

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 Stakeholder Contact Details

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. The BPCA Program is looking for stakeholders to participate in BPCA related program activities, including:

- 1) assisting with annual prioritization of drugs and therapeutic areas to inform pediatric studies
- 2) serving as an expert in therapeutic area working groups
- 3) participating in annual stakeholder meetings

NICHD has an active list of stakeholders who have been involved with the Program over the years. We would like to reach out to additional potential BPCA stakeholders recommended by the Pediatric Trials Network (PTN) to invite them to participate in BPCA activities. Many stakeholders within the PTN are academicians, clinicians, and researchers that have not formally been formally a part of the BPCA stakeholder list. Their inclusion will enhance the Program’s outreach to healthcare providers. In order to add interested individuals to the BPCA Stakeholders Distribution List, basic contact details will be required. A form was created to streamline the process of collecting this information.

In addition to name and email, job title, institution, and subspecialty area are requested (but not required) so that future stakeholder activities can be targeted to those in particular subspecialty areas or with specific job types.

DESCRIPTION OF RESPONDENTS:

Respondents are researchers, clinicians, and site investigators with the Pediatric Trials Network (PTN). The PTN is an alliance of clinical research sites cooperating in the design and conduct of pediatric clinical trials, funded by BPCA. The list of respondents was provided by the PTN as potential BPCA stakeholders who could help to advance the mission and mandate of BPCA.

TYPE OF COLLECTION: (Check one)

- Data Catalogue
- Recommendations of scientific reviewers
- Call for Nominations

- Repository of Tools and Best Practices
- Resources
- Other: Call for Stakeholders for a NIH sponsored listserv

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
Individuals or Households	500	1	2/60	17
Totals		500		17

Category of Respondent	Total Burden Hours	Hourly Wage Rate*	Total Burden Cost
Individuals or Households	17	\$84.28	\$1,432.76
Totals			\$1,432.76

* 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 \$1,859.94

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	5 hours		\$282.85
Travel					
Other Cost					
Total					\$1,859.94

*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 Pediatric Trials Network stakeholders who have similar interests to the BPCA program. These participants are not already on the BPCA stakeholder list. 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