

**ENVIRONMENTAL PROTECTION AGENCY**

[ORD-2005-0010, FRL-7897-8]

**Agency Information Collection Activities: Proposed Collection; Comment Request; Population-Based Pilot Study of Children's Environmental Health in Support of the National Children's Study, EPA ICR Number 2187.01****AGENCY:** Environmental Protection Agency.**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that EPA is planning to submit a proposed Information Collection Request (ICR) to the Office of Management and Budget (OMB). This is a request for a new collection. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection as described below.

**DATES:** Comments must be submitted on or before June 13, 2005.

**ADDRESSES:** Submit your comments, referencing docket ID number ORD-2005-0010, to EPA online using EDOCKET (our preferred method), by email to [oei.docket@epa.gov](mailto:oei.docket@epa.gov), or by mail to: EPA Docket Center, Environmental Protection Agency, Office of Environmental Information Docket, Mail Code 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

**FOR FURTHER INFORMATION CONTACT:** Susan Auby, Environmental Protection Agency, Office of Information Collection, Office of Environmental Information, 1200 Pennsylvania Ave., NW., Mail Code 28221T, Washington, DC 20460; telephone number: (202) 566-1672; fax number: (202) 566-1753; email address: [auby.susan@epa.gov](mailto:auby.susan@epa.gov).

**SUPPLEMENTARY INFORMATION:** EPA has established a public docket for this ICR under Docket ID number ORD-2005-0010, which is available for public viewing at the Office of Research and Development Docket in the EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566-1744, and the telephone number for the Office of Research and Development Docket is (202) 566-1752. An electronic version of the public docket is available through

EPA Dockets (EDOCKET) at <http://www.epa.gov/edocket>. Use EDOCKET to obtain a copy of the draft collection of information, submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in the docket ID number identified above.

Any comments related to this ICR should be submitted to EPA within 60 days of this notice. EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EDOCKET as EPA receives them and without change, unless the comment contains copyrighted material, Confidential Business Information (CBI), or other information whose public disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EDOCKET. The entire printed comment, including the copyrighted material, will be available in the public docket. Although identified as an item in the official docket, information claimed as CBI, or whose disclosure is otherwise restricted by statute, is not included in the official public docket, and will not be available for public viewing in EDOCKET. For further information about the electronic docket, see EPA's **Federal Register** notice describing the electronic docket at 67 *FR* 38102 (May 31, 2002), or go to <http://www.epa.gov/edocket>.

**Affected entities:** Entities potentially affected by this action are women aged 18-40 years, pregnant women, their husbands or partners, and their children who live in selected areas of North Carolina.

**Title:** Population-based pilot study of children's environmental health in support of the National Children's Study.

**Abstract:** An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9. The proposed study will be conducted by the Epidemiology and Biomarkers Branch, Human Studies Division, National Health and Environmental Effects Research Laboratory, Office of Research and Development, U.S. EPA. The U.S. EPA will conduct this research in partnership with the National Children's Study (NCS) Program Office

at the National Institute of Child Health and Human Development (NICHD) as well as the other lead agencies of the NCS: the Centers for Disease Control and Prevention (CDC) and the National Institute of Environmental Health Sciences (NIEHS). The purpose of this study is to pilot test protocols, policies and procedures for the NCS with the goal of improving the efficiency of study procedures and enhancing the likelihood of successful implementation in probability-based population study locations across the US. In particular, this study will test procedures for population-based sampling and subject recruitment, test proposed study logistics and estimates of subject burden, and evaluate data collection strategies including interviews and acquisition of biologic and environmental samples. Under the Children's Health Act of 2000, NICHD is charged with leading a cooperative federal effort with EPA and other agencies of the Department of Health and Human Services to plan and implement a comprehensive study of children's environmental health. Further details on the NCS, including the Study Plan, can be found at: <http://www.nationalchildrensstudy.gov>. Population-based sampling was a strong recommendation from the NCS Federal Advisory Committee and an expert panel workshop on sampling held in March 2004 recommended a pilot test of sampling strategies. Given the scale and complexity of the proposed NCS strategy for recruiting pregnant women and women attempting pregnancy, this pilot study will address uncertainties related to sampling and recruitment.

