

**Memorandum**

**Date** September 20, 2011

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

**Subject** IRB Approval of Amendment to CDC Protocol 5536, "Health survey of former Marines, dependents, and employees potentially exposed to contaminated drinking water at USMC Base Camp Lejeune." (Expedited)

**To** Perri Ruckart, MPH  
ATSDR/DHS

CDC's IRB-B has reviewed and approved your request to amend protocol 5536, "Health survey of former Marines, dependents, and employees potentially exposed to contaminated drinking water at USMC Base Camp Lejeune". These changes included the following: An error was made in Question A1 (on page 5) of the survey instrument for the next of kin. The name of the deceased relative should have been printed for this question because this is the person that is the focus of the survey. However, instead, the next of kin's name was printed for this question. The next of kin who receives this survey could be confused and think that the survey requests information about him/herself rather than the deceased relative. About 17,000 next of kin surveys with this mistake were mailed on 9/8/11. Our contractor, WESTAT, proposes to send a letter to each of these 17,000 next of kin explaining that a mistake was made and clarifying that the survey requests information on the deceased relative, not the next of kin. The second mailing of the survey will be corrected so that the deceased relative's name is printed in Question A1. Protocol table of contents was amended to include Appendix 10.

The action was reviewed in accordance with the expedited review process outlined in [45 CFR 46.110(b)(1), Categories 0 and 7 or 46.111(b)(2), minor changes to previously approved research during the period (of one year or less) for which approval is authorized].

**Reminder: IRB approval of protocol #5536 will still expire on 11/11/2011.**

**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](mailto:huma@cdc.gov).

cc:

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

NCEH/ATSDR Human Subjects  
Marlena Wald