Supporting Statement A for

GENERIC CLEARANCE FOR SURVEYS OF CUSTOMERS AND PARTNERS OF THE OFFICE OF EXTRAMURAL RESEARCH OF THE NATIONAL INSTITUTES OF HEALTH

Date: 11/15/2010
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SUPPORTING STATEMENT

Voluntary Partner and Customer Satisfaction Surveys,
Office of Extramural Research, National Institutes of Health

A. JUSTIFICATION

A.1 CIRCUMSTANCES MAKING THE COLLECTION OF INFORMATION NECESSARY

This is a request for approval by the Office of Management and Budget (OMB), under the Paperwork Reduction Act of 1995, for a generic clearance to conduct voluntary Partner and Customer Satisfaction Surveys for the Office of Extramural Research (OER), Office of the Director (OD), National Institutes of Health (NIH) to implement Executive Order 12862 within the agency.

Executive Order 12862 directs agencies that "provide significant services directly to the public" to "survey customers to determine the kind and quality of services they want and their level of satisfaction with existing services." The mission of the National Institutes of Health (NIH) is to improve human health through biomedical and behavioral research. The NIH implements this mission by conducting intramural research in its own laboratories; supporting extramural research by scientists at universities, medical schools, hospitals, and research institutes; training basic and clinical research investigators; and fostering and supporting biomedical communication as well as public health information dissemination. OER/OD/NIH exercises overall oversight for the policies and procedures governing the award of financial support representing more than 80% of the total NIH budget ($30.5 billion in FY2010) to the extramural scientific community and academic research institutions through both assistance and acquisition mechanisms by the Institutes and Centers (ICs) which comprise the NIH.

In order to carry out its mission, OER develops, coordinates the implementation of, and evaluates NIH-wide policies and procedures for the award of extramural funds, including but not limited to:

- the publication of notices of availability of financial assistance and requests for applications in the NIH Guide to Grants and Contracts;
- the management of the electronic Research Administration (eRA) grants administration system and the NIH eRA Commons;
- the peer review of grant applications and contract proposals;
- the NIH Grants Policy Statement;
- the implementation of Federal laws, regulations, policies and requirements, e.g. PHS Policy on the Humane Care and Use of Laboratory Animals, 45CFR 46, OMB requirements for financial and programmatic accountability, HHS Grants Administration Manual, peer review regulations, financial conflict of interest regulations, etc.
    - providing guidance and interpretation;

    - supporting educational programs to promote compliance;
    - monitoring and ensuring grant recipient compliance;
- the implementation of mandates from Congress and the Executive Branch, e.g. NIH Public Access Policy; registration and results reporting for NIH-funded applicable clinical trials in ClinicalTrials.gov, human embryonic stem cell legislation, data sharing policies, etc.
- the implementation of special initiatives from the NIH Director, e.g as the NIH Roadmap for Biomedical Research, the Enhancing Peer Review Initiative, etc.
- data analyses and reports to audiences within and beyond the NIH related to NIH-supported research projects, to facilitate decision-making and grant-related activities within the NIH and other federal agencies, and provide accountability and transparency of NIH and other federal agencies' data to the public
- NIH extramural workforce diversity, research training and research career development initiatives;
- NIH Academic Research Enhancement Award (AREA) program;
- NIH Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs;
- the management of the NIH Loan Repayment Programs (LRPs);
- iEdison, the multi-agency electronic system for invention reporting.

OER/OD/NIH has in place a process to ensure that these survey activities are designed to gather and measure customer and partner satisfaction in accordance with the requirements and the spirit of Executive Order (EO) 12862. OER staff has reviewed the OMB "Resource Manual for Customer Surveys" and is confident all proposed survey activities will meet the requirements and follow the guidelines of this manual. Further, OER/OD/NIH agrees to adhere to the guidelines set forth in both EO 12862 and in the OMB Manual.

OER acknowledges that the generic clearance covers only voluntary surveys of our partners and customers. Participation in these surveys will be strictly voluntary. Personal identifiers, unless specifically justified, will be excluded from all surveys, and additional measures will be taken to ensure anonymity of respondents or confidentiality of the responses. Our surveys will be both qualitative and quantitative. The generic clearance is limited to collection of information from current and immediate past customers and partners of NIH.

