Request for Approval under the "Generic Clearance for the Collection of Routine Customer Feedback" (OMB#: 0925-0668; Exp. date: 02/2019)

TITLE OF INFORMATION COLLECTION: NIAID ClinRegs – Private Sector

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), 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   [X] Customer Satisfaction Survey
[ ] Usability Testing (e.g., Website or Software   [ ] Small Discussion Group
[X] Focus 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 <u>not</u> raise issues of concern to other federal agencies.

4. The results are <u>not</u> intended to be disseminated to the public.
5. Information gathered will not be used for the purpose of <u>substantially</u> informing <u>influential</u> 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? [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 (Survey)	5000	1	2/60	167
Private Sector (Focus group)_	50	1	1	50
Totals	**5050**	5050		**217**

Category of Respondent	Total Burden Hours	Hourly Wage Rate*	Total Burden Cost
Private Sector	217	$38.72	$8,402.24
Totals	**217**		$8,402.24

*Cite source per bls.gov if applicable

FEDERAL COST: The estimated annual cost to the Federal government is $16,000

Staff	Grade/Step	Salary	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
	AD-401	$200,000	1%		$2,000
Contractor Cost					
		100,000	3%		$3,000
		100,000	5%		$5,000
		60,000	10%		$6,000
Travel					$0
Other Cost					$0
Total					$16,000

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?

     1. We will invite users on the website to take the survey through pop-up notifications and static links
     2. We will send the survey link to our GovDelivery email list, which has approximately 5,500 subscribers
     3. We will also distribute the survey link through our social media accounts (Facebook and Twitter)
     4. We will invite users on the site to sign up to participate in the online focus groups
     5. We will work with the ClinRegs Steering Group to identify users to participate in the focus groups

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
     [X] In-person
     [ ] Mail
     [ ] Other, Explain
2. Will interviewers or facilitators be used? [ ] Yes [X] No