`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 Framework Initiative Resource Collection

PURPOSE: As part of the BPCA mandate, six public assemblies have been convened to develop a generic framework to provide an overall structure to enable pediatric drug development studies. The goal is to develop -- in collaboration with subject matter experts (SMEs) in pediatric care and research -- an annotated, selective, curated collection of resources that will assist drug developers, researchers, and clinicians conducting pediatric drug development research. As part of this process, assembly participants are asked to submit references for best practice and guidance documents for inclusion in the final framework. An online form has been created in Survey Monkey to streamline this process.

DESCRIPTION OF RESPONDENTS: Respondents are members of the public who have participated in one or more of six public assemblies in the following subject areas: biomarkers, pediatric-friendly formulations, systems pharmacology, PK modeling to inform dosing, advancing clinical trial design, and pharmacoepidemiology. Respondents are primarily pediatricians and researchers who work in academia, industry, and regulatory settings. Thus far, there have been an average of approximately 50 participants on each assembly call who would potentially respond to this survey. Participants may respond to the survey as many times as they would like. We anticipate an average of two responses per participant.

TYPE OF COLLECTION: (Check one)

[ ] Data Catalogue   [ ] Repository of Tools and Best Practices
[ ] Recommendations of scientific reviewers   [X] Resources
[ ] Call for Nominations   [ ] 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 <u>not</u> raise issues of concern to other federal agencies.
4. Information gathered will not be used for the purpose of <u>substantially</u> informing <u>influential</u> 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 question:

Personally Identifiable Information:
1. Is personally identifiable information (PII) collected? [X] Yes [ ] No
2. If Yes, is the information that will be collected included in records that are subject to the Privacy Act of 1974?   [X] Yes [ ] No
3. If Applicable, has a System or Records Notice been published? [X] Yes [ ] No

Gifts or Payments:
Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants? [ ] Yes [X] 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	300	2	5/60	50
Totals	**300**	600		**50**

Category of Respondent	Total Burden Hours	Hourly Wage Rate*	Total Burden Cost
Individuals or Households	50	84.28	$4,214
Totals			

* 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 __$1,939.78__

Staff	Grade/Step	Salary*	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
Program Officer	GS-14, Step 10	$159,286	1%	N/A	$1,592.86
Contractor Cost		$57.82 per hour	6 hours		$346.92
Travel					
Other Cost					
Total					$1,939.78

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?

                                                        [X] 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?

> Respondents will consist of any participants in the six BPCA public assemblies involved in the initiative to develop a framework to improve pediatric drug development who would like to contribute resources or references for consideration for inclusion in the framework.

Administration of the Instrument
1. How will you collect the information? (Check all that apply)
    [X] Web-based or other forms of Social Media
    [ ] Telephone
    [ ] In-person
    [ ] Mail
    [ ] Other, Explain

2. Will interviewers or facilitators be used? [ ] Yes [X] No