

**Request for genIC Approval  
CDC/ATSDR Formative Research and Tool Development**

**0920-1154**

---

**CIO:** NCBDDD/DBDID/IOMRPB/PSESRT

**PROJECT TITLE: American Academy of Pediatrics Resident Training in  
Developmental Continuity Clinics**

**PURPOSE AND USE OF COLLECTION:**

Prenatal exposure to alcohol and other teratogens can have serious neurodevelopmental impact including Fetal Alcohol Spectrum Disorders (FASDs). FASD is an umbrella term that encompasses several, more specific, diagnoses. These conditions are associated with lifelong physical and neurodevelopmental abnormalities, including growth problems and prenatal brain damage. Such brain damage may lead to developmental, behavioral and neurocognitive impairments. Infants with a FASD are rarely recognized at birth by hospital staff. Further, research has shown that at later ages, these children may be overlooked or misdiagnosed. While there is no cure for FASDs, early identification and intervention can mitigate adverse effects.

Pediatricians are critical in the process of early identification, referral and ongoing care of children with FASDs. Through regular well-child appointments, addressing parental concerns and managing a family's pediatric medical home pediatricians are in a key position to obtain (and document) prenatal exposure history to alcohol and other drugs. Relatedly, their role in monitoring development enables them to identify issues early which in turn facilitates timely treatment, especially early intervention. It is important for pediatricians to learn these skills early in their clinical training to make them routine throughout their clinical practice careers. To facilitate and strengthen pediatricians' role, with CDC funding, the American Academy of Pediatrics (AAP) is piloting a program to provide first year pediatric resident trainees with strategies, tools and resources necessary for: 1) obtaining prenatal history of exposure to alcohol and other drugs for all their patients, 2) recognizing clinical manifestation of FASDs in pediatric primary care settings to expedite diagnostic evaluation referrals, and 3) caring for affected children and their families in the pediatric medical home.

The project will be conducted in two phases. Phase one is a one-day, in-person, train-the trainers session for attending physicians who oversee resident training in developmental continuity clinics. Training will be provided by experts in identification, diagnosis and care of children with FASDs. For phase two, the trainer attending physicians will implement a curriculum of continuing medical education activities with their first-year pediatric residents. The curriculum contains both required and optional activities that residents complete with support and facilitation from attending physicians. It is estimated that five clinics will participate in the project which could include up to 10 attending physicians and 15 pediatric residents. Participant clinics are selected by a brief application to the AAP. All participation is voluntary.

An initial pilot project was conducted with three clinics (4 attending physicians and 8 residents). The current information collection request (ICR) is for a second, larger, pilot project. ICR approval is requested for a one-year period and is submitted under NCBDDD's Formative Research and Tool Development Generic ICR. The intent of this second pilot project is to improve and further refine training materials and resident curriculum.

Session, activity and program satisfaction surveys will be obtained to: 1) assess larger scale feasibility of the project, 2) ensure that specific information is conveyed and understood by participants, 3) solicit feedback regarding content, format and delivery of project materials and 4) understand participants' [attending physicians and resident trainees] experience with the program. In phase one, attending physicians will complete pre- and post-session surveys for each of four presentations plus one overall satisfaction survey for the entire training day and one overall program satisfaction survey at the end of the project (total 10 instruments). In phase 2, residents will complete a session satisfaction survey for the required activity and the overall program (total 3 instruments). In addition, residents can complete two optional activities that do not include satisfaction surveys. Survey instruments are in Attachments A1-A13:

- Attachment A1 – Attending physicians\_Screening & Diagnosis Pretest
- Attachment A2 – Attending physicians\_Screening & Diagnosis Posttest
- Attachment A3 – Attending physicians\_Treatment Across Lifespan Pretest
- Attachment A4 – Attending physicians\_Treatment Across Lifespan Posttest
- Attachment A5 – Attending physicians\_Overcoming Social Attitudes Pretest
- Attachment A6 – Attending physicians\_Overcoming Social Attitudes Posttest
- Attachment A7 – Attending physicians\_Educational Care Pretest
- Attachment A8 – Attending physicians\_Educational Care Posttest
- Attachment A9 – Attending physicians\_Training Program Evaluation
- Attachment A10 – Resident\_Overall Effects & Prevalence Video Pretest
- Attachment A11 – Resident\_Overall Effects & Prevalence Video Posttest
- Attachment A12 – Resident\_Overall Program Evaluation
- Attachment A13 – Attending physicians\_Overall Program Evaluation

No private information or personally identifiable data is collected. CDC staff will provide technical assistance in development of all sessions and all information collection instruments. This role will allow CDC to monitor the conduct and success of the project as well as quickly identify issues to be addressed. Such monitoring ensures a high-quality program that will contribute to CDC programs to build clinical capacity regarding children with FASDs and their families.

