

Request for Approval under the “Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (NICHD)

(OMB#: 0925-0648 Exp., Date: 05/2021)

TITLE OF INFORMATION COLLECTION: 2020 BPCA Post Stakeholders Meeting Assessment

PURPOSE:

The 2020 BPCA Stakeholders Meeting will be held virtually on December 14-15, 2020 due to the coronavirus pandemic. The purpose of this meeting is (1) to provide updates on the Best Pharmaceuticals for Children Act (BPCA) Clinical Program at the National Institutes of Health (NIH) and (2) to spearhead the development of a roadmap for identifying needs, prioritizing those needs, and for closing knowledge gaps in pediatric therapeutics that is applicable to a variety of stakeholders involved in pediatric drug development.

NICHD would like to collect feedback from participants on the virtual format, meeting content, speaker selection, breakout rooms, and roundtable discussion. Feedback will be collected using Survey Monkey. Participant feedback is used to determine which speakers were effective in meeting the goals of their presentations, to determine what content areas are of most interest to participants for future meetings, the relevance and quality of topics presented, and attendee interest in participating in future BPCA activities. Feedback is shared within OPPTB but not with the public.

DESCRIPTION OF RESPONDENTS:

The feedback questionnaire will be sent to all meeting participants which include BPCA stakeholders from FDA, NIH, industry, and academic institutions. Participants are primarily senior level pediatric specialists involved with clinical trials for pediatric therapeutics, drug development, and regulatory affairs. We estimate approximately 150 participants will attend.

TYPE OF COLLECTION: (Check one)

Customer Comment Card/Complaint Form
 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.

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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 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 No

ESTIMATED BURDEN HOURS and COSTS

Form Name	Category of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Principles of Pediatric Clinical Pharmacology Feedback Request	Private sector	150	1	10/60	25
Total			150		25

Category of Respondents	Total Burden Hours	Wage Rate*	Total Burden Cost
Private sector	25	\$84.28	\$2,107
Totals			\$2,107

*Citing median hourly wage for 29-1221 Pediatricians, General, May 2019, <https://www.bls.gov/oes/current/oes291221.htm>

FEDERAL COST: The estimated annual cost to the Federal government is \$1,732.30

Staff	Grade/Step	Salary	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
Program Officer	GS-15, Step 4	\$144,945	1.0	N/A	\$1,449.45
Contractor Cost (T&M Contract)		\$56.57 per hour	5 hours		\$282.85

Travel					
Other Cost					
Total					\$1,732.30

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 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?

The questionnaire will be sent to all participants at the 2020 BPCA Stakeholders Meeting.

Administration of the Instrument

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

Please make sure that all instruments, instructions, and scripts are submitted with the request.