

**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

Registration Form

Application

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? 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

Gifts or Payments:

Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants? Yes 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?

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)

- 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 No

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