

Supporting Statement A for

NIEHS DERT Extramural Grantee Data Collection

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Supporting Statement
for the
NIEHS DERT Extramural Grantee Data Collection
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Section A

Introduction

The National Institute of Environmental Health Sciences (NIEHS) is requesting a generic clearance for Extramural Grantee Data Collection funded by NIEHS. The authorization for this generic clearance request is Executive Order 12862 (1993). This data collection effort is strictly to assess extramural community satisfaction with procedures and initiatives. NIEHS will use a standard data collection tool (attachment 1) for all grantee data collection.

A.1 Circumstances Making the Collection of Information Necessary

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. The NIEHS supports a wide variety of research programs directed toward preventing health problems caused by our environment. We fund research across the United States through our extramural funding program. The largest portion of the NIEHS budget goes to fund laboratory research, population-based studies, and training programs at universities, hospitals, businesses and organizations.

The Division of Extramural Research and Training (DERT) at the NIEHS plans, directs and evaluates the Institute's grant program which supports research and research training in environmental health. It develops program priorities and recommends funding levels to assure maximum utilization of available resources in attainment of Institute objectives. Through cooperative relationships with NIH and with public and private institutions and organizations, the Division maintains an awareness of national research efforts and assesses the need for research and research training in environmental health.

Within DERT, the Program Analysis Branch (PAB) is tasked with:

- Providing guidance in shaping the direction of the portfolio through grant assignment and tracking, and coordination of division activities.
- Conducting long and short-term scientific evaluation and analyses of grant portfolio to provide a basis for priority setting, decision-making, and strategic planning.
- Developing methodologies to conduct impact analyses to assure maximum benefits of research funding.
- Using results of program analyses to recommend areas for program development and to identify emerging emphasis areas for consideration by the Institute Director and advisory groups.
- Communicating high impact science and public health relevance of extramural research.

In order to make informed management decisions about its research programs and to demonstrate the outputs, outcomes and impacts of its research programs NIEHS must be able to collect, analyze and report on data from extramural grantees. PAB must occasionally collect information directly from grantees who are currently receiving funding or who have received funding in the past on topics such as:

- Key scientific outcomes achieved through the research and the impact on the field of environmental health science
- Contribution of research findings to program goals and objectives
- Satisfaction with the program support received
- Challenges and benefits of the funding mechanism used to support the science
- Emerging research areas and gaps in the research

Similar past data collections have been approved for individual grant portfolio evaluations, such as the NIEHS Asthma Researchers Survey (OMB Control No. 0925-0588). This request is for a generic clearance to collect similar data collections for other NIEHS grant portfolios. Decisions about which portfolio evaluations to conduct in any given year are made based on strategic Institute and Division needs, project officers requests, emerging science trends and questions and requests from Congress and other stakeholders.

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.

A.2 Purpose and Use of the Information Collection

Information gained from this primary data collection will be used in conjunction with data from grantee progress reports and presentations at grantee meetings to inform internal programs and new funding initiatives. Outcome 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 extramural research funding and emerging areas of research. Satisfaction information to be collected includes measures of satisfaction with the type of funding or program management mechanism used, challenges and benefits with the program support received, and gaps in the research.

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

We provide our evaluation of NIEHS' grantees funded through the American Reinvestment and Recovery Act funding opportunity announcement (FOA) to conduct research on BPA as an example of how this survey will be used. The BPA grantees were funded to work together as a consortium to demonstrate replicable findings that the Environmental Protection Agency, the Food and Drug Administration and other federal agencies can use to inform policies and regulations on the use of BPA in consumer goods. We propose using the attached survey (see Attachment 1) to obtain information

from the 10 BPA grantees about the successes and challenges related to the consortium model of funding. We are collecting data from the grantees about their experiences participating in the consortium, the satisfaction with the support they have received from NIEHS program staff, and their experience conducting research in such a way as to inform regulatory decision-making. NIEHS will use this data to inform future program efforts, including whether or not to fund consortium projects in the future and how to support those projects to maximize their effectiveness. While grantees report the impacts of their research in their annual progress reports, they typically do not include information about their satisfaction with the funding process or program management.

Any grantee satisfaction or program management data collected through this survey will be used by DERT to inform future programming decisions.

A.3 Use of Information Technology and Burden Reduction

Because we will be collecting and storing data electronically, we conducted a Privacy Impact Assessment (PIA).

Survey respondents will be NIEHS extramural research and training grant awardees. NIEHS will identify survey respondents by searching an NIH-wide database of extramural research and training grants (IMPAC II). Data collection efforts will target specific research portfolios and only researchers who have been identified as conducting research within a defined portfolio will be asked to participate.

Potential research portfolios that will be analyzed during the three year timeframe of the OMB clearance include:

We will send an initial email to the respondents inviting them to participate in the survey. Respondents will have two options for completing the survey. NIEHS will provide a web-based system that will allow respondents the option of completing the survey electronically. This option will be encouraged. Data submitted using the electronic system will be transferred automatically to a database. Those grantees without access to the web-based survey can respond through a telephone interview or paper version of the survey. NIEHS staff will enter submitted using the telephone interview or paper survey into the database. 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.

