

**Memorandum**

Date September 7, 2010

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

Subject IRB Approval of New CDC Protocol #5975.0, "FoodNet Non-O157 Shiga Toxin-Producing E. coli Study: Assessment of Risk Factors for Laboratory-Confirmed Infections and Characterization of Illnesses by Microbiological Characteristics" (Expedited)

To Barbara Mahon
NCZVED/DFBMD

CDC's IRB-A has reviewed the request for approval of new protocol #5975.0, "FoodNet Non-O157 Shiga Toxin-Producing E. coli Study: Assessment of Risk Factors for Laboratory-Confirmed Infections and Characterization of Illnesses by Microbiological Characteristics" and has approved the protocol for the maximum allowable period of one year. **CDC IRB approval will expire on 09/06/2011.** 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 no greater than minimal risk to subjects. The IRB approved the inclusion of pregnant women in accordance with 45 CFR 46.204, the inclusion of children in accordance with 45 CFR 46.404, and the waiver of documentation of informed consent in accordance with 45 CFR 46.117(c)(2)

COLLABORATOR SITE RESTRICTION: CDC study activities may not begin with the following collaborators/sites 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:

- California Department of Health Services
- Colorado Division of Public Health and Environment
- Connecticut State Department of Public Health/CT Emerging Infections Program
- Georgia Department of Community Health
- Emory University
- VA Medical Center – Atlanta
- Maryland Department of Health and Mental Hygiene
- Minnesota Department of Health
- University of New Mexico Health Sciences Center
- New York State Health Department
- Oregon Health Division
- Tennessee Department of Health

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.

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 09/06/2011.**

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) 639-4721 or e-mail: huma@cdc.gov.

cc:
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NCEZIDHumanStudies