

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

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**TITLE OF INFORMATION COLLECTION:** 2021 BPCA Stakeholders Meeting Post-Meeting Assessment (NICHD)

**PURPOSE:**

The 2021 BPCA Stakeholders Meeting will be held virtually on December 2-3, 2021. The purpose of this meeting is to provide updates on (1) the Best Pharmaceuticals for Children Act (BPCA) Clinical Program at the National Institutes of Health (NIH) and (2) the development of the BPCA Framework to Enable Pediatric Drug Development.

NICHD would like to collect feedback from participants on the meeting content, speaker selection, breakout sessions, 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 will be 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)

- |  |  |
|--|--|
| <input type="checkbox"/> Customer Comment Card/Complaint Form          | <input checked="" type="checkbox"/> Customer Satisfaction Survey |
| <input type="checkbox"/> Usability Testing (e.g., Website or Software) | <input type="checkbox"/> Small Discussion Group                  |
| <input type="checkbox"/> Focus Group                                   | <input type="checkbox"/> 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: Perdita Taylor-Zapata, M.D, Medical Officer, BPCA Program Lead, Obstetric and Pediatric Pharmacology and Therapeutics Branch, NICHD

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**

Category of Respondent	No. of Respondents	No. of Responses per Respondent	Time per Response (in hours)	Total Burden Hours
Individuals or Households	150	1	5/60	13
<b>Totals</b>		150		

Category of Respondent	Total Burden Hours	Hourly Wage Rate*	Total Burden Cost
Individuals or Households	13	\$85.16	\$1,107.08
<b>Totals</b>			\$1,107.08

\*Citing median hourly wage for 29-1221 Pediatricians, General, May 2020, <https://www.bls.gov/oes/current/oes291221.htm>

**FEDERAL COST:** The estimated annual cost to the Federal government is \$1,874.51

Staff	Grade/Step	Salary*	% of Effort	Fringe (if applicable)	Total Cost to Gov't
<b>Federal Oversight</b>					
Program Officer	GS-15, Step 4	\$ 158,541	1.0	N/A	\$1,585.41
<b>Contractor Cost (T&amp;M Contract)</b>					
		\$57.82 per hour	5 hours		\$289.10
Travel					
Other Cost					

<b>Total</b>					\$1,874.51
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**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 registrants of the 2021 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.**