

RTIMS: Real-Time Immunization Monitoring System: A Johns Hopkins Bloomberg School of Public Health & Centers for Disease Control & Prevention Sponsored Study

Post-licensure safety monitoring through passive reports to the CDC's Vaccine Adverse Event Reporting System (VAERS) system involves delays, incomplete data and underreporting that could be avoided with an automated data collection system. The availability of data collected in real time could be invaluable with regard to assessment of concerns about new syndromes or problems associated with influenza vaccination. We propose to use an automated internet based system for active post-licensure monitoring of adverse events associated with influenza vaccines. The system is programmed to identify adverse events and is set up to send an alert that is displayed at central or satellite facilities allowing for prompt identification of individuals reporting serious symptoms. We would like to work with various clinics, hospitals and schools in your state in anticipation of a large scale administration of the seasonal and H1N1 pandemic influenza vaccine this fall.

Study Procedures

The goal would be to ask vaccine recipients if they are willing to be contacted about their experience with influenza vaccine at the time of vaccination. This contact information will be forwarded to study investigators at Johns Hopkins. On receipt of the contact information, an email will be sent to each vaccine recipient informing them about the study and asking for their consent to participate.

Methods for sharing contact information.

- 1) *Clinics for school aged children:*
 - a) We will ask schools to include a section on the parental consent form asking parents/legal guardians to indicate their willingness to be contacted about our study by checking a box (Yes/No) and sharing their email address with us.
 - b) At the end of each vaccination day, the school nurse/personnel will send a copy of all parental consent forms on which parents have provided consent to be contacted to study investigators at Johns Hopkins. The consent forms may be faxed, scanned or mailed using preaddressed and prepaid boxes provided by study investigators.

2) *Clinics for adults*

- a) For clinics capable of sending information electronically:
 - i) At the time of registration, vaccine recipients will be asked if they are willing to be contacted about their vaccine experience.
 - ii) If the vaccine recipient agrees to be contacted, their contact information would be electronically transmitted to study investigators at Johns Hopkins.
- b) For sites that use paper documentation:
 - i) At the time of registration, vaccine recipients will be asked if they are willing to be contacted about their vaccine experience.
 - ii) At the end of each vaccination day a person designated by the clinic would fax, scan or mail consent forms of persons who have agreed to be contacted to study investigators at JHSPH. Preaddressed and prepaid boxes will be provided by study investigators.

IRB Approval

Per OHRP guidance, 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. If you would like to review the OHRP guidance on this is, please go to the following link: <http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html>.

Read the section under: B. Institutions Not Engaged in Human Subjects Research for the details.