

## CONSENT FORM TO BE PART OF A RESEARCH STUDY: PATIENTS

**Title of Research:** Free Samples for Health (FreSH) Study 3

**UAB IRB Protocol #:** 3000010014

**Principal Investigator:** Sandra Japuntich, Ph.D.

**Sponsor:** National Institutes of Health

<b>General Information</b>	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. The procedures, risks, and benefits are fully described further in the consent form.
<b>Purpose</b>	The purpose of the study is to test whether samples of nicotine replacement therapy or electric toothbrushes change the smoking habits of dental patients.
<b>Duration &amp; Visits</b>	You will be in this study for six months. There will be 1 in-person visit and 4 follow-up assessments that are conducted via email or text.
<b>Overview of Procedures</b>	This study will include brief advice about your smoking from an oral health provider. You will receive either an electric toothbrush or a 2-week supply of nicotine replacement therapy patches or lozenges. You will be asked to participate in 5 surveys. The surveys will take place at your dental visit, after your dental visit, and at 1-, 3-, and 6-months following your dental visit. Each survey will take approximately 5-20 minutes to complete. These surveys can be completed on any personal device, such as a computer, tablet or a smartphone. You may be sent a self-administered CO (carbon monoxide) monitor to take an exhaled CO breath test. Finally, you may be asked to do a recorded telephone interview. The interview will ask for feedback about the procedures that you experience during the study. This interview will take approximately 60 minutes.
<b>Risks</b>	The most common risks include side effects of nicotine replacement therapy. The nicotine patch and nicotine lozenge are available over the counter. The most common side effects of the nicotine lozenge are nausea/stomach upset, mouth/throat irritation, and hiccups. The most common side effects of the nicotine patch include local skin irritation at the site of the patch, disturbed sleep and vivid dreams, headache, and nausea. Less common are allergic skin reactions to the patch.
<b>Benefits</b>	You may or may not improve your oral or physical health as part of the study by stopping smoking or improving your oral hygiene.
<b>Alternatives</b>	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. Not participating will not affect your care as a patient of your dentist.

### Purpose of the Research Study

We are asking you to take part in a research study because you smoke cigarettes, own a smartphone with reliable internet access (data plan and/or Wi-Fi) and are a dental patient at a National Dental Practice-Based Research Network practice participating in this study. The purpose of this current research study is to test whether giving patients samples of either nicotine replacement therapy (nicotine patch and nicotine lozenge) or electric toothbrushes changes their smoking behavior. This study will enroll approximately 1200 participants. There will be up to 24 participants enrolled from your dental practice.

## **Study Participation & Procedures**

In this study, you will receive:

- brief advice from your dental provider about your smoking
- a referral to your state quit line (telephone counseling program to help people stop or reduce smoking).
- a sample of either a 1) nicotine replacement therapy (a two-week supply of 14mg nicotine patches and 4mg nicotine lozenges); or 2) an electric toothbrush.

Your dental practice has been randomly assigned (like flipping a coin) to either give samples of nicotine replacement therapy or electric toothbrushes. You will not know which sample you will receive until after you have enrolled in the study.

You will also be asked to complete five surveys over 6 months about you, your tobacco use, and oral health. These surveys will be completed over the internet and will be sent to you via email or text message on your personal device (computer, tablet, or smartphone). If you do not complete the survey by email or text, we will call you to complete the survey and may send the survey by mail. It will take approximately 5 minutes to complete the baseline survey, 10 minutes to complete the after-visit survey, and 20 minutes to complete each of the three follow-up surveys. The surveys will be completed at the following times:

- Before or during your dental visit.
- After your dental visit (survey will be sent within 24 hours of your visit).
- 1 month after your dental visit.
- 3 months after your dental visit.
- 6 months after your dental visit.

In addition, six months after your dental visit, we may mail you a device called the iCO quit personal smokerlyzer that connects to your smartphone with Bluetooth (wireless connection) and works with the Smokerlyzer app. The Smokerlyzer looks like a tube. To take the test, you will hold your breath for 15 seconds and then slowly exhale into the tube. The Smokerlyzer measures the level of carbon monoxide (CO) in your breath. People who smoke cigarettes have more CO in their breath than people who do not smoke. You will download the Smokerlyzer app on your phone to take the CO test. You will take the CO test within 24 hours of receiving the CO monitor. It will take approximately 5 minutes to complete the CO breath test. You can delete the Smokerlyzer app from your smart phone after you have completed the CO test procedure.

Finally, six months after your dental visit, you may complete a telephone interview about your experiences in the study. This interview will be conducted by study investigators from Northwestern University and will be audiorecorded and professionally transcribed and will take approximately 60 minutes.

Participation in this study will last approximately six months.

You will be asked to provide emergency contacts who would know how to reach you if the study cannot reach you. If we cannot reach you for the surveys, breath test, or interview, we will call your emergency contacts and ask for updated contact information for you. We may also ask your dental provider for your updated contact information if we cannot reach you.

### **Additional Information:**

Your de-identified private information may be used for future research studies or distributed to another researcher for future research studies without additional informed consent.

The clinical results (including individual research results) will not be returned to you.

### **Risks and Discomforts**

You may have some side effects from taking the study drugs.

The side effects of the nicotine patch are:

- Local skin irritation at the site of the patch (about 15% of people)
- Disturbed sleep and vivid dreams (about 11% of people)
- Headache (about 4% of people)
- Nausea (about 4% of people)
- Allergic skin reactions to the patch (rare)

The side effects of the nicotine lozenge are:

- Nausea or upset stomach (about 8% of people)
- Mouth/throat irritation (about 7% of people)
- Hiccups (about 6% of people)

You may find the brief advice from your dentist, or study assessments to be upsetting. You are at risk of loss of confidentiality of your study information.

There may also be risks that are unknown at this time. You will be given more information if other risks are found.

You will be assigned to a group by chance, which may prove to be less effective or to have more side effects than the other study group or alternatives.

### **Information for Women of Childbearing Potential and Nursing Mothers**

Nicotine replacement therapy is not recommended for women who are pregnant or breastfeeding. Therefore, breastfeeding and pregnant women are not allowed to take part in the study. If you decide to take nicotine replacement therapy, you must be using an effective form of birth control. Effective birth control includes birth control pills, patch, IUD, condom, sponge, diaphragm with spermicide, abstinence, or any other method prescribed by your physician. If you become pregnant, do not take nicotine replacement therapy (patches or lozenges).

