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: 2020 NLM CT.gov Focus Group Survey

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 website. NLM will conduct in-person focus group testing to assess the usability and readability of two ClinicalTrials.gov newly revised informational webpages: (1) – "Background" and (2) "Learn About Clinical Studies" pages. The results of this survey will allow NLM to better understand the information that users expect to see related to clinical trials and to improve the educational information about clinical trials provided on the NLM website.

DESCRIPTION OF RESPONDENTS:

The plan is to obtain feedback from a general representation of the community searching clinical trial information on the ClinicalTrials.gov website. NLM wants to ensure the information meets the needs of the health professionals, older adults, and those with limited to no health literacy, which will represent the majority of the respondents.

[] Customer Satisfaction Survey [] Small Discussion Group [] Other:	
	[] Small Discussion Group

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: Anna Fine, PharmD, MS, Associate Director, ClinicalTrials.gov	
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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 [X] No

3.	If Yes, has an up-to-date System of Records Notice (SORN) been published?	[] Yes	[] No
	N/A	· -		

Gifts or Payments:

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

Participants for these in-person focus groups, who have to travel to the facility to participate will be compensated with a \$50 Gift Card (to Amazon) upon completion of the focus group process as token of appreciation for their participation.

ESTIMATED BURDEN HOURS and COSTS

Category of Respondent	No. of	No. of	Time per	Total
	Respondents	Responses per	Response	Burden
		Respondent	(in hours)	Hours
Individuals or Households				
	40	1	90/60	60
Totals		40		60

Category of Respondent	Total Burden	Wage Rate*	Total Burden
	Hours		Cost
Health professionals	12	\$68.73	\$824.76
Adult with limited health literacy	36	\$9.45	\$340.20
Older Adults (55 & over)	12	\$24.78	\$297.36
Totals			\$1462.32

^{*}May 2018 National Occupational Employment and Wage Estimates, the Family and General practitioners was chosen as most representative of the health professional respondents 25% hourly wage: https://www.bls.gov/oes/current/oes291062.htm

FEDERAL COST: The estimated annual cost to the Federal government is: \$6178.66

Staff	Grade/Step	Salary	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
Technical Information					
Specialist	GS 13/Step 1	102,663	0.1%		\$102.66
Contractor Cost					
On-site facilitator co-facilitator		84,000	2.8%		\$ 2352

[†] Dept of Labor Hourly Missouri Minimum Wage https://www.dol.gov/agencies/whd/minimum-wage/state#mo

[^]Bureau of Labor Statistics weekly and hourly earnings data from the Current Population survey https://data.bls.gov/pdq/SurveyOutputServlet 2019 Quarter 3 Median weekly salary for 55 years and older all occupations, sex, and race (\$991/40hr=\$24.775)

Co-facilitator	84,000	2.8%	\$ 2352
and note taker	49,000	2.8%	\$ 1372
Travel			
Other Cost			
Total			\$6178.66

^{*}The Salary in table above is cited from: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/20Tables/html/DCB.aspx

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?

Participants will be recruited through convenience sampling methods, including HLM's social media e.g., Facebook, Twitter @HealthLitMedia and @C3T_HLM that have approximately 6,000 followers combined. A message will be posted at the respective sites with an opportunity to participate. HLM will use existing community partnerships with an organization to identify individuals with specific backgrounds, such as those with low health literacy and health professionals.

Administration of the Instrument

1.	How will you collect the information? (Check all that apply)
	[] Web-based or other forms of Social Media
	[] Telephone
	[X] In-person
	[] Mail
	[] Other, Explain
2.	Will interviewers or facilitators be used? [X] Yes [] No