

**Memorandum**

Date December 6, 2013

From LaShonda Roberson, MPH
LCDR, USPHS
IRB-B Administrator
Human Research Protection Office

Subject Site Restricted CDC Approval of New Protocol 6542.0, "Community-Associated Clostridium difficile Risk Factor Study".(Expedited)

To SUSAN HOCEVAR, MD
NCEZID/DHQP

CDC's IRBB has reviewed the request for approval of new protocol 6542.0, "Community Associated Clostridium difficile Risk Factor Study", and has approved the protocol for the maximum allowable period of one year. CDC IRB approval will expire on 12/01/2014. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), category 7.

The IRB determined that the study poses minimal risk to subjects. The inclusion of children was reviewed under Subpart D and was determined to be permissible under 45 CFR 46.404. The inclusion of pregnant women was reviewed under Subpart B and was found to be permissible under 45 CFR 46.204. The IRB approves the waiver of documentation of informed consent for adults under 45 CFR 46.117 (c) (1). The IRB approved waiver of alteration of elements of informed consent for adults. The IRB approved waiver of assent for children capable of providing assent 45 CFR 46.408 (c).

COLLABORATOR/SITE RESTRICTIONS:

Institutions that receive federal support who are engaged in human subjects research are required to obtain and provide documentation of IRB approval. CDC investigators who interact with institutions that have failed to meet these requirements are collaborating with noncompliant institutions. Study activities may not begin with the collaborators listed below until documentation indicating current IRB approval has been received by CDC's Human Research Protection Office (HRPO) and the PI has been notified by HRPO that this restriction has been lifted and study activities may begin with:

- **Minnesota Department of Health**
- **Tennessee Department of Health**
- **Oregon Health Authority - Public Hlth Division**
- **Centerstone**
- **California Hlth & Human Services Agency**

- **Connecticut Dept of Public Hlth**
- **Maryland Dept Hlth & Mental Hygiene**
- **Department of Public Health**
- **Regents of the University of New Mexico**
- **New York State Dept of Hlth**

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 have approval to begin or continue research involving human subjects as described in this protocol.

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. 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 at least six weeks before the protocol's expiration date of 12/01/2014.

Any problems of a serious nature should be brought to the immediate attention of the IRB, and any proposed changes to the protocol should be submitted as an amendment to the protocol for 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 at (404) 639-7570 or email at huma@cdc.gov.

CC:
NCEZID Human Studies

DEPARTMENT OF HEALTH & HUMAN SERVICES

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