

water contaminated with TCE or PCE could not be reasonably evaluated in the 1998 study because of extreme under-ascertainment of cases using data from birth certificates.

In response to the PHA recommendation, ATSDR began the multi-step process of determining the appropriateness of conducting an epidemiological study of specific childhood cancers and birth defects at Camp Lejeune. Based on the scientific literature, ATSDR decided to focus on specific childhood cancers and birth defects: Childhood leukemia, childhood non-Hodgkin's lymphoma, spina bifida, anencephaly, cleft lip and cleft palate. ATSDR conducted a survey in 1999–2002 (OMB No. 0923–0023) to identify all cases of the specific birth defects and childhood cancers. About an 80 percent participation rate was achieved among the approximately 16,000 to 17,000 births that occurred among women who were pregnant while living at Camp Lejeune during the study period 1968–1985. These years were chosen because 1968 is the first year that birth certificates were computerized in North Carolina, and 1985 is the last year that VOC contamination was detected at the base. All of the participants who took part in the Camp Lejeune Survey in

1999–2002 gave permission to be contacted for future studies. Additionally, many survey participants have telephoned ATSDR to request the results of the survey and inquire about future studies.

The overall objective of the proposed case-control study is to examine whether there is an association between maternal exposures during pregnancy to TCE and PCE in drinking water at Camp Lejeune during the period of 1968–1985 and the risk of specific birth defects (spina bifida, anencephaly, cleft lip and cleft palate) and childhood cancers (childhood leukemia and Non-Hodgkin's Lymphoma) in offspring.

ATSDR continues to verify that the child had the birth defect or childhood cancer reported by the parents in the survey. The parents of the children with possible birth defects or childhood cancers of concern were contacted and asked to sign a medical records release form so that ATSDR could gain access to the medical records for their children. If the child had reached 18 years of age, he or she was contacted and asked to sign a medical records release form.

Once the review of medical records is complete, the final step is to conduct an epidemiological study that includes all the cases of birth defects and childhood cancers of concern. The study will also

include a control sample of children who did not have a birth defect or a childhood cancer and whose mothers lived at Camp Lejeune during their pregnancy over the period 1968–1985. The study plans to enroll 33 cases and 167 controls over the course of one year. The epidemiological study will require the computer modeling of the drinking water system at Camp Lejeune over the period 1968–1985 in order to determine as accurately as possible which mothers were exposed to the VOCs in the drinking water during their pregnancy and which mothers were not exposed during their pregnancy.

To reduce the amount of time required by the respondents, Computer Assisted Telephone Interviews (CATI) will be conducted. Following completion of all respondent interviews, the data will be tabulated and analyzed (the case group will be compared with the control group). Because only a very small number of studies have looked at the risk of birth defects and childhood cancers among children born to mothers exposed during pregnancy to VOCs in drinking water, the proposed study will aid in developing or contributing to generalizable knowledge.

The estimated annualized burden is 150 hours.

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)
Cases	33	1	45/60
Controls	167	1	45/60

Dated: April 26, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for Injury Prevention and Control Initial Review Group

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee Conference Call Meeting:

Name: National Center for Injury Prevention and Control (NCIPC) Initial Review Group (IRG).

Time and Date: 1 p.m.–2 p.m., May 7, 2004.

Place: National Center for Injury Prevention and Control, CDC, 2945 Flowers Road, Atlanta, Georgia 30341.

Status: Open: 1 p.m.–1:10 p.m., May 7, 2004.

Closed: 1:10 p.m.–2 p.m., May 7, 2004.

Purpose: This group is charged with providing advice and guidance to the Secretary, Department of Health and Human Services, and the Director, CDC, concerning the scientific and technical merit of grant and cooperative agreement applications received from academic institutions and other public and private profit and nonprofit organizations, including State and local government agencies, to conduct specific injury research that focuses on prevention and control and supports Injury Control Research Centers (ICRCs).

Matters To Be Discussed: Agenda items include an explanation of the call's purpose, panelists' responsibilities, and discussion and vote on the results of an April 27–28, 2004, site visit review of an ICRC application submitted in response to Program Announcement #04057. From 1:10–2 p.m., the Group will discuss details of the site visit and vote on the results. This portion of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Pub. L. 92–463.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Gwendolyn H. Cattledge, Ph.D., M.S.E.H., Executive Secretary, NCIPC IRG, CDC, 4770 Buford Highway, NE., M/S K02, Atlanta, Georgia 30341–3724, telephone 770/488–4655.

