Adult Flu Hosp IRB

DATE: 9/26/2007

FROM: IRB Administrator
Human Research Protection Office
Office of the Chief Science Officer, OD/CDC

SUBJECT: IRB Approval of Continuation of Protocol #5035, "Adult Influenza Hospitalization Surveillance Project" (Expedited)

TO: Laurie Kamimoto [LEK0]
NCHSTP/DHAP-SE

CDC's IRB A has reviewed and approved your request to continue protocol #5035 for the maximum allowable period of one year and it will expire on 9/26/2008. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), Categories 5 & 7.

NOTES: The expiration date was moved as requested by the PI for reasons related to the timing of the flu season and aid the PI in coordinating the collaborating sites with their approvals. This approval adheres to the regulations of no longer than a 12 month approval period, it just moved the expiration date ahead. Also, this approval does not include the University of California, San Francisco; the Oregon Department of Health; the California Department of Health Services; the Connecticut Department of Public Health; the Yale University School of Medicine; the Georgia Department of Human Resources; Emory University; and the University of Rochester until their current local letter of approval is received in this office.

If other institutions involved in this protocol are being awarded CDC funds through the CDC Procurement and Grants Office (PGO), you are required to send a copy of this IRB approval to the CDC PGO award specialist handling the award. You are also required to verify with the award specialist that the awardee has provided PGO with the required documentation and has approval to begin or continue research involving human subjects as described in this protocol.

As a reminder, the IRB must review and approve all human subjects research protocols at intervals appropriate to the degree of risk, but not less than once per year. There is no grace period beyond one year from the last IRB approval date. It is ultimately your responsibility to submit your research protocol for continuation review and approval by the IRB. Please keep this approval in your protocol file as proof of IRB approval and as a reminder of the expiration date. To avoid lapses in approval of your research and the possible suspension of subject enrollment and/or termination of the protocol, please

submit your continuation request at least six weeks before the protocol's expiration date of 9/26/2008.

Any problems of a serious nature should be brought to the immediate attention of the IRB, and any proposed changes to the protocol should be submitted as an amendment to the protocol for IRB approval before they are implemented.

If you have any questions, please contact the Human Research Protection Office at (404) 639-4721 or e-mail: huma@cdc.gov.

John A. Valosen
Administrator IRB A

cc:
CCID Human Studies Review
Laurie Reid
Dee Williamson

DATE: 9/26/2007

FROM: IRB Administrator
Human Research Protection Office
Office of the Chief Science Officer, OD/CDC

SUBJECT: IRB Approval of Amendment to Protocol #5035, "Adult Influenza Hospitalization Surveillance Project" (Expedited)

TO: Laurie Kamimoto [LEK0]
NCHSTP/DHAP-SE

CDC's IRB A has reviewed and approved your request to amend protocol #5035 by modifying the protocol report form to include change to age request; questions on race/ethnicity; new categorical response; addition of sites in New Mexico and Connecticut; and changes in co-investigators using the expedited review process outlined in 45 CFR 46.110(b)(2), "Minor changes in previously reviewed research during the period (of one year or less) for which approval is authorized."

NOTE: The board reviewer included this comment: "Should prisoners be included, information will best be gathered passively, (i.e., chart review). Physicians who work in correctional health facilities will be reluctant to provide information via phone without approval from the warden. Inmates may or may not be allowed to conduct phone interviews from a jail or prison cell without special permission and approval".

Reminder: IRB approval of protocol #5035 will still expire on 12/19/2007. Any problems of a serious nature should be brought to the immediate attention of the IRB, and any other proposed changes to the protocol should be submitted as an amendment to the protocol for IRB approval before they are implemented.

If you have any questions, please contact the Human Research Protection Office at (404) 639-4721 or e-mail: huma@cdc.gov.

John A. Valosen
Administrator IRB A

cc:
CCID Human Studies Review
Laurie Reid
Dee Williamson