Request for Approval under the "Generic Clearance for the Collection of Routine Customer Feedback" (OMB Control Number: 0925-0668)

TITLE OF INFORMATION COLLECTION: User Feedback on NIAID's International Clinical Research Regulatory Matrix (ICRRM).

PURPOSE: NIAID's ICRRM 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 ICRRM 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, will any information that is collected be included in records that are subject to the Privacy Act of 1974? [ ] Yes [ ] No *Not applicable*
3. If Yes, has an up-to-date System of Records Notice (SORN) been published? [ ] Yes [ ] No *Not applicable*

Gifts or Payments:

Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants? [ ] Yes [x] No

BURDEN HOURS

Category of Respondent	No. of Respondents	Participation Time	Burden
Federal	4000	3 min	200 hr
Totals			**200 hr**

FEDERAL COST: The estimated annual cost to the Federal government is: $400

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?

Since this is a web site customer satisfaction survey, we will have information on the site that asks users to take the survey. We may also reach out to NIAID users to ask them to take the survey when they are using the ICRRM.

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.