SAMHSA's Fetal Alcohol Spectrum Disorders (FASD) Center for Excellence Project CHOICES

THE SUPPORTING STATEMENT

A. JUSTIFICATION

1. Circumstances of Information Collection

Substance Abuse and Mental Health Services Administration's (SAMHSA), Center for Substance Abuse Prevention (CSAP) requests OMB approval for the data collection on the Fetal Alcohol Spectrum Disorders (FASD) Center for Excellence Project CHOICES. The purpose of the FASD Center for Excellence is to prevent alcohol exposed pregnancies among women of child bearing age and pregnant women; and improve the quality of life for individuals affected by FASD.

This data collection effort requests clearance for the following seven data collection instruments (Attachment I).

A. Project CHOICES Screening Form
B. Project CHOICES Motivational Interviewing Sessions
C. Project CHOICES Contraceptive Counseling Visit
D. Project CHOICES End of Program Form
E. Project CHOICES 6 month follow-up Form
F. Project CHOICES 12 month follow-up Form
G. Client Participation Tracking Form

The FASD Center for Excellence (CFE) 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 DHHS, 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 receive OMB clearance is submitted in response to that requirement.

Project CHOICES is being integrated into current service delivery organizations at six sites (Attachment II). The Project CHOICES screening form is administered to all women at the participating sites. After screening all sites will administer the motivational interviewing form and the contraceptive counseling form to all clients who screen eligible. The end of program form is administered at the end of the intervention, and the 6 month and 12 month follow-up forms are administered at 6 month and 12 months after the end of the intervention. The client participation tracking form is used to record information on clients who are lost during intervention or during the follow-up time period.

Consistent with federal efforts to address issues of accountability, capacity, and effectiveness the integration of Project CHOICES at the sites will advance the field of FASD prevention and treatment by learning what works in specific settings with specific populations. This data collection is designed to monitor the integration of Project CHOICES by measuring whether abstinence from alcohol is achieved as women progress through the intervention. In addition process information about motivational and contraceptive visits will also be obtained.

Project CHOICES which is an evidence-based program created by the CDC [1-4] will be integrated into service delivery organizations (participating sites) through subcontracts with the FASD Center of Excellence. Project CHOICES uses motivational interviewing and contraceptive counseling with the goal of eliminating alcohol use thereby, preventing alcohol-exposed pregnancies among women at risk. Most women do not realize they are pregnant until they are in the first trimester, and many drink alcohol during this time. Project CHOICES focuses on reducing drinking and preventing pregnancy through contraception with women 18 to 44 who are sexually active and who are participating in alcohol treatment (residential or outpatient) or in drug treatment (if the women also use alcohol). After screening women for the intervention, those who are eligible are referred to 4 motivational interviewing counseling sessions (related to alcohol use), plus one contraceptive counseling session. The goal of the FASD Project CHOICES intervention is to help these women prevent an alcohol-exposed pregnancy by abstaining from alcohol and using contraceptive measures of their choice consistently and correctly.

2. Purpose and Use of Information

The practical utility of this new project is to collect data from participating sites to monitor the integration of the Project CHOICES motivational and contraceptive intervention sessions with women at risk of having a child with a FASD.

Purpose of Data Collection

The purposes of the data collection activities are to: 1) determine whether Project CHOICES interventions were provided (and to document the details of the intervention as they are integrated), and 2) assess the extent to which women achieved the desired outcomes (abstinence from alcohol use and consistent and correct use of contraceptive methods). In order to assess these broad goals, specific outcome and process questions have been devised and are provided below:

- How many women enter the program and are identified as eligible for the intervention (women of childbearing age who are using alcohol and who inconsistently and/or incorrectly use contraceptive measures)?
- How many women participate in Project CHOICES?
- How well is Project CHOICES integrated into the existing organizations?
- Is Project CHOICES being implemented as intended? (fidelity)
- How many women achieve abstinence from alcohol with fewer motivational sessions at the end of program?

- How many women demonstrate consistent and correct use of contraceptive methods at end of program?
- How many women continue to achieve abstinence at follow- up (6- and 12-months)?

Baseline Alcohol Screening Measures

At baseline, an assessment tool will be administered by a counselor to assess drinking, sexual activity, contraceptive use, and demographic information. Eligibility is determined on response to questions on drinking behavior, sexual activity, and use of contraceptive methods. All eligible women will receive 4 motivational interviewing (MI) sessions and one contraception session. At the end of each MI and contraceptive session, the case manager records basic information about the session (date, duration, and the reason why the session did not occur, should that happen.)

