

**SAMHSA Fetal Alcohol Spectrum Disorders (FASD) Center for
Excellence Knowledge-Base Expansion Program: Screening and
Brief Intervention Project (SBI) and Project CHOICES**

THE SUPPORTING STATEMENT

A. Justification

1. Circumstances of Information Collection

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Prevention (CSAP) requests for the reinstatement-revision of data collection under the Fetal Alcohol Spectrum Disorders (FASD) Center for Excellence (CFE) Screening and Brief Intervention (SBI) and Project CHOICES evidenced-based prevention programs. The purpose of the FASD Center for Excellence is to promote the prevention of FASD and address the needs of individuals and families affected by FASD by providing technical assistance and training, a range of services, information, and support to communities to prevent alcohol-exposed pregnancies. Data will be collected from women served across approximately ten sites in local/community-based agencies. Women will be screened for alcohol use and provided with appropriate program based on their status as either pre-conception (non-pregnant) or pregnant.

History and Legislative Requirements

The FASD Center for Excellence has been established as a result of *legislative mandates from the Children's Health Act of 2000 (P.L. 106-310)*. The data outlined in this document will enable the SAMHSA FASD Center for Excellence to monitor the delivery and quality of the services provided. Section 501 (d)(4) of the Public Health Service Act requires that the Secretary of the Department of Health and Human Services, acting through the Administrator, shall “. . . assure that the Administration conduct and coordinate demonstration projects, evaluations, and service system assessments and the activities necessary to improve the availability and quality of treatment, prevention, and related services.” The request to reinstate OMB clearance for SBI and Project CHOICES is being submitted in response to that requirement.

Description of Reporting Forms

Form A. Knowledge-Base Expansion Assessment Form (Attachment A). This is a data collection form with a sequence of questions that includes appropriate skip patterns based on pregnancy status. A common data collection form allows determination of eligibility at baseline, and data collection at periodic intervals as defined by the program model, end of program, and follow-up. As a result, programs may collect data from women in either status using one data collection form for the SBI and Project CHOICES programs.

Form B. SBI Process Information Form (Attachment B). This data collection form is used to collect data that are helpful during delivery of the program.

Form C. Client Satisfaction (Attachment C). This data collection form is administered at the end of the program and will measure satisfaction of the women with the program.

2. Purpose and Use of the Information

Federal Use of Information- The data are collected to allow SAMHSA to monitor program performance and progress toward achieving the long-term goal of reduction of alcohol-exposed pregnancies. The practical utility of this program is to collect data to:

- Determine whether the programs were provided (and to document the details of the program as they are integrated); and
- Monitor to what extent the women achieved the desired outcomes (abstinence from alcohol use and use of effective contraception).

Subcontractor Use of Information- The FASD CFE subcontractors use the data to respond to other federal, state, and local performance requirements and the needs of the women who are served. A minimum data set will be collected to determine progress of this program as the evidence-based programs are implemented at the sites.

Changes - This is a modification to two previously administered programs; SBI (OMB No. 0930-0302) and Project CHOICES (OMB No. 0930-0303). The data collection forms from each program have been merged and now women are screened for SBI and Project CHOICES using one assessment form. Sites will have the option of implementing one or both programs. Also, existing database systems and user manuals may be used which minimizes the upfront database development costs.

3. Use of Improved Information Technology and Burden Reduction

For reporting and analysis purposes, the FASD CFE will use Microsoft Access to combine all individual responses into summary tables and comprehensive data files. The FASD CFE will submit the aggregated data files to CSAP's Data Collection Analyses and Reporting (DCAR) contract in April and October (or annually as appropriate). SAMHSA's DCAR and the previous subcontractors identified common data measures for FASD prevention. As part of their contractual agreement with SAMHSA/CSAP, the DCAR will use these data for secondary analysis to aid SAMHSA/CSAP in responding to GPRA and other federal reporting requirements, and to inform SAMHSA/CSAP policy and program planning. Data collection is anticipated to begin immediately after OMB clearance is received, although there may be slight differences in start-up by site. Data collection will continue through the end of the program (4/20/15).

