agree to participate, you will be asked to complete surveys before and after patients' recruitment. You will also be asked if you agree to allow the study team to retain administrative data on how long you spend on each screen on the tablet as you deliver the study intervention. This information is being used to determine the amount of time the intervention would take in real-world practice. You may also be invited to complete a 60-minute telephone interview to provide feedback about nicotine replacement therapy sampling and how it could be implemented in real world clinical practice. The interview will be recorded and transcribed.

Your participation is voluntary, and your participation and responses will remain confidential.

This research will not directly benefit you. However, study results may contribute to the evidence of best practices for addressing smoking cessation during dental visits.

A possible risk of this study is loss of confidentiality. All data will be stored in a secure manner and accessible only by authorized study personnel. All questionnaires will be completed electronically and managed by the coordinating center at Kaiser Permanente Center for Health Research (KPCHR). All interviews will be completed and managed by Northwestern University.

Taking part in this research is not a part of your work duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your job. Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in it. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. You are free to withdraw from this study at any time. Contact the study Principal Investigator Dr. Sandra Japuntich at 612-873-6856, if you want to withdraw from the study. You may be removed from the study without your consent if the sponsor ends the study, if the study principal investigator decides it is best for the study for your practice to stop recruiting.

Information about you for this study will be kept confidential to the extent allowed by law. However, research information that identifies you may be shared with people or organizations for quality assurance or data analysis, or with those responsible for ensuring compliance with laws and regulations related to research.

They include:

- The University of Alabama at Birmingham, Hennepin Healthcare Research Institute, and Health Partners Institutional Review Boards (IRB). An IRB is a group that reviews the study to protect the rights and welfare of research participants.
- National Institutes of Health
- The Office for Human Research Protections (OHRP)
- National Dental Practice-Based Research Network Administrative and Resource Center (University of Alabama at Birmingham)
- Network Coordinating Center for the National Dental Practice-Based Research Network (Kaiser Permanente Center for Health Research)
- Landmark Associates (a professional transcription service) for transcribing the interviews
- Hennepin Healthcare Research Institute

- University of Rochester
- Health Partners
- Northwestern University (one of the institutions conducting the study)

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

The information from the research may be published for scientific purposes; however, your identity will not be given out in those publications.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child or elder abuse and neglect or harm to self or others. The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have
consented to in this informed consent document.

There will be no cost to you for taking part in this study.

There is no compensation for completing the surveys. Participating practitioners and staff will receive $50 remuneration for completing the interview.

If you are interested in participating in this study or have any questions, please contact me by replying to this email or by telephone at xxx-xxx-xxxx.

If you have any questions, concerns, or complaints about this research, you may contact Dr. Sandra Japuntich at 612-873-6856.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1- 855 860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday. You may also call this number in the event the research staff cannot be reached, or you wish to speak with someone else.

Thank you for your participation in the National Dental Practice-Based Research Network! I look forward to hearing from you.

Sincerely,

<Insert Regional Coordinator(s) Name(s)>
<Insert Region Coordinator(s) Telephone Number(s)

FreSH study Ask-Advise-Refer Script

Ask: “Do you smoke or use tobacco products? I take the time to ask all my patients about tobacco use because it’s important.”

Advise: “Quitting smoking is the best thing you can do for your oral health. Cigarette smoking can cause gum disease, tooth loss, and oral cancer. Quitting smoking will allow these problems to start healing and prevent future damage.”

Refer: “If you are willing, I’d like to place an electronic referral to the state quit line. The quitline offers free, confidential cessation support that you can use anytime you want, even if you’re not ready to quit. If you agree, a coordinator from the quit line will call you to offer you counseling to help you make changes in your smoking. Would it be ok if I placed that referral?”