At the end of the intervention (after the 4 MI sessions and 1 contraceptive counseling session), women will be assessed on their alcohol consumption and contraceptive use in the past 30 days. At 6- and 12- months after the end of the intervention, women will be assessed on alcohol consumption and contraceptive use using the same core assessment tool as used at baseline.

GPRA Measures

For this project, National Outcome Measures (NOMs) will be collected using one measure from the CSAP Adult Programs (and community) Survey forms:

- During the past 30 days, on how many days did you drink one or more drinks of an alcoholic beverage?

Dissemination

Findings from this data collection effort will be disseminated in a way that addresses the various needs of multiple stakeholders and maximizes the multiple uses to which the findings may apply. Stakeholders with active interests in the FASD Center for Excellence include:

- FASD program staff in CSAP charged with implementing the program, monitoring adherence, and quality improvement.
- Other federal agencies with substantive or evaluative interests overlapping with those of SAMHSA such as the Centers for Disease Control and Prevention (CDC) and the National Institute of Alcohol Abuse and Alcoholism (NIAAA).
- State leaders for development and implementation of FASD State Plans.
- FASD Prevention Programs at the State and Local Levels: Alcohol treatment programs (NASADAD), Maternal and Child Health programs (STO, AMCHP), Special Supplemental Foods Program for Women, Infants, and Children.
- FASD Treatment Programs at the State and Local Levels: Child mental health services (NASMHPD), Foster care services (Child Welfare League of America), National Association of Councils on Developmental Disabilities.

- Juvenile Courts: National Council of Juvenile and Family Court Judges, National Juvenile Defenders Center, Office of Juvenile Justice and Delinquency Prevention.
- WIC and Healthy Start program staff, counselors, and nutritionists that promote health improvement at the individual and organizational levels.
- The chartered FASD Center for Excellence (CFE) Expert Panel.
- Individuals with FASD, families, service providers and researchers concerned about appropriate and timely prevention and intervention that is delivered in culturally competent manner and inclusive.

3. Use of Information Technology

Data will be collected directly by staff at each of the six participating sites and will be transferred electronically for data analysis. Data will be collected during face to face meetings with women of childbearing age (18-44) who seek care through existing programs administered at the six sites. The counselors administering the survey will enter responses onto paper surveys or directly into a standardized locally installed electronic database to reduce burden on staff and data will be stored electronically in secured files. All data will be kept private through standard procedures to protect privacy, including the use of a file transfer system that uses industry standard secure socket layer data encryption, firewall protection against unauthorized access; data stored on a secure partition of the dedicated Windows-based server are also encrypted. Access to data on the server is username and password protected.

Burden for data collection at sites is eased by the use of a standard database for data entry and electronic transmission of data either by email or disk to the project liaison at the Center for Excellence. Sites either will send data-encrypted diskettes via a delivery service such as Fed Ex or will transmit encrypted data (using standard encryption software) via e-mail to their project liaison at the Center for Excellence.

4. Efforts to Identify Duplication

The data collection proposed is not available elsewhere, is not duplicative, and is seen as critically valuable for assessing the effectiveness of Project CHOICES.
Efforts were made to utilize already established and valid questions for ascertaining drinking behavior (refer to section number 2 above for full description). Further, questions utilized by the Federal Government for other substance abuse and prevention data collection activities (NOMS) are imbedded in these surveys.

5. Involvement of Small Entities

There is no significant involvement of small entities.

6. Consequences if Information Collected Less Frequently

It is anticipated that data will be collected throughout the intervention from screening through the follow-up period. Data collection will occur at screening, during the intervention phase, end of

program, at 6-months after end of intervention, and at 12 months after end of intervention. Project CHOICES intervention was designed to collect follow-up data at 6 month, 9 month and 12 months after the end of intervention, however the Center for Excellence in adapting the intervention decided to only collect information at 6 and 12 month follow-up. This helps reduce burden on respondents and does not have any implications on reporting data to SAMHSA. SAMHSA requires follow-up data at two time points after the end of the interventions and hence a decision was made to only record the required data.

