



Memorandum

Date September 20, 2011

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

Subject Protocol #5536: Incident Report #1

To Perri Ruckart, MPH
ATSDR/DHS

The CDC IRB B has reviewed the incident report: Protocol #5536, "Health survey of former Marines, dependents, and employees potentially exposed to contaminated drinking water at USMC Base Camp Lejeune."

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.

The IRB accepted this report. No additional action required. Thank you for reporting these events to the IRB.

cc:
NCEH/ATSDR Human Subjects
Marlena Wald