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

TITLE OF INFORMATION COLLECTION: National Institutes of Health National Center for Advancing Translational Sciences Toolkit for Patient-Focused Therapeutic Development (NCATS Toolkit) Website User Feedback Survey

PURPOSE:

The National Center for Advancing Translational Sciences Toolkit for Patient-Focused Therapeutic Development (NCATS Toolkit) is a program under the NCATS Office of Rare Diseases Research at the National Institutes of Health (NIH). It provides the public with access to current, reliable, and easy-to-understand information about how rare disease patient groups can effectively engage in the research process to develop therapies (drugs, biologics, and medical devices) from start to finish. In the United States, a rare disease is defined as one that affects fewer than 200,000 people. While rare diseases affect 1 in 10 Americans, only 5% of rare diseases have approved treatments. Involving the rare disease patient voice into the therapy development process is recognized by the FDA, researchers, and pharmaceutical industry as a way to increase the pace of therapy development for rare diseases. To elucidate this complex process, this website (https://toolkit.ncats.nih.gov/) serves as a repository of best practices that educates patient groups.

The NCATS Toolkit website is currently undergoing a redevelopment effort in terms of content and user experience. NCATS would like to collect targeted user feedback on the current website to inform our development of the new website.

DESCRIPTION OF RESPONDENTS:

The respondents will primarily be patient group members.

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 program or may have experience with the program in the future.

Name: Linda Ho

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	500	1	5/60	42
Totals		500		**42**

Category of Respondent	Total Burden Hours	Hourly Wage Rate*	Total Burden Cost
Individuals or households	42	$25.72	$1,072
Totals			$1,072

*Source: https://www.bls.gov/oes/current/oes_dc.htm

FEDERAL COST: The estimated annual cost to the Federal government is $601.29.

Staff	Grade/Step	Salary*	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
Health Specialist	9/Step 1	60129	1%		$601.29
Travel					
Other Cost					
Total					$601.29

The Salary in table above is cited from https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/21Tables/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?

  Survey respondents will be visitors to NCATS Toolkit website pages and choose to respond to the survey by selecting the "Provide Your Feedback" button. See attached sample survey.

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