### **Benefits**

As a result of the study treatment, you may improve your physical or oral health by stopping smoking or improving your oral hygiene. You may not benefit directly from taking part in this study. However, this study may help us better understand how oral health practitioners can help patients stop smoking.

### **Alternatives**

You do not have to take part in this study if you do not want to, it is your choice. Not participating will not affect your care as a patient of record with your dentist.

## Confidentiality

Information obtained 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 Institutional Review Board (IRB). An IRB is a group that reviews the study to protect the rights and welfare of research participants.
- National Institutes of Health (the study sponsor)
- the Office for Human Research Protections (OHRP)
- Landmark Associates (a professional transcription company)
- National Dental Practice-Based Research Network Administrative and Resource Center (University of Alabama at Birmingham) and National Coordinating Center for the National Dental Practice-Based Research Network (Kaiser Permanente Center for Health Research)
- Hennepin Healthcare/Hennepin Healthcare Research Institute (Minneapolis, MN; one of the institutions conducting the study)
- Northwestern University (Chicago, IL; one of the institutions conducting the study)

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 Institute of Dental and Craniofacial Research 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 or neglect, risk of 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.

A description of this clinical trial will be available on [www.ClinicalTrials.gov](http://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.

**Voluntary Participation and Withdrawal**

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. Your choice to leave the study will not affect your dental care in any way. Contact the study doctor 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 your personal doctor or the study principal investigator decides it is not in the best interest of your health, or if you are not following the study rules.

**Cost of Participation**

There will be no cost to you for taking part in this study. All study treatments are provided to you at no cost.

**Payment for Research-Related Injuries**

UAB has not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

**Payment for Participation**

You will receive \$20 for completing the after-visit survey and \$20 for completing each of the three follow-up surveys (1-month, 3-month, and 6-month). If you are selected to take a CO test, you will be sent an iCO quit personal smokerlyzer CO monitor and will receive \$50 for completing the CO test. If you are selected to complete a telephone interview, you will receive \$50 if you complete the interview.

You will receive payments via ClinCard, a reloadable debit card. Money will be added to the card within two weeks of completing surveys or interviews.

**New Findings**

You will be told by the study doctor or the study staff if new information becomes available that might affect your choice to stay in the study.

**Questions**

If you have any questions, concerns, or complaints about the research or a research-related injury including available treatments, please contact the study doctor. You may contact Dr. 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.

**Legal Rights**

You are not waiving any of your legal rights by signing this consent form.

**Signatures**

Your signature below indicates that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

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Signature of Participant

Date

**Contact Information**

**Please complete the contact information form so we can reach you for study participation.**

1. Name: \_\_\_\_\_

2. Mailing Address (to receive study materials and/or payment):

\_\_\_\_\_  
\_\_\_\_\_

3. Please provide your email address below to receive online survey links, reminders to complete surveys, and/or payment. All emails will be sent from Fresh@hhrinsitute.org.

Email address:

\_\_\_\_\_

Confirm email address:

\_\_\_\_\_

4. What is your date of birth? \_\_\_\_\_

Please provide your phone number(s) below. Please only provide phone numbers where we can leave a message saying we are calling from the FreSH study.

5. Home phone: (     ) \_\_\_\_\_

6. Cell phone: (     ) \_\_\_\_\_

7. Are you willing to receive texts about this study, including links to the surveys?   Yes   No

8. Do you prefer to receive study surveys via email or text?   Email   Text

9. Would you like to receive notifications when payment has been added to your card?

          Email           Text           None

10. In case we cannot reach you, please list up to 3 alternate contacts who we can contact to get your updated contact information.

Name	Relationship	Phone
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_____	_____	_____
_____	_____	_____
_____	_____	_____

Subject ID# \_\_\_\_\_  
Date \_\_\_\_\_

**FreSH**  
**(Free Samples for Health)**  
**Baseline Patient Survey**

**The following questions are about you:**

1. What was your biological sex at birth?

- Male
- Female
- Intersex
- None of these describe me
- Other \_\_\_\_\_
- Prefer not to say

2. What is your current gender identity?

- Male
- Female
- Transgender
- Non-binary
- Something else: \_\_\_\_\_
- Prefer not to answer

3. What is your age?

\_\_\_\_\_ years

4. Are you of Hispanic or Latino Origin?

- Yes
- No

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

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

**The following questions are about your oral health:**

6. How often do you brush your teeth?

- Do not
- Once per day
- Twice per day
- More than twice a day
- Sporadically
- N/A (Full dentures – upper and lower)



7. What type of toothbrush do you use when you brush your teeth?

- Mostly or always a manual or non-electric toothbrush
- Mostly or always an electric toothbrush
- Sometimes a manual toothbrush and sometimes an electric toothbrush

**The following questions are about your tobacco use:**

8. On average, how many cigarettes do you smoke each day?

\_\_\_\_\_ cigarettes

9. How soon after you wake up do you smoke your first cigarette?

- Within 5 minutes
- Within 6-30 minutes
- Within 31-60 minutes
- After 60 minutes

10. In the past, have you ever made a serious attempt to quit smoking? That is, have you stopped smoking for at least one day or longer because you were trying to quit?

- Yes
- No

11. In your lifetime, how many times have you stopped smoking for one day or longer because you were trying to quit smoking for good?

\_\_\_\_\_ times

12. After you started smoking regularly, what is the longest period of time you ever went without smoking?

- |   |  |
|---|--|
| <input type="checkbox"/> Less than a day    | <input type="checkbox"/> Between 1 and 3 months  |
| <input type="checkbox"/> 1-7 days           | <input type="checkbox"/> Between 3 and 6 months  |
| <input type="checkbox"/> 8-14 days          | <input type="checkbox"/> Between 6 and 12 months |
| <input type="checkbox"/> 15 days to 1 month | <input type="checkbox"/> More than a year        |

13. Have you ever used any of the following quit smoking methods? Select all methods that you have ever tried, even if you did not quit successfully or continued smoking while using the method.

