REQUEST FOR OMB REVIEW

PART A: JUSTIFICATION

PROGRAM ASSESSMENT AND EVALUATIONS FOR NIEHS – ASTHMA RESEARCH

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A.1. Circumstances Making the Collection of Information Necessary

The National Institute of Environmental Health Sciences, Division of Extramural Research and Training (DERT), with contract support from Battelle Centers for Public Health Research and Evaluation, is examining the impact of its extramural research portfolio. To date, a framework for examining research impact has been developed. This method has been applied to a limited extent to DERT's asthma research portfolio. The limitation is that only extant data have been used to date. DERT proposes to extend this analysis through primary data collection.

The purpose of the proposed primary data collection is to obtain information from grantees regarding the impact of their funded asthma research in the short-, intermediate- and long-term. This will be done through a survey of grantees that includes questions about the impact of funding on career development, the field of asthma research, public attitudes, commercial product development, clinical practice, business and industry practices, and long-term human and environmental health.

The mission of the NIEHS is to reduce the burden of human illness and disability by understanding how the environment influences the development and progression of human disease. To have the greatest impact on preventing disease and improving human health, the NIEHS focuses on basic science, disease-oriented research, global environmental health, and multidisciplinary training for researchers. One way in which NIEHS achieves its mission is through extramural research and training, funded by grants and contracts, to scientists, environmental health professionals, and other groups worldwide. This data collection falls within the mandate of the National Institute of Environmental Health Sciences (NIEHS) written

in 42 USC 285 l (Section 463 of the Public Health Services Act), as amended by the Health Research Extension Act of 1985.

Because other federal agencies also support asthma research, DERT proposes to collect the same information from asthma researchers whose research support comes from a select number of other agencies for purposes of comparison. These agencies include the Centers for Disease Control and Prevention (CDC), the Agency for Healthcare Research and Quality (AHRQ), the US Environmental Protection Agency (EPA) and selected NIH institutes: The National Heart, Lung, and Blood Institute (NHLBI), the National Institute of Allergy and Infectious Diseases (NIAID), and the National Institute for Child Health and Development (NICHD).

This data collection is authorized under section 2851 of the Public Health Service Act (42 U.S.C. 2851).

A.2. Purpose and Use of the Information

Information gained from this primary data collection will be used in conjunction with previous evaluations using extant data sources to evaluate the impact of NIEHS' DERT program, and to inform internal programs and new funding initiatives. Information to be collected includes measures of agency-funded research resulting in dissemination of findings, investigator career development, grant-funded knowledge and products, commercial products and drugs, laws, regulations and standards, guidelines and recommendations, information on patents and new drug applications and community outreach and public awareness relevant to asthma-related extramural research funding.

Without this research, NIEHS would have little information regarding the impact of its extramural research and training program, and thus little information on which to base future program decisions.

A.3. Use of Information Technology and Burden Reduction

Survey respondents will be identified through a search of two databases for principle investigators with the word 'ASTHMA' in either research or training grant abstracts or titles: an NIH-wide database of extramural research and training grants (IMPAC II), and an EPA grants database. An initial email will be sent to the respondents inviting them to participate in the survey. There will be two options for completing the survey. A web-based system will be developed to allow respondents the option of completing the survey electronically. This option will be encouraged. Data will be downloaded electronically from the web-based system. For those respondents without the resources to fill out a web-based survey, a hard copy will be made available. The pages of the hard-copy surveys will be separated and scanned for data entry. Both options are designed to minimize burden to the respondent and obtain data as efficiently as possible. The survey instrument is provided in Attachment 1.

A.4. Efforts to Identify Duplication and Use of Similar Information

In June, 2006, NIEHS convened a meeting of experts to discuss the evaluation of the NIEHS extramural research and training programs. As part of the discussion, experts reviewed existing data sources for their adequacy to support a thorough evaluation of the impact of the NIEHS asthma research portfolio. A conclusion of the meeting was that the data that are requested in the proposed survey do not already exist.

A.5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this study.

