



JOHNS HOPKINS  
BLOOMBERG  
SCHOOL of PUBLIC HEALTH



October 13, 2009

Re: Influenza vaccine safety monitoring through the **Real-Time Immunization Monitoring System (RTIMS)**: A Johns Hopkins Bloomberg School of Public Health (JHSPH) project in collaboration with CDC.

Dear Influenza Vaccine Provider:

We are seeking your collaboration to enhance the monitoring of influenza vaccine safety in your state. With support from the CDC, we have created an automated internet-based system that will follow up on any self-reported adverse symptoms after vaccination.

While we understand the substantial coordination efforts involved in conducting your vaccination program, we are seeking your assistance to help us identify persons willing to be contacted after influenza vaccination by our monitoring system. We are asking that you kindly help us collect the full name and email address of participants at the time of vaccination. We will provide simple, step-by-step instructions on how to send us this contact information and we will pay for all materials and logistics.

Please note that providing contact information on persons who have agreed to be contacted does not constitute active research. Therefore participating sites do not need to apply for IRB approval and are exempt from HIPAA Privacy Rules as per the guidelines from the Office for Human Research Protections (OHRP). Please refer to the attached letter from the OHRP.

Your efforts in collecting this contact information are much appreciated and will be an important contribution to public health surveillance efforts in your state and across the country. We sincerely appreciate any assistance and support you can offer and thank you for your time.

Thank you for your time and cooperation.

A handwritten signature in black ink that reads "Neal Halsey".

Neal A. Halsey, M.D.  
Professor and Director


We appreciate the time and planning constraints you are dealing with at this time of the year and will make every effort to minimize the burden of this study on your staff. We are seeking your assistance in asking vaccine recipients if they are willing to be contacted about their experience with influenza vaccine at the time of vaccination. We provide *all* materials required and will cover all shipping costs.

**Process:**

1. We will send you study information cards (see sample attached), posters, and FedEx® shipping boxes with pre-paid, pre-addressed shipping labels. The study information card will provide some information about our study and have fields for vaccine recipients to fill in their contact information.
2. We would like you to give out these cards to vaccine recipients on the day of vaccination together with your influenza vaccine consent form. We would appreciate it if your staff can make an effort to ensure that each vaccine recipient gets a card.
3. Vaccine recipients interested in being contacted about this study will fill out the card and place them in a box.
4. At the end of each week or every other day, clinic personnel will need to place the cards in the provided FedEx® box and mail it to us. We can arrange for FedEx pick-up from individual sites.

Please do not hesitate to contact the study coordinators at [flustudy@jhsph.edu](mailto:flustudy@jhsph.edu) or 410 502 5202 if you have any questions. Thank you for your time and assistance.

**Sample study information cards:**

<div style="border: 2px solid black; padding: 5px; text-align: center; margin-bottom: 10px;"> <b>Real-Time Immunization Monitoring System</b> </div> <div style="display: flex; justify-content: space-between;"> <div style="background-color: #90EE90; padding: 10px; border-radius: 5px;"> <p>Please take a few minutes to help us monitor your influenza vaccine experience.</p> </div> <div style="background-color: #D3D3D3; padding: 10px; border-radius: 5px;"> <p>Our goal is to detect any unanticipated problems as quickly as possible.</p> <p><i>If you are interested, please fill out your contact information on the back of this card.</i></p> </div> </div> <div style="text-align: center; margin-top: 20px;">  <p><b>JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH</b></p> </div> <div style="background-color: #FFD700; padding: 5px; font-size: small;"> <p>A Johns Hopkins University/CDC funded study IRB No. 00001626 If you have any questions please contact the study coordinators at 410-502-5202 or go to <a href="http://www.myflushot.org">www.myflushot.org</a></p> </div> <p style="text-align: center; font-weight: bold; font-size: large;">FRONT</p>	<div style="border: 1px solid black; padding: 10px; margin-bottom: 10px;"> <p><b>If you are interested in being contacted by Johns Hopkins about this study, please fill out this card and place it in the box provided.</b> <i>Your information is confidential.</i></p> <p><b>First Name:</b> _____</p> <p><b>Last Name:</b> _____</p> <p><b>Email address:</b> _____</p> <p><b>Date of Vaccination:</b> mm ____ dd ____ yr ____    <b>State:</b> ____</p> </div> <p>We will send you an invitation to join this study by email within 48 hours of vaccination. If you agree to participate, you will be asked to complete an online survey that asks a series of questions including demographic information, influenza vaccine history, type of influenza vaccine received, and any medical problems you may have developed since vaccination.</p> <p>The initial online survey will take 3-4 minutes to complete, with two short follow-up online surveys at 1 week and 6 weeks after vaccination.</p> <p>If you have any unanswered questions please email the study coordinators at <a href="mailto:flushot@jhsph.edu">flushot@jhsph.edu</a> or call 410-502-5202.</p> <p style="text-align: center; font-weight: bold; font-size: large;">BACK</p>
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