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: NCATS ORDR Usability Testing of Web Resources for Rare Disease Patients

PURPOSE:
The National Center for Advancing Translational Sciences (NCATS) Office of Rare Diseases Research (ORDR) has created several online resources for patients with rare diseases, their caregivers, and patient groups. NCATS is conducting user testing activities to better understand user's needs and how they interact with the websites in order to improve website usability. The following websites are included in these activities:

- The Genetic and Rare Diseases Information Center (GARD) provides the public with access to current, reliable, and easy-to-understand information about rare or genetic diseases in English or Spanish.

- The Toolkit for Patient-Focused Therapy Development (Toolkit) provides a collection of online resources that can help patient groups advance through the process of therapy development.

- The Rare Disease Registry Program (RaDaR) provides easily accessible advice for constructing and maintaining good-quality rare disease patient registries to enable therapeutics development.

The user testing activities will be conducted in person at Rare Disease Day, an event for the public held at the NIH campus on February 28, 2019. Prior to and during the event there will be announcements and communications promoting the websites asking for volunteers to review, ask questions, and provide feedback. There will also be signage in the conference center during the event.

There will be several computers setup in a conference room for users to complete 3-5 tasks to test the website usability and ask several questions to assess the content relevance, value and meaning. The test and survey will be unmoderated and we will use an online usability testing tool *Loop11* to screen-capture the tasks and record their survey answers. There will be between 2-5 support staff to help with instructions and questions and/or clarify feedback.

Study procedures include:
- In person, unmoderated, task-based usability test with survey questions
- Each study will be no more than 15 minutes, though participants may stay longer to interact and have conversations with support staff
- No incentives will be offered
- Limited background information may be collected
- No personally identifiable information will be collected
- The testing will be screen recorded
- There will not be note-takers, however support staff will be answering questions

- The only limit to the number of participants is the availability of computers and number of persons stopping by the conference room to learn more about GARD, Toolkit, or RaDaR

DESCRIPTION OF RESPONDENTS:
All persons attending Rare Disease Day at the NIH campus have a personal or professional interest in rare disease information. The room is open to all attendees who have an interest in learning about and providing feedback for the GARD, Toolit, or RaDaR websites.

TYPE OF COLLECTION: (Check one)

[ ] Customer Comment Card/Complaint Form
[X] Usability Testing (e.g., Website or Software)
[ ] Focus Group
[ ] 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: __Stephen Seidel, Project Clearance Liaison, NCATS__2/11/19_____

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	Type of Form	No. of Respondents	No. of Responses per Respondent	Time per Response (in hours)	Total Burden Hours
Individuals from the General Public	GARD website	25	1	15/60	6
Individuals from the General Public	RaDaR website	25	1	15/60	6
Individuals from the General Public	Toolkit website	25	1	15/60	6
Totals		**75**	75		**18**

Category of Respondent	Total Burden Hours	Wage Rate*	Total Burden Cost
Individuals from the General Public	18	$24.34	$438.12
Totals			$438.12

* BLS May 2017 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 $2,589.44

Staff	Grade/Step	Salary	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
Staff Scientist	GS 12/ Step 1	$39.07/hr	8 hrs		$ 312.56
Contractor Cost					
Facilitator		$136.58/hr	8 hrs		$1,092.64
Facilitator		$ 92.26/hr	8 hrs		$ 738.08
Facilitator		$ 55.77/hr	8 hrs		$ 446.16
Travel					N/A
Other Cost					N/A
TOTAL					$2,589.44

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?

[X] Yes [ ] 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?

Every year NIH hosts a Rare Disease Day on the NIH campus in Bethesda, Maryland. Rare Disease Day is a free and public event that attracts patients and patient groups of rare diseases to learn about rare disease research and help raise the level of awareness about rare diseases. All attendees, people interested in learning more about rare diseases, are potential users of the website.

We plan to use convenience/voluntary response sampling for recruitment purposes. All visitors have registered for the event, however we do not plan to use the registration for sampling purposes. The usability testing may be promoted through social media, speaker announcements, signage, and unstructured casual hallway conversations by staff.

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
   - [X] Other, Signage, networking at the event
2. Will interviewers or facilitators be used? [X] Yes [ ] No

   The usability tests will be in person, however they will be setup to be unmoderated. Facilitators will be in the room to assist anyone who needs help or has questions.