DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Memorandum

Date March 19th, 2015February 12, 2016

From Denise M. Marshall, BS
IRB Administrator, Human Research Protection Office

Subject IRB Approval of Amendment #22 to CDC Protocol #5768 .0, "Proposal for the National ALS Registry " (Expedited)

To Paul Mehta, MD
OD/DTHHS

CDC's IRB C has reviewed and approved your request to amend protocol # .0, " ." The amendment includes waiving documentation of consent for the in-home component for subjects who are able to express their consent, but are physically unable to provide a signature. The IRB has approved the following alterations of consent procedures:

- In-home component: signature of a witness will be accepted if the subject is physically unable to sign [45 CFR 46.117(c)]
- Eligibility screening for post-mortem component: informed consent will be obtained through telephone script and documented via the HIPAA authorization, with an approved alteration [45 CFR 46.116(d)] of element (a)(7)
- Post-mortem tissue collection: signature of a witness will be accepted if the subject is physically unable to sign, as the specific procedures for which consent is sought fall outside the scope of 45 CFR 46 [paragraph 102(f)].

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 of one year for which approval is authorized.

Reminder: IRB approval of protocol # .0 will still expire on 10/18/2015 6.

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) 639-7570 or e-mail: huma@cdc.gov.

cc:

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