



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; 60-day comment request: Gulf Long-Term Follow-Up Study (GuLF STUDY)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) The quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

TO SUBMIT COMMENTS AND FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Dale P. Sandler, Chief, Epidemiology Branch, NIEHS, Rall Building A3-05, PO Box 12233, Research Triangle Park, NC 27709 or call non-toll-free number 919-541-4668 or E-mail your request, including your address to: [Sandler@niehs.nih.gov](mailto:Sandler@niehs.nih.gov). Formal requests for additional plans and instruments must be requested in writing.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

PROPOSED COLLECTION: Gulf Long-Term Follow-Up Study (GuLF STUDY), 0925-0626, Expiration Date 01/31/2014 – REVISION, National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

Need and Use of Information Collection:

The purpose of the GuLF STUDY is to investigate potential short- and long-term health effects associated with oil spill clean-up activities and exposures related to the Deepwater Horizon disaster, and to create a resource for additional collaborative research on focused hypotheses or subgroups. Exposures range from negligible to potentially significant; however, potential long-term human health consequences are largely unknown due to insufficient research in this area.

The study has enrolled 32,762 participants with a range of jobs/exposures, including participants who performed various types of clean-up-related work (“exposed”) and other who did not (“unexposed” controls). Of the 32,762 enrolled into the Full Cohort, 20,000 have been assigned to the Active Follow-up Sub-cohort, and 6,000 of these have been assigned to the Biomedical Surveillance Sub-cohort.

In order to minimize loss to follow-up, updated contact information will be collected yearly for the Full Cohort. Follow-up questionnaires will be administered biennially to the Active Follow-up Sub-cohort to assess changes in health status and factors that could confound associations between exposures and outcomes. A supplemental mental health questionnaire will be administered repeatedly over a 2-year period to a subset of 4,600 participants in the Active Follow-up Sub-cohort to assess mental health trajectories among those affected by the oil spill and utilization of mental health services in the Gulf region. Participants in the Biomedical Surveillance Sub-cohort will be invited to take part in a comprehensive research-based clinical examination. The clinical exam provides an opportunity to carry out more comprehensive clinical testing and mental health evaluations than could be completed during the baseline home visit. The exams will allow for a much more in-depth assessment of pulmonary, neurological, and mental health outcomes that may be associated with the Deepwater Horizon oil spill

exposures and experiences.

OMB approval is requested for 3 years. There are no costs to respondents other than their time.

The total estimated annualized burden hours are 21,724.

Estimated Annualized Burden Hours

<b>Type of Respondent</b>	<b>Form/Activity</b>	<b>Number of Respondents</b>	<b>Number of Responses per Respondent</b>	<b>Average Time per Response (in hours)</b>	<b>Total Burden Hour (for 3 years)</b>	<b>Annualized Burden Hour</b>
Cleanup & non-Cleanup Workers	Annual Recontact Questionnaire	32,762	3	15/60	24,572	8,191
Cleanup & non-Cleanup Workers	Supplemental Mental Health Telephone Questionnaire	4,600	4	15/60	4,600	1,533
Cleanup & non-Cleanup Workers	Follow-up Telephone Questionnaire	20,000	2	30/60	20,000	6,667
Cleanup & non-Cleanup Workers	Clinical Exam	4,000	1	4	16,000	5,333

October 30, 2013.

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[FR Doc. 2013-26647 Filed 11/06/2013 at 8:45 am; Publication Date: 11/07/2013]