# Improving Fetal Alcohol Spectrum Disorders Prevention and Practice through National Partnerships\*

OMB # 0920-1129

**Supporting Statement Part A** 

**Reinstatement with Changes** 

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\*The previously approved project was titled, Improving Fetal
Alcohol Spectrum Disorders Prevention and Practice through
Practice and Implementation Centers and National Partnerships.

The name has been updated for this submission to more accurately reflect the work being done through new cooperative agreement funding.

- Goal of the study: The purpose of this information collection is to assess and address the knowledge, attitude, skills and practice behaviors of healthcare professionals to prevent, identify, and treat fetal alcohol spectrum disorders (FASDs).
- Intended use of the resulting data: Data will be used to measure whether the efforts of the grantees have resulted in knowledge and practice changes among targeted healthcare providers; to evaluate and improve project trainings and FASD prevention messages; and to provide recommendations for future training efforts.
- Methods to be used to collect: Data will be collected through electronic, online or paperpencil assessments and pre/post/follow-up surveys of training efforts (as well as other surveys of grantee target disciplines and audiences), and qualitative key informant interviews conducted in-person or via telephone.
- The subpopulation to be studied: The target population is healthcare practitioners and students in the following disciplines: medical assistants, nursing, obstetrics and gynecology, pediatrics, social work, and family physicians.
- How data will be analyzed: Quantitative analyses planned by grantees and the cross-site
  evaluator include cross-tabulations, t-tests, bivariate regression analysis, chi-square and
  McNemar's tests, repeated measures ANCOVA, and MANOVA/MANCOVA. Qualitative
  content analyses will also be conducted.

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#### LIST OF ATTACHMENTS

#### **Attachment A: Applicable Laws or Regulations**

Section 301 of the Public Health Service Act (42 U.S.C. 241)

#### Attachments B1 – B17 Survey Instruments

- **B1.** Health Professionals Survey
- B2. FASD Core Training Survey Pre-Test
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- B17. TCU Organizational Readiness Survey

## **Attachment C: FASD Evaluation Working Group Members**

# **Attachments D1-D3: Screenshots**

- D1. Medical Assistants Change in Practice Survey
- D2. Social Work and Family Physicians Pre-Training Survey
- D3. Social Work and Family Physicians 6-Month Follow Up Survey

#### A. Justification

#### A.1. Circumstances Making the Collection of Information Necessary

This Information Collection Request is submitted under the classification "reinstatement with changes". The length of data collection requested for Office of Management and Budget (OMB) approval is 3 years. The National Center of Birth Defects and Developmental Disability (NCBDDD) at the Centers for Disease Control and Prevention (CDC) is making this request as authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241) (Att.A).

#### **Background**

Prenatal alcohol use is the cause of a range of birth defects and developmental disabilities, collectively known as fetal alcohol spectrum disorders (FASD). This term is used to define the spectrum of physical, mental, behavioral, and/or learning disabilities that can result from prenatal alcohol exposure. Although it is not known how many people have FASDs, some recent estimates indicate the prevalence of fetal

alcohol syndrome (FAS), the most severe condition in the spectrum, to be 6 to 9 out of 1,000 children, and prevalence of FASD to be 24 to 48 per 1000 children (May, Baete, Russo et al., 2014).

FASDs are completely preventable if a woman does not drink alcohol during pregnancy. However, data from a 2012 report indicate that one in 13 pregnant women reports alcohol use in the past month, and one in 17 pregnant women reports binge drinking in the past month. In addition, more than half of all women of childbearing age report some alcohol use, and one in seven reports binge drinking in the past month (CDC, 2012). Many of these women are at risk for an alcohol-exposed pregnancy, even if they are not intending to become pregnant. In 2005, the U.S. Surgeon General re-issued a 1981 advisory that women who are pregnant or considering becoming pregnant should abstain from using alcohol.

Healthcare professionals play a crucial role in identifying women at risk for an alcohol-exposed pregnancy and in identifying effects of prenatal alcohol exposure in individuals. However, despite the data regarding alcohol consumption among women of childbearing age and the prevalence of FASDs, screening for alcohol use among female patients of childbearing age and diagnosis of conditions along the FASD continuum are not yet routine standards of care. New data collection is needed to evaluate both FASD training programs for healthcare professionals addressing the prevention, identification, and treatment of FASDs

Although most primary care providers ask patients about their alcohol use, research suggests they do not follow recommended methods of screening or delivering brief interventions to patients who drink too much. Vinson and colleagues (2013) found that most primary care physicians are not screening systematically, but instead rely on their own intuition about whether the patient is likely to be using too much alcohol. Findings from their study indicated that clinician judgment missed most patients with a potential problem. Similarly, a systematic review found that healthcare professionals require sufficient knowledge about alcohol guidelines and risks in order to implement screening and interventions (Johnson et al., 2011). Findings such as these affirm the need for systems to be in place that allow providers to systematically screen, identify risky drinkers, provide evidence-based interventions, and bill appropriately for these services.

