

Supporting Statement A for

NIEHS DERT Extramural Grantee Data Collection Revision (NIEHS)

OMB No. XXXX-XXXX

Exp. Date XX/XX/XXX

Date: July 1, 2018

Check off which applies:

- New
- Revision
- Reinstatement with Change
- Reinstatement without Change
- Extension
- Emergency
- Existing

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Attachments

Attachment A. DEGDC Survey February 2018

Attachment B. PIA for NIEHS DERT Extramural Grantee Data Collection Survey

Attachment C. NIEHS DEGDC Table Shells

A. Justification

Abstract: The National Institute of Environmental Health Sciences (NIEHS) is requesting the Extramural Grantee Data Collection Survey be converted to a “Common Form” to include EPA 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);
- National Cancer Institute (NCI); and
- Environmental Protection Agency (EPA).

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, NCI, and EPA will use a standard data collection tool (Attachment A) 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

The collection has been converted to a “Common Form.” 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, NCI, and EPA 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. As a Common Form, EPA will be able to access this survey to collect information about the accomplishments and impacts of their grantees.

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. Below we provide details of each ICs survey use and how the findings were used to inform decision (Table A.2-1).

A.2-1 Summary of IC Survey Use

IC	Name of Program Surveyed	Number of Surveys Sent	Number of Surveys Returned	How were Findings Used
NINDS	Translational Cooperative Agreement Program (CAP)	9	4	Help measure program success
NINDS	Neurological Emergencies Treatment Trials (NETT) Network	320	149	To obtain feedback from program participants as part of broader effort to evaluate the program and identify future programmatic priorities
NIEHS	Children’s Environmental Health Centers	32	32	To obtain descriptions of program products and impacts to share with other grantees in an effort to encourage resource sharing.
NIEHS	Environmental Health Core Centers	29	29	To obtain descriptions of program products and impacts to share with other grantees in an effort to encourage resource sharing.
NIEHS	Virtual Consortium for Translational Environmental Research	68	25	To obtain descriptions of program products and impacts in order to make decisions about future funding initiatives.
NIEHS	Climate Change	19	7	To obtain descriptions of program products and impacts in order to

				make decisions about future funding initiatives.
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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). A copy of the PIA is included as Attachment B.

Survey respondents will be extramural research and training grant awardees from NICHD, NIDCD, NIMH, NINDS, NIEHS, NCI, and EPA. 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 using a paper version of the survey. Staff will enter data submitted using paper survey into the database. This process is designed to minimize

burden to the respondent and obtain data as efficiently as possible. The survey instrument is provided in Attachment A.

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.

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.

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, NCI, and EPA 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.8.1 Comments in Response to the Federal Register Notice and

The proposed request for a revision of the data collection clearance was posted in the Federal Register on May 1, 2018, Volume 83, Number 84, page 19073 and allowed 60-days for public comment. No public comments were received.

A.8.2 Efforts to Consult Outside Agency

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, NCI, and EPA 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 A.

A.12.1 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, NCI, and EPA in the next 3 years, we have estimated that approximately 1,400 grantees will complete a 30-minute survey. In the event that participants do not have web access, we will provide a paper version of the survey provided in Attachment A.

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	1400		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. 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 2017 was approximately \$93,010, with variation in salary by rank

(http://www.bls.gov/oes/2017/may/oes_nat.htm#00-0000. Salary rate was identified using Occupation Code 25-1042, Biological Sciences Teachers, Postsecondary.) Table A.12-2 summarizes the costs to respondents.

A.12-2. Annual Cost to Respondents

Type of Respondents	Total Annual Burden Hours	Hourly Wage Rate*	Respondent Cost
University Level Professors	700	46.51	\$32,557.00
Totals	700		\$32,557.00

* Bureau of Labor Statistics: The General Public rate was obtained from the http://www.bls.gov/oes/2017/may/oes_nat.htm#00-0000, using Occupation Code 25-1042, Biological Sciences Teachers, Postsecondary.

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 \$20,638.10 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, NCI, and EPA) 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					
NCI Program Analyst	13/5	\$109,900	2%		\$2,199.98
NICHD Program Analyst	12/5	\$102,932	2%		\$2,058.64
NIDCD Science Policy Analyst	14/10	\$ 148,967	2%		\$2,979.34
NIEHS Program Analyst	12/5	\$102,932	2%		\$2,058.64
NIMH Info	12/5	\$102,932	2%		\$2,058.64
NINDS Program Analyst	12/5	\$102,932	2%		\$2,058.64
Contractor Cost NCI		None			
Contractor Cost NICHD		None			
Contractor Cost NIDCD		None			
Contractor Cost NIEHS		None			
Contractor Cost NIMH		None			
Contractor Cost NINDS		None			
Travel					
Other Cost					
Total Cost					\$13,413.88

*the Salary in table above is cited from <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2018/DCB.pdf>

A.15 Explanation for Program Changes or Adjustments

This submission has been converted to a common form. The only program changes or adjustment is a request to add nine new questions related to scientific goals and objectives, RFA Goals, and Program Support. These new questions are highlighted in the attached survey (Attachment A). The new questions do not add to the response burden because we do not require respondents to answer every question, but rather we pick those questions that are most relevant to the scientific program we are analyzing.

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

Data analysis plans are detailed in Attachment C NIEHS DEGDC Table Shells. Upon completion of the data analyses, NICHD, NIDCD, NIMH, NINDS, NIEHS, NCI, and EPA 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. 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	
Activity	Time Schedule
Identify grantees in the research portfolio	1 week after OMB approval
Invite grantees to participate via email contact, trace and correct email bounce backs	1 month after OMB approval
Monitor web-based and paper based data submissions	2-3 months after OMB approval
Conduct email follow-ups	2-3 months after OMB approval
Data coding, entry, and cleaning	4 months after OMB approval
Data analysis	4 months after OMB approval
Final report	4 months after OMB approval

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.