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

The notice required in 5 CFR 1320.8(d) was published in the *Federal Register* on December 9, 2008, Vol.73, No. 237, pages 74728-74729. No written comments were received. Summaries of the outside consultations (separate from the publication of the notice in the *Federal Register*) regarding proposed data collection instruments are provided below:

- First, the FASD Center for Excellence staff conducted extensive discussions with the project directors at the sites to ensure information is clearly presented and collected in a least burdensome manner. As a result, initial drafts of the instruments were revised and a beta (test) version of the ACCESS data was similarly revised. The data collection instruments use plain, coherent, and unambiguous terminology.

- Second, the FASD Center for Excellence sought consultation outside of the agency from its evaluation subcontractors while developing the proposed forms. The subcontractors incorporated measures that were necessary to meet federal reporting requirements and assisted with the development of data collection procedures that would minimize respondent burden while maximizing the collection of data. Evaluation subcontractors who were consulted while developing the instruments include:

  Virginia Mulkern, Ph.D
  Senior Vice President
  (617) 876-0426 ext. 2315

  Deborah Potter, Ph.D
  Senior Research Specialist/HSRI Project Director
  (617) 844-2506

  Sandra Richman, MSW
  Research Analyst III
  (617) 852-9490

9. Payment to Respondents

Respondents will not receive any payments 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 projects 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.

Nonetheless, participation in this intervention is voluntary. All survey introductions inform respondents that their information will be kept private and that they are free to skip any question that they do not wish to answer. Additionally, all survey introductions include the purpose of the information collection, intended use of the information, and mentions that this activity is sponsored by the Federal Government. 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.

Furthermore, data that 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)]. No direct identifiers will be included in order for the data to be considered a "limited data set". A summary of the actions which will be taken in order to comply with HIPAA follows:

- When creating a unique identification code, ensure that the code does not contain information that can be used to identify the individual.
- The data collected by the sites constitutes a limited data set. A data use agreement can therefore be used while collecting data for evaluation purposes.

11. Questions of a Sensitive Nature

Many questions in these surveys are sensitive in nature, asking respondents whether they are drinking and using contraception effectively. The purpose of collecting this sensitive information is to address the issue of alcohol use and ineffective use of contraception to avoid an alcohol exposed pregnancy. The Federal Government has already established its interest in collecting this type of data.

Respondents will be provided standard informed consent processes applicable to the participating sites. All of the participating sites have informed consent documents (Attachment III) that are slightly different because they are integrating Project CHOICES into their existing service delivery systems. Instructions to the surveys will include 1) The name of the site that is involved in the information collection 2) The purpose of the information collection and the uses

which will be made of the results 3) Whether providing the information is voluntary, required to obtain or retain a benefit, or mandatory.

12. Estimates of Annualized Hour Burden

The first component of the total hourly costs is the estimated wages of participating clients. Clients will be receiving services from the participating sites. 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 $6.55/hour).

Instrument / Activity	No. of Respondents	No. of Responses per Respondent	Average Burden per Response	Total Burden Hours per Collection	Hourly Wage Cost	Total Hour Cost(s) ($)
Alcohol Use and Contraceptive Methods Assessment (Screening Form/ Form A)	913	1	.25	228	$6.55	$1,493
Project CHOICES process questions assessing whether sessions were delivered and their duration (4 MI sessions and 1 contraceptive use session – Forms B and C) -- 75% of baseline	684	5	0.08	274	$6.55	$1,795
Alcohol Use and Contraceptive Methods Assessment: End of program, 6 mo, and 12 mo follow-up (Forms D, E & F) -- 50% of baseline	456	3	0.25	342	$6.55	$2,240
TOTAL*	**2,053**	**9**	**-**	**844**		**$5,528**

In addition, a separate form (Form G: Client Participation Tracking) is filled out by staff, not by participants, if the participants are not able to be located. This form has not been included in the table above because it does not require any participant time.

Costs (from the federal contract including SAMHSA salary and contractor's/evaluator's salaries) are outlined separately in section 14, below.

13. Estimates of Annualized Cost Burden to Respondents

Respondents will not incur any costs beyond the hour burden shown in Item 12. Data collection and reporting are carried out by the Center for Excellence as part of its contractual agreement with SAMHSA.

14. Estimates of Annualized Cost to the Government

SAMHSA/CSAP has planned and allocated resources for the efficient and effective management and use of the information to be collected, including the processing of the information in a manner which shall enhance, where appropriate, the utility of the information to agencies and the public. The total cost of this data collection effort being performed under a Task Order, is $999,380.

