"Request for Approval under the "Generic Clearance for NIH Citizen Science and Crowdsourcing Projects"
(OMB#: 0925-0766 Exp., Date: 04/30/2023)

TITLE OF INFORMATION COLLECTION: Connecting Awardees with Regulatory Experts (CARE) (NCI)

PURPOSE: The NCI SBIR Development Center would like to send out an application for NCI-funded companies to apply for a program called CARE – Connecting Awardees with Regulatory Experts and implement a survey for companies that participated in the CARE program. The CARE program aims to connect NCI-funded small businesses with the FDA to receive feedback on their regulatory questions during early-stage product development. In addition, CARE educates companies about the FDA process and the existing resources available to them. This program is free and open to NCI-funded small businesses.

DESCRIPTION OF RESPONDENTS: NCI SBIR funded companies that would like to participate CARE program and the participants of the CARE program.

TYPE OF COLLECTION: (Check one)

[ ] Data Catalogue   [ ] Repository of Tools and Best Practices
[ ] Recommendations of scientific reviewers   [X] Resources
[ ] Call for Nominations   [X] Other: Survey

CERTIFICATION:

I certify the following to be true:
1. The collection is voluntary.
2. The collection is a low burden for respondents and a 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. Information gathered will not be used for the purpose of <u>substantially</u> informing <u>influential</u> policy decisions.
5. 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: Monique Pond

To assist review, please provide answers to the following question:

Personally Identifiable Information:
1. Is personally identifiable information (PII) collected? [X] Yes [ ] No
2. If Yes, is the information that will be collected included in records subject to the Privacy Act of 1974?   [X] 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 - Application	50	1	10/60	8
Individuals - Survey	50	1	2/60	2
Totals		**100**		**10**

COST TO RESPONDENTS

Category of Respondent	Total Burden Hours	Hourly Wage Rate*	Total Burden Cost
Individuals	10	$ 49.44	$ 494.40
Total			**$ 494.40**

**Source of the mean Hourly Wage Rate is provided by the Bureau of Labor Statistics, Occupation title "Medical Scientists" 19-1040, https://www.bls.gov/oes/2021/May/oes_nat.htm#19-1040.

FEDERAL COST: The estimated annual cost to the Federal government is $ 2,692.98.

Staff	Grade/Step	Salary**	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
Program Director	14/3	$ 134,649	2%		$ 2,692.98
Contractor Cost					$ 0
Travel					$ 0
Other Cost					$ 0
Total					$ 2,692.98

**The salary in the table above is cited from: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/22Tables/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?

$$[X] \text{ Yes} \qquad [\ ] \text{ No}$$

If the answer is yes, please describe both below (or attach the sampling plan).   If the answer is no, please tell how you plan to identify your potential group of respondents and how you will select them.

An email will be sent to the eligible companies and the participants of the CARE program.

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 ensure that all instruments, instructions, and scripts are submitted with the request.