Subject ID# _____
Date _____

FreSH
(Free Samples for Health)
Staff Implementation Measures Survey

Organizational Readiness for Implementing Change (ORIC)

1. Please rate your level of agreement with the following statements.

	1 Disagree	*2 Somewhat disagree*	*3 Neither agree nor disagree*	*4 Somewhat agree*	*5 Agree*	*777 Prefer not to answer*
a. People who work here feel confident that the organization can get providers invested in giving patients samples of nicotine replacement therapy.	**1**	**2**	**3**	**4**	**5**	**777**
b. People who work here are committed to giving patients samples of nicotine replacement therapy.	**1**	**2**	**3**	**4**	**5**	**777**
c. People who work here feel confident that they can keep track of progress in implementing nicotine replacement therapy sampling.	**1**	**2**	**3**	**4**	**5**	**777**
d. People who work here will do whatever it takes to implement nicotine replacement therapy sampling.	**1**	**2**	**3**	**4**	**5**	**777**
e. People who work here feel confident that the organization can support providers as they adjust to providing nicotine replacement therapy samples.	**1**	**2**	**3**	**4**	**5**	**777**
f. People who work here want to implement nicotine replacement therapy sampling.	**1**	**2**	**3**	**4**	**5**	**777**
g. People who work here feel confident that they can keep the momentum going in implementing nicotine replacement therapy sampling.	**1**	**2**	**3**	**4**	**5**	**777**
h. People who work here feel confident that they can handle the challenges that might arise in implementing nicotine replacement therapy sampling.	**1**	**2**	**3**	**4**	**5**	**777**

i. People who work here are determined to implement nicotine replacement therapy sampling.	**1**	**2**	**3**	**4**	**5**	**777**
j. People who work here feel confident they can coordinate tasks so that implementation of nicotine replacement therapy sampling goes smoothly.	**1**	**2**	**3**	**4**	**5**	**777**
k. People who work here are motivated to implement nicotine replacement therapy sampling.	**1**	**2**	**3**	**4**	**5**	**777**
l. People who work here feel confident that they can manage the politics of implementing nicotine replacement therapy sampling.	**1**	**2**	**3**	**4**	**5**	**777**

Acceptability of Intervention Measure

2. Please rate your level of agreement with the following statements.

	1 ***Completely Disagree***	**2** ***Disagree***	**3** ***Neither agree nor disagree***	**4** ***Agree***	**5** ***Completely agree***	**777** ***Prefer not to answer***
a. Nicotine replacement therapy sampling meets my approval.	**1**	**2**	**3**	**4**	**5**	**777**
b. Nicotine replacement therapy sampling is appealing to me.	**1**	**2**	**3**	**4**	**5**	**777**
c. I like nicotine replacement therapy sampling.	**1**	**2**	**3**	**4**	**5**	**777**
d. I welcome nicotine replacement therapy sampling.	**1**	**2**	**3**	**4**	**5**	**777**

Intervention Appropriateness Measure

3. Please rate your level of agreement with the following statements.

	1 ***Completely Disagree***	**2** ***Disagree***	**3** ***Neither agree nor disagree***	**4** ***Agree***	**5** ***Completely agree***	**777** ***Prefer not to answer***
a. Nicotine replacement therapy sampling seems fitting.	**1**	**2**	**3**	**4**	**5**	**777**
b. Nicotine replacement therapy sampling seems suitable.	**1**	**2**	**3**	**4**	**5**	**777**
c. Nicotine replacement therapy sampling seems applicable.	**1**	**2**	**3**	**4**	**5**	**777**
d. Nicotine replacement therapy sampling seems like a good match.	**1**	**2**	**3**	**4**	**5**	**777**

Feasibility of Intervention Measure

4. Please rate your level of agreement with the following statements.

	1 ***Completely Disagree***	**2** ***Disagree***	**3** ***Neither agree nor disagree***	**4** ***Agree***	**5** ***Completely agree***	**777** ***Prefer not to answer***
a. Nicotine replacement therapy sampling seems implementable.	**1**	**2**	**3**	**4**	**5**	**777**
b. Nicotine replacement therapy sampling seems possible.	**1**	**2**	**3**	**4**	**5**	**777**
c. Nicotine replacement therapy sampling seems doable.	**1**	**2**	**3**	**4**	**5**	**777**
d. Nicotine replacement therapy sampling seems easy to use.	**1**	**2**	**3**	**4**	**5**	**777**

5. **The following questions are about you:**

a. What was your biological sex at birth?

- □ Male
- □ Female
- □ Intersex
- □ None of these describe me
- □ Other _____
- □ Prefer not to say

b. What is your current gender identity?

- □ Male
- □ Female
- □ Transgender
- □ Non-binary
- □ Something else:_____
- □ Prefer not to answer

c. What is your age?