A.6. Consequences of Collecting the Information Less Frequently

We plan to administer one survey after receipt of OMB approval. No further iterations of the survey will be administered.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This study complies fully with the guidelines of 5 CFR 1320.5. No exceptions to the guidelines are required.

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. The proposed data collection was posted in the Federal Register on May 9, 2007, Volume 72, page 26399. No comments were received.

B. The study protocol, including the survey instrument, sampling plan, and data collection procedures were designed in collaboration with researchers at Battelle Centers for Public Health Research and Evaluation through Contract No.HHSP23320045006XI, Task Order HHSP233000015T, entitled "Program Assessments and Evaluations for NIEHS." Input into survey development was obtained from nine researchers who have been funded by NIEHS to conduct asthma research.

A.9. Explanation of Any Payment or Gift to Respondents

No payment or gift will be made to the respondents.

A.10. Assurance of Confidentiality Provided to Respondents

The NIEHS Privacy Act Officer has reviewed this application and has determined that the Privacy Act is applicable. The data generated in this survey constitutes a system of records under the Privacy Act: System Notice 09-25-0200, Privacy Act of 1974: Annual Publication of Systems of Records, September 26, 2002 Federal Register, Vol. 67, No. 187, pp 60776-60780.

Battelle staff will be responsible for conducting the survey, and tabulating and storing the data. The Institutional Review Board (IRB) of Battelle has approved the study protocol. Approval is provided in Attachment 3. The informed consent process approved by the IRB includes the following steps. Step 1: respondents will first receive an invitation letter from NIEHS that states the purpose of the survey, tells them why they were selected, and gives them information about how long the survey will take. Step 2: an email sent by Battelle will reiterate the purpose of the study and provide telephone numbers for respondents to call to clarify questions they may have about the survey, the purpose of the study, and how data will be used. Respondents will be told that their participation is voluntary and that they have the option to skip any question they would prefer not to answer and to quit the survey at any time. They will also be told that no data will be retained that will permit anyone to personally identify them and that no individual information will be presented in any reports. Respondents will not be asked to complete a consent form. Each respondent's willingness to go to the web link and complete the survey (or complete a hardcopy version) will be interpreted as evidence of implied consent.

To protect the confidentiality of respondents Battelle study training will emphasize the steps that will be taken to protect the confidentiality of the data that are collected. Completed hardcopy survey questionnaires will be stored in locked file cabinets. All project files will be password protected and access to the files will be limited to authorized project staff. Surveys entered online will be password protected and will not allow access once the respondent has completed the survey. The web survey will be hosted on a secure server protected with a Secure Sockets Layer (SSL) certificate and 128-bit encryption, the strongest online data encryption protection available. The tracking database with individual contact information will be stored separately from the data. The database will contain IDs only. The tracking database that links IDs to individual information will be destroyed at the end of the project. Project reports will not identify individuals who completed the survey. No names, university names, or personal identifying information will be used in any published reports of this study. Survey reports will present all findings in aggregate so individual responses cannot be identified.

A.11. Justification for Sensitive Questions

Topics typically considered to be of a sensitive nature include sexual practices, alcohol or drug use, religious beliefs or affiliations, immigration status, and employment history. No questions regarding these topics or any other topic of a sensitive nature are included in this survey. The survey is provided in Attachment 1.

A.12. Estimates of Hour Burden Including Annualized Hourly Costs

The total burden hours for screening and survey administration are 387.5. A 15-minute, close-ended, multi-mode (web and paper) survey will be administered to the universe of NIEHS-

funded asthma researchers (N= 179) and comparison agency asthma researchers (N=1371). Comparison agencies include other NIH institutes (NICHD, NIAID, NIA, NHLBI), the CDC, AHRQ, and the EPA.

