

**Request for Approval under the “Generic Clearance for the Collection of Routine
Customer Feedback” (OMB#: 0925-0668 ExpDate: 02/2019)**

TITLE OF INFORMATION COLLECTION: User Feedback on NIAID's ClinRegs Website

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

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 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
Private Sector (for profit)	2000	1	3/60	100
Private Sector (non-profit)	2000	1	3/60	100
Totals	4000	4000		200

Category of Respondent	Total Burden Hours	Wage Rate*	Total Burden Cost
Private Sector	200	\$35.00 (bls.gov)	7,000.00
Totals	200		7,000.00

*Cite source per bls.gov if applicable

FEDERAL COST: The estimated annual cost to the Federal government is \$1,580.00

Staff	Grade/Step	Salary	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
	AD-401	\$196,000	.005		\$980
Contractor Cost					
		60,000	1		\$600
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?

Since this is a web site customer satisfaction survey, we will invite users on the site to take the survey. We may also reach out to users to ask them to take the 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.