CDC funded Fetal Alcohol Spectrum Disorders Regional Training Centers (FASD RTCs) beginning in 2002 to train healthcare professionals and students in the prevention, identification, and treatment of FASDs. The FASD RTCs were evaluated by an external peer review panel in July 2013. The panel reaffirmed the need for the RTCs, with several changes. The panel identified a need for more comprehensive national coverage, discipline-specific trainings, increased use of technology, greater collaboration with medical societies, and stronger linkages with national partner organizations to increase the reach of training opportunities. The panel suggested that the focus of the training centers should be demonstrable practice change and sustainability and should emphasize primary prevention of FASDs.

In response to the panel's recommendations, CDC undertook a program redesign. Each center, called a Practice and Implementation Centers (PICs)\*, was charged with developing discipline-specific trainings and other learning opportunities to be implemented, shared across centers, and disseminated by organizations such as medical societies, national professional organizations, and national partner organizations. While a major focus of the grantees' work was national, regional approaches were also used to develop new content and test the feasibility and acceptability of materials, especially among healthcare providers and medical societies. Evaluation efforts were primarily dedicated to measuring practice change among targeted healthcare providers and systems change within healthcare systems.

#### A.2. Purpose and Use of Information Collection

The current FASD project focuses on the enhancement of FASD training, provider education, and practice change. Information on training and resource needs must be collected to inform development of trainings and resources (Attachment B1). In order to assess whether the project's trainings and other outreach efforts meet these goals, information must be collected to assess whether participants are satisfied with trainings and whether their knowledge and behavior have changed. Information about core project trainings will be collected at two points in time – pre-training (Attachment B2), and immediate post-training (Attachment B3). The FASD Core Training Surveys contain a set of items for assessing knowledge, practice behaviors, and comfort and self-efficacy to perform certain skills related to the prevention, identification, and treatment of FASDs, allowing for the evaluation of certain aspects of the collective grantee activities using consistent measures. This will provide CDC's Health Communication and Research Translation Team information regarding the effectiveness of the project as a whole and will assist with future program planning. Without this information collection, it will not be possible to ascertain whether the grantees are effective in improving knowledge, skills, and practice behaviors within their respective disciplines.

In addition to the core training surveys, the grantees have also created tailored evaluation instruments (**Attachments B4-B17**) to gather survey or interview data from their specific target populations. The results of these supplemental data collection efforts will assist each grantee in understanding whether they have reached and met the needs of their specific target audiences.

**Attachments B9, B10, B13, and B14** include several questionnaires that are utilized across various projects in our specific area. Specifically, regarding this project, they will be used with a different population of pediatricians, who attend Grand Rounds presentations and who work in a variety of settings. The results from this population of pediatricians will inform grantee efforts in understanding whether they have reached and met the needs of this audience of pediatricians.

#### A.3. Use of Improved Information Technology and Burden Reduction

All instruments are planned to be administered either electronically, via paper/pencil, or both. Instruments that will be administered online (or are planned to have the option of online administration) include the survey on one instrument specific to Medical Assistants (**Attachment D1**); two instruments specific to the Social Work and Family Physicians (**Attachments D2-D3**). This means that 18% of data collection instruments (3 out of 17 instruments) will be conducted via advanced information technology. (See Burden Table in section A12.) This will reduce the burden to the participants by allowing instant submission of responses and by not requiring responses to be returned via mail. If more funding becomes available, additional instruments will be modified to be used online.

In some instances, trainings may be administered in-person. It is not feasible to conduct the evaluations at the beginning and end of the in-person trainings electronically, since internet access may not be available and response rates for surveys to be completed later from a different location (rather than immediately at the end of the training) would be significantly lower. Qualitative data collections, such as key informant interviews, cannot generally be conducted online. Doing so would place a high burden on respondents to type answers to open-ended questions, and would likely lead to less complete data being collected because an interviewer would not be able to follow-up on unclear information. When possible, however, qualitative data collection will be conducted via telephone to decrease burden on respondents. In addition, interview scheduling will be flexible in order to meet the needs of varying respondent work schedules.