	YES	NO
Abruptly quit on my own (cold turkey)	<input type="checkbox"/>	<input type="checkbox"/>
Gradually cut down prior to quitting	<input type="checkbox"/>	<input type="checkbox"/>
Nicotine patch	<input type="checkbox"/>	<input type="checkbox"/>
Nicotine gum	<input type="checkbox"/>	<input type="checkbox"/>
Nicotine lozenge	<input type="checkbox"/>	<input type="checkbox"/>
Nicotine nasal spray	<input type="checkbox"/>	<input type="checkbox"/>
Nicotine inhaler	<input type="checkbox"/>	<input type="checkbox"/>
Nicotine lozenge	<input type="checkbox"/>	<input type="checkbox"/>
Zyban (Bupropion SR)/Wellbutrin	<input type="checkbox"/>	<input type="checkbox"/>
Chantix (Varenicline)	<input type="checkbox"/>	<input type="checkbox"/>
Electronic cigarette	<input type="checkbox"/>	<input type="checkbox"/>
Individual sessions or counseling	<input type="checkbox"/>	<input type="checkbox"/>
Group sessions/ group classes	<input type="checkbox"/>	<input type="checkbox"/>
Called a quitline	<input type="checkbox"/>	<input type="checkbox"/>
Consulted my healthcare provider	<input type="checkbox"/>	<input type="checkbox"/>
Consulted the internet	<input type="checkbox"/>	<input type="checkbox"/>
Smartphone application	<input type="checkbox"/>	<input type="checkbox"/>
Other (specify)_____	<input type="checkbox"/>	<input type="checkbox"/>

14. How important is stopping smoking to you?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1	2	3	4	5	6	7	8	9	10

**Not  
important  
at all**

**Most  
important  
goal of  
my life**

15. How ready are you to quit smoking in the next month?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1	2	3	4	5	6	7	8	9	10

**Not at all  
ready**

**100%  
ready**

16. If you decided to quit, how confident are you that you could quit smoking within the next month and stay quit for good?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1	2	3	4	5	6	7	8	9	10

**Not at all**

**100%  
Confident**

17. Are you considering quitting smoking during the next 6 months?

- Yes, plan to stop within the next 30 days,
- Yes, plan to stop within the next 6 months but not within the next 30 days
- No, not thinking of quitting in the next 6 months

18. Which of the following best describes how you feel about using the nicotine patch?

- |  |  |
|--|--|
| <input type="checkbox"/> I plan to start using the nicotine patch in the next 30 days  | <input type="checkbox"/> I may use the nicotine patch some day |
| <input type="checkbox"/> I plan to start using the nicotine patch in the next 6 months | <input type="checkbox"/> I will never use the nicotine patch   |

19. Which of the following best describes how you feel about using nicotine lozenges?

- I plan to start using nicotine lozenges in the next 30 days
- I plan to start using nicotine lozenges in the next 6 months
- I may use nicotine lozenges some day
- I will never use nicotine lozenges

20. Nicotine replacement therapy products (also known as NRT) include the nicotine patch, gum, lozenge, nasal spray, and inhaler. On a scale from 1 to 5, where 1 is not at all and 5 is very, how concerned are you about the safety of NRT products?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
Not at all			Very	

21. On a scale from 1 to 5, where 1 is not at all and 5 is a lot, how much do you think NRT products improve a smoker's chance of quitting successfully?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
Not at all			Very	

Subject ID# \_\_\_\_\_  
Date \_\_\_\_\_

**FreSH**  
**(Free Samples for Health)**  
**After Visit Patient Survey**

**The following are questions about your most recent dental visit:**

Our records indicate that you visited your dentist on \_\_\_\_\_ (date). Thinking back on that visit, did your dentist or hygienist....

1. Ask whether you smoke cigarettes?

- Yes
- No
- Don't know/not sure
- Prefer not to answer

2. Advise you to quit smoking?

- Yes
- No
- Don't know/not sure
- Prefer not to answer

3. Ask about your willingness or readiness to quit smoking?

- Yes
- No
- Don't know/not sure
- Prefer not to answer

4. Discuss medications that may help you to quit smoking?

- Yes
- No
- Don't know/not sure
- Prefer not to answer

5. Advise you to use medication to quit smoking?

- Yes
- No
- Don't know/not sure
- Prefer not to answer

6. Provide you with medication to quit smoking?

- Yes

- No
- Don't know/not sure
- Prefer not to answer

7. Refer you to the state smoking cessation quitline?

- Yes
- No
- Don't know/not sure
- Prefer not to answer

**The following are questions about you:**

8. Indicate your highest level of formal education

- Less than high school diploma
- High school diploma or GED
- Some college/associate's degree
- Bachelor's degree
- Graduate degree
- Prefer not to answer

9. How would you describe the community where you live?

- Urban
- Suburban
- Rural
- Prefer not to answer

10. What is the zip code where you live? \_\_\_\_\_

- Prefer not to answer

11. Including you, how many people live in your household? \_\_\_\_\_

- Prefer not to answer

12. What is your current family household income?

- Up to (less than or equal to) \$25,000
- \$25,001-\$50,000
- \$50,001-\$100,000
- Over \$100,000
- Prefer not to answer

13. The next question asks about your health insurance or health coverage plans. In answering this question, please exclude plans that pay for only one type of service (such as nursing home care, accidents, family planning, or dental care) and plans that only provide extra cash when hospitalized. Are you currently covered by any of the following types of health insurance or health coverage plans? (Select all that apply.)

- No health insurance
- Insurance through a current or former employer or union (of yours or another family member's). This would include COBRA coverage
- Insurance purchased directly from an insurance company (by you or another family member) This would include coverage purchased through an exchange or marketplace, such as healthcare.gov
- Medicare, for people 65 and older, or people with certain disabilities
- Medicaid or any kind of state or government-sponsored assistance plan based on income or disability
- TRICARE or other military health care, including VA health care
- Indian Health Service
- Any other type of health insurance coverage or health coverage plan
- I don't know
- Prefer not to answer

14. What type of dental insurance do you have? (Check all that apply)

- No dental insurance
- Private insurance (e.g., employer sponsored, commercial, HMO, etc.)
- Public/government insurance (Medicaid, military or veterans benefit, etc.)
- Other \_\_\_\_\_
- I don't know
- Prefer not to answer

15. In the past 30 days, on how many days did you use each of the following products (if you did not use the product, enter 0):

- Electronic cigarettes, e-cigarettes, or vapes: \_\_\_\_\_ days (0-30)
  - Prefer not to answer
- Cigars, little cigars, cigarillos: \_\_\_\_\_ days (0-30)
  - Prefer not to answer



- Smokeless tobacco, chewing tobacco, snuff, or snus: \_\_\_\_\_ days (0-30)
  - Prefer not to answer

- Hookah or pipe tobacco: \_\_\_\_\_ days (0-30)
  - Prefer not to answer

**The following questions are about your dental care:**

16. How long have you been going to this practice to receive dental care? Answer in months or years. If you do not know, provide your best guess.

