



Memorandum

Date March 25, 2011

From Barbara DeCausey, MPH, MBA
Chief, Human Research Protection Office

Subject IRB Approval of Amendment to CDC Protocol #5923.0, "Proposal for the State and Metropolitan Area-Based ALS Surveillance" (Expedited)

To Oleg Muravov, MD, PhD
NCIRD/DVD

CDC's IRB A has reviewed and approved your request to amend protocol #5923.0, "Proposal for the State and Metropolitan Area-Based ALS Surveillance". These changes included:

1. A waiver of authorization for the use and disclosure of protected health information under the Privacy Rule in accordance with 45 CFR 164.512.
2. Clarifications to the protocol based on review by the Office of Management and Budget.
3. The addition of Philadelphia, PA (Philadelphia County), Detroit, MI (Wayne County), and Atlanta, GA (Fulton, Dekalb, Cobb, Gwinnett, and Clayton Counties).

The requests for Emory University, Detroit Department of Health and Wellness Promotion, and Southeastern Michigan Health Association to rely on the CDC IRB are being processed. At this time, the CDC IRB approval does not cover these institutions. Once we receive the signed IRB Authorization Agreements from each institution we will send a revised approval letter to include these institutions.

The action was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(2), minor changes to previously approved research during the period for which approval is authorized.

Reminder: IRB approval of protocol #5923.0 will still expire on 05/17/2011.

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

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

cc:
Joe Posid

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)

Dolly Sinha