NIEHS will review all progress reports and other grantee materials prior to conducting the survey to ensure that we capture all reported impacts and outcomes. This will reduce respondent burden by minimizing duplicate data reporting.

It was determined that this data collection request does not require a privacy impact assessment.

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 NIEHS' research portfolios. 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

NIEHS will only collect this data one time from grantees in a specific research portfolio.

If NIEHS is not able to collect this data, we will be forced to make future program decisions in a vacuum, without being able to consider the impact our programming actions have on grantees and their science.

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 Agency

The proposed data collection was posted in the Federal Register on October 19, 2011, Volume 76, page 64954. No comments were received.

NIEHS obtained input from representatives of the Food and Drug Administration as well as the Environmental Protection Agency. Researchers from the Battelle Centers for Public Health Research and Evaluation, who have conducted evaluations for NIEHS under contract number HHSP23320045006XI, Task Order HHSP233000015T also

provided input on the data collection design, survey instrument, sampling plan, and data collection procedures.

A.9 Explanation of Any Payment of 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 not applicable.

NIEHS or our contractors will conduct the survey, and tabulate and store the data. NIEHS will send respondents an email:

- inviting them to participate,
- describing how they were selected,
- stating the purpose of the survey,
- informing them that participation is voluntary,
- providing information about how long the survey will take,
- providing information about how the data will be used, and
- providing a phone number and email address for a data collection liaison who can answer any questions they may have.

Respondents will 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 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. After conducting a Privacy Impact Assessment (PIA) we determined that no questions regarding these topics or any other topic of a sensitive nature are included in this survey. Specifically, no personal identifying information (PII) will be collected. The only information collected is federal contact information, which does not qualify as personal identifying information (PII) according to the E-Government Act of 2002. 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 300 hours. Because this is a request for a generic clearance for any potential portfolio evaluations conducted by NIEHS in the next 3 years, we have estimated that approximately 200 grantees will complete a 30 minute survey or telephone interview.

A.12 – 1 Estimates of Hour Burden

| Type of Respondent | Number of Respondents | Frequency of Response | Average Time per Response | Annual Hour Burden |
|--------------------|-----------------------|-----------------------|---------------------------|--------------------|
| NIEHS Grantee | 200 | 1 | .50 Hour | 100.0 hours |

There are no costs to respondents except for their time to participate. The approximate burden over the course of 3 years is 300 hours (300.0). The burden estimate is based on pretests along with NIEHS' experience with surveys with similar administration protocols and lengths. The survey respondents will most likely be scientists and post-secondary professors. The average annual salary for full-time professors in 2010 was approximately \$78,490, 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 \$37.74, so the cost for completing the .5 hour survey is approximately \$17.00

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

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

A.14 Annualized Cost to the Federal Government

The annualized cost to the Fed Government is approximately \$100,000 per data collection activity. (see Estimated Timeline – Table A16-1). This cost includes the salary and benefits of a project officer, and a project analyst for 4 months. The NIEHS costs are estimated as follows: Salary \$60,000; Fringe (\$40,000); Administration \$0 (administrative costs are subsumed into the salary estimate).

A.14-1 Estimates of Total Cost-Government

| Types of Cost | Amount |
|-----------------------------|-----------|
| Salaries | \$60,000 |
| Benefits and Administrative | \$40,000 |
| Total cost-Government | \$100,000 |
| Annualized cost-Government | \$100,000 |

A.15 Explanation for Program Changes or Adjustments

This is a new data collection and therefore has no changes or adjustments.

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

a. Calculation of Sampling Weights

Because we intend to collect data from the full population or census of grantees in a given research portfolio, 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.

We will apply these weights 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 in given research portfolio.

b. Data Analysis

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

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

Participation in commissions, task forces, advisory panels, workgroups

Intermediate Outcomes:

Laws, regulations and standards

Healthcare guidelines and recommendations

Accumulation of knowledge

Changes in attitudes

Process Measures

Satisfaction with funding process (consortium, collaborations, centers)

Satisfaction with program management support

Research gaps

Table shells that NIEHS will use in analyses are included in Attachment 2.

B. Publication Plan

Upon completion of the data analyses, NIEHS will prepare technical reports intended for internal audience. If the findings warrant further dissemination, we will publish the results of the various portfolio evaluations in peer-reviewed journals.

C. Project Time Schedule

Because this is an application for generic clearance for future NIEHS research portfolio evaluations we do not have a defined time schedule. However, once a research portfolio is identified for an evaluation, we will follow the standard schedule below.

A.16 -1 Project Time Schedule for a Standard Portfolio Evaluation

| Activity | Schedule (months after OMB clearance) |
|--|--|
| Identify grantees in the research portfolio | Week 1 |
| Invite grantees to participate via email contact, trace and correct email bounce backs | Month 1 |
| Monitor web-based and paper based data submissions | Month 2-3 |
| Conduct email follow-ups | Month 2-3 |
| Conduct telephone interviews with any grantees who have not submitted data but would like to participate | Month 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.