\_\_\_\_\_ months, or \_\_\_\_\_ years

- Prefer not to answer

17. How much would you say you trust your dentist and the other staff (e.g., dental hygienists) at this practice?

- Do not trust at all
- Somewhat trust
- Moderately trust
- Completely trust
- Prefer not to answer

**The following are questions about your oral health:**

18. How would you rate your overall oral health (teeth, gums, inside of mouth)?

- Excellent
- Good
- Fair
- Poor
- Don't know
- Prefer not to answer

19. During the past month, have you...

	<b>0 Never</b>	<b>1 Hardly ever</b>	<b>2 Occasionally</b>	<b>3 Fairly often</b>	<b>4 Very often</b>	<b>Prefer not to answer</b>
a. Had difficulty chewing any foods because of problems with your teeth, mouth, dentures or jaw?	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>777</b>
b. Had painful aching in your mouth?	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>777</b>
c. Felt uncomfortable about the appearance of your teeth, mouth dentures or jaws?	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>777</b>
d. Felt that there has been less flavor in your food because of problems with your teeth, mouth, dentures or jaws?	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>777</b>
e. Had difficulty doing your usual jobs because of problems with your teeth, mouth, dentures or jaws?	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>777</b>

**[NRT condition only] The following questions are about your experience with receiving nicotine replacement therapy samples and talking to your provider about your smoking during the FreSH study:**

**[ET condition only] The following questions are about your experience with receiving an electric toothbrush and talking to your provider about your smoking during the FreSH study:**

20. How would you rate the quality of service you received from the FreSH study?

- Excellent
- Good
- Fair
- Poor
- Prefer not to answer

21. Did you get the kind of service you wanted from the FreSH study?

- No, definitely not
- No, not really
- Yes, generally
- Yes, definitely
- Prefer not to answer

22. To what extent has the FreSH study met your needs?

- Almost all of my needs have been met
- Most of my needs have been met
- Only a few of my needs have been met
- None of my needs have been met
- Prefer not to answer

23. If a friend were in need of help quitting smoking, would you recommend the FreSH study intervention to them?

- No, definitely not
- No, I don't think so
- Yes, I think so
- Yes, definitely
- Prefer not to answer

24. How satisfied are you with the amount of help you received from the FreSH study?

- Quite dissatisfied
- Indifferent or mildly dissatisfied
- Mostly satisfied
- Very satisfied
- Prefer not to answer

25. Have the services you received from the FreSH study helped you to deal more effectively with your smoking?

- Yes, they helped a great deal
- Yes, they helped somewhat
- No, they really didn't help,
- No, they seemed to make things worse
- Prefer not to answer

26. In an overall, general sense, how satisfied are you with the service you received from the FreSH study?

- Mostly Satisfied
- Very satisfied
- Indifferent or mildly dissatisfied
- Quite dissatisfied
- Prefer not to answer

27. If you were to want help with your smoking in the future, would you come back to the FreSH study?

- No, definitely not
- No, I don't think so
- Yes, I think so
- Yes, definitely
- Prefer not to answer

Subject ID# \_\_\_\_\_

Date \_\_\_\_\_

**FreSH**  
**(Free Samples for Health)**  
**Follow Up Patient Survey**

**The following questions are about your tobacco use:**

1. Since your [visit with your dentist on (date)]/[your last survey on (date)], have you had any cigarettes at all, even a puff?

- Yes [go to question 2]
- No [go to question 4]
- Prefer not to answer

2. [if yes to question 1] How many cigarettes did you smoke on:

Day 1 (this day last week) \_\_\_\_\_ cigarettes

Day 2: \_\_\_\_\_ cigarettes

Day 3: \_\_\_\_\_ cigarettes

Day 4: \_\_\_\_\_ cigarettes

Day 5: \_\_\_\_\_ cigarettes

Day 6: \_\_\_\_\_ cigarettes

Day 7 (yesterday) \_\_\_\_\_ cigarettes

- Prefer not to answer

3. [if 0 on all of the past 7 days] When was the last day you had a cigarette? (If you do not remember the exact date, take your best guess) \_\_\_\_\_

- Prefer not to answer

4. Have you used any other tobacco products besides cigarettes in the past 7 days? Check all that apply.

- Electronic cigarettes (e-cigarettes) or vapes
- Hookah
- Cigars
- Chewing tobacco, smokeless tobacco, or snuff
- Snus
- Pipes
- Other: \_\_\_\_\_
- Prefer not to answer

5. Since your [visit with your dentist on (date)]/[last follow-up survey on (date)] have you made a serious attempt to quit smoking? That is, have you stopped smoking for at least one day or longer because you were trying to quit?

- Yes
- No
- Prefer not to answer

6. If yes: How many times did you stop smoking for at least one day or longer because you were trying to quit? \_\_\_\_\_

- Prefer not to answer

7. When was the first such attempt to stop smoking? (Enter the date it started.)

\_\_\_\_\_

- Prefer not to answer

8. Of the number of times you tried to stop smoking since [date], think about the longest - how many days did that last? \_\_\_\_\_

- Prefer not to answer

**Medication use:**

5. Since your [visit with your dentist on (date)]/[last follow-up survey on (date)], have you used a nicotine patch?

- Yes [**continue to item 6**]
- No [**skip to item 11 if NRT condition, item 13 for ET condition**]
- Prefer not to answer

6. Since your [visit with your dentist on (date)]/ [last follow-up survey on (date)], on how many days did you use a nicotine patch?

\_\_\_\_\_

- Prefer not to answer

7. Did you use the patch on: (check all that apply)

- Day 1 (this day last week)
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7 (yesterday)
- Prefer not to answer
- N/A – Did not use patch in the last 7 days

8. Why did you use the patch? (check all that apply)

- To help me try quit smoking completely
- To help me try to reduce how much I smoke
- To help me get through times when I cannot smoke
- I was curious or I wanted to see if I liked it
- Other: (describe)  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_
- Prefer not to answer

9. On a scale from 0-10, how much did you like the patch?

\_\_\_\_\_ (0 = didn't like it at all, 10 = loved it)

- Prefer not to answer

10. On a scale from 0-10, how effective was the patch in helping you deal with cravings to smoke? \_\_\_\_\_ (0 = not effective at all, 10 = extremely effective)

- Prefer not to answer

11. (NRT only) What did you do with the nicotine patches that you received from your dental office for the FreSH study?