Two locations will be selected (one urban and one rural), each of which approximately corresponds to a NCS Primary Sampling Unit (PSU). Within each location, two geographic areas will be defined as "segments." The NCS is interested in exploring ways of defining segments that may lead to more natural communities, so two of the segments will be drawn based on elementary school catchment areas in addition to two segments drawn using more traditional census boundaries. Comparing census-based segments to school-based segments, we plan to evaluate the time, cost, and efficiency of collecting community measures; and the impact on recruitment and community engagement. We plan to evaluate strategies for enumerating the population such as counting and listing, as well as the use of commercial postal lists.

Once the segments are enumerated, we plan to visit approximately 10,000 occupied households (approximately

2,500 per segment) to identify any female occupants who may be eligible for the pilot study. The initial household visit is expected to take up to 5 minutes per household, and any adult household member can provide the necessary information. Each potentially eligible woman in the household will then be administered a 15-minute screening interview to determine her eligibility for the study. Like the NCS, this pilot will recruit women prior to pregnancy who are planning to become pregnant or who are likely to become pregnant and women who are in the first trimester of pregnancy at the time of screening. This pilot will also enroll women at screening who are pregnant but past the first trimester and a small number of women may be recruited during the birth hospital stay. The pilot study recruitment and enrollment procedures include up to five household visits, determining if a lower number of visits would achieve optimal efficiency. Each segment will have a consistent visit schedule protocol to avoid confusion. Like the NCS, eligible women who are planning pregnancy or likely to become pregnant will be aged 18–40 years. For the pilot study, women who are currently pregnant are eligible if they are 18 years of age or older. Since the sample is based on residence at delivery, only women who plan to reside in the same area at delivery (*i.e.*, not move out of the segment before giving birth) will be eligible. The household screening phase of the project is expected to take approximately four months to complete.

We plan to follow the visit schedule proposed in the NCS Study Plan. Women with a high likelihood of pregnancy (*i.e.*, planners) will be visited in their homes approximately every two months for up to four visits (or until they conceive) with short telephone interviews in the intervening months. Women with a moderate likelihood of pregnancy will have one home visit and short telephone interviews every three months to update pregnancy status. Women with a low likelihood of pregnancy will be contacted by telephone twice—at six months and at one year after enrollment—to determine if their pregnancy status has changed. (These three groups are defined by the NCS Study Plan as high, moderate, and low risk of pregnancy, respectively.)

During pregnancy, we plan to make a home visit in the first trimester and a clinic visit in both the second and third trimester. At each clinic visit, we plan to complete a brief interview and to conduct various clinical exams or tests (such as ultrasound exams, venous

blood draw, etc.). In addition to these three pregnancy visits, women who are enrolled early (before 8–10 weeks of pregnancy) may be invited to an additional study clinic visit for an oral glucose tolerance test.

As with the NCS, we plan to attempt to collect a number of biologic specimens at delivery. Many of these specimens (*e.g.*, cord blood, meconium) will involve minimal or no burden to the mother or infant. After birth, we plan to visit the family in the home when the child is 1 month, 6 months, 12 months, and 18 months of age. At each home visit we anticipate collecting interview data; biologic specimens that are non-invasive (*e.g.*, nails, hair) or minimal risk (such as venous blood drawn by a trained phlebotomist); and environmental samples (such as dust wipes).

