**Supporting Statement for:**

Prenatal Alcohol and Other Drug Exposures in Child Welfare Project

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**THE SUPPORTING STATEMENT**

**Prenatal Alcohol and Other Drug Exposures in Child Welfare Study**

1. **Justification**

**1. Circumstances Making the Collection of Information Necessary**

The Children’s Bureau, Administration on Children, Youth & Families (ACYF), Administration for Children and Families (ACF), U.S. Department of Health & Human Services (DHHS), seeks approval for the data collection instruments and procedures described herein. The proposed information collection is necessary to understand the child welfare (CW) system’s response to prenatal substance exposure (PSE) (including opiates, methamphetamines, marijuana and other substances), with an emphasis on prenatal alcohol exposure (PAE) and resulting conditions.

The Prenatal Alcohol and Other Drug Exposures in Child Welfare Study (hereafter referred to as the PAODE-CW Study) is sponsored by the Children’s Bureau (CB) in collaboration with the Centers for Disease Control and Prevention (CDC) under an Intra-agency Agreement. The study involves the conduct of cross-sectional mixed-methods descriptive study with 28 sites identified in collaboration with the CB. The instruments and procedures described in this statement represent new data collection with representatives of the study sites. The CB intends for information collection to begin upon Office of Management and Budget (OMB) approval and continue through October 2019.

There are no legal or administrative requirements that necessitate the collection. The CB is undertaking the collection at the discretion of the agency. The CB is aware that many children who were exposed to alcohol and other drugs prenatally escape the attention of child welfare systems. For example, Ira Chasnoff, MD, and colleagues[[1]](#footnote-2) published a study in which he discovered that over 80% of the children in foster care who had a fetal alcohol spectrum disorder were not identified when they first entered foster care. The CB and CDC funded an exploratory study that was conducted in one CW jurisdiction. Preliminary findings revealed some potential contributing factors to the under-identification of children, including inadequate screening policies and tools, lack of training and knowledge on how and when to evaluate risk, and limited documentation practices to support identification and referrals.[[2]](#footnote-3) The current study is designed to further explore identification of prenatal substance exposure and agency policies and practices in a larger sample of CW agencies. The findings will help to elucidate the training needs for staff, and the training and service needs for children and families.

In addition, a recent report from ACF found that communities with high rates of opioid overdoses and opioid hospitalizations also had increasing rates of children entering their foster care systems.[[3]](#footnote-4)  Thus, research on the policies and practices of children in child welfare who come from households with substance abuse issues is very timely and addresses the National Opioid Public Health Emergency.

**2. Purpose and Use of the Information Collection**

The information collection described in this request will allow the CB to better understand the child welfare (CW) system’s response to prenatal substance exposure (PSE) and challenges of responding to PSE in a diverse set of CW agencies. The new knowledge will be disseminated to the field and will have an impact on the CB and CDC recommendations for future technical assistance, research and federal resource allocation.

The data collected will address critical research questions posed by the CB and the CDC[[4]](#footnote-5):

1. What are the current policies and practices in place in CW agencies and related organizations for the identification of children with prenatal substance exposure and/or diagnosed with a resulting condition (such as Fetal Alcohol Syndrome [FAS] or Fetal Alcohol Spectrum Disorders [FASDs])? The needed information is not now available in any useful form. What is available is buried in case notes at individual agencies.
2. What type of training and dissemination activities are currently used, and what consensus is there, if any, among CW professionals in the studied settings, regarding what practice changes are likely to improve identification and documentation of children with PSEs and resulting conditions in the CW system?

Proposed data sources for this effort includes interviews and surveys collected from representatives at 28 local CW agencies (referred to as sites), and additional interviews, surveys, and focus groups collected in 8 of these sites (referred to as the “in-depth data collection” sites). The 28 sites will be purposively selected to match criteria from a design options report developed in conjunction with an expert technical workgroup and submitted and approved by the CB. The objective with site selection is to maximize variation in order to understand diverse practices and policies in CW systems’ response to PSE. Six priority states will be selected by the CB and invited to participate, with alternates identified if a state declines. Within each selected state, the team will work with the director to identify 4 to 6 local CW agencies (sites) within the state to invite to participate. The instruments and procedures described in this statement represent new data collection with representatives of the 28 study sites.