- Used them myself
- Haven't tried them yet but plan to try them in the future
- Haven't tried them yet and don't plan to try them in the future
- Threw them away
- Gave them away
- Other \_\_\_\_\_
- Prefer not to answer



12. (NRT only) Did you obtain any of your own patches (patches that you did NOT receive from your dental office for the FreSH study)?

- Yes
- No
- Prefer not to answer

13. Since your [visit with your dentist on (date)]/[last follow-up survey on (date)], have you used a nicotine lozenge?

- Yes [**continue to item 14**]
- No [**skip to 22 for ET condition, 20 for NRTS condition**]
- Prefer not to answer

14. Since your [visit with your dentist on (date)]/[last follow-up survey on (date)], on how many days did you use a nicotine lozenge? \_\_\_\_\_ days

- Prefer not to answer

15. On a typical day when you used the lozenge, how many lozenges did you use?

\_\_\_\_\_ lozenges

- Prefer not to answer

16. How many lozenges did you use on:

\_\_\_\_\_ Day 1 (this day last week)

\_\_\_\_\_ Day 2

\_\_\_\_\_ Day 3

\_\_\_\_\_ Day 4

\_\_\_\_\_ Day 5

\_\_\_\_\_ Day 6

\_\_\_\_\_ Day 7 (yesterday)

- Prefer not to answer

17. Why did you use the lozenge? (check all that apply)

- |   |   |
|---|---|
| <input type="checkbox"/> To help me try to quit smoking completely        | <input type="checkbox"/> I was curious or I wanted to see if I liked it |
| <input type="checkbox"/> To help me try to reduce how much I smoke        | <input type="checkbox"/> Other: (describe)<br>_____                     |
| <input type="checkbox"/> To help me get through times when I cannot smoke | _____   |
|   | _____   |
|   | <input type="checkbox"/> Prefer not to answer                           |

18. On a scale from 0-10, how much did you like the lozenge?

\_\_\_\_\_ (0 = didn't like it at all, 10 = loved it)

- Prefer not to answer

19. On a scale from 0-10, how effective was the lozenge in helping you deal with cravings to smoke? \_\_\_\_\_ (0 = not effective at all, 10 = extremely effective)

- Prefer not to answer

20. **[NRTS only]** What did you do with the nicotine lozenges that you received from your dental office for the FreSH study?

- |  |   |
|--|---|
| <input type="checkbox"/> Used them myself  | <input type="checkbox"/> Gave them away       |
| <input type="checkbox"/> Haven't tried them but plan to try them in the future       | <input type="checkbox"/> Other<br>_____       |
| <input type="checkbox"/> Haven't tried them and don't plan to try them in the future | _____   |
| <input type="checkbox"/> Threw them away   | <input type="checkbox"/> Prefer not to answer |

21. **[NRTS only]** Did you obtain any of your own lozenges (lozenges that you did NOT receive from the FreSH study)?

- Yes  
 No  
 Prefer not to answer

22. Nicotine replacement therapy products (also known as NRT) include the nicotine patch, gum, lozenge, nasal spray, and inhaler. On a scale from 1 to 5, where 1 is not at all and 5 is very, how concerned are you about the safety of NRT products?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
<b>Not at all</b>				<b>A lot</b>

Prefer not to answer

23. On a scale from 1 to 5, where 1 is not at all and 5 is a lot, how much do you think NRT products improve a smoker's chance of quitting successfully?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
<b>Not at all</b>				<b>A lot</b>

Prefer not to answer

24. Which of the following best describes how you feel about using the nicotine patch?

- |  |  |
|--|--|
| <input type="checkbox"/> I am currently using the nicotine patch                       | <input type="checkbox"/> I may use the nicotine patch some day |
| <input type="checkbox"/> I plan to start using the nicotine patch in the next 30 days  | <input type="checkbox"/> I will never use the nicotine patch   |
| <input type="checkbox"/> I plan to start using the nicotine patch in the next 6 months | <input type="checkbox"/> Prefer not to answer                  |

25. Which of the following best describes how you feel about using nicotine lozenges?

- |   |   |
|---|---|
| <input type="checkbox"/> I am currently using nicotine lozenges                       | <input type="checkbox"/> I may use nicotine lozenges some day |
| <input type="checkbox"/> I plan to start using nicotine lozenges in the next 30 days  | <input type="checkbox"/> I will never use nicotine lozenges   |
| <input type="checkbox"/> I plan to start using nicotine lozenges in the next 6 months | <input type="checkbox"/> Prefer not to answer                 |

26. Since your [visit with your dentist on (date)]/[last follow-up survey on (date)] have you.....

	YES	NO	Prefer not to answer
Used Nicotine Gum?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Used Nicotine Inhaler?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Used Nicotine nasal spray?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Used Zyban (Bupropion SR)/Wellbutrin)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>IF YES:</b> Was the Zyban/Bupropion/Wellbutrin prescribed for smoking cessation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Used Chantix (Varenicline)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Talked to a physician or healthcare provider about quitting smoking?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Consulted the internet or used a smartphone app about quitting smoking?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Seen a counselor for smoking cessation or participated in smoking cessation classes or groups?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Called a quitline or phone-based quit smoking service	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other (Describe) _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

27. Since your [visit with your dentist on (date)]/[last follow-up survey on (date)] have you experienced....?

	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>777</b>
	<b>None</b>	<b>Mild</b>	<b>Moderate</b>	<b>Severe</b>	<b>Prefer not to answer</b>
Nausea	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>777</b>
Headache	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>777</b>
Heartburn	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>777</b>
Mouth soreness	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>777</b>
Dizziness or light headedness	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>777</b>
Dry mouth	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>777</b>
Sore jaw	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>777</b>
Excess salivation	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>777</b>
Insomnia or trouble sleeping	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>777</b>
Hiccups	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>777</b>
Burning in throat/mouth	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>777</b>
Skin irritation	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>777</b>
Skin redness	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>777</b>
Skin itchiness	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>777</b>