The Director, Management Analysis and Services office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: April 28, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: HHS/ACF/ASPE/DOL Enhanced Services for the Hard-to-Employ Demonstration and Evaluation Project Baseline Survey (Revised).

OMB No.: 0970-0251.

Description: The Enhanced Services for the Hard-to-Employ Demonstration and Evaluation Project (HtE) is the most ambitious, comprehensive effort to learn what works in this area to date and is explicitly designed to build on previous and ongoing research by rigorously testing a wide variety of approaches to promote employment and improve family functioning and child well-being. The HtE project will "conduct a multi-site evaluation that studies the implementation issues, program design, net impact and benefit-costs of selected programs"¹ designed to help Temporary Assistance for Needy Families (TANF) recipients, former TANF recipients, or low-income parents who are hard-to-employ. The project is sponsored by the Office of Planning, Research and Evaluation (OPRE) of the Administration for Children and Families (ACF), the Office of the Assistant Secretary for Planning and Evaluation (ASPE) in the U.S. Department of Health and Human Services (HHS), and the U.S.

Department of Labor (DOL). The evaluation involves an experimental, random assignment design in six sites, testing a diverse set of strategies to promote employment for low-income parents who face serious obstacles to employment, including physical and mental health problems, substance abuse, human capital deficiencies, and situational barriers. As many as two of the sites included in the evaluation will feature "two generation" models, serving both parents and their children. Over the next several years, the HtE project will generate a wealth of rigorous data on implementation, effects, and costs of these alternatives approaches. The data collected will be used for the following purposes:

- To study the extent to which different HtE approaches impact employment, earnings, income, welfare dependence, and the presence or persistence of employment barriers;
- To collect data on a wider range of outcome measures than is available through Welfare, Medicaid, Food Stamps, Social Security, the Criminal Justice System or Unemployment Insurance records in order to understand the family circumstances and attributes and situations that contribute to the difficulties in finding employment; job retention and job quality; educational attainment; interactions with and knowledge of the HtE program; household composition; childcare; transportation; health care; income; physical and mental health problems; substance abuse; domestic violence; and criminal history.
- To conduct non-experimental analyses to explain participation decisions and provide a descriptive picture of the circumstances of individuals who are hard-to-employ;
- To obtain participation information important to the evaluation's benefit-cost component; and to obtain contact information for possible future follow-up, information that will be important to achieving high response rates for additional surveys.

Materials for the HtE baseline survey were previously submitted to OMB on April 28, 2003, and were subsequently approved. The purpose of this revision is to introduce new instruments for the collection of baseline data in the mental health barriers site. Much of the substantive content in these instruments was included in the Mental Health

Module and Core Survey that were approved in our original submission. All other instruments included in this submission remain unchanged since OMB approval.

Respondents: The respondents of the baseline survey are TANF recipients, former TANF recipients, or low-income individuals who are hard-to-employ from the five states currently participating in the HtE project: Kansas, New York, Pennsylvania, Maine, and Rhode Island. Survey respondents can be grouped according to four target populations: ex-offenders with children; low-income parents with mental health barriers; populations connected to the TANF system; and programs working with two-generations (parents and their children). Prior to random assignment, basic demographic information for all survey respondents will be obtained wherever possible from the program's automated system.

We had originally planned to administer a core set of questions via Audio-Computer Assisted Self Interview (ACASI-Core) to survey respondents in all sites. However, the revised mental health instruments have eliminated the need for a Core survey in this site, so we have reduced the number of Core survey respondents that were estimated in the previous OMB submission by 2,000 (the number of respondents originally estimated for the mental health site). The criminal justice site, which is the only site that has begun random assignment, ultimately did not implement the Core survey, using baseline data supplied by the program instead. However, we did not deduct the number of criminal justice sample members from the number of Core survey respondents for the purpose of comparability.

A separate set of questions will be administered in two stages (via a mail-out/telephone screener and a detailed telephone interview) in the site operating a program aimed at survey respondents with mental health problems. Approximately 918 respondents will complete the full 30 minutes of baseline data collection.

Finally, in the two-generation sites (as many as two of the six sites), survey respondents will complete a two-generation survey administered by a Computer Assisted Personal Interview (CAPI), in addition to the Core survey.

¹ From the Department of Health and Human Services RFP No.: 233-01-0012