“Evaluation of Pharmacy Syringe Access Linked to HIV Testing for Injection Drug Users in New York City (Pharm-HIV)”

Attachment 6A

IRB Determination – Centers for Disease Control and Prevention

DATE: 9/4/2008

FROM: IRB Administrator
Human Research Protection Office

Office of the Chief Science Officer, OD/CDC

SUBJECT: IRB Approval of New Protocol #5425, "Evaluation of Pharmacy Syringe Access Linked to HIV Testig for Injection Drug Users in New York City (Pharm-HIV)" (Expedited)

TO: Paul Weidle, Pharm.D., MPH,
NCHHSTP/DHAP/IRS

New protocol #5425 has been approved by CDC IRB "B" for the maximum allowable period of one year and it will expire on 9/3/2009. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), categories 2b, 6, 7.

Collaborator Site Restriction: Study activities may not begin with the following collaborators/sites until documentation indicating current IRB approval has been received by CDC's Human Research Protection Office and is on file:

NY Academy of Medicine

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 9/3/2009.

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.