SAMHSA /CSAP estimates the GS-15 Government Project/Task Order Officer (GPO/TOO) principally involved in the oversight and analysis of these activities will spend on average approximately 0.5% of her time (0.25 hours weekly) overseeing various components of this project. On an annualized basis this would be the equivalent of $756 in federal employee personnel costs (based on an annualized GS-15 salary of $121,000). Therefore, the contract costs and the personnel costs associated with data collection, including SAMHSA and project specific costs (but not indirect costs associated with the participation of clients), total $1,000,136.

15. Changes in Burden

This is a new project.

16. Time Schedule, Publication and Analysis Plans

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

Activity	Planned Start Time
Train sites on submitting data	*OMB approval + 2 weeks*
Transmit baseline data	*OMB approval + 3 weeks*
Transmit monthly assessment and process data	*OMB approval + 4 weeks*
Develop quarterly data reports	*OMB approval + 12 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 Oct 2008 through October 2011, to be submitted by 1/15/2012 (report to SAMHSA due 3/30/2012)*
Deliver Final Files	End of Contract
Send project documentation	End Of Contract

Analysis Plan

Almost all survey 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 the initial screening questions from baseline with exit and follow-up times. ANOVAs will also be used to compare scores between sites at single points in time (cross-sectional) and across time (longitudinally). In addition, an event history analysis will be conducted by modeling the transition from “current alcohol usage” to “non-usage” and possibly back to the state of usage for those women who fail to abstain from alcohol.

Sample table shell is shown below.

Sample Table Shells Highlighting Important Analyses
To what extent does Project CHOICES influence abstinence in women at risk of a 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			

Unique Identifier
Each client will be assigned a unique identifier which meets HIPAA requirements for privacy. Most sites will adopt the proposed convention for this project to use a multi-level identification number in the format of "xxxzzz-yyyy" (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). For example: 123456-0579. In practice, the lists of unique identification numbers which are generated may be sub-divided within the participating sites 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.

For reporting and analysis purposes, the FASD Center for Excellence will use Microsoft Access to combine all individual responses into summary tables and comprehensive data files. The Center will submit the aggregated data files to CSAP's Data Analysis Coordination and Consolidation Center (DACCC) in April and October. SAMHSA's DACCC and the subcontractors have identified common data measures for FASD treatment and prevention. As part of their contractual agreement with SAMHSA/CSAP, the DACCC 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.

17. Display of OMB Expiration Date

The expiration date for OMB approval will be displayed.

18. Exceptions to Certification Statement

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

References

1. Floyd RL, Sobell M, Velasquez M, Ingersoll K, et al. Preventing alcohol-exposed pregnancies: a randomized controlled trial. American Journal of Preventive Medicine 2007;32(1):1-10.

2. Centers for Disease Control and Prevention. Motivational intervention to reduce alcohol-exposed pregnancies - Florida, Texas, and Virginia, 1997-2001. Morbidity and Mortality Weekly Report 2003;52(19):441-444.

3. Project CHOICES Intervention Research Group. Reducing the risk of alcohol-exposed pregnancies: A study of a motivational intervention in community settings. Pediatrics 2003;111(5):1131-1135.

4. Project CHOICES Research Group. Alcohol-exposed pregnancy: Characteristics associated with risk. American Journal of Preventive Medicine 2002;23(3):166-173.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

1. Respondent Universe and Sampling Methods

Six sites from across the U.S. have been selected to integrate Project CHOICES into its current service delivery system. All women who are seeking care through the selected sites will be screened. All of those who meet the eligibility criteria (see below) will be invited to participate. As such, no sampling will be conducted; the complete universe of eligible participants will be screened and invited to participate.

2. Information Collection Procedures

Copies of the survey instruments are included in Attachment I as Appendices A through G. Each potential participant will be informed of the purpose of the request for their participation, their right not to participate, the degree to which the information they provide will be kept private. All data collection instruments have an introduction script describing the above.

Screening Form(Form A)
The screening form determines whether or not women are eligible to participate in Project CHOICES. This form is administered once at the beginning of the intervention.

To qualify, clients need to be:

- female and between 18-44 years old,
- currently using alcohol, sexually active, and using contraception ineffectively
- currently not/or trying to become pregnant within the next 6 months

Process Information(Form B and Form C)
"Process" information is documented after each Motivational Intervention visit (this form will be completed up to 4 times for each participant). This form documents whether the interventions were provided. At the Contraceptive Counseling visit, counselors will document similar information plus the type of contraceptive method(s) the clients intend to use.

