

Social Mixing And Respiratory Transmission in Schools (SMART Schools) Project DISCLOSURE DOCUMENT

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.

WHO IS DOING THIS RESEARCH: SMART Schools is being conducted by the University of Pittsburgh (Pitt), Graduate School of Public Health. Pitt has received a grant from the US Centers for Disease Control and Prevention. The research is under the direction of Shanta Zimmer MD (Pitt) and Derek Cummings PhD MHS MS (Johns Hopkins University). Canon McMillan and Propel Charter school districts have agreed to participate.

WHAT IS BEING DONE: An important part of this project is to figure how often kids come in contact with each other. This includes holding a conversation, sharing items, and being close together. This project will use different methods to determine the contact, including:

1. Children will receive a mote at the beginning of the school day and will wear it all day. The mote will be retrieved at the end of the school day. A mote is a small (1"x3"x3/4") electronic device powered by 2 "AA" batteries. These devices are much lower energy than cell phones and other electronic devices commonly used by students and have been shown to be safe. They have been used successfully in previous studies. The motes send out a weak signal - similar to a cordless phone - every 20 seconds. Motes record the signal of other motes within about 9 feet. Some children will be asked to wear the mote to afterschool activities and to take it home.
2. Children will fill out an assessment form which lists the people who they have come in contact with.
3. Parents of absent students will be contacted during flu season (Jan-April, 2013) to determine if their student has the flu or flu-like symptoms. You will be asked if your student was ill, and what symptoms they have.
4. Students with the symptoms of flu, or students who may have come in contact with the flu, may be tested for the flu. This involves taking a simple nasal swab.

This research will be used to create models of flu transmission. Using several methods to measure social contacts allow the investigators to form a more complete picture of disease transmission. These models would be used to create policies and recommendations for the response to flu and other similar diseases.

All of this will be done confidentially. Students will be assigned code numbers. All information will be kept on secured computers. Paper forms will be kept in locked cabinets in locked rooms.

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

There may be some benefit to the schools. The investigators will provide science education, if desired, on:

- Social networks
- Motes: How they work, what they do, data and analysis
- Disease transmission
- Vaccines

They may also provide education on the research process. Some of the data collected could be shared anonymously to illustrate the research and analysis process.

Findings of this study will be shared with the schools. It will provide a firm basis for school policy and practice in response to communicable disease outbreaks. It will help form national policy.

An iPad will be made available for a drawing for all students who participate in this study. Additional small rewards, such as small flash drives, pens, pizza parties, etc., will be made available to the school for students who participate. The value of these items will not exceed \$10/student. All incentives will be distributed through the school to enhance the school mission. Students who provide a nasal swab sample will be eligible for a separate iPad drawing.

RISKS: There is minimal risk involved with this study. All records are confidential. The children will be assigned numbers for control purposes. 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. The motes operate on the same frequency as cordless phones and are considered to be ultra low power. They use 2 AA batteries. Flu testing involves taking a small sample of mucus from the nose. There may be some discomfort associated with this, but the discomfort is momentary.

PARTICIPATION: Participation is voluntary. You have the right to opt-out. There is no penalty for not participating. Not participating will not affect your child's normal privileges and activities in school. Educational activities are open to all students, regardless of participation.

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

1. Please contact Project Manager Chuck Vukotich at 412-383-2400 or charlesv@pitt.edu with your questions about SMART Schools.
2. If you have any questions or concerns about participating in research, please contact Human Subject Protection Advocate of the University of Pittsburgh Institutional Review Board at 1-866-212-2668.
3. 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