At all 28 sites, the *Interview Protocol for Local Agency Director* will be conducted in person to obtain information about policies, practices, and priorities, and to gather contextual information about agency culture, relevant trends among the populations they serve, and their perspective about staff responsibilities and practices. The *Interview Protocol for Local Agency Staff* will be conducted in person to obtain more detailed information about agency policies, staff knowledge and behaviors, the agency’s data system and documentation processes, how children access services, and the kinds of services and supports provided to families and caregivers. There are 3 versions of this interview that are administered based on the role and responsibilities of the staff person: *Frontline-only* (i.e., intake and investigation responsibilities); *Ongoing-only* (i.e., case management activities); *Frontline and Ongoing* (for staff responsible for both activities).

The *Interview Protocol for Local Agency Medical Staff* will be conducted in person to obtain information similar to the local agency staff interviews but with questions regarding practices related to medical assessment and diagnosis. The *Survey Instrument for Local Agency Staff (Form A General, Form B General, and Form B Differential Response)* will be administered to a larger group of agency staff to learn about staff knowledge, practices, and training history related to PSE, and will include vignettes to ask the respondent to describe a common response to PSE situations. There are three versions. One version is adapted to fit sites that apply *Differential Response*, a CW systems reform that enables child protective services to differentiate its response to reports of child abuse and neglect based upon a number of factors, including level of risk to the child. The two other versions (*Form A General* and *Form B General*) are identical, except for the inclusion of different vignettes that vary by age, gender, and situation.

The number of surveys distributed at each agency will be roughly proportional to the size of the agency (between 12 and 28 staff members), to better represent and capture the variety of practice and knowledge among staff, particularly at larger agencies. The interviews and staff surveys will capture information from diverse staff perspectives and promote validity within individual agencies and transferability of overall thematic findings.

At 8 of the 28 sites, additional, more in-depth, data collection is proposed. The *Interview Protocol for Data Staff* will obtain information about agency policies, information on the structure and composition of the data systems, where relevant information on PSE is likely to be documented, and data operationalization issues. The *Survey Instrument for Service Providers* will be administered to medical and service providers who expressly partner with or receive referrals from these agencies, in order to gather information about how the service providers and CW agencies may work together in the identification, assessment, and possible diagnosis of PSE or related medical conditions (e.g., ADHD) and to learn if and how information is transferred across agencies. One *Focus Group with Caregivers* will be held at each in-depth site in explore how information related to PSE is communicated to foster and adoptive families and to learn more about these families’ PSE-related knowledge and training needs.

**3. Use of Improved Information Technology and Burden Reduction**

Wherever possible and appropriate, information technology will be used to capture information and reduce burden relative to other methods of data collection. Instrument questions are designed to collect only information not provided by existing sources, further reducing the burden.

Administration of the surveys will be Web-based,[[5]](#footnote-6) utilizing email notification and Internet-based survey technologies creating efficiencies for survey administrators and allowing flexibility and convenience for respondents. Most items are quantitative with skip patterns to reduce burden. The surveys will be administered electronically so respondents can respond at their convenience. Respondents are expected to have the capabilities to access the Web link to the survey.[[6]](#footnote-7)

The interviews and focus groups will be conducted to obtain more detailed information on the CW system’s response to PSE. It is not appropriate to use computer-based interviewing given the nature of the items. All data collectors will undergo training on sensitive and responsive interviewing techniques, protection of participants’ privacy, and data security procedures. The responses will be qualitative in nature. Skip patterns will be used. Interviews will be scheduled with the respondents to minimize the disruption on daily activities.

**4. Efforts To Identify Duplication and Use of Similar Information**

Through an extensive literature review and contacts with researchers and other individuals with CW and PSE expertise within federal agencies, as well as the study technical work group, the team determined that there are no similar data publicly available that can address the study questions without this data collection. The proposed instruments have been designed to be completed in the shortest amount of time possible by the fewest number of respondents while eliciting the necessary information. These instruments have been pre-tested for both understanding and time required by the respondents.

**5. Impact on Small Businesses or Other Small Entities**

The full range of information will be requested of all respondents responding to each instrument. Organizational size will not affect the relevance of particular questions. Information being requested has been held to the minimum sufficient to address the intended research questions.