_____ years

- □ Prefer not to answer

d. Are you of Hispanic or Latino Origin?

- ☐ Yes
- ☐ No
- ☐ Prefer not to answer

e. What racial categories best describe you? (Check all that apply)

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Hispanic or Latino
- ☐ Native Hawaiian or other Pacific Islander
- ☐ White/Caucasian
- ☐ Prefer not to answer

f. What is your current job role?

- ☐ Dentist
- ☐ Dental Therapist
- ☐ Dental Hygienist
- ☐ Other_____

_____

g. How many years have you been in practice?

_____ years

h. How long have you worked at your current practice? ____ years

FreSH Study 3

Key Informant Interviews - Provider Interview Guide

***Synopsis**: Hennepin Healthcare researchers will conduct one-on-one phone interviews with 10-12 dentists and 10-12 other staff from dental practices that participated in FreSH Study 3 in the NRTS condition. The purpose of these telephone interviews is to obtain feedback regarding feasibility and acceptability of study interventions and future implementation of NRT sampling in dental practices. Interviews will be conducted at the end of site data collection. Telephone interviews will be recorded using a digital audio recorder and transcribed to support thematic analysis.*

Provider Interview

When the dentist/hygienist answers the phone, the interviewer will introduce themselves, review the consent form, and obtain verbal consent for the interview.

A. BACKGROUND

***INTERVIEWER SECTION INTRODUCTION:** If I ask any question that you are not comfortable answering, that's ok and you do not have to answer. Just tell me "I prefer not to answer" and I'll move on to the next question.*

I'd like to start by asking a few questions about your background. The NIH requires us to ask these for reporting purposes.

1. What was your biological sex at birth?
   - Male
   - Female

2. What is your current gender identity?
   - Male
   - Female
   - Non-binary
   - Something else: _____

3. How would you describe your race? Tell me all that apply.
   - American Indian or Alaska Native
   - Asian
   - Black/African American
   - Native Hawaiian/Other Pacific Islander
   - White
   - Other _____

4. Do you identify as Hispanic/Latinx?
   - Yes

- No

5. What is your age?

6. What is your profession/job title? Tell me a little bit about your role in the practice.

B. CONTEXT AND RECIPIENT FACTORS

INTERVIEWER SECTION INTRODUCTION: *Next, I'd like to talk about your experience in counseling patients who use tobacco before participating in the FreSH study.*

B1. Experience with tobacco cessation and recommending NRT to patients prior to FreSH

7. What do you think should be the role of the oral health practitioner in tobacco cessation?

   PROBE: Did this change as a result of participating in this study?

8. How does tobacco cessation fit into the priorities and culture of your clinic?

   PROBE: Before the FreSH study, what if any challenges or barriers have you encountered surrounding patient tobacco use and cessation?

9. Before participating in the FreSH study, did you ever counsel patients about their tobacco use? What sorts of things would you do to address tobacco use?

   PROBE: Ask? Advise? Refer?

10. Before participating in the FreSH study, did you ever recommend that patients use nicotine replacement therapy– that is, medicinal nicotine products like nicotine patch, gum, and lozenge?

    PROBE: Did you ever prescribe NRT to patients (Dentists only)? Any other stop-smoking medications?

    [If they recommend or prescribe NRT] How do patients react to this? Is it a standard part of a visit or ad hoc (e.g., depends on patient engagement or readiness to quit)?

C. INNOVATION AND FACILITATION FACTORS

INTERVIEWER SECTION INTRODUCTION: *As I mentioned at the beginning, the main purpose of this interview is to learn about your experiences with the FreSH study and to get your feedback on whether and how brief counseling and nicotine replacement therapy sampling could be implemented in dental practices outside of a research study. In this next section, I'd like to talk about your experiences with implementing the FreSH study in your practice.*

C1. Feedback on interventions

Feedback on delivering AAR

11. Did you deliver "ask, advise, refer" counseling to any patients?

    IF NO, ASK: Who in your practice typically provided "ask, advise, refer" to patients?

    IF YES, ASK: Could you talk a bit about your experience with providing AAR to patients?

    Did any other staff in the practice also provide AAR? How did you decide who would provide AAR to each patient?