28. If yes to any of the above, do you believe that your [symptom] was caused by using the nicotine patch or lozenge?

	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>NA</b>	<b>777</b>
	<b>No</b>	<b>Unlikely</b>	<b>Possibly</b>	<b>Probably</b>	<b>Definitely</b>	<b>Did not have this symptom</b>	<b>Prefer not to answer</b>
Nausea	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>NA</b>	<b>777</b>
Headache	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>NA</b>	<b>777</b>
Heartburn	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>NA</b>	<b>777</b>
Mouth soreness	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>NA</b>	<b>777</b>
Dizziness or light headedness?	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>NA</b>	<b>777</b>
Dry mouth	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>NA</b>	<b>777</b>
Sore jaw	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>NA</b>	<b>777</b>
Excess salivation	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>NA</b>	<b>777</b>
Insomnia or trouble sleeping	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>NA</b>	<b>777</b>
Hiccups	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>NA</b>	<b>777</b>
Burning in throat/mouth	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>NA</b>	<b>777</b>
Skin irritation	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>NA</b>	<b>777</b>
Skin redness	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>NA</b>	<b>777</b>
Skin itchiness	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>NA</b>	<b>777</b>

**The following questions are about your motivation to quit smoking:**

29. How important is stopping smoking to you?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1	2	3	4	5	6	7	8	9	10	N/A
<b>Not important at all</b>									<b>Most important goal of my life</b>	<b>I have quit smoking</b>

Prefer not to answer

30. How ready are you to quit smoking within the next month?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1	2	3	4	5	6	7	8	9	10	N/A
<b>Not at all ready</b>									<b>100% ready</b>	<b>I have quit smoking</b>

Prefer not to answer

31. Are you considering quitting smoking during the next 6 months?

- Yes, plan to stop within next 30 days
- Yes, plan to stop within next 6 months, but not within next 30 days
- No, not thinking of quitting in next 6 months
- N/A, I have already quit
- Prefer not to answer

32. If you decided to quit, how confident are you that you could quit smoking within the next month and stay quit for good?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1	2	3	4	5	6	7	8	9	10	N/A
<b>Not at all</b>									<b>100% Confident</b>	<b>I have quit smoking</b>

Prefer not to answer



**The following questions are about your oral health. Select the best answer for each item:**

33. How often do you brush your teeth?

- Do not
- 1/day
- 2/day
- >2/day
- Sporadically
- N/A (full dentures - upper and lower)

34. What type of toothbrush do you use when you brush your teeth?

- Mostly or always a manual or non-electric toothbrush
- Mostly or always an electric toothbrush
- Sometimes a manual and sometimes an electric toothbrush

35. Since your [visit with your dentist on (date)]/[last follow-up survey on (date)], have you used an electric toothbrush?

- Yes **[Go to item 36]**
- No **[Go to item 37]**

36. **[ET only]**: did you use the electric toothbrush that you received from your dental office for the FreSH study?

- Yes **[go to 38]**
- No **[go to 37]**

37. **[ET only]**: What did you do with the electric toothbrush you received from your dental office for the FreSH study?

- Haven't tried it but plan to try it in the future
- Haven't tried it and don't plan to try it in the future
- Threw it away
- Gave it away

38. During the past month, have you had difficulty chewing any foods because of problems with your teeth, mouth, dentures or jaw?

- Never
- Hardly ever
- Occasionally
- Fairly often
- Very often

39. How would you rate your overall oral health (teeth, gums, inside of mouth)?

- Excellent
- Good
- Don't know
- Fair
- Poor

40. During the past month, have you felt uncomfortable about the appearance of your teeth, mouth dentures or jaws?

- Never
- Hardly ever
- Occasionally
- Fairly often
- Very often

41. During the past month, have you felt that there has been less flavor in your food because of problems with your teeth, mouth, dentures or jaws?

- Never
- Hardly ever
- Occasionally
- Fairly often
- Very often

42. During the past month, have you had difficulty doing your usual jobs because of problems with your teeth, mouth, dentures or jaws?

- Never
- Hardly ever
- Occasionally
- Fairly often
- Very often



[DATE]

Dear Research Participant:

Thank you for joining the Free Samples for Health (FreSH) study during your visit to your Dentist!

It has been \_\_\_ weeks/month(s) since your dental visit, so it is now time for your follow-up survey. We have tried to contact you several times but have been unable to reach you. We would love to hear from you regardless of whether or not you are smoking. It is very important that we hear from as many participants as possible.

[optional text: We are attaching a copy of the follow-up survey. We hope that you will complete it and send it back to us in the stamped envelope provided. It should take less than 15 minutes.] You can do the survey by phone (call us at 612-791-3919) or you can do the survey online at:

*[LINK to REDCap survey]*

When we receive your completed survey (mail, phone, or online), we will send you your payment of \$20 via a prepaid debit card. If your phone number has changed, please call or email us to update your phone number 612-791-3919 or [fresh@hhrinstitute.org](mailto:fresh@hhrinstitute.org).

We sincerely appreciate your time and effort to take part in our study. If you have any further questions about the study, please call us at 612-791-3919.

Sincerely,

Sandra Japuntich, Ph.D.  
FreSH study  
Principal Investigator

## FreSH study contact scripts:

### Email/text consent script:

“Thank you for your interest in the Free Samples for Health (FreSH) Study. Please click the following link to view the study consent form. Complete the form to enroll in the FreSH study. If you have questions about the FreSH study, contact us at: (612) 791-3919 or [fresh@hhrinstitute.org](mailto:fresh@hhrinstitute.org)”

### Survey email/text script:

“Thank you for enrolling in the FreSH study. Please complete the following survey as soon as possible at [LINK]. If you have questions about the FreSH study, contact us at: (612) 791-3919 or [fresh@hhrinstitute.org](mailto:fresh@hhrinstitute.org).”

### Survey call script:

“Hello, my name is \_\_\_\_\_. Am I speaking with \_\_\_\_\_?”

[If participant confirms identity] “I’m calling to follow up on a survey we sent you about the FreSH study that you joined during your last dental visit. Would you be willing to complete this survey? You will be paid \$20 for completing the survey.”

[If willing to complete the survey] “Wonderful. We can complete the survey by phone today. It should take no more than 10 minutes. Do you have time now?”

[If available now] Complete survey by phone.

[If doesn’t have time now] “I can either email or text the survey again for you to complete on your own, or I can schedule a time for someone to call you so that you may complete the survey by phone. Which would work best for you?” [Schedule a time, or email/text the survey]

[If unwilling to complete the survey] “I understand. Would you be willing to receive the survey by email/text to complete later?”

