

**Memorandum**

**Date** February 1, 2011

**From** Barbara R. DeCausey, MPH, MBA  
Chief, Human Research Protection Office

**Subject** IRB Approval of Continuation of CDC Protocol #5558.0, "Clostridium Difficile Infection Surveillance Through the Emerging Infections Program" (Expedited)

**To** Fernanda Lessa  
NCEZID/DHQP

CDC's IRB A has reviewed and approved your request to continue protocol #5558.0 for the maximum allowable period of one year and it will expire on **02/11/2012**. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), categories 4 and 7.

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.

**Please note that the IRB approval for the following research partners has expired or was not included with your submission: Atlanta VA Medical Center; Sky Lakes Medical Center; MidState Medical Center; and the Georgia Department of Human Resources. In addition, the Waterbury Hospital FWA number expired on 01/31/2011. Please send the appropriate documentation to HRPO as soon as possible.**

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 along with available IRB approvals from all collaborators. 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 along with all completed supporting documentation at least six weeks before the protocol's expiration date of 02/11/2012.**

**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.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

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](mailto:huma@cdc.gov).

cc:

Joe Posid

NCEZIDHumanStudies