End of Program Questions (Form D)
At the end of the program (after the 4 MI sessions and the Contraceptive Counseling visit), clients will again be asked about their use of birth control methods and consumption of alcohol (the 30-day GPRA measure). In addition, clients will be asked if they are currently participating in residential treatment or outpatient alcohol treatment.

Follow-Up Questions at 6- and 12- months post intervention(Form E and Form F)
The follow-up visit questions assess the outcomes of the intervention (e.g., has the client stopped drinking alcohol? Has the client consistently and correctly used their contraceptive method of choice? Is the client pregnant or trying to become pregnant?). In addition, clients will be asked if they are currently participating in residential treatment or outpatient alcohol treatment.

Client Participation Tracking (Form G)
This form will be used to keep track of clients participating in the intervention from eligibility through follow-up. In instances when a client in lost during intervention and can't be located the case manager will record the relevant information on the form.

3. Methods to Maximize Response Rates

The contractor (and a research subcontractor) has been working with the Project CHOICES sites to create appropriate monitoring/evaluation plans. The estimate is that 913 respondents annually will be assessed across the 6 sites, of which 75% (or 684) will participate in Project CHOICES and 50% (or 456) will be available for follow-up at 6-months and then again at 12-months. Factors influencing response rates include: a) refusal of an eligible participant to participate during one of her subsequent visits; c) missed appointments; etc. The strategy sites will be using to maximize their response rates and minimize burden on respondents is by establishing rapport with clients from the start of the first session which includes:

a. Creating and maintaining a tracking form which includes Client ID numbers, client identifying information, and checkboxes to denote whether or not client completed each step of the intervention (assessment, MI appointments, etc.) This will help to closely track clients in order to identify clients with missing data and follow them.
b. Leaving a reminder voice mail or sending a reminder email to clients a few days before their upcoming appointment, to reduce the chance of a missed appointment.
c. Using publicly available services to track down the client's current address or phone number. For example, calling information (411) or using various internet sites (such as www.zabasearch.com).

4. Tests of Procedures

All survey instruments were pilot tested among the project team members in fall 2008. Each of the six sites was then provided copies of all survey tools for comments and feedback. Sites provided feedback and as a result subsequent revisions were made to these forms before they were finalized.

Revision1: Questions on other types of contraception not mentioned in the screening form were added to the Screening Form (Form A) as a result of the feedback from the sites. Questions on IUD, Depo-Provera, Implanon, and "Other" were added to the screening form to ensure that responses from women who reported using the above mentioned contraception methods would be recorded appropriately. Hence questions 30 through 36b were added to the screening form.

Revision 2: The Client Participation Tracking Form (Form G) was created to record information on clients who may be lost during the intervention or during the follow-up period. The sites felt it was important to create the form and record the reason why the client could not be located. This will also help staff at the sites to accurately report on number of women currently receiving intervention.

5. Statistical Consultants

Data collection will be conducted by the company subcontracting to the SAMHSA FASD Center for Excellence. The evaluator for the FASD Center for Excellence Project CHOICES intervention, Vinitha Meyyur, Ph.D. will oversee the data collection at the sites and the data analysis performed by the subcontractor. Data analysis will be performed by the subcontractor, Human Services Research Institute under the supervision of the Project Director, Virginia Mulkern, PhD.

Contractor:		Phone
Vinitha Meyyur Ph.D.	Northrop Grumman Corporation	301-527-6512

Sub Contractors:		
Virginia Mulkern, Ph.D.	Human Services Research Institute	617-876-0426
Deborah Potter, Ph.D.	Human Services Research Institute	617-844-2506
Sandra Richman, MSW	Human Services Research Institute	617-852-9490

SAMHSA Project Officer:
Patricia B. Getty, Ph.D.
Acting Director
Division of Systems Development
Center for Substance Abuse Prevention
Substance Abuse & Mental Health Services Admin.
One Choke Cherry Road, #4-1027
Rockville, MD 20857
(240) 276-2577
(240) 276-2580 (FAX)
patricia.getty@samhsa.hhs.gov

List of Attachments

I In-Person Surveys

A) Project CHOICES Screening Form

B) Project CHOICES Motivational Interviewing Sessions Form

C) Project CHOICES Contraceptive Visit Form

D) Project CHOICES End of Program Form

E) Project CHOICES 6-Month Follow-Up Form

F) Project CHOICES 12-Month Follow-Up Form

G) Project CHOICES Client Tracking Form

II List of FASD Project CHOICES Sites

III Informed Consent Forms