



Date: January 7, 2026
To: Paul Mehta, MD
From: CDC Institutional Review Board
Protocol Title: Proposal for the National ALS Registry
Protocol Number: 5768

Dear Dr. Mehta:

The CDC Institutional Review Board (IRB) reviewed and approved the continuation to CDC Protocol 5768, "Proposal for the National ALS Registry." This approval is effective from January 6, 2025, to January 5, 2027.

The protocol was reviewed and approved in accordance with the expedited review process outlined at 45 C.F.R. §46.110(b), categories 2b, and 5.

Please comply with the approved protocol, as well as any subsequent modifications approved by the IRB in accordance with CDC policies and procedures.

Please note that any changes to the protocol, informed consent process or materials, or any other aspect of this activity must be reviewed and approved by the IRB before they can be implemented. Failure to obtain IRB approval may result in the suspension or termination of the protocol. Unanticipated problems or noncompliance of a serious or continuing nature should be promptly reported to the CDC's Human Research Protections Office in accordance with CDC policies and procedures.

A Certificate of Confidentiality applies to this protocol to protect the privacy of individuals who are subjects of this protocol, pursuant to subsection 301(d) of the Public Health Service Act.

Thank you for your attention to these matters. We appreciate your commitment to responsible conduct of this protocol and your cooperation with the IRB review process.

If you have any questions or concerns regarding the conduct of this protocol or the IRB review process, please do not hesitate to contact your Center Human Subjects Contact or the Human Research Protection Office at huma@cdc.gov.