Justification for Non-substantive Changes to OMB Package 0923-0042

April 2011

Through 1985 the drinking water from two of eight treatment plants at Marine Corps Base Camp Lejeune was contaminated with volatile organic compounds including perchloroethylene, trichloroethylene, and benzene. In 2008, President Bush signed H.R. 4986: National Defense Authorization Act for Fiscal Year 2008 which requires the Agency for Toxic Substances and Disease Registry (ATSDR) to develop a health survey of individuals possibly exposed to contaminated drinking water at Camp Lejeune that would collect: "…personal health information that may lead to scientifically useful health information associated with exposure to trichloroethylene (TCE), [tetrachloroethylene or perchloroethylene] (PCE), vinyl chloride, and the other contaminants identified in the ATSDR studies that may provide a basis for further reliable scientific studies of potentially adverse health impacts of exposure to contaminated water at Camp Lejeune." The Information collection package for this health survey received OMB approval in November 2010.

The contractor who will be conducting the survey for ATSDR has requested changes to the information collection tool and to the procedures for conducting this project. The changes are based on the extensive experience of the contract staff in developing and conducting survey-type data collections. Most of these changes have received IRB approval. ATSDR and the contractor are in the process of obtaining IRB approval for the remainder of the changes. These changes will not affect the number of participants, the burden to the participants, or the overall cost of this information collection. Therefore we are requesting approval from OMB to implement these non-substantive changes to the information collection tool and procedures.

1. The wording of some questions in the Health Survey Questionnaire (Attachment C) has been changed to improve responsiveness

2. To improve ease of administration, the Health Survey Questionnaire (Attachment C) has been renumbered and reorganized into sections.

3. Various changes have been made to the wording of the letters of invitation (Attachments D and E) and other correspondence (Attachments G, H, I, and J) and consent materials (Attachments L, M, and R) to clarify the process.

4. Changes have been made to the procedures for obtaining consent for medical records review and the names of treating physicians. This will be done only for a subset of the survey participants and only after the determination has been made to verify medical conditions.

Approval for an amended Medical Records Request form will be submitted at a later time if a decision is made to verify self reported medical conditions.

5. To lessen confusion, the investigators have revised consent material (Attachment R) going to the next of kin for deceased individuals to provide them with materials specific to their situation instead of using the documents intended to be completed by living respondents.