**6. Consequences of Collecting the Information Less Frequently**

This is a one-time project. If the collection is not conducted, the CB will not have access to this type of information to understand the CW system’s response to PSE, to make recommendations for future research and grant funding, or to make recommendations for improved services, service planning and coordination, and documentation of PSE and related conditions for children in the CW system.

**7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

There are no special circumstances associated with this data collection.

**8. Comments in Response to the Federal Register Notice and Efforts To Consult Outside the Agency**

No requests were received from the general public for copies of the proposed information collection instruments following the publication of the notice that appeared in the Federal Register, Volume 82, Number 202, Friday, October 20, 2017, pages 48818–48819. No comments were received. Consultants, stakeholders, and Federal staff reviewed and offered comments on the data collection and instruments (see further description in B4 and Appendix B).

**9. Explanation of Any Payment or Gift to Respondents**

No cash payments will be offered to individual respondents at local agencies or service providers. For the foster parent/adoptive parent focus groups at the eight in-depth data collection sites, each participant will receive a $15 gift card and babysitting and food will be provided during the data collection. The gift card, babysitting and food are offered to offset extenuating circumstances including costs of transportation and childcare that may preclude caregiver participation. The goal is to avoid response bias by ensuring that lower-income caretakers are not systematically discouraged from participating due to the costs of participation (transportation, child care, and food that might be needed due to juggling this project with other responsibilities) Proposed incentives will undergo review and approval by an Institutional Review Board (IRB).

**10. Assurance of Confidentiality Provided to Respondents**

Respondents will be informed of all planned uses of the data, that their participation is voluntary, and that their information will be kept private to the extent permitted by law. The study team will not disclose any individual-level survey or interview information to the persons outside the study team. Information will not be published that could be used to identify individual respondents or participating agencies. All Web-based surveys, interviews, and focus group results will be analyzed and reported in aggregate for all reports, presentations, and publications.

All study team members will sign a study Data Security and Protection of Confidentiality agreement and any required site agreements.[[7]](#footnote-8) All of the study materials including all instruments and consent documents will be reviewed and approved by an IRB prior to initiation of the study. If required, all study materials will be submitted and approved by agency and state IRBs.

*Personally Identifiable Information (PII).* The study team will collect limited PII in order to identify appropriate respondents for the interviews, surveys, and focus groups, and to contact and invite them to participate. PII will only include the following data elements: contact information (name, agency/organization, email address, phone number); gender; position; and number of years in position. Information will not be maintained in a paper or electronic system from which they are actually or directly retrieved by an individual’s personal identifier. After consultation with ACF’s Office of the Chief Information Officer (OCIO), it was determined that a Privacy Impact Assessment (PIA) should be conducted, and is underway at the time of this submission. The OCIO determined that while a PIA is required, a Systems of Records Notice and/or an Authority to Operate (ATO) are not required. The CB will work with the ACF and HHS OCIO to comply with any requirements related to the PIA.

Why this information is needed: Contact information will be collected to facilitate interview and focus group scheduling and survey administration, to track response, to provide aggregate-level descriptions of respondents, and to allow for analysis of data by role and agency.

Instrument types and storage: Contact information will be stored separately from respondent data. The following instruments will collect PII (PII data elements included in parentheses*): Interview Protocol for Local Agency Director* (position and number of years in position); *Interview Protocol for Local Agency Medical Staff* (position); *Interview Protocol for Data Staff* (position); *Interview Protocol for Local Agency Staff – Frontline only, Ongoing Only*, and *Frontline and Ongoing* versions (position).

Protections: All PII collected is private and will not be shared with anyone outside of the study team. Only the study team will have access to contact information. The study team will store all PII data in separate files in password-protected, secure data systems in order to ensure privacy. Data will be coded using the study identification numbers (no personal identifiers). Any PII revealed in interviews, focus groups, or survey responses will be manually redacted by study team members from transcripts and data files. Identifiers will not be used in any study reporting.[[8]](#footnote-9)

**11. Justification for Sensitive Questions**

There are no questions or requirements of a sensitive nature contained in the survey and interview instruments described herein.

