

Middle School Cluster RCT to Evaluate E-Cigarette Prevention Program: CATCH My Breath

NCT04843501

Version Date: 6/20/2018

School Year 2019-2020

Dear Parent or Guardian:

Your son/daughter has been invited to participate in the Coordinated Approach To Child Health (CATCH) My Breath Youth E-Cigarette Prevention Program Survey. The purpose of this survey is to gather information about students' knowledge, attitudes and E-cigarette use. The CATCH Global Foundation, in conjunction with the University of Texas Health Science Center (UTHealth), School of Public Health in Austin, is conducting the implementation and evaluation of this survey. The information gathered from the survey will allow the CATCH Global Foundation & UTHealth to enhance the CATCH My Breath Youth E-cigarette Prevention Program.

Please read the attached consent form and return to the contact person at your school, _____, as soon as possible. Should you have any questions, please call me at [REDACTED]

Thank you for taking part in a grant to promote the health of children!

Sincerely,



Steven H. Kelder, MPH, PhD
Professor, Division of Epidemiology
Beth Toby Grossman Professor in Spirituality and Healing
Michael & Susan Dell Center for Advancement of Healthy Living
University of Texas School of Public Health, Austin Regional Campus

CATCH My Breath Youth E-cigarette Prevention Program

Parent/Guardian Information Sheet and Consent Form

Parent/Guardian Information and Invitation to Take Part in Project:

1. This information sheet is about the Coordinated Approach To Child Health (CATCH) My Breath Youth E-cigarette Prevention Program Survey at your son's/daughter's school. This study is being conducted by Dr. Steven Kelder of the University of Texas Health Science Center at Houston (UTHealth). For this research project, he will be called the Principal Investigator or PI. Your son/daughter is invited to take part in this survey.
2. The purpose of this survey is to learn more about middle school students' knowledge, attitudes and E-cigarette use. The information collected is anonymous and kept in a secure location. It is available only to scientists and their staff. The results of the study may be published, but results will never mention any student or school by name.
3. The measurements include a survey about your son's/daughter's knowledge, attitudes and possible experience with E-Cigarettes. The surveys administered during the grant are considered safe and pose no risk to your son/daughter.
4. With this consent form, we are asking your permission for your child to participate in up to 6 surveys over a period of 3 years occurring every Fall and Spring semester. With this consent form, we are asking you for your permission for your son/daughter to participate in all 6 surveys. However, we will notify you prior to each survey, so that you are aware that the survey will take place.
5. The surveys will be conducted outside of school. These surveys will take about 20 minutes to complete and will be administered using a web-based survey. These surveys will be completely confidential and use secure methods to transfer the data to our research center. The total amount of time your son/daughter will take part in this research study is 2 hours, if they take all the surveys.
6. There is always a possibility of loss of confidentiality during a research study. Every effort is made to prevent this by removing the page with your child's name and contact information on it (Student Assent Form) from the survey. Your child's name will never be used after that.
7. Your son's/daughter's involvement in this study will not cost you any money, and it is completely voluntary. As a thank you for your son's/daughter's involvement in the follow-up surveys, we will provide your child with a \$15 gift card for each survey, for a total of up to \$90.
8. You may refuse to have your son/daughter take part or you may withdraw your child from the project at any time. Doing so will neither change the services that are available to your son/daughter from his/her school nor affect his/her grades, extracurricular activities, eligibility in the free or reduced school lunch program, or overall standing in the school. Refusal will not affect your son/daughter's relationship with the University of Texas, either. In addition, your child may also refuse to participate in any of the surveys, and will be asked for their assent for each survey.

9. 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.
10. If you would like to meet a project staff member or if you have any questions or concerns, please contact Steven Kelder, PhD., at [REDACTED] or at [REDACTED]
11. This study [HSC-MS-18-0254] has been reviewed by the Committee for the Protection of Human Subjects (CPHS). If you have questions about your son's/daughter's rights as a research subject, call the CPHS at the University of Texas Health Science Center at Houston at [REDACTED]

The CATCH My Breath Youth E-cigarette Prevention Program is co-sponsored by the CATCH Global Foundation and is conducted by the UT School of Public Health, Austin Regional Campus. Steven H. Kelder, MPH, PhD, is the Principal Investigator. He can be reached at [REDACTED]

PLEASE TURN TO NEXT PAGE

**Decision about My Son's/Daughter's Participation
in the Coordinated Approach To Child Health (CATCH) My Breath Youth E-cigarette
Prevention Program Survey**

**If you WANT your son/daughter to take part in the
CATCH MY Breath Youth E-cigarette Prevention
Program Survey, sign this sheet and return it
immediately to your son/daughter's teacher.**

We expect that most children and parents will want to participate in the CATCH My Breath Program.
You must sign below if you want your son/daughter to take part.

If You WANT Your Son/Daughter to Participate, fill out this form and send it to his/her teacher.

I, _____, WANT MY CHILD, _____,
(printed parent/guardian's name) (student's name)

TO PARTICIPATE IN THE CATCH My Breath Youth E-cigarette Prevention Program Survey,
co-sponsored by the CATCH Global Foundation and UTHealth School of Public
Health in Austin.

PARENT/GUARDIAN _____ Date _____
(signature)

*If you have questions or concerns about the survey or your son's/daughter's
participation, contact . . .*

Steven H. Kelder, MPH, PhD
Principal Investigator
UT School of Public Health



If you have any questions about your son's/daughter's rights as a research subject, call
the Committee for the Protection of Human Subjects at UT Health Science Center at
Houston at _____

Thank you for your son's/daughter's participation.


Austin Regional Campus

1616 Guadalupe St., _____
Austin, Texas 78701
www.sph.uth.tmc.edu/Campuses/Austin

Michael & Susan Dell Center for Healthy Living

1616 Guadalupe St., _____
Austin, Texas 78701

www.sph.uth.tmc.edu/dellhealthyliving

 IRB NUMBER: HSC-SPH-18-0254
IRB APPROVAL DATE: 06/20/2018
The University of Texas
Health Science Center at Houston