

**Memorandum**

Date February 14, 2012

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: At the time the contract request and OMB package were prepared, an estimate was made of the number of people expected to register with the Marine Corps to receive the health survey. This estimate was incorrect. The number of people who registered with the Marines by June 30, 2011 and for whom ATSDR agreed to send a survey package exceeded the original estimate by approximately 66,000 people. ATSDR has modified the consent process and document in surveying these additional registrants.

1) There will only be one mailing instead of also sending a pre-survey letter notifying them to expect the survey.

Only the package containing the letter of invitation, the consent document, and the survey questions will be sent.

2) The consent document and the survey instructions were modified because the help desk and web-based survey were staffed by Westat and are no longer active, thus for these survey participants, the number to call for information about the survey will be changed to a number staffed by CDC and the web-based survey option will not be available.

Protocol table of contents was amended to include Appendices 11 and 12 and page 62 was amended to describe slight changes to surveying registrants - no web-based survey, different help line number, and no prenotice letter.

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 11/11/2012.

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.

If you have any questions, please contact your National Center Human Subjects Contact or the CDC Human Research Protection Office (404) 639-7570. At the time the contract request and OMB package were prepared, an estimate was made of the number of people expected to register with the Marine Corps to receive the health survey. This estimate was incorrect. The number of people who registered with the Marines by June 30, 2011 and for whom ATSDR agreed to send a survey package exceeded the original estimate by approximately 66,000 people. ATSDR has modified the consent process and document in surveying these additional registrants.

1) There will only be one mailing instead of also sending a pre-survey letter notifying them to expect the survey.

Only the package containing the letter of invitation, the consent document, and the survey questions will be sent.

2) The consent document and the survey instructions were modified because the help desk and web-based survey were staffed by Westat and are no longer active, thus for these survey participants, the number to call for information about the survey will be changed to a number staffed by CDC and the web-based survey option will not be available.

Protocol table of contents was amended to include Appendices 11 and 12 and page 62 was amended to describe slight changes to surveying registrants - no web-based survey, different help line number, and no prenotice letter.

or e-mail: huma@cdc.gov.

cc:

NCEH/ATSDR Human Subjects

Marlena Wald