

Request for Approval under the “Generic Clearance for NIH Citizen Science and Crowdsourcing Projects”

(OMB#: 0925-0766 Exp., date: 04/2023)

TITLE OF INFORMATION COLLECTION: 2022 Best Pharmaceuticals for Children Act (BPCA) Prioritization Nomination Form

PURPOSE: NIH, in consultation with the U.S. Food and Drug Administration (FDA) and experts in pediatric research, is mandated to develop and publish a priority list of needs in pediatric therapeutics, including drugs or indications that require study, and update this list every 3 years. As part of the prioritization process, NICHD solicits nominations from BPCA stakeholders to be considered for priority areas for the following year. These nominations are reviewed, scored, and tiered by expert volunteers. This year, NIH will also be collecting feedback on areas for continued discussion and collaboration. An online form has been created in Survey Monkey to collect both nominations and input on areas for future discussion.

DESCRIPTION OF RESPONDENTS: Responses will be solicited via RFI. The RFI is open to the public and anyone may submit a nomination. An email will be sent to BPCA stakeholders including researchers from academia, hospitals, industry, NIH, and FDA notifying them of the RFI. Recipients of this email are expected to be the core group of respondents. Participants may respond to the survey as many times as they would like. We anticipate an average of 2-3 submissions per respondent.

TYPE OF COLLECTION: (Check one)

- | | |
|--|---|
| <input type="checkbox"/> Data Catalogue | <input type="checkbox"/> Repository of Tools and Best Practices |
| <input type="checkbox"/> Recommendations of scientific reviewers | <input type="checkbox"/> Resources |
| <input checked="" type="checkbox"/> Call for Nominations | <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. Information gathered will not be used for the purpose of substantially informing influential 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: Perdita Taylor-Zapata, MD

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

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
Private sector	50	3	15/60	38
Totals	50	150		38

COST TO RESPONDENT

Category of Respondent	Total Burden Hours	Hourly Wage Rate*	Total Burden Cost
Private sector	38	85.16	\$3,236.08
Totals			3,236.08

* 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 \$2,589.34

Staff	Grade/Step	Salary*	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
Program Officer	GS-14, Step 10	\$164,102	1%	N/A	\$1,641.02
Contractor Cost		\$59.27 per hour	16 hours		\$948.32
Travel					
Other Cost					
Total					\$2,589.34

*the Salary in table above is cited from <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2022/DCB.pdf>

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?

An email will be sent to BPCA stakeholders involved with pediatric research, clinical care, or regulatory/federal oversight who have been involved with the BPCA program, attended a BPCA Stakeholders Meeting, participated in a public assembly facilitated by BPCA, or requested to be notified of BPCA activities, notifying them of the RFI and nomination form. Responses are also open to the public.

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