NIH is an international model of excellence in biomedical and behavioral research. Input from partners and customers, both within the scientific community and the public at large, is an essential component of efforts to continuously improve our processes and operations. Results gathered in these surveys will be used to help us improve and refine our interactions with and responsiveness to the scientific community and the general public, refocus the strategies that are used to accomplish our objectives, and identify areas in need of improvement and enhancement. These surveys will not be used to formulate or change policies. Rather, they will be used to enable the Agency to be responsive to its constituents.

To move forward with our initiatives to ensure success in accomplishing the NIH mission, input from partners and customers is essential. Quality management principles have been integrated into OER's culture and these surveys will provide customer satisfaction input on various elements of OER's business processes. The data collected from these surveys will provide the feedback to track and gauge satisfaction with NIH's statutorily mandated operations and processes. OER/OD/NIH will present data and outcomes from these surveys to inform the NIH staff, officers, leadership, advisory committees, and other decision-making bodies as appropriate. Based on feedback from these stakeholders, OER/OD/NIH will formulate improvement plans and take action when necessary.

NIH is authorized to conduct information collections related to its activities and initiatives in accordance with 42 USC 241; 281-290, which establishes the mission and authority of NIH.

A.2 PURPOSE AND USE OF THE INFORMATION COLLECTION

The primary use for information gathered through voluntary partner and customer surveys is to identify strengths and areas for improvement in current policies, programs, operations and services provided by OER/OD/NIH and the other components of the NIH that support and promote research conducted by the extramural scientific community to benefit the Nation's health. Obtaining information about the satisfaction of partners and customers is consistent with EO 12862, as well as a good business practice. NIH is the world's premier biomedical research organization and as leader must strive continually to improve and devise new ways of carrying out its mission. Vital input regarding customer and partner satisfaction and involvement in continuing to attain the NIH goals can only be obtained through inviting broad feedback from the public served by NIH. NIH intends to draw on information as an initial step to develop, implement and refine policies, programs, products, and services in a manner most consistent with the needs of its partners and customers. The information collected in these surveys will be used OER/OD/NIH personnel to gauge:

1) the responsiveness of programmatic initiatives and dissemination of scientific findings to the research community and the public;
2) the impact of existing and proposed programmatic and policy changes on the NIH public constituencies;
3) the perceived quality and relevancy of the reorganization and re-engineering of the procedures for application, review, award and oversight of the scientific activities supported by NIH;
4) input relevant in the design of modifications of these operations, processes, and services;
5) customer and partner need in developing new modes of operation;
6) partner and customer feedback about the efficacy of implemented modifications; and
7) the quality of the changed operations and processes used to award NIH support for areas of basic and clinical research;

These surveys will almost certainly lead to quality improvement activities that will enhance and/or streamline NIH's operations. The satisfaction surveys are tailored to the specific changes NIH has implemented or is implementing. Some surveys may be repeated periodically to ascertain changes in customer and participant satisfaction.NIH will submit specific survey

instruments as they become available and will report the results of completed surveys to DHHS and OMB as requested or required. OER will retain a log tallying the total burden hours approved and used (as associated with each survey).

A.3 USE OF INFORMATION TECHNOLOGY AND BURDEN REDUCTION

As appropriate, automated information technology will be used to collect and process information for these surveys. In many instances the most appropriate methodology will involve Internet administration of surveys, but some may be written or other qualitative survey methodologies to explore in further depth the basis for responses. NIH's Senior Official for Privacy has been contacted and her office will be consulted throughout the process of conducting a Privacy Impact Assessment (PIA) in the HHS Security and Privacy Online Reporting Tool (SPORT) for all IT systems (e.g. websites posting surveys; respondent databases that reside "behind" the website; etc.) associated with the surveys, regardless of whether or not they contain personally identifiable information.

A.4 EFFORTS TO IDENTIFY DUPLICATION AND USE OF SIMILAR INFORMATION

Each survey will be designed to reflect the specifics of the related change being considered or implemented. Any potential duplication will be identified in the internal OER review and approval process. Information about plans for customer and partner surveys will also be shared among NIH components at an early stage so activities can be coordinated.

A.5 IMPACT ON SMALL BUSINESSES OR OTHER SMALL ENTITIES

The majority of surveys will not have an impact on small businesses. However, in seeking to collect information on the NIH SBIR/STTR program, activities and operations, small businesses will be included. When the surveys address concerns related to small businesses, the response burden will be kept to the minimum consistent with the aims of customer and partner satisfaction. All responses will be voluntary and presented to small businesses as an opportunity to contribute to improvement of the SBIR/STTR programs of NIH.