The content of the interviews and analytic plan for the biologic and environmental samples collected are focused on factors related to child growth and development. Questions will be asked about diet and activity as well as demographic information, medical history, occupational and other exposures, alcohol and smoking (including environmental tobacco smoke exposure), mental health and feelings about pregnancy and parenthood, social support, pets, neighborhood characteristics, and measures of child health and development. Specific data elements are intended to capture some of the domains that will be measured in the NCS which has a broad definition of environment including biologic, chemical, physical, and psycho-social. We expect to interview subjects regularly about their feelings about study participation to capture the qualitative assessments of acceptability and enhance the lessons that can be learned which may enhance the successful implementation of the NCS.

The EPA would like to solicit comments to:

- (i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;
- (ii) Evaluate 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;
- (iii) Enhance the quality, utility, and clarity of the information to be collected; and
- (iv) Minimize the burden of the collection of information on those who are to respond, including through the

use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

*Burden Statement:* The public reporting and recordkeeping burden for this collection of information varies depending on the eligibility and pregnancy status of women at the time of enrollment. Women who are not pregnant at the time of enrollment will have varying burden levels depending on their time to pregnancy and their likelihood of pregnancy (as described above). Women who are enrolled in the pilot study while pregnant or at delivery will be folded into the visit schedule at the appropriate point. Detailed estimates regarding the number of potential respondents and burden associated with each visit are provided in the EDOCKET. Table 1 provides the average burden hours per respondent and the total cumulative burden hours for the entire study period (approximately 3 years and 1 month).

Approximately 5 minutes per household is required to determine potentially eligible occupants. Potentially eligible women are asked to complete a 15-minute screening interview. The estimated total burden for a fully participating woman ranges from 8 hours (for a woman enrolled at delivery) to 21 hours (for a “high likelihood” woman who receives all contacts in the preconception period) over a three year period. The burden for men is somewhat more consistent because they only receive one visit in each of the preconception, pregnancy, and childhood visit periods; each visit is approximately 1 hour. The burden for children ranges from 10 minutes at the birth visit to approximately 2 hours for full participation up to 18 months of age.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

TABLE 1.—ESTIMATED AVERAGE AND TOTAL BURDEN FOR ALL CONTACTS

Type of respondent	Estimated number of respondents	Average burden hours per respondent	Estimated total burden hours	Total burden cost
Household Unit .....	10,000	0.1	1,000	<sup>2</sup> \$16,070
Women Screened, Not Enrolled .....	4,346	0.3	1,303	<sup>2</sup> 21,070
Women Screened and Enrolled.				
High likelihood of pregnancy .....	167	6.2	1,786	<sup>2</sup> 28,880
Moderate likelihood of pregnancy .....	572	3.7	2,527	<sup>2</sup> 40,862
Low likelihood of pregnancy .....	1,797	1.5	3,000	<sup>2</sup> 48,510
Pregnant at enrollment <sup>1</sup> .....	169	4.0	1,952	<sup>2</sup> 31,564
Enrolled at delivery .....	35	7.1	248	<sup>2</sup> 4,010
Men .....	1,074	0.8	1,286	<sup>2</sup> 20,795
Children .....	406	1.5	603	<sup>3</sup> 3,105

<sup>1</sup> Includes 48 volunteers assumed to be pregnant at enrollment.

<sup>2</sup> \$16.17/hour. Source: Bureau of Labor Statistics, State Wage Data for North Carolina. [http://www.bls.gov/oes/current/oes\\_nc.htm](http://www.bls.gov/oes/current/oes_nc.htm).

<sup>3</sup> \$5.15/hour (minimum wage).

Dated: March 29, 2005.

**Rebecca L. Calderon,**

*Director, Human Studies Division.*

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**ENVIRONMENTAL PROTECTION AGENCY**

[FRL-7898-1]

**Proposed CERCLA Administrative Cost Recovery Settlement Pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act; Greenberg Salvage Yard, Murphysboro, IL**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice; request for public comment.

**SUMMARY:** In accordance with section 122(h) of the Comprehensive Environmental Response, Compensation, and Liability Act, as amended ("CERCLA"), 42 U.S.C. 9622 (h), notice is hereby given of a proposed administrative settlement by consent, pursuant to CERCLA 122(h), 42 U.S.C. 9622(h) concerning Cox Parts & Services, Inc. and Thomas D. Cox Trucking, Inc. and the Greenberg Salvage Yard Site.