Burden for sites is eased by the prime contractor's provision of a database that can be used for both data entry and electronic transmission of data either by email or disk. Data will be submitted by the sites electronically to the contractor. Sites either will send data-encrypted diskettes to the contractor via a delivery service such as Fed Ex or will transmit encrypted data (using standard encryption software) via e-mail to the project liaison at the FASD CFE.

Burden for data collection is also eased based on lessons learned from the previously administered SBI (OMB No. 0930-0302) and Project CHOICES (OMB No. 0930-0303) data collection efforts. The lessons learned were used to streamline the data collection effort and reduced the fifteen (15) forms used by the previous SBI and Project CHOICES programs to the current three (3) data collection forms. The use of electronic forms will increase the ability to efficiently collect data while increasing the time that the worker can spend with personal interactions about alcohol use--a potentially sensitive area of questioning.

4. Efforts to Identify Duplication and Use of Similar Information

The data collection proposed for this program among behavioral health settings is not available elsewhere, is not duplicative, and is seen as critically valuable for the monitoring of the SBI and Project CHOICES programs for reducing alcohol-exposed pregnancies. Efforts were made to utilize already established and valid questions (TWEAK) for ascertaining drinking behavior for SBI. Further, questions utilized by the Federal Government for other substance abuse and prevention data collection activities (NOMS) are included in these data collection forms. The individual respondents provide information that is not collected elsewhere in the service delivery process.

5. Impact on Small Businesses or Other Small Entities

There is no significant involvement of small entities.

6. Consequences of Collecting the Information Less Frequently

The schedules for data collection for SBI and Project CHOICES are determined by their evidence-based protocol which specifies the frequency of treatment; the specific topics and approaches to use; and the theoretical approach such as motivational interviewing. If the data is not collected or collected as frequently the program and federal reporting requirements would be unmet.

7. Consistency with the Guidelines in 5 CFR 1320.5(d) (2)

This information collection fully complies with 5 CFR 1320.5(d) (2).

8. Consultation Outside the Agency

A notice was published in the Federal Register on July 25, 2013 (78, page 44956). No comments were received. The SAMHSA FASD CFE has consulted with the Principal Investigators for both SBI and Project CHOICES. This was done to ensure the development of data collection methodology consistent with the research that generated the programs and to achieve the desired results. They provided information on the frequency of data collection, the clarity of instructions, record keeping, and appropriate data elements.

9. Payments to Respondents

Respondents will not receive additional monies to collect or report these data.

10. Assurance of Confidentiality

SAMHSA retains final authority to conclude whether or not the human intervention activities fall under the regulations protecting human subjects. The law 45 CFR 46 101(c) allows for SAMHSA agency heads to “adopt such procedural modifications as may be appropriate from an administrative standpoint” to waive IRB review. Such modification has occurred. SAMHSA concurred that these programs are not research projects, but programs that add FASD prevention services to existing service delivery organizations. Hence consent for participation in the FASD program is obtained as part of the services provided by each of these service delivery organizations and their consent process is used.

Participation in this data collection is voluntary. All data collection form introductions inform respondents that privacy is protected and that they are free to skip any question that they do not wish to answer. Additionally, all data collection forms include the purpose of the information collection, intended use of the information, and that this activity is sponsored by the Federal Government. All

participating sites will maintain personally identifiable information of their clients for service delivery purposes, but the sites will keep such information private to the maximum extent allowable by laws. Data will be collected at the site level and sites will be instructed to keep personal data secure in a specified location. To further ensure privacy of individual responses, all data will be reported at the aggregate level so that individual responses cannot be identified; no data will be reported at the individual participant level. There will be no generalized national estimates.