## A.4. Efforts to Identify Duplication and Use of Similar Information

There are no similar data. The trainings held by the grantees are unique and not conducted by other organizations, so ongoing data collection to evaluate these trainings, and their resulting systems and practice changes, is needed.

#### A.5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection.

#### A.6. Consequences of Collecting the Information Less Frequently

For core project trainings, information will be collected at two points in time from participants: immediately prior to the training (**Attachment B2**), and immediately following the training (**Attachment B3**). It is important to assess the effectiveness of the trainings for all participants, and it is necessary to conduct a follow-up survey to assess whether the trainings were effective to allow retention in knowledge gained through the trainings, as well as to assess change in actual behavior in medical professionals who attended the trainings. Collecting information less frequently would not allow accurate evaluation of the trainings, and particularly their impact on practice change.

All other data collection efforts are planned to occur only once.

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

This request fully complies with the guidelines of 5 CFR 1320.5.

# A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

- A. A copy of the agency's 60-day Federal Register Notice, as required by 5 CFR 1320.8 (d), was published on October 13, 2020 (volume 85, pages 64469-64470) (**Attachment C1**)
- B. No public comments were received.
- C. From August 2019 to July 2020, representatives from several organizations outside of CDC were consulted and asked to review the data collection instruments for this study. Please see **Attachment E** for a detailed list of collaborators.

# A.9. Explanation of Any Payment or Gift to Respondents

This collection of information does not involve any payment or gift to respondents.

#### A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

#### **Privacy Impact Assessment**

This submission has been reviewed by the NCBDDD Privacy Officer, who determined that the Privacy Act does not apply (see Attachment PIA Statement). Activities do not involve the collection of individually identifiable information.

#### 1.1 Privacy Impact Assessment

# (i) Overview of the Data Collection System

A core set of FASD trainings have been developed, with input from representatives from all grantees. These core trainings will be offered to healthcare professionals across all disciplines targeted by the project. To assess the effectiveness of these core trainings, a set of core evaluation instruments have been developed to gather data immediately prior to training (**Attachment B2**), and immediately after training (**Attachment B3**). The core instruments contain items that assess knowledge, practice behaviors, comfort, and self-efficacy to perform certain skills related to the prevention, identification, and treatment of FASDs. To meet the needs of the specific grantee target audiences, however, each grantee plans to create their own discipline-specific trainings. The discipline-specific trainings will be assessed through pre, post, and follow-up instruments tailored to each training (**Attachments B4-17**). These instruments will be administered electronically, via paper and pencil, by phone or in-person.

Any electronic data will be stored on password-protected servers within each grantee organization. Paper-pencil surveys, when conducted, will contain no personally-identifiable information, but will be stored in a locked file room at the grantee organization's respective offices separate from all other project data. The data and subsequent analyses will be stored electronically for five years, at which time they will be destroyed. Access to raw data will be limited to project collaborators (as identified in **Attachment M**). CDC will receive only summarized, aggregate data in the form of evaluation reports, interim progress reports, and final project reports.

Screenshots of all instruments that will be administered online are attached to this submission. **Attachment D1**is a screenshot of an instrument for Medical Assistants; **Attachments D2-D3** are screenshots of instruments for Social Work and Family Physicians.

## (ii) <u>Items of Information to Be Collected</u>

No personally-identifiable information will be collected. Data collection will be anonymous for data collection activities; the evaluation forms themselves will have no identifying information or any link to names or contact information.

Several surveys (which are designed to be administered at pre-test, post-test, and follow-up) will use a code to link to an individual respondent; this code, however, will not be stored by project staff. The code will be created by the respondent, and will comprise a series of letters and numbers that the respondent can remember and reproduce on each survey in order to link them.

#### (iii) Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

No website content directed at children under 13 years of age is involved in this information collection request.

## A.11. Institutional Review Board (IRB) and Justification of Sensitive Questions

#### I. IRB Approval.

This is non-research data collection. The NCBDDD Human Subjects Officer has reviewed this collection and determined that IRB approval is not required for this activity (see attachment IRB Form)

#### II. Sensitive Questions

No sensitive questions will be asked.

## A.12. Estimates of Annualized Burden Hours and Costs

The information will be collected from the following types of respondents: FASD core training participants, nurses, pediatricians, obstetrician-gynecologists, family medicine physicians, students in allied health professions, residency directors, training coordinators, clinical directors, certified medical assistants, social workers, and social work students. Burden estimates are based on projections from each grantee of how many participants they will reach annually and how long each evaluation instrument is estimated to take for a respondent to answer. As noted in the table of estimated annualized burden hours, each organization plans to use a variety of instruments to evaluate their own activities. See **Attachments B1-B17** and **D1-D3** for all proposed evaluation instruments.