**DESCRIPTION OF RESPONDENTS:** Actively practicing pediatricians, both attending physicians and pediatric resident trainees.

**CERTIFICATION:**

I certify the following to be true:

1. The collection is voluntary. **YES**
2. The collection is low-burden for respondents and low-cost for the Federal Government. **YES**
3. The collection is non-controversial and does not raise issues of concern to other federal agencies. **YES**
4. Information gathered will not be used to substantially inform influential policy decisions. **YES**
5. The study is not intended to produce results that can be generalized beyond its scope. **YES**

Name: Jacquelyn Bertrand, PhD

To assist review, please answer the following questions:

**Personally Identifiable Information:**

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

Participant and AAP membership ID numbers are obtained to grant CME credit; however, these are not linked to data in any way, thus there is no sensitive or personally identifiable data. CDC does not receive this information.

**Gifts or Payments:**

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

**BURDEN HOURS**

<b>Category of Respondent</b>	<b>Form Name</b>	<b>Annual # of Respondents</b>	<b>Participation Time (minutes)</b>	<b>Burden in Hours</b>
Pediatricians	Attending physicians Screening & Diagnosis Pretest (A1)	10	10/60	2
	Attending physicians Screening & Diagnosis Post test (A2)	10	10/60	2
	Attending physicians treatment across lifespan pretest (A3)	10	10/60	2
	Attending physicians treatment across lifespan post test (A4)	10	10/60	2
	Attending physicians overcoming social attitudes pretest (A5)	10	10/60	2
	Attending physicians overcoming social attitudes post test (A6)	10	10/60	2
	Attending physicians educational care pretest (A7)	10	10/60	2
	Attending physicians educational care post test (A8)	10	10/60	2
	Attending physicians training program	15	15/60	3

	evaluation (A9)			
	Resident overall effects & prevalence pretest (A10)	15	15/60	3
	Resident overall effects & prevalence post test (A11)	15	15/60	3
	Resident overall program evaluation (A12)	15	15/60	3
	Attending physicians overall program evaluation (A13)	10	20/60	4
<b>Totals</b>		<b>160</b>		<b>32</b>

**FEDERAL COST:** The estimated annual cost to the Federal government is \$97,804

**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?

Participant clinics are selected by a brief application to the AAP.

**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 [ X ] No

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

## Instructions for completing genIC Request for Approval for CDC/ATSDR Formative Research and Tool Development

---

**TITLE OF INFORMATION COLLECTION:** Provide the name of the collection that is requested.

**PURPOSE and USE:** Provide a brief description of the purpose of this collection and how it will be used. If this is part of a larger study or effort, please include this in your explanation.

**DESCRIPTION OF RESPONDENTS:** Briefly describe the targeted group/groups for this collection.

**CERTIFICATION:** Please read the certification carefully. If you incorrectly certify, the collection will be returned as improperly submitted or it will be disapproved.

**Personally Identifiable Information:** Provide answers to the questions.

**Gifts or Payments:** If you answer yes to the question, please describe the incentive and provide a justification for the amount.

### **BURDEN HOURS:**

**Category of Respondents:** Identify who you expect the respondents to be in terms of the following categories: (1) Individuals or Households; (2) Private Sector; (3) State, local, or tribal governments; or (4) Federal Government. Only one type of respondent can be selected.

**Form:** Provide the title of the information collection form.

**No. of Respondents:** Provide an estimate of the Number of respondents.

**Participation Time:** Provide an estimate of the amount of time required for a respondent to participate (e.g. fill out a survey or participate in a focus group).

**Burden in Minutes:** Multiply the Number of responses and the participation time and divide by 60.

**FEDERAL COST:** Estimate the annual cost to the Federal government for this collection.

**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.** Please provide a description of how you plan to identify your potential group of respondents and how you will select them. If the answer is yes, to the first question, you may provide the sampling plan in an attachment.

**Administration of the Instrument:** Identify how the information will be collected. More than one box may be checked. Indicate whether there will be interviewers (e.g. for surveys) or facilitators (e.g., for focus groups) used.