The settlement requires that the Settling Parties shall pay to the EPA Hazardous Substance Superfund in eleven monthly installments the principal sum of \$13,157 plus interest as defined in the Agreement for Recovery of Past Response Costs. The settlement includes EPA's covenant not to sue the Settling Parties pursuant to 107(a) of CERCLA, 42 U.S.C. 9607(a), to recover Past Response Costs. This covenant not to sue is conditioned upon the satisfactory performance by Settling Parties of their obligations under the

Agreement. U.S. EPA is proposing this Agreement because it provides reimbursement to U.S. EPA for part of its past costs at the Greenberg Salvage Yard Site.

For thirty (30) days following the date of publication of this notice, the agency will receive written comments relating to the settlement. The Agency will consider all comments received and may modify or withdraw its consent to the settlement if comments received disclose facts or considerations which indicate that the settlement is inappropriate, improper, or inadequate. The response to any comment received will be available for public inspection at the Superfund Division Record Center, U.S. Environmental Protection Agency, 77 West Jackson Blvd., Chicago, Illinois 60604-3590.

**DATES:** Comments must be submitted on or before May 12, 2005 pursuant to 122(i) of CERCLA, 42 U.S.C. 9622(i).

**ADDRESSES:** Comments should be addressed to Virginia Narsete, Public Affairs Specialist, Superfund Division, Emergency Response Branch, Mail Code SE-5J, U.S. Environmental Protection Agency, Region 5, 77 West Jackson Blvd., Chicago, Illinois 60604-3590, and should reference the Greenberg Salvage Yard site, Murphysboro, Illinois. The settlement agreement and additional background information relating to the settlement are available for public inspection at the U.S. Environmental Protection Agency, Region 5, Superfund Division Record Center (address above), or a copy of the AOC may be obtained from Virginia Narsete.

**FOR FURTHER INFORMATION CONTACT:** Virginia Narsete, Public Affairs Specialist, Superfund Division, Emergency Response Branch, Mail Code SE-5J, U.S. Environmental Protection Agency, Region 5, 77 West Jackson Blvd., Chicago, Illinois 60604-3590 or call (312) 886-4359.

**SUPPLEMENTARY INFORMATION:** The Greenberg Salvage Yard Superfund Site, encompassing two parcels of approximately 2.34 acres, located in Murphysboro, Jackson County, Illinois is generally designated by the following property description: The Site's northern parcel is bordered to the north by Thomas D. Cox Trucking, Inc., to the east by the American Legion and to the west by private residences. The Site's southern parcel is bordered by a lumber yard and to the east and west by private residences. In response to the release or threatened release of hazardous substances at or from the Site, EPA undertook response actions at the Site pursuant to 104 of CERCLA, 42 U.S.C. 9604. A lead stabilizing agent was mixed with lead-contaminated soil at the Site to treat the soil to below hazardous waste characteristic levels for lead. Then the soil was transported off the site for disposal as non-hazardous waste. A total of 12,050.6 tons of treated/low level contaminated lead soil were disposed of at an off-site disposal facility. The Site was then backfilled with clean soil. The settling parties are: Cox Parts and Services, Inc. and Thomas D. Cox Trucking, Inc. The Settling Parties shall be jointly and severally liable for all obligations imposed upon them under the Agreement for Recovery of Past Response Costs, 122(h)(1) of CERCLA 42 U.S.C. 9622(h)(1). Based upon the information submitted by the parties, EPA determined that each Settling Party has limited financial ability to pay for response costs incurred at the Site. However, the Site property was owned by Cox Parts and Services, Inc. and was sold after the removal action was completed. The settlement represents the amount of profit received by Cox Parts and Services, Inc. from the sale of the property. Settling Parties shall pay to the EPA Hazardous Substance