Supporting Statement A for

NIEHS DERT Extramural Grantee Data Collection Revision

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Paperwork Reduction Act Submission

Section A

Introduction The National Institute of Environmental Health Sciences (NIEHS) is requesting a revision for the Extramural Grantee Data Collection Survey (OMB Clearance #0925-0657, exp 6/30/15) for use by:

- *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD);
- National Institute on Deafness and Other Communication Disorders (NIDCD);
- National Institute of Mental Health (NIMH);
- National Institute of Neurological Disorders and Stroke (NINDS);
- National Institute of Environmental Health Sciences (NIEHS); and
- National Cancer Institute (NCI).

The authorization for this clearance request is Executive Order 12862 (1993). This data collection effort is strictly to assess extramural community satisfaction with procedures and initiatives. NICHD, NIDCD, NIMH, NINDS, NIEHS, and NCI 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 NIH must be able 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

This request is similar to other data collections that have been approved for individual grant portfolio evaluations, such as the NIEHS Asthma Researchers Survey (OMB Control No. 0925-0588, exp. 4/30/2011). 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 NIH 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, NICHD, NIDCD, NIMH, NINDS, NIEHS, and NCI 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 Children's Environmental Health Centers funding opportunity announcement (FOA) as an example of how this survey has been used. We collected data from the grantees about their experiences participating in the Children's Center program, 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. The Children's Environmental Health Center Grantees completed the survey and responses from the

survey were used to highlight for institute leadership as well as policy makers the products and impacts of the environmental health research conducted by the Children's Centers. 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 the ICs to inform future programming decisions.

Since we received approval for the survey in 2012, NIEHS has used the survey to assess three grant portfolios:

- NIEHS Children's Environmental Health Centers (15 surveys sent/11 responses)
- NIEHS Breast Cancer and the Environment Centers (12 surveys sent/7 responses)
- Exposure and Exposome Grant Portfolio (53 surveys sent/19 responses)

In addition, NICHD has used the survey with the Autism Centers of Excellence program (75 surveys sent/44 responses).

For each of these evaluations we have summarized the findings and produced final reports for program staff.

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 extramural research and training grant awardees from NICHD, NIDCD, NIMH, NINDS, NIEHS, and NCI. We 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. We 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. 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.

We 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

NICHD, NIDCD, NIMH, NINDS, NIEHS, and NCI will only collect this data one time from grantees in a specific research portfolio.

If we are 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 request for a revision of the data collection clearance was posted in the Federal Register on March 16, 2015, Volume 80, Number 50, page 13562. 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.

Staff or contractors from NICHD, NIDCD, NIMH, NINDS, NIEHS, and NCI will conduct the survey, and tabulate and store the data. ICs 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 700 hours. Because this request covers potential portfolio evaluations conducted by NICHD, NIDCD, NIMH, NINDS, NIEHS, and NCI in the next 3 years, we have estimated that approximately 1,400 grantees will complete a 30 minute survey or telephone interview.

A.12 – 1 Estimates of Annual Hour Burden

Type of Respondent	Number of Respondents	Frequency of Response	Average Time per Response	Annual Hour Burden
NICHD Grantee	200	1	30/60	100
NIDCD Grantee	200	1	30/60	100
NIMH Grantee	200	1	30/60	100
NINDS Grantee	200	1	30/60	100
NCI Grantee	400	1	30/60	200
NIEHS Grantee	200	1	30/60	100
Total	**1,400**			**700 hours**

There are no costs to respondents except for their time to participate. The approximate burden over the course of 3 years is 700 hours (700.0). 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). Table A.12-2 summarizes the costs to respondents.

A.12-2. Annualized Cost to Respondents

Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Time per Respondents (in hours)	Hourly Wage Rate*	Respondent Cost
University Level Professors	1400	1	30/60	37.74	$23,800.00

Totals	1400				$23,800.00

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 $70,060.35 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 3 months. The costs for each participating institute (NICHD, NIDCD, NIMH, NINDS, NIEHS, and NCI) are estimated in Table 1.14 below.

A.14. Annualized Cost to the Federal Government

Staff	Grade/Step	Salary	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
Project Officer	13/5	$102,932	25%	$61,759	$41,172.75
Project Analyst	11/5	$72,219	25%	$43,331	$28,887.60
Contractor Cost					
Travel					
Other Cost					
Total Cost					**$70,060.35**

A.15 Explanation for Program Changes or Adjustments

This is a revision request for data collection. In June 2014 we received approval to allow other ICs to use the survey as well (NICHD, NIDCD, NIMH, NINDS, NIEHS, and NCI). NIEHS is leading the request to obtain a revision of this clearance for the ICs listed. We have proposed adding a few new response options to some of the questions based on our experience using the survey over the last 3 years. And we have added one new question related to product commercialization. These changes are highlighted in the attached survey (Attachment 1) and copied below:

Grant Number _____

How did you learn about this funding opportunity?