A.6 CONSEQUENCES OF COLLECTING THE INFORMATION LESS FREQUENTLY

Surveys will be conducted only at intervals that are considered appropriate to measure the impact of changes implemented as a result of initial satisfaction surveys and to monitor the continued level of performance. In most instances, a satisfaction survey is likely to be conducted on an annual or biennial basis after establishment of a baseline. Collection on a less frequent basis would reduce the practical utility of the information and inhibit the program's ability to monitor changes.

A.7 SPECIAL CIRCUMSTANCES RELATING TO THE GUIDELINES OF 5 CFR 1320.5

These surveys will be implemented in a manner fully consistent with 5 CFR 1320.5

A.8 COMMENTS IN RESPONSE TO THE FEDERAL REGISTER NOTICE AND EFFORTS TO CONSULT INSIDE AND OUTSIDE AGENCY

The 60 day notice required in 5 CFR 1320.8(d) was published in the Federal Register on September 13, 2010 (Volume 75, Number 176, page 55585). One (1) comment was received regarding this 60 day notice. A copy of the comment is included (see Attachment 3).

A.9 EXPLANATION OF ANY PAYMENT OF GIFT TO RESPONDENTS

As appropriate, there may be a need for nominal remuneration to focus group participants who are asked to leave their usual location and travel to a central location to compensate them for the time and inconvenience required. A justification for the incentive amount will be submitted in the mini supporting statements for each of the projects that uses an incentive. The level of remuneration will depend on the amount of respondent time and expense projected for each focus group. As appropriate, some focus group sessions may use teleconferencing to limit burden. On other occasions, regional group meetings sponsored by NIH/OER will have ready access to respondents.

A.10 ASSURANCE OF CONFIDENTIALITY PROVIDED TO RESPONDENTS

The appropriate customer and partner groups sampled for each survey conducted in association with this general clearance will vary based on their suitability for the survey topic. In general, a sample of customers and partners from among reviewers, applicants, and recipients of NIH funding from each fiscal year will be asked to participate in some of the surveys. Those records are kept by NIH under the System of Records pursuant to 5 USC 552a (Privacy Act of 1974). In addition, a sample of the public will be asked to participate in some of the surveys. Generally the responses to the questionnaire surveys will be entirely anonymous and will have no identifiers to link them to individual respondents. Thus, participants' privacy is ensured by the anonymity. This confidentiality will be explained to respondents. For web-based surveys, respondents will be given the Internet address and a unique access code and password to the survey web site. The system is programmed so only a respondent who has a password can access a survey form. The password will expire automatically after the form is completed and submitted. Furthermore, the surveys themselves will not contain any identifying information. Surveys that are not web-based will not collect or contain identifying information

Whenever possible, surveys will be electronically collected and collated by an independent contractor or by NIH Division of Information Services staff. The electronic responses will be downloaded automatically into the data set. Contractors or NIH information services staff will perform the analyses. All other NIH staff will see only aggregate data. Email addresses, which could possibly identify individual respondents, will be separated from the survey responses as they are entered into the data set. Furthermore, as the computer server receives the completed surveys, the identity of the responding computer will be eliminated. No individual information will be able to be extracted.

In rare instances, responses may need to be directed to individuals in a manner in which responses can be associated with them. In these instances, the information collection will be carried out in compliance with the regulations for the protection of human subjects (45 CFR 46) and appropriate safeguards to maintain confidentiality will be incorporated into the surveys.

Respondents will be informed that their participation is voluntary and that no consequences will be associated with not responding or with responding. This procedure will be explained to respondents. Individuals contacted in the course of these surveys will be assured of the confidentiality of their replies under 42 USC 1306, 20 CFR 401 and 422, 5 USC 552 (Freedom of

Information Act), 5 USC 552a (Privacy Act of 1974), Privacy Act System of Records Notice: 09-25-036, and OMB Circular No.A-130

A.11 JUSTIFICATION FOR SENSITIVE QUESTIONS

These voluntary customer surveys will not involve personal information of a sensitive nature.

A.12 ESTIMATED ANNUAL HOURS OF BURDEN AND ANNUALIZED HOURLY COSTS

The projected survey schedule is approximately 14 per year (approximately 10 quantitative surveys and 4 qualitative surveys) related to different aspects of NIH mission and activities (see section A.16). Respondents are expected to be a mix of adult scientists connected to the research community and members of the general public depending on the objectives of the survey. It is not anticipated that each respondent type noted below will participate in each survey, so the estimated annual frequency of response per type of respondent is 14 surveys.

