## Request for Approval under the Generic Clearance for the “Conference, Meeting, Workshop, and Poster Session Registration Generic Clearance (OD)”

## (OMB#: 0925-0740, Expiration Date: 07/31/2022)

**TITLE OF INFORMATION COLLECTION:** HEALthy Brain and Child Development (HBCD) Study Kickoff (NCI)

**PURPOSE:**

The HBCD Study is an exciting NIH initiative to help researchers and clinicians address a critical gap in our knowledge of how environmental exposures, especially opioid and other drug use, affect infant and child brain development. HBCD aims to contribute to our understanding of normal cognitive, behavioral, social, and emotional function from the prenatal period through childhood. It is a part of the NIH’s larger Helping to End Addiction Long-term (HEAL) Initiative, a multi-agency effort to curb the national opioid crisis.

This virtual meeting will bring together HEALthy Brain and Child Development consortium investigators to launch the Phase II study.

**DESCRIPTION OF RESPONDENTS**:

Investigators and NIH collaborators

**TYPE OF COLLECTION:** (Check one)

[ ] Abstract [ ] Application

[X] Registration Form [ ] 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.

Name: **Michelle Freund**

**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

**Gifts or Payments:**

Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants? [ ] Yes [ X ] No

Amount: \_\_\_\_\_\_\_\_\_

Explanation for incentive: (include number of visits, etc)

**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 | 125 | 1 | 3/60 | 6 |
| **Totals** |  | **125** |  | **6** |

|  |  |  |  |
| --- | --- | --- | --- |
| **Category of Respondent** | **Total Burden Hours** | **Hourly Wage Rate\*** | **Total Burden Cost** |
| Individuals | 6 | $48.45 | $290.70 |
| **Total** |  |  | **$290.70** |

\*Source of the mean Hourly Wage Rate is provided by the Bureau of Labor Statistics, Occupation title “Medical Scientists” 19-1040, <https://www.bls.gov/oes/2020/May/oes_nat.htm>.

**FEDERAL COST:** The estimated annual cost to the Federal government is $1,138.87

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Staff** | **Grade/Step** | **Salary\*\*** | **% of Effort** | **Fringe**  **(if applicable)** | **Total Cost to Gov’t** |
| **Federal Oversight** |  |  |  |  |  |
| Program Director | 14/5 | $138,866 | .01% |  | $138.87 |
| **Contractor Cost** |  |  |  |  | $1,000.00 |
| Travel |  |  |  |  | $0 |
| Other Cost |  |  |  |  | $0 |
| **Total** |  |  |  |  | **$1.138.87** |

\*\*The salary in the table above is cited from <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/21Tables/html/DCB.aspx>.

**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**

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?

This workshop is by invitation only and the invitees are current HEALthy Brain and Child Development consortium investigators.

**Administration of the Instrument**

How will you collect the information? (Check all that apply)

[ X ] Web-based or other forms of Social Media

[ ] Telephone

[ ] In-person

[ ] Mail

[ ] Survey Form

[ ] Chart Abstraction

[ ] Other, Explain

Will interviewers, facilitators, or research coordinators be used? [ ] Yes [ X ] No

**Please make sure that all instruments, instructions, and scripts are submitted with the request.**