    PROBE:
    - What, if anything, was challenging about delivering AAR?
    - What, if anything, went well?
    - How long did it take to provide AAR?
    - Were you able to electronically refer patients to Quit Partner or the quit line?
    - Did you ever conduct AAR with patients not enrolled in the study? Why/why not?

12. In what type(s) of visits was it most feasible to provide AAR?

    PROBE: During a typical preventive or restorative care visit? Other visit types?

13. How did patients react to receiving AAR in the context of a routine dental visit? Were they accepting of it? Please explain.

    PROBE:
    - Were some patients more accepting than others?
    - Are their common characteristics of patients who are more or less accepting? (e.g., age, race/ethnicity, gender, motivation to quit or stage of change [pre-contemplative vs. already taking steps to reduce or quit])?

Feedback on providing NRT samples

14. Did you personally provide patients with samples of NRT?

    IF NO, ASK: Who in your practice typically provided NRT samples to patients?

    IF YES, ASK: Could you talk a bit about your experience with providing NRT samples to patients?

    PROBE:

- What, if any, challenges or problems came up when providing NRT samples?
    - How did you address those challenges?
- Did any other staff in the practice also provide NRT samples?
    - How did you decide who would provide NRT samples to each patient?

15. In what type(s) of visits was it most feasible to provide NRT samples?

    PROBE: During a typical preventive or restorative care visit? Other visit types?

16. How did patients react to receiving NRT samples during a dental visit? Please explain.

    PROBE:
    - How did they say they planned to use the sample?
    - What types of questions or concerns did patients raise about NRT, if any?
        - For example, safety concerns?
    - Did anyone call you after their visit to ask questions or express concerns about NRT? How did you respond?
    - Were some patients more accepting than others?
    - Did this vary by patient characteristics (e.g., age, race/ethnicity, gender)?

C2. Maintenance and sustainability

17. In the future how will you address tobacco use for patients who smoke as a result of participation in the FreSH study? Please explain.

    PROBE:
    - In what ways – if any – has the FreSH study changed how your clinic approaches patient smoking cessation?
    - Specific study components: screening for tobacco use, AAR, NRTS, referral process?

18. How sustainable do you think the FreSH study components (AAR, NRTS) are in the long-term?

    PROBE:
    - Are there any aspects of the FreSH study that you plan to or are interested in continuing into the future?
    - Specific study components: screening for tobacco use, AAR, NRTS, referral process?
    - Are there any factors associated with your practice that make it more or less likely to sustain these components? What about other dental practices?

19. What –if any– are/were the major barriers to continuing the study interventions (AAR; NRTS) in your practice after the study?

PROBE:

- What components have you discontinued?
- Why did you discontinue them?
    - Perceived value/effectiveness for patients?
    - Staff burden or availability (e.g., not enough time)?
    - Costs associated with NRT (for your practice; for patients)?
    - Patient willingness to engage in AAR/NRTS?

20. What would be the cost of maintaining these components (e.g., purchasing more NRT, staff time/training, visit length) for your practice?

PROBE:

- Do you think these costs would be manageable for your practice? For other practices? Please explain.
- Who do you think should (or would) pay for NRT samples if NRTS was implemented in dental practices outside of a study context (e.g., Quitlines, pharmaceutical companies, health insurance companies)?

C3. Facilitation and future implementation

21. Do you think that AAR and NRT sampling could or should be implemented in other practices as part of routine dental care? Why or why not.

PROBE:

- What barriers do you anticipate to adoption in other dental practices (e.g., cost, staff buy-in, legal)?

22. What factors do you think may be needed in order for other dental practices to adopt NRT sampling outside of a study context? (e.g., implementation support, structural changes, payer considerations)

PROBE:

- What would need to change in order to allow for widespread adoption of NRT sampling?
- What benefits and challenges would you anticipate if NRT sampling was to be offered in *all* dental practices as part of routine dental care?

23. What factors might help to increase fidelity to the brief counseling and NRT sampling intervention components (i.e., delivering the interventions as designed/intended) outside of a study context?

PROBE:

- (If not already discussed) Were there any other changes you made to the study protocol to adapt to your practice?

24. What are the main benefits and challenges of AAR and NRT sampling that you would want to share with other dental practices who may be looking for ways to help their patients who use tobacco?

