U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30329-4027

March 19, 2024

Lisa Cooper, MA, MPA
NCCDPHP/DHDSP
las0@cdc.gov

RE: CDC IRB Approval of Continuation of CDC Protocol 5373, "Paul Coverdell National Acute Stroke Registry." Continuation 16

Dear Lisa Cooper:

On March 18, 2024, the CDC Institutional Review Board (IRB) reviewed and approved your continuation for CDC Protocol 5373, "Paul Coverdell National Acute Stroke Registry.". This approval is effective from March 26, 2024, to March 25, 2025.

Please comply with the previously approved protocol, as well as any subsequent modifications approved by the CDC IRB in accordance with CDC policies and procedures. Additionally, please be attentive to the following requirements:

- Continuation of Research: The continuation of your research study requires investigators to adhere to the research study design, methodology, and subject eligibility criteria, as outlined in the protocol approved by the CDC IRB. Any changes to the research study design, methodology, or subject eligibility criteria must be submitted to the CDC IRB for review and approval before implementation.

- Subjects Recruitment: You must continue to recruit subjects in accordance with the recruitment methods and procedures approved by the CDC IRB. Any changes to the recruitment methods or procedures must be submitted to the CDC IRB for review and approval before implementation.

- Informed Consent: You must continue to obtain informed consent from subjects in accordance with the approved consent form and procedure. Any changes to the consent form or procedure must be submitted to the CDC IRB for review and approval before implementation.

- Data Collection and Analysis: You must continue to collect and analyze data in accordance with the approved methods and procedures. Any changes to the data collection or analysis methods or procedures must be submitted to the CDC IRB for review and approval before implementation.

- Reporting of Incidents: Any unanticipated problems or noncompliance of a serious or continuing nature, as defined by CDC policies and procedures should be promptly reported to the CDC's Human Research Protections Office.

Please note that failure to comply with the above requirements may result in suspension or termination of your research.

Thank you for your attention to these matters. The CDC IRB appreciates your commitment to responsible conduct of research and your cooperation with the IRB review process.

If you have any questions or concerns regarding the conduct of your study or the IRB review process, please do not hesitate to contact your Center Human Subjects Contact or Jerrell Little, IRB Administrator, at 404-639-3536, or via email at jiv4@cdc.gov.

Sincerely,

For Robert Chirila, Lead
Human Research Protections Office