ESTIMATED ANNUAL HOURS OF BURDEN

Quantitative survey, e.g. email/mail survey measuring customer satisfaction (see Table A12-1.a., below):

- 9,820 respondents = total number of respondents per survey
- 15 minutes = average time per response to each email/mail surveys
- 1 response = annual frequency of response per survey
- 2,455 hours = total hours of burden per quantitative survey
- 24,550 hours = total hours of burden per year based on 10 quantitative surveys

Qualitative survey, e.g. focus group on customer satisfaction(see Table A12-1.b., below):

- 30 respondents = total number of focus group members per survey
- 1 hour = average time per focus group
- 1 response = annual frequency of response per survey
- 30 hours = total hours of burden per qualitative survey
- 120 hours = total hours of burden per year based on 4 qualitative surveys

Based on an estimated 10 quantitative and 4 qualitative surveys per year:

- 24,670 hours = total annual hours of burden in each of the 3 years
- 74,010 hours = total combined hours of burden to respondents for 2011, 2012, and 2013

TABLE A12-1.a. ESTIMATED ANNUAL HOURS OF BURDEN PER QUANTITATIVE SURVEY

Type of Respondents	Number of Respondents	Frequency of Response	Average Time per Response (in hours)	Annual Hours of Burden Per Survey

Science professionals – applicants, reviewers, Institutional Officials	3,820	1	0.25	955
Adult science trainees	2,000	1	0.25	500
General public	4,000	1	0.25	1,000
Totals	9820	1	0.25	2,455

TABLE A12-1.b. ESTIMATED ANNUAL HOURS OF BURDEN PER QUALITATIVE SURVEY

Type of Respondents	**Number of Respondents**	**Frequency of Response**	**Average Time per Response (in hours)**	**Annual Hours of Burden Per Survey**
Science professionals – applicants, reviewers, Institutional Officials	12	1	1	12
Adult science trainees	6	1	1	6
General public	12	1	1	12
Totals	30	1	1	30

ESTIMATED ANNUALIZED HOURLY COSTS

Estimated costs to the respondents consist entirely of their time. Costs for time were estimated using a rate of $45.00 per hour for science professionals, $25 for adult science trainees, and $17 for members of the public.

Quantitative survey, e.g. email/mail survey measuring customer satisfaction (see Table A12-2.a., below):

- $72,475 = annualized cost to respondents per quantitative survey
- $724,750 = total annualized cost to respondents per year based on 10 quantitative surveys

Qualitative survey, e.g. focus group on customer satisfaction(see Table A12-2.b., below):

- $894 = annualized cost to respondents per qualitative survey
- $3,576 = total annualized cost to respondents per year based on 4 qualitative surveys

Based on an estimated 10 quantitative and 4 qualitative surveys per year:

- $728,326 = total annualized cost to respondents in each of the 3 years
- $2,184,978 = total combined cost to respondents for 3 year duration of generic clearance (2011, 2012, and 2013)

TABLE A12-2.a. ESTIMATED ANNUALIZED COST TO RESPONDENTS PER QUANTITATIVE SURVEY

Type of Respondents	Number of Respondents	Annual Hours of Burden (from Table A12-1)	Hourly Wage Rate	Annualized Cost to Respondents Per Survey
Science professionals – applicants, reviewers, Institutional Officials	3,820	955	$45	$42,975
Adult science trainees	2,000	500	$25	$12,500
General public	4,000	1,000	$17	$17,000
Totals	9820	2,455	--	$72,475

TABLE A12-2.b. ESTIMATED ANNUALIZED COST TO RESPONDENTS PER QUALITATIVE SURVEY

Type of Respondents	Number of Respondents	Annual Hours of Burden (from Table A12-1)	Hourly Wage Rate	Annualized Cost to Respondents Per Survey
Science professionals – applicants, reviewers, Institutional Officials	12	12	$45	$540
Adult science trainees	6	6	$25	$150
General public	12	12	$17	$204
Totals	30	30	--	$894

A.13 ESTIMATE OF OTHER TOTAL ANNUAL COST BURDEN TO RESPONDENTS OR RECORD KEEPERS

Qualitative survey participants, as appropriate, will be reimbursed for any travel or incidental costs associated with traveling to a central location for interview. Except for focus groups, costs to respondents will be limited to their time to provide the requested information.