[If willing to receive survey] “Great! What is the best email/phone to send the survey?”

[If not willing to complete the survey] “Thank you for letting me know. Are you willing to complete future surveys for the FreSH study?”

[If willing to complete future surveys] “Thank you, we will email/text you when your next survey is due. Have a nice day.”

[If unwilling to complete future surveys] “I understand, we will remove you from the FreSH study and will no longer contact you. Thank you for your participation. Have a nice day.”

### Survey voicemail messages (if permission to leave message has been granted):

If participant does not answer:

“Hello, this is \_\_\_\_\_ calling from Hennepin Healthcare. We have been trying to reach you about the FreSH study that you enrolled in during your last dental visit. Please call us back at (612) 791-3919.”

If someone else answers:

“My name is \_\_\_\_\_. I’m calling from Hennepin Healthcare. We are trying to reach \_\_\_\_\_ about a research study. Do you know when they would be available for us to call back? Thanks! We will try to give them a call then. Please also let them know they can call us at (612) 791-3919. Thank you very much!”

#### iCOquit email/text

“Thank you for taking part in the FreSH study. You should have received a package containing an iCOquit personal CO monitor. Please follow the instructions and complete your CO test within 24 hours. If you have questions, respond to this message, or call us at (612) 791-3919.”

#### iCOquit phone script

“Hello, this is \_\_\_\_\_ calling from the FreSH study. XX days ago, you should have received a package from us containing a personal CO monitor called the iCOquit. I’m calling to encourage you to follow the instructions and take the CO test. Do you have any questions about taking the test? It’s very important to the study that you take the test as soon as possible.”

#### iCOquit voicemail

“Hello, this is \_\_\_\_\_ calling from the FreSH study. I’m calling because you should have received a package from us containing a test. Please open the package and follow the instructions as soon as possible. If you have questions about the test, please call us at (612) 791-3919.”

If someone else answers:

“My name is \_\_\_\_\_. I’m calling from Hennepin Healthcare. We are trying to reach \_\_\_\_\_ about a research study. Do you know when they would be available for us to call back? Thanks! We will try to give them a call then. Please also let them know they can call us at (612) 791-3919. Thank you very much!”

#### Interview scheduling e-mail/text:

“Thank you for taking part in the FreSH study. It is now time to schedule your end of study interview. Please reply to this message with 3 times when you would be available for a 1-hour phone interview.”

#### Interview scheduling call:

“Hello, this is \_\_\_\_\_. I’m calling from the FreSH study. We are calling to schedule your interview. The interview will last about an hour. The purpose of the interview is to gather your feedback about your experiences in the FreSH study. We have the following times available for an interview XXX, which would

work best for you? Or, if none of those times work, let us know what time you need and we will work around your schedule.”

Voicemail:

“Hello, this is \_\_\_\_\_ calling from Hennepin Healthcare. We have been trying to reach you about the FreSH study that you enrolled in during your last dental visit. Please call us back at (612) 791-3919.”

If someone else answers:

“My name is \_\_\_\_\_. I’m calling from Hennepin Healthcare. We are trying to reach \_\_\_\_\_ about a research study. Do you know when they would be available for us to call back? Thanks! We will try to give them a call then. Please also let them know they can call us at (612) 791-3919. Thank you very much!”

## NRT samples script

“In your bag, you will find samples of the nicotine patch and nicotine lozenges. These products can help people who smoke to quit, especially when they are used together. They won’t take all your withdrawal symptoms away but they will take the edge off. You can use either or both of them, though we encourage you to use both. Even if you’re not yet ready to quit, you might find that these products help control the craving to smoke. You can use these samples however you like. For example, you could use them to reduce smoking, to get started on quitting, to make a practice quit attempt, or during times when you cannot smoke. This is an opportunity to learn about two nicotine replacement therapy products that can be used individually or together. What you do with these products is up to you. I recommend you give these a try in the next week.”

“The nicotine patch provides a steady flow of nicotine throughout the day. Place the patch on your shoulder or back. Replace the patch every morning. Move the site of the patch each day to avoid getting a rash. If the patch causes trouble sleeping, you may take the patch off 1-2 hours before bed, although best results come from wearing it for 24 hours. I am giving you the 14mg patch, which is safe for all smokers to use. Heavier smokers (people who smoke more than 10 cigarettes per day), can use the 21mg patch if the 14mg patch does doesn’t control your cravings.”

“The nicotine lozenge is used by placing it between your cheek and your gums. The nicotine absorbs through your cheek. Do not chew or swallow the lozenge or it could upset your stomach. Try to use a lozenge every 1-2 hours (up to 20 per day). I am giving you the 4mg lozenge. If the lozenge feels too strong, you can spit it out halfway through.”

“If you have questions about the use of either medication, contact the FreSH study.”

## **Electric toothbrush script**

“Here is your Sonicare electric toothbrush. Studies show that electric toothbrushes result in better oral health than manual (non-powered) toothbrushes. Like manual toothbrushing, I recommend brushing twice a day with this toothbrush. Make sure you charge the toothbrush before you use it. The toothbrush has a two minute timer that will let you know you have brushed your teeth for the appropriate time, and a quadrant timer where the toothbrush vibrates every 30 seconds. Unlike a manual toothbrush, electric toothbrushes do the brushing for you. Starting with the outside surfaces of your teeth, gently guide the brush head slowly from tooth to tooth, holding the brush head in place for a few seconds against each tooth before moving to the next one. Do not press hard or scrub. Repeat with the inside surfaces of the teeth, the chewing surfaces, behind the back teeth, and along the gum line. I encourage you to use this toothbrush exclusively.”

“If you have questions about the electric toothbrush, contact the FreSH study.”



## FreSH Study 3

### Key Informant Interviews - Patient Interview Guide

*Synopsis: Hennepin Healthcare researchers will conduct one-on-one phone interviews 10-12 patients 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 patient participation in the study. Telephone interviews will be recorded using a digital audio recorder and transcribed to support thematic analysis.*

### Patient Interview

*When the patient answers the phone, the interviewer will introduce themselves, review the consent form, and obtain verbal consent for the interview.*

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.

#### A. RECIPIENT FACTORS

**INTERVIEWER SECTION INTRODUCTION:** In this next section, I'd like to discuss your experiences with and perspectives on nicotine replacement therapy – that is, nicotine patches, gum, or lozenges.

