

INFORMATION SHEET

School Kids Influenza Prevention Program (SKIPP)

Principal Investigator: Stanley Schaffer, MD, MPH

This form describes a research study that is being conducted by Dr. Stanley Schaffer from the University of Rochester's Department of General Pediatrics.

The purpose of this study is to evaluate a public health model to offer influenza vaccinations in a school setting. Although most of the time children are vaccinated at their doctor's office, not all children are able to get to their doctor during the flu season. Providing influenza vaccination clinics during school hours may be able to increase the percentage of children who are protected against influenza disease. You are being invited to take part in this study as your child attends a school that is participating in this project.

If you decide to take part in this study, you will be asked to read the Vaccine Information Sheet and then complete the consent process for vaccination. Once you have completed the consent process and enroll your child, you will receive reminders as the clinic date approaches along with contact information if you have questions or want to change your mind. After your child has been vaccinated, he/she will receive an immunization card to bring home. We ask that you notify your child's doctor that he/she received the influenza vaccine so that they can put it in their records. We estimate that approximately 64 schools in Monroe County will take part in this study this year.

The cost of the vaccine will be covered by health insurance just as it is at your child's doctor's office. If your insurance requires a co-pay, the vaccinator will mail you an invoice. You are encouraged to discuss your coverage with your child's insurance provider if you have any questions. Your child can get the flu vaccine even if he/she does not have health insurance. A federal program (Vaccines for Children) will pay for the vaccine.

The only risks related to participation are the potential invasion of privacy or breach in confidentiality. We will protect against risks by storing study documents in a secure manner and by restricting access to the study team only. Sometimes, however, researchers need to share information that may identify you/your child with people that work for the University, Monroe County Department of Public Health (vaccinator), COMET Informatics LLC (website administrators), regulators or the study sponsor. If this does happen we will take precautions to protect the information you have provided. Results of the research may be presented at meetings or in publications, but your child will not be individually identified.

Your participation in this study is completely voluntary. You are free to not participate or to withdraw, for whatever reason. Please be advised that you will need to contact the study team at least 24 hours before the vaccination clinic if you decide to not participate. No matter what decision you make, there will be no penalty or loss of benefits to which you are otherwise entitled.

For more information or questions about this research you may call Kristine DiBitetto, the project coordinator at (585) 273-4086. Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420315, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.