**12. Estimates of Annualized Burden Hours and Costs**

Having applied hourly wage estimates to burden hours in each respondent category, the current annual cost to the respondents is as follows: (1) $821.80 for the *Interview Protocol for Local Agency Director*; (2) $377.01 for the *Interview Protocol for Data Staff*; (3) $485.80 for the *Interview Protocol for Local Agency Medical Staff* (4) $670.45 for the *Interview Protocol for Local Agency Staff – Frontline On*l*y*; (5) $670.45 for the *Interview Protocol for Local Agency Staff – Ongoing Only*; (6) $457.13 for the *Interview Protocol for Local Agency Staff– Frontline and Ongoing*; (7) $1,706.60 for the *Survey Instrument for Local Agency Staff - Form A General*; (8) $1,097.10 for the *Survey Instrument for Local Agency Staff - Form B General*; (9) $609.50 for the *Survey Instrument for Local Agency Staff - Form B Differential Response*; (10) $301.80 for the *Survey Instrument for Service Providers*; and (11) $1,045.92 for the *Focus Group of Caregivers*[[9]](#footnote-10). Rates were obtained from https://www.bls.gov/oes/2016/may/oes\_nat.htm; different rates for different assumed respondent positions (as closely aligned as possible) were used which included: General and Operations Managers, Database Administrators, Registered Nurses, Social Workers, Nurse Practitioners, and Mixed Professionals. Please see the supplementary spreadsheet for additional detail on the wage rates.

The total annual cost to the respondents if data collection of instruments occurs equally across two years is $8,243.56.

**Exhibit A-12. Annual Burden Estimates**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Instrument** | **Annual Number of Respondents** | **Number of Responses Per Respondent** | **Average Burden Hours Per Response** | **Total Annual Burden Hours** |
| Interview Protocol for Local Agency Director | 14 | 1 | 1 | 14 |
| Interview Protocol for Data Staff | 6 | 1 | 1.5 | 9 |
| Interview Protocol for Local Agency Medical Staff | 14 | 1 | 1 | 14 |
| Interview Protocol for Local Agency Staff – Frontline Only | 28 | 1 | 1 | 28 |
| Interview Protocol for Local Agency Staff – Ongoing Only | 28 | 1 | 1 | 28 |
| Interview Protocol for Local Agency Staff– Frontline and Ongoing | 15 | 1 | 1.25 | 19 |
| Survey Instrument for Local Agency Staff - Form A General | 140 | 1 | 0.5 | 70 |
| Survey Instrument for Local Agency Staff - Form B General | 90 | 1 | 0.5 | 45 |
| Survey Instrument for Local Agency Staff - Form B Differential Response | 50 | 1 | 0.5 | 25 |
| Survey Instrument for Service Providers | 12 | 1 | 0.5 | 6 |
| Focus Group of Caregivers | 32 | 1 | 1.5 | 48 |
| Annual Total | 429 |  |  | 305 |

**13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers**

No additional cost burden will apply for respondents or record keepers.

**14. Annualized Cost to the Federal Government**

The associated costs for developing, administering, and analyzing the instruments are outlined in Table A-14 below. Rates associated with researcher staff time (Social Scientists and Related Workers Hourly Rate of $39.13/hour obtained from https://www.bls.gov/oes/current/oes\_nat.htm#00-0000, 21-0000, multiplied by 1.5 to account for fringe/overhead) and Federal Program Officers’ time ($56.54/hour for GS-15, Step 5, obtained from <https://www.generalschedule.org/2017>, multiplied by 1.5 to account for fringe/overhead) was applied. The total annual cost to the federal government if all data collection occurs equally across two years is $165,452.78.

**Exhibit A-14. Estimated Annualized Costs for Survey Development, Administration, and Analysis**

|  |  |  |  |
| --- | --- | --- | --- |
| **Instrument & Other Costs** | **Administration Activities** | **Staff Time (Hours)** | **Total Cost[[10]](#footnote-11)** |
| Interview Protocol for Local Agency Director | Instrument Development, Administration & Analysis | 97 | $8,044.14 |
| Interview Protocol for Data Staff | 52 | $3,267.56 |
| Interview Protocol for Local Agency Medical Staff | 93 | $5,014.17 |
| Interview Protocol for Local Agency Staff – Frontline Only | 215 | $8,081.38 |
| Interview Protocol for Local Agency Staff – Ongoing Only | 215 | $8,081.38 |
| Interview Protocol for Local Agency Staff– Frontline and Ongoing | 121 | $46,52.94 |
| Survey Instrument for Local Agency Staff - Form A General | 598 | $22,104.54 |
| Survey Instrument for Local Agency Staff - Form B General | 388 | $14,424.84 |
| Survey Instrument for Local Agency Staff - Form B Differential Response | 220 | $8,281.08 |
| Survey Instrument for Service Providers | 360 | $26,838.68 |
| Focus Group of Caregivers | 112 | $4,144.08 |
| Other Direct Costs | Travel costs to support data collection at sites | N/A | $52,518.00 |
| Total |  | 2,471 | $165,452.78 |

**15. Explanation for Program Changes or Adjustments**

This is a new data collection.