D. ADDITIONAL FEEDBACK

25. Have you heard any other feedback from patients about their experiences with the study interventions (AAR & NRTS)?

26. Do you have any other comments, questions, or suggestions that we have not yet discussed?

Thank you for your time!
END

FreSH Consecutive Eligible Patient SCREENING & ENROLLMENT Log

Practitioner Name: _____ Page Start Date: _____/_____/_____

Practitioner ID: _____ Page End Date: _____/_____/_____

Patient eligibility Criteria		**Dentist exclusion criteria**	**Dentist decline criteria**
• ≥18 years (≥19 years in Nebraska) • Smokes at least 1 cigarette per day or 25/month • Has & willing to use smartphone for study • Not previously participated in the study • Speaks and reads English • Willing to comply with all study procedures and be available for the duration of the study	• Is not currently pregnant or breastfeeding • Willing and able to provide informed consent • No Myocardial infarction or stroke in the past 3 months • No Use of tobacco cessation medication in the past week	• Patient does not meet eligibility criteria	• Too busy to recruit patient • Patient has history of noncompliance • Other practice issue

Only patients who meet <u>all</u> eligibility criteria above should appear on this log.

WEEK #	**DATES**	**DID NOT RECRUIT THIS WEEK**	**REASONS FOR NOT PARTICIPATING** **Check (√) mark under a reason for each person who is screened eligible but does not participate**		
	Enter dates for this week (Sunday-Saturday)	***Check (√) if no recruitment occurred this week***	***Patient declined screening (eligible, but declined)***	***Dentist excluded (Patient was not eligible)***	***Dentist declined (see above)***
Example	***1/2/22 - 1/8/22***		***√√***	***√***	
Week 1					
Week 2					
Week 3					
Week 4					
Week 5					
Week 6					
Week 7					

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Week 29					
Week 30					

Thank you for joining the Free Samples for Health (FreSH) study during your visit to your Dentist! As a part of this study, you received a ClinCard.

In order to activate your ClinCard, please call or text our team to let us know you've received it: 612-791-3919

Each time you complete a visit, you will be paid on this card. It works the same as a debit card. With your ClinCard, you received some information which we highly recommend you take some time to read. We wanted to point out a few key pieces of information:

-You will not be able to be paid until your card is active.

-If your card is stolen, please call our team instead of the ClinCard support line (612-791-3919). We will be able to provide you a new card without a fee.

-Just like other ATMs, you may have to pay to remove cash. However, you can avoid this fee by using ClinCard's in-network ATMs (via Fifth Third Bank). You can find one near you at this website, by selecting "5/3 ATMS"
https://locations.53.com/search.html

-If you don't use your ClinCard/receive a new payment for six months, there is a fee that will be deducted your balance. Be sure to use your ClinCard or withdraw the balance within 6 months of payment.

If you have any further questions about how to use your ClinCard, please call us at 612-791-3919 or email at fresh@hhrinstitute.org.

Sincerely,
FreSH study team
fresh@hhrinstitute.org

Medication distribution SOP

FreSH

04/24/2023

Medication acquisition:

- Medication (nicotine patch 14mg and nicotine lozenge 4mg) will be obtained directly from GlaxoSmithKline by Hennepin Healthcare Research Institute.
- Hennepin Healthcare Research Institute will keep a log of all medication in its possession including when it was obtained and expiration dates.

Medication distribution:

- Hennepin Healthcare Research institute will package sample medications into sample bags and ship pre-packaged bags directly to practices.
- Medication expiration dates will be closely monitored and samples will be sent out in batches to practices to avoid risk of medication being very close to the expiration date when distributed. If samples become expired, Hennepin Healthcare Research Institute will send new samples with instructions to discard old samples.
- Upon shipping, Hennepin Healthcare Research Institute will note in the FreSH study 3 sample tracking log the practice to which the samples are shipped, the condition to which the practice was assigned (NRTS), the shipping date, tracking number, the date the samples were confirmed received by the practice, the medication expiration date and lot number.

Sample storage:

- Samples are to be stored at room temperature.
- Samples must be discarded if they are past expiration date, noted in the log.

In case of recall:

- If there is a recall on any of the lots of medication distributed to a practice, all participants from that practice will be notified directly by Hennepin Healthcare Research Institute to discard affected medications. If the participant has unused medications, Hennepin Healthcare Research Institute will work with the participant to obtain replacements.