- ❑ NIEHS Website
- ❑ Grants.gov
- ❑ Social Media (Twitter, Linked In, etc.)
- ❑ Colleague/Word of Mouth
- ❑ Conference/Webinar
- ❑ University-based Resource (Tech Transfer Office)
- ❑ Federal Register

In what type of research do you engage? (*Please check all that apply*)

Indicate whether you research in a specific area was basic or applied (*Please check all that apply)*	Basic	Applied	
	❑	❑	Biochemistry
	❑	❑	Biophysics
	❑	❑	Botany
	❑	❑	Cellular biology
	❑	❑	Ecology
	❑	❑	Environmental Sciences
	❑	❑	Epidemiology/Human or Cohort studies (new association between biological, social, and/or behavioral states determined)
	❑	❑	Epigenetics
	❑	❑	Genetics (GWAS)
	❑	❑	Immunology
	❑	❑	Medicine
	❑	❑	Microbiology
	❑	❑	Molecular biology

	❑ ❑	Neuroscience
	❑ ❑	Physiology
	❑ ❑	Toxicology
	❑ ❑	Other please specify_____

Research Outputs

Research Output	Check all that apply:	Provide a brief description.
Animal Models	● Animal model developed	
Biological Materials	● Biological material or application identified or developed as a result of the research study	
Clinical Products	● Medication, drug compounds, clinical devices (includes development and testing of these products)	
Databases, Software, Algorithms	● Database resulting from the research study	
	● Software resulting from the research study	
	● Algorithm resulting from the research study	
License Agreements	● License agreement executed for intellectual property generated by the research study.	
Measurement Instruments, Assays & Methods	● Measurement instrument developed by the research study	
Research Data (public or restricted)	● Research data generated by the research study	
Economic Outcomes	● Research study findings result in a cost-effective intervention for a disease, condition, or disorder	
	● Research study findings result in enhancement of existing resources and expertise	
	● Research study findings result in increased performance, quality, and consistency in the delivery of health care services	
Health Care Outcomes	● Research study findings result in clinically effective approach in the management and treatment of a disease, disorder or condition	
Quality of Life	● Research study findings leads to enhancement of well-being among community members	

Knowledge Transfer Outputs

Knowledge Transfer Output	Check all that apply:	Provide a brief description.
Alternative/ Informal Dissemination	● Research study is referred to or cited in a blog, tweet, wiki or other alternative mode of dissemination.	
	● Research study is cited in a presentation, speech or teaching materials.	
Biological Materials	● Subsequent use of a particular biological material or application of the material generated by the research study in a bench study (basic science) or clinical trial study.	
	● Preclinical data generated in support of investigational new drug (IND) application or to the receipt of an IND.	
	● Clinical data generated in support of marketing a biological material (Biologic License Application) generated by the research study.	
Clinical Guidelines	● The clinical guideline refers to the research study or recommends the study for background readings.	
Curriculum Guidelines	● The curriculum guideline refers to the research study or recommends the study for background readings.	
License Agreements	● License agreement granted for use of intellectual property generated by the research study.	
Mass Media	● Mass media publication refers to the research study.	
Material Transfer Agreements (MTA)	● MTA executed for transfer of tangible property generated by the research study.	
Medical Devices	● Clinical trial study testing of a medical device generated by the research study.	
	● Clinical data generated in support of marketing a medical device (510(k); Investigational Device Exemption, IDE; or Premarket Approval, PMA) generated by the research study.	
Meta-Analyses	● Research study cited in a meta-analysis.	

Career Development Outputs

Career Development Output	Check all that apply:	Provide a brief description.
University Leadership Positions	● Serve as Center Director, Department Chair, or other university leadership position	
Organizational/ Conference Leadership Position	● Serve as conference chair, organizational leader (Society of Toxicology, International Society of Environmental Epidemiology, etc.)	
Nominated for Membership in Prestigious Organization	● Nominated for membership in prestigious organization such as Institute of Medicine, American Association for Advancement of Science, etc.	
Employment Promotion	● Received promotion to higher level of employment, such as next level of professor, or scientist	
Obtained Tenure Status	● Obtained tenure status for research or teaching position	
Trained or Mentored Students	● Served as a mentor or trained students in the field of selected science portfolio	
Additional Training or Certification Received	● Obtained additional training (K awards) or certifications within the field of environmental health science	

Training/Certifications Outputs

Career Development Output	Check all that apply:	Provide additional information.
Teaching	● Taught courses in the area of the selected science portfolio	Number of courses taught: Number of students taught: Description of courses taught:

Have you **commercialized** your innovation based on your patent(s)?

❑ Yes ❑ No

[IF YES] How many units have you sold? _____

What is your total sales? $_____

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:

<u>Outputs and Short-term Outcomes:</u>

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 NICHD, NIDCD, NIMH, NINDS, NIEHS, and NCI will use in analyses are included in Attachment 2.

B. Publication Plan

Upon completion of the data analyses, NICHD, NIDCD, NIMH, NINDS, NIEHS, and NCI 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

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.

List of Attachments:
Attachment 1: DEGDC Survey February 2015
Attachment 2: Table Shells
NIEHS DEGDC support_stmt_b 2015
DERT Extramural Grantee Data Collection ScreenShots