**16. Plans for Tabulation and Publication and Project Time Schedule**

Frequency and proportion distributions will be calculated to generate summaries and to examine variability in the data for the Web-based surveys. Cross-tabulations and significance tests will be conducted as appropriate. SPSS will be used for the quantitative analysis. Content analysis will be conducted on open-ended survey items and will entail systematic coding and thematic analysis. Qualitative online secure software (e.g., Dedoose) will be used for the qualitative analysis. Analyses will be conducted to determine subgroup variation, as appropriate.

The findings will be summarized in a site-level report, state-level report, and in the final report due to the CB in September 2019. The site- and state-level reports are intended as internal documents for the sites, states, and the CB, while the final report is anticipated to be disseminated to stakeholders and on CB’s Web site. It is anticipated (based on OMB approval) that the information collection activities will be administered and analyzed between May 3, 2018 and April 30, 2019 and report development will occur between April 30 and September 30, 2019.

**17. Reason(s) Display OMB Expiration Date Is Inappropriate**

The OMB expiration date for the information collection and the OMB control number will appear on the instruments. A statement will appear that describes the public reporting burden and explains that an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

**18. Exception to Certification for Paperwork Reduction Act Submissions**

No exception is requested to the certification statement identified in Item 19, “Certification for Paperwork Reduction Act Submissions.”

1. Chasnoff, I., Wells, A.M., & King, L. (2015). Misdiagnosis and missed diagnoses in foster and adopted children with prenatal alcohol exposure. *Pediatrics*, Retrieved online: http://pediatrics.aappublications.org/content/135/2/264. [↑](#footnote-ref-2)
2. Usher, K. P., Leicht, C., Briggs, A., Wang, K., & Santucci, A. *Prenatal exposure to alcohol and other drugs: An exploration of child welfare policies and practices*. ICF:  Fairfax, VA;  2016, Unpublished Final Report under Contract No.:  HHSP23320110015YC.  Sponsored by the Administration for Children Youth and Families and Centers for Disease Control and Prevention.     [↑](#footnote-ref-3)
3. Radel, L., Baldwin, M., Crouse, G., Ghertner, R., & Waters, A. (2018). *Substance use, the opioid epidemic, and the child welfare system: Key findings from a mixed methods study*. Research Brief, Office of the Assistant Secretary for Evaluation and Planning, U.S. Department of Health and Human Services. Retrieved online: https://aspe.hhs.gov/system/files/pdf/258836/SubstanceUseChildWelfareOverview.pdf [↑](#footnote-ref-4)
4. The research questions are further delineated in Appendix A. [↑](#footnote-ref-5)
5. The surveys will be administered electronically and are referred to collectively as the Web-based surveys. [↑](#footnote-ref-6)
6. A paper copy of the surveys will be provided to those who cannot or choose not to access the surveys online. [↑](#footnote-ref-7)
7. The CB and CDC federal project officers are considered part of the immediate study team and therefore will have access to PII/confidential information from participants and held to all of the data security standards. [↑](#footnote-ref-8)
8. The study team will secure, store, and dispose of PII data according to the procedures and systems included in the study’s approved data security and monitoring plan, which are in accordance with the federal requirements outlined in the contract with the CB and are undergoing approval in the study’s PIA with OCIO. [↑](#footnote-ref-9)
9. The annualized respondent burden and cost varies by year and depends upon the data collection strategies employed in the particular year. Burden and costs were estimated assuming 2 equally-distributed years of data collection. Costs were estimated applying average hourly wages listed on the Bureau of Labor Statistics website. [↑](#footnote-ref-10)
10. The annual cost assumes that all activities occur in equal distribution across two years. [↑](#footnote-ref-11)