

**Request for Approval under the “Generic Clearance for the Collection of Routine Customer Feedback” (OMB#: 0925-0678 ExpDate:08/2016)**

**TITLE OF INFORMATION COLLECTION: NINDS Common Data Elements (CDE) Survey**

**PURPOSE:**

The proposed information collection is a survey of individual investigators who have used, developed, or may wish to use the National Institute of Neurological Disorders and Stroke (NINDS) Common Data Elements (CDEs). The purpose of this survey is to assess user satisfaction with the availability, accessibility, and utility of the NINDS CDEs that have been developed thus far. The survey will also assess how well known the NINDS CDEs are to the target research communities, which will provide feedback for ongoing outreach efforts.

The NINDS CDE Project began in 2005 with the primary goal to develop data standards for clinical research involving neurological disorders so that data are captured consistently across different studies. This harmonization effort helps increase data quality and efficiency of clinical research by enabling more effective data collection, analysis, and sharing. Broad use of the CDEs is crucial to the overall goal of facilitating meta-analysis and comparison of data from different studies. NINDS strongly encourages researchers to incorporate CDEs in all applicable NINDS-funded studies via specific language in Funding Opportunity Announcements and in the Terms of Award for large epidemiology studies and Phase III clinical trials. For easy access and use by investigators, all of the technical information and forms needed for utilization of the CDEs are publicly available on the CDE website.

The results of this survey will be used to identify strengths and weaknesses of current services and will directly inform program improvements.

**DESCRIPTION OF RESPONDENTS:**

The survey target population is anyone who has, or may, use NINDS CDEs now or in the near future, including individuals who participated in developing the current sets of CDEs. These individuals include researchers working in academia, industry, and government or non-government organizations in the U.S. and abroad.

**TYPE OF COLLECTION:** (Check one)

- |  |  |
|--|--|
| <input type="checkbox"/> Customer Comment Card/Complaint Form          | <input checked="" type="checkbox"/> Customer Satisfaction Survey |
| <input type="checkbox"/> Usability Testing (e.g., Website or Software) | <input type="checkbox"/> Small Discussion Group                  |
| <input type="checkbox"/> Focus Group                                   | <input type="checkbox"/> Other: _____                            |

**CERTIFICATION:**

I certify the following to be true:

1. The collection is voluntary.
2. The collection is low-burden for respondents and low-cost for the Federal Government.
3. The collection is non-controversial and does not raise issues of concern to other federal agencies.

4. The results are not intended to be disseminated to the public.
5. Information gathered will not be used for the purpose of substantially informing influential policy decisions.
6. The collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the future.

Name: \_\_\_\_\_ Katie Pahigiannis \_\_\_\_\_

To assist review, please provide answers to the following question:

**Personally Identifiable Information:**

1. Is personally identifiable information (PII) collected? [ ] Yes [X] No
2. If Yes, is the information that will be collected included in records that are subject to the Privacy Act of 1974? [ ] Yes [ ] No
3. If Applicable, has a System or Records Notice been published? [ ] Yes [ ] No

**Gifts or Payments:**

Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants? [ ] Yes [X] No

**ESTIMATED BURDEN HOURS and COSTS**

Category of Respondent	No. of Respondents	No. of Responses per Respondent	Time per Response (in hours)	Total Burden Hours
Individuals or households	544	1	10/60	91
<b>Totals</b>	<b>544</b>			<b>91</b>

Category of Respondent	Total Burden Hours	Hourly Wage Rate	Total Burden Cost
Individuals or households	91	39.1	\$3,546
<b>Totals</b>	<b>91</b>		<b>\$3,546</b>

**FEDERAL COST:** The estimated annual cost to the Federal government is \_\_\_\$1834.06\_\_\_

Staff	Grade/Step	Salary	% of Effort	Fringe (if applicable)	Total Cost to Gov't
<b>Federal Oversight</b>	14/5	123,406	1.0		1234.06
	N/A (AD-0401-00)	60,000	1.0		600.00

<b>Contractor Cost</b>					
Travel					
Other Cost					

**If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:**

**The selection of your targeted respondents**

1. Do you have a customer list or something similar that defines the universe of potential respondents and do you have a sampling plan for selecting from this universe?  
 Yes       No

If the answer is yes, please provide a description of both below (or attach the sampling plan)? If the answer is no, please provide a description of how you plan to identify your potential group of respondents and how you will select them?

The survey is targeted to NINDS grantees who have used or developed CDEs, as well as other investigators who may or may not have any experience with or be aware of the CDEs. Individual researchers with a history of funding from NINDS in the past 5 years involved in neurological research using human subjects (n=1114) will be asked to respond. We will also ask individuals who have served on one of the committees that helped develop the CDEs to respond (n=700). We anticipate a response rate of approximately 30%, given the semi-targeted nature of our survey.

**Administration of the Instrument**

1. How will you collect the information? (Check all that apply)  
 Web-based or other forms of Social Media  
 Telephone  
 In-person  
 Mail  
 Other, Explain
2. Will interviewers or facilitators be used?  Yes  No

**Please make sure that all instruments, instructions, and scripts are submitted with the request.**