

## ANNUALIZED BURDEN TABLE

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden per response	Estimated total annual burden hours requested
Asthma grantee survey .....	1550	1	.25	387.5
Total .....				387.5

*Request for Comments:* Written comments and/or suggestions from the public and affected agencies are invited on 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) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to 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.

*Direct Comments to OMB:* Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Jerry Phelps, Division of Extramural Research and Training, National Institute of Environmental Health Sciences, P.O. Box 12233, MD EC-21, 111 T.W. Alexander Drive, RTP, NC 27709. Phone (919) 541-4259. E-mail: [phelps@niehs.nih.gov](mailto:phelps@niehs.nih.gov).

*Comments Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: November 7, 2007.

**Marc Hollander,**

*NIEHS, Associate Director for Management.*  
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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Child Health and Human Development; Proposed Collection; Comment Request; Pilot Study for the National Children's 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 Child Health and Human Development (NICHD), the 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.

*Proposed Collection: Title:* Pilot Study for the National Children's Study, *Type of Information Collection Request:* NEW, *Affected entities:* Households and individuals. *Types of respondents:* People potentially affected by this action are pregnant women, women age 18-49 years of age, their husbands or partners, and their children who live in selected areas within the seven (7) National Children's Study Vanguard sites enumerated below. A small number of health care professionals, community leaders, and child care personnel are also potential respondents. *Frequency of Response:* On occasion. See burden table for estimated number of annual responses for each respondent. *Need and use of information collection:* The purpose of this Study is to pilot test protocols, policies, and procedures for the National Children's Study (NCS) with the goal of improving the efficiency of study procedures and enhancing the subsequent implementation of the NCS. The NCS is a long-term cohort study of environmental influences on child health and development authorized under the Children's Health Act of 2000. The Act specifies a broad definition of environment, including biologic, chemical, physical, and psycho-social factors and authorizes NICHD to plan, develop, and implement a prospective cohort study, from birth to adulthood, to evaluate the effects of those exposures

on child health and human development. This data collection will test procedures for population-based sampling and recruitment of pregnant women and women of child-bearing age, test study logistics, and estimates of subject burden, and evaluate data collection strategies including interviews and acquisition of biologic and environmental samples. In addition, participants will also be asked to provide qualitative and quantitative input on their feelings regarding participation in this Study, to enhance the lessons that can be learned and applied to improve the efficiency of the full NCS. Further details pertaining to the NCS background and planning, including the NCS Research Plan, can be found at: <http://nationalchildrensstudy.gov>. This Pilot Study will be carried out in the seven NCS "Vanguard" locations previously selected as the initial study sites. These sites are Orange County, CA; Duplin County, NC; Queens County, NY; Montgomery County, PA; Salt Lake County, UT; Waukesha County, WI; and the aggregate of Lincoln, Pipestone, and Yellow Medicine Counties, MN and Brookings County, SD. This data collection is intended to begin with household enumeration and enrollment of women, proceed through pregnancy and birth, and continue with follow-up of children for up to 21 years. This application is for the first three years of data collection, which includes data collection through the visits at which some of the children will be 24 months old. Details of data collections beyond this period will be addressed at the time of renewal or in future applications. Women who are pregnant will be eligible for participation if, at the time of household enumeration and screening, they are within the first trimester of pregnancy. Women who are not pregnant will be eligible if, at the time of household enumeration and screening, they are 18-49 years of age, are neither surgically nor medically sterile, and can participate in the consent process. A subset of age-eligible women with a high likelihood of pregnancy (e.g., planning to become pregnant) will be enrolled to enable assessment of peri-conceptual

exposures, should they become pregnant. The remainder of the study population will comprise women enrolled early in pregnancy. The seven centers combined will follow approximately 1000 infants born to women enrolled in the first year of this Pilot Study. Infants born to women enrolled in this Pilot Study but born after the eligibility period for the Pilot will be eligible for enrollment in the full NCS. The schedule of participant contacts for this data collection includes home visits, clinic visits, and phone contacts, and is described in the NCS Research Plan: <http://nationalchildrensstudy.gov>. Home visits before and during pregnancy will include collection of interview data,

environmental specimens such as air and dust samples, maternal and paternal biospecimens such as blood and hair samples, and a brief physical examination including anthropometric measures and blood pressure. During pregnancy, women will receive up to three fetal ultrasounds to assess fetal growth. At birth, cord blood and placental samples will be collected and the infant will receive a brief developmental assessment. During infancy, home visits will include collection of interview data, environmental specimens, biospecimens from the infant and parents, a brief physical examination of the infant, and assessment of infant development and parental-infant interactions. *Burden*

*statement:* The public burden for this Study will vary depending on the eligibility and pregnancy status of potential participants at the time of household screening. Women who are not pregnant at the time of screening will have varying burden depending on their likelihood of pregnancy and, should they become pregnant, the time to pregnancy. The burden for women enrolled during pregnancy will depend on when during pregnancy they are identified and enrolled in the Study. The table provides an annualized average burden per person for each stage of the Pilot Study over the three year period of the Study.

ESTIMATED AVERAGE ANNUAL BURDEN FOR PILOT STUDY FOR NATIONAL CHILDREN'S STUDY, BASED ON THREE YEAR TOTALS

Types of respondents (estimated hourly rate)	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours
Household activities (\$12/hr):				
Household enumeration .....	76,911	0.33	0.08	2,051
Eligibility screening .....	45,316	0.33	0.08	1,208
Preconception activities (\$12/hr):				
High probability women .....	4,117	1.33	1.15	6,285
Moderate prob. women .....	5,500	1	0.08	458
Low probability women .....	3,578	0.33	0.08	95
Pregnancy activities—women (\$12/hr) .....	954	7	0.62	4,134
Birth activities—mothers & children (\$12/hr) .....	912	2	0.38	684
Postnatal activities—mothers & children (\$12/hr) .....	893	4	0.81	2,887
Fathers (\$12/hr) .....	954	2	0.72	1,370
Health care providers (\$90/hr) .....	500	0.33	0.05	8
Community leaders (\$75/hr) .....	500	0.33	0.05	8
Child care providers (\$25/hr) .....	364	0.33	1.00	121
Total .....	*79,229	.....	.....	19,209

\*Total number of respondents is less than the sum of the column since the mothers will be identified in the household enumeration and screening.

The estimated annualized cost to respondents is \$234,488 based on the differential hourly rate estimates in the above table. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

*Request for Comments:* Written comments and/or suggestions from the public and affected agencies are invited on 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) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to 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.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Kenneth C. Schoendorf, MD, MPH, National Institute of Child Health and Human Development, Building 6100, 5C01, 6100 Executive Blvd, Bethesda, Maryland, 20892, or call non-toll free number (301) 594-9147, or e-mail your request, including your address to [ncsinfo@mail.nih.gov](mailto:ncsinfo@mail.nih.gov).

*Comments 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.

Dated: November 6, 2007.

**Paul Johnson,**  
*NICHD Project Clearance Liaison, National Institutes of Health.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Notice of Establishment**

Pursuant to the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), the Director, National Institutes of Health (NIH), announces the establishment of the Emerging Neuroscience and Training Integrated Review Group.

The Emerging Neuroscience and Training Integrated Review Group shall