A.12 – 1 Estimates of Hour Burden

Type of Respondent	Number of Respondents	Frequency of Response	Average Time per Response	Annual Hour Burden
Asthma Grantee	1550	1	.25	387.5

There are no costs to respondents except for their time to participate. The approximate annualized burden is 387.5 hours. The burden estimate is based on pretests along with NIEHS' experience with surveys with similar administration protocols and lengths. The survey respondents (asthma grantees) will most likely be scientists and post-secondary professors. The average annual salary for full-time professors in 2004-2005 was approximately $70,000, with variation in salary by rank (http://www.bls.gov/oco/ocos066.htm). Assuming 2080 working hours in a year, the average hourly rate is $33.65.

A.12 – 2 Annualized Cost to Respondents

Type of Respondent	Number of Respondents	Frequency of Response	Hourly Wage Rate	Respondent Cost
Asthma Grantee	1550	1	$33.65	$13,039.38

A.13. Estimate of Other Total Annual Cost Burden to Respondents or Recordkeepers

The data collection entails no additional costs to respondents or recordkeepers.

A.14. Annualized Cost to the Federal Government

This study will take approximately 4 months to complete (see Estimated Timeline – Table A16-1). The estimated total cost to the government is $218,011. The NIEHS costs are estimated as follows: Salary $3,500; Fringe ($500); Administration $0. The estimated cost of the Battelle contract (NIEHS Contract No.HHSP23320045006XI, Task Order HHSP233000015T, entitled "Program Assessments and Evaluations for NIEHS.") is $214,011 which covers the cost of survey administration, distribution and collection, data entry, coding, and data cleaning. Therefore, the annualized cost to the government is $218,011.

A.14-1 Estimates of Total Cost-Government

Types of Cost	Amount
Contractual Costs	$214,011
Salaries	$4,000
General and Administrative	$0
Total cost-Government	$4,000
Annualized cost-Government	$218,011

A.15. Explanation for Program Changes or Adjustments

This is a new data collection.

A.16. Plans for Tabulation and Publication and Project Time Schedule

A. Tabulation Plan

a. Calculation of Sampling Weights

Due to surveying a census of principal investigators receiving asthma-related research and training funding, weighting of the survey data need only be performed to reduce bias due to patterns of non-response. If non-response is low, or non-differential, the analyses will be unweighted.

To adjust for non-response we will use sample weighting class adjustments. The variables that are the best candidates for the formation of weighting classes are those variables that are: (1) available for respondents as well as non-respondents; (2) highly correlated with the survey variables; and (3) highly correlated with the likelihood of non-response. Variables available for the non-response analysis will be limited to university affiliation, date of first award, and educational degrees of principal investigator.

These weights will be applied to all analyses described below if necessary. By using weights to adjust for non-response we will obtain estimates that will be unbiased and generalizable to the universe of principal investigators receiving asthma-related funding for research or training.

b. Data Analysis

The survey data will be analyzed using standard univariate and bivariate descriptive statistics (e.g. means, frequencies, crosstabs) and multivariate analyses. The following types of variables will be examined:

Intermediate Outcomes:

Laws, regulations and standards

Healthcare guidelines and recommendations

Accumulation of knowledge

Knowledge and attitudes

Outputs and Short-term Outcomes:

Dissemination

Training and career development

Training and certifications

Curricula/Interventions

Patents and new drug applications

Community outreach

Communities of science

Replication and new research

Commercial products and drugs

Public awareness

Commissions, Task Forces, Advisory Panels, Workgroups

Table shells that will be used in the analysis are included in Attachment 5.

B. Publication Plan

Upon completion of the data analysis, a technical report will be prepared for NIEHS. The results of the study will also be disseminated to various stakeholders through the publication of

manuscripts in peer-reviewed journals.

C. Project Time Schedule

A.16 -1 Project Time Schedule

Activity	Schedule (months after OMB clearance)
First Survey Iteration	
Identify respondents	Week 1
Conduct initial email recruitment, tracing email bounce backs	Month 1
Conduct email follow-up and paper survey mailings	Month 2-3
Data coding, entry, and cleaning	Month 4
Data analysis	Month 4
Final report	Month 4

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

No exemption from display of expiration date is requested.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions to certification are sought.