Request for Approval under the "Generic Clearance for the Collection of Routine Customer Feedback" (OMB#: 0925-0648 Exp., date: 06/30/2024)

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

PURPOSE: The Connecting Awardees with Regulatory Experts (CARE) program is an interagency collaboration between the National Cancer Institute (NCI) and Food and Drug Administration (FDA). The goal of the program is to connect small businesses with the FDA and support communications 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 and NHLBI-funded small businesses that have not discussed their technology with FDA.

The NCI Small Business Innovation Research (SBIR) Development Center and the NHLBI Office of Translational Alliances and Coordination would like to implement a survey that aims to receive feedback on their experiences, communications, understanding of the FDA process, and how satisfied the businesses are with the program during early-stage product development.

DESCRIPTION OF RESPONDENTS: The small businesses in the CARE program.

TYPE OF COLLECTION: (Check one)					
[] Customer Comment Card/Complaint Form [] Usability Testing (e.g., Website or Software [] Focus Group		[X] Customer Satisfaction Survey[] Small Discussion Group[] Other:			
FREQUENCY OF REPORTING: (Check one)					
[] Once [] Monthly [X] Annually	[] Quarterly [] On Occasion [] Other				

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. The results are <u>not</u> intended to be disseminated to the public.
- 5. Information gathered will not be used to inform influential policy decisions substantially.
- 6. The collection is targeted to soliciting 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 answer the following question: If you collect names and emails, check yes for PII.

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, a 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 – Survey	60	1	3/60	3
Totals		60		3

Category of Respondent	Total Burden Hours	Hourly Wage Rate*	Total Burden Cost	
Individuals	3	\$ 49.44	\$148.32	
Totals			\$148.32	

^{**}The salary in the table above is cited from: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/21Tables/html/DCB.aspx

FEDERAL COST: The estimated annual cost to the Federal government is \$2,863.83.

Staff	Grade/Step	Salary	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
Program Director	15/1	\$155,700	1%		\$1,557.00
Program Director	13/6	\$130,683	1%		\$1,306.83
Contractor Cost					\$0
Travel					\$0
Other Cost					\$0
Total					\$2,863.83

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If you are conducting a focus group or survey or plan to employ statistical methods, please provide answers to the following questions:

Th	ne selection of your targeted respondents	
1.	Do you have a customer list or something similar that defines the universe of	potential

	[X] Yes	[] [N(
If yes, please describe both below (or attach the sampling plan). If the how you plan to identify your potential group of respondents and how		
An email will be sent to the participants of the CARE program	ı .	
Administration of the Instrument		
 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 all instruments, instructions, and scripts are submitted with the request.

respondents, and do you have a sampling plan for selecting from this universe?