Furthermore, data will be collected to meet the criteria of a “limited data set” as defined in the Privacy Regulations issued under the Health Insurance Portability and Accountability Act (HIPAA), (HIPAA Privacy Rule, 45 C.F.R. _ 164.501) [45 C.F.R. 164.514(e)(4)(ii)]. A computer generated coding system will be used to identify the records, and access to records will be limited only to authorized personnel. In addition, the identifiers will be stored separately from the data. No direct identifiers will be included in order for the data to be considered a “limited data set.” A summary of the actions the contractors will take in order to comply with HIPAA follows:

- Ensure that the personal health information respondents disclose to outside entities does not violate the Privacy Rule.
- When creating a unique identification code, ensure that the code does not contain information that can be used to identify the individual.
- Sign a data agreement that states all HIPAA requirements will be adhered to consistent with a limited data set.
- Agree to maintain the confidentiality of alcohol and drug abuse client records according to the provisions of Title 42 of the Code of Federal Regulations, Part II.

11. Questions of a Sensitive Nature

There are questions of a sensitive nature because the program is asking woman of childbearing years about pregnancy status, alcohol use, sexual activity, and contraceptive use in order to determine risk of an alcohol exposed pregnancy. Asking women of child bearing age or women who are pregnant about alcohol use can be sensitive as this information is generally considered private. Given that the general public’s impression of drinking while pregnant is considered harmful to the developing fetus, disclosing this information can be perceived as risky. The purpose of collecting this sensitive information is to address alcohol use during pregnancy; the Federal Government has already established its interest in collecting this type of data.

Respondents will participate and use standard informed consent processes already in place at the participating agencies. All consent forms will inform respondents in the instructions of: 1) The name of the agency that is involved in the information collection; 2) The purpose of the information collection and the uses which will be made of the results; and 3) Whether providing the information is voluntary, required to obtain or retain a benefit, or mandatory.

12. Estimates of Annualized Burden Hours and Costs

Clients will be receiving services from the participating sites. Clients will receive different forms based on pregnancy status. The first component of the total hourly costs is the estimated wages of participating clients. Based on the populations served at these sites, we estimate that approximately 20% of clients will be unemployed and that the remaining 80% will receive minimum wage (currently \$7.25/hour) for an average hourly wage cost of \$5.80.

Estimated annualized burden hours

Instrument/Activity	No. of Respondents	No. of Responses per Respondent	Total No. of Responses	Average Burden per Response	Total Burden Hours per Collection	Hourly Wage Cost	Total Hourly Cost (\$)
Pregnant Women (SBI)							
Baseline Assessment (Form A)	9,273	1	9,273	.25	2,318	\$5.80	\$13,444.40
Process Assessment for all Eligible women (Forms A and B) (26.6% of baseline)	2,468	2	4,936	.21	1,037	\$5.80	\$6,015.60
Process Assessment for women actively drinking (Forms A and B) (16% of 2,468 eligible women)	395	1	395	.21	83	\$5.80	\$481.40
End of Program Assessment (Forms A and C) (50% of eligible women)	1,234	1	1,234	.16	197	\$5.80	\$1,143.60
SBI Sub Total	9,273	---	15,838	---	3,635	\$5.80	\$21,085.00
Non-Pregnant Women (Project CHOICES)							
Baseline Assessment (Form A)	1,220	1	1,220	.25	305	\$5.80	\$1,769.00
End of program Assessment (Forms A and C) (50% of 629 eligible women)	314	1	314	.25	79	\$5.80	\$458.20
Follow-up Assessment (Form A) (50% of 629 eligible women)	314	2	628	.25	157	\$5.80	\$910.60
Project CHOICES Sub Total	1,220	---	2,162	---	541	\$5.80	\$3,137.80
TOTALS	10,493	---	18,000	---	4,176	\$5.80	\$24,222.80

13. Estimates of Annualized Cost Burden to Respondents

There are no capital, startup, operational, or maintenance costs to respondents.

14. Annualized Cost to the Federal Government

The total cost of the program being performed under a Task Order is \$155,758.

The GS-13 level Government Project/Task Order Officer (GPO/TOO) principally involved in the

program will spend on average approximately 1% of his/her time (.5 hours weekly) overseeing various components of this program. On an annualized basis this would be the equivalent of \$717 in federal employee personnel costs (based on an annualized GS-13 salary of \$71,674).

