

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: BPCA Prioritization – Identification of Knowledge Gaps in Pediatric Drug Development

PURPOSE:

The Best Pharmaceuticals for Children Act (BPCA) Program at the NIH is a pediatric drug development program for off-patent therapeutics used in children. The Program, led by the NICHD, is responsible for identifying gaps in pediatric therapeutics, prioritizing studies that need to be done to close those gaps, sponsoring clinical trials in those prioritized areas, and disseminating data to the public. In preparation for the 2020 BPCA Annual Stakeholders Meeting December 14-15, 2020, the BPCA Program is looking for feedback from stakeholders on therapeutic gaps in pediatric drug development in order to inform the 2021 prioritization process. The survey will be administered via Survey Monkey.

BPCA Stakeholder Meetings include presentations about the status of the program, progress from BPCA-funded research, review and discussion of proposed future therapeutic areas, and updates on currently funded studies. This year’s meeting will also include discussion of a more detailed framework and roadmap to further define future activities.

DESCRIPTION OF RESPONDENTS:

Respondents consist of BPCA stakeholders who are academicians, clinicians, and researchers. Many BPCA stakeholders have been involved with the BPCA Program for years and regularly contribute to identification of pediatric needs and prioritization of therapeutic areas in pediatric research.

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 type="checkbox"/> Call for Nominations | <input checked="" type="checkbox"/> Other: <u>Recommendations of scientific experts</u> |

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, Medical Officer, 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 |
|------------------------|--------------------|---------------------------------|------------------------------|--------------------|
| Private Sector | 590 | 1 | 15/60 | 148 |
| Totals | | 590 | | 148 |

| Category of Respondent | Total Burden Hours | Hourly Wage Rate* | Total Burden Cost |
|------------------------|--------------------|-------------------|-------------------|
| Pediatricians | 148 | \$84.28 | \$12,473 |
| Totals | | | \$12,473 |

* 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 \$1,746.80

| Staff | Grade/Step | Salary* | % of Effort | Fringe (if applicable) | Total Cost to Gov't |
|---|----------------|------------------|-------------|------------------------|---------------------|
| Federal Oversight | | | | | |
| Program Officer | GS-14, Step 10 | \$157,709 | 1% | N/A | \$1,577.09 |
| | | | | | |
| Contractor Cost (T&M Contract) | | \$56.57 per hour | 3 hours | | \$169.71 |
| Travel | | | | | |
| Other Cost | | | | | |
| | | | | | |
| Total | | | | | \$1,746.80 |

*the Salary in table above is cited from <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2020/general-schedule/>

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 list is of approximately 590 BPCA stakeholders from the National Institutes of Health (NIH), U.S. Food and Drug Administration (FDA), academia, the pharmaceutical industry, and members of pediatric advocacy groups who have interest in improving pediatric drug development. The survey link will be sent to the full list.

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.