



SEP 24 2009

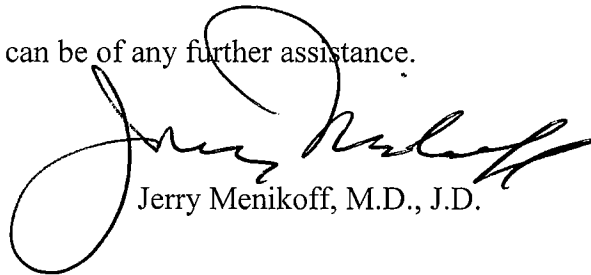
TO: Daniel Salmon, Ph.D.
National Vaccine Program Office

FROM: Director, Office for Human Research Protections

SUBJECT: H1N1 Vaccine Real Time Immunization Monitoring System

The Office for Human Research Protections has determined that, based on the description included in the Research Plan for the Real Time Immunization Monitoring System that you provided to us, the schools and vaccine-providing institutions (including state and local health departments and hospitals) would not be considered to be engaged in research and accordingly would not be required to have an institutional review board at their institutions approve their activities.

Do not hesitate to contact us if we can be of any further assistance.



Jerry Menikoff, M.D., J.D.