Request for Approval under the "Generic Clearance for the Collection of Routine Customer Feedback" (OMB#: 0925-0648 Exp. Date: 05/31/2021)

TITLE OF INFORMATION COLLECTION: 2021 ClinicalTrials.gov Usability Feedback Study (NLM)

PURPOSE:
The goal of this National Library of Medicine (NLM) survey is to collect qualitative customer service delivery feedback from users of the National Center for Biotechnology Information (NCBI) ClinicalTrials.gov (CTG) website. The databank website is the NIH's comprehensive, up-to-date database of clinical studies. This invaluable public resource is being modernized to deliver an improved user experience will accommodate growth and enhance efficiency. The usability data collection will solicit the public's level of satisfaction with the ongoing CTG website redesign efforts. Users participating in the testing study will be asked to provide feedback on features offered, what users expect to see, and their comments on the website.

DESCRIPTION OF RESPONDENTS:
The respondents will be members of the public who are interested in voluntarily testing the useability of the proposed enhancements to the ClinicalTrials.gov website.

TYPE OF COLLECTION: (Check one)

[ ] Customer Comment Card/Complaint Form	[ ] Customer Satisfaction Survey
[X] Usability Testing (e.g., Website or Software)	[ ] Small Discussion Group
[ ] 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 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 ClinicalTrials.gov program or may have with our website in the future.

Name: Anna Fine, PharmD

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
Individuals or Households	140	1	1	140
Totals		140		**140**

COST TO RESPONDENT

Category of Respondent	Total Burden Hours	Wage Rate*	Total Burden Cost
Individuals or Households from the General Public	140	$25.72	$3,600.80
Totals			**$3,600.80**

* BLS May 2019 National Occupational Employment and Wage Estimates, United States https://www.bls.gov/oes/current/oes_nat.htm#00-0000

FEDERAL COST: The estimated annual cost to the Federal government is: **$14,892.00**

Staff	Grade/Step	Salary	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
Staff Scientist	T42	$142,000	2%		$2,840.00
Contractor Cost					N/A
Moderator/Facilitator		$86,000	8.2%		$7,052.00
Note-taker		$50,000	10 %		$5,000.00
Total					**$14,892.00**

* Cited from https://ohr.od.nih.gov/intrahr/Documents/title42/NIH_TITLE_42_PAY_MODEL_RANGES.pdf

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?

Respondents will be users of the ClinicalTrials.gov website who click on the provided survey link and dial in via their home internet network to participate in the online usability testing and virtual call.

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? [X] Yes [ ] No