A.14 ANNUALIZED COST TO THE FEDERAL GOVERNMENT

The surveys are likely to be carried out under contract. Assuming contract costs for each survey will vary between $10,000 - $100,000 (approximately) depending on the methodology:

- Total contract costs could average approximately $770,000 per year (14 x $55,000.).
- An additional annual cost of about $76,608 for agency staff would be associated with this, assuming 14 surveys per fiscal year with 2 GS 13/14 program analysts or project officers (average $94,824 annual salary) and 1.5 weeks of time per project (21 weeks per staff person each fiscal year).
- The total annual cost to the government is estimated to be $846,608.

A.15 EXPLANATION FOR PROGRAM CHANGES OR ADJUSTMENTS

This is a new Information Collection request.

A.16 PLANS FOR TABULATION AND PUBLICATION AND PROJECT TIME SCHEDULE

The projected survey schedule is 10 quantitative and 4 qualitative surveys per year. Topics over the 3 years may include but not be limited to:

- NIH Guide to Grants and Contracts user experiences;
- Streamlining funding opportunity announcements;
- Electronic Research Administration (eRA) grants administration system and the NIH eRA Commons user experiences;
- View of enhanced peer review of grant applications;
- NIH-provided guidance on Federal laws, regulations, policies and requirements, e.g. PHS Policy on the Humane Care and Use of Laboratory Animals, 45CFR 46, OMB requirements for financial and programmatic accountability, HHS Grants Administration Manual, peer review regulations, financial conflict of interest regulations, etc.
- Implementation of NIH-supported educational programs;
- Awardee experiences of NIH monitoring of grant recipient compliance;
- Views of NIH implementation of mandates from Congress and the Executive Branch, e.g. NIH Public Access Policy; registration and results reporting for NIH-funded applicable clinical trials in ClinicalTrials.gov, human embryonic stem cell legislation, data sharing policies, etc.
- Views of NIH implementation of special initiatives from the NIH Director, e.g. as the NIH Roadmap for Biomedical Research, the NIH Directors Pioneer Award Program, etc.
- Views of NIH-generated analyses and reports related to NIH-supported research projects, and their role in facilitating decision-making and grant-related activities within the NIH

and other federal agencies, and providing accountability and transparency of NIH and other federal agencies' data to the public

- Experiences of NIH extramural workforce diversity, research training and research career development initiatives;
- Experiences of NIH Academic Research Enhancement Award (AREA) program recipients and reviewers;
- Experiences of NIH Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) program applicants, awardees, and reviewers;
- Views of the NIH Loan Repayment Programs (LRPs);
- Experiences and functionality of iEdison, the multi-agency electronic system for invention reporting.

In general, surveys will be distributed electronically. Some surveys, however, may need to be conducted in small focus groups or using paper-based methods. Information collected from the surveys will be analyzed within two months of receipt. Analysis plans will be specific to the goals and designs of the individual surveys. For all types of surveys, the analyses will be mostly descriptive, rather than inferential. The results of any analysis will be disseminated to key management officials at OER, NIH management within six months of the survey's completion. Relational databases will be designed and analysis-ready data inputted. Analyses will include cross tabulation of the questions that indicate consistency and validity of responses. Analysis result tables will be designed and produced to present the information in an aggregate format in order to maintain confidentiality. Content analysis will be performed on the narrative responses. A narrative report with accompanying charts will be provided to OER management.

TABLE 16.1 EXAMPLE TIMETABLE – WEB-BASED SURVEY

Month 1	Construct relational databases and produce coded survey instruments
Month 2	Construct survey collection Internet website
Month 3	Post survey instrument and send email invitations to participate
Month 4	Reminder notices to respondents
Month 5	Download survey responses and input data
Month 6&7	Analyze coded and narrative data and write reports for OER management
Month 8	OER management study report and recommendations for any proposed operational or programmatic changes or other appropriate response
Month 9	Plan for new customer/ partner satisfaction survey to gauge result of agency response

A.17 REASON(S) DISPLAY OF OMB EXPIRATION DATE IS INAPPROPRIATE

No exemption is being requested.

A.18 EXCEPTIONS TO CERTIFICATION FOR REDUCTION ACT SUBMISSIONS

This collection of information involves no exceptions to the Certification for Paperwork Reduction Act Submissions.