`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: NIAID ClinRegs Country Specific SME Interest Form

PURPOSE:

NIAID ClinRegs (clinregs.niaid.nih.gov) is a web-based resource providing country-specific clinical research regulatory information for the purpose of enhancing efficiency and quality in global clinical trials. Making this verified information publicly available informs clinical trial planning, and resource and feasibility assessments. To assure that ClinRegs is meeting its objectives, it is necessary to solicit feedback from users about the accuracy of content on the site and whether additional information should be included. In an effort to engage and empower members of the public to contribute knowledge, NIAID will ask Subject Matter Experts (SMEs) if they have interest in providing country specific information to add to the site. The information collected will allow NIAID to identify individuals within the scientific community whose knowledge and expertise can help assure the currency and accuracy of the information on the site and keep ClinRegs a trustworthy resource.

DESCRIPTION OF RESPONDENTS:

Anticipated respondents include, but are not limited to, U.S. and international clinical researchers (e.g., academic, industry, not-for-profit, and government), pharmaceutical research and human subjects research regulators, clinical research managers and coordinators, and policy makers.

TYPE OF COLLECTION: (Check one)

[ ] Data Catalogue
[ ] Recommendations of scientific reviewers
[ ] Call for Nominations
[ ] Repository of Tools and Best Practices
[ ] Resources
[X] Other: Subject Matter Expert interest e-form

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: Jonathan Kagan

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

Personally Identifiable Information:

1. Is personally identifiable information (PII) collected? [X] Yes [ ] No
2. If Yes, is the information that will be collected included in records that are subject to the Privacy Act of 1974? [X] Yes [ ] No
3. If Applicable, has a System or Records Notice been published? [X] 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
Private Sector	50	1	5/60	4
Totals		50		**4**

Category of Respondent	Total Burden Hours	Hourly Wage Rate*	Total Burden Cost
Private Sector	4	$34.91	$139.64
Totals			$139.64

*The hourly wage rate is based on the national average salary of $34.91 for Clinical Research Associate, as provided by glassdoor.com

FEDERAL COST: The estimated annual cost to the Federal government is $7,000

Staff	Grade/Step	Salary*	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
Assistant Director for Special Projects	AD-401	$200,000	1%		$2,000
Contractor Cost		100,000	5%		$5,000
Travel					$0
Other Cost					$0
Total					$7,000

*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:

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 [X] 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?

We will invite SME users on the website to volunteer to provide information about new regulations or to point out outdated information on the ClinRegs site.

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