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**Memorandum**

DATE: 3/15/2010

FROM: IRB Administrator  
Human Research Protection Office  
Office of the Chief Science Officer, OD/CDC

SUBJECT: CDC Approval of Changes to Protocol 5536.0, "Health survey of former Marines, dependents, and employees potentially exposed to contaminated drinking water at USMC Base Camp Lejeune." (Expedited)

TO: Perri Ruckart, MPH  
CCEHIP/NCEH/ATSDR/DHS

CDC's IRB B has reviewed and approved the request to make changes to protocol 5536.0, " Health survey of former Marines, dependents, and employees potentially exposed to contaminated drinking water at USMC Base Camp Lejeune." These changes included the following: The title of the protocol was changed to "Morbidity Study of Former Marines, Dependents, and Employees Potentially Exposed to Contaminated Drinking Water at USMC Base Camp Lejeune" to better describe how the survey information will be utilized. The protocol was amended to delete the pilot health survey (pages 6, 49-53 in marked copy). The protocol was amended to clearly state that the study participants are those who are identified a priori (page 4 and that those who are identified because they are registrants only will be analyzed separately in a descriptive fashion (pages 6, 60), Language was added to the protocol to explicitly state that exposure to BTEX compounds will also be evaluated (page 33). Language was added to the protocol to state that during the phone contact, the first 1,000 morbidity study non-responders will be asked their reasons for not participating to obtain additional information that could be used to assess the likelihood of selection bias (page 36). There was a change in person-time accumulation from the date the person first resided or worked at Camp Lejeune (or Camp Pendleton) until date of death or the date that the health surveys are mailed (page 49). The Selection Bias and Disease Reporting Bias sections were separated (pages 38, ) and additional language was added to these sections describing sensitivity analyses (also discussed on page 52). Language was added to the protocol on convening an expert panel to make recommendations on the study (pages 39-40). Language was added to the protocol to provide additional details as to why Camp Pendleton was chosen as the comparison population (page 44). More details were added to describe how ATSDR will communicate the study results to community members (page 57). This was done in response to discussions with OMB.

The action was reviewed in accordance with 45 CFR 46.110(b)(1), categories 0 & 7 or 46.110(b)(2), minor changes to previously approved research during the period (of one year or less) for which approval is authorized.

CDC IRB approval of protocol 5536.0 will still expire on 11/11/2010. 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 a request for review of changes to the protocol for IRB review and 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) 639-4721 or by e-mail at [huma@cdc.gov](mailto:huma@cdc.gov).

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Cc:  
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