

Request for Approval under the “Generic Clearance for NIH Citizen Science and Crowdsourcing Projects”

(OMB#: 0925-0766 Exp., date: 04/2023)

TITLE OF INFORMATION COLLECTION: The National Institute of Neurological Disorders and Stroke (NINDS) Common Data Elements (CDE) Project Request Form

PURPOSE: The Common Data Elements (CDE) are content standards that enable clinical investigators to systematically collect, analyze, and share data across the research community. The NINDS strongly encourages researchers who receive funding from the Institute to ensure their data collection is compatible with these common data elements (CDEs). The CDE Project Request form can be used by the public to propose 1) development of a new Common Data Element (CDE) for neurological disease research areas with no existing CDEs, 2) development of a new subgroup of CDEs for an existing CDE set, or 3) revising an existing CDE set. The goal is to make the CDE project development a transparent process in which all stakeholders can have the opportunity to nominate a new CDE or provide input for NINDS’s internal use that would help improve the current program. NINDS only has one contract to develop one CDE per year so collecting information about research needs and the rationale for development of new CDEs or revising an existing CDE will inform NINDS efforts to prioritize those areas that address the most urgent and unmet research needs.

DESCRIPTION OF RESPONDENTS: Potential respondents include researchers at academic institutions, non-profit organizations, or other federal agencies, etc. that might become aware of this form via an email or a listserv advertising this form. NINDS Program staff will send an announcement about the CDE Project Request form through a listserv. Anyone among the listserv subscribers (e.g., neuroscience researchers) who are interested in submitting feedback about the existing CDEs or nominations for a new CDE can voluntarily fill out the form. Based on previous CDE evaluation data, we expect not more than 20 responses per year. The form will also be posted on the NINDS CDE Project website (<https://www.commondataelements.ninds.nih.gov/>) which will have a separate page where researchers will be provided with general information about the form and will be able to complete and submit it, if they desire to do so.

TYPE OF COLLECTION: (Check one)

- | | |
|--|---|
| <input type="checkbox"/> Data Catalogue | <input type="checkbox"/> Repository of Tools and Best Practices |
| <input type="checkbox"/> Recommendations of scientific reviewers | <input type="checkbox"/> Resources |
| <input checked="" type="checkbox"/> Call for Nominations | <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. Information gathered will not be used for the purpose of substantially informing influential policy decisions.
5. 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: Sophia Jeon, Ph.D. Health Science Policy Analyst, NINDS OSPP

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

Personally Identifiable Information:

1. Is personally identifiable information (PII) collected? Yes 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 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
Individual (Researchers)	20	1	20/60	7
Totals		20		7

Category of Respondent	Total Burden Hours	Hourly Wage Rate*	Total Burden Cost
Individual (Researchers)	7	\$40.19	\$281.33
Totals	7		\$281.33

*Hourly wage rates for 19-1029 Biological Scientists is \$40.19 (based on <http://www.bls.gov/oes/current/oes191029.htm>).

FEDERAL COST: The estimated annual cost to the Federal government is \$5,133.15

Staff	Grade/Step	Salary*	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
General Health Scientist	13/1	\$102,663	5%		\$5,133.15
Contractor Cost					

Travel					
Other Cost					
Total					\$5,133.15

*the Salary in table above is cited from <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2020/general-schedule/>

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

**This will not be a focus group/survey. There are no plans to employ statistical methods.*

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?

Administration of the Instrument

1. How will you collect the information? (Check all that apply)

[x] Web-based or other forms of Social Media

[] Telephone

[] In-person

[] Mail

[] Other, Explain

2. Will interviewers or facilitators be used? [] Yes [x] No

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