#### A1. Previous experiences with and perceptions of NRT

1. Before this study, had you ever tried nicotine patches, gum, or lozenges?

**IF YES, ASK:**

- 1a. What was your previous experience using those products?

PROBE:

- Types of products?
- Duration of use?
- Reasons for discontinuing?
- How did you get them (bought over the counter, got the during hospitalization, was prescribed by a doctor, borrowed from a friend etc.)?

**IF NO, ASK:**

- 1b .What, if anything, did you know or think about NRT (e.g., from friends or family, advertisements, your doctor or dentist, etc.)?

1c. Had you ever considered using NRT? Why or why not?

## **B. CONTEXT FACTORS**

***INTERVIEWER SECTION INTRODUCTION:*** Next, I'd like to talk a little bit about your experiences with and feelings about talking to your dentist about smoking and related issues.

### **B1. Experiences receiving smoking cessation counseling/assistance during dental visits**

2. Before participating in this study, when you would go to the dentist, what, if anything, did your dentist or hygienist typically say about your smoking during your dental visits?

### **B2. Comfort with receiving smoking cessation assistance from a dental provider**

3. Before participating in the FreSH study, how comfortable were you with talking to your dentist or dental hygienist about quitting smoking?

## **C. INNOVATION**

***INTERVIEWER SECTION INTRODUCTION:*** In this section, I'll be asking for your feedback on different components of the FreSH study. First, I'd like to talk a bit about your initial thoughts about and interest in the study.

4. Can you tell me your experience with participation in the FreSH study?

PROBE: What went well or what did you like about the study? What didn't go well or what didn't you like about the study?

### **C1. Feedback on AAR**

5. How comfortable were you with talking to your dentist/hygienist about quitting smoking?

(ASK SEPARATELY)

- Did the dentist/hygienist ask you about your tobacco use?
  - Did the dentist/hygienist advise you to quit in a non-judgmental way?
  - Did the dentist/hygienist refer you to any resources (e.g., doctor, quitline, other program)?
6. What questions (if any) did you have for your dentist/hygienist about quitting smoking?
  7. About how long did you talk with your dentist/hygienist about quitting smoking? Would you have liked it to be longer or shorter? Why?

## **C2. Feedback on NRTS**

8. What was your initial reaction when you were offered a free sample of nicotine patches and lozenges from your dentist?
9. Did you have any questions or concerns about the sample of NRT you received? Please explain.

### **PROBE:**

- What question(s) (if any) was your dentist/hygienist unable to answer?
  - Did you seek out any additional information or feedback about NRT (e.g., online, asking a friend/family member, asking your primary care doctor, etc.)?
10. Did you try the nicotine patches or lozenges that you got from your dentist's office?

### **IF YES, ASK:**

**10a.** What did you use (patch; lozenge; both)?

**10b.** Why did you use the samples?

### **PROBE:**

- To experiment and try them out (no real reason)
- To reduce your smoking
- To quit smoking
- To see if it would make me more interested in quitting ?

**10c.** What was that experience like?

**10d.** Are you still using NRT?

**10e.** Did you obtain any additional NRT after getting the sample from your dentist?

**PROBE (IF YES):** How did you get additional NRT (e.g., bought it over the counter with your own money, through a state quitline, got a prescription for it from your dentist, got a prescription from your primary care doctor)?

### **If NO, ASK:**

**10f.** Why not?

**10g.** What did you do with the sample (e.g., kept it; gave it to a friend or family member; threw it away)?

**10g.** Do you plan to use the NRT sample in the future? Please explain.

**11.** How helpful (if at all) do you think it was (or could be) to try nicotine patches/lozenges?

**12.** How, if at all, did getting a free sample change how you think or feel about nicotine patches or lozenges?

PROBE:

- Did you learn anything helpful or new about the nicotine patches or lozenges from your dentist/hygienist?
- What else would you want to know about NRT?

**13.** Would you be open to using nicotine replacement therapy like the nicotine patch or lozenge to help quit smoking at some point in the future? Why or why not?

PROBE:

- What types of products would you consider using?
- Specific preferences (patch/gum/lozenge; flavor; etc.)?

### **C3. Perceived impact of FreSH**

**14.** How did receiving the counseling and NRT from your dentist/hygienist affect your perceptions of your dentist/hygienist?

PROBE: How did this affect your satisfaction with your dental care?

**15.** How, if at all, did participating in the study affect your thoughts about your smoking? About quitting smoking?

**16.** How interested are you in quitting smoking now?

PROBE: Have you taken any steps to quit or reduce your smoking? Please explain.

**17.** Were there any other benefits or drawbacks of nicotine replacement therapy samples or counseling about smoking you got from your dentist or dental hygienist?

### **C4. Attitudes toward adoption of AAR and NRTS in dental practices**

**18.** Do you think tobacco counseling and NRT samples should be a part of regular dental care? Why or why not?

PROBE: How do you think other people who smoke cigarettes would feel about their dentist offering tobacco counseling and NRT samples?

19. Would you be more or less likely to go to a dentist that had tobacco counseling and NRT samples as part of routine care? Please explain.

**C5. Feedback on NRT costs**

20. If you were interested in using NRT at some point in the future, would you be willing to buy your own NRT (i.e., purchase it with your own money out-of-pocket)?

PROBE: On patches? On lozenges?

21. A box of nicotine patches costs around \$40 for a 2-week supply (14 patches). A box of nicotine lozenges cost around \$40 for a 1-week supply.

Would you be willing to spend this much of your own money on patches? On lozenges?

PROBE: How much would you be willing to spend on patches if you had to purchase them with your own money? On lozenges?

22. How would being able to receive NRT at no cost to you affect your interest in using it (this could include getting NRT for free from state quitlines, pharmaceutical companies that make NRT, or possibly billing your health insurance)?

**D. ADDITIONAL FEEDBACK**

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

**Thank you for your time!**

**END**

**Patient Termination Form**

To be completed [by study staff] if the patient terminates or withdraws early from the study.

1. If the termination happened at a study visit, mark the visit otherwise mark between visits.

- Baseline
- Year 1
- Year 2
- Year 3
- Between visits

2. Date of termination: \_\_\_\_\_

3. Reason for termination

- Moved out of area/unable to contact patient
- Patient no longer interested in study/declines participation
- No longer physically/mentally able to continue attending visits
- Death, fill out an SAE form
- Administratively withdrawn:
  - o Specify reason: \_\_\_\_\_
- Other:
  - o Specify reason:

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