

Paperwork Reduction Act Statement: According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The public reporting burden for this collection of information has been estimated to average 1 minute per response. Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden to PRASStaff@fda.hhs.gov.

ATTACHMENT 11a: Initial Lead Letter: Baseline and Replenishments (Print on DHHS or FDA letterhead)

Dear Adult Resident:

The U.S. Food and Drug Administration (FDA) is conducting the Health and Media Study across the United States. Your address was randomly chosen along with approximately [BASELINE = 300,000; F2 REPLINISHMENT = 145,000] other addresses nationwide. RTI International, a nonprofit research organization, was selected by the FDA to conduct this study.

We ask that an adult member of your household (18 or older) answer a few general questions online to determine your household's eligibility for this study.

- The person completing the questions at the link below is welcome to **keep the enclosed \$1** in appreciation for their time.
- If an eligible member of your household is chosen for the study, they will be offered **\$25** to complete the online survey on or before [END DATE] and a bonus **\$5 (\$30 total)** if they do so on or before [EARLY BIRD DATE].

To determine your household's eligibility:

1. **Visit [SURVEY LINK] (or scan the QR code below)**
2. **Enter your Participant Code: [PASSWORD] and PIN: [PIN]**
3. **Follow on-screen instructions to answer the general questions.** This will take only a few minutes.

Your participation in the study is voluntary. Your identity will not be known in the results of the study. Everything you share will be kept private to the extent allowed by law. There are no direct benefits to you from taking this survey. However, you will be contributing to important research related to tobacco. The information collected by this study will also improve our understanding of how public education campaigns affect attitudes, beliefs, and behaviors toward tobacco use.

For more information about the study, you can call our project assistance hotline toll-free at [866-800-9177 or 877-834-7065] or email us at [HealthAndMediaStudy@rti.org OR HMS@rti.org]. If you have a question about your rights as a study participant, you can call the Advarra Institutional Review Board toll-free at 877-992-4724.

Sincerely,

Anna MacMonegle
Study Director

You may also access the survey by scanning this QR code with your smartphone or tablet.

[QR CODE]

Please enter your **Participant Code** ([PASSWORD]) and **PIN**: [PIN] once you are ready to begin.

RTI International

Initial Lead Letter: Follow Up Waves (Print on DHHS or FDA letterhead)
TO PARENT OF YOUTH <14

[PARENT FNAME] [PARENT LNAME]
[ADDRESS 1]
[ADDRESS 2]
[CITY, STATE ZIP]

Dear [PARENT FNAME],

The U.S. Food and Drug Administration (FDA) is conducting the next round of the **Health and Media Study**. Your child, **[CHILD]**, is one of approximately [INSERT NUMBER OF STUDY PARTICIPANTS] youth who took part in the first round of the study, and we sincerely thank you and your child for your help with this important research.

By taking part in this new round of the study, your child will have a unique opportunity to contribute to valuable research related to how public education campaigns affect youth's attitudes, beliefs, and behaviors toward tobacco use. RTI International, a nonprofit research organization, was selected by the FDA to conduct this study.

If [CHILD FNAME] completes the survey on or before **[END DATE]** they will receive a **\$25** Visa gift card or **\$25** cash and an additional **\$5** if they complete it on or before **[EARLY BIRD DATE]**.

To complete the online survey, please:

1. **Visit this link to access the survey:** [SURVEY LINK]
2. **Enter the Participant Code:** [PASSWORD] **and PIN:** [PIN]
3. **Follow the on-screen instructions.** A parent or legal guardian must follow the steps to provide permission before your child can complete the survey.

Your help with this round of the study is voluntary but greatly appreciated. All information provided will be kept private to the fullest extent allowable by law and used only for statistical purposes. You or your household will never be identified in any analysis, reports, or publications, and no one will try to sell you anything.

If you have any more questions about this study, call the project assistance line toll-free at **[866-800-9177 OR 877-834-7065]** or email **[HealthAndMediaStudy@rti.org OR HMS@rti.org]**. If you have a question about your child's rights as a study participant, you can call Advarra's institutional review board (IRB) toll-free at **877-992-4724**.

Thank you in advance for your help.

Sincerely,

Anna MacMonegle
Study Director
RTI International

You may also access the survey by scanning this QR code with your smartphone or tablet.

[QR CODE]

Please enter your **Participant Code** ([PASSWORD]) and **PIN:** [PIN] once you are ready to begin.

TO YOUTH ≥14

[YOUTH FNAME] [YOUTH LNAME]
[ADDRESS 1]
[ADDRESS 2]
[CITY, STATE ZIP]

Dear [YOUTH/YOUNG ADULT FNAME],

The U.S. Food and Drug Administration (FDA) is conducting the next round of the **Health and Media Study** and would like to invite you to participate. You are one of approximately [INSERT NUMBER OF STUDY PARTICIPANTS] participants who took part in the first round of the study, and we sincerely thank you for your help with this important research.

By taking part in this new round of the study, you will have a unique opportunity to contribute to valuable research related to how public education campaigns affect attitudes, beliefs, and behaviors toward tobacco use. RTI International, a nonprofit research organization, was selected by the FDA to conduct this study.

Because your continued contribution is important, you will be offered a **\$25** Visa gift card or **\$25** cash if you complete the survey on or before **[END DATE]** and a bonus **\$5** if you complete it on or before **[EARLY BIRD DATE]**.

To complete the online survey, please:

1. **Visit this link to access the survey:** [SURVEY LINK]
2. **Enter your Participant Code:** [PASSWORD] **and PIN:** [PIN]
3. **Follow the instructions to complete the survey.**

Your participation in this round of the study is voluntary but greatly appreciated. All information provided will be kept private to the fullest extent allowable by law and used only for statistical purposes. You will never be identified in any analysis, reports, or publications, and no one will try to sell you anything.

If you have any more questions about this study, you can call the project assistance line toll-free at **[866-800-9177 OR 877-834-7065]** or email **[HealthAndMediaStudy@rti.org OR HMS@rti.org]**. If you have a question about your rights as a study participant, you can call Advarra's institutional review board (IRB) toll-free at **877-992-4724**.

Thank you in advance.

Sincerely,

Anna MacMonegle
Study Director
RTI International

You may also access the survey by scanning this QR code with your smartphone or tablet.

[QR CODE]

Please enter your **Participant Code** ([PASSWORD]) and **PIN:** [PIN] once you are ready to begin.