The annualized cost to the government is \$156,475.

15. Change in Burden

This is a reinstatement; it is a new data collection.

16. Time Schedule, Publication, and Analysis Plans

The Table below outlines the program schedule with timelines for data collection, analysis, report delivery, and presentation to stakeholders.

<i>Activity</i>	<i>Planned Start Time</i>
Train programs on submitting data to contractor	OMB approval + 12 weeks
Develop quarterly data reports Transmit data quarterly	OMB approval + 24 weeks to coincide with project reporting periods, each year, of: February 1, May 1, August 1, November 1
Submit data to produce final report and recommendations	Data for November 1, 2013 through March 31, 2014, to be submitted to contractor by April 1, 2014 (subcontractor’s report due April 15, 2014)
Deliver Final Files	By April 20, 2014
Send program documentation	End of subcontracts April 21, 2015

Analysis Plan

Almost all data collection items are closed-ended questions. Respondents will be given the opportunity to add clarifying comments regarding their responses. These will be written down by trained case managers, or other staff.

The analyses of data will be descriptive, and, where suitable, inferential. Basic statistics will be calculated to derive frequency distributions, means, and other measures of central tendency. Outcome data will also be linked with participant demographic data to allow comparisons of program effectiveness between subpopulation groups. Because of differences in program size, organization, and culture, differences among organizations are expected, as are differences due to respondent characteristics.

T-tests will be performed to compare alcohol scores upon entry in to the program and upon exit and follow-up times. For Project CHOICES we will calculate overall risk of an alcohol exposed pregnancy by combining alcohol use and effective contraception measures at end of program and follow-up. Two sample table shells are shown below.

Sample Table Shell Highlighting Important Analyses

To what extent does Screening and Brief Intervention influence abstinence in pregnant women at risk of an FASD birth?

		Mean number of drinks: During the past 30 days, on how many days did you drink one or more drinks of an alcoholic beverage? (NOMs Measure)	
	t-test	BASELINE SCORE	36-WEEK FOLLOW-UP

			SCORE
Site 1			
Site 2			
Site 3			
Etc			

To what extent does Project CHOICES influence abstinence in women at risk of an FASD birth?

		Mean number of drinks: During the past 30 days, on how many days did you drink one or more drinks of an alcoholic beverage? (NOMs Measure)	
	t-test	BASELINE RESPONSE	POST-INTERVENTION RESPONSE (End of program)
Site 1			
Site 2			
Site 3			
Etc			

For reporting and analysis purposes, the FASD CFE will use IBM SPSS Statistics to combine all individual responses into summary tables and comprehensive data files. The FASD CFE will submit the aggregated data files to CSAP’s DCAR in April and October. SAMHSA’s DCAR and the subcontractors have identified common data measures for FASD prevention. As part of their contractual agreement with SAMHSA/CSAP, the DCAR will use these data for secondary analysis to aid SAMHSA/CSAP in responding to GPRA and other federal reporting requirements, and to inform SAMHSA/CSAP policy and program planning. Data collection is anticipated to begin immediately after OMB clearance is received, although there may be slight differences in start-up by site. Data collection will continue through the end of the contract.

Unique Identifier

Each client will be assigned a unique identifier which meets HIPAA requirements for privacy. Most sites will adopt the subcontractor’s proposed convention for a multi-level identification number in the format of “xxxzzz-yyyy,” for example 123456-0579 (with “xxxzzz” being a randomly generated 6-digit number and “yyyy” being the “check-digits” which are the sum of xxx+zzz to guard against incorrect data entry of follow-up data). In practice, the lists of unique identification numbers, generated by subcontractor, may be subdivided within the participating agencies so that individual providers are assigned specific numbers to guard against clerical errors. Sites which elect to use an alternate strategy will select a format which conforms to HIPAA requirements. The unique identifier will be used only to determine when the next assessment is due for a client and for tracking purposes.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The expiration date for OMB approval will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

This collection of information involves no exceptions to the Certification for Paperwork Reduction Act Submissions.