It is estimated that data collection will include 16,938 participants each year, for a total of 50,814 over the three year approval period. The total estimated annual burden is 2,338 hours. (See Table 1 for details.) There are no costs to respondents other than their time.

**Table 1. Estimated Annualized Burden Hours** 

Type of Respondents	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
	Health				
	Professionals				
Health Professionals	Survey	4013	1	9/60	602
FASD Core	FASD Core				
Training	Training Survey –				
Participants	Pre-Test	4013	1	9/60	602
FASD Core	FASD Core				
Training	Training Survey –				
Participants	Post-Test	4013	1	5/60	335
Nurses	Health Professionals Survey (Nursing)	667	1	9/60	101
	Key Informant Interviews with				101
Nurses	Champions	14	2	45/60	21
Certified Medical	Medical Assistant	334	1	10/60	56

Type of Respondents	Form Name	No. of Respondents	No. Responses per	Average Burden per	Total Burden Hours
			Respondent	Response (in hours)	Hours
Assistants and					
students	– Pre-Test Survey				
Certified Medical	Medical Assistant				
Assistants and	– Post-Test	22.4	_	10/60	F.C.
students Certified Medical	Survey	334	1	10/60	56
Assistants and	Medical				
students	Assistants Change in Practice Survey	250	1	15/60	63
Students	Pre-Test	250	1	15/00	03
	Screening,				
	Assessment, and				
Pediatricians	Diagnosis	120	1	10/60	20
1 caraci retario	Post-Test	120	1	10/00	20
	Screening,				
	Assessment, and				
Pediatricians	Diagnosis	120	1	10/60	20
Pediatricians	Pre-Test ND-PAE	120	1	10/60	20
	Post-Test ND-				
Pediatricians	PAE	120	1	10/60	20
1 calati felano	Pre-Test	120	1	10/00	20
	Treatment Across				
Pediatricians	the Lifespan	120	1	7/60	14
	Post-Test				
	Treatment Across				
Pediatricians	the Lifespan	120	1	7/60	14
Family medicine	Social Work and				
physicians, social	Family Physicians				
workers, social	Pre-training				
work students	Survey	1167	1	8/60	156
Family medicine	Social Work and				
physicians, social	Family Physicians				
workers, social	6-Month Follow		_		
work students	Up Survey	1167	1	8/60	156
II bl.C	TCU				
Health Systems	Organizational	240	3	10/60	00
Professionals	Readiness Survey	246	2	10/60	82
TOTAL		16,938			2,338

Estimates of annualized cost to respondents for the burden hours for collections of information were based on the mean hourly wage from the U.S. Department of Labor's "May 2019 National Occupational Employment and Wage Estimates." (See <a href="http://www.bls.gov/oes/current/oes\_nat.htm">http://www.bls.gov/oes/current/oes\_nat.htm</a>.) (See Table 2 for details.) For rows containing multiple respondent types or where the specific occupation of the respondent is unclear, our wage rates were calculated as follows:

• Health Systems Professionals: Average of rates for "Medical and Health Services Managers" and "Health Diagnosing and Treating Practitioners."

- Students in Allied Health Professions: Rate for "All Occupations." (This wage rate was selected because the jobs that students might have while in school are unknown.)
- FASD Core Training Participants: Average of rates for "All Occupations" and "Health Diagnosing and Treating Practitioners."
- Healthcare Organization Representatives: Rate for "Medical and Health Services Managers."
- Residency Directors, Training Coordinators, Clinical Directors, Obstetrician-Gynecologists: Rate for "Physicians and Surgeons."
- Certified Medical Assistants and Students: Average of rate for "Medical Assistants" and "All Occupations."
- Family Medicine Physicians, Social Workers, Social Work Students: Average of rates for "Family and General Practitioners," "Healthcare Social Workers," and "All Occupations."

