Request for Approval under the "Generic Clearance for the Collection of Routine Customer Feedback" (OMB#: 0925-0668 Exp., date: 04/2022)

TITLE OF INFORMATION COLLECTION: NIAID ClinRegs Pop-up Survey Questions

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. To assure that ClinRegs is meeting its objectives, it is necessary to solicit feedback from users about its content and functionality, and to obtain suggestions on ways that it may be improved.

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)

[ ] Customer Comment Card/Complaint Form
[ ] Usability Testing (e.g., Website or Software
[ ] Focus Group
[X] Customer Satisfaction Survey
[ ] Small Discussion Group
[ ] 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: Jonathan Kagan

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
Private Sector	10000	1	1/60	167
Totals		10,000		167

Category of Respondent	Total Burden Hours	Hourly Wage Rate*	Total Burden Cost
Private Sector	167	$34.91	$5,829.97
Totals			$5,829.97

*The hourly wage rate is based on the national average salary of $72,622 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 of Special Projects	AD-401	$200,000	1%		$2,000
Contractor Cost		100,000	5%		$5,000
Travel					$0
Other Cost					$0
Total					$7,000

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 users on the website to answer the survey question through pop-up notifications. Note: Only one pop-up question will be active on the site at any given time.

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.