

Approval Date: March 19, 2015 Approved Consent Version No.: 2 PI Name: Derek Cummings

IRB No. 00005474

P.I. Derek Cummings IRB #5474

Version 12, March 16, 2015

## Surveillance, Monitoring Absenteeism And Respiratory Transmission in Schools (SMART<sup>2</sup>) Project Consent form

PURPOSE: The purpose of this research is to figure out how influenza and other respiratory diseases are spread in schools and from schools out into the community. This will provide a firm base of scientific data for school policy and practice in response to communicable disease outbreaks.

WHO IS DOING THIS RESEARCH: SMART Schools is being conducted by Johns Hopkins University (Hopkins) and University of Pittsburgh (Pitt), School of Medicine. Hopkins has received a grant from the US Centers for Disease Control and Prevention from which Pitt receives funding. The research is under the direction of Derek Cummings PhD MHS MS (Hopkins) and Shanta Zimmer MD (Pitt).

WHAT IS BEING DONE: Parents will be asked to provide basic information about who is in your family, including some basic characteristics, such as age, sex and role in the family (mother, father, etc.) This will take about 12 minutes or less. Parents will be asked to login to a website each week for 12 weeks to report if anyone has had symptoms of the flu. This will take less than 5 minutes per week. Other members of the household will be asked to provide information to parents on illnesses to report. Members of the household will be asked to provide a nasal swab sample to be tested for flu whenever you are any other member of the household has a flu-like illness. We will send you a kit and ask you to place a foam swab inside your nostril and gently sweep the inside of your nose. Then you are asked to return this swab in the mailing envelope that will be provided to you. Results of these tests will not be returned to you but will inform the study.

COSTS/BENEFITS: There is no cost to anyone for participating in this study. There are no direct benefits.

RISKS: There is minimal risk involved with this study. All records are private. All data will be analyzed anonymously. All data will be kept on secure computers. Paper forms will be kept in locked cabinets in locked rooms. Flu testing involves taking a small sample of mucus from the nose. There is a small risk that the privacy of your data may be lost (i.e. data may be revealed to others by theft or loss). There may be some discomfort associated with the nasal swab, but the discomfort is momentary.

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PARTICIPATION: Participation is voluntary. We are asking all students at your school and their families if they would like to participate. There is no penalty for not participating. Not participating will not affect your child's normal privileges and activities in school, or your relationship with the University of Pittsburgh or any other institutions associated with this research. You may also refuse any study-related activity without penalty. Participates can withdraw at any time. There is no penalty for withdrawing.

PAYMENT: Households will be given a \$20 gift card for enrolling in this study. Each week when you provide information, you will be entered into a drawing for a \$200 gift card. Your chances of winning this are approximately 1 in 30. You will be given any additional \$20 gift card if you complete 5 of the first 6 weekly reports. You will be given an additional \$20 gift card if you complete 5 of 6 weekly reports in weeks 7-12. All cards will be sent at the conclusion of the 12 weeks. Gift cards will be provided to parent or guardian providing information for families.

QUESTIONS: There are numerous people who are available to answer your questions.

- 1. Please contact Project Manager Chuck Vukotich at 412-246-6957 or charlesv@pitt.edu with your questions about SMART Schools.
- 2. If you have any questions or concerns about participating in research, or if you have questions about your/your child's rights as a research participant, please contact Human Subject Protection Advocate of the University of Pittsburgh Institutional Review Board at 1-866-212-2668 or the Johns Hopkins University at 1-888-262-3242.
- 3. If you have questions about the study or feel you/your child may have been harmed by participating in the study please contact the PI of the study, Derek Cummings at 410-502-9319.
- 4. If you would like to contact the funder of this research, the US Centers for Disease Control and Prevention, contact Jeanette Rainey, Senior Epidemiologist and Project Officer 404-639-0689

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## For parents,

† agree to participate in SMART<sup>2</sup> research project as defined above to provide information about my family members and their illnesses as well as my own and consent to my child(ren) participating.

Name Printed:	
Signature:	Date:
Names of children	_
For members of household 18 and over who are not parents,	
agree to participate in SMART <sup>2</sup> research project	ct as defined above to provide
information on my illnesses and to provide a nas	sal swab if asked.
Name Printed:	
Signature:	Date:
For children in the household 13 and over,	
This research has been explained to me and I a information to my parents when I am sick and pr	•
Name Printed:	
Signature:	Date:
SMART <sup>2</sup> Signature:	_
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