**Table 2. Estimated Annualized Burden Costs** 

Type of Respondents	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Health Professionals	Health Professionals Survey	602	\$34.17	\$20,570.34
FASD Core	-			
Training	FASD Core Training			
Participants	Survey – Pre-Test	602	\$34.17	\$20,570.34
FASD Core	EACD C. T			
Training	FASD Core Training	225	d0.4.17	Ф11 14C ОБ
Participants	Survey – Post-Test	335	\$34.17	\$11,446.95
Nurses	Health Professionals Survey (Nursing)	101	\$33.55	\$3,388.55
Nurses	Key Informant Interviews with Champions	21	\$33.55	\$704.55
Certified Medical	•			
Assistants and	Medical Assistant – Pre-			
students	Test Survey	56	\$18.86	\$1,056.16
Certified Medical				
Assistants and	Medical Assistant – Post-			
students	Test Survey	56	\$18.86	\$1,056.16
Certified Medical Assistants and students	Medical Assistants Change in Practice Survey	63	\$18.86	\$1,188.18
	Pre-Test Screening,			
Pediatricians	Assessment, and Diagnosis	20	\$84.33	\$1,686.60
	Post-Test Screening,		<b>.</b>	
Pediatricians	Assessment, and Diagnosis	20	\$84.33	\$1,686.60
Pediatricians	Pre-Test ND-PAE	20	\$84.33	\$1,686.60
Pediatricians	Post-Test ND-PAE	20	\$84.33	\$1,686.60
Pediatricians	Pre-Test Treatment Across the Lifespan	14	\$84.33	\$1,214.40

Type of	Form Name	Total	Hourly	Total
Respondents		Burden	Wage	Respondent
		Hours	Rate	Costs
	Post-Test Treatment Across			
Pediatricians	the Lifespan	14	\$84.33	\$1,214.40
Family medicine	-			
physicians, social	Social Work and Family			
workers, social	Physicians Pre-training			
work students	Survey	156	\$46.02	\$7,179.12
Family medicine	Social Work and Family			
physicians, social	Physicians 6-Month Follow			
workers, social	Up Survey			
work students	op survey	156	\$46.02	\$7,179.12
Health Systems	TCU Organizational			
Professionals	Readiness Survey	82	\$47.73	\$3,913.86
TOTAL		2,338		\$87,428.63

# A.13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no other annual cost burdens to respondents or record keepers.

## **A.14. Annualized Cost to the Government**

The average annualized cost to the Government to collect this information is \$830,120 for the OMB approval period that is requested. It is anticipated that costs for the future years will be comparable to those shown, with appropriate adjustments for budget changes, inflation, and salary increases.

**Table 3. Average Annualized Cost to the Government** 

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to		
the Federal		
Government		
	CDC Project Officer (GS-13, 0.10 FTE)	\$12,496
	Subtotal, Direct costs	\$12,496
Cooperative	Cooperative Agreements, Task orders, or	\$817,624
Agreement or	Contracts for implementation or information	
Contract	management (including indirect costs)	
	TOTAL COST TO THE GOVERNMENT	\$830,120

## A.15. Explanation for Program Changes or Adjustments

This Information Collection Request is for a "Reinstatement with Changes" of the previously approved 0920-1129. The previously approved project was titled, *Improving Fetal Alcohol Spectrum Disorders Prevention and Practice through Practice and Implementation Centers and National Partnerships.* The name has been updated for this submission to more accurately reflect the work being done through new cooperative agreement funding. This new work builds upon the accomplishments of the previous funding cycle and lessons learned. In addition, the number of instruments in this ICR has been reduced from 50 to 17, thereby significantly reducing the burden hours and associated burden costs.

#### A.16. Plans for Tabulation and Publication and Project Time Schedule

Project trainings will begin soon after OMB approval is received (Winter 2020-2021). Grantees are working to develop the content of the trainings so that they will be ready for implementation upon receipt of OMB approval. Grantees are required to provide CDC with progress reports each year.

Data will be summarized across respondents in all reports. For rating and categorical scales, the percent of each answer chosen compared to the total number of answers given will be reported per item. Open ended questions will be reviewed and summarized by themes. When applicable, qualitative and quantitative data will be synthesized to provide a more complete picture of the findings.

**Table A.16. Project Time Schedule** 

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	Activity	Timeframe	
Identify and invite participants to trainings		Starts 1–2 months after OMB approval, ongoing	
	Deliver training	Starts 1–2 months after OMB approval, ongoing	
Conduct trainings	Conduct pre and post surveys	Starts 1–2 months after OMB approval, ongoing	
	Conduct follow-up survey	6 months after each training	
Analyze and Report Data	Grantee Progress Reporting	Semi-annual, with progress report (mid-year) and annual report (end of year)	

# A.17. Reason(s) Display of OMB Expiration Date Is Inappropriate

Expiration dates are displayed, no exception is sought.

# **A.18.** Exceptions to Certification for Paperwork Reduction Act Submissions There are no exceptions to the certification.

#### References

Centers for Disease Control and Prevention. (July 20, 2012). Alcohol use and binge drinking among women of childbearing age — United States, 2006–2010. MMWR, 61(28), 534-538.

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